

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

April 14, 1983

MEMORANDUM

TO: Commission

FROM: Timothy J. Muris *TM*
Director

SUBJECT: Proposed Trade Regulation Rule
for the Hearing Aid Industry JO1
R511006

I am forwarding the staff's Reanalysis of Record and Revised Recommendations and accompanying memoranda on the proposed trade regulation rule for the hearing aid industry. I concur in the Deputy Director's recommendation.

1983 APR 19 AM 9:05
FBI/DOJ

HEARING AID INDUSTRY
Re-Analysis of Record
and
Revised Recommendations
(16 C.F.R. Part 440)

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ACKNOWLEDGEMENTS

The staff would like to acknowledge gratefully the assistance provided by a number of individuals in the preparation of this report.

Roberta Gross and Barbara Kagan, two attorneys no longer with the Commission, did a substantial amount of work on the report.

Many secretaries helped with the enormous duties connected with the project. Shirley Jones, in particular, deserves special recognition for her work in preparing a substantial portion of the report and in co-ordinating its final production. Barbara Better deserves special recognition as well, for her efforts during the earlier phases of staff's efforts. Other secretaries who contributed to the report include: Clovia Hutchins, Delores Johnson, Nancy DeLuca, Iwon Gardner, John Corrigan, Dianna Sizemore, Linda Reese, Bernita Lofty, Sherrie Williams, Elsie Flaherty, Josephine Prince, Sharon Wester, Janet Clemens, Brenda Whitmore, Shirley Stamps, Brenda Prout, JoAnn Riley, and Gloria Boyd.

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INTRODUCTION

RECOMMENDATION

Staff recommends that the Commission issue a Trade Regulation Rule for the hearing aid industry. The rule we recommend is concise and straightforward. It would require that all dispensers provide a trial period with every hearing aid sale (except sales of "identical" replacement aids), and would specify key features of the trials.

This recommendation is based on staff's conclusion that the Commission can consider virtually all of the information in the staff report, despite jurisdictional and other questions. It is further based on the conclusion that the Commission can legally mandate a trial and that the Commission can and should set a maximum cancellation fee for trials. If any of these conclusions is rejected, staff recommends that no action be taken.

A. The Nature of this Document

The hearing aid industry Trade Regulation Rule was proposed on June 24, 1975. 40 Fed. Reg. 26646. Hearings were held from April 12 through August 17, 1976. The Presiding Officer issued his report on August 1, 1977,¹ and the original staff issued its Staff Report in

¹ A far more detailed history through August 1977, appears in the Presiding Officer's Report. R9/Dipl-6.

September 1978. The Commission met in October 1979 to discuss the rule, and questioned whether the original report adequately reflected the record.

Staff has consequently prepared a new document, based on a thorough review of the record evidence.

B. The Basis for the Recommendation

Staff believes that the record provides a basis for the proposed remedy. Staff also believes that the Commission has the authority to issue the proposed remedy.

The basis for the rule is the subject of most of this report. A close review of the record leads staff to the following conclusions, discussed in detail later in this report:

Hearing aids are unique products. (The Commission itself recently noted "quasi-medical peculiarities" in the hearing aid market.)² They are expensive medical devices, often sold to elderly persons who may have limited resources and do little comparison shopping. But although hearing aids cannot help everyone with a hearing impairment, buyers cannot know in advance how well an aid will help them. Even where buyers wear an actual hearing aid during testing, they cannot, for example, evaluate how well it will work with normal background noise present. The buyer may even be

² Beltone Electronics Corp., Docket 8928, Slip op. at 6 (July 6, 1982).

tested with a "master hearing aid" (which produces substantially better sound than a regular aid), and never wear a regular aid prior to purchase.

Uninformed buyers could thus believe, mistakenly, that they have adequately evaluated the aid during testing. However, hearing impairment is complex, and neither amplification nor testing for amplification can address all of these complexities. The informed buyer might understand this--but absent a trial period still must rely on testing to evaluate the aid.

However, testing is often done by the very person who dispenses the aid. In many cases, these dispensers receive all of their income from the sales of the aids which they recommend. The dispenser, in other words, has a strong financial incentive to promote amplification--an interest which may conflict with a customer's needs.

Finally, some dispensers base recommendations on inadequately performed tests. Poor testing, in turn, may be a product of poor or inadequate training. While many dispensers have formal academic training, and many doubtlessly are trained by qualified and experienced dispensers, others are trained primarily as salespersons.

To sum up, hearing aids are unique because they are expensive medical devices, and because the purchaser is dependent on third-party advice for assurance that an aid will work--advice that is inherently limited, and that may also be clouded by the dispenser's profit motive and further limited by poor testing and fitting technique.

Consequently, many consumers buy aids which provide no significant benefit. The result is substantial consumer injury. Well over half a million consumers, many of limited means, each spend several hundred dollars for aids each year. But tens of thousands of these buyers receive no significant benefit from their aids. They may soon abandon amplification and, absent a trial period, be left with a \$400 aid that sits in a drawer. In the worst case, a buyer may even have two unuseable aids (one for each ear).

In describing this unique market, our report outlines two sets of practices which, staff believes, constitute violations of section 5 of the Federal Trade Commission Act. First, the record shows a pattern of sales abuses. These include affirmative misrepresentations, and failures to disclose material facts, by dispensers and manufacturers. The record also shows substantial use of high-pressure tactics by hearing aid salespersons. Together, these constitute the "sales abuse" basis for staff's recommendation.

Also, the record shows that hearing aids are often sold without trials. Given the complex nature of hearing impairment, the prospect of deception in the advertisement and sale of hearing aids, the inherent difficulty of obtaining an accurate assessment of an aid through store tests, and the often inadequate training of hearing aid dispensers, staff believes that the failure to offer a trial period with the sale of a hearing aid is, in and of itself, an unfair act or practice. This constitutes the "risk of no significant benefit" basis for the rule.

Staff recommends this rule because we believe it would provide substantial benefits, which would exceed its costs, and because staff believes the rule would address substantial problems of deception and unfairness in the sale of hearing aids. Staff also believes the rule would withstand judicial review.

C. Critical Issues

Nevertheless, we recognize that there are a number of legal and policy issues which must be resolved in this rulemaking. These issues are discussed below, along with staff's assessment of each.

Broadly stated, there are three sets of issues the Commission must confront: impediments to considering certain evidence; questions about the adequacy of the evidence; and questions about the proposed relief. Several of these issues are critical to the rulemaking.

1. Questions About the Consideration of Evidence

There are possible impediments to the consideration of two bodies of evidence: advertisements for hearing aids, and evidence dealing with seller competence and the quality of testing.

a. The Medical Device Amendments Act

Industry has argued that the Commission lacks jurisdiction over hearing aid advertisements (and indeed, over hearing aids generally) because of the Medical Device Amendments Act of 1976. The advertise-

ments are an essential part of the sales abuse basis for the rule.

A provision of the Act does affect the FTC's jurisdiction over certain aspects of hearing aid advertising; the provision specifically removes certain jurisdiction under Sections 12 through 15 of the FTC Act. Staff believes, however, that the Commission retains jurisdiction over all hearing aid advertising under section 5. This parallels the Commission's interpretation of other limitations on its Sections 12 through 15 authority. Staff's conclusion is based on an extensive analysis of the law, which is set forth in Appendix C.

This is a critical issue for the rulemaking. If the Commission cannot consider the advertisements, staff does not believe the record would support a finding of industry-wide sales abuses. While the Commission could technically promulgate the rule solely on a "risk of no benefit" theory,³ moreover, staff would not recommend that it do so.

b. Evidence of Testing Procedures

The record shows that poor testing procedures contribute to the risk that a hearing aid will not provide significant benefit. There is evidence that testing procedures are sometimes deliberately

3 The Federal Trade Commission Improvements Act of 1980 prohibits the Commission from beginning a rulemaking premised solely on unfairness in 1980, 1981, or 1982. Pub. L. No. 96-252, § 11(b), 94 Stat. 374. However, the instant proceeding began in 1975.

abused, and that some testers are unable to test properly. This evidence supports the theory that there is a risk of no significant benefit -- a risk that can be substantially cured by the proposed mandatory trial period. However, it could be argued that this evidence involves the quality of professional performance and thus should not be considered by the Commission, but instead should be left to state regulatory bodies and private standard-setting organizations.

To address these concerns, staff believes it is necessary to focus on the concerns which underlie the "quality of care" debate -- concerns that the Commission will improperly intrude upon state regulation, or self-regulation by private standard-setting bodies, of the quality of care provided by professional groups. Clearly, staff's proposal would do neither.

Looking first to state action, the critical fact about this proposal is that the remedy would not define how testing service is to be provided. Thus, it would pre-empt no state standards which define how these services are to be provided.⁴

Similarly, it would not interfere with professional self-regulation of how these services are to be provided; assuming that the National Hearing Aid Society is a professional association (even

⁴ The rule would only pre-empt laws and regulations that require trial periods in the sales of hearing aids, but set specific terms which give consumers less protection than the proposed remedy.

though its members lack university level training in audiology), the proposed remedy would not interfere with the NHAS' ability to take steps to insure quality care. NHAS, for example, requires a non-waivable medical examination of a hearing aid users who appear to suffer from any of seven specified medical conditions; the rule would not affect this or other regulations dealing with how service is to be provided.⁵

Testers could thus continue to use any testing procedures, with any level of precautions to promote accuracy, which they deem appropriate. They would be subject only to any appropriate state regulation or private standards.

What the rule does affect is the sale of an aid without a trial period. When a dealer sells a hearing aid on the basis of a recommendation derived from inadequate testing (and/or deceptive representations), it is the sale itself, a business practice, which could be found unfair or deceptive. This contention is buttressed by the fact that traditional hearing aid sellers (sellers other than

⁵ The proposed rule would only affect NHAS' regulations dealing with trials. NHAS already requires its members to give trial periods to first-time users who request them, unless the user has a specific recommendation from a medical doctor or audiologist to buy a particular aid. The proposed rule is somewhat broader and more comprehensive than the NHAS requirement, particularly insofar as it sets cancellation fees. However, the proposed rule certainly does not interfere with any NHAS effort to regulate quality of care -- and, it has the advantage that all hearing aid sellers, and not merely those who choose to join and remain in NHAS, must comply.

university-trained audiologists) frequently offer testing as a free service; the test subject pays only if an aid is purchased. Hearing testing, in other words, is ancillary to the sale of an aid.

The record contains evidence of substantial consumer dissatisfaction with hearing aids. Some of these complaints may be due to dispensers who deliberately sold an unnecessary aid, some may be due to unavoidable risk factors, and some may result from poor testing procedures. Regardless of the cause, however, the ultimate consideration for the "risk of no significant benefit" basis for the rule is that, without a trial period, consumers may be unable to protect themselves against the prospect of receiving an aid which does not provide significant benefit.

Staff recommends that, in addressing this issue, the Commission look to the proposed remedy: a mandatory trial remedy, which will neither prescribe how hearing testing should be done, nor prevent public or private entities from prescribing norms they choose to promulgate.

2. Questions about the Quality of Evidence

Other questions involve the quality of evidence. There are two major issues. First, is the evidence adequate to sustain the rule? (This question has two components: Does the evidence establish the factual propositions asserted by staff? And do these propositions, if established, set out a violation of Section 5?) Second, what is the impact of post-record changes?

a. The Sufficiency of the Evidence

On the first issue, there is currently substantial debate within the Commission about the appropriate evidentiary standard in rulemaking. What evidence is needed to show an industry-wide problem? Is the level of evidence required to support a rule increased where the proposed remedy acts indirectly, by imposing affirmative obligations on an entire industry? The issue goes well beyond internal Commission discussion. There is also uncertainty as to what standard the courts will apply. Staff nevertheless believes the evidence in this record will meet the legal prerequisites for rulemaking, and that the record supports the recommended rule.

In establishing sales abuses, staff relies upon hundreds of advertisements, as well as sales manuals of major manufacturers. In staff's view, these establish substantial misrepresentations about hearing aids and high-pressure sales tactics, as a basis for the rule. There is also evidence of misrepresentations concerning seller competence and, while this evidence is weaker, staff recommends it, too, as a basis for the rule. It is well-established that these types of acts or practices violate Section 5.

In establishing the inherent risk of no significant benefit in every hearing aid purchase, staff relies primarily upon expert testimony explaining why the risk exists, and on evidence that even dealers who currently offer trials (and thus have little incentive to deception and even sales pressure) still have five to ten percent

return rates. Staff believes that this evidence, detailed in Section V, establishes that there is a risk of no significant benefit.

In establishing that this risk is magnified by poor procedures, staff relies primarily on the testimony of informed experts, and on a number of studies cited in the record.

Unlike the sales abuse basis for the rule, the "risk of no significant basis" analysis is an admittedly novel basis for finding a Section 5 violation. Staff's analysis is based on the conclusion that this market, with its "quasi-medical peculiarities," is unique. Precisely because of these unique factors, staff concludes that the sale of this one product without a trial is unfair. Much of the rulemaking has been premised on this theory from its inception in 1975. While the theory is novel, the current staff, like our predecessors, recommends it.

Staff believes that this evidence, taken together, establishes substantial Section 5 violations, sufficient to justify this remedy. Staff's analysis is set forth in detail in Section VIII, following the summary of evidence on which the conclusion is based.

Staff reaches this conclusion, moreover, even though the remedy is in part an indirect remedy, and even though a similar remedy was rejected in Katherine Gibbs v. FTC, 612 F.2d 658 (2d Cir. 1977). In Gibbs, the court rejected a mandatory pro rata refund in the Commission's Vocational School Rule, but spoke favorably of another fencing-in provision (the cooling-off period). The court also criticized the Commission's failure to specify deceptive and unfair

acts and practices in the text of the rule. (The practices were described in the Statement of Basis and Purpose.)

In staff's view, there are two reasons why Gibbs would not block this rule. First, the staff has set out the Section 5 violations in the text of the rule itself. Second, the trial period here is not merely a fencing-in provision. The risk of no significant basis for the rule says that the failure to offer a trial is itself an unfair act or practice. Hence, the remedy works directly on the unfairness, although it only works indirectly on the sales abuses.

b. Post-Record Changes

A final consideration is the question of post-record changes. Because of the range of legal and factual issues involved, the question of post-record changes is detailed in depth in a separate appendix, Appendix D. The material and recommendations in the Appendix are summarized below.

The record evidence dates from 1976 or earlier.⁶ In 1977, FDA adopted comprehensive regulations governing hearing aid labeling, and requiring medical pre-clearance of buyers, unless they execute a written waiver. Also, the Commission itself entered into six consent orders in 1976.

⁶ See text accompanying note 1, supra.

In the recent Beltone decision,⁷ the Commission itself found that there have been significant changes in hearing aid distribution since 1974. The Commission found substantial growth in the audiologist's and physician's roles, and attributed much of this growth to FDA's rulemaking. Our record suggest that, at least where an audiologist or physician recommends a specific aid, they generally insure trials for the clients. A growth in this referral market, in other words, would imply substantial growth in existing trial periods, and might have broader impact on sales abuses as well.

However, staff nonetheless believes that the existing record continues to justify a rule. Our record shows, for example, that physicians may limit their role to treating medically correctable problems; they may not be involved with selecting an aid at all. Moreover, evidence in our record indicates that physicians and audiologists already played a significant role in the market in 1974 through 1976, when the record nonetheless documented substantial sales abuses. Finally, there is and will remain a substantial market which does not operate through physician or audiological referrals, as the Beltone decision itself recognized.

If the core circumstances have changed, of course, it would be necessary to reopen the record. However, staff reluctantly concludes that it would be difficult to reopen the record on a narrow question. Indeed, virtually all of the evidence of deception, sales

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Beltone Electronic Corp., supra n. 2.

abuses, and poor testing would be called into question. Conceivably the Commission could look at a narrow question, the extent of current trial periods. However, even a narrow study would doubtlessly add substantial time to the proceeding. Moreover, if the use of trials has spread, this has implications for both the costs and benefits of the rule. If dealers are already offering trials comparable to those the rule would require, the benefits of the rule would be reduced--but so would its costs.⁸ The record nevertheless shows that there are problems in sales without trials--and the problematic sales are the ones least likely to have trials. Therefore, staff would probably continue to urge a rule even if trials have become more widespread.

Should the Commission conclude that there is a substantial question about staleness, therefore, staff hesitates to recommend without qualification that the record be reopened. Rather, we recommend the Commission only reopen the record if the Commission is prepared to tentatively approve a rule on the current record.

3. Questions about the Proposed Remedy

a. Is the Remedy Reasonably Related to the Deception and Unfairness?

Staff believes that the proposed trial period would substantially address the deception and unfairness outlined in this report. It

⁸ Indeed, virtually the only cost would be a slight paperwork burden.

would directly remedy the risk of no significant benefit, and would be a significant disincentive to sales abuses. Moreover, staff believes that the benefits of the remedy would exceed its costs. The full discussion of these issues appears below, following the summary of evidence on which it is based. However, there are several issues raised by the remedy: Does the Commission have the power to require a trial? If it did have the power before 1976, was it removed by the Magnuson-Moss Act (the warranty issue)? Is the remedy overbroad? Should the commission adopt the remedy even though it entails fee-setting? Finally, given all of these problems, is any less restrictive remedy available?

b. The Power to Require a Trial

The Commission has previously required trials in the Cooling-off Period for Door-to-Door Sales Rule, 16 C.F.R. § 429,⁹ and in several cases.¹⁰

Staff believes these precedents establish that the Commission can require a trial here. There is one difference here, though, which should be highlighted. In this rule, unlike the precedents cited, one basis for the rule would be the risk of no significant benefit.

⁹ A 14-day cooling-off period was adopted for the Vocational School Rule, and was not challenged on appeal.

¹⁰ Windsor Distributing Co., 77 FTC 204 (1970), aff'd, 437 F.2d 443 (3d Cir. 1971); Household Sewing Maching Co., 76 FTC 207 (1969); Universal Electronics Corp., 78 FTC 265 (1971).

The precedents use a trial to fence in abusive sales practices; the current rule is in part a fencing-in remedy, but would also be based on a finding that it is unfair not to offer a trial. In staff's view this issue should not affect the Commission's power to require a trial.

c. Overbreadth

Another problem is the breadth of the remedy. It affects all hearing aid sales, and all consumer dissatisfaction for any reason.

While the sales abuse remedy is based on evidence of deliberate deception and high pressure sales tactics, the risk of no significant benefit results from a range of factors. It results from the nature of hearing loss, and the quality of amplification; it results from the psychological responses of the user, and from an industry structure where the person who recommends an aid may depend exclusively on sales of aids to make a living. It results from poor testing. In staff's view, it is impossible to separate out these factors, and to suggest that some consumers receive no significant benefit for "good" reasons, and others for bad reasons.

Assume first, that a consumer receives adequate testing. Now consider a man who buys an aid after this testing, who can hear and understand speech somewhat better with the hearing aid -- but who cannot understand voices in the noisy environment where he spends his day, and therefore abandons the aid. Should he have to absorb the full cost of the aid, and should the dispenser reap the full benefit

of the sale? Suppose further that there is another factor present: He feels the aid makes him look too old or infirm, and would prefer not to wear it. Should he then have to bear the loss? Taking the analysis a step further, suppose he has trouble hearing in his everyday life, and also feels the aid makes him look old and infirm -- he was visibly reluctant to try to aid, and a high-pressure door-to-door salesperson pressured him, and he then rejected the aid because of the range of factors suggested above. Does this affect whether he should have to bear the risk of failure? Or taking this analysis yet another step, suppose the dispenser had suspected the consumer might fail, but sincerely believed that the aid could provide significant benefit. Should the dispenser's motivation affect the need for a trial?

The problem is that these factors are all intermingled. While some failures may be due to clearly inappropriate fittings, others are more difficult to attribute to a single cause. Ultimately, though, the insufficient benefit provided by the aid will always be a factor. If the consumer rejects an aid, it is because the aid did not provide sufficient benefit to overcome any reluctance to use amplification. Given this, staff believes the focus of the analysis should be as follows: Consumers must rely on third-party advice prior to purchase of this expensive medical device, but the advice is intrinsically limited by the nature of amplification, and further limited by the tensions between selling and objective advice, as well as by poor procedures. The consumer can only evaluate this advice

through actual use, measuring the benefit found in daily life against the costs of wearing an aid, and therefore failure to provide this essential trial use is always unfair. Following this reasoning, staff concludes that a mandatory trial is not an overbroad remedy.

d. The Warranty Issue

The next question is whether a trial period is precluded by the Magnuson-Moss Act. Industry argued that a trial period was a "Commission mandated warranty"¹¹ beyond the Commission's power. Specifically, HAIC urged that the legislative history of the Magnuson-Moss Act,¹² combined with the definition of warranty in section 101(6)¹³ and the flat prohibition on Commission-mandated warranties in section 102(b)(2),¹⁴ demonstrated congressional intent that the Commission not be authorized to require consumer product warranties.

However, Section 102(b)(2) of the Magnuson-Moss appears in Title I of the Act and reads only:

Nothing in this title . . . shall be deemed to authorize the Commission . . . to require that the consumer product or any of its components

11 HAIC, R3/3916-19.

12 H. Rep. No. 93-1107, 93d Cong. 2d Sess. (1974), reprinted in 1974 U.S. Code Cong. & Admin. News at 7702, 7706.

13 15 U.S.C. 2301(6).

14 15 U.S.C. 2302(b)(2).

be warranted.¹⁵ (Emphasis supplied)

The Proposed Rule, however, would not be promulgated under Title I. Rather, it would come substantively under section 5 of the FTC Act, and procedurally under Title II of Magnuson-Moss.

Moreover, section 111(a)(1) of Title I states:

Nothing contained in this title shall be construed to repeal, invalidate, or supersede the Federal Trade Commission Act (15 U.S.C. 41 et seq.)¹⁶

Subdivision (d) of the same section states:

This title . . . shall be inapplicable to any written warranty the making or content of which is otherwise governed by Federal law.¹⁷

If the Recommended Rule is approved, hearing aid trials will be governed by Federal law other than Title I of the Magnuson-Moss Act. Thus the HAIC argument is without statutory foundation. There are no ambiguities in the text of Magnuson-Moss giving rise to limitations on the Commission's authority to mandate conditions for sale under Title II of the Act (procedurally) and section 5 of the FTC Act (substantively).

Indeed, the Senate Commerce Committee Report stated, in reference to the text of section 102(b)(2);

While it is the intent of the Committee that the

15 15 U.S.C. 2301(b) (emphasis added).

16 15 U.S.C. 2311(a)(1) (emphasis added).

17 15 U.S.C. 2311(d).

Commission under authority of title I of this bill may not prescribe the substance of written warranties . . . this limitation is to be read in conjunction with the savings provision in section (111) which states, "Nothing contained in this title shall be constructed to repeal, invalidate or supersede the Federal Trade Commission Act (15 U.S.C. 41 et seq.). . . ."18

In other words, the Commission could mandate conditions of sale under Section 5 and, further, that Title I of Magnuson-Moss did not affect this authority in Title II rulemaking.

A reason for this dichotomy is the different procedures under the two titles. The Commission can promulgate rules under either Title I or II. Title I rules, which must be related to warranties,¹⁹ use the procedure of section 553 of Title 5 of the U.S. Code (the Administrative Procedure Act).²⁰ This is simple "notice and comment" rulemaking. Title II, however, is the broader rulemaking provision,²¹ and it provides that

the Commission shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (1) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (2) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (3)

18 S. Rep. No. 93-151, 93d Cong., 1st Sess. 16 (1973).

19 15 U.S.C. 2302.

20 15 U.S.C. 2309.

21 15 U.S.C. 57(a). Title II rules may go to any violation of Section 5.

provide an opportunity for an informal hearing in accordance with subsection (c); and (4) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in subsection (e)(1)(B)), together with a statement of basis and purpose.²²

Title II thus provides substantial procedural safeguards not present under Title I, and this may explain why the remedial limitations under Title I do not apply under Title II. Staff therefore concludes that a trial period is not prohibited by the Magnuson-Moss Act.

e. The Fee-Setting Issue

Even if the Commission has the power to require trial periods, another problem remains. If the trial period is to be effective and enforceable, staff believes that the Commission must establish maximum cancellations fees.²³ To provide some flexibility, staff recommends that the basic cancellation fee be set at 10% of the purchase price of the aid; the basis for this recommendation appears in Section IX.D.

While staff believes a fixed cancellation fee is essential to the remedy, and that this formula is reasonably flexible, it is true that there is little record evidence to justify the fee chosen; the strongest evidence that the recommended fee is reasonable is existing state practices. Consequently, staff does not maintain that the fee

22 Id.

23 See Section IX.

is compensatory in every sale, although evidence, noted below, does show that scrupulous dealers can adapt to the fee.

More significantly, it can be argued that the Commission has never set charges for a whole industry before. In both cases and rulemaking where the Commission required trials, however, it has set a cancellation fee: zero.²⁴ Staff believes that it is equally appropriate to set a fee higher than zero.

We are acutely conscious that any effort to prescribe a fee will be highly controversial. Nevertheless, staff believes that the rule should only be adopted if the Commission sets a cancellation fee. If the market sets the fee, the fee could equal the full purchase price of the aid. At this asymptote, however, the trial period is merely a disclosure that no trial is really offered,²⁵ and the consumer would not even know why a trial is needed in the first place.

During the proceeding, the various staffs have considered several ways to set a cancellation fee.²⁶ The current staff recommends

24 Maximum fees for services (and not merely for trials of the service) have been set in an adjudication. Arthur Murray Studio of Washington, Inc., 76 FTC 1063 (1969), aff'd, 458 F.2d 622 (5th Cir. 1972).

25 It might be argued that this would not really be a trial, and would violate the rule. However, this raises the question of whether a seller who returned one dollar, would comply with the rule, or a seller who returned twenty dollars. When would the Commission charge a violation of the rule, and pursue the substantial penalties allowed by statute?

26 See Appendix A, supra.

that dispensers be allowed to retain 10% of the selling price of the aid (or aids). A percentage formula is desirable because it automatically compensates for inflation. Moreover, states with mandatory trials have used percentage formulas.

The 10% figure chosen is reasonable, in staff's view. A \$40 fee (for a \$400 aid) should deter frivolous cancellations, particularly when added to the battery and earmold charges allowed under the rule. It is also comparable to the cancellation fee most dispensers charge when they voluntarily give trials.²⁷ Thus, while there is no evidence that the fee is compensatory on a case-by-case basis, there is substantial evidence that comparable fees have worked no hardship on dispensers who offer trials.

f. Alternative Remedies

In response to all of the problems discussed above, as well as the Commission's duty to consider less restrictive remedies, staff has endeavored to develop an effective alternative remedy, which it could recommend to the Commission. While we have not succeeded, possible alternatives are outlined below.

1. An Informational Rule

The first possible approach is a rule requiring disclosure of information. An informational remedy would tell consumers about the

27 See Section VI.D.2, supra.

need for a trial period and give them information about the dispenser's trial period policy. It has several advantages over the recommended rule. It is less costly. It can be based purely on a deception theory.²⁸ It does not raise the "warranty" issue.

In staff's view, however, there are several problems with an informational remedy. The most important failing of any informational remedy is that it cannot convey information which the consumer needs to evaluate the need for a trial. In essence, the remedy cannot adequately convey enough information to enable consumers to make an accurate assessment of the importance of a trial. The informational remedy might encourage trials; but if that is the goal, the Commission can more directly require trials. An informational remedy should produce informed consumer choice.

The first limit of an informational remedy is that consumers cannot determine the value of a trial period without evaluating their own, personal, risk of receiving no significant benefit. However, it is not possible to order the provision of information which, taken alone, will enable individual consumers to evaluate their own risks. The risk depends on factors individual to each sale or to each consumer.²⁹ A uniform disclosure cannot meaningfully address these

28 The risk of no significant benefit is a material fact, and non-disclosure is deceptive.

29 For example, users with very severe or very mild losses are less likely to benefit from an aid than users with moderate losses. Moreover, the risk is a function of various

(CONTINUED)

issues. To a certain extent, consumers can evaluate their own risks. If they wear an aid during the fitting process,³⁰ for example, they will have some idea of how much it increases their ability to understand speech. However, the information is limited, as will be detailed below. In the tester's office, for example, consumers will not detect their ability to understand speech in the presence of normal background noise. Moreover, even if they encounter some background noise in testing, they cannot evaluate a dispenser's assurances that they will adjust to the noise in time.³¹

Thus, a purely informational remedy can alert consumers to the fact that there is some risk of no significant benefit. But even having been alerted, the consumer will have at best limited ability to evaluate the risk. Only a trial period will allow adequate evaluation of the risk.

As for the sales abuse basis, this too depends on factors

29 (FOOTNOTE CONTINUED)

avoidable factors, including the presence or absence of a medical examination, the quality of testing, and the extent of deception and pressure in the sale. These factors are discussed throughout Section I.

30 Some consumers are tested with higher fidelity instruments and do not wear an actual aid before purchase. See Section IV.A.1.B.

31 Indeed, because they are deseparate to hear and may view the seller as an "expert," they may be open to exaggerated promises of an adequate adjustment.

individual to each sale. But there is also a more telling problem: as a practical matter, the Commission could not, and should not, force all sellers to disclose, prior to sale, that there are substantial abuses in the industry.

Another problem with an informational remedy is that the Food and Drug Administration already requires a disclosure about trials. In staff's view, this disclosure is both incomplete and limited.³² This is not surprising. When FDA's rule was promulgated, the agency expected the Commission to require a trial, and viewed its remedy as an interim action. FDA's disclosure certainly does not obviate the need for a mandatory trial; indeed, FDA endorsed the mandatory trial when it promulgated its hearing aid regulations. However, the fact that any disclosure exists raises substantial question about why another agency should require an additional disclosure.

Despite staff's doubts about this remedy, we have endeavored to outline an informational rule, so that the Commission need not address a possible informational alternative in a vacuum. The discussion appears at Appendix E, and a fuller discussion of FDA's existing disclosure appears at Part II of Appendix D.

2. A Rule Limited to Door-to-Door Sales

32 See Appendix D, Section II.

The record suggests an increased chance of high-pressure sales³³ and inadequate testing³⁴ where aids are sold at home. Staff considered a rule which would only require trials in home sales. There are several problems with this remedy. First, all sales -- not only door-to-door sales -- have a risk of no significant benefit. Second, advertising abuses lead to deception which affect office sales as well as home sales. Finally, home sales are a valuable service for some consumers, and a rule for home sales only would create disincentives for sellers to perform desired and perhaps necessary home sales.

3. Case-by-Case Adjudication

Another alternative, of course, is to forego all rulemaking and address instances of unfairness or deception, as they arise, through case-by-case adjudication. Staff does not recommend this as an alternative to rulemaking, for several reasons.

First, efficient use of agency resources suggests that, if there is an adequate basis for a desirable rule, the Commission should promulgate the rule.

Second, case-by-case adjudication was used by the Commission to address abuses in the hearing aid industry for years. A list of consumer protection orders involving hearing aid companies appeared

33 See, e.g., Section IV.B, supra.

34 See, e.g., Section I.B.5.b.(4), supra.

in Appendix E of the 1978 Staff Report. Despite continual efforts, industry-wide problems remained and are documented herein.

Third, while some manufacturers have a large share of the hearing aid market, there are thousands of independent dispensers selling aids to consumers. Case-by-case litigation against the bad actors among these firms, even if they could not be located, would simply not be efficient.

4. An Advertising Rule

Another possible rulemaking approach would be to regulate advertising claims directly. Such direct regulation was proposed in prior versions of the rule, but was eliminated, in part, because it was thought that such deceptions might be indirectly remedied by a trial period. If the Commission now rejects the trial period, it might reconsider direct regulation of deceptive claims.

In staff's view, there are severe limitations to this approach. First, it is a remedy for deception alone, and not for the risk that the aid will provide the buyer no significant benefit.

Second, an advertising rule is necessarily limited to misrepresentations which occur in written advertisements or in recorded commercials. It cannot reach oral misrepresentations which occur at the point of sale. Yet, certain false claims are rarely made in writing; for example, exhortations to "act now" to

prevent further hearing impairment.³⁵

Third, any advertising rule runs the risk that it will be so broad as to burden non-deceptive practices unduly,³⁶ but in seeking to narrow the rule, other problems may arise.³⁷ Another

35 See Section IV.A.1.f.

36 § 440.6 of the 1978 rule, for example, would have required dispensers to identify themselves as sellers. It was addressed to the efforts of sellers, generally in "lead generation", to obscure their sales interest. These efforts generally occur in oral encounters, in person or by telephone, but they sometimes appear in writing; some advertisements, for example, position a dispenser's testing as a public service, and they sometimes are set out in a "public service" format. Unfortunately, it is difficult to limit a remedy to these deceptive advertisements, and the recommended rule did not do so. But disclosure of sales intent in advertising would often be unnecessarily burdensome; it is generally clear from an ad that the advertiser sells hearing aids.

37 § 440.7 of the 1978 text, for example, said a firm should not be called a "clinic" unless it is supervised by a physician. A "hearing and speech center" however, could be supervised by a physician or audiologist. Staff sees no basis for these precise definitions in the record.

Indeed, the definition of "audiologist", which is incorporated in the definition of a "hearing and speech center", is itself problematic. Staff believes the use of the term by someone with no formal training is deceptive. See Section IV.A.2.b.(2). However, the precise meaning of the term "audiologist" is a matter frequently addressed by state licensing laws. The original staff recommendation could have pre-empted these laws. The current staff disagrees with the prior staff's assessment, and does not recommend that the Commission precisely define the term. However, the definition of audiologist is integral to three sections of the 1978 advertising rule: §§ 440.7, 440.8, and 440.9. If the Commission does not define the term, staff could not recommend any of these provisions.

provision previously posed would have enabled the Commission to raise difficult factual issues in a rulemaking enforcement context;³⁸ in the current staff's view, this could have resulted in an undue burden on the hearing aid industry.

An advertising rule could be written so as to address some significant deceptions, such as claims that an aid will restore "normal" or "natural" hearing. An advertising rule could also require that hearing aid advertisements carry a disclosure that an aid may provide no significant benefit, an informational remedy akin to the informational rule discussed earlier. Nonetheless, on balance, staff hesitates to recommend an advertising rule. In staff's view, the costs of such a rule are not warranted by the limited benefits it would provide consumers.

38

§ 440.17, for example, would have required manufacturers to set out their basis for "uniqueness" and similar claims. (There are many uniqueness claims in the record, although the current staff has focused on those which are demonstrably false). § 440.19 would have required a reasonable basis for claims, including these explanations. However, if the Commission were to challenge an advertiser's reasonable basis, staff questions whether the advertiser should face civil penalties for violating a rule; at the least, advertisers in this one industry should not be singled out for such treatment.

I. The Risk of No Significant Benefit

This section describes the inherent limitations of amplification. Part A details the complexity of hearing loss and explains why aids can only provide limited (and not necessarily adequate) correctives. Part B explains the limitations of testing and fitting in addressing these complexities, as well as other, avoidable, problems which can further reduce the value of testing and fitting procedures.

A. Nature of the Product

1. Characteristics of Hearing Loss

The ear, a highly complicated organ, is composed of three sections: the outer ear, the middle ear and the inner ear. The outer ear collects sound waves and transmits these signals through the middle ear into the inner ear, where they are transformed into nerve impulses. These nerve impulses are then transmitted to the brain for interpretation.³⁹

A variety of factors can interrupt this chain of transmission and cause various kinds of hearing impairment.⁴⁰ The three basic types

39 Kojis, R8/1023; AAOO, R8/4082; See generally, S. Fletcher, "Anatomy and Physiology of the Auditory System," in Audiological Assessment (D. Rose ed.) SPXD/17-42; AAOO, R8/4072-79; McCurdy, TR 13-14, 16-17; Qualitone, R8/2534; Winston, R8/7425, 7440; ASHA, R10/2587.

40 MPIRG, R8/1200-02. Noise pollution is rapidly becoming one of the major causes of hearing loss in the United States

(CONTINUED)

of hearing impairment are the conductive, sensorineural, and mixed loss.⁴¹

A "conductive loss" involves either the outer or middle ear. With this type of impairment, sound pressure waves either fail to reach the inner ear, or reach it with reduced intensity.⁴² A small

40 (FOOTNOTE CONTINUED)

today. A 1968 estimate places at approximately one million the number of workers who have serious hearing losses due to high noise levels in their working environment. Public Health service officials estimate that 50% of the machines used in heavy industry may produce noise at levels that are potentially damaging to a worker's hearing. Id., R8/1198.

41 Several other types of hearing loss exist as well. They include central loss and nonorganic or functional loss. A central loss refers to a malfunction in the auditory portion of the nervous system which prevents the processing of auditory signals by the brain. Newby, SPXA/57-59; Rassi, R8/5354; Harford, TR 137-138; NHAS Basic Course, R8/4255. The nonorganic or functional loss is a psychological hearing loss, often precipitated by stress or tension. A hearing aid is contraindicated for both types of impairment. Newby, Disorders of Hearing, supra at 59-60; NHAS Basic Course, R8/4255, 4259; Smith, B., TR 318-19; Delk, R10/7123; Matkin and Olsen, SPXD/348; AAOO, R8/4094.

42 E.g., Winston, R8/7440; NHAS Basic Course, R8/4255; Delk, R10/7149; Price, SPXD/190-91; AAOO, R8/4067; Consumers Union, R8/1189L⁴. External ear conductive loss may be due to build-up of wax or foreign bodies, infection, or congenital malformations. Corliss, NBS, U.S. Department of Commerce, "Facts about Hearing and Hearing Aids", R8/615ip6-7; L.L. Price, "Pure-Tone Audiometry," Audiological Assessment, (1971), SPXD/190-91; AAOO, R8/4082; MPIRG, R8/1200; ASHA, R10/2588; Kojis, R8/1023. Middle ear conductive losses may result from perforation of the ear drum, infection, tumor, injury to the head or ear, or an interruption in the bones that link the middle and inner ear caused by congenital malformations or disease. Kojis, R8/1023; Corliss, R8/615ip6-7; Price, SPXD/183, 191, 193; ISPIRG, R8/1402; ASHA, R10/2588; MPIRG, R8/1201; AAOO, R8/4085, 4088; Glorig, R8/2001; NHAS Basic Course, R8/4256; Audivox, R13/1209; Consumers Union, R8/1044.

percentage of hearing impairment is due to purely conductive loss.⁴³ Moreover, medical and surgical treatment is usually effective in the treatment of a conductive loss.⁴⁴ Consequently, the need for a hearing aid may be eliminated or at least mitigated by medical intervention.⁴⁵

"Sensorineural loss," or nerve loss, results from damage to the nerve mechanisms in the inner ear.⁴⁶ Sensorineural losses are sometimes divided into two classifications: sensory and neural.⁴⁷ Sensorineural losses may result from hereditary defects, viruses accompanied by a high fever, allergic reactions to drugs, hemorrhage or impaired blood supply to the ear, diseases of the nervous system,

43 Estimates place the percentage of the hearing impaired with a loss that can be medically healed at 15%-20%, Marcus, TR 5507-08, and 5-15%, NHAS, R3/3338.

44 Consumers Union, R8/1189M⁴; Winston, R8/7440; Delk, R10/7149; Price, SPXD/195; ISPIRG, R8/1402; ASHA, R10/2588.

45 McCurdy, TR 30; Yantis, R8/2164; Rose, R8/4177; Shallop, R6/337; McGargill, R5/46.

46 Kojis, R8/1023-24.

47 Sensory pathologies describe an impairment of the systems in the inner ear which convert mechanical energy (sound waves) into electrical energy (nerve impulses). Neural pathologies are those which interfere with the transmission of electrical energy through the acoustic nerve system to the cortex portion of the brain. Individuals with sensorineural losses either have sustained damage to the cells of the inner ear--cells which are essential for the transmission and perception of sound--or they have insufficient nerve elements leading to the brain to transmit the acoustic signal. Yantis, R8/2163; Traynor, R8/6157.

injury to the head or ears, or the normal process of aging.⁴⁸ The characteristics of a sensorineural loss are described in Section I.A.1.b.

A "mixed loss" occurs when a person suffers from both a conductive and sensorineural loss in the same ear.⁴⁹

a. Decline in Loudness

The decibel is the basic unit for measuring sound intensity or loudness.⁵⁰ Decibels are a logarithmic measure of the ratio of sound intensity to the intensity of the weakest sound the average normal ear can hear.⁵¹ The following chart associates familiar sounds with various decibels levels:⁵²

-
- 48 Price, SPXD/195-96; P.O. Report, R9/Dlip45; Gardner, R8/4155; NHAS Basic Course, R8/4258; Alpiner, R8/5450, 5490; Corso, R8/8996, R10/180-81, 183; Rupp, R8/4068, 7146; RPAG, R8/2837; Schmitz, R8/7297; AAOO, R8/4086-87; Hull, R8/6179; MPIRG, R8/1203; Kojis, R8/1023; ISPIRG, R8/1402; ASHA, R10/2588.
- 49 P.O. Report, R9/Dlip43; Corliss, supra note 42, R8/615ip6; SPXD/190-91.
- 50 Consumers Union, R8/1189M⁴.
- 51 Id. at R8/1045. An increase of one decibel constitutes an increase in the "just noticeable" loudness level of most sounds. AAOO, R8/4069.
- 52 See Berger, "Acoustic Descriptions of Hearing Aids", in Hearing Aid: It's Operation and Development, Table 6-1, R8/5064.

LoudnessFamiliar Sounds

0	Threshold (technical) ⁵³
10	Threshold (practical)
20	Whisper
30	Quiet street
40	Quiet office
50	Average office
60	Soft conversation
70	Moderate - Loud Conversation
80	Heavy Traffic
90	Elevated Train
100	Symphony Orchestra
110	Airplane piston engine
120	Airplane Jet Engine
130	Incipient Pain
140	Pain

Normal sensitivity of hearing is a range, called the "dynamic range." The dynamic range extends from the "threshold of hearing," which defines the softest sound a person can hear 50% of the time,⁵⁴ to the "threshold of discomfort," the loudest sound a person can hear without pain or discomfort.⁵⁵

The following chart refers to the extent of disability that will be associated with various degrees of hearing loss, and the degree of benefit that might be achieved with a hearing aid.⁵⁶ Note that people whose hearing is close to normal may not achieve significant benefit from an aid, because their problem is not very severe.

53 The technical threshold represents the softest sound that the human ear is theoretically capable of perceiving. Berger, R8/5064.

54 Scott, TR 2317; Buris, TR 2490.

55 Delk, R10/7225; Price, SPXD/228; Consumers Union, R8/1045; Harford, R8/7553.

56 Eglit, HX93/348; Glorig, R8/2000.

People with an extreme hearing loss also may obtain little benefit, because their hearing impairment may be too severe to be corrected by amplification.

Extent of Hearing Loss, in Decibels	Degree of Loss	Hearing Disability
0-15 (in the worse ear)	Normal	No difficulties
15-30 (in the better ear)	Near normal	Difficulty-faint speech
30-45 (in the better ear)	Mild Impairment	Difficulty-normal speech
45-60 (in the better ear)	Moderate Impairment	Difficulty-loud speech
60-90 (in the better ear)	Severe Impairment	Can hear only amplified sound

A conductive hearing loss is characterized primarily by a decline in the loudness and intensity of sounds, and not by a decline in the quality of the sound heard. The rise will be uniform in all frequencies. Moreover, the "top" as well as the "bottom" of a hearing range may rise, so discomfort or pain only begins with a louder sound.⁵⁷

Individuals who have a purely conductive loss can expect maximum benefits from a hearing aid. Generally, all that is needed to correct a conductive hearing loss is to make sounds louder.⁵⁸ Most

57 P.O. Report, R9/Dlip44; Yantis, R8/2163; Eglit, HX93/348.

58 Johnson, E., R8/4524; Rose R8/4177; McCurdy, TR 29; Beiter, R5/1448, 1469; McGargill, R5/46; Wehr, R6/337; RPAG, R8/2833.

users with a conductive loss will find that an aid is effective in helping to solve their communication problems.⁵⁹

b. Decline in quality

Unlike a conductive loss, a sensorineural loss often limits understanding as well as hearing. With sensorineural loss, however, the threshold of hearing shifts for different frequencies, so that there is a deterioration in the quality of sound.⁶⁰ Thus, a 15 decibel bass tone may be audible, but a 30 decibel mid-ranged tone may be inaudible. Other variations in sensorineural loss, for example, "holes" or "gaps" in the auditory frequency range, may prevent certain isolated tones from being heard normally.

Frequencies determine whether a sound is "high" or "low," (e.g., bass or treble). Sounds are characterized by different frequencies or combinations of frequencies. "S" and "F," for example, share certain common frequencies, but are differentiated by other frequencies. Differential frequency loss may produce a loss of understanding--for example, someone with a high frequency loss may be unable to distinguish "s" from "f." A hearing aid can amplify sound, but only has limited abilities to improve understanding. In the example above, the user may be unable to distinguish "s" from "f" even with

59 RPAG, R8/2833.

60 P.O. Report, R9/Dlip44; Yantis, R8/2163; Traynor, R8/6157.

an aid, although the indistinguishable sound will be louder.⁶¹

The consequence may be a speech discrimination problem, a consumer problem which leads to the complaint: "I can hear but I can't understand."⁶² Individuals with poor speech discrimination ability generally have significant communication problems.⁶³

Many sensorineural losses are accompanied by other complications which reduce understanding, and which limit the potential effectiveness of amplification. For example, there may be a continuous hissing or ringing ("tinnitus").⁶⁴

Another complication is "recruitment." Recruitment is a condition where small increases in sound intensity produce substantial increases in the volume of audible sounds. Persons so

61 Consumers Union, R8/1189L⁴-1189M⁴.

62 Rupp, R8/7155; Corso R8/6314; AAOO, R8/4140; AARP, R10/1496, 1405, 1257, 937, 344; Combs, R10/3140; McGee, R10/5332; ASHA, TR 2279; Rassi, TR 5732-33; Kleiman, TR 6911; Johnson, E., R8/4526; Miller, TR 4762-63. More than 2/3 of a group of hearing aid wearers, indicated that they have difficulty in understanding sounds rather than hearing them, when using a hearing aid. Rupp, supra. In a survey, 33% of the hearing aid wearers indicated that they were not receiving the anticipated benefits from their aid. The vast majority of the respondents attributed their dissatisfaction to discrimination problems. Alpiner, R8/5448.

63 To the lay person, the confusions of auditory messages seen among the elderly may be synonymous with the term "senility." To the elderly, the confusion is embarrassing and can result in withdrawal from other possible communication situations. A bright, alert elderly person may have a devastating discrimination problem that inhibits social interaction. Hull, R8/6186, 6323. See generally Section II.

64 Cody, SPXD/47.

afflicted may ask a speaker to talk louder, however when the speaker's voice is raised, the sounds are disturbingly loud.⁶⁵

Recruitment thus reduces the dynamic range between the threshold of hearing and the threshold of discomfort.

Complications are sometimes associated with particular diseases. Presbycusis, for example, is the loss of hearing due to the natural process of aging. It is both progressive and irreversible and is characterized by a decrease in sensitivity to sound as well as a decrease in the ability to understand speech.⁶⁶ It is accompanied, as well, by other complications of aging.⁶⁷ Presbycusis is one of the most common types of sensorineural impairment, and approximately 13% of the population over 65 years of age evidence the advanced symptoms of this impairment.⁶⁸

Meniere's syndrome is a condition characterized by a fluctuating low tone loss attributable to increased amounts of fluid in the inner ear. Symptoms include vertigo, nausea and tinnitus.⁶⁹

For some individuals afflicted with sensorineural loss,

65 NHAS Basic Course, R8/4258; MPIRG, R8/1203; AAOO R8/4068; Kasten, R8/6981-82; Harford, R8/4548; Consumers Union, R8/1045; Eglit, HX-93. 10-15% of the hearing impaired are poor candidates for an aid because they suffer from noise recruitment. Carter, R., TR 3671-3672.

66 NHAS Basic Course, R8/4258; Alpiner, R8/5450; Corso, R8/8996-97, R10/180-81, 183; Rupp, R8/7146; RPAG, R8/2837; Schmitz, R8/7297; AAOO, R8/4086-87; Hull, R8/6179; MPIRG, R8/1203.

67 See Section II.E.1.

68 Corso, R10/179.

69 NHAS Basic Course, R8/4259; AAOO, R8/4090-91.

amplification may be of limited value,⁷⁰ or it may even have negative effects on their ability to hear and understand.⁷¹ Optimally, a device is needed that will make sounds clearer or more distinct to overcome the distortion effect associated with sensorineural or mixed losses.⁷² A hearing aid, however, essentially makes sounds louder.⁷³

Because of individual characteristics, a measurably identical sensorineural loss that is debilitating for one individual may prove negligible for another individual, since the distortion effect can manifest itself in a more tolerable fashion in the second individual.⁷⁴

A hearing aid may help an individual with a sensorineural loss, but the improvement will be limited because of these complications.⁷⁵ Accordingly, persons with sensorineural loss face a greater risk than those with conductive loss that they will not obtain significant benefit from an aid.

70 Corso, TR 1185-86; Shannon, TR 1874; Stahl, TR 5541; NCSC, R10/4427; Glorig, R8/2005.

71 Traynor, R8/6802-03; Jerger, R8/4574; Miller, TR 4823; Burris, R13/814; Epstein, R10/424; Holmes, TR 9616-17.

72 RPAG, R8/2833; Traynor, R8/6157.

73 AAOO, R8/4140; Winston, R8/7407; NHAS Basic Home Study Course, R8/4288; Miller, TR 4823; Harford, TR 53, 139.

74 Krebs, TR 11853-54; Rompala, TR 9129; Payne, John, TR 9249; Harford, TR 53.

75 Traynor, R8/6157; Johnson, E., R8/4524; Payne & Payne, R8/1453; Georgescu-Roegen, R8/1189L. Sanders, SPXB/ 334-35.

A person with a mixed loss is most likely to benefit from an amplification device if the loss is primarily conductive.⁷⁶

2. The Operation of a Hearing Aid

A hearing aid increases sound pressure,⁷⁷ but cannot "cure" the organic basis of deafness. It cannot reproduce normal or natural sound as it is heard by an individual with normal hearing.⁷⁸ When properly fitted, a hearing aid can amplify certain sounds and can thereby help an individual to hear better.⁷⁹

A hearing aid has a limited frequency range, and thus can not amplify sounds of all frequencies equally. Since aids amplify

76 Burriss, TR 2493; Kojis, R8/1023.

77 Corliss, supra note 42 at 14; P. O. Report, R9/Dlip50.

78 Pasiewicz, TR 8920; Scott, TR 2344; Dunlavy, TR 3397; Johnson, E., R8/4528; Alpiner, SPXB/170, R8/5428; Graham, S., R8/7461, 7384; Schein, R8/5685, 5686; Payne & Payne, R8/1460; HEW Task Force Final Report, R8/3208; Burriss, TR 2560; Butz, TR 6622; Corso, R10/194; Teter, R13/2045; Burke, M., TR 6421, 6424; Giglia, R10/2922; Keyes, TR 10724; NHAS Basic Home Study Course R8/4288; Williams, TR 3763.

79 Teter, "Clinical Considerations of Hearing Aids," in Hearing Disorders, (1976), R13/2045; Berger & Millin, "Hearing Aids" in Audiological Assessment, (1971), SPXD/498-99; Zelnick, TR 443-44 ("you fit when there are vocational and social needs for amplification"). "(A)mplification can often improve the effectiveness with which a person uses sound, sometimes to the extent of normalizing auditory competence." Sanders, SPXB/351.

sound within a relatively restricted frequency range (300-4000 hertz),⁸⁰ sound quality is poor,⁸¹ often characterized as "tinny,"⁸² "brassy",⁸³ "metallic"⁸⁴ or "unnatural."⁸⁵

The hearing aid consists of four basic parts: the microphone, the amplifier, the power source, and the receiver or earphone. The microphone picks up sound waves from the air and converts them into electrical impulses. The amplifier increases the strength or intensity of these impulses. The receiver converts the electrical impulses from the amplifier back into sound vibrations. (The power source is generally a battery.) The discussion which follows shows

80 Hertz is a unit of frequency close to one cycle per second. Websters New Collegiate Dictionary (1975). It takes close to the full range of normal hearing, about 50 Hz to 10,000 Hz to provide reasonably accurate timbre. Since most hearing aids work in a narrower frequency range, sounds will sound unnatural but perceptible. Consumers Union, R8/1191D; Miller, TR 4762-63.

81 RPAG Report, R8/2742.

82 Jerger, R8/4579; RPAG Report, R8/2742; Rose, R8/4173; Consumers Union, R8/1191D; Alpiner, R8/5462. When asked, "What was your first reaction to your hearing aid?" 5.4% responded that it was "tinny" or "raspy". Payne & Payne, R8/1447.

83 Consumer Union, R8/1191D; ASHA, R10/2539.

84 Harford, R8/7562-63.

85 Consumers Union, R8/1191D; Lentz, R8/7991 (artificial); AARP, R10/1312; ASHA, R10/2539; P.O. Report R9/D1pl108. One consumer reported that "My first experiences with the aid were novel and perplexing ... voices sounded scrambled, like Mickey Mouse or Donald Duck cartoon characters." Brennen, TR 245.

how these various components, taken together, introduce distortion.⁸⁶

a. The Microphone and Receiver

The receiver may be an air-conduction receiver, which transmits air vibrations into the outer ear;⁸⁷ insofar as sound travels this pathway, the device simulates the manner in which a person hears normally.⁸⁸ A bone conduction receiver transmits vibrations to the mastoid bone behind the ear; they travel directly through the skull to the inner ear.⁸⁹ The bone conduction receiver has narrower frequency range and is a less efficient transmitter of sound signals than the air conduction receiver. Consequently, it is not widely used unless mandated by the physical condition of the patient.⁹⁰

86 Winston, R8/7408; Staff on HAIC, R13/907; Zelnick, TR 427-428; Burris, R13/814; Pollack, SPXB/49; Bode, SPXB/298; ASHA, R10/2539; Miller, TR 4778, 4762-63. Distortion occurs when the output contains more component sounds than the input because neither the microphone nor the receiver are capable of producing an exact copy of the signal received. RPAG, R8/2747. In re Mather Hearing Aid Distributors, Inc. (Rulon), R8/2296.

87 It might be fitted into a plastic earmold, worn in the ear (with the rest of the aid on the body, behind the ears, or also in the ear); it can be built into the side-piece of a pair of eyeglasses with plastic tubing connecting the receiver to the earmold. NHAS Basic Course, R8/4289; Corliss, supra note 42 at 14; P.O. Report, R9/Dlip51.

88 NHAS Basic Course, R8/4292.

89 Id., R8/4292; Corliss, supra note 42 at 14.

90 National Center for Health Statistics, R8/51lip11, 31 (Table 12); Masticola estimates that the bone-conduction arrange-
(CONTINUED)

Specific characteristics of the receiver's earmold influence reproduction. As noted below,⁹¹ a dealer can use these characteristics to improve a person's hearing; where not properly analyzed, however, they can be a source of unwanted distortion. Under the best of circumstances, moreover, the earmold cannot provide a perfect sound seal.⁹² As a consequence, sound emanating from the hearing aid receiver may reach (or feed-back into) the microphone, where it is amplified until it builds-up into a high-pitched whistle or squeal.⁹³

It is more difficult, if not impossible, to solve this problem in

90 (FOOTNOTE CONTINUED)

ment is suitable for less than one percent of her clinic population, Masticola, TR 8620-21. These aids are available in eyeglass, body and behind-the-ear versions. The in-the-ear hearing aid, the most cosmetically desirable instrument is inappropriate for use by the vast majority of the hearing impaired.

91 See Section I.B.2.

92 Berger, R8/5094.

93 The source of these whistling noises may be attributable to either sound leakage from the receiver or from the earmold. Berger, R8/5094; Alpiner, R8/5462; Winston, R8/7413; Delk, R10/7140 [feedback acoustic]. In some instances, however feedback is desirable, deliberately introduced to add to the amplification factor (positive feedback) or subtract from the amplification factor (negative feedback) to lessen distortion. However, internal feedback into the aid is due to a mechanical defect and should be repaired. Winston, R8/7414. Several consumers reported that their aid buzzes and hums which could possibly be eliminated with adjustment. Mabe, R8/7833-34; AARP, R10/1408, 1452, 1453, 4046; Bowe, R8/6950-51; Lentz on Samole, R13/1968-69; Sanders, TR 3583; RPAG, R8/2842; Brennen, TR 245, 264.

the miniaturized aids where the components are so close together.⁹⁴

As noted by Berger and Millin:

". . . difficulties of further miniaturization of hearing aids . . . are found in the microphone and receiver. First, if they are placed too close together, acoustic feedback will occur, even at low gain levels. Second, the size of these transducers cannot be reduced without also drastically reducing their ability to respond to the signal with good fidelity.⁹⁵

There is evidence on the record that miniaturization has reduced the high frequency performance of aids,⁹⁶ producing an unnatural auditory signal that "flattens" or "clips" high frequency sounds.

Like the receiver, the microphone limits sound quality. Locating it on the body, for example, introduces the rustle of clothing.⁹⁷ Also, the length and diameter of the tubing extending from the microphone to the amplifier exerts a subtle yet significant effect on the reproduction of sound. Altering the length of the tubing or its diameter will affect the frequency response of the aid. This will affect the quality of sound.⁹⁸ This is a variable which the dispenser can deliberately alter. However, taken together, the operation of these component parts may introduce distortion and new sounds. This creates a risk that the purchaser will not receive

94 Berger, R8/5046-47; Pollack, SPXB/25, 33.

95 Berger and Millin, SPXD/473.

96 Sandlin & Krebs, R13/915. Contra, Keyes, TR 10745, 10758-59.

97 Jerger & Lewis, R13/40; AA00, R8/4139-40; Berger, TR 5073.

98 Berger, R8/5069.

significant benefit from the aid.

b. The Amplifier and Output Limiting Devices

Output limiting devices control the output of a hearing aid. They address the problem arising from a reduced dynamic range. If the softest sounds were magnified to be audible, the loud sounds would become painful absent some output limiting device. However, these devices also introduce a number of problems that affect sound quality.⁹⁹

Peak clipping devices cut off ("clip") part of the signal. Peak clipping tends to eliminate vowels from speech¹⁰⁰ and may also worsen the signal-to-noise ratio,¹⁰¹ thereby increasing the masking effects of background noise.

Automatic volume control ("AVC") can avoid the distortion problems that peak clipping causes. Automatic volume control "flattens" responses; the loudest sounds are not clipped but they are compressed. However, AVC aids can fail to perform, and allow annoying (and potentially harmful) sound levels to occur and interfere with speech discrimination.¹⁰² In addition, AVC can be debilitating to discrimination because it reduces the level of weaker sounds along with the stronger sounds. Moreover, AVC sometimes

99 Sandlin & Krebs, R13/929.

100 Pollack, SPXB/60. See also Berger, R8/5081.

101 Bode, SPXB/292.

102 Sandlin & Krebs, R13/936-37.

increases the amplification of softer sounds, which includes unwanted background noise.¹⁰³

Thus, output limiting devices can compensate for certain inherent limitations of amplification -- but the correction is imperfect, and necessarily introduces its own distortion.

c. Background Noise and Reverberation

Hearing aids also reduce the clarity of auditory signals by indiscriminately amplifying unwanted sounds.¹⁰⁴

Amplification of all noise is particularly serious in crowd and group situations, where the user is bombarded by already distorted sounds.

The problem is further compounded by the fact that new hearing aid users may suddenly begin hearing background noises that they have not heard for some time, or have never heard before.¹⁰⁵ The Illinois Speech and Hearing Association has characterized such noise as "the nemesis of most hearing aid users".¹⁰⁶ As one commentator noted:

103 Ross, R13/3711.

104 AARP Letters, R10/1044, 1272, 1318, 1437, 1450, 1500, 4291; Percy Letters, R8/246-47, 300; ASHA, R10/2539; Pasiewicz, TR 8907; in re Mather Hearing Aid Distributors, Inc. (Manning) R8/2124, (Harvey) R8/2220-21; Johnson, J., TR 2265; Brewer, TR 3963-64. Bowen, R8/6952; Schmitz, R8/7262; Drew, R10/5186; Giglia, TR 2755; Corso, TR 1184-85; Gawron, R8/8283; Bode, SPXB/292-93.

105 ASHA, R10/2548; in accord, Masticola, TR 8635; Staab, TR 7042; Dunlavy, TR 3402; P.O. Report, R9/Dlip203; Epstein, TR 4613-14; NHAS, R3/3210-12.

106 ISHA, R10/4904.

People with normal hearing automatically ignore most disturbing background noise they do not wish to hear. The new hearing aid user rarely can perform this function on his first attempts as the mind has forgotten or never knew how to distinguish and separate sounds.¹⁰⁷

The user must, if possible be reeducated to adjust to background noise.

Another major problem is reverberation. Reverberation is the movement of sound off walls, furniture, rugs and other points of interference in a room. Since sound waves require time to decrease in intensity, reverberations can affect speech intelligibility. If a room has no rugs or little furniture to absorb sound, the effects of reverberation will be exacerbated.¹⁰⁸

Inevitably, use of hearing aid in an environment cluttered by competing noise from reverberation and indiscriminate amplification will reduce discrimination.¹⁰⁹ The inability of the hearing aid user to separate such noise from the "wanted sound" may cause anxiety and frustration,¹¹⁰ as well as disappointment.

107 HAIC, R3/3613; For further elaboration on this adjustment process, see Section III.

108 Lentz, TR 11273-74. In many public facilities, the hearing impaired cannot hear clear conversations. Id. TR 11221-23, 11186-88.

109 Id. R8/7995, TR 11186-88, 11221-23; Winston, R8/7409-10; Harford, R8/7549.

110 Hull, R8/6216; Syfert, R10/815. It has been reported by Bergman (1971) that speech intelligibility in older individuals decreases under stressful listening conditions.

(CONTINUED)

Directional microphones can reduce background noise by focusing on sounds from the front of the wearer. However, tests show that the results are equivocal. Studies by Lentz indicate that they did improve speech discrimination in nonreverberant rooms, when background noise is present behind the user and speech in front of the user.¹¹¹ When noise was introduced from several directions, however the directional did not consistently aid discrimination unless fitted binaurally (a separate aid in each ear).¹¹² Moreover, in reverberant rooms, sounds from behind the listener will eventually approach the listener from a variety of directions, including the front; this will diminish the value of a directional aid.¹¹³

Like output limiting devices, then, directional microphones are only a partial corrective for the limits of amplification.

110 (FOOTNOTE CONTINUED)

When words were overlapped or interrupted, changes in performance were observed starting in the fourth decade; and by the seventh decade, the performance of the older adults declined to less than half that of the younger. Corso, R8/8973, TR 1134-85.

111 Lentz, R8/8018-29.

112 Id. R3/3029.

113 Id. R8/8037.

B. Selecting And Fitting

The testing and fitting of a hearing aid is not an exact science.¹¹⁴ Specialized equipment exists to measure hearing loss and, while a variety of tests are used to assess the degree of an impairment, they cannot always succeed in fitting an appropriate hearing aid. Darrell Rose, Director of Audiology at the Mayo Clinic, stated that,

testing and fitting cannot determine an individual's ability to tolerate, adjust to, and benefit from amplification in his own world, or acquaint the wearer with the various problems of amplification.¹¹⁵

HAIC testified that there is "much room for error in an audiologist's recommendations."¹¹⁶

114 LeBlanc, R3/2500; Warberg, R3/2936; Krebs, R8/1189II; Kojis (Senate Hearings, 1968), R8/882; Elia, TR 7492; Sandlin, TR 10122; Huffman, R10/6915; Burris, TR 2554; Fortner, TR 8889; Hoover, R6/181; Dunlavy, TR 3397; Pigg, R8/1188H³; Payne, James, HX39/9; Kenwood, TR 9285; Barnow, TR 1692; Simms, R3/125; Delk, TR 10923; Lankford, TR 8037; DuHaime, R3/2905; Mynders, TR 11548; Hulser, R3/2521; HEW Task Force Final Report, R8/3395; RPAG, R10/6820; Krebs, R8/1189II; Berger, R8/4971; ASHA, R13/3599; P.O. Report, R9/Dlip190; see also Delk, TR 10952 (testing is "far more art than science"); Kenwood, TR 9285; Berger, R8/5054. Audiologist Robert Sandlin, Ph.D., stated that "science is the ability to predict what a patient can do with a device and we are not there yet." Sandlin, TR 10150.

115 Rose, R8/4173.

116 HAIC, R8/1189R³. "... at the present time each individual researcher and clinician must make arbitrary, well considered, but tentative decisions" [during the testing process] Pollack and Bode, SPXB/293; "ambiguity in the interpretation of test results", Matkin and Olsen, SPXD/356.

The methods of selecting and fitting a hearing aid vary widely. No method can be consistently and reliably repeated.¹¹⁷ Joseph Millin, Professor of Audiology at Kent State University, noted that "when it comes to the . . . selection of the appropriate hearing aid . . . the superiority of audiometric procedures cannot be demonstrated experimentally".¹¹⁸ NHAS said that currently there is no consensus as to what is the most valid, reliable technique for selecting the best hearing aid.¹¹⁹ Audiologist Robert Sandlin stated that many dealers have developed effective procedures through trial and error, but that,

Acceptable hearing aid procedures, whether performed by speech and hearing center staff or by hearing aid dispensers, are points of debate. There simply is no one procedure accepted regardless of by whom it is performed. There is no university program, no specified curriculum, which suggests that the procedures for hearing aid evaluation is contained within that program or curriculum. . . . It is perhaps a sad commentary about the present status of the hearing aid evaluation process and objective procedures, but they simply do not exist. If they do

117 Griesel, R10/6819; Sandlin, TR 10126.

118 Millin, SPXB/116; accord, Pollack, SPXB/145.

119 HEW Task Force Final Rpt. (NHAS), R8/3352. Lindsey Pratt, M.D., Chairman of the American Council on Otolaryngology's Subcommittee on Hearing Aids and the Hearing Aid Delivery System, testified that if ten people were to define the best method for testing hearing, ten different answers would be given, with each person believing that the method he used was the best because he had successfully fitted someone who was not satisfied with the results produced by the other procedures. Pratt TR 3689-90. Accord, Griesel, R8/11880⁴; Mynders, TR 11548; Curran, TR 10809; P.O. Report, R9/Dlip48; Scott, TR 2315.

exist, the they are certainly not generally
accepted.¹²⁰

In such an environment, both dispensers and users of hearing aids must take every precaution to maximize the prospects of a successful fitting--and even then, success is not guaranteed. The record shows, moreover, that the chance of success can be diminished in a number of avoidable ways--failure to do even minimal tests, errors and poor procedures in doing those tests, and deliberate manipulation of testing variables.

The description which follows first describes competent testing and its inherent limitations. Since testing procedures vary so widely among dispensers, the methodology described below will not necessarily be representative of the testing performed by all members of the hearing health care community. The discussion then describes the avoidable problems which compound the risk of error.

1. Audiometric Testing

Hearing tests are performed with audiometers, portable or non-portable devices which produce various pure-tone signals.¹²¹ Some also produce high fidelity speech

120 Sandlin, TR 10126; accord, Hulser, R3/2821; HEW, R8/3223- 34.

121 NHAS, R8/4261; P.O. Report R9/Dlip48; Ventry, TR 1715; Qualitone, R8/2536; in re Mather Hearing Aid Distributors, Inc. (Manning), R8/2118; Griffing, R8/1189V.

signals,¹²² and some, but not all, can produce masking noise to prevent the non-test ear from overhearing a test signal.¹²³

The audiometer is not an indefectible instrument to measure hearing loss. Dr. Newby, Chairman of the Department of Hearing and Speech Sciences at the University of Maryland, stated:

. . . . [T]he audiometer is not a magical instrument which can be connected to a patient and yield automatically the exact amount of hearing loss that patient has at each frequency. In the hands of an experienced clinician, the audiometer is a useful tool for obtaining measures of the extent and type of hearing loss. The point is that the audiometer is a tool, and as such it can be operated skillfully by the craftsman or clumsily and ineffectively by the amateur. . . . The audiogram . . . is the best estimate by an audiometrist of the state of the patient's hearing. . . .¹²⁴

At a minimum, proper testing requires that pure tone and speech and speech reception tests be administered through an audiometer.¹²⁵

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- 122 NHAS Basic Course, R8/4273; Hearing Instruments, R13/1110-12.
- 123 NHAS Basic Course, R8/4267; AAOO Guide, R8/4100-01. For discussion of the importance of masking, See Section I.B.5.b.(3).
- 124 Newby, Audiology 73, (1972).
- 125 Wilson, TR 10062; Scott, TR 2317; Harford, TR 79; Epstein, TR 4605-07; Burris, TR 2488; NHAS, R8/1188S 7; Staab, TR 7034-36; Corso, R8/8975; Rupp, R8/7111; Eglit, HX/93; Bailey, HX/103; Byrne and Silverman, R10/3126; Griesel, R10/6820, 6893; Qualitone, R8/2534-36; in re Mather Hearing Aid Distributors, (Causey) R8/2031, (Yantis) R8/2151-52, (McNeill) 2244-45; NHAS (Johnson), R13/2593; NHAS, R3/6463; Graham, S., R8/7460; HEW Task Force Final Report, R8/3203; Consumers Union, R8/1189M⁴; ISPIRG; R8/1364; Mettler, TR 11393; Lentz, R8/8258, 8268.

a. Pure Tone Tests

Pure tone tests are performed to determine thresholds¹²⁶; for hearing,¹²⁷ speech reception¹²⁸ and discomfort.¹²⁹ Air conduction and bone conduction are tested with pure tones. The pure tones presented are short, soft beeps. Air conduction thresholds are derived when pure tones of standard frequencies are emitted through earphones, and pass through the normal hearing mechanism.¹³⁰ Bone conduction thresholds are derived when these signals are presented through a bone oscillator, which is placed on the mastoid bone behind the ear or on the frontal bone of the forehead. Testing by bone conduction bypasses the conductive mechanism in the outer and middle ear and identifies sensorineural impairment.¹³¹

There are several inherent limitations to these pure-tone

126 Staab, R10/6454-6455; Kasten on Briskey, R13/2085.

127 The threshold of hearing is the softest sound a person can R8/1045; Eglit, HX/93.

128 The speech reception threshold is a level at which the listener can just barely understand speech. Price, SPXB/212; NHAS, R8/4262; P.O. Report, R9/lip49.

129 The threshold of discomfort, or the uncomfortable loudness level, indicates the level at which speech becomes uncomfortable. Price, SPXD/228; NHAS, R8/4283; P.O. Report, R9/Dlip49; Consumers Union, R8/1045; Scott, TR 2317; Eglit, HX/93.

130 Price, SPXD/174; AAOO, R8/4069.

131 NHAS Basic Course, R8/4270; Price, SPXD/175; AAOO, R8/4069.

audiometric tests. First, they measure the subject's response to artificial tones which are rarely heard in everyday life. Second, since the audiogram necessarily provides a picture of the subject's threshold responses, it does not reveal facts about hearing at ordinary listening levels. Third, the results of pure-tone audiometry are entirely dependent on the responses of the subject,¹³² which are subject to extraneous factors.¹³³

Given these limitations, testing can not rely entirely on a pure tone audiogram.¹³⁴ Speech threshold and discrimination tests can be used to address some of these limitations.¹³⁵

b. Speech Threshold and Discrimination Testing

Speech threshold and discrimination tests provide indications of the test subject's potential to understand

132 Price, SPXD/197-98.

133 NHAS Basic Home Study Course, R8/4273, accord Pollack, Traynor R8/6802; Capano, R8/6963.

134 Kasten, R8/6982, TR 801; Hardick, R8/6847; Frisina, R8/7696; Hecker, TR 5257; Kasten on Briskey, R13/2085.

135 NHAS Basic Home Study Course, R8/4273-74; Hull, R8/6217; Hardick, R8/6511, 6847; Harvey, R8/6897; Frisina, R8/7696; Lentz, R8/8237; Miller, R10/4765-66, R8/5822; Griesel, R10/6893; Delk, TR 10924; Mettler, TR 11393; Scheurer, TR 11419; Masticola, R8/647; Wilson, TR 10062; Harford, TR 79; Kasten, R8/6983, TR 801; Hecker, TR 5257; Staab, TR 7036; Corso, R8/8975; Sanders, R8/7594; Rupp, R8/7111; NHAS, R3/6463; AAOO, R8/4106; Briskey, TR 7241; Scott, TR 2315; Pollack, SPXB/75.

speech.¹³⁶ Speech threshold tests consist of two syllable words, presented very softly. Speech discrimination tests use one syllable words, presented at a comfortable loudness. The results from both tests suggest whether reasonably loud speech can be understood. These tests should be performed both without and with a hearing aid. Using a hearing aid, the word lists should be presented without and then with background noise.¹³⁷

Even when done accurately, these tests are limited. They have been criticized as indicating merely how well an individual understands word lists which contain both low and high frequencies of speech but are not indicative of actual conversation.¹³⁸ They are at best imperfect predictors of how well the user will understand conversation. Kenneth Berger, an audiologist at Kent State university, observes:

. . . . in the opinion of this writer, [a] more basic criticism of . . . word lists, is that there may be a poor relationship between an individual's performance with them and how well he functions in daily conversational speech demands . . .¹³⁹

136 Berger, SPXD/225; P.O. Report R9/Dlip49; in re Mather Hearing Aid Distributors, Inc. (Causey), R8/2035-36; Jerger, R8/5230-31; Miller, R8/5822.

137 Griesel R10/6895; Berger, SPXD/225; Harford, TR 80; Burris, TR 2493-97; in re Mather Hearing Aid Distributors, Inc. (Manning) R8/2114-2117, (Yantis) R8/2156-58; AAOO, TR 4106- 07; Jerger, R8/5227-28.

138 Jerger, R8/5231; in re Mather Hearing Aid Distributors, Inc. (Yantis), R8/2158-59.

139 Berger, SPXD/212.

c. Other Tests

These tests may be modified for a special population such as children.¹⁴⁰ A number of expert witnesses also indicate that a recommendation for a hearing aid should be based on additional testing,¹⁴¹ although others indicate that pure tone and speech reception tests provide sufficient information necessary to fit an aid.¹⁴² These additional tests are aspects of "differential audiology." This involves various complex diagnostic tests to isolate, with greater definition, the cause of the hearing disorder, the physical location and nature of the hearing problem. This additional information also enables the medical diagnostician to analyze the audiometric records with greater precision.¹⁴³ However even the more sophisticated special auditory tests cannot determine the specific pathology

140 For example, the child's name or a dog's bark may be introduced at various frequencies, to detect responses, ASHA, R10/2589.

141 Beiter, TR 9081; Krebs, TR 11869; Griesel, R10/6820; Sanders, R8/7594; AAOO, R8/4108; Hull, R8/6167; William, TR 3795; Stein, R8/991. These might include the Loudness Balance Test (Matkin and Olsen, SPXD/329-32); Short Increment Sensitivity Index test (Id., 332-34); Bekesy Audiometric Test (Id., 334-38); Threshold Tone Decay Test (Id., 338-39); and the Sensorineural Acuity Test (AAOO, R8/4108). For others, see Mettler, TR 11391; Krebs, TR 11869; AAOO R8/4104-11.

142 See note 136, supra.

143 Matkin and Olsen write, "the diagnosis of the auditory disorder is the responsibility of the physician, not the audiologist; thus, caution must be exercised when analyzing audiometric records." SPXD/324, 328.

underlying the disorder.

2. Fitting an Aid

The testing described above indicates the broad parameters of the hearing loss, and provides a preliminary basis for aid selection. Two evaluation methods can then be used for aid selection. These are the comparative method and the master hearing aid method.

a. The Comparative Method

With the comparative method, the user tries several aids during the fitting.¹⁴⁴ Tests are performed to compare their relative benefits,¹⁴⁵ and the individual wears the selected aid for a limited period; the time can be extended into a 30-day (or longer) trial period.¹⁴⁶ The client's subjective experience and the tester's results together determine the final selection.¹⁴⁷ If a trial period is provided, a follow-up

144 Stockler, R10/3195, 3202; Griesel, R10/6820; Sullivan, R8/911; Schmitz, R8/7261; Burney, R8/4784-86; in re Mather Hearing Aid Distributor Inc. (Causey), R8/2082; Hull, R8/6167; Kasten, TR 1433; Rose, TR 466. The tester may use custom earmolds. Delk, TR 10992-94; Alpiner, SPXB/165.

145 Berger, SPXD/487, 500-01.

146 Alpiner, SPXB/168-69; Lentz, R8/7991; Loavenbruck, TR 1554.

147 Alpiner, SPXB/169, 173; Berger and Millin, SPXD/502; Harford, TR 80-83; Pollack, SPXB/261; Kasten, R8/6983; Hardick, R8/6844; Rose, R8/4176, 4179.

evaluation will often be done at the end of the trial.¹⁴⁸
Some commentators asserted that the comparative hearing aid evaluation exposes the consumer to many of the factors that affect satisfaction with an aid.¹⁴⁹

b. The Master Hearing Aid Method

In lieu of using the comparative method, the dispenser may use a master hearing aid. A 1975 study published in Hearing Instruments found that 71% of non-audiologist dispensers use a master hearing aid.¹⁵⁰ The master hearing aid simulates the characteristics of various hearing aids. It does not duplicate their performance, however; the performance of the master hearing aid differs substantially from the performance of an individually worn aid.¹⁵¹ The master hearing aid has better sound amplifying capabilities than

148 Wilson, TR 10025. For a discussion of the adjustment period, see, infra.

149 Rassi, TR 5741-42. See Griesel, R10/6820. The record indicates that many dispensers maintain a large inventory. For example, John Kuptz, a hearing aid seller, testified that the clinical audiologist has an average of 60 hearing aids of various manufacturers in his clinic. Kuptz, TR 5651. Judith Rassi, audiologist, indicated that the Northwestern University Medical Clinic has approximately 60-70 hearing aids. Rassi, TR 5751. Clinical audiologist Bruce Graham has over 100 hearing aids in stock. Graham, S., TR 7433.

150 Frame, R10/6679.

151 Norris, R10/6497. See also ASHA, R10/1760-61; Krebs, TR 11862; Lankford, R10/4892; Frisina, R8/7696; Franks, TR 9810.

commercially available hearing aids.¹⁵²

The master hearing aid was not designed to demonstrate the performance a consumer can expect from a hearing aid.¹⁵³ Rather, it was designed to determine the individual's needs and provide predictive information.¹⁵⁴ Using this information and a fitting guide, the dispenser selects a brand and model of aid.¹⁵⁵

Questions have been raised about the adequacy of the fitting guide. Record evidence indicates that the fitting guide may not bear a substantial similarity to the performance features of commercially available hearing aids.¹⁵⁶ Some witnesses

152 The earphone, microphone, receiver and tubing length in the master hearing aid are different from those found in commercially available hearing aids. See ASHA, R10/1760-61; Norris, TR 6839; Graham, A, R8/7540; Burris, TR 2558-59; Barnow, TR 1644; Lentz, R13/1933, citing Berger, SPXB/319-20; Curran, TR 10857; MPIRG, R8/1239; Krebs, TR 11832, 11896, 11897; Frisina, R8/7696; Leale, TR 11732-35.

The frequency range of the master aid is greater, resulting in a richer fuller sound. There is a better signal-to-noise ratio, that is, less background distortion introduced by the aid. See Hardick, R8/6848; Pollack, SPXB/49.

153 Delk, TR 10948; Barnow, TR 1644; Krebs, TR 11863; Gardner, TR 10104.

154 Stewart, R8/832-33; Krebs, TR 11862-63; Delk, TR 10942, 10948; Keyes, TR 10700-01; Briskey, TR 7289.

155 Keyes, TR 10704.

156 Krebs, TR 11862; Berger, "The Search For A Master Hearing Aid" Amplification for the Hearing Impaired, Pollack, ed., Grune and Stratton, (1975), SPXB/318; Ruben, TR 3975-76.

claimed that master hearing aids are designed to duplicate the acoustic parameters of a manufacturer's line of hearing aids rather than evaluate a client's performance;¹⁵⁷ one of the criticisms of master hearing aids was that their results cannot be readily applied to a range of brands and models.¹⁵⁸ Other witnesses indicated that measurements of an aid's characteristics, used in fitting guides, may not reflect the actual sound produced in the ear.¹⁵⁹

157 Lentz on Rickenberg, R13/1783; Keyes, TR 10693; Norris, TR 6838, R10/6497; accord, Norris, TR 6839.

158 NHAS, R3/3830; Gherig, R8/820; Stewart, R8/832. A survey of clinical attitudes regarding master hearing aids in the 1960's was generally unfavorable for this reason. The record does not indicate that this situation has changed substantially. SPXB/312-13; P.O. Report, R9/Dlip84.

159 The original staff focused on quality control issues as one basis for this problem. However, FDA has since required that manufacturers provide technical data with an aid. 21 CFR 801.420. A manufacturer can comply either by maintaining high quality control, so a single specification sheet is reasonably accurate for all aids, or by separately measuring specifications for each aid. Because FDA has directly addressed many of the quality control problems addressed at the hearing, staff has not detailed this evidence.

Nevertheless, a substantial problem does remain. The 2cc coupler is used, under FDA regulations, to measure an aid's response. However, studies have shown that responses in the coupler are significantly different from those in the ear. Pollack, SPXB/74; Langford, SPXB/95. Consequently, while these specifications are valued for industry-wide comparisons, they cannot accurately predict how an individual will hear with a particular aid.

c. Choosing Parts and Styles

The fitter and user also selects a style of aid. The selection should be based on needs. CROS aids, for example, should be considered where an individual has a unilateral hearing loss but needs to hear from both sides.¹⁶⁰

There are also significant judgments in selecting parts. For example, plastic tubing is used to couple most earmolds to the hearing aid.¹⁶¹ The diameter and length of the tubing selected will alter frequency response of the aid.¹⁶²

The fitter of hearing aids also can choose from a variety of earmolds: Open, closed, vented and tubular shaped earmolds will affect the volume, gain, and output of the hearing aid and thus produce differences in sound quality.¹⁶³ Each hearing aid model is designed and manufactured for use with an earmold having specific acoustic properties. Varying the earmold can change the hearing aid's acoustic responses. To the extent these are controlled, earmold alterations can be beneficial.

160 Berger, R8/5078-79. CROS aids have a microphone in the user's poor ear, and route the sound to the better ear. Pollack, SPXB/260. However, these aids are difficult to fit and often have mechanical problems. Lentz, R8/7997 (50% failure rate); Harford, R8/7562-63.

161 P.O. Report, R9/Dlip61.

162 See n.98 and accompanying text, supra.

163 Berger, SPXB/298; Bode, TR 5097. For example, a closed earmold may cause the wearer to hear his own voice as if he were speaking with his head in a barrel. Rose, R8/4173.

Altering an earmold without knowledge of the acoustic effects, however, can produce unwanted and unknown deviations.¹⁶⁴

In addition to acoustic permutations, comfort must be considered when selecting an aid or altering its shape. The discomfort of wearing a hearing aid is a serious problem for many users.¹⁶⁵

d. Other Factors in Dispensing an Aid

In addition to the previous factors, dispensers consider other factors in recommending amplification, and selecting a style, brand and model. The dispenser should assess the client's needs. For example, some elderly people may lack the manual dexterity necessary to manipulate an aid.¹⁶⁶

Arthritis, Parkinson's Disease, and other conditions may affect the hands and impede the ability to use an aid¹⁶⁷ or make use

164 Pollack, SPXB/74; Harford, R8/814; Bode SPXB/298; Harford, TR 160-65.

165 Eleven percent of consumers responding to the Market Facts study were dissatisfied with aids because of poor earmold fit. Four percent of consumers surveyed stated that they were dissatisfied with their aid because the mold was uncomfortable. Market Facts, R8/660, 662.

166 E.g., Powers, R13/995. In re Mather Hearing Aid Distributors, Inc. (Manning) R8/2140, (Harvey) R8/2220, (Yantis) R8/2181; Market Facts, R8/661.

167 E.g., Powers, R13/995; In re Mather Hearing Aid Distributors, Inc., (Yantis), R8/2180-81; Market Facts, R8/661; RPAG, R8/421; Epstein, R10/423.

of the aid completely impossible.¹⁶⁸ The fitter needs to evaluate the prospective user's ability to remove the aid, put it in the ear, adjust it, and change the batteries.¹⁶⁹ Visual impairments, too, may impair an individual's ability to use an aid.¹⁷⁰

A hearing impairment in a child may be one expression of a neurological problem.¹⁷¹ In addition, some elderly people experience varying degrees of brain deterioration.¹⁷² Failure to address these problems will increase the risk of failure.

3. Overfitting: The Risk of Physical Harm

The record contains evidence that poor selection leading to excessive amplification might cause physical harm: witnesses said it can damage remaining ("residual") hearing.¹⁷³ Others said that, although it has not been established conclusively that residual hearing can be damaged by excessive amplification,

168 E.g., Kasten, R8/6982.

169 Mynders, TR 11587; Corso, R10/195.

170 See Hull, R8/686.

171 Stein, TR 8984.

172 Stewart, (Senate Hearings, 1968), R8/828.

173 Kinney, R13/3664-72; Macrae and Farrant, R13/3673-83; Braunlin, R13/42-69; Ross and Lerman, R13/3684-89; Rintelman, R13/4-30; Lentz, R8/8181; ASHA, R13/3593-96; Marcus, TR 5479, 5488-89; Shattuck, TR 6776; Gerstman, TR 2467; Burris, TR 2575-76; Stein, R10/6305, TR 8975. See Norris, R10/5329, R10/177; Jerger and Lewis, R13/40-41.

there is sufficient evidence of potential danger to justify a cautious approach when fitting a hearing aid.¹⁷⁴ Various industry witnesses testified that hearing aids are harmless devices.¹⁷⁵ However, Stephen Epstein, M.D., stated that while hearing aids are not inherently dangerous, harm can result when a wrong aid is placed in a person's ear.¹⁷⁶ The FDA agrees that harmful side effects can result from misfittings.¹⁷⁷

The potential for damage is particularly acute with children. Testing cannot determine a child's exact threshold of hearing.¹⁷⁸ Threshold levels change rapidly in a growing child.¹⁷⁹ Overamplification, which can cause temporary shifts in threshold levels, may cause permanent harm.

4. The Unavoidable Limitations of Testing and Fitting, and the Resulting Risk of No Significant Benefit

a. The Nature of the Risk

The record shows that testing and subsequent fitting have

174 Markides, R13/3694-95; Jerger and Lewis, R13/38-41.

175 Staab, TR 7111; Briskey, TR 7252; Campagna, TR 2615; Fortner, TR 2932; Curran, TR 10891-92; HAIC Memorandum, R1/D281ipl.

176 Epstein, TR 4609-10.

177 42 Fed. Reg. 9286, 9290 (Feb. 15, 1977).

178 See Jerger, R13/40; Stein, TR 8975; Kasten and Braulin, R12/43-46.

179 Jerger, R12/40; see Kasten and Braulin, R13/43-46.

only limited ability to predict success with an aid.¹⁸⁰ Tests can only identify the client's potential to benefit from aid.¹⁸¹ Despite the best testing and selection techniques, it is difficult if not impossible to predict whether an individual will benefit from an aid.¹⁸² Despite identical test scores, two people may experience significantly different results from an aid.¹⁸³ Doctors Lentz and Willeford, for example, have seen many patients who they felt would not benefit from

180 E.g., Zenith, R3/3086.

181 Williams, TR 3759-60; Urban, TR 1858-59; Beiter, TR 9032, 9058; Rose, R5/708, R8/4173; Madell, TR 5912 (can make a reasonable guess); Rupp, R8/7112; Wilson, TR 10104; Stahl, TR 5538; Marcus, TR 5525; Simmons, R13/809; Kasten on TR 1541; Zelnick, TR 429; Corso, TR 1246; Loavenbruck, TR 1598; Noffsinger, R8/5400-01, 5403; Hardick, R8/6844; Link, TR 1125; Harford, R5/844, R8/7549, 7550; Alpiner, SPXB/159, R8/5430, 5452.

182 Graham, S., R8/7464; Rassi, TR 5733, R8/5354, 5359; Harford, TR 57, 103, R8/4546, 4548-49, 7550, R5/852; Fennema, R10/18; Hardick, R8/6843; Minn. Hearing Aid Industry, R8/1295; Bess, R10/4869; Zelnick, TR 418; Rose, TR 495, 540, R8/4178, 4173; Barwell, TR 5187; Zennith, R3/3116; Williams, TR 3759-60; Brewer, TR 3960; Urban, TR 1852, Smith, B., TR 326; Norris, R10/6495-97; HAIC (May), R13/2223, 2234; (McGann) R13/2247; Butts, TR 4202; Schmitz, R8/7262; Tyszka, R8/5659; Nygren, R8/4940; Loavenbruck, TR 1598; Ruben, TR 3890; Griesel, R10/6020-21; Norris, TR 6871; Corso, TR 1246; ASHA, R13/3592; Kasten, R8/6981; Noffsinger, R8/5399, 5400-02; HEW Task Force Final Report, R8/3182; Rupp, R8/7112; Teter, TR 10230; Wilson, TR 10104; Marcus, TR 5525; Epstein, R10/424; Hopmeier, HX 52; Kasten on Briskey, R13/2085; Giglia, TR 2755; Schmitz, R8/803; Beiter, TR 9032; Berger and Millin, SPXD/497; Sanders, R8/7593; Shepherd, R8/5321; RPAG Report, R8/11880, 2738; Moneka, R8/5386; NHAS, R8/1188V 6 .

183 Williams, TR 3759-60; ACO, TR 3711; Giglia, TR 2757.

amplification, based upon testing, but who did benefit. At the same time, there is evidence of instances where acoustic data indicated that individuals would benefit from an aid, yet they did not because of problems in adjusting to the use of the aid.¹⁸⁴

Properly performed testing measures some variables which affect success with amplification. However, both pure tone and speech tests have significant limitations.¹⁸⁵ A patient who does well in a hearing aid test may have difficulty in a normal listening environment, as testing cannot duplicate the real world listening situation.¹⁸⁶ In the real world, people mumble, and talk while competing with background noise.

In addition, different users have different needs. Even a limited benefit may be significant to some users. There may be

184 Lentz, R8/7992; In accord, Hopmeier, HX52/3-4; Harford, R8/7550; Hardick, R8/6844; Marcus, TR 5512. Darrell Teter testified that one of his colleagues examined how well various factors can predict potential hearing aid user's ability to use an aid successfully; he found that the personality test was a better predictor of success with an aid than the acoustic data. Teter, TR 10230.

185 See Section I.B.1.

186 Barwell, TR 5187; Tobin, TR 4112-13; Delk, TR 10990; Wilson, TR 10104; Simmons, R13/810; Rassi, TR 5762-5763; Madell, TR 5885-86; Rose, TR 509; Syfert, R10/816; Holmes, TR 9596; Franks, TR 9759; Griesel, R10/6228; Noffsinger, R8/5399; Berger and Millin, SPXD/497, 503; Sanders, R8/7593; Dunlavy, R8/1611; Kasten, R5/1433, R8/6981; Hill, R8/7828; RPAG Report, R8/2738; Byrne & Stockler, R10/3195; Harford, R5/852; Millin, SPXB/116, 130.

benefits to using a hearing aid other than understanding speech.¹⁸⁷ Sound has at least three levels of meaning: a social level (where speech is understood), a signal level, (where an individual can respond to sound) and a so-called primitive level (where sound endows the human being with a sense of contact with the environment). Benefit may be on any of these levels.¹⁸⁸ Children may benefit if a hearing aid only enables them to hear the warning horn of an automobile.¹⁸⁹ Older individuals may benefit if they maintain contact with their surroundings, even if they do not understand speech.¹⁹⁰ Thus, the economic and social value received from a hearing aid covers a broad range; to some, the successful use of amplification is not to be assessed as complete understanding of speech, but rather as improvement in overall communicative

187 HAIC, Rousey) R3/3736.

188 Id.

189 HAIC, R3/3715.

190 Zenith, R2/D2ip13; Consumers Union, TR 1966; Elia, TR 7472; Rompala, TR 9126; Moneka, TR 6150; Fechheimer, TR 188-89; Millin, SPXB/135. See Berger and Millin, SPXD/489. In some cases, even a deaf person could be a successful hearing aid user: the aid would supplement the primary input channel (visual) with a secondary input channel (auditory). HAIC, R3/3707. However, fitting an aid to a deaf individual poses a high risk situation as it is clinically difficult to measure any benefit from amplification in a test situation. A trial period would be important to determine if a person with a severe hearing loss can receive a benefit from an aid. In re Mather Hearing Aid Distributors, Inc. (Yantis) R8/2163; Noffsinger, R8/5402.

behavior.¹⁹¹

Successful amplification thus depends on an individual's needs, and how well an aid fulfills these needs. The record indicates that it is difficult if not impossible to predict with certainty how these individual factors will affect a person's total experience with amplification.¹⁹² A minority of witnesses stated that properly performed testing can determine whether a client can benefit from a hearing aid,¹⁹³ and that there are situations where we can generally know whether an aid will be beneficial.¹⁹⁴ However, most witnesses said objective testing cannot predict how well a person will function with a hearing aid.¹⁹⁵

191 Sanders, SPXB/347; Curran, TR 10809 (improvement in the ability to understand speech at ordinary conversational levels); ASHA, R10/1727.

192 Rassi, TR 5735; Beiter, TR 9058, 9043; Harford, TR 61; Rose, TR 466, 540, 509, 495; Zelnick, TR 418; ACO, TR 3693-3695; Williams, TR 3759-60; Brewer, TR 3960; Ruben, TR 3975-76; Holmes, TR 9596; Sanders, R8/7593; RPAG Report, R8/2738; Harvey, R8/2220-21; Millin, SPXB/116; Caine, R8/1179; Berger & Millin, SPXD/503; P.O. Report, R9/Dlip97-98.

193 Vreeland, TR 3833 (benefit can be determined from testing, but satisfaction cannot). Kleiman, TR 6910; Johnson, J., TR 2264; Scott, TR 2368 (you can predict with the greatest of certainty whether a person will receive a benefit [in 95% of the cases]).

194 Beiter, TR 9058; Rose, TR 466, 520, R5/708; Urban, TR 1858-59.

195 Tobin, TR 4112-13; Delk, TR 10990; Beiter, TR 9032, 9058; Rassi, TR 5762-63; Harford, TR 611; Bess, R10/4869; Rose, TR 495, 540, R8/4173, 4178; Wilson, TR

(CONTINUED)

b. The "No Significant Benefit" Standard

The use of "significant benefit" and "significant additional benefit,"¹⁹⁶ as standards to assess hearing aid performance, have generated considerable debate. The debate focuses principally upon the value of an objective versus subjective determination of benefit.

Objective benefit is determinable to someone other than the consumer. Subjective benefit is determined by consumers, when they conclude that an aid improves their hearing sufficiently to outweigh the limitations and cost of the aid.¹⁹⁷

195 (FOOTNOTE CONTINUED)

10104; Zelnick, TR 418; American Council of Otolaryngologists, TR 3692-3693, 3745-46; Franks, TR 9759; Millin, SPXB/116; Sanders, R8/7593; Dunlavy, R8/7593, TR 3400-3401; Shepard, R8/5321; Palmquist, R8/3513; Glorig, R8/1188K⁶; Caine, R8/1179; Kasten, R8/6981; Hill, R8/7828; RPAG Report, R8/2738; Schmitz, R8-803; Byrne & Stockler, R10/3195, 3202; Griesel, R10/6820; Vreeland, R10/3419; Urban, TR 1853, 1856, Krebs, R8/1189II; Mather (Manning), R8/2134; Shattuck, TR 6817.

196 "Significant Additional Benefit" refers to the benefit provided by a binaural fitting over and above that provided by a monaural fitting, or the benefit provided by a new hearing aid over and above that provided by an aid a user already owns. As used in this report, the term "significant benefit" is generally inclusive of the idea of "significant additional benefit." P.O. Report, R9/Dlipl17.

197 Miller, TR 4815. Some witnesses said the standard was essentially equivalent to consumer satisfaction. Heisse, TR 3284; Norris, TR 6838; ACO TR 3692-93. See NHAS, R3/3182 (benefit is objective, satisfaction is

(CONTINUED)

According to one point of view, objective benefit is the only meaningful measure. During rulemaking proceedings, NHAS criticized the subjective standard ("significant benefit") as unrelated to the demonstrable rehabilitative or objective benefits that are obtainable with a hearing aid.¹⁹⁸ Industry also criticized the subjective standard as vague¹⁹⁹ and varying from individual to individual.²⁰⁰ For example, NHAS indicated that "significant benefit" may mean "normal hearing" to a patient, whereas an audiologist or dispenser might interpret it to mean "improved hearing capability and speech discrimination".²⁰¹

As witnesses who endorsed a subjective standard testified, however, there are significant limitations to an objective measure. A tester can only make a preliminary guess that an aid will prove useful.²⁰² The final test is how the aid actually

197 (FOOTNOTE CONTINUED)

subjective); Pollack, SPXB/251 (binaural amplification).

198 NHAS, R3/3181-83.

199 See Zenith, R2/12, R3/3087.

200 Beltone, R3/3130.

201 NHAS, R3/3217. As detailed below, industry also contends that the risk of no significant benefit from a hearing aid is similar to the risk in every purchase, and should be treated equivalently.

202 See n. 181, supra.

helps, in daily use, after the adjustment period.²⁰³ Is the user's ability to communicate, in the context of the user's own needs, significantly improved? Does incessant background noise make it impossible to wear the aid? Is the aid painful?²⁰⁴ For example, Vincent Giglia, Chairman of NHAS's Consumer Affairs Committee testified about his own aid:

....I derive a benefit from it but I am just not comfortable with it. I don't think the benefit I get is worth the uncomfortable feeling that I get with it.²⁰⁵

Objective benefit cannot account for these highly relevant concerns. In consequence, the objective standard is not meaningful to an individual. Rather, a subjective standard, unique for each individual, provides a more practical basis for evaluating the usefulness of an aid.²⁰⁶

Industry, however, contends that every consumer purchase carries with it a risk that the buyer will be dissatisfied, and that the risk in a hearing aid purchase is indistinguishable

203 Beiter, TR 9032; Ruben, TR 3980; Kasten, R8/6979, 6983; Noffsinger, R8/5424; Wilson, TR 10104; Hardick, R8/6884; Denoux and Chill, R10/3119.

204 See Powers, R13/1024; Stockler, R10/3192; ISPIRG, R8/1367.

205 Giglia, TR 2783; accord, Johnson, TR 4322.

206 Zenith, R3/3086; Bowe, R8/6952; WAG-Hat, R10/243; Harford, R5/843; Kojis, TR 1986; Burke, M., TR 6414; Giglia, TR 2757; P.O. Report, R9/Dlip103, 104.

from risks with other consumer products.²⁰⁷ Witnesses indicated that there is no more risk involved in hearing aid selection than in any other product that a consumer might buy.²⁰⁸ Accordingly, they argued that a right to cancel is unnecessary.²⁰⁹

However, since hearing loss is complex, hearing aids complex but limited instruments, and testing an inexact art, failure to adjust to an aid may not be a matter of fault at all.²¹⁰ Indeed, where there is "fault", as discussed below, it may well be the dispenser's.²¹¹ Ultimately, the user's success or failure measures the predictive ability of the testing, and not vice versa. Subjective benefit is therefore the proper basis for evaluating the appropriateness of an aid.

The central conundrum, however, is that an aid's usefulness depends on variables which are independent of the product and of

207 HAIC (May), R13/2223.

208 Mynders, TR 11561-11563; HAIC (May), R13/2237.

209 Id., R13/2223.

210 Industry analogized the purchase of a hearing aid to the purchase of an automobile. However, after assessing one's needs and requirements, a buyer compares cars mainly on objectively determinable characteristics such as size, price, horsepower and maintenance costs, augmenting this information with a test drive. Yet the record reflects that objective criteria have limited ability to predict aid performance. The buyer has no choice but to rely on these limited criteria to guide the purchase.

211 See Section I.B.5 (avoidable risk factors).

testing. Ability to use an aid depends on the nature of loss, as well as counseling, motivation and rehabilitative therapy.²¹² The central problem in attempting to compare the experience of is that one can evaluate other products mainly on objective characteristics visible to all. Hearing aids, however, can be properly evaluate only subjectively, and the data needed to make any evaluation is unavailable until after a period of usage.

c. Conclusion

The evidence thus establishes an unavoidable risk of no significant benefit in every hearing aid transaction. The evidence relied upon is primarily expert testimony. The record also contains independent confirmation that a problem exists, and that consumers with hearing impairment may fail to achieve significant benefit from amplification.

Before turning to that evidence, in Section V, the report will detail other reasons for failure which, unlike those already described, are not inherent limitations of technology and circumstances.

5. Avoidable Risk Factors

Section A and B outlined the inherent limitations of an aid. This section examines other flaws in testing and in the

212 See Section III.

broader hearing health care delivery system, which add to the risk that a consumer will receive no significant benefit.

a. Failure to Discover Medical Problems

A potential user should have a medical examination prior to audiometric testing.²¹³ The FDA now requires pre-clearance by a physician before the purchase of a hearing aid--but it can be waived by the client.²¹⁴ The reasons for medical examination are compelling. A hearing loss may be the first symptom of disease.²¹⁵ It may be attributable to drug use.²¹⁶ An examination may reveal that the hearing loss can be treated medically or surgically,²¹⁷ although individual patients may

213 NHAS, R8/1188L⁶; Burris, TR 2488-89; HEW Task Force Final Report, R8/3203; Rupp, R8/711; Bailey, HX103; Eagles (NINDB), R8/823; Hull, R8/6200; Sanders, R8/7594; Scott, TR 2315; NCSC (Penalver), R10/1453; NHAS Basic Home Study Course, R8/4265; Gherig, R8/820; RPAG, R8/2619; Ruben, R8/11840²; ACO, TR 3705; Oberhand, TR 3409; Epstein, R10/421; Wilson, TR 10021.

214 21 CFR § 801.421.

215 Sanders, R8/7594. Some diseases, such as cancer, diabetes, or syphilis, can lead to further hearing loss or can be life-threatening. Kremen, R8/3704; NHAS R8/118⁷ Consumers Union, HX93/347; Craddock, R5/22; Stephens, R5/1104; Smith, B., TR 280-81; Plotkin, TR 6055; Glorig, R8/1968; Berkowitz, R8/1189s⁶; MPIRG, R8/1243; Ruben, TR 4026-27, R13/776; Rupp R8/7118.

216 For example, the cumulative use of certain drugs such as aspirin, quinine, and many of the mycin drugs (for example, streptomycin and dihydromycin) may result in hearing loss in the inner ear. Price, SPXD/191.

217 The treatment may be simply removing wax from the ear

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prefer amplification, if it would work, to potentially risky surgery.²¹⁸ It is estimated that 15-20% of the hearing impaired population have problems that could be addressed by medical or surgical treatment.²¹⁹ Surgery may reduce or eliminate the need for a hearing aid,²²⁰ or enable a patient to eliminate part of his loss, and use a weaker aid.

A medical examination might also reveal that a hearing aid

217 (FOOTNOTE CONTINUED)

by suction or irrigation, or draining fluids which accumulated in the middle ear due to colds or allergies. ASHA, R10/2276; Israel, TR 938; Urban, TR 1850.

218 The physician can outline the possible benefits of surgery. In a given case, the physician might thus advise that a hearing aid will produce benefits equal to or greater than surgery. Smith, A., TR 8147, 8166-68; Ruben, TR 4036; Vreeland, TR 3875. The physician can also advise about the risks in surgery, including possible paralysis of the face or further hearing loss. Sandstrom, TR 3112; Smith, A., TR 8166; Cooper, TR 10769; Perrill, TR 11610; Marcus, TR 5519. Conductive losses are generally most susceptible to medical or surgical treatment. Gardner, TR 10404 (80% to 90%); McCurdy, TR 30; ASHA, R10/2280; Epstein, R10/422; NBS, R8/615ip11; Anthony, TR 8449-50; Smith, A., TR 8146. Some sensorineural losses, however, can also be treated medically. ACO, R10/3700.

219 Rupp, R8/7111 (20%); NHAS, R3/3638 (5-15% of adults and slightly higher for children); Marlin, R10/452; Glorig, R8/3493 (5-10%); Ince, R8/3422-23; NCSC, R10/451-52 (15%); Israel, TR 938; see also, HAIC, R3/3547 (only a small percentage can be helped medically or surgically).

220 Consumers Union, R8/1044; Ruben, R13/776; Epstein, R10/422; 52; AARP (consumer letters), R10/4045, 4010; Hecker, R10/4834.

is contraindicated.²²¹ For example, a physician may determine that a patient with an ear tumor, or a profusely draining ear would not benefit by wearing a hearing aid²²² because the medical condition would only interfere with the functioning of the hearing aid.

The record, compiled before FDA's medical pre-clearance requirements were promulgated, contains instances where an aid was purchased by users with undiagnosed, medically treatable condition, such as ear wax, or contraindications, such as draining ears.²²³ Dr. Kasden, Ph., D., studied 2369 cases of otosclerosis and found that, of the 1500 who were first seen by a dealer, 98.86% were sold a hearing aid without being told that medical or surgical treatment was available.²²⁴ Other evidence also indicates that individuals were deprived of necessary medical treatment because of inadequate examinations by dispensers.²²⁵

221 NHAS, R8/1188t 7 ; Wiedenmayer, R8/1188c 5 .

222 Rupp, R8/7118.

223 NCSC, R8/457, R10/4737; Byrne, R8/6449; Silverman, R8/7326; Gherig, R8/820; Stroup, TR 948; Holloway, R13/773; Gannaway, R13/1614-17; RPAG, R8/2616-17; Anderson, R13/405; Kramer, R13/1619, 1620; Black, R8/7524; Dolowitz, R5/1607; Person, TR 9270; Abramowitz, R8/4216; ASHA, R10/1720; Jerger, R8/4575; Nardick, R8/6840; Willeford, R8/8200; Menjel, R10/4551; Frazier, R8/7845.

224 Kasden, R5/1282.

225 Holloway, R13/773; Gannaway, R13/1614-17; Kramer,

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The record also contains survey evidence on the extent to which, prior to FDA regulation, the hearing impaired bought an aid without first seeing anyone other than a dealer.²²⁶

225 (FOOTNOTE CONTINUED)

R13/1619-21; Hecker, R10/4834; Hardick, R8/6657; Hill, R8/7831. See, Payne & Payne, R8/1501. RPAG has many letters and surveys which show consumers have been sold hearing aids only to find out later they had a medical problem. Griesel, R10/6848.

Some witnesses did say that a dispenser could evaluate the need for medical examinations. Berkove, TR 11009; Elia, TR 7477; Stallons, TR 7866; Murphy, R10/4947; Leale, TR 11947; Baesemann, TR 7338, 7400; Carter, R., TR 3682; Williams, TR 3777; Winslow, R10/6939; Vreeland, TR 3836; Burris, TR 2506, 2529; Martinucci, TR 8385, 8408; Giglia, R8/3440; Payne & Payne, R8/1502 (the general position of dealers he surveyed).

However, this was contradicted by FDA's determination and by other testimony in this record. Cody, SPXD/43; Rupp, R8/7111; Hardick, R8/6510-11; Hull R8/6200; Burris, TR 2488; Eagles (Senate Hearings, 1968), R8/823; Scott, TR 2315. Record evidence also indicates that some dispensers are derelict in obtaining case histories. David Rompala, audiologist at Schwab Rehabilitation Hospital in Chicago, reported that only 2 out of 40 hearing aid users had a medical case history taken prior to an examination for a new aid. Rompala, TR 9103. See also Hardick, R8/6725; NCSC, R10/4701. To assess the cause of a hearing loss, it is necessary to obtain a case history of past and present ear complaints as well as those referable to other systems.

226

The evidence showed that 66% to 75% of those surveyed bought an aid without seeing a doctor. RPAG Report, R8/2612; Bailey, "Total Hearing Rehabilitation" (Arch Otolaryngol, June 1976), HX103/323; HEW Task Force Report, R8/3203-04; Epstein, TR 4563. On the other hand, the Payne and Payne survey indicated that 61.4% of the hearing aid users surveyed (all of whom saw NHAS members) consulted physicians. Payne & Payne, R8/1445. Payne & Payne also found, however, that

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Indeed, sales manuals advised dispensers how to address the "objection" that the buyer wanted to see a doctor.²²⁷

Medical pre-clearance can thus eliminate the risk that a medical problem will not be discovered. Even if physicians do get involved, however, their role will generally be limited. While some physicians will select an aid and others will give some guidance to their patients,²²⁸ many physicians limit their role to medical diagnosis or remediation, and not aural

226 (FOOTNOTE CONTINUED)

hearing aid dealers referred 23.8% of their consumers to physicians or audiologists. R8/1492. This was confirmed by the Market Facts Study and other record evidence. Market Facts Study, R8/625 (only 3% of hearing aid wearers responding were referred by a seller to a physician prior to purchase). See NCSC, R10/464 (6 out of 8 dealers made no recommendations for consultation with a doctor); Woodward, HX65 (Only 19 out of 86 Los Angeles dealers responded affirmatively to the question, "Do you think I should see a doctor before I buy a hearing aid?"); RPAG, R8/2602; MPIRG, R8/1250 (none of the volunteers in the survey told to see a doctor); ISPIRG, R8/1361; Holloway, R13/773.

227 The Dahlberg manual, for example, recommended that the dispenser ask to call the client's doctor immediately, because, "in most instances, it will not be necessary to make the call . . . as the customer will come to the realization that he does believe in you." R8/7055. (If the buyer does place the call, the dispenser is told to truthfully discuss the test results.) Another urges its dispensers to say, "Come on, now, John, let's be truthful with one another. In all this time, has he done one concrete thing to improve your hearing?" Mather, R8/3683.

228 See Barwell, TR 5186.

rehabilitation.²²⁹ HAIC said

once the specialist determines that medical or surgical treatment is not warranted, he generally considers his participation . . . at an end.²³⁰

Additionally, physicians (even ear specialists) usually have little or no training in aural rehabilitation, including hearing aid selection.²³¹

Doctors may thus terminate their responsibility towards the patient once they have completed their medical diagnosis, and neither inform nor counsel their patients as to subsequent steps.²³² Consequently, while medical pre-clearance would solve one "avoidable" problem, it would not eliminate the other "avoidable" risk factors, or inherent risk factors.

229 Graham, A., TR 7426; Gardner, TR 10350, 10395.

230 HAIC, R3/3582. See also Gardner, TR 10395; Consumers Union, R8/1044; AARP, R10/1310, 1318; ASHA, R10/2203; Mosley, R10/3512; Shuford, TR 644; Ashford, R10/1860.

231 Rompala, TR 9095-96; Sanders, SPXB/324; Gerstman, TR 2406; Graham, A., TR 7425-26; AARP, R10/4257; Harrington, R8/1602; Dunlavy, R8/1609; Shuford, TR 644; Morgan, TR 9523; Hopmeier, TR 3356-57; Denoux & Chill, R10/3118; Smith, B., TR 312.

232 AARP (consumer letters), R10/1310, 1318; Perrill, TR 11610. Some consumers strongly criticized their doctors for inadequate counseling. AARP (consumer letters), R10/932; R10/1310, 1318, 4012; Perrill, TR 11610; David Rompala, an audiologist, also criticized doctors for not adequately counseling their patients, particularly as to the possible role of the audiologist, and the need for an adjustment period and possible therapy. Romapala, TR 9110-13. See also, Rich, R8/1097; RPAG, R8/118, 804.

b. Inadequacies in Testing

(1) Types of Problems, in General

The record indicates that in some instances no testing is done prior to recommending an aid,²³³ and in other cases only air conduction tests are performed.²³⁴

Testing can also be done poorly. In certain tests, for example, testers might give unintended cues if they are visible to the subject.²³⁵ Speech tests, too, can be done poorly or in a deliberately deceptive manner. The word lists can be presented either by a tape recording or by reading them aloud, but they should be presented with a consistent level of intensity, degree of enunciation, and voice quality. Live voice testing is more likely to fail these prerequisites; the tester may not speak the words the same way or with the same intensity each time.²³⁶ Moreover, record evidence refers to instances where testers deliberately lowered the tone of their voice during testing to indicate the subject's profound need for an aid; they then raised their voices when the individual listened

233 NCSC, R10/1426, 1553, 4673, 4483, 4582; Minnesota (Kelly) R10/5699, R10/5648, R10/5816; ISPIRG, R8/627-28; Simon, TR 9160; Ludwig, R8/61; Hill, R8/7831.

234 Miller, R10/4770-71; Rompala, TR 9103; RPAG, R8/1188L⁴; Hardick, R8/6725; R8/6729; R8/6730.

235 NHAS, R8/4274.

236 NHAS, R8/4274; Hardick, R8/6848; Schmitz, R8/7264; Rupp, R8/7116.

with an aid to show the dramatic affects of amplification.²³⁷
In other instances, testers would use high frequency word discrimination tests (which are harder to understand) for unaided hearing, and low frequency word discrimination tests for aided hearing²³⁸ to demonstrate the potential for "benefit" from a hearing aid.

In addition, the evaluation should be performed in a proper testing environment with appropriate and properly maintained equipment.²³⁹ Problems shown in the record, however, include the use of an uncalibrated audiometer, the improper use of masking, and the presence of environmental noise in the test room.²⁴⁰ The subsections which follow discuss these problems.

(2) Calibration

Audiometers must be calibrated regularly.²⁴¹ Stationary

237 Miller, R10/31; see AARP, R10/3939.

238 P.O. Report R9/Dlip81; Morgan, R10/7331-32.

239 See generally, Newby, Audiology, 84-85, 90 (1972); Rompala, TR 9095; ISPIRG, R8/1362, 1364, 1368; Moneka, R8/5386; Glorig, R8/2001; Schein, R8/5683; Johnson, J., TR 2264; Graham, S., R8/7465; Pascoe, R8/7374-78.

240 Michigan Hearing Aid Board, R8/6549; Norris, R8/4341; Kasten, R8/4222; Glorig, R8/2001; Yantis, R8/4399; Ross, R8/4726; Olsen, R8/4436; ASHA, R8/1188L 5, R13/2662; Miller, R10/4765-66; Butz, R10/5203; Wilber, TR 1399; Rupp, R8/7116; Hardick, R8/4328; Hattler, R8/4728.

241 NHAS, R8/1188T⁷; Eagles (NINDB), R8/823; Glorig, R8/2001; P.O. Report, R9/Dlip81; Anderson, R8/1159;

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audiometers should be recalibrated at least once a year.²⁴²

Portable audiometers should be recalibrated at least once every six months.²⁴³

An improperly calibrated audiometer will be inaccurate.²⁴⁴ Record evidence shows, however, that audiometers are often improperly calibrated.²⁴⁵ For example, a study of audiometers

241 (FOOTNOTE CONTINUED)

Stewart, R8/832; Rich, R8/6601; Munger, TR 4536-37; FTC Rebuttal on Scheurer, R13/428-29; Wilson on Scheurer, R13/2009-2012; ASHA, R8/1188L⁵; R13/2662; Miller, R10/4765-66; Griesel R10/6893; Scheurer, HX210, TR 11419; Giglia, TR 2740; Butts, TR 4193; RPAG, R8/1188W⁴; HX-93; Bess, R10/4870; Michigan Speech and Hearing Aid Association, R8/6601-03; Mather (Yantis), R8/2161; AAOO, R8/4096, 4097, 4099; Herrink, R8/8387. The American National Standards Institute has adopted standards for calibration. NHAS, R8/6601; Wilson on Scheurer R13/2010; Senate Subcommittee on Consumer Interest of the Elderly (Griffing), R8/1189Y.

242 Giglia, TR 2740; Scheurer, TR 11442, HX210; Rupp, R8/7119. These tests should be done more often if biological testing reveals it is not functioning properly. Lentz, R8/7993.

243 Scheurer, TR 11442-43; Giglia, TR 2740; Portable audiometers are more frequently exposed to situations such as car vibrations, temperature changes and sudden movement. Stroup, TR 959.

244 RPAG R8/1188W⁴; Glorig, R8/2001; P.O. Report, R9/Dlip81; Munger, TR 4536-37; Griesel, R10/6893; Giglia, TR 2740; Ryan, TR 1530; Bess, R10/4870; Calibration Survey Reports, R13/442; AAOO R8/4099. The error can be as high as 26 decibels. Jerger, R8/4570; Hayes, R8/4954.

245 Hattler, R8/4728; RPAG Report R8/2753; Lentz, R8/7995, 8265-66, 8273; NHAS, R8/1188L; Eagles (NINDB), R8/823; Glorig, R8/2001; P.O. Report, R9/Dlip81 (citing Walton and Williams); Anderson, R8/1159; FTC Rebuttal on

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used in Texas school screening for 1971-74 showed that 77.1% of the 515 audiometers were defective.²⁴⁶ A three-year Public Health Service survey initiated by the University of North Carolina's Audiometric Calibration Center in 1964 sampled audiometers in clinics, hospitals, public schools, and professional offices throughout North Carolina. It found that all were unsatisfactorily calibrated, and that operators were unaware of the need for periodic calibration.²⁴⁷ In 1975, audiologist William Lentz, Director of the Hearing Clinic at Colorado State University, attributed substantial discrepancies between test results obtained at his clinic and those obtained by dealers to inadequately calibrated equipment and to poor test procedures.²⁴⁸ John Kuptz, a former salesman of audiometers, testified that at least 50% of the equipment in use was out of calibration.²⁴⁹

245 (FOOTNOTE CONTINUED)

Scheurer, Williams, R13/2014-2021; RPAG, R8/1188L⁴; Klein, TR 7574; Conlin, TR 7855; Calibration Survey Report, R13/429; Detroit Free Press (2/26/73), R8/1431.

246 Tx. D.H.R. R13/442. The study, by the Texas Department of Health Resources, used ANSI standards. Even among the 250 audiometers calibrated within 12 months of the test, 73.2% were defective. Id., R13/443.

247 RPAG, R8/1188W⁴, 2753; Eagles (NINDB), R8/823; Stewart, R8/832.

248 Lentz, R8/7995; accord, Legal Research and Services for The Elderly, R8/3889.

249 Kuptz, TR 5707.

There are several reasons for inadequate calibration. According to the record, the necessary instrumentation is not readily available to the typical dispenser;²⁵⁰ even if the instrumentation is available, calibration is expensive.²⁵¹

State laws and regulations in some cases do require calibration,²⁵² but the statutes and regulations are often unclear on how many functions needed to be calibrated.²⁵³ Moreover, record evidence indicates that licensing agencies were often not able to check the accuracy of calibration, even in some cases where they had statutory authority to do so.²⁵⁴

(3) Masking

Masking is the practice of deliberately introducing noise through earphones. This prevents the non-test ear from

250 . Bess, TR 6231, R10/4870; Rupp R8/7119; Lentz, R8/8256-57.

251 These costs in 1973 reportedly ranged from \$70.00 to \$150.00 for each calibration. RPAG, R8/2753.

252 NHAS, R8/4034.

253 Zumbrunnen, TR 11935.

254 HEW Task Force Final Report, R8/3218 (1975 report found "few states have developed effective enforcement programs" for licensing requirements including calibration). The 1975 Percy Committee surveyed all the states, and concluded that, in nearly half the states, the board could not check on the accuracy of calibration. In most states requiring calibration, dealers needed only file a statement that their equipment was calibrated -- a statement, the committee said, which "is hardly a guarantee of accuracy." R8/3823.

overhearing a test signal,²⁵⁵ and assures that the tested ear (and not the other ear) has heard the signal. Testing without adequate masking is inaccurate.²⁵⁶

Since masking noises are not equally effective at all frequencies, a range of masking noises is needed for accurate testing.²⁵⁷ However, while some audiometers do provide various types of noise to "mask out" sound from the better ear,²⁵⁸ many audiometers have little or no ability to mask noise.²⁵⁹

Even with proper equipment, many witnesses questioned whether dealers were capable of proper masking.²⁶⁰ The NHAS

255 NHAS Basic Course, R8/4267; AAOO Guide, R8/4100-01; Mowry, R13/1123; AAOO, R8/4099.

256 Graham, S., & Winston, R8/7465; AAOO, R8/4099; Hardick, R8/6851; Staff Rebuttal Submission, R13/1121-23. Masking is particularly important in bone conduction testing, where the better ear is most likely to pick up the test signal and distort the result. AAOO, R8/4100; Kasten, R8/6983; Mowry, R13/1122-23. Masking must be used for air conduction testing if the poorer ear is worse than the better ear by at least 30 dB.

257 NHAS R8/4267; Newby, Audiology 80, 139 (1972). Sanders, R8/4267, 7596; Hardick, R8/6851; Price, SPXD/180; Berger, SPXD/219; Sandlin & Krebs, R13/930.

258 NHAS Basic Home Study Course, R8/4267; Newby, Audiology 15 (1972); Price, SPXD/179. Sawtooth noise has a buzzing sound. White noise sounds like a steady "sh" sound. These and other noises are necessary to mask various frequencies of the test signal. Mather (Manning), R8/2120.

259 NHAS, R8/4267; Sanders, R8/7596; Bess, TR 6232.

260 Kasten, R8/6983; HEW Task Force Preliminary Report,

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Course on Hearing Aid Evaluations²⁶¹ handles this entire topic in only a cursory fashion.²⁶² ASHA suggests that it would be

difficult to imagine a hearing aid dealer who completes this course [as] being even remotely capable of making valid pure tone measurements [where] masking would be necessary.²⁶³

Dr. Ralph Rupp, Professor of Audiology at the University of Michigan Medical School, testified that it takes at least a year for audiology students in his graduate program to grasp and accomplish masking procedures.²⁶⁴

Proper masking is difficult to accomplish, and audiometric equipment is often inadequate to perform this function, according to the record. Accordingly, improper masking poses a substantial risk that a recommended aid will not meet the acoustical characteristics required by an individual.

(4) Environment

There was substantial testimony that hearing evaluation

260 (FOOTNOTE CONTINUED)

R8/3278; ASHA, R8/1621; Mowry, R13/1121-23; Hardick, R8/6849; Kuptz, TR 5707-08.

261 See Section I.B.5.b.(5).(a).

262 See NHAS, R8/4267-68, 4271.

263 ASHA, R8/1621, R10/2664.

264 Rupp, R8/7116; accord Hardick, R8/6850. No precise rule can be laid down as to the intensity of masking needed in all cases; as with all audiometric testing, clinical experience must be the guide. AAOO, R8/4101.

should be conducted in a sound treated room, as a hearing loss cannot be accurately measured with distracting noise present.²⁶⁵ Extraneous noise in a test room will exaggerate hearing loss²⁶⁶ and produce inaccurate test results and an inaccurate recommendation.²⁶⁷ (Some witnesses commented that testing in a non-sound proof environment allows the dispenser to deliberately make a hearing loss appear more pronounced.)²⁶⁸

The norms for hearing loss are established by testing young

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- 265 Yantis, R8/4399; Wilber, R8/5330; Wallenberg, R8/4397; Shore, R8/1164-65; Schmitz, R8/7261; Rupp, R8/7115; Ross, R8/4726; Olsen, R8/4436; Rich, R8/6601; Moneka, R8/5392; Miller, TR 4817-18, R10/4765-66; Griesel, R10/6423, 6893; Rompala, TR 9095; Fennema, TR 1753; Gerstman, TR 2476-2477; ISPIRG, R8/1359, 1368; Legal Research for the Elderly, R8/3889; Rose, TR 518; Munger, TR 4534; Marlin, TR 4545; Epstein, TR 4605-07; MPIRG, R8/1232; Norris, R8/4311; Elia, TR 7509; Glorig, R8/2001; Kasten, R8/4222; Resnick, R10/508; Williams, R10/3438, 3762; Oberhand, TR 3072; NYPIRG, R8/1335K; RPAG Report, R8/2604; Millin, SPXB/131; Mather (Yantis) R8/2161, (Harvey) R8/2214; Loavenbruck, TR 1554, Johnson, K. R13/2662; Payne, James, R8/1497; Pascoe, R8/7374; Hardick, R8/6849, 4328; Hattler, R8/4728; Winston & Graham, S. (Interview), R8/7465; AAOO, R8/4099; P.O. Rpt., R9/Dlip105, 137; Bowen, HX35/12.
- 266 Legal Research for the Elderly, R8/3889; Price, SPXD/189; Harford, TR 132; Fennema, TR 1753; NHAS Basic Home Study Course, R8/4265; Glorig, R8/2001; Oberhand, TR 3072; NYPIRG, R8/1335K; Munger, TR/4534.
- 267 Rompala, TR 9095; Wilber, TR 1401; Fennema, TR 1753; Griesel, R10/6423; Lentz, R10/6535; Shore, R8/1164-65; Moneka, R8/5392; AAOO, R8/4099; Unitron News, R8/5406; Hull, and Traynor, R8/6128; Corbett, R10/13; Splansky, TR 9024; Ryan, TR 1530.
- 268 Legal Research for the Elderly, R8/3889; Miller, TR 4784, 4817-18; MPIRG, R8/1252; Resnick, TR 5390; Wilber, TR 1399; Bess, R10/4870; Anderson on Scheurer, R13/370.

people with normal hearing in a sound-proof room; and witnesses said that identical environment is necessary to produce meaningful measures with hearing impaired individuals.²⁶⁹

Tests are often done in sound-proof or sound-treated rooms-- but perhaps because of the expense, which at the time of the proceeding could be well in excess of \$10,000,²⁷⁰ few non-audiologist dispensers have these rooms.²⁷¹

However, FDA has found there is no evidence that compliance with ANSI standards for background noise (which non-sound proof rooms may fail) is necessary.²⁷² A number of comments in this proceeding stated that they are unnecessary,²⁷³ if the noise

269 Price, SPXD/170-172; Munger, TR 4534; Smith, B., TR 320; RPAG (Hamburger), TR/5309, R8/1188N; Bess, R10/4870; NYPIRG, R8/1335K; Griesel, R10/6779; Schein, R8/5683; ISPIRG, R8/1359; Glascock, TR 13/777; Rupp, R8/7116; Mather (Causey) R8/2038, (Yantis) R8/2153.

270 Jerger, R8/4570 (\$10,000 for a sound room); Kasten, R8/6982 \$13,000-\$14,000 for a sound-proof test room); Wilson, TR 10078 (\$1,500-\$2,000 for a small sound booth; \$6,000 for a double-wall booth).

271 Williams, TR 3762; Hardick, R8/6847; NYPIRG, R8/1335I; Wilson, TR 10079; Hearing Instruments Survey, R10/6679 (9% of the respondents have sound-treated rooms).

272 45 Fed. Reg. 67334 (1980).

273 See Stallons, TR 7866; Iliff, R10/3429; Vreeland, R10/3419; Curran, TR 10850. A sound-proof room is different from a sound-treated room. A sound-proof room resembles a bank vault. The only sound that may enter the chamber is that which is introduced by the tester through an intercom system designed to filter out extraneous noise. Griesel, R10/6893. A sound-treated room is carpeted, has acoustical tile on ceilings and at least two walls but is not considered

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level surrounding the test site is carefully regulated.²⁷⁴

Others agreed, observing that we do not live in a soundproof world.²⁷⁵

There is much evidence that testing is in fact often done with substantial noise present, although some of the evidence of problems turns on comparisons to ANSI standards.

(a) Office Testing

Ronald Scheurer, audiologist and NHAS witness, surveyed 20 hearing aid offices in Oregon and Washington, and reported that only 4 hearing aid offices had ambient noise in excess of the ANSI standard at any common testing frequency.²⁷⁶ However, Wesley Wilson, Ph.D., discussed shortcomings in Mr. Scheurer's study. He asserted that Scheurer failed to adjust his

273 (FOOTNOTE CONTINUED)

sound-proofed. As a result, a certain amount of noise will necessarily intrude, Lentz, TR 11185; Mather (Yantis), R8/2153. Griesel regards sound-treated rooms as inadequate for audiometric testing. R10/6893.

274 NHAS Rebuttal Submission, R13/2488; NHAS, R8/1188a⁷; Anthony, TR 8466 (uses otocups - ear phones - to reduce ambient noise); Whitman, TR 8578; Miller, TR 4817-18; Curran, TR 10850; ASHA, R8/1621; Williams, R10/3438; ASHA, R10/2664 reviewing the NHAS Basic Course; NHAS R8/4265; Kojis, R8/892; Stallons, TR 7866; Hull R8/6228; Interview with Hull and Traynor, R8/6127.

275 Harford, TR 133; NHAS, R8/1188p⁶, 1188v⁶; RPAG, 41.

276 Scheurer, Ronald "Hearing Aid Office Test Area Sound Levels" Hearing Instruments, (February 1975), R10/7316.

measurement to account for a 1969 change in standards of measurement.²⁷⁷ When the figures are adjusted to be compatible, Wilson said, the average office failed ANSI standards air conduction tests at one common frequency. Wilson further asserted that even less noise can be tolerated for bone conduction tests, and that the average office Scheurer tested was inadequate for bone conduction tests at 3 frequencies.²⁷⁸

The record also contains a number of consumer complaints that refer to excessive noise in office test rooms.²⁷⁹ One ISPIRG volunteer stated that she could hear street sounds and people walking during audiometric tests.²⁸⁰ At a number of Washington, D.C. dealerships, doors to testing rooms were left open during tests.²⁸¹ One dispenser gave a hearing test while

277 The data was measured by a 1969 standard, but the appropriate noise level figure used for comparison was based on a 1960 standard. Wilson, R13/2011.

278 Wilson, R13/2011-12. Wilson also observed that Mr. Scheurer did not indicate whether the noise levels reported were peak or average levels. Peak levels would be the more desirable phenomenon to measure, since they represent the maximum noise which might interfere with testing. Wilson further noted that the results reported are averages, with no indication of the dispersion or standard deviation, which are needed to allow a proper understanding of the data collected.

279 Griesel, R10/6423; Lentz, R10/6535.

280 ISPIRG, R8/1361; accord, Marlin, TR 4544; MPIRG, R8/1252-53; Griesel, R10/6423; Powers, HX218.

281 Legal Research and Services for the Elderly, R8/3889. This occurred at other dealerships as well; MPIRG, R8/1252; Griesel, R10/6423.

six jackhammers were being used in the street below.²⁸² In another instance, tests were given while fire engines passed the testing area.²⁸³

(b) Home Testing

Other evidence focused on home testing and fitting. Some witnesses testified that hearing aid fitting would be better done in the home environment.²⁸⁴ Dr. August Martinucci testified that most homes are sufficiently quiet for accurate testing.²⁸⁵ Ronald Scheurer studied noise levels in different residential areas in Portland, Oregon. He said the average home fell within the range permitted by ANSI for accurate testing.²⁸⁶ However, Wesley Wilson contended that an improper standard was used, as he said it was in Scheurer's office test study.²⁸⁷

In a 1971 report to Congress, the Environmental Protection Agency indicated that noise levels in some homes are extremely

282 MPIRG, R8/1253.

283 RPAG, (Hamburger), R8/1188N.

284 Vreeland, R10/3419; Williams, TR 3762; Anderson, R13/369-70; Briskey, TR 7243; Levy & Tuttle, TR 11642.

285 Martinucci, TR 8387; accord, Briskey, TR 7243.

286 Scheurer, TR 11422-23.

287 Using a proper standard, he said, the average home is an inadequate environment for air conduction testing at 2 frequencies, and for bone conduction testing at 4 frequencies. Wilson, R13/2011-12.

high.²⁸⁸ Many witnesses testified that the home environment is not conducive to an accurate evaluation of hearing loss.²⁸⁹ Otolaryngologist Robert Oberhand testified that in-home tests "are not reliable; they are a screening device."²⁹⁰

288 Staff Rebuttal on Scheurer, R13/493.

289 Resnick, R10/495, TR 5390; ASHA, R10/1731; Moneka, R8/5392; ISPIRG, R8/495, TR 5390; ASHA, R10/1731; Moneka, R8/5392; 5258; Wimmer, TR 6518, R10/5325; Butz, TR 6623; Wilson on Scheurer, R13/2009-2012; Fennema, TR 1753; Butts, TR 4153; Anderson on Scheurer, R13/370; Lentz, R8/8234; Unitron News, R8/5406; P.O. Report, R9/Dlip81; Gerstman, TR 2476.

290 Oberhand, TR 3073. Only in extenuating circumstances, the Georgia Speech and Hearing Association indicated, may it be necessary to use these results. Bess, R10/4870; In accord, Anderson on Scheurer, R13/370; Hull & Traynor, R8/6797-98.

(5) Competence Questions

The record indicates that some dispensers lack minimal competence. This evidence confirms the existence of poor testing procedures.

(a) Issues Involving Dispensers Generally and NHAS Certified Dispensers

The hearing aid dealer is a salesperson, often recruited primarily from persons with sales (rather than technical) experience.²⁹¹ The record indicates that dealers provide valuable services. For example, they seek out the hearing-impaired to provide amplification.²⁹² However, as the record indicates, this sales practice also leads to sales abuse.²⁹³ The dealer also tests hearing and conducts hearing aid evaluations,²⁹⁴ and provides post-sale services.²⁹⁵ However, the record contains evidence that some

291 Feder, TR 8527; Winston (Graham), R8/7393; Whitman, TR 8601, 8610. Beltone solicited salesmen in an ad entitled "Sick Salesmen Wanted." The reference was to salesmen sick of selling vacuum cleaners, aluminum siding, encyclopedias, cosmetics or other hard to sell products. Davis, TR 8563.

292 Wiedenmayer, R8/1188C⁵; HAIC, R8/1189B; NHAS, R3/3536; West, TR 10417. See Beltone Electronics Corp., Docket 8928, slip op. at 48 (July 6, 1982).

293 See Section IV.

294 NHAS, R3/3536; Williams, TR 3761; Mettler, TR 11405; Elia, TR 7475; Oberhand, TR 3035; Sandlin, TR 10120; Barwell, TR 5186; NBS, R8/615Q; HAIC, R3/3733; Barnow, TR 1612.

295 Dunlavy, TR 3401; Payne, J., (HEW Hearings), R8/3480; Barwell, TR 5184; Eglit, HX 93/351.

dealers are ill-equipped to offer these services.

The educational background of dealers vary widely. Many dealers only have a high school education,²⁹⁶ and state laws never require more than a high school diploma.²⁹⁷ Many others have had some college background, at least among the minority of dealers certified by NHAS.²⁹⁸ This additional education, however, is not necessarily related to hearing impairment.

Dealers may obtain their training from several different sources.²⁹⁹ Individual manufacturers often provide programs or resources,³⁰⁰ and these are also available from HAIC, (the manufacturers' association),³⁰¹ from other industry groups and from

296 See, Minnesota Hearng Aid Industry, R8/1290; RPAG, (Ruben), R8/2770.

297 Hearing Aid Journal, Sept. 1977. This remains true today.

298 The May, 1975 issue of the Hearing Dealer reported that 79% have some college training or are college graduates. NHAS, R3/3395.

299 The NHAS members Payne interviewed for his survey reported the following in response to a question about the time they devoted to updating their knowledge about the hearing aid field: 89% reported reading the literature on the average of 152 hours a year; 8% reported attending formal classes, with an average of 66.7 hours spent doing class work; 71% reported attending seminars and meetings with an average of 42 hours per year spent at the meetings); Payne and Payne, R8/1497. See also, Sandlin, TR 10167; HAIC, R13/2268.

300 Berkove, TR 11000; Resnick, TR 5384-85; NHAS, R8/11880³; Waters, R8/4004; Samole, TR 6729, 6732, 6738, 6670, 5671. See MAICO, R13/851-902; Dahlberg, R13/1297-1335, R8/7034-56.

301 HAIC, R13/2268; see, Delk, TR 10921.

various schools.³⁰² NHAS also promotes a two-year program leading to an associate of applied science degree. The program is offered at various colleges and universities under the direction of the non-profit, NHAS-funded Hearing Instruments Institute.³⁰³

Although these programs and resources are available, however, the record shows that few companies require training as a condition for dealers to sell their aids, or set any minimum qualifications for experience or knowledge.³⁰⁴

The record also contains extensive evidence relating to the training of the approximately 2,200 dispensers certified by NHAS.³⁰⁵ At the time of the hearings, NHAS certification required first, completion of a twenty-lesson home correspondence course. The course, developed by a committee of doctors and audiologists, included three tests and a final exam.³⁰⁶ The candidate for NHAS

302. Resnick, TR 5384-85; Scheurer, R10/6680; HAIC, R13/2268; Samole, TR 6729, 6732, 6670; Zelnick, TR 408.

303. NHAS, R3/3238-40; Percy Report, R8/3813.

304. Kleiman, TR 6938; Samole, TR 6672; Kefauver Committee Hearings, R8/713; MAICO, R3/3074. See Sandlin, TR 10167. But see, RadioEar, R8/2492.

305. Resnick, R8/1188A⁶; HEW Task Force Preliminary Report, R8/3278; Woodard, HX65; but see, Kenwood, TR 9285 (this witness believes NHAS members supply about 85 to 90% of all hearing aids sold in the U.S.).

306. The lessons essentially include instruction in the principles of acoustics; the decibel, the acoustics of hearings and speech; the anatomy of the human ear, the hearing process; disorders of hearing (conductive, sensorineural, central, and non-organic); hearing analysis,
(CONTINUED)

certification also had to: 1) secure the approval of local dispensers and other community leaders as to character and credit rating; 2) secure a medical doctor's affirmation of competence; and 3) pledge to uphold NHAS' Code of Ethics.³⁰⁷ NHAS also required two years of supervised experience as a hearing aid dispenser.³⁰⁸

Various commentators questioned the adequacy of this course and certification program.³⁰⁹ The Percy Report secured three evaluations of the NHAS course: one by the Veterans Administration, one by ASHA (audiologists) and one by the ACO (medical doctors).³¹⁰

These evaluations were critical, although NHAS said they failed to consider the broader context of certification.³¹¹

The V.A. evaluation stated that the NHAS course was

306 (FOOTNOTE CONTINUED)

the audiogram, and the auditory area; history of hearing aids; characteristics and components of hearing aids; fitting of hearing aids; the ear mold, recommendations for the delivery of the hearing aid and conducting post-fitting checkups; Kenwood, TR 9287; Percy Report, R8/3813; NHAS, R8/4225; NHAS (Pigg), R8/1188K³.

307 Percy Report, R8/3814; Kenwood, TR 9287-88; NHAS (Pigg), R8/1188L³. See generally Section VI.C.1.a.

308 NHAS, R8/4026; NHAS (Pigg), R8/1188L³.

309 Georgia Speech & Hearing Association (Bess), R10/4868, TR 6228; ASHA, R8/1620-21, R10/2592; Griesel, R10/6850; Percy Report, R8/3830; HEW Task Force Preliminary Report, R8/3278; RPAG (Kloze), R8/1188K.

310 Percy Report, R8/3814-16.

311 NHAS said that the course should be viewed in a broader context of other training opportunities, including supervised experience, seminars and other programs. R8/4026.

. . . not only inadequate but potentially dangerous. It is dangerous in the same way that 'quack' medicine is dangerous. . . . It postpones or prevents adequate evaluation, diagnosis, and treatment of hearing loss and its accompanying pathology. Some of these pathological entities are life-threatening and require immediate and aggressive medical or surgical treatment. (emphasis in the Committee report)

* * *

The V.A. course analysis found "much of the specific information incorrect . . . (and) oversimplified." It also found some data "presented in a very complex manner . . . apt to be well beyond the ability of those taking the course to understand."³¹²

Regarding the course material on cholesteatoma, a serious medical condition, the Percy Report noted:

. . . [T]he NHAS "described [cholesteatoma] simply as a tumor of the middle ear which sometimes perforates the ear drum, invades the external auditory canal, and is accompanied by a constant discharge." The V.A. panel said the ear abnormality is "one of the most dangerous pathologic states of the temporal bone with potentially deadly complications . . . (A) patient complaining of a hearing loss due to a dry destructive cholesteatoma risks loss of life if diagnosis and treatment are delayed because his first contact for help was with someone interested only in the fitting of a hearing aid to improve the hearing."³¹³

312 Percy Report, R8/3814-15. Even though one member of the V.A. evaluation panel, Hayes Newby, wrote one of the three texts prescribed for the NHAS course, the panel was unanimous in these findings. Id., R8/3829.

313 Id., R8/3814. NHAS replied that this condition was very rare, and could be isolated on the basis of such "red flags" as dizziness and sudden hearing loss. R13/4029. In one instance, at least, a physician reported that a dealer had failed to detect the condition. Kramer, R13/1620.

The Committee Report also quoted the V.A. evaluation of the course material on the fitting of aids:

"Most remarkable" to the [V.A. evaluation panel] was the "paucity of information" on hearing aids and their fitting. It called the data on this subject "meager, often incorrect; and very outdated. . . . The technical discussion of the fitting of hearing aids is simply wrong. The lesson on 'the Ear Mold' is 10 years behind the times and does not include any of the modern discoveries. . . ." ³¹⁴

While ASHA said there were no "gross errors" in the course, their evaluation concluded that

. . . the hearing aid dealer who completes the course would still be ill-prepared to make the kinds of objective professional judgments and recommendations necessary for the satisfactory and ethical rehabilitation of patients with hearing impairment. ³¹⁵

314 Percy Report, R8/3814.

315 Id., R8/3816. Like the V.A. evaluation, the ASHA evaluation found the NHAS material inadequate in its coverage of medical conditions:

The student is told the various medical conditions which may exist, but nowhere is he told how to recognize them in a client or what factors to consider in raising an index of suspicion. The very common perforations or ruptures of the tympanic membrane, for example, are covered in exactly eight lines. This important question of how to recognize or even suspect the existence of a perforation from visual or audiometric measurement is not even mentioned. Yet this is the most common medical problem that the hearing aid dealer is likely to encounter, and failure to recognize its presence in a particular client can have potentially serious consequences.

Id., R8/3815. ASHA's evaluation, the Report notes, also criticized (1) the "extremely superficial treatment" of hearing loss evaluation in the course, specifically the

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The ACO evaluation concurred in the V.A. criticism that the course materials are excessively technical, and beyond the comprehension of persons without college and post-graduate education.³¹⁶

Supplementing this formal training, it was noted, many dealers work under the supervision of an experienced dealer for a period of time.³¹⁷ A number of commentators said that experience provides the knowledge and ability which dealers need,³¹⁸ but other

315 (FOOTNOTE CONTINUED)

omission of any reference to the American National Standards Institute standards for acceptable ambient noise levels for testing hearing; and (2) the failure of the material to appropriately emphasize the fact that "certain sensory-neural hearing impairments are amendable to medical treatment and [that] some are indications of a life-threatening condition requiring swift medical intervention." Id., 3815-16.

316 Id., R8/3815. NHAS asserted that ACO's critique was contradicted by ASHA's assertion that the course is superficial. R8/4026. However, the criticisms are consistent; complex material could be presented in a superficial manner. Other criticisms are that NHAS fails to allow independent accreditation of its training procedures; Silverman, R8/7328, and that there is no evaluation of the dispenser's practical skills included in the NHAS examination. Smith, K., SPXB/410.

317 Graham, S., R8/7463; Leale, TR 11740; Fortner, TR 2968; Payne, John, TR 9223.

318 Harris, TR 10417; Dunlavy, R8/1609; Zelnick, TR 422-23. See Vreeland, R10/3415, TR 3832; HAIC, R8/1189X³, R4/4036; Williams, TR 3761; Rose, TR 529; Keyes, TR 10691-93; Scheurer, TR 11423, 11437, 11494-97; Zumbrunnen, TR 11980; Winslow, R10/6939; NHAS (Pigg), R8/1188G³. See also, Doran, R13/2111 (a hearing aid wearer); Eichenberger, R13/2117; Englin, R13/2120-21; Goldsmith, R13/2130; Knudsen,
(CONTINUED)

commentators criticized the training dealers provide their trainees. They contend that dealers fail to provide their trainees adequate, sustained supervision.³¹⁹ Critics stated that dealers are more interested in getting their trainees out in the field selling than in supervising them.³²⁰

Given the limits of supervised experience, and the absence of formal training, some commentators concluded that dealers may merely repeat errors.³²¹

Various commentators discussed the consequences of inadequate training and education. These consequences include: 1) an inability to do reliable tests, particularly with difficult-to-test subjects,³²² and with clients who need extensive

318 (FOOTNOTE CONTINUED)

R13/2138; AARP, R10/1551; Rohl, R13/2332; Zelnick, TR 437; Vreeland, R10/0825; Smith, A., R10/6386, 4966, TR 8156; Kojis, TR 2100; Sanders, TR 3578; Carter, R., TR 3669-70; Kleiman, TR 6901; Teter, TR 10323-24; Harris, TR 10413-17; Berkove, TR 11001; Elia, TR 7475; Briskey, TR 7249; West, TR 10417-18; Oberhand, R10/3413; Mettler, TR 11405; Scott, TR 2319, 2326, 2346-47; Fortner, R13/1048.

319 E.g., Krebs, TR 11873-74; see also, Hardick, R8/6849. State laws often require only minimal supervision.

320 Anderson, TR 11786; Graham, S., R8/7486. See, Barnow, TR 1670; RPAG (Kloze), R8/1188L.

321 Rose, TR 535-36; See P.O. Report, R9/Dlip67; Georgia Speech & Hearing Association (Bess), R10/4868, TR 6228.

322 Bess, TR 6229; Simon, TR 9180; Hardick, R10/6403-04, R8/6850; Wimmer, TR 6516; Traynor (Hull), R8/6805; Schiavetti (Miller), R8/5683; Hill, R8/7828-31; Fausti, R13/1715; Lentz, R13/1700-08; Willeford, R13/1709-10; Anderson, R13/1711-12.

masking;³²³ 2) an inability to detect cases for medical referral;³²⁴ and 3) a failure to appropriately direct the rehabilitation of the customers.³²⁵ Indeed, record evidence from physicians,³²⁶ audiologists, and clinics,³²⁷ and the Percy Committee³²⁸ suggests that there are numerous occasions where dealers select or fit aids inappropriately. NHAS suggests these problems arise in relatively few instances, based on an analysis of complaints filed with state agencies; this evidence is discussed below.³²⁹

(b) Impact of State Licensing Law

Record evidence also discusses whether licensing statutes insured

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- 323 See Section I.B.5.b.(2).
- 324 Bess, TR 6229; ASHA (Johnson), R8/1188F⁵; Kasten, R8/6980. See also Section I.B.5.a.
- 325 ASHA (Johnson), R8/1188F⁵; ASHA, R10/1597; Beltone, R13/777; Traynor (Hull), R8/6800; Smith, B., TR 274, 322-23; Berkowitz, R8/1189S⁶; Resnick, R8/1188LL; Whitman, TR 8593. See Sullivan, R8/1188X²; Beiter, TR 9046, 9062; Rompala, TR 9090; Ehritt, R8/4800.
- 326 Holloway, R13/773; Ruben, TR 4021, R10/5679, 5910; Kramer, R13/1619-21. See Rupp, R8/7115.
- 327 Gannaway, R13/1614-17; Rose, TR 511-12, 535-36; Hecker, R10/4834; Mosley, R10/5313; Stahl, TR 5536 (replacement aid); Graham, S., R8/7540.
- 328 According to the Report the V.A. turned to audiologists rather than dealers to dispense aids for their program due to dissatisfaction with the dealers' abilities. R8/3858.
- 329 See Section V.

dealer competence. Some witnesses said that it did; licensing ensures that dispensers are both knowledgeable and qualified.³³⁰ Alfred Dunlavy, the Vice-President of the NHAS, said the licensing of dispensers would solve the abuses in the industry.³³¹

However, educational requirements for obtaining a license are met with, at most, a high school diploma.³³² In addition, experience requirements are often limited or non-existent. Some states require continuing education after licensing.³³³

While most states employ a licensing test, many dealers have been exempted from testing, and as discussed below, the record indicates substantial problems with the tests.

(i) "Grandfathering"

"Grandfathering" enables persons who were dispensing when the licensing statute was passed to automatically obtain a license. According to witnesses, twenty-nine states licensed dispensers who were in the business for two to three years before adoption of their

330 Fortner, TR 2842, 2847; Wallace, TR 3457-67; Zumbrunnen, TR 11916-28; Vreeland, TR 3838; Gardner, TR 10368; Curran, TR 10885; Mettler, TR 11371-72; Lucke, R3/1637, 1375, 1380; Whalen, R8/8444.

331 ASHA, R10/2575.

332 Hearing Aid Journal, Sept. 1977, as updated by staff.

333 Hearing Aid Journal, Sept. 1977, as updated by staff.

licensing laws.³³⁴ Only 7 of these 29 required any subsequent testing of grandfathered dispensers; they allowed from 18 months to 6 years to pass the exam.³³⁵ The Percy Report stated that in 1975 nearly 2,500 of the 5,700 licensed dealers in the country had been grandfathered,³³⁶ although presumably the number is somewhat smaller today.

Record evidence described problems with grandfathering.³³⁷ On the other hand, the Chairman of the Tennessee Board for Hearing Aid Dispensers testified that, because dealers who fail to abide by the standards of practice established under the law risk losing the right to practice, it is irrelevant that certain individuals actually

334 Griesel, R10/6773.

335 Id.

336 Percy Report, R8/3816. In its rebuttal to the Percy Report, NHAS stated that it was unable to verify this statistic. See also Plemmon, R8/8476 (54 of 74 dispensers grandfathered in South Carolina); Byrne, TR 1067 (105 of 185 dispensers in Kentucky); MPIRG, R8/1268 (in North Dakota and South Dakota, it would take 15 years of licensing until more than half the dispensers were not grandfathered); PIGRIM, R8/1344 (150 out of 185 Michigan dispensers).

337 A case file from Arkansas illustrates that unqualified dispensers can be grandfathered. The Arkansas State Board learned of a dealer who had been licensed for six years under a grandfather clause, and who was fitting hearing aids although she did not have a functioning audiometer. When she was brought before the Board for a hearing the board members concluded that she did not have a basic understanding of audiometric measurements. She then took an examination, and failed to demonstrate basic proficiency. Graham, S., R8/7475.

receive a license through a grandfather clause;³³⁸ NHAS concurred.³³⁹

(ii) Trainee Licenses

All of the states with licensing provisions allow temporary permits or "trainee" licenses. Trainees can work for a specified period (up to 2 full years) regardless of proficiency, knowledge, or experience;³⁴⁰ these licenses are available to anyone meeting minimum age and educational requirements (high school or equivalent). They can generally be renewed if one fails the licensing examination.

A representative of the Virginia Hearing Aid Dealers testified that the Virginia General Assembly adopted trainee licensing so that an individual might obtain the training needed to pass the state licensing exam. The Assembly concluded that consumers were protected because the trainee is responsible to a licensed dealer who in turn is answerable to the state licensing board.³⁴¹ However, the only personal contact in Virginia required between the supervising dispenser and a holder of a temporary permit was 20 hours of formal

338 Wallace, TR 3459-60.

339 NHAS, R8/4029.

340 Griesel, R10/6773; Morgan, TR 9507; RPAG Report, R8/2644.

341 Shuford, TR 659.

training per month.³⁴²

There was other evidence which criticized the quality of supervision required. ASHA stated that while some statutes require that a trainee be "supervised" or "directly supervised" by, or "work under," a licensed hearing aid dispenser, there are no standards for enforcing the supervision criteria.³⁴³ In 1973, RPAG sent a questionnaire to the state agencies responsible for administration of hearing aid licensure laws. One question was, "Are trainees required to work in the same office (in the same dealership) as the person who is supervising their training?" Seven of the 15 who answered said no.³⁴⁴ This was confirmed by evidence reported from various states.³⁴⁵

Because of grandfather licensing, the supervisor of a trainee might - like his trainee - have never passed a licensing exam.³⁴⁶ Moreover, many trainees (perhaps a majority) never obtain full

342 Creech, TR 5224. This is still true today. Rules and Regulations of Hearing Aid Dealers and Fitters Board. § 3.03.

343 ASHA, R10/1664.

344 RPAG, R8/2645.

345 Morgan, TR 9506, 9525. In Colorado, Rules and Regulations defined "supervision" as 40 hours of "personal contact" with the supervisor during the first week and 4 hours per week thereafter. Colorado Rules and Regulations R13/1117. Under Rule 16 of the Colorado Board, adopted in 1982, trainees are now only required to have a total of 40 hours of training.

346 ASHA, R10/1659-61; PIRGIM, R8/1334AA-CC.

licensure.³⁴⁷ For example, during the three-year period 1973-1975, approximately 80% of temporary licensure in Ohio and Virginia never met full statutory licensure standards.³⁴⁸

Thus, according to the record, it is possible for some individuals who have not demonstrated competence in fitting hearing aids to fit and sell aids without substantial supervision, over an extended period of time.

(iii) Testing

In addition to questions about the competence of those licensed under grandfather provisions or selling under trainee provisions, there was debate as to whether full license testing insured competence.

Various industry witnesses testified or implied that state exams adequately demonstrate testing proficiency.³⁴⁹ However, there was dispute on this issue, even as to individual states.³⁵⁰ One witness emphasized the wide variety of subjects that dispensers were tested on in Oregon,³⁵¹ but an audiologist employed by the State

347 Shuford, TR 659; Barden, R8/6579; AHSA, R10/1664.

348 ASHA, R10/1667.

349 Huffman, R10/6915; Teter, TR 10293; Mettler, TR 11371-72.

350 Willeford, R13/1709-10; Lentz, TR 11249; Anderson, TR 11785; Pelson, R13/1713-14; Fausti, R13/1715; Bartels, TR 6327-31; Percy, R8/431; Faught, R3/3449.

351 Mettler, TR 11371-72.

Health Division, who had been responsible for administering the examination for 15 years, testified that it was "intentionally a low fence type of exam and not an attempt to upgrade the hearing aid dealers by requiring them to pass a difficult test." He stated that "even those with the highest test scores were . . . only marginally competent to deal with the hearing impaired public."³⁵²

In Colorado, there was testimony that dispensers who take licensing examinations are well trained to help the public.³⁵³ However, Dr. William Lentz, Ph.D., Director of the Hearing Clinic at Colorado State University, testified that one could pass the test questions without an understanding of basic principles.³⁵⁴

David Bartels, a North Carolina audiologist, spoke about his own experience in taking the state's licensing examination and concluded that it was inadequate.³⁵⁵ The President of the North Carolina

352 Anderson, R10/7282.

353 Teter, TR 10293; Cooper, TR 10771, 10774.

354 Lentz, TR 11247, 11249; R13/1700-04. See also, Willeford, R13/1709. These witnesses each took, and administered a portion of, the examination. Lentz testified that 8 of the 10 candidates who tested him sat where he could see them at the audiometer. This is poor testing procedure.

355 Bartels, TR 6327-31. He noted that the exam did not cover physical examination of the ear. Although an earmold fitting was required, there was no discussion of the problems that often occur with earmolds. The test dealt only with "peripheral" matters in the identification of a hearing loss. He believed that the questions on masking had been formulated by someone who did not understand masking, since the questions could not be answered based on the information given. Moreover, the examination did not test speech discrimination.

State Board, however, disagreed.³⁵⁶ An audiologist who took the Virginia examination similarly criticized that state's examination.³⁵⁷

The record also contains submissions regarding the simplicity of the testing given in various other states, including Florida, Indiana, and Kentucky.³⁵⁸

(c) Competency of Audiologists

Audiologists test hearing and frequently recommend amplification; they may also direct their client to buy a particular aid; audiologists may also sell aids.³⁵⁹ As of 1973, there were over 2400 health professionals certified as clinically competent in the

356 To rebut the testimony of Mr. Bartels, NHAS submitted an affidavit from Harlan Cato, President of the North Carolina State Hearing Aid Licensing Board. Mr. Cato offered opinions contrary to the general assertions of Mr. Bartels. R13/2283.

357 Butts, TR 4163-64, 4179-80. Mr. Butts noted that the examination did not discuss the limits of hearing aids. Mr. Butts was informed that he had passed the Virginia dealers' exam with the highest score ever attained. Id., TR 4201.

358 Percy, R8/431; Kasten, R8/6980; Byrne, R8/6445.

359 Butts, TR 4211. Prior to 1974, ASHA members could generally dispense (although VA audiologists had dispensed for over 25 years). Butts, TR 4211; Rose, TR 526. After 1974, ASHA members were allowed to dispense "at cost." Stroup, TR 9878; Dalton, TR 8745. After 1978, they could dispense "for profit."

field of audiology.³⁶⁰

The record does not show that minimal competence is a substantial problem with audiologists. The record rather shows that audiologists all receive substantial training and supervised experience, unlike all dealers. To obtain a master's degree in audiology, a student must attend a college or university with a graduate program approved by ASHA.³⁶¹ Basically, ASHA requires the successful completion of a program consisting of academic and supervised clinical work.³⁶² The academic courses usually cover a broad range of subject areas.³⁶³ Commentators also stressed the quality of the

360 This total was expected to double by 1978. McGarry, R10/219.

361 ASHA, R10/2174, 2174(a). The National Commission of Accrediting has delegated to ASHA the sole authority to accredit these programs. ASHA standards are generally uniform, although the curriculum at individual colleges and university training centers varies. Hecker, TR 5287; Alpiner (Hayes), R8/5628.

362 Ryan, TR 1539; ASHA, R13/3727, HX109/1-2, R10/2174(a); NYPIRG, R8/1335G. ASHA - certified audiologists now must earn an M.A. At one time, the Association's membership requirement was a bachelor's degree, and half of ASHA's membership held a bachelor's degree. By 1970, however, the percent of individuals with only a B.A. decreased to 15%.

363 These include the processes of normal speech, hearing and language; the handicapping effects of auditory impairment; acoustics; anatomy and physiology as it relates to hearing impairment; the nature of disorders of speech, hearing and language; the measurement and evaluation of speech and hearing; and the clinical treatment and instruction of children and adults with communication difficulties. Ventry, TR 1707-11; R10/804-08; ASHA, HX109/1-2, R10/2174(a); Harford, TR 67-68.

supervision of audiologists during training.³⁶⁴

To qualify for the ASHA Certificate of Clinical Competence, a person must also spend nine to twelve months in supervised clinical employment with a certified audiologist (the Clinical Fellowship Year), and pass a national examination.³⁶⁵

Some commentators challenged the extent of the audiologists' training in the testing and other procedures specifically related to the selection and fitting of hearing aids.³⁶⁶ One commentator indicated that these programs do not prepare the students in the area of selecting and fitting hearing aids.³⁶⁷

ASHA strongly disputed this contention. An ASHA survey of graduate training programs in speech pathology and audiology

364 At Arizona State University, on the average, each student is responsible for the fitting and management of one hearing aid candidate per week in a general clinic. The student is under constant supervision, so that when situations arise which the student can not handle, supervisory personnel are present. Franks, R13/3987-90. Dr. Kasten of Wichita State University indicates that his clinic at Wichita State University is primarily a training facility, where graduate students get maximum exposure to practical problems. Kasten, TR 711-12; see also Miller, TR 4824.

365 ASHA, R13/3727, HX109/3.

366 Teter, TR 10228, 10259-60; Delk, TR 10978; Markle, R3/3480; MPIRG, R8/1272; Kojis, TR 1976; Curran, TR 10888; Oberhand, TR 3036, R10/3413; Sandlin, TR 10125, 10198; Lentz, TR 11251, 11256, 11257, 11258 (reporting that he received a number of communications from audiologists regarding limitations in their education). Iliff, R10/3429-30; Brakebill, TR 1284; Dunlavy, TR 3405; Staab, TR 7027-29, 7033; Scheurer, TR 11511, 11520-21; Vreeland, R10/3415.

367 Williamson, R13/3956.

indicated that the 84 respondent schools offer 95 to 145 hours of course work in amplification.³⁶⁸ The survey respondents generally indicated that their curricula adequately prepare student audiologists in hearing aid selection and fitting.³⁶⁹ The record clearly indicates that audiologists receive training relating to hearing and fitting.

Industry questions, however, whether any educational advantages affect quality of service. Consumers and other commentators stated that audiological pre-clearance does not increase consumer

368 ASHA, R10/1616-17.

369 Kaplan, R13/3911-13; O'Neill, R13/4047-49; Young, R13/4053-54; Hoops, R13/4078-88; Sheeley, R13/4050-52; Cox, R13/3977-78; Klim, R13/3916-17; Metz, R13/3947; Mullendore, R13/3949-51; Miller, M., R13/3953-55; Yoder, R13/3943-45; Morris, R13/3960-61; Wark, R13/3914-15; Craven, R13/3829-40, 3973-74; Fox, R13/3843-50; Lankford, R13/3851-52; Hull, R13/3855-75; Brewer, R13/3739-40; Ansberry, R13/3757-58; Voroba, R13/3775-77, R13/4068-69; Borton, R13/4071-72; Maufer, R13/4073-75; Ferullo, R13/3980-81; Martson, R13/4016-17; Siegenthaler, R13/3909-10; Kohler, R13/4018-19; Horner, R13/4120-21; Weiss, R13/4092-93; Goeth, R13/4095-4100; Newby, R13/4101-02; Franks, R13/3987-90; Beedle, R13/4084-85; Gerber, R13/3986; Mazor, R13/3938-84; Goldstein, B., R13/3794; Skinner, R13/3876-77; Bate, R13/3879-87; Miller, G., R13/4036-44; Johnson, R., R13/3882-84; Dalton, R13/4021-23; Luper, R13/3778-80; Knight, R13/3819-23; Goldstein, D., R13/3825-26; Balas, R13/3830-37; Ahaus, R13/3893-98; Willeford, R13/3890-91; Calvert, R13/3994; Graham, J., R13/4017-18; Wentland, R13/3900-06; Laas, R13/3932-34; Hill, R13/3929-31; Yantis, R13/3921-24; Kasten, R13/3936-39; Hardy, R13/4019-20; Lovrinic, R13/4065-66; Chermak, R13/4076; Lamar University, R13/4107-09; Rainbolt, R13/3752-55; University of Georgia, R13/4068-69. See Barkley, R13/3918-19 (University of Akron program lacks enough attention to the area of practical experience and selection in fitting procedures); Balas, R13/3832; Hill, R13/3929-31 (the students at William Paterson College of New Jersey receive minimal training in the area of amplification).

satisfaction.³⁷⁰ For example, the Market Facts study suggests that the average level of satisfaction or dissatisfaction was not affected by whether a user saw an audiologist or doctor prior to purchasing an aid.³⁷¹ However, there may be significant limitations in the Market Facts data.³⁷²

While the record indicates that audiologists are at least minimally competent,³⁷³ dissatisfaction with them may be due to

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- 370 The Payne & Payne Study, for example, found that 23 out of 26 users surveyed were not happy with the services provided by a clinic. Payne, James, TR 2135. See also AARP (consumer letters), R10/1011-12, 1305, 4764; Perrill, TR 11611; Sandstrom, TR 3117.
- 371 Market Facts, R8/658.
- 372 Only current users were used in this tabulation, but the study also showed that 15% of non-users had tried an aid and failed. Id., R8/647. It is thus unclear if audiologists and dealers have comparable failure rates, because the report contains no data on whom the former users had consulted. Moreover, the people who saw an audiologist may have had more severe problems than those who went to a dealer. See, e.g., Madell, TR 5917.
- 373 The record also contains substantial debate about a distinctly different question: are audiologists superior to even competent dealers? ASHA argues that all persons should see an audiologist before buying an aid, e.g., R8/1189K⁸. Reasons cited include audiologist's alleged superior testing ability. E.g., Harford, TR 56, 65; Ventry, TR 1707-08, 1733; Lentz, R13/1719; Rose, TR 497. Others, however, asserted that any extra skill is superfluous, and that the testing is an unnecessary expense, e.g., Berkove, TR 11011; HAIC, R8/1189Y³; William, TR 3761; Holmes, TR 9582; Delk, TR 10959; Teter, TR 10228.

It was also asserted that audiologists are best trained to use alternative methods, in place of or in addition to hearing aids (e.g., lip reading). ASHA, R8/1189K⁸,

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another factor. When audiologists recommend amplification, they may leave the specific selection and fitting to the dealer,³⁷⁴ and merely recommend an aid that meets certain specifications.³⁷⁵ Alternatively, audiologists may recommend a specific aid.³⁷⁶ The consumer who gets a "prescription" may face an additional risk of no significant benefit. Although many witnesses believe that audiologists are the best able to counsel the hearing impaired effectively,³⁷⁷ many audiologists are not actively involved in

373 (FOOTNOTE CONTINUED)

11189S⁶; Glorig, R8/1188J⁶; Loavenbruck, TR 1550; Ryan, TR 1522.

374 Eichelberger, TR 8683; Harris, TR 10447; Nygren, R8/4938; Freeman, R8/4044; Capano, R8/6965.

375 Specifications include the type of instrument, the amount of power, or the frequency response, the maximum power output, and general criteria regarding the ear mold. Capano, R8/6964; Berger & Millin, SPXD/487; Sandlin, TR 10217-18; Ehritt, R8/4799; Eichelberger, TR 8683.

376 Kemker, R8/6934; Payne & Payne, R8/1479; Hardick, R8/6842; Nygren, R8/4938 (describing practice of Master Plan, a dispenser selling only on referral); McMahon, R8/4308; RPAG, R8/2846; Johnson, E., R8/4489; AARP (consumer letter), R10/945; NCSC (Penalver), R10/4447; Sullivan, R8/910; Berger & Millin, SPXD/487; Kasten, R8/6978; Wilson, L., TR 10041; McMahon, R8/4308.

377 Summers, TR 8067; Resnick, TR 5385-86; Wilber, TR 1345; Sullivan, R8/910; Griesel, TR 9379; Beiter, TR 9028, 9071-72; Traynor, R8/6800; Rompala, TR 998; NBS, R8/615ip11; Lankford, TR 8009; Davis, HX 150; Rose, R10/87, R10/8088; Kolman, TR 1885; McPherson, TR 5118-19, 5124; P.O. Report, R9/Dlip138; Hull, R5/1396-99; Consumers Union, R8/1189P⁴; Resnick, TR 5385.

counseling and other rehabilitation activities.³⁷⁸

As a consequence, audiologists may not be aware of problems with their recommendations (although they may learn of them indirectly, from the dealer who actually sold the aid.)³⁷⁹

6. The Profit Motive: Benefits and Disadvantages.

Most hearing aid dealers receive almost all of their income from the sale of hearing aids. The traditional dealer does not charge separately for the aid and services, but rather "bundles" all charges together;³⁸⁰ the Commission recently found that this is one

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This evidence pertains to referring, rather than dispensing, audiologists. One article states that the use of referring audiologists "combines the training but lack of adequate feedback of the audiologist with the adequate feedback but lack of training of the hearing aid dealer." Studebaker, R13/175. See Kojis, R10/647; Alpiner, R8/5633; Miller, TR 4797.

Some commentators said that audiologists are not interested in this work. Johnson, K., TR 4355; Alpiner (McConnell, F.), R8/5506-07; Alpiner, R8/5633, 5634; Sanders, TR 3576; Staab, TR 7065; Rich, R8/1095-97; Payne, James, TR 2136; Oberhand, TR 3101. The audiologist's large caseload was also cited. Payne & Payne, R8/1481, 1485-86, 1487, 1519; NCSC, R10/4446; Capano, R8/6963; Norris, TR 6811.

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Harvey, R8/6890, 6893; Moneka, R8/5390; Johnson, E., R8/4489; Wilson, TR 10044; Wilber, TR 1381; Krebs, TR 11867; RPAG, R8/2695, 2699. But see, AARP (consumer letter), R10/3999 (this consumer strongly resented the audiologist's insistence he see a specific dealer. He suspected a commercial tie-in between the dealer and audiologist); accord, Pasiewicz, TR 8966-67.

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Harford, TR 117. In a 1975 survey of hearing aid sellers conducted by Hearing Instruments, only 11% of the respondents separated (unbundled) the cost of the hearing

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distinctive characteristic of the market.³⁸¹ Thus, even though dealers make housecalls and spend time with customers, they make no money unless the customers buy hearing aids.³⁸²

The consumer must rely upon dispensers to advise them about corrective measures.³⁸³ But audiologists, physicians, state government officials, and public interest representatives stated in the record that this pricing structure pressures the dispensers they rely upon to make sales, in order to cover costs and make a living.³⁸⁴ These commentators believed that this financial pressure to maximize sales conflicts with the seller's obligation to offer service that meets the actual needs of the hearing impaired.

380 (FOOTNOTE CONTINUED)

aid from fees for connected services, Frame, R10/516; NHAS (Pigg), R8/1188³. Dispensers often provide "free tests." See generally Section IV.A.2.a.(2)(b).

381 Beltone Electronics Corp., Docket 8928 (1982), slip op. at 4.

382 Harford, TR 117.

383 Beltone, supra. n. 381, at 5.

384 Gerstman, TR 2433; Beiter, TR 1030; Person, TR 9271; Langley, TR 11294; Whitman, TR 8593-94; Davis, TR 8550; Jeffries, TR 5588, 5638-51; Stahl, TR 5538, 5540; Marcus, TR 5483; Miller, TR 4784-85; Harford, TR 117-18; Rose, TR 483; Smith, B., TR 277; Ryan, TR 154; Loavenbruck, TR 1561; Johnson, K., TR 4297-98, 4315, 4260; Anderson, TR 11787; Creech, TR 5239-40; Kuptz, TR 5644; Conlin, TR 776; Klein (MPIRG), TR 7581; McShane, TR 8110; RPAG, R8/1188⁵, 1189C⁶, 2599; Resnick, R8/1188M², R10/506; Rupp, R8/7115; ASHA, R8/1188E²; PIRGIM, R8/231; HEW, R8/3351, 3516; Nygren SPXC/258; Griesel, R10/6800; Bartels, R10/5624; Hecker, R10/4835-36; Drew & Eiler, R10/5193; ASHA, R10/1596; NCSC, R10/45; P.O. Report, R9/Dlip94.

It was cited as the reason for poor practices.³⁸⁵ The problem is illustrated by sales manuals prepared by hearing aid manufacturers for dealer instruction and use, which view all hearing aid users or potential users as "prospects."³⁸⁶ For example, the Audiovox Manual stated:

[W]hat many dealers lack is just a little more fire in their eyes and ginger under their tail. Cynics have said that the hearing aid business requires a combination of 60% perspiration, 30% psychology and 10% audiology . . . if you want to serve the reluctant hard of hearing public, you must be a salesman first, a psychologist second and an audiologist third, in that order and no other.³⁸⁷

The Dahlberg Manual stated that

every lead is a prospective customer. He is sold and becomes an actual customer when a competent salesman helps him to make the final decision and buy now!³⁸⁸

Some commentators stated that the conflict between serving the best interests of clients and making a sale is exacerbated by manufacturers' incentives to increase sales.³⁸⁹ The record

385 Elkins, R13/4130; Holloway, R13/773; Kramer, R13/1620. See, Burke, R13/1367; ASHA, R10/1602; Whitman, TR 8594; Loavenbruck, TR 1561; Scharf, R10/6335; Hardick, R8/6716; Johnson, K., TR 4315; RPAG, R8/2835.

386 Sonotone, R8/1631-34; Dahlberg, R13/1298-1302, 1314, 1316, 1321; Audivox, R13/1219; see also Dahlberg/Wilson, R13/1330-37.

387 Audivox, R13/1219. (emphasis added).

388 Dahlberg, R13/1301.

389 Miller, TR 4805 (trips); Lankford, R10/4887; RPAG, R8/1188P⁴ - Q⁴.

indicates that some manufacturers provide "free" aids,³⁹⁰ trips,³⁹¹ prizes, awards and bonuses to dealers who sell more aids or contact more consumers.³⁹² The problem is heightened because dealers often "motivate" reluctant consumers to try amplification.³⁹³ This can induce a reluctant consumer to buy an aid which provides significant benefit; however, the result may also be a sale to a buyer with no commitment to adjust to amplification.

Other commentators disagree that a conflict exists between the dealer's desire for profit and the desire to help clients' hearing problems.³⁹⁴ They agree that the profit motive causes dispensers to aggressively engage in selling their product and carrying their message to the hearing impaired, but argue that because many hearing impaired individuals who can benefit from amplification are reluctant

390 See, Lankford, R10/4887.

391 Lankford, R10/4887. Siemens, a manufacturer, offered a free trip to Germany for a two day seminar. ASHA, R10/2380, 2405, R8/1188P⁴. Fidelity offered a Hawaiian celebration for its dealers. Samole, TR 6730-31.

392 Beltone I.D., R13/219. Another manufacturer gave dealers 25¢ for every lead that led to personal contact; 50¢ for every lead he obtained on his own; and \$2.00 every time a demonstration, fitting, or audiogram was given, RPAG, R8/2613-14.

393 See Section III.B.

394 Leale, TR 11717; Murphy, TR 7966; Holmes, TR 9595; Dunlavy, TR 3419; Briskey, TR 7276; Williams, TR 3778; Baird, TR 3616; Martinucci, TR 8424; Zelnick, TR 436; Sandstrom, TR 3113; Sanders, TR 3576; Oberhand, TR 3094-95; Iliff, R10/3432; Payne, John, TR 9187; Payne & Payne, R8/1500; NHAS, R8/1188N³; Ince, R8/1189V; Wood, R13/2359; and Dahlberg, R3/3063-64.

to try a hearing aid,³⁹⁵ this aggressiveness is a good and necessary part of selling hearing aids.³⁹⁶ They assert that the "conflict of interest" charge could be equally applied to lawyers, dentists or audiologists who profit from charges to their clients or patients.³⁹⁷

Some commentators also state that the dealer must compete with other dealers. Thus, the dealer first must look to customer satisfaction.³⁹⁸ The customer's satisfaction is also important to maintain the dealer's reputation in the community³⁹⁹ which may be a factor in attracting referrals and repeat business.⁴⁰⁰

7. Binaural Fittings

ASHA stated in the record that it is common practice for two aids (i.e. binaural amplifications), to be sold when a single aid would have been appropriate.⁴⁰¹ Some witnesses felt that the sale of two

395 See Section II.

396 HAIC (Ince), R8/1189B⁴. See, Heisse, TR 3286-87; Griesel, R10/6800.

397 Payne, John, R10/5592; Iliff, R10/3432; Wood, R13/2359.

398 Sanders, TR 3576-77; Oberhand, TR 3094-95, R10/3413; Zelnick, TR 431; see AARP (consumer letter), R10/4527. See also Dunlavy, R3/5366.

399 See, e.g., Scheurer, TR 11519; Dunlavy, TR 3409-10; Barnow, TR 1652; Briskey, R., TR 7276.

400 Scheurer, TR 11519; Staab, TR 7043-44; Scott, TR 2334.

401 Lankford, TR 8042-43, R10/4891; NHAS, R13/2461; ASHA, R10/1744; AARP, R10/3965; Kasten, R5/1435.

hearing aids when only one was appropriate is one of the most frequent selling abuses.⁴⁰²

Even absent abuses, there is substantial difficulty in predicting when a binaural fitting will work, and thus a risk that any binaural fitting will not provide significant benefit.⁴⁰³ In a 1974 study, 972 patients with presbecuysis (aged 70 to 80) were given free binaural aids. One-fourth abandoned one of the aids, and two percent abandoned both of the aids.⁴⁰⁴

There is substantial dispute as to the value of binaural amplification. Some indicated it is generally superior to a monaural system,⁴⁰⁵ that it improves sound quality and the ability to distinguish speech from surrounding noise, and that it reduces strain

402 Harford, R5/843; Kasten, R5/1435; Kefauver committee, R8/719; NCSC, R10/4588; Butts, TR 4181-82, 4161; Rose, R5/708; Noffsinger, TR 7640.

403 Butts, TR 4190; Noffsinger, TR 7640. A "significant benefit" means more in this context than elsewhere; it means that binaural amplification provides greater benefit than a single aid.

404 Corso, R10/186-88. In a 1968 study of 48 subjects over age 65, 4 abandoned binaural amplification, and 2 others abandoned both aids. Id.

405 Zelnick, TR 387-391; Bentzen, R13/2394; Briskey, R13/1683-90; Corso, TR 1193-94, 1186-87; Scott, TR 2323-24; Powers, R13/995; Hopmeier, HX52; Stewart, R8/841; Hearing Instruments, R8/D554ipl9; Enid, R4/4014; Markle, R4/4025; HAIC, R3/3877; NHAS, R3/3643; Nielsen, R13/2693-96; Enzweiler, HAIC, R13/83; North, HAIC, R13/2147; Delk, TR 10926; Bruns TR 10602; Anthony, TR 8467-68, 8472; Sandlin/Krebs, R13/912-13.

and fatigue after long use.⁴⁰⁶ Other commentators disagreed, however, stating that a binaural system provides little or no additional benefit beyond that provided by one hearing aid,⁴⁰⁷ and can even reduce discrimination.⁴⁰⁸

There was consequently a wide discrepancy of opinion as to how many users can benefit from binaural amplification. Estimates ranged from 5% to 95% of hearing aid wearers.⁴⁰⁹ Several witnesses felt

406 HAIC, R3/3737; Whetnall, Edith (London), "Binaural Hearing", Journal of Laryngology & Otology, (1964); Langford, Bryon, "Why Binaural?" Audicibel, (Fall 1970), R4/4016; Norland & Fritzell, "The Advantages of Binaural Hearing for the Understanding of Speech: Fifteenth Congress of the Scandinavian Autolaryngological Society (June 15-18, 1963)", R4/4040; NHAS, R3/3341-46; Corso, R10/188, TR 1186-1187; Zelnick, R10/48, TR 387-93; Audivox, R13/1161; Pollack, SPXB/243-53; Briskey R13/1683-90; Hopmeier, HX52; NBS, R8/D222ipl5; Hearing Instruments, R8/D554ipl9; Consumers Union, R8/1189R⁴.

407 Bentzen, et al., R13/2398-2400, 2384; Rose, R8/4183; Hardick, R8/779; Rassi, R8/659; Briskey, TR 7257-58; Krebs, TR 11884; Butts, TR 4190; Byrne and Stockler, R10/3191-92; Noffsinger, TR 7640; Lankford, TR 8042-43, R10/4891; Stahl, TR 5541; Kasten, R8/6983; AARP, R10/3983, 3965, 4118; Corso, R10/189; Harford, R8/7555; Kasten, HX226; Tobin, TR 4105-06.

408 Graham and McGee, R10/5332-34; Zelnick, TR 402-04; Corso, R10/189-90; Norris R10/5329; ASHA, R13/3593-94; Miller, TR 4754; Pollack, SPXB/251.

409 Ernest Zelnick, a dispenser with 25 years experience, estimated that over 80% of monaural users will derive benefit from binaural aids. Zelnick, TR 386-87. Audiologist Robert Briskey, stated that 85% of those who can use amplification will benefit from a binaural fitting. Briskey, TR 7257-58. Ole Bentzen, of the Danish State Hearing Centre, indicated that 78% of his patients could use binaural aids with some success. Bentzen noted, however,

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that the only reasonable implication that can be drawn is that current clinical evaluation tools are inadequate to measure the benefits of binaural amplification.⁴¹⁰

Witnesses also did not agree on who should be fit binaurally. Binaural fitting is generally considered more appropriate for a symmetrical loss (similar in both ears).⁴¹¹ Although the record indicates differences of opinion, a binaural system appears more appropriate for individuals with a conductive hearing loss and for

409 (FOOTNOTE CONTINUED)

that both hearing aids were used full time by only 31% of his patients and part-time by 47%. Bentzen, R13/2394. Darrell Rose, Director of Audiology at the Mayo Clinic, estimated that only 15% of his patients are able to wear binaural aids successfully. Rose, TR 514. David Rompala, an audiologist at the Schwab Rehabilitation Hospital in Chicago, stated that binaural amplification is appropriate for only 5% of his elderly patients. Rompala, TR 9118-19.

410 Some witnesses testified that objective tests have not yet demonstrated a significant improvement in understanding speech when two aids are used instead of one. Zenith, R3/3418; Kasten, TR 716-18, 754-55, R10/6065; ASHA, R10/1744; Zelnick, R10/48; Consumers Union, R8/1189R⁴, 1191-E; Berger & Millin, SPXD/506. Other witnesses testified that the statistical superiority of binaural amplification has been subjectively demonstrated but the clinical differences are insignificant. Kasten, R8/6984; Johnson, TR 2268-69; Zenith, TR 3418. In the minds of other witnesses, the benefit that can be derived from a binaural system is largely subjective. Zelnick, R10/48; Byrne and Stockler, R10/3191-92; Payne, James, HX39/15; Pollack, SPXB/243-53; Johnson, J., TR 2268-69; Consumers Union, R8/1189R⁴.

411 Rassi, R8/659; Harford, R8/4549-50; Zelnick, TR 401, 387-93, R10/7; Teter, R13/2047; Hardick, TR 779.

children.⁴¹² A minority stated that binaural systems should always be considered.⁴¹³

412 Studies have shown that a binaural system provided no additional benefit in subjects with a sensorineural hearing loss while those with a conductive hearing loss demonstrated improved speech discrimination. See Zelnick, R10/48, TR 387-93 and ASHA, R13/3593-94 for summary of studies.

413 Hopmeier, TR 3352-53; HAIC, R3/3578; NHAS, R3/3343; Griffing, R13/7696; Stey, R10/433; Burris, TR 2501.

II. The Hearing Impaired Consumer

There is a a great deal of record evidence that the hard of hearing are in some ways emotionally affected by their impairment. The record debate, however, turns largely upon whether these characteristics affect their ability to shop critically for a hearing aid. The debate is summarized by the testimony of two witnesses. One said:

By its very nature, decreased hearing ability simulates the sensation of increased distance between the person and source of sound. As hearing fades, sound seems to be coming from farther and farther away. Ultimately, some sounds disappear altogether; others are distorted; patterns of sound are no longer recognizable. The resultant sense of isolation, of detachment from the world, is forced upon all whose hearing no longer serves to keep them in 'touch' with life.⁴¹⁴

Another, however, said:

The question that you and I are now discussing is will [the hearing impaired] complain and will they make their needs known? Yes, sir they will. Not less, but at least as much and maybe more.⁴¹⁵

Throughout the debate, many witnesses referred to the hearing impaired⁴¹⁶ as a homogeneous group, sometimes identifying sub-groups as well. In one respect, the homogeneous group referred to as

414 Levine, R8/5738-38a.

415 Teter, TR 10286.

416 For purposes of this Summary, the term "hearing impaired" generally means all those persons who have serious trouble hearing or who have suffered noticeable loss of ability to hear. See National Center for Health Statistics, R8/511ip3; Perrin, R8/563.

the "hearing impaired" does not exist. The record reveals considerable diversity among hearing impaired individuals and the manner in which their impairment affects them.⁴¹⁷

Nevertheless, the record also reveals a particular set of psychological, demographic, and other changes that generally accompany a hearing loss. This section discusses characteristics of the hearing impaired generally (as well as the elderly and the young hearing impaired), and their impact on market behavior.

A. Demographics

A significant portion of Americans are hearing impaired. Estimates of their number range from 8 million⁴¹⁸ to 17 or 20 million,⁴¹⁹ with several estimates in the 13 to 15 million range.⁴²⁰ It has been estimated that approximately half of the

417 For example, the consequences of a rapid hearing loss during youth may differ from those of a gradual loss with age. See, Section II.E.

418 Data from the National Center for Health Statistics, R8/511ip3.

419 McCurdy, TR 31; Plotkin, TR 6026-27; results from Health Examination Survey quoted by Edward B. Perrin, Director of the National Center for Health Statistics, Health Resources Administration, HEW, before the Subcommittee on Government Regulation, Select Committee on Small Business, U.S. Senate, May 20, 1975, R8/587.

420 A 1971 Health Interview Survey of the Public Health Service estimated that there were 14.5 million noninstitutionalized hearing impaired civilians in the United States. N.C.H.S., R8/544, 586. A 1974 National Association of the Deaf survey, based on 1971 figures, estimated that there were

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hearing impaired have significant impairment (hearing impairment in both ears) and that slightly over a quarter of those are totally deaf.⁴²¹

Hearing impairment is most common among the nation's elderly. It has been estimated that 40% of the hearing impaired are at least 65 years old.⁴²² Arthur Fleming, former Commissioner on Aging, testified that 5 million people over 65, nearly one-quarter of that population, have significant hearing impairment.⁴²³ Others have estimated that 30%⁴²⁴ of the approximately 20 million Americans over 65⁴²⁵ are hearing impaired. Another estimate calculated that

420 (FOOTNOTE CONTINUED)

slightly over 13.3 million such individuals. Schein and Delk, SPXA/16. See also Kojis, TR 1970 (14.5 million); Barnow, TR 1631 (10 million). These estimates may not include several hundred thousand additional institutionalized hearing impaired individuals. For example, the Public Health Service survey in the preceding footnote did not include the estimated 1.2 million persons living in retirement or nursing homes, although a 1973 survey reported that the prevalence of hearing impairments in such institutions is about five times that of the general population. Perrin, R8/585-86.

421 Schein and Delk, SPXA/16, estimates bilateral hearing impairment at 6,548,842 (or 3,236 per 100,000 population) as opposed to 13,362,842 (6,603 per 100,000) hearing impaired persons in the general population and 1,767,046 totally deaf individuals.

422 See Health Resources Administration (1971), R8/544.

423 Fleming, TR 608.

424 See Coleman (Senate Hearings, 1973), R8/1189z⁶.

425 See Fleming, TR 608.

62% of persons with very serious hearing impairments are 65 years or older.⁴²⁶

However, hearing impairments are also spread throughout the population. In 1971, approximately 6% of the hearing impaired, or 863,000 persons, were under 17 years of age, and 84,000 of those were less than six years old.⁴²⁷

The 1971 Health Interview Survey of the Public Health Service, Health Resources Administration, found that the hearing impaired tend to have families with a lower income and a lower educational level than the population as a whole.⁴²⁸

B. Physiological and Psychological Characteristics

426 Perrin, R8/589.

427 See Health Resources Administration, R8/544, (1971 estimates). One witness estimated that there are 3 million hearing impaired children, Kojis, TR 1970.

428 Health Resources Administration (1971), R8/544. With a respect to family income, approximately 23% of the 14.5 million civilian noninstitutionalized hearing impaired are part of families with an annual family income of less than \$3,000, R8/553, compared with 10% for the population as a whole. Id., R8/544. At the highest end of the income scale of the survey, approximately 12% have family income over \$15,000. Id., R8/553, compared with 17% for the population as a whole. With respect to educational level (of the head of household), the 1971 study concluded that 38% of the hearing impaired have heads of family with an educational level of less than nine years, Id., R8/544, compared with only 23% for the population as a whole R8/553. At the higher end of the educational level, however, approximately 19% of all hearing impaired have heads of family who have completed 13 years or more of schooling, Id., R8/544, compared with 26% for the entire United States population Id., R8/553.

There was much evidence that hearing impairment causes withdrawal, isolation, and loss of communication.⁴²⁹ In her book, The Psychology of Deafness, Edna Simon Levine, describes an aspect of the embarrassment and resulting danger of withdrawal by the hearing impaired:

To a person with obstructive deafness, his voice may sound disproportionately loud, and to avoid what he perceives as shouting, the individual tends to speak lower and lower until he can hardly be heard at all. On the other hand, in cases of severe nerve deafness, the person experiences difficulty in hearing the sound of his own voice, and to overcome this he speaks with unnecessary loudness. As time goes on and hearing lessens, defective enunciation commonly appears together with other poor speech habits that make it difficult for a listener to understand what the hearing impaired person is saying. As a result, . . . 'many of these hard-of-hearing people live in fear of their own voices. They are constantly on the alert to detect the unfavorable reaction of those with whom they talk, trying to regulate by this reaction the volume of their voice.' Thus, to the continuing strain of trying not to misunderstand what is said is added the burden of trying not to be misunderstood. From the tensions thus imposed on interpersonal communication, a rift is apt to develop between the hearing-impaired individual and his human environment. [Citations omitted]⁴³⁰

Another commentator explained that isolation results from the

429 E.g., Bowen, TR 1903; Stein, TR 8971; Harford, R10/142-46; Pastalan, TR 4723-24, R10/418; Lentz, R8/8001; Bennett, R8/8592, 8618-19, 8645; RPAG, R8/2655; Rich, R. (Senate Hearings, 1968), R8/988; Anthony, R10/3450; Kojis (Senate Hearings, 1968), R8/1022; HEW Task Force Report, R8/3200-01; Hull, R8/6168; Bowen, TR 1944; Rassi, TR 5750; Consumer, R8/7213-15; Waddell, R8/5750; Chown, R8/5899-5925; Corso, R8/6326; Hull (Traynor), R8/6142; Griesel, R8/3427; Beltone, R8/2552; Alpiner, R8/5451, 5511; Traynor, TR 6811; Epstein, R10/421; Levine, R10/5738-39; Gardner, R8/4154-55; Rich, T. (Senate Hearings, 1967), R8/7213-14; Lawton (Senate Hearings, 1967), R8/7214-15.

430 Levine, R8/5738-29.

embarrassment of hearing impairment and that the problem may become so severe that communication becomes more threatening than rewarding.⁴³¹ Thus, people with hearing impairments may lose the benefit of the interaction and knowledge that can be gained from family, friends and other supportive individuals.⁴³² Because the hearing impaired realize that other people hear sounds that they cannot, they tend to rely on others for information.

For many of the hearing impaired, these feelings of isolation and reliance may be complicated by the anxiety of confronting the cause and possible cure of their problems. There is general agreement that the hearing impaired are reluctant to admit their handicap and to purchase and wear hearing aids.⁴³³ The reasons for this include general embarrassment,⁴³⁴ the desire to avoid using a device that

431 Gardner, R3/4154-55.

432 Rich (Senate Hearings, 1968), R8/988; Kojis (Senate Hearings, 1968), R8/1022, HEW Task Force Report, R8/3200-01.

433 Beltone Electronics Corp. Docket 8928 (1982) slip-op. at 4. See also, e.g., HAIC, R4/3714; Campagna, TR 2597-98; Fechheimer, TR 6963-64; Fortner, TR 2856-57; Hardick, R8/6851, R10/6401; Gardner, R8/4159; Beltone, R3/3135, 3139; Consumers Union, R8/228; Alpiner, R8/5434; Kasten, R13/2095; Zenith, R3/3120; Dahlberg, R3/3069; Bryan, R8/6442; RPAG, R8/2660, 2793; Oberhand, TR 3041; Kojis, R8/880, TR 2072-73, R8/1025, 2047; Kleiman, TR 6909-10; Hamburger, TR 5339; Clinkscapes, TR 10649; Beiter, TR 9052; Epstein, TR 4571; NHAS, R3/3648; Griesel, TR 9381; Sandlin, TR 10124; Corbett, TR 192; Schein, TR 228; Lesko, TR 7213; HAIC, R8/1189 EE; Barnow, TR 1626-31; Corso, TR 1188; MPIRG, R8/1213; HEW, R8/3202; Scott, TR 2321; Maico, R13/885; Staab, TR 7038; Smith, R., TR 8149

434 E.g., Hardick, R8/6851; Byrne, R8/6442; RPAG, R8/2793; Alpiner, R8/5493.

may be considered a sign of old age,⁴³⁵ and vanity.⁴³⁶ Apparently, the decision to use an aid is a difficult one, even absent the expense. Indeed, there is evidence in the record that consumers are hesitant to accept and use hearing aids even when they are free.⁴³⁷ According to a witness connected with Beltone, HEW spent years looking for and found relatively few hearing impaired persons who would accept free aids.⁴³⁸ A HAIC witness testified that buyers normally resist a dispenser's efforts to sell them hearing aids for reasons other than price.⁴³⁹

Nevertheless, the record also indicates that the high price of a

435 E.g., Barnow, TR 1626-30; RPAG, R8/2793; Harris, TR 10415; Kojis, R8/1025; Kleiman, TR 6933; Hamburger, TR 5339.

436 E.g., Smith, A., TR 8149; Beiter, TR 9052; NHAS, R3/3285-86, 3348; Clinkscapes, TR 10649; Epstein, TR 4570-71. One report determined that many people fail to acknowledge the seriousness of their hearing loss and do not buy an aid, for fear that it will make their hearing loss apparent, be considered a sign of aging, or make them look different. The report concluded that many of the hearing impaired reject aids because they believe aids carry a social stigma. As another submission explained, two significant characteristics of hearing impaired adults their reluctance to admit a loss and, should they admit it, their hesitation to seek assistance. Some witnesses stated that there tends to be a gap of as much as 5 to 10 years before an aid is purchased even after the problem is recognized. E.g., Barnow, TR 1632; Scott, TR 2321; Staab, TR 7038; Kojis, R8/880; Campagna, TR 2598. However, one submission suggested that most consumers purchased a hearing aid less than one year after realizing their need for such a device. Powers, R13/980.

437 Kojis, TR 2072-73; RPAG, R8/1188; contra, Madell, R8/4343.

438 Barnow, TR 1630.

439 Kojis, TR 2072.

hearing aid contributes to buyers' reluctance to purchase aids.⁴⁴⁰ According to one report,⁴⁴¹ the \$350-\$400 which a hearing aid cost at the time was an economic barrier to low and lower middle income groups.⁴⁴²

440 E.g., Johnson, K., TR 4259; HEW Task Force Report, R8/3232; Griesel, TR 9381; NHAS, R8/3648; RPAG, R8/2660; Sandlin, TR 10124; Corbett, TR 192; Schein, TR 228; Lesko, TR 7213; Corso, TR 1188; Minn. PIRG, R8/1213.

One survey, a RPAG survey in 1972 of the members of the Council of Organizations Serving the Deaf, obtained the following results with respect to why the hearing impaired resist purchasing hearing aids or become dissatisfied with the aids they have purchased: aids are priced too high, 19%; aids are unattractive and signal old age, 20%; follow-up services and information for aids are inadequate, 21%; aids performed poorly, 15%. RPAG Report, R8/2659. Another survey found that 25% of those surveyed listed "cannot afford one" as the reason for not purchasing an aid. Minnesota Hearing Aid Industry, R8/1316.

441 RPAG Report, R8/2660.

442 While Medicare will not cover hearing aids or evaluations, some state Medicaid programs will.

However, in nine jurisdictions (Alaska, Arizona, Mississippi, North Dakota, Utah, Vermont, Virginia, West Virginia, and Wyoming) Medicaid will not pay for either.

In Delaware, it will pay for the evaluation, but not the aid, and then subject to two conditions: the recipient must be under 21, and must be "categorically needy." ("Categorically needy" people must meet stricter income tests than other Medicare recipients who are classified as "medically needy.")

Medicaid will pay for the hearing aid, but not the hearing evaluation, in six jurisdictions. In four of these (Louisiana, Nebraska, New York, and Wisconsin) both medically needy and categorically needy are covered. In the other two, (Rhode Island and Washington) only the categorically needy are covered.

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Thus, the record suggests that many of the hearing impaired are faced with a choice between gradual social withdrawal and what many consider an expensive and stigmatizing cure.

C. Expectations Based on Expertise

There is considerable record evidence that hearing aid consumers are poorly informed about the nature of hearing loss, hearing aids, and the hearing aid market.⁴⁴³ An aspect of this lack of consumer knowledge, stressed by many commentators and detailed in the next section, is that consumer misunderstanding as to the potential

442 (FOOTNOTE CONTINUED)

Thirty-four jurisdictions will pay for both hearing aids and evaluations. However, seven of these jurisdictions (Alabama, Colorado, Georgia, Idaho, Nevada, South Carolina, and South Dakota) will only cover persons who are both categorically needy, and under 21. Another nine jurisdictions will cover both the categorically needy and medically needy, but only if they are under 21 (Arkansas, Kentucky, Maine, Maryland, Oklahoma, Pennsylvania, North Carolina, the District of Columbia, and Tennessee). Nine other jurisdictions will cover recipients of any age, but only if they are categorically needy (Florida, Iowa, Missouri, New Jersey, New Mexico, Ohio, Oregon, and Texas). Only 9 jurisdictions (California, Illinois, Kansas, Massachusetts, Michigan, Minnesota, Montana, New Hampshire, and Indiana) will cover both the hearing aid and the hearing evaluation, for both the medically needy and the categorically needy, of all ages.

443 See Section D, infra.

effectiveness of hearing aids leads to unreasonably high expectations.⁴⁴⁴

Because they know little about the causes or cures for their impairment, the hearing impaired tend to rely heavily on the dispenser's expertise.⁴⁴⁵ And, as one witness testified, consumers, pleased that the dealer has recognized and apparently analyzed their problem, imbue with a "halo" the dealer's expertise, positively accepting the dealer's promises of relief.⁴⁴⁶ In the eyes of many consumers, dealers become "doctors."⁴⁴⁷

D. The Controversy Over Their Capacity to Shop For and Rationally Purchase an Aid

There was little disagreement that the demographics for persons with hearing impairments vary from the general population's, that for many there are psychological consequences of a hearing loss, and that the purchasers of aids rely on dealer expertise. Witnesses did disagree, however, about whether these or other factors seriously affect a consumer's capacity to purchase aids rationally.

444 Id.

445 E.g., Schein, TR 199-200; Vreeland, TR 3873; Schreiber, TR 4048; Dunlavy, TR 3453-54; Morgan, TR 9508-09; Loavenbruck, TR 1547; Shannon, TR 1860-61; Traynor, R8/6811; Scheen, R10/199-200; NHAS, R8/4023, S. Graham, R8/5284; Loavenbruck, TR 1547; Griesel, (HEW Task Force Hearings), R8/3428; Shannon, TR 1860-61; AARP, TR 1463; Morgan, TR 9510; Schaie, R8/6238; Rupp, R8/7120; Corso, R8/8973; NCSC, R8/457.

446 See Corso, R8/8973. As noted previously, there is also evidence that the hearing impaired generally rely on authority figures. See Section II.B.

447 Loavenbruck, TR 1547; Shannon, TR 1860-61.

There is a great deal of record testimony that the hearing impaired population is more susceptible to sales abuses, or has traits that make it more susceptible to such abuses, than does the general population.⁴⁴⁸ The reasons for this susceptibility vary.

Numerous witnesses and commentators stated that hearing impaired consumers are poor comparison shoppers.⁴⁴⁹ Their reluctance to acknowledge their hearing loss reduces the likelihood that they will shop comparatively. Furthermore, it makes them hesitant to replace

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E.g., Harford, R10/144; Schein, TR 199-200, R10/3738; Smith, B. TR 285-86; Fabray (Senate Hearings, 1963), R8/871; Bowen, TR 1903-10; Rich (Senate Hearings, 1968), R8/988; Anthony, R10/3450; Kojis (Senate Hearings, 1968), R8/1022; HEW Task Force Report, R8/3200-01; Stein, TR 8971; Lentz, R8/8001-02, R8/8195; R13/1748-50; Bartels, R10/5623; Beiter, TR 9034, 9064-65; Graham, S., R8/5275, 5284; Noffsinger, R8/5404; Sanders, R8/7597; Martinucci, TR 8432; Alpiner, R8/5434, 5451, 5511; Kasten, R10/70; Loavenbruck, TR 1547; Griesel (HEW Task Force Hearings), R8/3428; Shannon, TR 1860-61; Traynor (Hall), R8/6811; Silverman, R8/7332-34; Rassi, TR 5750; Vreeland, TR 3873; Schrieber, TR 4048; Dunlavy, TR 3453; Morgan, TR 9508-09; Wilson, TR 10024; Scitovsky and Hardy (Senate Hearings, 1963), R8/700; Pastalan, TR 4694-98, 4703-39; Luzi, TR 7718; Bennett, R8/882; Tannenbaum, R8/7305-06; Tobin, TR 49094-05; Adkins, TR 6071; Brickfield, TR 1461; Jungheim, TR 8893; Vick, TR 10565; Jeffries, TR 5629; Smathers, R8/7175; NYPIRG, R8/1335; Church, R8/814; Percy, R8/175; Waddell, R8/5749; Ohio Consumer Protection, R8/2930; Schaie, R8/6238-43; Shanta, TR 8863; Wimmer, TR 6544; AARP, R10/886; Legal Research, R8/3883; Hayes, R8/4962; Madell, TR 5868; Stutz, TR 8997; Corso, R8/8973; Montgomery, R8/1675; Willeford, R8/7984; NCSC, R8/457; Rupp, R8/7120; Kelly, TR 7531; Ruben, TR 4013; Splansky, TR 9012-13; Ginsberg, TR 4685.

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Schein, R10/38. TR 200; Traynor R8/6811; McGurk, R8/8565; Ginsberg, TR 4640; Pastalan, TR 4709; Murray, TR 4851; Murphy, R13/2068; Conlin, TR 7772; Alphiner, R8/5450; MPIRG, R8/1215; HEW, R8/3202-03; ASHA, R10/1800-01; Stallons, TR 7870-71; Bowen, TR/1944; Beltone, R13/262.

one dealer with another.⁴⁵⁰

Their lack of knowledge about their loss and their desire to remedy it leaves them susceptible to exaggerated claims. As one witness stated, the loss of hearing imposes feelings of emptiness, guilt and self-pity, leaving them vulnerable to unrealistic promises about the value of hearing aids.⁴⁵¹

There is evidence on the record that the hearing impaired not only feel frustrated and depressed, but desperate for any possible hearing improvement.⁴⁵² The "despair, panic, rage, and feelings of

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See generally Section II. B supra. One witness explained:

. . . the basic problem is in finding someone who won't convey all of the impatience when you go in and you can't be understood the first time and you don't understand what is told you the first time. Here is someone with whom you shared the secret. I don't hear well. You have to tell someone in order to begin the process of purchase. Your own experience, for most hearing-impaired people, is that in the past when you are known to be deaf, or hard-of-hearing, is that people begin to pull away from you. We talk often about the withdrawal of the deaf person. That is what is apparent. What is not apparent, is the withdrawal of the general society from the person who is going to be a bother to communicate with. I think that is a part of what is feared: first of all, the fear of admitting the loss. You share it with that person. Secondly, it is the difficulty, the terrible difficulty in communicating, so that this combines into a social situation which tends one to stay along with the older, admittedly less satisfactory contact, but likely to be better than a new one. Schein, TR 100.

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Harford, R10/144.

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E.g., Fabray (Senate Hearings), R8/871; RPAG, R8/2600; 2639; Schiavetti (Miller), R8/5689; Hardick, R8/6952; Smothers, R8/7175; Waddell, R8/5750-53; Hull, R8/6141;

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worthlessness" that grow as hearing fades can prompt searches for a miracle cure.⁴⁵³

Lacking knowledge and tending to accept authority, they may thus become dependent upon the dispenser's "expertise."⁴⁵⁴ Even when consumers are dissatisfied with their aids, one audiologist testified that they return to the same dealer in hope that a "revolutionary new" model will improve hearing.⁴⁵⁵ Others, less dependent on a single dealer, may also buy one aid after another,

shop[ping] from one dealer or clinic to another, misled by advertising claims of better, best, improved, smallest, et cetera, . . . seeking what amounts to be the perfect hearing aid -- invisible to the eye, with high fidelity amplification for speech signals.⁴⁵⁶

452 (FOOTNOTE CONTINUED)

Beiter, TR 9064-65; Tannenbaum, R8/7306; Beltone, R8/2552; Bryan, R8/8973; AARP, R10/886; Legal Research, R8/3883; NCSC R8/457; Plotkin, TR 6023; Schein, TR 202; P.O. Report, R9/Dlip42; Burke, TR 6411; ASHA, R10/2617. This desperation, one witness said, is similar to that of patients with cancer. Smith, B., TR 285.

453 Levine, R8/5739.

454 See Section II.C.

455 Lankford, TR 8049.

456 Burke, M., TR 6410. See also Kasten, R5/1439; Fabray (Senate Hearings, 1973), R8/871, R10/68; Traynor, R8/6811; Owens, R8/6486; P.O. Report, R9/Dlip150; B. Smith, TR 285-86; Fabray, (Senate Hearings), R8/5689; Hardick, R8/6952; AARP, R10/1242, 1246, 1351, 1367, 1464, 3943; Burke, M., TR 6410, 6413; Gunterman, TR 9660-66; Stroup, R10/142; Lankford, TR 8049; Noffsinger, R8/5404; Georgescu/Roegen, R8/1189M8; ASHA, R10/2125, Byrne and Morgan, R10/3113; Hull, R8/6141-42; Dow, R13/1639; Audivox, R13/1153; Rose, TR 507-08; Corbett, TR 173-76.

Other evidence indicates that as a group, the elderly and hearing impaired are less likely to complain.⁴⁵⁷ Reasons cited included fear of intimidation or testifying at trial, reprisals from the dealer,⁴⁵⁸ or embarrassment at having been taken advantage of or

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"Their passivity, insurity and willingness to rely on the judgment of the perceived experts act as a strong deterrent to returning the aid and requesting a refund for the trial of another aid." Silverman, R8/7336.

Madell, TR 5917; ASHA, R13/3653-56, 3659, 4145 (Maryland State Attorney's Office), 4144 (Office of Indiana Attorney General), 4135 (Delaware Division of Consumer Affairs), 4128 (Office of California Attorney General), 4142 (Hawaii Office of Consumer Protection), 4131 (Los Angeles District Attorney), 4148 (Office of Massachusetts Attorney General), 4159 (District Attorney of Clark County, Nevada), 4155 (Missoula County, Montana Attorney's Office), 4162 (Pennsylvania Bureau of Consumer Protection), 4156 (Nevada Consumer Affairs Office), 4176 (Norfolk, Virginia Office of Consumer Affairs), 4181 (Virginia, Office of Consumer Affairs), 4184 (District Attorney of New York City), 4192 (Fairfax, Virginia, Department of Consumer Affairs), 4164 (South Carolina Department of Consumer Affairs), 4161 (Oregon Office of Consumer Services), 4140 (Florida, Office of Attorney General), 4209 (Hennepin County, Minnesota Attorney's Office), 4201 (Wisconsin Department of Regulation and Licensing), 4217 (District Attorney of Topeka, Kansas), 4220 (District Attorney of Johnson County, Kansas); Gunterman, TR 10791; Penalver, TR 4910-14; Cooper, TR 9651; Miller, TR 4752-53; Fennema, TR 1751; Minnesota Kelly, R10/5646, R10/5849; Griesel, TR 9375; Hardick, R8/6853; Flemming, TR 617; Brickfield, TR 1459, 1461; Bowen, TR 1942; Schreiber, TR 4049, 4059, 4062, 4072; Pastalan, TR 4716; Stahl, TR 5561; Jeffries, TR 5586, 5616, 5627; Rassi, TR 5744, 5750; Madell, TR 5868; Filwett, TR 6106; Griesel, TR 9463, 9464; Morgan, TR 9650, 9727; Conlin, TR 7858; Levy and Tuttle, TR 11643, 11688, 11689; Vick, TR 10560-10608; Lentz, R10/6535; NCSC (Finkel) R10/4600; Winston, R8/7392; Rassi, TR 5744; Jerger, R8/4578; Stroup, TR 947; Lundberg, R13/4156; Sattler, R13/4153; 59.

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ASHA, R13/4128, 4218, 4211, 4209, 4192, 4176, 4163, 4159, 4156, 4151, 4162, 4155, (letters from state attorneys

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being considered senile,⁴⁵⁹ as well as poor health and lack of transportation and money to pursue their claim.⁴⁶⁰

However, the record also contains evidence, primarily from dealers and industry representatives, suggesting that the hearing impaired are no more vulnerable to sales abuses than is the general

458 (FOOTNOTE CONTINUED)

general); NCSC, R10/4404-05; Kelly, TR 7537; Hardick, R8/6853; Fox, R8/7249; Minnesota, Kelly, R10/152, TR 5646; HEW Task Force Hearings, (DiRocco) R8/494, TR 3472; Jeffries, TR 5627; Morgan, TR 9509; Filwett, TR 610, R13/784; ASHA Rebuttal Exh., No. IV-30, Tawb, R13/4195; NCSC, R10/4537, 4522; Hodges, R13/843.

One consumer wrote that dealer stated "Beltone had lots of money and could whip anybody in court." Ohio Department of Consumer Protection, R8/2974; in accord: Kirwin, R13/4203-08; Madell, TR 5868; Liversidge, TR 1094; ASHA, R13/3656.

459 ASHA, R13/4144, 4135, 4128, 4159, 4156, 4149 (letters from state attorneys general); Fox, R8/7249, 7250; Moneka, R8/659, TR 5389; Lentz, TR 8003; Graham, S., R8/811, TR 7467; Stroup, TR 640, 947; Wilber, TR 1396; Getchell, TR 4409; Finkel, TR 4462; Munger, TR 4504; Pastalan, TR 4707, 4708, 4727; Rassi, TR 5744, 5745, 5750; Gunter, TR 8821, 8238; Gunterman, TR 9651; Nevells, TR 4431; Jungheim, TR 8882-98; Conlin, TR 7858; NCSC, TR 4503-04; Finkel, TR 4460; Levy and Tuttle, TR 11643; Rupp, R8/7121.

460 ASHA, R13/4220, 4217, 4209, 4192, 4184, 4176, 4166, 4166, 4164, 4157 (letters from state attorneys general); Finkel, TR 4463 (elderly have difficulty filling-out forms, writing letters); accord: Jeffries, TR 4637; Gunter, TR 8213; Brickfield, TR 1460-61; Bowen, TR 1943, 1944; Griesel, TR 9375, 9464; Teter, TR 10287; Freundlich, R13/1977; Winston, R8/7393; Graham, S., R8/5286; Hardick, R8/6853; Lentz, R8/8002, R10/6535 (elderly lacked energy to complain); Pastalan, TR 4696, 4716, 4725, 4726, 4728; Rassi, TR 5746; Adkins, TR 6071; NCSC, R13/4248, 4294; Flemming, TR 622; Stroup, TR 640, 947; ASHA Rebuttal Exh., No. IV-30, Taub, R13/4195; Vick, TR 10560-10608; ASHA, R13/3655.

population.⁴⁶¹ Several testified that the hearing impaired are as capable of handling their affairs as other groups.⁴⁶² Robert Briskey, Advisor on Professional Affairs at Beltone, said the hearing impaired are not so "mentally incompetent and so incapable of making decisions that someone must dictate to them what they need."⁴⁶³ Others agreed.⁴⁶⁴

One witness testified that the hearing impaired are "quite vocal and eager" to complain.⁴⁶⁵ As for their ability to shop, an economist claimed that the uncertainties faced by the hearing impaired when they purchase a hearing aid are comparable to those faced by them when they purchase any other costly durable product.⁴⁶⁶ He also stated that, based on studies he had made,

461 E.g., Barnow, TR 1693; Johnson, J., TR 2262; Baesemann, TR 7358-61, 7412; HAIC, R3/3895; Dahlberg, R3/3378; Gardner, TR 10352; Harris, TR 10413; Fechheimer, TR 6972-73; Samole, TR 6752-53; Plotkin, TR 6056; Clinkscales, TR 10629-30; Hall, TR 11062; Berkove, TR 11047; Mettler, TR 11413-16; Scheurer, TR 11517-18; Teter, TR 10284-89, 10291; Kleiman, TR 6953; Briskey, TR 7288; Shannon, TR 18691; NHAS, R3/3499; Krebs, TR 11846, 11871; Kojis, TR 2001; James Payne, TR 2146-47; Campagna, TR 2598.

462 Id.

463 Briskey, TR 7249.

464 E.g., Barnow, TR 1693; Fechheimer, TR 6972-73 (citing HX-106); Plotkin, TR 6059; Hall, TR 1106; Berkove, TR 11047; Teter, TR 10284-89; Shuford, TR 699-700; Kojis, TR 2000-01; Brakewell, TR 1294; Campagna, TR 2611, 2680; Nader Report, R13/3583-88.

465 Kojis, TR 2000.

466 Baesemann, TR 7360.

"buyers in the hearing aid market are as capable of shopping as they are in any other market."⁴⁶⁷

E. Special Groups

Several commentators singled out two groups of hearing impaired consumers as particularly vulnerable: the very young and the elderly. These two groups represent nearly half of all potential hearing aid sales.⁴⁶⁸ In each case witnesses argued that their capacity to rationally evaluate an aid (even absent sales abuses) is particularly diminished by physical or psychological characteristics.

1. The Elderly

According to several witnesses, the average elderly hearing impaired consumer has to contend with shopping disabilities beyond just partial deafness. They are disabilities related to physiological and psychological changes that come with age. While there was disagreement⁴⁶⁹, and some evidence that the elderly have a good

467 Baesemann, TR 7358. One audiologist who said that 20% of the clients he saw shopped around for hearing aids. Krebs, TR 11871.

468 See Section II.A., supra.

469 Fechheimer TR 6972-73 (citing HX-106); Samole, TR 6752-53. Witnesses, generally those representing industry and dealers, argued that the elderly are not afraid to complain. E.g., Gardner, TR 10352; Plotkin, TR 6059; Hall, TR 1106; Shuford, TR 699-700; Schreiber, TR 4059, 4071; Splansky, TR 9022; Shanta, TR 8863. One witness explained that people who don't have much to do complain more than others. Hall, TR 11062.

self-image,⁴⁷⁰ the record indicates that the elderly hearing impaired are particularly susceptible to mistreatment in this market.⁴⁷¹

In addition to sharing the problems of the hearing impaired generally, many commentators said that, with increased age, people must cope with decreased attention spans, increased fatigue, reduced retention abilities, and characteristics relating to a lessening of

470 A Lou Harris survey of the elderly sponsored by the national Council on Aging indicates that the elderly feel more positively about their personal health than do younger people and that 69% of those over 65 believe they are "very wise from experience. HX-106/53.

471 E.g., Lentz and Willeford, R8/7998-8003; Tobin, TR 4906-11; Pastalan, TR 4694-98, 4730-39; Luzi, TR 7718; Schaie, R8/6238-41; Bowen, TR 1906-07, Adkins, TR 6071; Brickfield, TR 1461; Jungheim, TR 8893; Vick, TR 10565; Jeffries, TR 5629; NHAS, R3/3499, 3586, R8/4023; Montgomery, R8/1675; NYPIRG, R8/1335; Graham, S., R8/5275; Price, R8/2017; Church, R8/814; Consumer, R8/7213-16; Percy, R8/174; Subcommittee on Fraud (Rather), R8/6109; Ohio Division of Consumer Protection, R8/2930; ISPIRG, R8/1374; Hull (Traynor), R8/6140; Beiter, TR 9064-65; Splansky, TR 9012, 9023; Shanta, TR 8863; Fleming, TR 630; Wimmer, TR 6544; MPIRG, R8/1215; Traynor, R8/6811; HEW Task Force Report, R8/3202-03; Bennett, R8/882, 8592, 8645; Beltone, R8/2552; Bryan, R8/6442, 8973; RPAG, R8/2600; Waddell, R8/5749-53; Rupp, R8/7120; Rose, R8/4181; Alpiner, R8/5436, 5450; Hardick, R8/6853; Willeford, R8/7983-84; Smathers, R8/7175; AARP, R10/886; Legal Research for Elderly, R8/3883; Smith, B., TR 331; NCSC, R8/457, 4460; Hayes, R8/4962; Giglia, TR 2762-63; Woodruff, R8/6016-17; Corso, R8/6309; Gilbert, R8/5958; Chown, R8/5920; Walsh, R8/5860-81; Rassi, TR 5746-78; Ginsberg, TR 4685; Ruben, TR 4013; Kelly, 1462; Morgan, TR 9510; Madell, TR 5868; Stutz, TR 8997; Schreiber, TR 4056; Flemming, HX8/592; Estes, R8/6500, 6502. The Presiding Officer found that the elderly, along with parents of hearing impaired children, are particularly susceptible to hearing aid abuses involving home sales. P.O. Report, R9/Dlip77.

learning or evaluation skills.⁴⁷² Manual dexterity also declines.⁴⁷³ But perhaps the most serious physical loss is their weakening eyesight. Over 20% of all persons over 65 years of age may have visual impairment.⁴⁷⁴ Thus, many of the elderly hearing impaired are losing sight as well as sound.

Advancing age brings psychological changes as well. There is considerable evidence that the elderly have a greater incidence of

472 E.g., Pastalan, TR 4694-96, 4723-24; Schaie, R8/6239-40; Woodruff, R8/6017; Corso, R8/6309, R10/195; Lentz, R8/8001; Gilbert, R8/5958; Chown, R8/5920; Walsh, R8/5860-81; Giglia, TR 2761-62; AARP, R10/1463; Ruben, TR 4013; Beiter, TR 9064-65. According to Dr. Warner Schaie, older people can generally learn a given task as well as younger people, but it takes them longer to do so. He explained that this declining of intelligence may be due to a number of factors: (1) psychological factors such as the slowing down of the central nervous system; (2) lack of environmental stimulation (friends and relatives may be dead, the elderly no longer may be working); (3) effects of childhood diseases; and (4) effects of cardiovascular problems (the blood may not be pumped as reliably to the brain). Schaie R8/6239-40. The attention span of the elderly is shorter and that it is necessary to repeat information slowly to ensure that they understand what is being said. Giglia, TR 2761-62.

473 In re Mather Hearing Aid Distributors, Inc., (Yantis) R8/2181, (Manning); Willeford, R8/7977; Powers, R13/995; Hull, R8/686, 6218; RPAG, R8/421, 2744, Byrne, R8/6464; Alpiner, R8/5427; FTC Kasten, R8/6982; Minn. Hearing Aid Industry, R8/1212; Traynor, R8/776; Byrne, R8/691; Jeffries, R10/5457; Brakebill, TR 1335-36; Epstein, TR 4590-91; R10/38; Miller, TR 4778; Teter, R13/68A; Krebs, TR 11904; Harford, TR 51; See also, Section I.B.2.b.

474 Health Resources Administration (1971), R8/541. One submission pointed out that, not only does eyesight decline with age, but also other senses such as the sense of touch and smell also decline, with the result that less sensory information reaches the brain. Woodruff, R8/6025.

depression, loneliness, and isolation,⁴⁷⁵ characteristics that create a reluctance to complain and a substantial trust in authority figures.⁴⁷⁶ For a complex of reasons this is especially true among elderly women.⁴⁷⁷

These characteristics, and depression from various sources, have several implications. First, they make the elderly more likely to accede to sales pressure. For example, one commentator noted that the elderly withdraw from noisy and group situations where understanding is difficult. Over time such withdrawal can lead to deep depression and loneliness, creating a greater susceptibility to

475 E.g., Tannenbaum, R8/7306; Beltone, R8/2552; Bryan, R8/8973; RPAG, R8/2600; Smathers, R8/7175; Waddell, R8/5750-53; Hull (Traynor), R8/6140-41; Beiter, TR 9064-65; AARP, R10/886; Adkins, TR 6071; Legal Research for the Elderly, R8/3883; Smith, B., TR 331; Consumer, R8/7213-15; Woodruff, R8/6012-27; Corso, R8/6324-26; Bennett, R8/882, 8592-95; 8618-19; Chown, R8/5899, 5925; Schaie, R8/6243; NCLD, TR 1908; Lentz, R8/8001; Willeford, R8/7984; Jungheim, R8/8893; NCSC, R8/457; Flemming, HX8 592; Griesel, R8/3427; Beltone, R8/2552; Alpiner, R8/5451, 5511; Traynor, R8/6811; Estes, R8/6500.

476 E.g., Rupp, R8/7120; NHAS, R8/4023; Rose, R8/4181; Alpiner, R8/5436; Hardick, R8/6853; Willeford, R8/7983-84; Pastalan, TR 4730-31; Hayes, R8/64962; Waddell, R8/5756; Bennett, R8/8594; Schaie, R8/6238-41; Giglia, TR 2762-63; Splansky, TR 9023; NCLD, TR 1908, 1923; NCSC, R8/457; Willeford, R8/7120; Price, R8/2017; Hayes, R8/4962; Alpiner, R8/5436; Byran, R8/6442; Lentz, R8/8002; Morgan, TR 9510; Corso, R8/8973; Hardick, R8/6853.

477 Dr. Ruth Bennett said they readily agree with whatever is said. They are relatively more likely to rely on persons who qualify as "experts" or assert themselves authoritatively. Bennett, R8/8593-94.

sales pressure.⁴⁷⁸ According to Dr. Waddell, Professor of Gerontology at Antioch College, the elderly often experience grief complicated by hostility and depression, thus increasing vulnerability. Dr. Waddell believes that older persons often tend to feel helpless and are likely to accept the decisions and persuasions of others.⁴⁷⁹

Second, they may have diminished mobility. Commentators explained that many of the elderly are unable to use transportation to visit dealers; thus, they are hindered in comparative shopping for aids.⁴⁸⁰ Many, one report noted, cannot or do not use the telephone and social service agencies.⁴⁸¹ Such factors reduce the ability of the elderly hearing impaired to shop for and evaluate the benefits claimed by dealers for their aids.⁴⁸²

478 Lentz (Willeford), R8/8001. Those elderly in nursing homes are even more isolated and consequently are more at risk. See, e.g., Estes, R8/6500.

479 Waddell, R8/5750. Another witness stressed that the elderly hearing impaired especially are lonely and do not want to disappoint the seller by not relying on his advice. Traynor, R8/6811.

480 E.g., Adkins, TR 6071; Traynor, R8/6811; NHAS, R3/3586; Alpiner, R8/5450; MPIRG, R8/9215; RPAG, R8/2655.

481 HEW Task Force Report, R8/3202-03. Bertha Adkins, Chairperson of the Federal Council on Aging, also testified that "many of the elderly lack the mobility due to inadequate transportation, or social withdrawal or physical debilities to do comparative shopping" Adkins, TR 6071.

482 The testimony of Leon Pastalan, a gerontologist and sociologist, illustrates the various points made by many

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2. The Young Hearing Impaired and Their Parents

The record strongly suggests that the prevocationally deaf,⁴⁸³ and the parents of deaf or hearing impaired children, are particularly ill-equipped physically and emotionally to judge without

482 (FOOTNOTE CONTINUED)

witnesses concerning the elderly. He stated that, although he was not familiar with the "specifics of consumer fraud," the elderly have less control over their general life, and they tend to be more trusting and are more subject to the hazards of salesmen. Pastalan, TR 4703-04. Physical and psychological losses contribute to the elderly's loss of control over their environment and to their loss of perceptual skills. He listed these losses: (1) loss of spouse and friends, (2) loss of mobility, and (3) loss of status, (4) sensory losses dues to physical changes which damage the intellectual process, i.e., vascular accidents, strokes and chronic conditions such as high blood pressures. Id., TR 4694-96, 4723.

The elderly's losses affect their ability to handle complex information in short periods of time and decrease their reaction time and cognitive processes. Id., TR 4712-13. (Under these conditions, for example, the elderly must avoid certain stressful situations such as heavy traffic and, because of poor eyesight, they may not be able to read labels. Id., 4713-14. These limitations lead the elderly to begin to feel incompetent because of their lessened sensory acuity, and they tend to withdraw. Id., TR 4723-24. Dr. Pastalan stated that studies demonstrate that the elderly are reticent to seek resolution for inappropriate purchases and have limited skills in making bureaucracies deal with their needs. Id., TR 4727. And in any event, elderly have a greater tendency to accept the word of an authority if they see him as an expert. Id., TR 730-31.

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There are an estimated 400,000 prevocationally deaf (persons who have suffered loss of hearing before the age of 19) in the United States. Schein and Delk, SPXA/15-16.

trial the usefulness of a hearing aid.⁴⁸⁴

The typical prevocationally deaf child grows to adulthood without proper educational training (It was estimated that the average reading level for a prevocationally deaf or impaired adult is 3.5 years)⁴⁸⁵ or social development.⁴⁸⁶ One witness testified that deaf or hearing impaired children either attend deaf schools and do not have much contact with the hearing world, or attend schools for the hearing impaired, where they are not encouraged to be aggressive. Even after they become adults, they attempt to hide their ignorance of what is occurring around them by playing "nod and smile," pretending to understand what is being said when in fact they do not.⁴⁸⁷ According to one witness, they are taught to accept the superiority of persons who can hear.⁴⁸⁸ Their life experiences, one witness summarized, makes them poor purchasers.⁴⁸⁹

There was also evidence that parents of hearing impaired children

484 E.g., Stein, TR 8973-74; Bowen, R8/6954, Schein, R8/7824-25, R10/39. See generally, n. 490-492, infra.

485 Schreiber, TR 4054.

486 A specialist in children's audiological handicaps testified that even moderately hearing impaired children may, without obtaining proper training, sometimes miss 50-75% of what occurs in the classroom. The isolation caused by never being able to communicate fully results in underachievement, isolation, and frustration. Stein, TR 8973.

487 Bowen, TR 1909.

488 Schreiber, TR 4048.

489 Schein, R8/7825.

often lack knowledge about hearing aids or otherwise have traits that make them prone to sales abuses.⁴⁹⁰ One witness testified that these parents look for the miracle cure.⁴⁹¹ A teacher of the deaf explained that a parent's emotions can overtake rational thinking when dealing with a hearing impaired child. She said that parents who are trying desperately to help their children regain normal hearing can easily be fooled by exaggerated advertisements.⁴⁹²

490 E.g., Stein, TR 8978-79; Feder, TR 8517-18; Warren, R8/5310; Schein, R8/7825. The Presiding Officer found that parents of hearing impaired children seemed particularly vulnerable to objectionable home sales of hearing aids. P.O. Report, R9/D1ip77.

491 Stein, TR 8978-79.

492 Feder, TR 8517, 8522.

III. Adjusting to the Aid

The purchase and use of a hearing aid is a more complicated process than most persons realize. Although hearing aids are often compared to simple prosthetic devices such as eyeglasses, adaptation to a hearing aid is much more difficult. It may entail a considerable period of physical, educational and psychological adjustment. Often the dispenser must provide careful modulated motivation and guidance, from the time of purchase through the end of adjustment, if the user is to significantly benefit. Unrealistic promises, made to motivate a purchaser to try amplification, may actually harm the buyer who becomes frustrated by the aid's failure to perform as promised or believed.

This section reviews the record evidence concerning adjustment and the role of expectations, counselling and motivation in adjustment. The analysis also describes the debate over a trial's effect on successful adaptation.

A. Consumers Expectations

Record evidence indicates that many consumers have unrealistic expectations and significant misconceptions about the benefits that a hearing aid can provide.⁴⁹³ Many consumers expect that a hearing

⁴⁹³ ACO, R10/248; Plotkin, R10/4934; Lentz, R8/8001, TR 11233; Masticola, TR 8625-26; Harford, TR 59, 140; Tweed, R8/7629; Jerger, R8/4958; Syfert, TR 5203; Tobin, TR 4118; Fortner, R13/1054; Whitman, TR 8570; Schmitz, R8/7208; Stallons, TR 7869; RPAG, R8/2608; Payne & Payne, R8/1460; McPherson, TR 5139; Vick, TR 10614; Hardick, R8/6851; Franks, TR 9826-27; ASHA, R10/1725, 1723, 1694, 1724; AARP, R10/931,

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aid will solve all of their hearing problems,⁴⁹⁴ for example, or will restore normal hearing.⁴⁹⁵ Others expect it to retard or stop hearing loss, and restore the hearing ability that they had when they were younger.⁴⁹⁶ Many consumers do not expect an aid to amplify background noise.⁴⁹⁷ These expectations arise from a number of sources.

493 (FOOTNOTE CONTINUED)

1504; Griesel, R10/6244. Bartels, R10/5623; Beiter, TR 9034; Graham, S., R8/5284; Noffsinger, R8/5404; Sanders, R8/7597; Martinucci, TR 8432; Bowe, R8/6952; Kasten, R10/68-70; Willeford, R8/7983; Powers, R13/985, R13/1023; Burke, M., TR 6410, 6434; Lankford, TR 8065; ASHA, R8/1787; Smith, B., TR 285-86, 333; Fabray (Senate Hearings), R8/871; Georgescu/Roegen, R8/11890M8; Schmitz, R8/7267; Alpiner, R8/5434.

494 Penalver, R10/4458; Hardick, R8/6851; Johnson, E., R8/4492, 4527; Alpiner, R8/5435; Corbett, TR 182; AARP, R10/4104; NCSC, R10/4497; AARP, R10/958; AARP, R10/3979.

Some of the hearing problems referenced in the letters supplied by AARP and NCSC involved participating in group conversations, understanding television, and understanding all speech more clearly. The author reported that they had expected the hearing aid to solve these problems, and that their aids failed to provide the expected results.

495 Fortner, TR 2963-64; Pollack, SPXB/287; Sanders, R8/7597; Whitman, TR 8570; Keyes, TR 10695; Pasiewicz, TR 920; Jerger, R8/4574; Burke, M., TR 6422; Payne, James, HX39/7-8; ASHA, R10/1728; RPAG, R8/2608; Winston, R8/7403; Stallons, TR 7869.

496 Martinucci, TR 8432; Heisse, TR 3314.

497 Many consumers do not realize that a hearing aid will amplify all noise not merely speech or selected noise from an environment. Willeford, R8/7073; Hardick, R8/6852; Kasten, R8/6979; Brewer, TR 3963; Sanders, *supra*, SPXB/334; Richenberg, TR 3547; Winston, R8/7407-08; Giglia, TR 2790. Mr. Giglia related stories about consumers he had served who felt there were problems with their hearing aids when they were hearing the sounds of a motor starting or a bird chirping for the first time in 20 years.

First, consumers expect their hearing deficits to be restored through the use of hearing aids in much the same way that vision deficits are corrected with eyeglasses.⁴⁹⁸

In addition, some commentators have said that advertising and dispenser practices contribute to unrealistic expectations;⁴⁹⁹ indeed, many of consumers' specific misconceptions parallel advertising claims detailed in the rulemaking record. Some commentators have stressed the fact that consumers lack a good understanding of hearing impairment and the limitations of hearing aids.⁵⁰⁰ Beyond existing consumer misconceptions and expansive advertising, others cited misinformation from dispensers, some of which are documented in Section IV. For example, ASHA and RPAG believe that first time users' unrealistic expectations derive, at least in part, from dispenser misrepresentations.⁵⁰¹

Even where dealers do not affirmatively misrepresent what an aid

498 Hardick, R8/6844; Smith, B., TR 333-34; Schein, R10/38; RPAG, R8/2608. See Section IV.A.1.

499 See Sanders, R8/7597; Smith, B., TR 333; Stroup, TR 963; Burke, M., TR 6451; Pownell, R8/4463. In this connection, one consumer wrote complaining that he had seen an advertisement in his local paper for a new "miracle" hearing aid. He responded to the advertisement by going in to be tested and fitted for a hearing aid. Only after his custom fitted aid arrived and proved to be worthless did he realize that there was no such thing as a "miracle aid". ASHA, R10/2617.

500 Sanders, SPXB/334-35; Wilson, TR 10023-24; Rose, TR 505; Corbett, TR 190; Smith, A., TR 8150; Pownell, R8/4463; Brewer, TR 3963. See also Section II.C.

501 ASHA, R10/1728; RPAG, R8/2595-2641; accord Lentz, R8/8001.

can do, the record shows that dispensers often fail to reveal the aid's limitations in advance.⁵⁰² Some commentators indicate that first time users have particularly unrealistic expectations of amplification.⁵⁰³ Other testimony indicates that misconceptions are not limited to that group. Indeed, audiologist William Lentz said:

few individuals, including experienced hearing aid users are as knowledgeable about hearing aids as they should be.⁵⁰⁴

Witnesses indicate that excessive expectations can be a serious problem, as the next sections detail. Where consumers lack knowledge as to hearing loss, their expectations may be so high that nothing short of a "miraculous recovery of their hearing" will satisfy them.⁵⁰⁵

Of course, not all consumers misperceive hearing aid effectiveness. As NHAS President Luke Fortner testified, consumer expectations concerning the usefulness of amplification vary greatly.⁵⁰⁶

502 McPherson, R10/289; Penalver, R10/4458; AARP, R10/1504; Powers, R13/1005.

503 ASHA, R10/1728-29; Giglia, R10/2922; see also NHAS, R3/3517.

504 Lentz, R10/6533. See also Section II.C.

505 Harford, TR 53, 59; Accord, Alpiner, R8/5435; Penalver, R10/4458. Ideally, a counselor should be able to help such a consumer to accept more realistic expectations of the product without dampening his desire to use it. Harford, TR 53.

506 Fortner, TR 2963-64. Fortner said that contact with medical
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in the form of either required trial periods or required disclosures, is unnecessary.

Respectfully submitted,

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B. The Adjustment Period: Psychological and Physical Adaptation.

The inexperienced hearing aid buyer needs to be introduced to the aid and counseled as to its use.⁵⁰⁷ People fitted with a hearing aid often have not heard normally for years.⁵⁰⁸ The sudden onset of forgotten sounds such as refrigerator hum, air-conditioner noise, florescent lights, or the rustling of paper may overwhelm them.⁵⁰⁹ Adults who lost their hearing during middle age may need to relearn the rules of language and listening skills. Accordingly, an adjustment period is necessary.⁵¹⁰ Without audiologic

506 (FOOTNOTE CONTINUED)

ear specialists and experiences of family members who have previously purchased aids are also factors shaping consumer expectations. Accord, Fleming, R10/592.

507 Corso, R8/8968; Rassi, R8/5367; Schmitz, R8/7263; Giglia, TR 2750; Alpiner, SPXB/173-74; Sanders, SPXB/323-70; Sullivan, R8/910; Keyes, TR 10724; Glorig, R8/3498-99.

508 Winston, R8/7409; Masticola, TR 8635; Epstein, TR 4613-14.

509 Epstein, TR 4613-14; ASHA, R10/2548; Masticola, TR 8635, 8636; Dunlavy, TR 7402; Sandstrom, TR 3119; NHAS, R3/3265-66, 3210-12; Corso, R10/195; Lentz, R8/8084; NBS, R8/615ipl8; Fabray, R8/870-71.

510 Staab, TR 7042. See Keyes, TR 10724; Curran, TR 10814; Hecker, R10/89; ASHA, R10/57, TR 2540, R10/2539, 2239; Rompala, TR 9096; Drew and Eiler, TR 7170-71; Briskey, TR 7285, 7246-47; Johnson, J., TR 2265; Williams, J., TR 3767; Brewer, TR 3963-64; Epstein, TR 4615; Fennema, TR 1790; NHAS, R2/103, R3/3265-66; Corso, R10/194; Epstein, TR 4614; Consumers Union, R8/225; Lentz, R8/8084; NBS, R8/615ipl8; Traynor, R8/6156; Bartel, TR 6303; Kojis, TR 1986; Pastalan, TR 4722-32; Barnow, TR 1685; Sanders, SPXB/352-53; Silverman, R8/7325, 7333; Hull, R8/6219; Rosch, R8/557; Shanta, TR 8862; P.O. Report, R9/Dlip203-04; Blood and Danhauer, R13/134; Rassi, TR 5732; Ehritt, R8/4799; Owens,
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rehabilitative therapy this task becomes more difficult.⁵¹¹

Adjustment to amplification has been described as preparing for a new method of living.⁵¹² Witnesses explain that users must adjust to the unnatural quality of amplified sound;⁵¹³ to the amplification of background noises;⁵¹⁴ to the fact that a hearing aid can not make speech sound any clearer than the resolving capacity of an individual's hearing system;⁵¹⁵ and finally, to the need to wear foreign objects in the ear, and to adjust volume and tone

510 (FOOTNOTE CONTINUED)

R8/6487; Fabray, R8/870-71; NHAS, R3/3265-66, 3702; HAIC, R3/3610; in re Mather Hearing Aid Distributors, Inc., (Causey) R8/2048; Dunlavy, TR 3400-01; Giglia, R10/2922; Hurt, R8/8258.

511 P.O. Report, R9/Dlip203-04; Gerstman, TR 2385-89; Corso, TR 1196; Elia, TR 7479-81; Tobin, TR 4106-07, 4118; NHAS, R3/3402-03, HAIC, R3/3910; NBS, R8/615ipl8; Lentz, R8/8087, 8084; Payne & Payne, R8/1446; Johnson, E., R8/4536-38; Qualitone, R8/2536; Alpiner, R8/5429.

512 ASHA, R10/1860; Wallace, TR 3474.

513 Rassi, TR 5732; P.O. Report, R9/Dlip108; Traynor, R8/6156-57; Consumers Union, R8/1050A; in re Mather Hearing Aid Distributors, Inc. (Rulon) R8/2296; RPAG, R8/2828; Corso, R10/195; Briskey, TR 7295.

514 Rassi, TR 5732; P.O. Report, R9/Dlip108; Payne & Payne, R8/1460; Traynor, R8/6157; in re Mather Hearing Aid Distributors, Inc. (Manning), R8/2124; Mabe, R8/7833-34; Hamburger, TR 5316; Elia, TR 7479-80; Dalton, TR 8749; Pasiewicz, TR 8916; Staab, TR 7042; Johnson, J., TR 2265; Brewer, TR 3963-64; Epstein, TR 4613-14; Minnesota Hearing Aid Industry, R8/1281; Alpiner, R8/5448.

515 Rassi, TR 5732-33; P.O. Report, R9/Dlip108; in re Mather Hearing Aid Distributors, Inc. (McNeill) R8/2243; Traynor, R8/6157; Payne & Payne, R8/1447-49; Consumers Union, R8/1050A; Pasiewicz, TR 8916; Staab, TR 7042; Alpiner, R8/5448.

controls to accommodate different listening situations.⁵¹⁶

Prior to purchase, clients need to be made aware of the limitations of an aid.⁵¹⁷ Even if the user has this advance information, adaptation requires time. The user should wear the aid in a quiet environment,⁵¹⁸ gradually increasing the length of the wearing time and the complexity of the listening situation.⁵¹⁹ The

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Rassi, TR 5732; P.O. Report, R9/Dlip108; Epstein, TR 4613-14; Market Facts, R8/639, 663, 662, 660; Elia, TR 7480; Burns, TR 10612; AARP, R10/3972; Schmitz, R8/803; in re Mather Hearing Aid Distributors, Inc. (Manning), R8/2140; Byrne, R8/691.

Alternatively, the purchaser of a replacement aid needs to learn to operate the new aid and evaluate its performance characteristics as compared with those of the old aid. The user of a binaural system must also have time to assess whether the benefits provided by the second aid justify the purchase of the additional device. Rassi, TR 5732.

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Loavenbruck, TR 1595; Burris, TR 2540; Lentz on J. Williams, R13/1723-24.

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Winston, R8/7409; ASHA, R10/2237; Barnow, TR 1685; Traynor, R8/6157; Fabray, R8/862.

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Winston, R8/7409; Johnson, E., R8/4529; ASHA, R10/2237; Traynor, R8/6157-62; Warren, R8/5307; Briskey, TR 7246-47; Kasten, R8/6977.

Technically, there are six states of listening situations through which the new user should pass. Winston, R8/7410. See Wiley, R8/7667.

First, the individual wears the aid in quiet familiar surroundings for short periods of time. Volume control should be practiced so that simple background noises are not magnified beyond tolerance. Winston, R8/7410, 7408; Wiley, R8/7665-66; NBS, R8/615ipl9.

Second, the user learns to control his voice to that he can become familiar with listening to voices, including his own, with a hearing aid. One way to practice listening to speech
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user and dispenser must work together to ease this adjustment process.⁵²⁰ Post-diagnostic services such as speech reading,⁵²¹

519 (FOOTNOTE CONTINUED)

is reading aloud. The user may practice reading aloud so as to become accustomed to hearing his own voice once again in normal tones, and to practice controlling the volume and tone mechanisms on his aid in preparation for conversations with other. Winston, R8/7409.

Third, the user adjusts to conversations with one individual at a time. Winston, R8/7410; Wiley, R8/7665-66. See NBS, R8/615ip20. He or she tries to speak in natural conversational tones and utilizes speech reading or lip reading techniques to aid in understanding the words that the hearing aid is amplifying. Winston, R8/7409; Owens, R8/6492; Rassi, R8/5369; Wiley, R8/7666-68; NBS, R8/615ip20; HEW, R8/867.

At the fourth stage, the user starts to listen to radio or television broadcasts. He or she adjusts the volume of the radio or television to a normal level, with the help of a person with normal hearing. Then, the hearing aid user experiments with distances to find the best distance from the set for most comfortable hearing. Winston, R8/7410, 7412.

In the fifth stage, the user should begin to experiment with group conversation. Winston, R8/7409, 7412; Wiley, R8/7667, 7669.

Finally, in the sixth stage, the user should attend public gatherings and practice concentrating on the speaker and blocking out background noise. Winston, R8/7410; Wiley, R8/7665. The choice of seating in a public gathering is important, and hearing aid users should consider the distortions that are introduced by walls and balconies in public places. Winston, R8/7410. With regular practice, the hearing aid user should learn to concentrate on the speaker. Winston, R8/7666.

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Blood and Danhauser, R13/134; Payne, James, HX39; Payne & Payne, R8/1446.

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as well as other counseling, hearing aid orientation and rehabilitation⁵²² may be valuable. While counseling may be valuable, however, it is rarely required as a condition for a trial period.⁵²³

Family counseling as to psychological factors is also important, for the families of very old and very young people with hearing impairments.⁵²⁴

521 (FOOTNOTE CONTINUED)

521 Traynor, R8/6157; Johnson, R8/4505-14, 4536-38; Winston, R8/7410; Dunlavy, TR 3399 (augment hearing with lip reading, still able to understand only 50% of spoken words in quiet); Wilson, TR 10025; McLaughlin R8/3455; Consumers Union, R8/1043; Alpiner, R8/5492.

522 Corso, TR 1196-99; ASHA, R10/1728; Consumers Union, R8/1043; Alpiner, R8/5429, 5448; Hull, R8/6219, 6130.

523 NHAS cites numerous witnesses who allegedly require counseling during the trial period. Final Brief, at 29, n. 23. However, only one dispenser actually required counseling. Leale, TR 11743. Some audiologists who did not dispense said they "require" or offer counselling, e.g., Fargo, R5/672. It is not clear that they would require clients who did not come in to keep the aid.

524 For the elderly persons, family counseling may enable the family to help the individual to adjust to the differences in sound that result from amplification. Hull, R8/6223.

In the case of hearing impaired children, parents require counseling so that they will have realistic expectations of the difference amplification will make in a child's ability to hear. Many parents of hearing impaired children anticipate a dramatic shift to normal speech and language when the aid is first fitted. They are not aware that in many instances a child will hear only some sounds, parts of words. Counseling is crucial in these families so that parents will not become disillusioned and can continue to help motivate their children to utilize hearing aids. Sanders, supra, SPXB/337; Naiman, R8/8580; Moneka, R10/5222. Dr. Naiman, an educator who works with the deaf, comments that she has seen many parents of hearing impaired

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There was substantial testimony as to how long the adjustment takes, even with counseling. While many witnesses said that it can take no more than a month,⁵²⁵ others said it could take several months⁵²⁶ or even years.⁵²⁷ Elderly persons are likely to take the longer time periods to adjust.⁵²⁸

Since repeat users generally have more realistic expectations,

524 (FOOTNOTE CONTINUED)

children who have become disillusioned and who refuse to purchase a hearing aid without the protection provided by a trial period.

525 Sullivan, R8/911; Capano, R8/6968; Epstein, TR 4613-14. Dr. Hull, an audiologist, said that 97% of the cases he has seen could decide whether to cancel within 30 days. Hull, R8/6137.

526 See Elia, TR 7479-80 (far longer than 30 days); Giglia, R10/2922 (six months).

527 Fabray, R8/862; NHAS, R3/3266; Tobin, TR 4107; Pasciewicz, TR 8917; Wilson, TR 10081.

On this point, James Payne, NHAS witness, states that in the first week and continuing up to one year or more in some cases, after purchase, the consumer must face the reality that a hearing aid can not restore normal hearing but can merely aid in amplifying residual hearing. For individuals first encountering this frustration, counseling is terribly important. Payne, James, HX39/7-8. However, a number of witnesses stated that if adjustment did not occur within a relatively short period of time that this is probably an indication of improper fit. Fennema, TR 1791; NBS, R8/615ipl8.

528 Hull and Traynor, R8/6137; Lentz, R8/8084; in re Mather Hearing Aid Distributors, Inc., (Manning) R8/2124-45, (Yantis) R8/2167, (Harvey) R8/2220-21; Minnesota Hearing Aid Industry, R8/1282; Schaie, R8/6239; Corso, R10/193-94 Alpiner, R8/5434; NHAS, 3510-12; Sandstrom, TR 3119; Shanta, TR 8862; McShane, TR 8112; Senate Hearings, 1968 (Wiedenmayer), R8/1166.

their adjustment period is usually easier. However, even for repeat users, counseling and rehabilitation work are required and an adjustment period should be expected.

Trial periods are commonly offered for an adjustment period of 30 days.⁵²⁹ The adjustment period provides an opportunity for users (and their families) to confront the limitations of hearing aids. Adequate counseling helps the client adjust to new and often abrasive sounds.⁵³⁰

However, the record notes a few instances where no services are available after the sales visit and fitting.⁵³¹ One witness said that door-to-door sales may be completed in one visit, which does not allow for medical referral, a trial period, or a hearing aid recheck.⁵³²

In summary, psychological adjustment to a hearing aid can be eased if individuals are aware of the stages of adjustment and understand the limitations of an aid before the buy, and are assisted in adjusting after the purchase.

C. The Need to Motivate a Consumer to Try Amplification

Motivation can be very important in helping an individual benefit

529 Rompala, R10/5278. See also Section VI.D.2.b.

530 Pollack, SPXB/323; Giglia, TR 2789-90; Brewer, TR 3962-63.

531 NCSC, R10/79; Resnick, R10/41.

532 Bess, R10/4871.

from amplification;⁵³³ as one doctor noted, motivation is the most important factor in determining whether a hearing aid user can benefit from an aid.⁵³⁴

However, as detailed in Section II, many consumers are reluctant to address their hearing loss and hesitant about searching for an aid. Some commentators state that many individuals simply are not motivated to improve their hearing capabilities unless a dispenser motivates them.

If adjustment does often require a fair degree of patience and effort, then there is little value in selling an aid to a consumer who does not want one. Regardless of how much the dispenser may feel that the consumer needs it, the aid will not be used if the consumer fails to adjust.

Dispensers can nevertheless play a significant role in motivating consumers.⁵³⁵ From the outset, for example, the consumer must be

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E.g., Alpiner, R8/5437; Sanders, R8/7594, 7593, 7598, SPXB/342; Harford, TR 53, 60-61, 126; Capano, R8/6971; in re Mather Hearing Aid Distributors, Inc. (Harvey) R8/2220, (Yantis) R8/2177; Stutz, TR 8939; Summers, TR 8085-86; Fortner, R13/1093; Vreeland, R10/3420, R13/2341; Wilson, TR 10022, 10096; Scott, TR 2351, 2340, Byrne & Johnson, R10/3212; Zumbrunnen, TR 11938, 11982, Corso, TR 1220, 1222; Teter, TR 10273; Miller, R8/5841, Rickenberg, TR 3549; Johnson, E.W., R8/4490; Barwell, TR 5190-5141; HAIC, R4/4013; Gardner, TR 10368; Dunlavy, TR 3408; Brewer, TR 3943; Costello, R8/4794; Hull, R8/6157; McShane, TR 8112; Martinucci, TR 8415; AARP, R10/1511; West, R10/7364; Griesel, R10/6897; Urban, TR 1837; AARP, R10/1551; Kasten, R8/6979.

534

Sanders, TR 3570.

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NHAS, R3/3213 n. 46 and accompanying text. Witnesses also
(CONTINUED)

given realistic expectations. Vincent Giglia attributed most hearing aid failures to the poor counseling provided at the first stage, the time of purchase.⁵³⁶

Many commentators observed problems where the dispenser motivates a consumer to try amplification. These result from the blending of counseling and selling functions,⁵³⁷ discussed in Section I.B.6. Some commentators also suggest that counseling performed by some dealers amounts to "sales reinforcement", which does not provide hearing impaired consumers with an understanding of their loss or help them in adapting to their loss.⁵³⁸ An article submitted by NHAS blurred the line between selling and counseling. The article noted that "much counseling is required...to overcome the natural

535 (FOOTNOTE CONTINUED)

contend that it takes a concentrated effort on the part of the dispensers to make customers use post sale service, even when they are included in the purchase price of an aid. Barnow, TR 1634. See Rassi and Harford, TR 5371.

536 Giglia, R10/2922. Most commentators agree that counseling can play a significant role in helping the consumer to form realistic expectations about how a hearing aid can improve his hearing and about the adjustments involved in successful hearing aid use. Brewer, TR 3963; Keyes, TR 10725; Dunlavy, TR 3443, 3446; Briskey, TR 7284-85; Heisse, TR 3314; Giglia, TR 2750; Madell, TR 5913; Traynor, R8/6799, 6806 (Statement of Dr. Raymond Hull); Willeford, R8/7981; Corso, TR 1260; Minnesota Department of Health, R13/2709; Richenberg, TR 3547; Harford, TR 61; Rose, TR 505; Masticola, TR 8651.

537 Ruben, R13/777; McPherson, R10/289.

538 Johnson, K., TR 4325-26; Marcus, TR 5482-83.

purchase resistance of the client."⁵³⁹ Sales manuals also indicate the emphasis placed by manufacturers on selling aids.⁵⁴⁰ Similar observations were also made about post-sale counseling, which witnesses said was often sales reinforcement rather than adjustment guidance.⁵⁴¹

In essence, this discussion highlights a conflict noted previously: some witnesses believed that, because of the hesitancy of persons to use a hearing aid, strenuous sales efforts to increase motivation are necessary. However, problems arise where the dispenser's attempt to provide motivation fails, and the consumer is unsuccessful with a purchase. The question then is whether the dispenser can always disown responsibility for consumer disappointment or disaffection with the aid, on the grounds that consumers do not make a sufficient effort to improve their aural skills once the sale has been completed. If the dispenser uses aggressive selling tactics to produce motivation, should the buyer bear the full brunt of inadequate motivation?

D. Effect of a Trial Period on Consumer Adjustment.

Most witnesses felt that a trial period will not harm the

539 NHAS, R3/3536.

540 See Section IV.B., supra.

541 Kasten, R8/4223; Stahl, TR 5559; Klein, TR 7581, K. Johnson, TR 4325-20; AARP, R10/949.

consumer's adjustment,⁵⁴² or would even aid motivation.⁵⁴³

Various commentators maintained that a trial period is important in the psychological adjustment for the hearing impaired individual.⁵⁴⁴ These commentators believe that without a trial period, many consumers will not even consider amplification as an option.⁵⁴⁵ Nor is it necessary, in many commentators' view, that the entire cost of the aid be "at risk" in order to motivate the buyer: the alternative cancellation fees previously proposed by staff, and detailed in Section IX.10., were deemed sufficient financial incentive (if such were needed) to motivate a full effort

542 Paschell, TR 871, Harford, TR 140; Jerger, R8/5339; Mastricola, TR 8669-70; Schein, TR 205, TR 224-5; Jungheim, TR 8899; Stein, TR 8987; Giglia, TR 2748, 2750; Kasten, R8/6990; Link, TR 1144.

543 Brewer, TR 3915; Shannon, TR 1876; Siefert, R10/0813; Paschell, TR 871, 872-73; Griesel, TR 9380; Jerger, R8/5339; Stein, TR 8987, 8974-77; Giglia, TR 2748-50; Kasten, R8/6990; ACO, TR 3697; Oberhand, TR 3037; Capano, R8/6966; Willeford, R8/7974; Conlin, TR 7774-76; Traynor, R8/6804; Corso, R8/8973; Urban, TR 1837-38.

544 Schein, R8/5824. Accord Mastricola, TR 8614; Costello, R8/4794.

545 On this point, Dr. Darrell Rose, audiologist, states that he advises his patients to rent aids prior to purchase because he believes that a trial period increases the likelihood of acceptance. Rose, TR 455, 506.

In this regard, Dr. Naiman notes that she has seen many parents who have been terribly disillusioned by experiences with amplification for their children and they have indicated that they would not purchase hearing aids in the future without the protection of a trial period. Naiman, R8/8580.

to adjust.⁵⁴⁶

On the other hand, numerous witnesses testified the rule would actually harm consumers because it would reduce the motivation to adjust to an aid. Some take the position that a right to cancel a hearing aid sale will "foster indecision" and "encourage consumers who could benefit from amplification to forego it."⁵⁴⁷ These commentators suggest that some hearing impaired individuals may have become accustomed to their disability, and the trial period would hamper emotional or financial commitment. Many witnesses indicated that the financial risk entailed by the full purchase price itself was needed to inspire motivation,⁵⁴⁸ and that a right to cancel would reduce this motivation.⁵⁴⁹

546 Bowen, HX-35; Schreiber, TR 4051; Kasten, R8/6989; Jerger, R8/5339; Noffsinger, R8/5405; Urban, R10/0075. One witness said that a \$30 fee could be substantial for an elderly person. Splansky, TR 9012.

547 NHAS, R3/ 3687; Harris, TR 10415; Payne, I., TR 3601.

548 Beltone, R8/1661, R3/3137; HEW Task Force Final Report, R8/3377; HAIC, R3/3733, 3738; Keyes, TR 10713; Splansky, TR 9017; Williams, R10/3441.

549 Fortner, TR 2856-57; Johnson, J. TR 2266, 2300-2301, R10/761-3, 2263; Scott, TR 2373, 2330, 2322; Martinucci, R10/5144, TR 8399, 8388, 8432; Anthony, TR 8476, 8451, R10/3450; Mynders, TR 11544, 11593; Winslow, R10/6939; Kennedy, TR 11171; Plotkin, TR 6005; Rose, R8/4185; Scheurer, TR 11432; Iliff, TR 3950, 3904; Staab, TR 7043; Carter, R., TR 3651; Krebs, TR 11830-31; Harris, TR 10446, 10415; Lentz/Williams, R13/1723; Keyes, TR 10693; ACO, TR 3697; HAIC, R3/3677, 3609, 3611; NHAS, R13/3626; Fechheimer, TR 7007; Burke, M., TR 6436; Curran, TR 10862; Williams, TR 3764; Gerstman, TR 2395; Campagna, TR 2602; Vreeland, TR 3835; Barnow, TR 1686, 1689; Sanders, TR 3569; Elia, TR 7479; Berkove, TR 11002; Resnick, TR 5396-97; Costello, R8/4794; Smith, A., TR 8154;

(CONTINUED)

In addition, some witnesses believe that trial periods insure more effective counseling.⁵⁵⁰ These commentators suggest that dealers as well as audiologists will provide more counseling with trial periods, to avoid cancelled sales.⁵⁵¹ They believe that a mandatory trial period will encourage dispensers to assist in adjustment.⁵⁵² NHAS disagrees. They said that dispensers will be forced to limit their risk of financial loss on patients they anticipate will cancel, and will therefore limit their services to these clients.⁵⁵³

Thus, there is record evidence that a trial period can facilitate realistic evaluation of an aid's performance. It enables clients to

549 (FOOTNOTE CONTINUED)

Kojis, TR 1996; Beltone, R3/3137; Briskey, TR 7248, 7250, Winslow, R10/6939-42; Pasiewicz, TR 8930; Byrne & Johnson, R6/3213; Williams, TR 3756, 3764.

550 E.g., Lentz, R10/6534.

551 Schein, R8/5824; Lentz, R10/6534-65.

552 Silverman, R8/7325; Schein, R8/5824.

553 NHAS, R3/3392. Furthermore, some commentators feel that a right to cancel will further discredit the use of amplification as a corrective measure and will be a deterrent to the aural rehabilitation of some consumers. E.g. Payne, I., TR 3601. The existence of FTC-mandated "right to cancel" would impair motivation, by reflecting adversely on the industry. Some witnesses believed that the mere existence of a regulation (as opposed to a voluntary right to cancel) would impair motivation because consumers would lose confidence in the seller and, by extension, in his product. Scheurer, TR 11423; Plotkin, TR 6005; Kennedy, TR 11171; Winslow, R10/6939; Anthony, TR 8451; Mynders, TR 1154; Martinucci, TR 8338; Johnson, J., TR 2263; Staab, TR 7043; Scott, TR 2373; Williams, TR 3764; HAIC, R3/3609.

evaluate whether the aid will be useful in the context of their living and working environment.⁵⁵⁴ The client's subjective experience with the aid, augmented by counseling and objective tests, is used to evaluate performance.⁵⁵⁵

554 Wilson, TR 10104; Beiter, TR 9058; Rassi, TR 5762-63; Harford, TR 61; Rose, R5/708, TR 466; Barwell, TR 5187; Syfert, R10/816; Franks, TR 9759; Palmquist, R8/3513; Sullivan, R8/911; Kasten, R5/1433.

555 Loavenbruck, TR 1554; Sullivan, R8/910-11; NHAS, TR 104-05; Hecker, R10/89; Franks, TR 9757-58; ASHA, R10/2548; Mynders, TR 11557; Wilson, TR 10095; Payne, John, TR 9256; Briskey, TR 7425-47; Sandstrom, TR 3119; Williams, TR 3767; Link, TR 1123; Glorig, R8/3498-99; McLaughlin, R8/3455; HEW Task Force Hearings (James Payne), R8/3479; Silverman, R8/7325; NHAS, R2/6, R3/3565-66; P.O. Report, R9/Dlip203-04; ASHA, R13/134; Tremmel, TR 8345 in re Mather Hearing Aid Distributors, Inc. (Causey), R8/2048; Rassi, R8/5352; Payne, James, HX 39; Consumers Union, R8/1050A, 1191D; NHAS Rebuttal, R13/2601 (Blood & Danhauer, "Are We Meeting the Needs of Our Hearing Aid Users", ASHA, June 1976 at 343).

IV. Sales Practices

The record contains substantial evidence concerning sales practices and claims in the hearing aid industry. Some abuses involving deliberate chicanery with test procedures have been detailed previously.⁵⁵⁶

This first section below focuses on representations made by dealers and manufacturers.⁵⁵⁷ The second section explores how hearing aid dealers locate potential customers (both for in-home and office sales), and discusses the incidence of high-pressure sales practices. The evidence is drawn primarily from advertisements and sales manuals. The advertisements were from the mid-1970's, and were directed to consumers and in some cases, dispensers.⁵⁵⁸ Record evidence proves that most of the manuals were in use at least as late as the mid-1970's.⁵⁵⁹ The final section details record evidence concerning home sales.

556 See Section I.B.5.b.

557 At the time the record was compiled, few audiologists sold hearing aids, and the record contains no advertisements by audiologists or evidence of their selling abuses.

558 The advertisements to dispensers include claims that manufacturers expect dispensers to believe and, presumably to pass on to consumers.

559 The key sales manuals were prepared by Beltone, Dahlberg, Maico, and Audivox. The Beltone manual, copyright in 1965, was still in use in 1975, according to testimony in Beltone Electronic, Docket 8928. See Staff Rebuttal, R13/1940. The Dahlberg pamphlets were in use in 1974, according to the firm's counsel, R13/1294-96. The salesman who submitted the Maico manual indicated that his employer had used it in 1972, Kuptz, R13/850. The Audivox manuals were returned pursuant to a 1971 subpoena. Staff Rebuttal, R13/1128.

Much as the problems created by these claims and practices reinforce (and are reinforced by) the risk of no significant benefit, so the specific claims and practices discussed below reinforce each other. Very broadly, they serve three interrelated purposes: to misrepresent the abilities of the aid, to add credibility to these claims by overstating the ability of the seller, and to pressure the consumer into a purchase before the deceptions are discovered.

The extent to which the various interact claims was suggested by a Beltone Manual in the record,⁵⁶⁰ which described techniques used by successful Beltone salespersons. Salespersons were advised to do all of the following:

- (a) To surprise the buyer at the door.⁵⁶¹
- (b) To assume they will be invited in, and generally establish themselves as the "person in charge."⁵⁶²
- (c) To qualify as experts.⁵⁶³
- (d) To represent that their testing "takes all of the guess work out of a hearing examination"⁵⁶⁴ and to promise an aid which is "individually fitted."⁵⁶⁵
- (e) To add urgency to their presentation by writing "NEEDS HELP NOW" on the audiogram and, after completing some tests, asking "Mr. Prospect, why haven't you done something about

560 See n. 559 supra.

561 See R8/1647.

562 R8/1647-48.

563 R8/1646.

564 R8/1649.

565 R8/1661.

your hearing before now?"⁵⁶⁶

- (f) To use the "case history," in part, to anticipate sales objections and discover a "dominant buying motive," and to include such emotionally loaded questions as "What do you miss most?"⁵⁶⁷
- (g) To pace the presentation quickly, and to complete the sale by steps so the consumer is never even asked if he will buy the aid; the manual notes that "the most common close" is to ask for a glass of water to make an earmold impression; if the physical action requested is taken "there is no need for specific words to indicate that the sale had been closed."⁵⁶⁸

Thus, a single presentation contained deceptions which promise certain performance, with assurance by a purported "expert" and with little time to reflect on the claims.

A. Representations Made In Connection With Hearing Aid Sales.

This section analyzes claims, made in advertising and at the point of sale, about the capabilities of hearing aids and the qualifications of hearing aid sellers.

1. Representations About Hearing Aids

As detailed in Section I.A., there are numerous problems with the sound produced by hearing aids. These include limited frequency range, inability to isolate sounds over a din of background noise, and inability to compensate precisely for individual hearing loss.

566 R8/1651, 1654.

567 R8/1653, 1657.

568 R8/1663.

The record contains numerous performance claims which ignore these problems,⁵⁶⁹ or deceptively represent that they have been resolved. Some advertisements⁵⁷⁰ and sales manuals⁵⁷¹ broadly claim certain success for everyone. The remainder of this Section discusses more narrow performance claims: that the sounds amplified by an aid will be "normal" or "natural;" that particular sounds will not be drowned out by background noise; that performance is improved

569 In staff's view, performance claims as a class are quite prevalent. Although each individual performance claims detailed below is obviously less prevalent, staff believes the relevant criteria for ascertaining the need for rulemaking is prevalence of performance claims as a class.

570 Oticon, R8/3105 (pamphlet stating "There is an Oticon Aid for every type of hearing loss"); R8/3101 (Oticon's know-how will "guarantee selection of a perfect hearing aid . . ."); Beltone, R8/2575 ("There is no medical or surgical help for nerve deafness, but there is help."); Beltone Hearing Aid Service, R8/2334 (San Diego Yellow Pages ad, "We Can Help You HEAR CLEARLY!").

571 The Dahlberg Manual advised that consumers be told:

. . .we are permitted to fit Dahlberg hearing aids only when there is no question that it will be fully beneficial to you. R8/7038.

Maico recommended this speech,

We recently developed a new piece of equipment to evaluate hearing and this will certainly answer if you can be helped by a hearing aid, and if so, how much help you can get. R13/873.

The Beltone Hearing Aid Service of South Gate, California, advises,

Explain computer, this is a computer, Mr. Prospect and as you know a computer is never wrong. This type of equipment has been used over half a million times to diagnose hearing problems and has yet to make an incorrect diagnosis. [sic] HX158/5.

or insured by "new" or "unique" developments; that aids can be tailor-made to an individual's needs; and that an aid has therapeutic value.

These claims were partially addressed by six 1976 consent orders which prohibited representations about the performance of an aid, that all people would benefit from aids or that all users would be able to consistently understand in noisy situations.⁵⁷² Five of the orders prohibited representations that all users could consistently understand speech in group situations.⁵⁷³ Two contained provisions dealing with an aid's ability to restore "normal" and "natural" hearing.⁵⁷⁴ Five addressed "unique" or "superior" claims made without a reasonable basis.⁵⁷⁵ One order dealt with claims that an aid could reverse or retard hearing loss.

a. Claims that Sounds Heard Through Aid Will be "Normal" or "Natural"

572 Sonotone Corporation, 88 FTC 368 (1976); Beltone Electronics Corporation, 88 FTC 336 (1976); Dahlberg Electronics, Inc., 88 FTC 319 (1976); Radioear Corporation, 88 FTC 308 (1976); Maico Hearing Instruments, Inc., 88 FTC 298 (1976); Qualitone, Inc., 88 FTC 287 (1976). These orders each provide that any provisions they contain which are not in a final trade regulation rule will be imperative.

573 See Maico, Radioear, Dahlberg, Beltone, and Sonotone, n. 572, supra. The Qualitone, Maico, Radioear, Beltone, and Dahlberg orders also prohibited claims that an aid will help all or most persons to discriminate sounds in situations where they hear but do not understand.

574 See Qualitone, Dahlberg, Beltone, n. 572, supra.

575 See Qualitone, Maico, Radioear, Beltone, Sonotone, n. 572, supra.

A hearing aid cannot produce "normal" or "natural" sound, or even a close approximation of "normal" or "natural" sound. It can at best improve the "effectiveness with which a person uses sound, sometimes to the extent of normalizing auditory competence."⁵⁷⁶

However, the record contains numerous advertisements which directly or impliedly represent that a hearing aid can deliver normal/natural hearing.

Many of these directly refer to the quality of sounds that the user will hear with an aid. For example, Dahlberg advertisements said that its aids are "natural sounding,"⁵⁷⁷ and that they enable users to "hear naturally."⁵⁷⁸ Other advertisements are less explicit. Some Dahlberg advertisements, for example, represented that aids gather sound in a "natural" manner.⁵⁷⁹ Staff believes that many of these less explicit advertisements, included in the citations of the paragraph which follows, also represent that hearing aids enable users to hear "normally" or "naturally."

These claims appeared in record advertisements to consumers for

576 Sanders, SPXB/351. See generally Section I.A.

577 R8/3658, R8/3659, R8/3661, R8/3662 ("natural sounding"); R13/1897 (brochure, "utilizes your own natural hearing potential to the fullest extent").

578 R8/3653 (mailout, "hearing as naturally as wearing a pair of regular glasses").

579 R13/1895 ("Nature provides the setting. Your own ear . . . your own hearing . . . Contour . . . helping nature help you hear better") [brochure]; R13/1863 ("'A miracle . . . worn in the ear' . . . picks up sound where nature intended.") [Oregon yellow pages 1975/76; identical to R13/1844].

Audibel (Metro Hearing Aid Center),⁵⁸⁰ Audiotone,⁵⁸¹
Audivox,⁵⁸² Beltone,⁵⁸³ Custom Aids of Houston,⁵⁸⁴ Hearing Aid
Company of Texas,⁵⁸⁵ Maico,⁵⁸⁶ Oticon,⁵⁸⁷ Qualitone,⁵⁸⁸
Radioear,⁵⁸⁹ Starkey Labs,

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- 580 R10/6415 ("Just slip it in your ear and hear again as nature intended.")
- 581 R8/2401-03 (brochure claims that the aid "picks up sounds clearly, naturally").
- 582 R8/2342 (Aids provide "natural level hearing.") [ad by Audivox dealer in the Riverside, CA 1973 yellow pages].
- 583 R8/3110 ("the unstrained hearing nature intended") [TV ad].
- 584 R8/2398 (ad stated that requests for research data be sent to "'Hearing Naturally'") [Houston Chronicle, September 8, 1974 at 22].
- 585 R13/1910 (Large print caption says "Normal Hearing" with smaller print immediately below "relationships re-established") [The Voice of Texas Senior Citizens Association, March, 1976].
- 586 R8/2430 ("...hear sounds at the ear, as nature intended").
- 587 R8/3102 (brochure claims "natural, almost hi-fi sound"). See also R8/2426 (aid gives a "natural tone quality"); R10/2367 [claims that with the Oticon's new aid, "Annoying background noise is dampened or eliminated (just as it is in normal hearing)", and the wearer discriminates sounds from the rear, side, or front, "(Just like a person with normal hearing can.)"] [parenthesis in original; National Hearing Aid Journal, November, 1972 at 39].
- 588 R8/2531 at 2533 ("many hear natural-like again"). See also R8/2537 ("Hearing is at ear level where nature intended") [booklet]; See also R8/2540 at 2540, 2544, 2545 ("more natural-like hearing") and 2541 ("hear . . . as nature intended") [brochure]; R10/2374 (Promotional literature sent to dealers to distribute which promises "more natural-seeming sound.")
- 589 Two packages of dealer ad mats end with the slogan,

(CONTINUED)

Inc.,⁵⁹⁰ Telex,⁵⁹¹ Texas Hearing Instruments Inc.,⁵⁹²
Vicon,⁵⁹³ Vanco,⁵⁹⁴ Widex,⁵⁹⁵ and Zenith.⁵⁹⁶ Hearola,⁵⁹⁷
Analog of MPLS,⁵⁹⁸ Thermo Electron

589 (FOOTNOTE CONTINUED)

- "Radioear for Better Hearing Naturally!" R8/2473-76 (8 ads), 2479-83 (10 ads), 2469-70 (7 ads). Two ads promise that "tones are so natural she hardly knows she's wearing it." R8/2483.
- 590 R10/2385 ("significant natural assistance to hearing").
- 591 R8/1406 ("ENJOY Music, THRILL To all the joys of sound, CLEARLY understand conversations").
- 592 R8/2359 at 2364 (brochure states that aids are "prescription 'Booster' made to fit entirely inside your own 'million dollar' ears to catch, separate, and clarify sounds . . . naturally!")
- 593 R8/2277 (identical to 2408), 2313 (Promising to help one hear "in the manner nature intended!") [card mailouts]; R8/2409 (identical ad to 2310, "enjoy the natural sounds of nature at play") [brochure]. See also R8/2311 (identical to 2410, "restore your hearing to a normal comfort level"), 2305 ("more NATURAL sound reception") (identical to 2315 and 2406) [brochures]; R8/2324 ("like nature designed your outer ear") [dealer ad mats].
- 594 R13/1916 (Aid "uses the outer ear to collect and repel sounds, as do normal hearing ears.") [brochure].
- 595 R8/3113 ("Hear once again all the lovely sounds of nature.")
- 596 R8/8276 ("as nature intended sound to be received"), 8277 ("provide tonal clarity and sound realism"), and 8281 (aid provides "a natural, elevated 'circle of sound'") [catalogue of aids offered by Zenith].
- 597 R10/2351 ("hear almost normally, even severe loss cases") [Hearing Aid Journal, March, 1973 at 23]; R10/2352 ("You can truthfully tell your customer . . . with Hearola you hear naturally") [Hearing Aid Journal, July, 1973 at 46].
- 598 R10/2313 ("new technique offers completely natural sound,
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Corp.,⁵⁹⁹ and Oticon,⁶⁰⁰ made the claims in publications for dispensers.

Other advertisements refer to "more" normal or natural sound,⁶⁰¹ although the record contains no evidence as to how consumers interpret these claims.

In addition, the Payne and Payne study indicated that 79 users (42.9% of his sample) said their aid sounded "natural," and James Payne concluded that they only meant "acceptable." However, there are severe methodological questions about Payne and Payne. These go in part to the issue of whether the questionnaire suggested the

598 (FOOTNOTE CONTINUED)

free from harsh and unpleasant loudness") [Hearing Aid Journal, September, 1973 at 36].

599 R10/2386 ("makes hearing a natural experience").

600 See n. 587, supra.

601 Beltone, R8/7657 (Sounds "closer to normal hearability"), R8/2546 ("The most normal hearing I have ever experienced with a hearing aid"); R8/2569, 2578 (aid makes "music, radio, and TV so much more full, realistic, and natural") [letters to consumers]; R13/1835, ("Higher fidelity hearing at natural ear level") [Yellow Page ad, 1976]; Capitol Hearing Aid Center, R8/7673 ("More Natural Hearing . . . More Natural Sound Reception") (ad for Starkey aid); R8/7674 ("more natural sound reproduction"); R8/7682 ("more Natural Hearing"); Custom Ear, R13/1458 ("more natural hearing . . . utilize the ear itself for more natural sound reception"); HX131 (using "outer ear natural shielding effects to ear oriented sounds," "results in more comfortable naturally balanced hearing"); Danavox, R10/2335 ("more natural sound impression"); R10/2331 ("as close to natural human hearing characteristics as possible"); Maico, R8/3696 ("full, clear, more 'normal' hearing") [brochure]; Norelco, R8/2431 ("better more natural hearing").

response they reported.⁶⁰²

b. Performance Claims Involving the Master Hearing Aid

The master hearing aid may also be used to make a performance claim. The master hearing aid is a testing device, whose performance differs substantially from the performance of an individually worn aid.⁶⁰³ The master hearing aid has better sound amplifying capabilities than commercially available hearing aids.⁶⁰⁴

According to the record, however, dispensers often compare the

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See Appendix B. Hal Kassarian testified that other phrases which Payne claims users consistently employed (e.g., "ear specialist" for doctors and "hearing aid specialist" for dealers) indicate that Payne must have rephrased questions and suggested answers. Here, the question Payne relied upon appeared on the questionnaire as follows: "What was your first reaction to your hearing aid? Natural _____ Too loud _____ Tinny/Raspy _____ Other _____." R8/1509. The fact that Payne's analysis classified all comments into one of these preconceived categories, and apparently reported all affirmative reactions as "natural," raises significant questions as to how many consumers actually used the term.

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See Section I.B.2.b.

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The earphone, microphone, receiver, and tubing length are all different. The frequency range of the master hearing aid is also greater, providing a richer and fuller quality of sound than is possible with a small amplifying device. Further, the master hearing aid has a much different signal-to-noise ratio than the small individual aid (in consequence, there is much less background noise with the master hearing aid). Hardick, R8/6848; Norris, TR 6839; Burris, TR 2558-59; Graham, S., R8/7540; Berger, SPXB/320; Delk, TR 10991-93.

master hearing aid's sound with the sound a hearing aid will produce.⁶⁰⁵ For example, the Beltone sales manual stated:

The last thing you did was fit your prospect with the binaural selectometer. [Master Hearing Aid]. He is now experiencing better hearing than he has known for perhaps many years. If he is like the vast majority of hard of hearing persons he is truly impressed by the dramatic improvement in his ability to hear. It's only logical that you ask him this question, "Wouldn't it be wonderful to hear this way again?"⁶⁰⁶

Four advertisements, by Audiotone,⁶⁰⁷ Maico,⁶⁰⁸ and Vicon⁶⁰⁹ made similar claims to consumers.

The above-quoted passage from the Beltone manual illustrates another critical fact, moreover. Customers may be sold hearing aids they never try on prior to purchase. They cannot personally evaluate

605 Brennan, TR 247; Leale, TR 11732-35; Luzi, TR 7726-27; ASHA, R10/1760-61; Stahl, TR 5539; ASHA, TR 1763; Norris, TR 6839; Leber, R10/6510; "...a gimmick to give an aura of the scientific method to hearing aid sales," Lentz, R13/1788-89; Berger, SPXB/320; Bartels, R10/5624; NCSC, R10/79; Norris, TR 6839.

606 Beltone, R8/1658; MPIRG, R8/1239 (re: Beltone Master Hearing Aid).

607 R8/2428, HX132 ("You will actually be hearing the world of sound through the auricon...skilled technician...select the components to give you hearing in the same quality as the auricon test.").

608 R8/2430 ("The complicated circuits of the 'Precision Ear' use actual hearing aid components to duplicate the performance of almost any hearing aid").

609 R8/2329 ("With the Comfort Level Equipment, you can hear with your new aid - before it is made for you").

while largely ignorant of the workings of amplification devices, constantly search for improved hearing aids and are particularly impressed by reports of advances or dramatic breakthroughs.⁶²⁰ An Audivox manual advised its dispensers that consumers

have been reflex-conditioned to consider the word "new" . . . as synonymous with "good." You can write "good" itself until you are blue in the face and no one will take notice, but "new" -- that's another matter.⁶²¹

They further advised,

[I]t does not matter that he may have bought his present aid 4 months ago. The nature of his impairment and its psychological implications will always keep him wondering whether he really hears as well as he might and should.⁶²²

In other words, recent buyers may purchase another aid if they can be convinced it has "new" features. The record contains a few instances where consumers were contacted about purchasing a new aid when the old one was less than a year old.⁶²³

Several witnesses testified about specific advertisements. Roger Kasten, Associate Professor of Audiology at Wayne State University, discussed an advertisement to dispensers which said

[B]ehind-the-ear power aid featuring an Electret front microphone and continuously adjustable

620 Stein, TR 8978; Harford, TR 59; Kasten, R5/1439, R10/68; Rose, TR 508; Lesko, TR 7227. See generally Section II, supra.

621 Audivox, Inc., R13/1135 "The Audivox Guide and Glossary," 63 (1962).

622 Id., R13/1153.

623 Masticola, TR 8617; Percy Letter, R8/274-77; Toaz, R13/1634-35; Dow, R13/1639.

output and tone controls.
These exclusive controls provide unique fitting flexibility . . . allowing continuous adjustment of both the output and frequency responses.⁶²⁴

Kasten described the microphones in this advertisement as "common for some time," the variable output as "a very common characteristic," and the continuous adjustment of output and frequency responses as available for years.⁶²⁵

Another advertisement directed to dispensers headlined "NOW from NORELCO . . . two more otodynamic innovations."⁶²⁶ Kasten described the advertised features as common items, widely available.⁶²⁷

William Lentz, commented that a consumer advertisement, for an "Exclusive new ostio-oscillation system," was referring to a common bone conduction aid.⁶²⁸

The record also contains uniqueness claims for directional

624 HX9 [Hearing Instruments, December, 1974 at 29 for Widex Hearing Aid Co., Inc.].

625 Kasten, TR 722.

626 HX-10 [Norelco ad, Hearing Aid Journal, November, 1975 at 53] (same as R8/4899).

627 Kasten, TR 723. In contrast, Kasten noted that a Unitron advertisement for "the first continuously adjustable directional microphone" accurately portrayed a real innovation. Id., TR 725. See HX15 (Unitron ad, Hearing Aid Journal, November, 1975 at 15).

628 Lentz, TR 11180-81, refers to R8/9087 [mailer from Pioneer].

microphones. This type of aid was available from Maico in 1971.⁶²⁹

Yet numerous advertisements to dispensers, which appeared in following years, made contradictory uniqueness claims for directional aids.⁶³⁰

Manufacturers have made other contradictory uniqueness claims. Two manufacturers falsely claimed uniqueness regarding the contour hearing aid,⁶³¹ which a third company, Vanco, said that they first introduced.⁶³² A Dahlberg advertisement described a "new" aid with "unique user-oriented features," including a "swing out battery compartment" and "variable venting."⁶³³ Yet these same features

629 Kojis, TR 1965.

630 See Maico Ads, R8/3040 (identical to R8/3694, ". . . a remarkable breakthrough . . . The new Direction Ear Mark 100 . . . Totally unique") [TV ad]; R8/277, Norelco letter from Hearing Unlimited Inc. (dealer) to consumer (May 9, 1974) ("Norelco has just developed a new 'Directional' type instrument"). See also a series of Hearing Aid Journal Ads: Radioear, R10/2376 (headlines "New from Radioear . . . Directional Hearing with AVC") [March, 1973]; Audivox, R10/2318 ("new concept in hearing"), [August, 1973].

631 Dahlberg Ads, R8/4932, 4846 (2 similar ads, "Dahlberg's Fabulous New customized ContourTM") [Hearing Aid Journal, November, 1975; Hearing Instruments, December, 1975]. See also 1975 Dahlberg Release, R13/1891 at 1892; Electone Ads: R13/2097 ("NOW . . . You can satisfy MANY of YOUR PROSPECTS") [Hearing Aid Journal, August, 1975], R8/4900 ("With Features in Front of All Competition . . . New Electone Feature") [Hearing Aid Journal, November, 1975].

632 Vanco Letter to hearing aid dealers, R13/1917.

633 R8/4932 [Hearing Aid Journal, November, 1975]. See also R8/4846 [Hearing Instruments, December, 1975], R13/1891 at 1892 (Deltaqram to Dahlberg sellers, September 12, 1975).

were advertised, in the same month, by two other companies.⁶³⁴

A Beltone consumer advertisement claimed uniqueness for a bone-conduction hearing aid. The advertisement stated that Beltone had

the hearing help that makes every other in-the-ear aid obsolete. This is the hearing aid you've been waiting for so different, it has four new patent pending features the first completely new hearing aid design in years.⁶³⁵

There was disagreement in the record, however, as to what is "new." John Kojis, President of Maico, testified that an aid might properly be considered new for the entire (17-year) life of a patent.⁶³⁶ In contrast, Laura Ann Wilber, M.D., testified that an aid is "new" only if it is very recently and not previously on the market.⁶³⁷ Darrell Teter stated that two years could be very old or very new depending on the specific developments.⁶³⁸ NHAS stated that a product could be "new" after more than a year.⁶³⁹ In Mather Hearing Aid Distributors, Inc., 78 FTC 709, 736 (1971) the Commission held that "newness" claims for hearing aids were only reasonable for one year.⁶⁴⁰

634 Electone, R8/4900; Texas Hearing Instruments, R8/4928.

635 R8/2547 (Beltone ad mat). Bone conduction aids are discussed in Section I.A.2.a.

636 Kojis, TR 2029.

637 Wilber, TR 1383.

638 Teter, TR 10303.

639 NHAS, R3/3305.

640 This decision was based on a "liberal interpretation" of

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e. Claims That an Aid is Fit in a Manner to Guarantee Performance

The record contains numerous advertisements promising performance from the way an aid is fit.

Some of these are "prescription" claims, and the record contains evidence that "prescription" claims represent both a general performance claim (i.e., ability to specify a product with a high predicability of success,⁶⁴¹ often equated with the rate of success for eyeglasses);⁶⁴² and a claim that an aid will restore normal hearing.⁶⁴³ Audiologists do refer to "prescriptions" where they select an aid for a dispenser to sell,⁶⁴⁴ and 1968 Trade Practice Rules allowed qualified prescription claims.⁶⁴⁵ But these claims

640 (FOOTNOTE CONTINUED)

Advisory Opinion Digest No. 120, released April 15, 1967, 71 FTC 729. The advisory opinion generally limited newness claims to a period of six months. The 1976 consent orders including hearing aid manufacturers, see n. 572, also limited "newness" claims to one year, with a proviso giving a limited examination for market tests.

641 Sypniewski, R10/114; Rose, R8/4186, TR 485; Winston, R8/7395; Jerger, R8/4579; Kenwood, TR 9335; McPherson, TR 5134, Harford, TR 104; Smith, B., TR 328; Rassi, TR 5782.

642 Hardick, R8/6855; Graham, S., R8/5280; Silverman, R8/7337.

643 Rose, R8/4186; ASHA, R10/1826; Jerger, R8/4579. See also Section IV.A.1.a, infra.

644 E.g., Payne and Payne, R8/1479. Some advertisements refer to these prescriptions. See Hearing Aid Center, R8/2337 ("We Fill Prescriptions For Hearing Aids.")

645 16 CFR § 214.7 (1968) allowed prescription claims for aid
(CONTINUED)

often go further, these witnesses indicated, and represent that an individually designed "prescription hearing aids" will be made. Indeed, NHAS agreed that "at present, a hearing aid cannot be prescribed as the term is normally defined."⁶⁴⁶

Vicon made a number of these "prescription" claims in advertisements.⁶⁴⁷ One advertisement also invited readers to send for a free booklet, entitled "'Personal as Your Portrait' explaining how I can hear better with a hearing instrument made especially for me!"⁶⁴⁸ Some Vicon advertisements drew out a comparison to eyeglasses to make a more explicit performance claim. One advertisement, for example, pictured a couple wearing glasses and said,

645 (FOOTNOTE CONTINUED)

made pursuant to a physician's direction, or to the direction of a qualified person other than a physician if it was disclosed that the "prescriber" was not a physician.

646 NHAS Final Comments at R9/1930. NHAS did suggest that this might change in the near future.

647 R8/2322 ("made to prescription"), R8/2406 (identical to 2305, 2315, "made to meet your individual prescription requirements"), 2407-08 (identical to 2276-77, "made-to-prescription"), 2410 (identical to 2311, "Prescription Hearing Instruments"), 2317 ("'built-to-prescription,'" "custom-made for you") [brochures]; R8/2321 ("made to your individual hearing requirements"), 2323 ("Made-to-Prescription"), 2325 ("prescription built," "prescribe a finely adjusted temple built just for you") [dealer newspaper mats]; R8/2327 at 2328-30 ("made-to-prescription") [booklet, "As personal as your portrait . . . Vicon"]; R8/8015 (Colorado Springs, 1975 Yellow Pages, "made-to-prescription").

648 R8/2317; "Personal as Your Portrait," R8/2327-31.

Hearing loss is usually no more serious than weakened eyesight. . . Test results of your hearing loss help our dealers give you an accurate . . . fitting for enjoyable listening under any circumstance.⁶⁴⁹

Other advertisers also made detailed prescription claims, or other claims which indicate that an aid would be personally fitted. These advertisers were: Custom Aids of Houston;⁶⁵⁰ Texas State Audio, Inc.;⁶⁵¹ Texas Hearing Instruments, Inc.;⁶⁵² Audivox;⁶⁵³

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- 649 R8/2309. See also R8/2327 at 2329 ("Eyeglass lenses are ground to prescription to fill the special seeing needs . . . A prescription for one person will not be the same as that required for another. This is true, too, of hearing.") [booklet]; R8/2311 (identical to 2410, "Impaired eyesight is corrected by prescription-made glasses. At VICON impaired hearing is corrected by prescription made hearing instruments." [mailer].
- 650 R8/2398 ("OTOMETRIC PRESCRIPTIONS* FILLED") [Houston Chronicle, September 8, 1974 at 22], 2393 (a "Custom-Prescription*" and the * refers to "Your Dr. or Qualified Otometric measurement") [Houston Chronicle, September 22, 1974].
- 651 R8/2400 ("100% PRESCRIPTION MADE*" with the * referring to "Electronic - color & size - Non Medical) [TV Times, October 4, 1970]. See also R13/738 (contract providing for optional "prescription hearing system").
- 652 R10/2390 [Hearing Aid Journal, November, 1974], R10/2391 (Hearing Aid Journal, March, 1973, advertisement for "the WORLD'S ONLY TOTALLY PRESCRIPTION (RX) INSTRUMENTS"); R8/2359 at 2364 (booklet by the Otological Rx Electronics Division states, "PERSONAL PRESCRIPTION 'BOOSTER' MADE TO FIT ENTIRELY INSIDE YOUR OWN 'MILLION DOLLAR' EARS.")
- 653 R8/3084 at 3085 ("bring it back into focus"), 3086 ("you must be custom - fitted," "Audivox Computer . . . scientifically computes the kind of hearing best suited for your exact need") [booklet]; R8/3091 (similar to 3096, 3100, dealer ad mat to send for free booklet "Hearing Out of

(CONTINUED)

Vanco;⁶⁵⁴ Montgomery Ward;⁶⁵⁵ Magnatone;⁶⁵⁶ Audiotone;⁶⁵⁷
Maico;⁶⁵⁸ and Sears.⁶⁵⁹

Several of these ads contained limited qualifying language. Typical was a Texas State Audio of Galveston advertisement, which headlined "PRESCRIPTION* HEARING SYSTEM." The asterisk referred to "YOUR DOCTOR'S OR ELECTRONIC ANALYSIS."⁶⁶⁰

Sales manuals suggest that these claims were made in oral presentations. Audivox told its salespersons to

insist that this particular prospect's loss is an individual hearing loss which can only be helped by one particular individual hearing aid. . . .

653 (FOOTNOTE CONTINUED)

Focus?"); R8/3098-99 ("for those whose hearing is OUT OF FOCUS") [mailer].

654 R13/1918 at 1919 (brochure to hearing aid dealers describing "Individual Prescription Circuits").

655 R8/3064 ("Custom-made IN-THE-EAR HEARING AID") [Sentinel Star, July 9, 1975].

656 R8/3689 ("Manufactured to customer's specifications") [The Arizona Republic, January 8, 1971]. See also 10/2142 (ad headlines "PRESCRIPTION HEARING AIDS") [Hearing Aid Journal, Nov., 1974].

657 R8/2401 at 2402, 2404 ("'Laboratory Custom-Fitted'") [brochure]. See also R8/2427 (similar to HX-132, ad headlines, "LABORATORY CERTIFIED CUSTOM FITTED" with a picture of an audiogram.

658 R13/1812 (Knoxville, Tenn. February, 1976 Yellow Pages); R8/3062 (Wichita Falls, Texas mailer) ("Precision fitted to the individual hearing impairment," stated in both ads).

659 R8/8017 (radio ad which ran in May, June, and July, 1972 in Knoxville (WBIR), Tenn., claims that aids are "scientifically fitted so that they're just right for you.")

660 R8/2344. See also n. 650, supra.

Never mind the fact that you may have a perfectly adequate aid in your kit. It is poor salesmanship to present this solution on the spot. Why? Because it is unsound psychologically. ⁶⁶¹

Beltone suggested that salespersons advised customers that its aids are not like "ordinary aids" -- because they give

loudness where you need it . . . for better understanding. A Beltone is a special kind of instrument . . . it is fitted to your own personal needs. ⁶⁶²

The manual further advised that a consumer who requests a trial period be told,

You almost have to have a free trial period for an unfitted aid, Mr. Prospect. Beltone is individually fitted and is not on trial -- but you are. ⁶⁶³

Both Dahlberg and Beltone Training manual instructed their salespeople to compare eyeglasses to hearing aids as one means of overcoming objections from prospective customers. ⁶⁶⁴

e. Miscellaneous Performance Claims

(1) Claims About CROS Aids

As noted previously, CROS aids position a microphone in the

661 Audivox, R13/1158-59.

662 R8/1655.

663 R8/1661.

664 R8/2423-C [identical to R13/1315; "I'm not blind either. . . but I wear glasses to help correct my vision just as you should wear an aid to correct your hearing."]. R8/1664 (advises dealers to compare shopping for an aid with trying different eyeglass prescriptions after a doctor's fitting).

user's ear with the more serious hearing impairment. The microphone collects sound, which is then transmitted to the better ear. The ear with the microphone does little to focus sound or otherwise aid hearing.

The record contains numerous advertisements which made representations that CROS aids actually use the deaf ear. Texas State Audio, Inc. for example, ran three advertisements which made these claims.⁶⁶⁵ One of these advertisements stated "Man Hears With* 100% Nerve Deaf Ear."⁶⁶⁶ A footnote explained that the claim referred only to the outer part of the deaf ear, the pinna. The text stated in part that:

This new device allows a person to hear equally "with" but not through BOTH EARS, although one ear is weaker or completely 100% DEAF.

Similar ads appeared from Custom Aids of Houston;⁶⁶⁷ Hearing Aid

665 R8/3073, 2412 (The Houston Post, May 5, 1971), 2414 (The Houston Post, June 16, 1974).

666 R8/2412. The State Attorney General obtained an assurance of voluntary compliance in which the company agreed to stop these claims. R13/641 [In re Bigham, No. 73-7348 (Dist. Ct. Tex. 1973)]. See also R13/609, unnamed dealer in Lubbock, Texas (ad headlines, "100% Nerve Deaf Ear Gathers Sound for Hearing").

667 R8/2394, R8/2397. These identical ads ran in the Houston Chronicle on September 24, 27 & 29, 1974, and began with a headline banner, "100% Deaf Ear* Aids Hearings." In a footnote, the starred item is explained: "External ear (Pinna) only." The relevant text states, "Even though one ear may be weak or even 100% DEAF internally, the outer ear may still be used to gather and CLARIFY speech." See also R8/2398 [which contains a reference to hearing "'WITH' BUT NOT THROUGH A USELESS OR 100% DEAF EAR (This Refers To Use of External, Ear, Pinna Only)"] Houston Chronicle, September 8, 1974 at 22.

Testing Company;⁶⁶⁸ North Texas Audio;⁶⁶⁹ Prescription Hearing Aid Services, Inc.;⁶⁷⁰ and Texas State Audio of Dallas.⁶⁷¹

A Radioear brochure incorrectly interpreted how a CROS hearing aid functions.⁶⁷² On the other hand, a Sonotone mailer to consumers explained correctly the functions of a CROS hearing aid.⁶⁷³

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- 668 Ten (10) of their ads were virtually identical; they described a field-test by a "90% Deaf Girl" and encouraged test, noting "Persons having ONE ear weaker or even 100% deaf, along with those who 'hear" even without an aid, but don't always 'understand' are of special interest." R8/4749-55, 4760, 5224, 5225. Ads ran in the Houston Chronicle and The Houston Post between October 5 and December 21, 1975. Four (4) similar ads also appeared on the record. R8/4756 (Houston Chronicle, June 22, 1975), 4758 (Houston Chronicle, December 7, 1975), 5226 (same as R13/755 Houston Chronicle, December 30, 1975), R13/752 (mailer; reprinted from The Houston Post, October 7, 1975).
- 669 R13/605, 607. (Two identical ads, run on different days, which headlined, "Man Hears 'With' 100% Deaf Ear;" text states in part, that the CROS aid "allows hearing with, but not through, BOTH EARS, even if one ear is weak or COMPLETELY 100% DEAF!") [emphasis in original] See also R13/730.
- 670 R8/2411. (Ad headlines "100% Deaf Ear used in Unique Hearing System," and text states that aid "allows a person to hear equally with, BUT NOT THROUGH BOTH EARS.") [Seattle Post Intelligencer, July 8, 1974]
- 671 R8/3073 (format similar to newspaper article, headlined "Loss of Hearing Sex Problem," then stated in the text that the aid "allows a person to hear equally from both sides even if one ear is COMPLETELY DEAF!") [Dallas Times Herald, March 19, 1972 at a-25.]
- 672 R8/2517 at 2518 (brochure said that "Sounds that you can hear naturally . . . pass into your open ear canal just as though you weren't wearing a hearing aid.
- 673 R8/3079 ("sound waves picked up on poor hearing side" are then "transferred into ear on better hearing side").

(2) Telephone Options

A telephone option on a hearing aid is designed to enable users to hear over the telephone because the background noise around them is not amplified.⁶⁷⁴ In 1973 approximately 50% of the aids in this country had a telephone option.⁶⁷⁵ The telephone option feature is not compatible with all telephones.⁶⁷⁶ Some companies advertised the phone option to consumers without disclosing their incompatibility with all phones: Beltone;⁶⁷⁷ Radioear;⁶⁷⁸ Zenith;⁶⁷⁹ Vicon;⁶⁸⁰

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- 674 Lee & Anderson, SPXC/309. The option involves a special circuit consisting of a magnetic induction pick-up coil mounted inside the hearing aid case. When the switch on the aid is turned to telephone, the inductive coil takes the place of the aid's microphone and picks up the magnetic field generated by the telephone's earpiece. Pollack, SPXB/31.
- 675 Knauer, R8/1189K.
- 676 In the late 1960's new telephones began to be introduced that allowed for little electromagnetic leakage from their earpieces; the telephone option could not work on these new telephones. A growing number of telephones are compatible with the option, however.
- 677 R8/2546 [dealer mat], 2559 [letter to consumers]; R8/2560, 2563, [letters to consumers]; R8/2562 [letter to consumers]; R8/2580-81 (letter to consumers offered booklet "Hear Better on the Telephone"); HX-62I, [mailer].
- 678 R8/2502 at 2503, 2504; R8/2482 (Two newspaper ad mats); R8/2517 at 2518, 2489 at 2490.
- 679 R8/8276 at 8279 and 8281.
- 680 R8/2276 at 2277 (identical to R8/2407 at 2408) and R8/2308 at 2309, 2325 [dealer mat]; R8/2319 [mailer]; R8/2321 [dealer newspaper mat].

Oticon⁶⁸¹ Maico;⁶⁸² Acousticon;⁶⁸³ Texas Hearing Instruments Corp.;⁶⁸⁴ Norelco;⁶⁸⁵ Unitron;⁶⁸⁶ Acoustic Earphone Corp.;⁶⁸⁷ Hearing Aid Testing Co.;⁶⁸⁸ and Audiotone⁶⁸⁹ contained these claims without disclosing the limits of the telephone option.

(3) Bone Conduction Aids

Bone conduction aids produce inferior sound, and are only useful for a small minority of the hearing impaired population who cannot benefit from other aids.⁶⁹⁰ However, because they operate with nothing in the ear, they may seem desirable to consumers who want to hide their impairment. Numerous advertisements in the record described this desirable feature without discussing the limited usefulness of bone conduction.

For example, a Dahlberg advertisement said:

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- 681 R8/3105 at 3106 [brochure].
- 682 R8/2430 at p. 1-3 [booklet]; HX92 [mailer].
- 683 R8/2416 at 2417 and 2418 [brochure].
- 684 R8/2411 [Seattle Post Intelligencer, July 8, 1974 at A-14].
- 685 R8/2429B&A (brochure).
- 686 R13/1925A (New Hope For Hearing Inc. ad featuring a Unitron aid).
- 687 R13/1913 (1976 Richmond, Virginia mailer).
- 688 R8/5226 [Houston Chronicle, December 30, 1975].
- 689 HX132 [brochure].
- 690 See Section I.A.2.a., supra.

Thanks to the principle of bone conduction, and the precision workmanship of the new Touche hearing aid you may enjoy the thrill of good hearing again. One unit serves as glasses and hearing aid. No cords. No tubes. No ear-mold. Nothing to wear in your ear.

Act now! See how Touche can help you. For more information about this remarkable instrument from Dahlberg Electronics, fill in the coupon and mail it today.

THESE ASTONISHING GLASSES MAY HELP YOU HEAR WITH NOTHING IN YOUR EAR.⁶⁹¹

Otarion similarly advertised "YOU HEAR with your INNER EAR," and described its new "tympano technique" as a "patented bone conduction method;" "so different you must try it to discover if this new Listener is for you."⁶⁹² An almost identical advertisement for Pioneer made these same claims; although the Pioneer advertisement spoke of an "osteo-oscillation system" instead of a Tympano technique.⁶⁹³ Riverside Hearing Aid Center⁶⁹⁴ and Sonar⁶⁹⁵

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- 691 R8/2370, see also Dahlberg, R8/3975; R8/3980. See R8/3650 (qualifying claims similar to above by concluding, "It wasn't designed to solve everyone's hearing problem, but it may well help yours."), R8/3552.
- 692 R8/3049. The ad also asserted that this bone conduction aid will provide a "superior extended range." However, bone conduction in fact has a particularly limited range.
- 693 R8/8976. This ad was forwarded by William Lentz, with a cover memo indicating that it had been distributed to box holders in Western Colorado. R8/3975. Another Otariion ad promises "Your Hearing May Be Improved With Nothing in Either Ear!" R8/3048.
- 694 R8/2342 (Yellow page ad describing an Otariion aid: "HEAR CLEARLY AGAIN WITH NOTHING IN EITHER EAR").
- 695 HX88, HX137 (company owned by J. Kenwood).

advertisements made comparable claims.

f. Therapeutic Claims for Hearing Aids.

Representations that hearing aids have therapeutic qualities take many forms, ranging from the claim that a hearing aid can halt, retard, or reverse the progress of a hearing loss, to an extreme claim that an aid can restore normal hearing even to one who is 100% deaf.⁶⁹⁶ Dispensers often claim that an aid prevents deafness by exercising or stimulating the nerves used in hearing.

Some of these claims contain an element of truth. One problem new users may experience is that they are unaccustomed to sound. Due to lack of practice they may have difficulty discriminating between similar sounds.⁶⁹⁷ Long delays in getting an aid may exacerbate this one problem. Many of the representations below went beyond this limited claim, however. They promised, sometimes explicitly, a halt

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There is a distinction between these therapeutic claims and claims that aids will improve quality to the point where sounds seem normal or natural. The latter category, summarized in Section IV.A.1.a., supra, covers claims that hearing aids will, in effect, work with a person's residual hearing so that its quality will improve to the point where the aided hearing is of a quality virtually as good as normal or natural hearing. On the other hand, the therapeutic claims summarized in this section promise more than "doing the best" with an impaired person's residual hearing. Instead, as indicated, these claims represent that hearing aids can alter, ameliorate and thereby actually affect the level of impairment from which a person suffers. Sometimes the distinction between the two categories of claims--normal/natural quality and therapeutic benefit--is blurred due to the execution of particular advertisements.

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See Tobin, TR 4108-12.

to physical deterioration, and suggested that even slight delay could be costly. The time pressure, in fact, is the prime reason those claims can serve as a basis for a trial period. A consumer would not discover, from wearing an aid for 30 days, that the therapeutic claim is false. However, the consumer would have a chance to use the aid, absent the sales pressure, further detailed below, which includes "act now" claims.

A booklet published by Monroe Hearing Aid Company, for example, said,

The stimulation given to the vital hearing nerve tends to strengthen it. . . . Moreover both hearing organs may be re-vitalized because the hearing nerve in each ear is put back to work. This stimulation may also retard the progressive tendencies of deafness.⁶⁹⁸

North Texas Audio made the following claims:

most hearing losses are permanent and will only get worse. A properly fitted hearing aid will stimulate your defective hearing and in most cases will keep it at least at the level at which it is. . .let us analyze your hearing to see whether or not you've waited too long.⁶⁹⁹

There are examples of oral presentations an aid would prevent the spread of nerve deterioration, which purportedly could go from a bad ear to a good ear⁷⁰⁰ or even cause brain damage.⁷⁰¹ Others

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- 698 HX28/2, DHEW Memorandum from Michael S. Gluck, August 27, 1974.
- 699 R13/608 (brochure).
- 700 R8/6896.
- 701 Hull, R8/6136.

orally claimed that aids will stimulate nerve endings and keep damaged nerves alive.⁷⁰²

Beltone, for example, sent out numerous letters to consumers. One said that, even though there is no medical or surgical help, Beltone aids can help nerve deafness. The letter urged readers to write for a booklet which would inform them "why immediate action is important" and "why delay can be costly." The letter further stated, "When you've read about nerve deafness. . .you'll know THE LONGER YOU DELAY, THE HARDER IT IS TO HELP NERVE DEAFNESS."⁷⁰³ Other letters made an identical claim: "every day you neglect a hearing problem is another day the problem could grow progressively worse."⁷⁰⁴ Similar claims were made in other Beltone letters and other advertisements.⁷⁰⁵

Beltone manuals frequently encouraged its dispensers to tout the therapeutic qualities of Beltone aids. For example, its manual instructed the dispenser to advise prospects that, "It is important that you not delay any longer. You simply cannot afford to lose any

702 R8/1234 (Beltone dealer as reported by MPIRG subjects); Lentz, R8/8163, 7997; Gunterman, TR 9656-57.

703 R8/2575-76.

704 R8/2571 at 2573, R8/2555 at 2556, and R8/2557 at 2558.

705 R10/2520-21 (letter to consumers advertises a book which covers "How to save the hearing you do have" and "prevention of hearing loss - especially further hearing loss"); R8/6608 (2 identical ads claimed "Early detection is important"); R8/6689 (Beltone Aid will "hold better hearing"); R8/2555-56 and R8/2557-58 ("when they put it off, their hearing gets progressively worse!").

more understanding." This manual provided other phrases which suggested that immediate action can produce therapeutic benefit i.e., "some people put off action so long that it is too late to help them." The manual also suggested phrases which imply a hearing aid has the capability of restoring lost hearing, i.e., "a cold is easier to cure than pneumonia."⁷⁰⁶

Beltone also advised dispensers to inform consumers that many persons cannot be helped by any aid, because they have let their hearing deteriorate irrevocably,⁷⁰⁷ and to point to the audiogram while citing a "need to do something about your hearing right away, because your ability to understand conversation is being destroyed."⁷⁰⁸

A Dahlberg Training Manual similarly instructed dispensers to explain to customers that "the longer you wait with a hearing loss, the worse it becomes AND THE HARDER IT WILL BE FOR YOU TO GET THE KIND OF HELP YOU WILL NEED."⁷⁰⁹ A Maico Manual offered the dispenser the following ambiguous advice:

706 R8/718 [Hearings on Prices of Hearing Aids Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 2d Sess. 415 (1962), cited by S. Rep. No. 2216, 87th Cong., 2d Sess. 33 (1962)]; R8/1234 [MPIRG Report on Hearing Aids and Hearing Aid Industry in Minnesota (November 13, 1972).]

707 HX158/2 ("many . . . let their hearing go to such a degree that there is nothing that can be done to help them"); see also R8/718.

708 Beltone, R8/1655.

709 R8/2423-C (same as R13/1315).

A word of warning, never say or imply that hard of hearing persons' loss will become worse. You do not know this for sure, and under no circumstances are you qualified to say this. However, to ask if the THOUGHT of losing more of their hearing bothers them is certainly important to you.⁷¹⁰

The record contains evidence of numerous instances in which dispensers were said to have told consumers that an aid would prevent deafness or worsening of hearing.⁷¹¹ Some witnesses who had contact with the hearing impaired reported that they frequently encountered such claims.⁷¹² Similarly, investigators studying the industry reported numerous examples of these claims.⁷¹³

710 R13/895.

711 R10/6466-67 (Belton dealer); R8/6443 (user was told she would become totally deaf within a short time if she did not buy her aid immediately); Estes, R8/6496 (Cal. state investigator reporting); ISPIRG, R8/1360; R10/4681, R10/4730; Hamburger, TR 5355-56; Brennan, TR 245; R10/5409; R10/5802; R8/5848; R10/4688; R8/6465; R13/1653; Stroup, TR 953; R10/4725; R8/5275; R8/2941; R8/8538-39 (customer was told he had waited too long before seeking help for left ear, but that right ear still had hope); R8/4958; Gunterman, TR 9656-58.

712 R8/6443 (audiologist reporting on experience of many of his patients); R10/2128; Stahl, TR 5535; Kelly, TR 7524 (Minn. Assistant Attorney General); Graham, S., R8/7461; Winston, R8/7386; HX212(5) (legal aid lawyer); HX212(12) (legal aid lawyer representing eight clients to whom these claims had been made); Morgan, TR 9559 (audiologist reporting experience of a number of patients); Resnick, TR 5381; R10/4898 (reports from members of ISHA); Leber, R10/6511; R10/5554 (Illinois Department of Public Health spokesman reporting that many aids were sold through these claims; Whitman, TR 8562-63; Morgan, TR 9512 (describing document of selling techniques); R10/3138 (letter from audiologist).

713 RPAG Study, R8/1188-LLLL [Hearing Aids and the Older American: Hearings Before the Subcomm. on Consumer Interests of the Elderly of the Special Senate Comm. on

(CONTINUED)

713 (FOOTNOTE CONTINUED)

Aging, 93d Cong., 1st Sess. 86 (1973)]; Kline, TR 7580 (MPIRG researcher reporting 3 instances); NYPIRG, R8/1335K (in survey 7 of 14 dealers contacted claimed aids would prevent further deterioration); RPAG, R8/2608 (nine instances in which six dealers cited the importance of nerve stimulation to prevent deterioration); ISPIRG, R8/1360 (3 instances).

2. Representations About Sellers

The record contains two categories of misrepresentations about sellers. Some are misrepresentations designed to hide their primary interest in selling. Others involve false claims of professional expertise.

a. Interest in Selling

(1) Oral Claims

The record contains evidence of numerous ways that some salespersons used to hide their interest in selling during oral communications. Sonotone, for example, set out the following script when using telephone calls to find leads.

"We are making a study of the hard-of-hearing people in your neighborhood. Does any one in your family (or office) have a hearing problem?"

. . .[A]sk for the names of the persons who are hard of hearing. If you are asked why you want the names, you can explain:

"We would like to sent them some educational literature. . ."

In response to the request for your name and company, explain that the literature is a service of the Educational Department of Sonotone Corporation and that your office is one of the more than 350 Sonotone offices throughout the U.S.

End the conversation as cordially as possible. However, you may find the person you are talking to wants more information and may even be interested in a hearing test. Make an appointment or arrangements for a test. Try to avoid a discussion of the test, the possible results or Sonotone hearing aids. If you are asked what Sonotone does after the test, you can say:

"If the tests show that hearing help is not needed, that is exactly what we'll tell you. Actually authorities report that three out of five persons with hearing losses do not need hearing aids. If hearing

help is needed, then we can show you how Sonotone's exclusive Personal Hearing Security Program can provide that help." ⁷¹⁴ (emphasis added)

Unless potential buyers specifically requested information about the company, they would thus only know that they have a test scheduled by someone who was making "a study of the hard-of-hearing."

Dahlberg used a similar script in telephone canvassing:

HELLO MR. OR MRS. PROSPECT. HOW ARE YOU THIS MORNING? THIS IS MRS. _____. WE ARE TAKING A HEALTH SURVEY OF CHARLESTON COUNTY TO DETERMINE THE NUMBER OF PEOPLE WHO ARE HARD OF HEARING. ARE YOU OR ANY MEMBER OF YOUR FAMILY HARD OF HEARING?

- IF NO ASK REFERRAL QUESTION, THEN, THANK YOU VERY MUCH. HANG UP.
- IF YES
1. HOW LONG HAVE YOU HAD HEARING PROBLEMS?
 2. ONE OR BOTH EARS?
 3. DO YOU HAVE TROUBLE HEARING IN CHURCH, THE TV?
 4. HAVE YOU EVER BEEN TESTED?
 5. MR. OR MRS. PROSPECT, WOULD YOU BE INTERESTED IN A FREE HEARING TEST? IN YOUR HOME UNDER NO OBLIGATION? ⁷¹⁵ (emphasis in original)

Dahlberg also advised its salespersons to disclaim an interest in selling when they came to the consumer's door. When a consumer objected, "wrote right on the card no salesman," the salesperson was

714 Sonotone, R8/1634-35.

715 Dahlberg, R8/7072. See also Dahlberg, R8/7093, 7097 (another telephone survey).

to reply, "I noted that, Mrs. Andrews, that is why I came myself."⁷¹⁶

Maico similarly advised salespersons: "Do not identify yourself or the company,"⁷¹⁷ [original emphasis]. The Maico sales manual also suggested the following falsehood when consumers objected that they are happy with their present aid

Say, ... I wonder if you would help me! [sic] I have a new piece of test equipment, the PrecisionEar, on which I would like your opinion and to have you compare it with the equipment you were tested⁷¹⁸ on when fitted with your hearing instrument.

Thus, the seller denied that his goal in doing the test is to sell an aid.

The record also contains evidence of the practice of a number of Oregon door-to-door sellers who represented that they were employed by the Oregon State Board of Health. As "proof," they showed certificates of registration with the board--registration required for all sellers.⁷¹⁹

716 Dahlberg, R13/1324.

717 Maico, R13/878. The manual explained "you are not important until you help the Prospect hear better. And, if the Prospect knows who you are and how to get a hold of you, he can always call and cancel [a scheduled] appointment." (original emphasis)

718 Maico, R13/871.

719 Anderson, TR 11784-85.

(2) Written Claims

(a) Test Programs.

One type of advertisement, positioning the dealer as someone whose primary interest is other than in selling, sought "volunteers" or test subjects. Bob's Hearing Service, for example, advertised

"PUBLIC NOTICE"
HARD OF HEARING

GOLDENTONE DIVISION, RACO ELECTRONICS CO-OPERATION [sic] of Minneapolis has chosen the Colorado Springs area to conduct field testing of a hearing aid featuring a custom circuit built to the patients individual hearing loss that is worn entirely inside the ear cavity with no attachments.

We wish to fit these hearing aids on a variety of age/occupation groups, both rural and urban. . . .

Persons electing to participate will be required to have their hearing tested, necessary ear impressions taken and report their wearing experience over a two week period and may purchase the hearing aids at a reduced price at the end of that time.⁷²⁰

Another company, the "Hearing Aid Testing Company," repeatedly solicited "test subjects," rather than "customers," for CROS aids.⁷²¹

720 R8/2015 (Colorado Springs newspaper advertisement, April 7, 1975) [emphasis added]. See also Custom Aids of Houston Ad, R8/2396 [Houston Chronicle, November 3, 1974 at 2].

721 R8/4749-56 (Houston Chronicle: June 22, October 5, November 2 & 30, 1975; Houston Post: October 15 & 18, 1975); R8/4758 (Houston Chronicle, December 7, 1975), 4760 (Houston Post, November 18, 1975), 5224-26 (Houston Chronicle: December 13 & 30, 1975; Houston Post, December 21, 1975); R13/752 (mailer to consumers with ad reprinted from The Houston Post, October 7, 1975); and R13/755 (The Houston Post, December 30, 1975).

(b) "Free Tests" & "Public Service" Announcements.

The record contains numerous advertisements promising free testing. These advertisements are designed to initiate customer contacts. They obscure the hierarchy of functions outlined in an Audivox manual: "you must be a salesman first, a psychologist second, and an audiologist third, in that order and no other."⁷²²

Moreover, they often use a format designed to particularly obscure the critical fact that the tests are offered by a hearing aid seller. Some advertisements were presented in the form of public service announcements, often identified as advertisements only in small type.⁷²³ The text of many advertisements obscured the sales motive of the testing. An advertisement for Beltone Hearing Aid Service, for example, was captioned, "Hearing Tests Set for Senior Citizens."⁷²⁴ Similar advertisements appeared for Mid-Atlantic Earphone Company,⁷²⁵ New Life Hearing Aid

722 Audivox, R13/1219.

723 R8/5664; R8/6506, R10/3094 (2 identical ads in the Lexington Herald, September 16 & 17, 1975); HX107 (Chicago Sun-Times, June 16, 1976); R8/2396 (Houston Chronicle, November 3, 1974) and 2399 (Houston Chronicle, August 31, 1974).

724 R10/4914 and R8/6608. See also R8/5664 (Beltone Office ad in Madison, Wisconsin newspaper, Jan. 16, 1973); R8/5665 (Beltone Ad, Wisconsin Rapids, Wisconsin); R8/5660 (Beltone Ad, Stevens Point, Wisconsin).

725 R8/7546 (same as R10/525, 2523 The Washington Post, February 22, 1976). See also R13/1925 (The Washington Star, June 27, 1976).

Center,⁷²⁶ and Artco Hearing Aid Center.⁷²⁷

Other advertisements offering a free test appeared for Beltone,⁷²⁸ Vicon,⁷²⁹ and other companies.⁷³⁰ Although there is of course no way of knowing how many of these offers involved a sales pitch, the record contains letters, statements, and affidavits of consumers who stated they responded to an offer of a free test and were given a sales pitch.⁷³¹

726 R10/2138 (newspaper ad, Glen Burnie, Md., March 16, 1976).

727 R8/7661.

728 Yellow page advertisements: R8/2334, 2336, 2338, 2340, 2341, 2344, and 2388 (same as 2390); Newspaper advertisements: R8/5664-67, 6608, 7686; R10/4911, 4910, 4917, and R13/1483, 1487 (identical ads except the date; given to Iowa Attorney General by an audiologist as samples of misleading ads).

729 R8/2323, 2425, 2325, 2317 and 2319.

730 Oticon, R8/4245; Audiotone, R8/2404; Zenith, R8/7691 (television advertisement); R8/2315 (identical to 2406), 2317, 2319, 2321, 2322, 2332-42, 2345, 2365 at 2366 & 2367, 2372 at 2374, 2376 at 2377, 2379 at 2380, 2382 at 2383, 2389, 2399, 2404, 2420-C, 2424 at 2425, 2427, 2429-D, 2431 2489 at 2492, 2497, 2498, 2499, 2548, 3050, 3051, 3059, 3070, 3077, 3110-12, 3689, 6506, 7453, 7546, 7635, 7653, 7659, 7660-61, 7672, 7680, 7681, 7686, 7691, 7937, 8017, 8106; R10/100, 523 at 524, 2138, 2459, 2464, 2480, 2523, 2684, 2690 (identical to 2695), 2691, 2699, 2703, 2705, 3094, 4686, 4705, 4912-13, 4916, 5284, 6177; R13/758, 1484, 1569, 1807, 1809, 1812, 1813, 1817, 1823, 1922, 1925A, 1828-31, 1834-39, 1841, 1843, 1845-46, 1848-50, 1853 (identical to 1857)-56, 1858-59, 1861, 1863-65, 1867-71, 1875, 1877-80, 2362, 2364, 2375, and HX107.

731 Percy, R8/283; AARP, R10/1419, 1423, 1495; NCSC, R10/4570, 4585, 4638, 4641, 4650-51, 4673, 4675, 4680-83, 4687-88, 4700-01, 4713, 4730, 4732, 4735, 4737, 4744, 4746; Hardick Letter, R8/6770; Minnesota Attorney General's Office, R10/5671, 5718; 5845. One consumer thought that the test

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Clinical audiologists, the NCSC and consumer affairs consultants felt that consumers responding to these advertisements for "free" hearing tests were not expecting a sales promotion.⁷³² Leonard Finkel, representing Legal Research and Services for the Elderly, said that half the affidavits detailing complaints submitted to him involved responses by consumers to offers for free testing.⁷³³

Indirect evidence suggesting that sales pressure is typically applied in conjunction with a "free" hearing test was supplied by industry sales manuals, which frequently instructed salespersons to tell their potential customers a free test will be offered, and then commence a high pressure sales presentation.⁷³⁴

Several dispensers felt that the general public should know that a "free test" will involve a sales presentation.⁷³⁵ One dispenser stated he had, in fact, "examined countless thousands" at no charge.⁷³⁶

731 (FOOTNOTE CONTINUED)

was being done by an independent testing lab and found out to the contrary only after responding to the offer. R10/5689.

732 Eiler, TR 7182-83; McShane, TR 8100; ASHA, R10/1768-70; Gunterman, TR 9652; Tyszka, R8/5659; Brewer, TR 3909-10; Finkel, TR 4445; RPAG, R8/2628. See Longley, TR 11293.

733 Finkel, TR 4445.

734 Beltone, R8/1642; Audivox, R13/1130 at 1136.

735 Keyes, TR 10717; West, TR 10527-28.

736 Giannetto, TR 5823.

(c) Counsellor or Consultant

The record contains many advertisements in which dispensers claimed to be counsellors or consultants.⁷³⁷ However, there was dispute as to whether the claim was deceptive. The Presiding Officer,⁷³⁸ and others⁷³⁹ concluded that they represented expert and unbiased advice, and that the claim was false. Others, however, said that dispensers, do in fact "consult" and "counsel,"⁷⁴⁰ and the claim therefore was not deceptive.

b. Expertise

(1) Claims that Dispenser is a Doctor

Numerous witnesses testified about the problems of some dealers representing to consumers that they were doctors.⁷⁴¹ One witness

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- 737 R8/2331, 2332, 2335, 2336, 2340, 2342, 2345 (yellow pages); R8/3059, 3067, 3115, 7937 (newspaper advertisements); R8/2383, 6689, 7687 (brochures); R8/4451, 4452, 7514 (business cards); R8/2457, 2490, 2506, 2534, 2536, 2538, 3089, 3109 (manufacturer's literature to consumers); R8/1644, 2496, 3121 (sales manuals). The bulk of these were "consultants" claims.
- 738 P.O. Report, R9/Dlipl46-149.
- 739 Rose, R8/4187; ASHA, R10/1783; Alpiner, R8/5434; Kolman, TR 1888-89; Butts, TR 4166; Shannon, TR 1878; Franks, R10/6523; Beiter, TR 9074; Powers, R13/970; Silverman, R8/7336; Bartels, R10/5621; Hardick, R8/6855; Pasiewicz, TR 8911; Peterson, R10/5290.
- 740 NHAS, R2/119; Freshley, R10/6644, 6655; Campagna, TR 2606; Oberhand, TR 3045-46; Heisse, TR 3289; Gayer, R9/3511; HIA, R9/2911.
- 741 Owens, R8/6487; Capano, R8/6969; Stroup, TR 969; Harford, R5/856; Goldstein, R8/4224; Hull, R8/6138; Rassi, R8/5360;
(CONTINUED)

testified that students from an audiology class visited 22 dealers, and that six of them referred to themselves as "doctor".⁷⁴²

Testimony also revealed other tactics on the part of dealers which could possibly mislead the consumer into believing that they were either doctors or had medical experience. Some dispensers or their personnel wore white coats,⁷⁴³ some carried black bags,⁷⁴⁴ and some used medical-like equipment (beyond the necessary testing equipment), which gave the appearance of a doctor's office.⁷⁴⁵ There were also testimony that consumers who called dealers "doctor" were not always corrected.⁷⁴⁶

(2) Claims that Dealer is an Audiologist

741 (FOOTNOTE CONTINUED)

Johnson, K., R8/957, R10/2649; Fennema, TR 1752; Kelly, TR 7254.

742 Wimmer, TR 6520. One dealer visited three different consumers and introduced himself as Dr. Richard Ostrander, even though he was not a doctor. NCSC Affidavits: R10/4669, 4677, 4698.

743 Bowen, TR 1947; Rassi, R8/5360; Stroup, TR 968-69; Johnson, K., R8/957; R10/2649; Consumers Union Article, (1966) R8/1045. There are 11 examples in the record of specific situations in which the dealers or personnel wore white coats. Gunterman, TR 9654; Wimmer, TR 6520; Wilson, R8/6723; visit of volunteers to 22 dealers' offices, Hardick, R8/6726; Hill, R8/7830; ASHA, R10/1638-9; Affidavits R10/4677, 4715, 4739; Graham, B., R10/5336.

744 Kuptz, TR 5697-8, Tremmel, TR 8340, Miller, R8/5845.

745 RPAG, R8/2632-33; Johnson, K., TR 4335-36.

746 Shannon, TR 1860-61; RPAG R8/2632; Harmon, R10/7290.

The record demonstrates that hearing aid sellers frequently used the title "certified hearing aid audiologist" or similar titles that included the term "audiologist."⁷⁴⁷ The record indicates that a significant portion of the public was unaware of the material differences in education as well as incentives between the hearing aid dealer (whether or not a NHAS "certified hearing aid audiologist") and the audiologist who had completed a graduate degree program in audiology.⁷⁴⁸

Many commentators expressed the view that use of titles containing the term "audiologist" by persons who did not have a graduate degree in audiology or ASHA certification created or added to existing confusion concerning the meaning of the term, and deceived hearing impaired persons.⁷⁴⁹ Some commentators objected

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See Section I.B.5.b.(5).(a) (discussion of NHAS certification of sellers as "hearing aid audiologists.") See also, Kojis, HX 37 (yellow pages ads for "certified hearing aid audiologists."); Kolman, TR 1895-96; Shannon, TR 1861-62; Conlin, TR 7770-71; Dalton, TR 8726; Powers, TR 9845; Byrne, R10/3343; Brakebill, TR 1297-98; Griesel, R10/6128, 6200; Hopmeier, HX 52; Morgan, TR 9514; Fennema, R10/23-24; Ventry, TR 1728; Loavenbruck, TR 1546; Masticola, TR 8657; Kuptz, TR 5691.

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See, HEW Public Health Service Survey, Characteristics of Persons with Impaired Hearing, R8/511ipl4-15 (Apparently some respondents had difficulty identifying the professional status of examiner.); ASHA, R10/1772; Giglia, TR 2711-14; Campagna, TR 2681-83; Klein (MPIRG), TR 7583; Sypniewski, TR 1616; Butts, TR 4166-67; Kasten, R5/1438; Owens, R8/6487; Bowe, R8/6954; HEW Task Force Hearings, Griesel, R8/3428. See also, Percy Report, R8/3831; Rompala, TR 9090-92; Shannon, TR 1860; Warren, R8/5310; Griesel, (ASHA, November 1974), HX 155/686; Lentz, R8/800.

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Kolman, TR 1888; Sandlin, TR 10147-49; Simon, TR 9160;

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to the use of the term "audiologist" by hearing aid sellers on the grounds that it lent an inappropriate aura of professionalism to the business of selling hearing aids,⁷⁵⁰ it concealed the seller's pecuniary interest,⁷⁵¹ and it implied a level of education and training that the seller did not actually possess.⁷⁵² In a study of 144 Utah hearing aid users, 29 said that an "audiologist" was a college-trained hearing professional; 36 said that a "certified

749 (FOOTNOTE CONTINUED)

Stroup, TR 968-69; Rompala, TR 9090-92; Wilson, TR 10081-82; Gardner, TR 10376-78; Mosley, TR 7749; Rose, TR 531-33, R8/4185; Morgan, TR 9568; Whitman, TR 8559-60; Smith, B., TR 273, 335; Tobin, TR 4049; Finkel, TR 4481; ASHA, R10/1671-73; HEW Task Force Hearings, Griesel, R8/3428; RPAG Report, R8/2634 (cited Hartford Life Insurance Company document describing a NHAS certified hearing aid audiologist as a "certified clinical audiologist"); MPIRG, R8/1244-45; Brewer, R10/2670; Silverman, R8/7332-33; Hull, R8/6138; Graham, S., R8/5278; Tweed, R8/7834; Alpiner, R8/5433; see also Byrne, R10/3066, 3070; Pasiewicz, TR 8906; Perrill, TR 11621; Brenner, TR 249-50; AARP, R10/1024, 1026, 1029, 1275, 1323, 1366, (letters from consumers referring to sellers as audiologists).

750 AARP/NRTA, TR 1434-35; Johnson, K., TR 4314-15; Conlin, TR 7769, 7851-52; Davis, TR 8536; Stein, TR 8979; Noffsinger, TR 7637; Beiter, TR 9035; Masticola, TR 8619; Woodward, HX 65/24; Loavenbruck, TR 1559; Lankford, R10/4896; Kasten, R8/6990; Goldstein, R8/4224; Lentz, R8/8230; Schein, R10/40; see also, HEW Task Force Hearings, R8/3466; Ryan, TR 1531-32.

751 Noffsinger, TR 7636-39; Ryan, TR 1531-32; Beiter, TR 9035; Morgan, TR 9536-37; Harford, R5/856.

752 Woodward, TR 4149-50; Feder, TR 8530-33; Beiter, TR 9074; NRTA/AARP, R10/869-70; Johnson, K., TR 4335-37; Kasten, R5/1437; Byrne and Porter, R10/3167; Harford, R5/856; Graham, S., R8/5278; see also, Fennema, TR 1792; Brennan, TR 249-50; Percy Report, R8/3831.

hearing aid audiologist" was college trained.⁷⁵³ In this limited sample, a "certified hearing audiologist" was more widely assumed to have college training than an "audiologist."

Other commentators opined that the term "audiologist" alone lacked specific meaning to the general public, and that its use by persons who do not have a graduate degree in audiology was neither deceptive nor inappropriate as long as it was preceded by the modifying words "certified hearing aid" audiologist.⁷⁵⁴ Some of these commentators said that hearing aid sellers were using the term "audiologist" as early as the mid-1930's, prior to the advent of audiology as an academic discipline.⁷⁵⁵

(3) Miscellaneous Claims in Name

Finally some establishments used names which might imply expertise, such as the "Medical Arts Hearing and Speech Center,"⁷⁵⁶ "Professional Hearing Aid Labs,"⁷⁵⁷ and the "Haywood Institute for the Deafened."⁷⁵⁸

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- 753 Powers, R13/986, 987.
- 754 Fortner, TR 2861-62, 2954; West, TR 10519, 10521-26; Kojis, TR 1996; Burris, TR 2571-72; Delk, TR 10920-21; Bess, TR 6276-80; see also HAIC, R3/3945-49, 4008-10.
- 755 Fortner, TR 2969-70; Bess, TR 6279-80; Kojis, TR 2089.
- 756 R10/100 (yellow pages). The advertisement was discussed at Kolman, R10/97-99.
- 757 AARP, R10/1508.
- 758 R8/5843.

B. Other Sales Practices

The record contains evidence of marketing abuses in various aspects of hearing aid sales.

1. Lead Generation

One type of lead generation, the use of deceptive representations concerning a seller's interest in selling, was detailed in the previous section. The record also contains evidence of other dealer activities to get the names of potential users.

For example, Sonotone recommend "cold canvassing:"

We do cold canvassing by ringing doorbells and asking people with normal hearing for the address of 'that gray-haired lady' or the old gentleman who lives somewhere in the neighborhood who is hard-of-hearing.' Two men working as a team on both sides of the street obtained 64 names in one day.

Recently, an employed worker was engaged by a progressive Manager to do part-time prospecting. In 15 days, he spent 20 hours seeking out hard-of-hearing persons. He obtained 60 names. Within a month from the time he started, 2 sales resulted, 6 additional appointments were made and 15 remained to be called upon. In this approach he said:

"Good morning. I am not selling anything, but I need your help. I have a (10 o'clock) appointment to fit a hearing aid to a lady living in this neighborhood. Unfortunately, I have lost the card with her name and I am too embarrassed to call my office and say so. Would you know who she might be?

"Mrs. Smith down at No. 217? No, I don't think Smith is the name. (Why limit yourself to one name, if you can get more?)

"Mrs. Granlocks, over on Elm Street? No, that isn't it.

"Mrs. Eberstat on Pine Ridge, No. 20? Now that sounds like it. Thank you very much. You have been most

helpful."

So you have three names to work on.⁷⁵⁹

Maico counselled on how to question clients for further lead generation. While taking a prospect's case history, Maico advised the salesperson to seek other leads. The manual advised

If . . . the person should ask why you want to know, say, "I would like to know if any of them are my users to correct any of the problems they are having of which I am not aware." Then list the names as they are given you for later references.⁷⁶⁰

Manufacturers⁷⁶¹ and dealers share in another means of generating names -- free offers. Offers for testing have already been discussed. In the case of testing offers, consumers know they will have a meeting with someone, although they might not realize that it will be a salesperson. However, other free offers merely indicated that material would be sent, with no indication that any salesperson would call.

Thus, the record contains numerous advertisements promising non-working models of aids,⁷⁶²

759 Sonotone, R8/1632.

760 R13/3900.

761 Manufacturers develop leads to pass on to their sellers.
Beltone, R8/1641.

762 Beltone, HX62I, R8/1410, 2549, 2550, 2552, 2557, 2597, 3053 (Wichita Falls, Texas, newspaper ad, Dec. 4, 1972); R8/3054 (Wichita Falls, Texas, newspaper ad, July 10, 1973); R8/3068 (ad for Beltone Hearing Aid Center, Sherman, Texas); R8/3069 (Wichita Falls Texas newspaper ad, Dec. 4, 1972); R8/7660 (Wisconsin newspaper ad); R8/3095; R13/757 (Dallas Times

(CONTINUED)

booklets,⁷⁶³ or functioning television "listening devices,"⁷⁶⁴ of uncertain value.⁷⁶⁵ Evidence that the "leads" were used to surprise consumers appears below.

2. "Getting in the Door"

After locating a consumer, the salesperson persuades the potential user to have a hearing test. With a "free testing" advertisement, the consumer has already expressed an interest in testing; in other cases, the consumer may raise objections. Sales manuals advised how to respond to them.

One Dahlberg manual, in describing how to "get in the door," included the proper response to these objections:

762 (FOOTNOTE CONTINUED)

Herald newspaper ad, Aug. 15, 1976); R13/1758 (Wichita Falls newspaper ad, Aug. 16, 1976); R13/1566 (Chicago newspaper ad); R13/1923 (Chicago Sun Times, June 21, 1976); R13/1925 (Washington Post, July 10, 1976); HX626 (TV Guide ad); HX63 (Kentucky advertisement); Oakland County Hearing Aid Service, R8/6678, (Michigan newspaper ad for an Electone aid); Metro Hearing Aid Center, R10/6415, (Michigan ad for audibel aid); Telex, R13/1924 (Chicago Sun-Times ad), R13/1924.

763 Vicon, R8/2320; Maico, R8/2357; Radioear, R8/2522, 2530; Beltone, R8/2552 (offering U.S. Government Report); Sonotone, R8/3071; Dahlberg, R8/3978.

764 Lentz, R8/8131 (Empire Hearing Aid Service offered a "free listening device" to help hear radio and television programs) [The Spokesman-Review October 27, 1972]; Evanston North Shore Hearing Aid Center, R10/5284 (Chicago Today, June 17, 1974); R13/1924 (Chicago Sun-Times, June 29, 1976).

765 A Dahlberg sales manual noted, "In the case of a T.V. device, the prospective customer is looking for an EASY way out. You must help him find the ONLY way out. R13/1302.

"I NEVER WROTE YOUR FIRM. I HEAR FINE."

You are a fortunate person, Mr. Jones. If you didn't send in this card, you have a relative or friend with such high regard for you he was concerned about your hearing. As long as I am here, would you take a few minutes to have your hearing tested? If it is o.k., I'll note it on your card so you won't be bothered again. But if it should be off -- even just a little --- wouldn't you rather know? There's no charge whatever, and we'll be finished in a matter of minutes.

o o o

"ALL I WANTED WAS INFORMATION. I EXPECTED A FOLDER IN THE MAIL, NOT A SALESMAN."

Did you want the information for yourself, or a member of your family, Mrs. Jones?

I didn't know who it was for, but I learned long ago that a booklet could cause a lot of unnecessary worry because the facts are not pinpointed. Could you spare a few minutes just to discuss your loss (or 's loss) with me? Then the booklet will be twice as valuable to you since you'll know exactly what you want to know!

o o o

"I HAD AN AID BEFORE AND ALL IT DID WAS IRRITATE ME! I DON'T KNOW WHY I SENT THAT CARD IN."

I agree with you, Mr. Samuels, there are few things more irritating than an aid that isn't working right. Perhaps it is just out of adjustment . . . or the earmold isn't right. Could I come in to see what help I can be to you? The best endorsement we can get is a happy hearing aid user. I want to make you happy!

o o o

"I HAVE A BELTEX AID AND IT WORKS FINE."

I'm delighted to hear that, Mr. Peters. If your hearing aid is giving you the satisfaction you want, you know what a blessing it can be. And since you wrote in to ask about our Miracle Ear, I know this fabulous tiny instrument will amaze you. May I come in so you will have the opportu-

nity to look it over and evaluate it? I'd like your opinion as an experienced hearing aid user. While I'm here, I can also check your aid, earmold and tube to make certain they are 100%.

o o o

"YOUR'RE WASTING YOUR TIME. I WANTED THE INFORMATION FOR A FRIEND."

Mr. Brown, I love to waste time with a man as considerate as you because I know it would never be really wasted. May I come in for just a few minutes to explain how a person's hearing can be evaluated so we can determine well in advance if a hearing aid will even help your friend and how much. Then if I make sense to you, you might even call and make an appointment for me with your friend.

o o o

"I KNEW THERE WAS A CATCH. I JUST WROTE FOR THE FREE _____ THAT WAS OFFEED. AND NOW YOU COME RUNNING OUT TO TRY TO SELL ME SOMETHING."

I'm not here to sell you a thing, Mrs. Smith. The _____ is a free gift exactly as the ad stated. But we have found there are so many unanswered questions when we just mail them, we now deliver them in person as an added service. It will only take a few minutes to explain this fully so the gift will be of genuine value to you. May I cooe in and answer all your questions. ⁷⁶⁶

The Maico sales manual advises dispensers to set an appointment for a test. In setting the appointment, the salesperson is given the following advice about consumer resistance at the door.

Whatever the objection raised at the door, make it the reason for the appointment. The number one mistake made at the door is to try to answer an objection raised against the appointment. An objection is the customer's way of telling you he wants an appointment. The Salesman's [sic] only thought should be how to convert this into a

reason for the APPOINTMENT. Let's take some examples from the objections listed on the previous page⁷⁶⁷ and convert them into reasons for an appointment.

- PROSPECT: "I know three people who have them and they all hate them."
- SALESMAN: "Isn't it unfortunate that this happens. Did you know some hard of hearing people cannot use a hearing aid? That is the very reason we do an evaluation of your hearing . . . to find out if you can be helped before we discuss it any further."
- PROSPECT: "I am not hard of hearing."
- SALESMAN: "This is what makes me so mad. People are rude enough to send me out to see you when you don't even have a hearing problem. I am going to do an evaluation of your hearing so you and I can show them in black and white you don't have a hearing problem."
- PROSPECT: "I don't have time today."
- SALESMAN: "That is the very reason I stopped. I don't have time today myself. Do you know Abner Green over on Elm Street? Well, he is a user of ours and I was on my way to see him and stopped to set an appointment to see you knowing you probably would be busy today; so I was planning to see you at 9:00 a.m. tomorrow or 6:30 tomorrow evening. Which time is best?"
- PROSPECT: "I am very happy with the one I have."
- SALESMAN: "That is sure good to hear. You deserve a badge of courage . . . do you know why? Because you are only 1 out of 6 hard of hearing persons who can get help for their hearing through a hearing aid, that has done something for their problem. Say, since you are happy with your hearing aid, I wonder if you would help me! I have a new piece of test equipment, the PrecisionEar, on which I would like your opinion and to have you compare it with the equipment you were tested on when fitted with your hearing instrument."
- PROSPECT: "I have tried four of them, but none of them will work for my loss."

SALESMAN: "I certainly can see why you would be doubtful and that is the reason we must evaluate your hearing first. Do you realize some hearing handicapped cannot be helped with a hearing aid? We recently developed a new piece of equipment to evaluate hearing and this will certainly answer if you can be helped by a hearing aid, and if so, how much help you can get. Is tonight⁷⁶⁸ at 7:00 or tomorrow morning at 9:00 best for you?"

Whatever objection the seller encounters at the consumer's door, the Maico sales manual warns: "Do not identify yourself or the company."⁷⁶⁹ The manual explains that this is desirable "because . . . if the prospect knows who you are and how to get a hold of you, he can always call and cancel the appointment."⁷⁷⁰

3. Testing

Technical aspects and limitations of hearing testing were discussed in Section I.B. Another side of testing involves its use as a sales device.

For example, Audivox described its "Audivox computer" as the "plan and tool with which you will develop your entire sales story."⁷⁷¹ Another Audivox manual advised its salespeople to watch for the point in the demonstration when

the time has come where you must "unveil" your Computer. All those dials, lights and controls are quite a sight -- nobody could fail to be impressed even if they cannot appreciate what a

768 Id., R13/870-73 [Emphasis in original.]

769 Id., R13/878. [Emphasis in original.]

770 Id.

771 Audiovox, R13/1155.

wonderful audiometric tool it is!⁷⁷²

Beltone similarly advised its salespersons to tell customers that the audiometer "takes all the guesswork out of a hearing evaluation."⁷⁷³ Dr. Donald Belt of Stanford University stated that some dealer's offices contain elaborate diagnostic equipment which implied undue professional expertise.⁷⁷⁴

The case history, too, can be a sales device. For example, information about employment and length of hearing loss may be useful in determining need for an aid, but according to the Maico sales manual, these questions should be asked "to identify the Hot Buttons of NEED and RESISTANCE."⁷⁷⁵ Questions about the nature of the hearing loss "identify the Hot Button of NEED in depth" and build "COMMITMENT for help by showing a genuine concern for the person and his problem." These questions included such inquiries as, "Do [your grandchildren] make fun of you because of your not hearing them correctly?"⁷⁷⁶

The Beltone manual similarly advised that each question of the case history further three objectives: it provides information useful in understanding a fitting or loss; it enables the salesperson to anticipate (and blunt) later objections; and it reveals the

772 Id., R13/1185.

773 Beltone, R8/1649.

774 RPAG, R8/2632-33.

775 Maico, R13/888.

776 Id., R13/893 [Emphasis in original].

"dominant buying motive" of the prospect, "essential in the sale of a hearing aid."⁷⁷⁷ Questions included "What in particular do you miss most?" The salesperson was encouraged to cite job, lodge, church, and family and the manual described these questions as a "dramatic and powerful way to get the prospect to reflect seriously on his problem."

John Kuptz, a hearing aid dealer who had dispensed aids on referral only, previously worked for three other dealers. Referring to a Maico case history form, he explained:

All these questions are designed to be used against the individual when it comes time for a signature to be placed on the dotted line. The questionnaire is the most effective selling tool a hearing aid dealer has . . ."⁷⁷⁸

4. Pacing and "Control"

The evidence indicates the importance which some sellers attach to gaining control of the potential buyer.

The Beltone Manual emphasized a rapid step-by-step approach to keep the salesperson in control in a home sale. The salesperson should go to the door and act "as if you expect to be invited into the prospect's home." The salesperson was quickly to ask if the consumer read the booklet (which was used for lead generation), and "regardless of his answer," stated that the most important questions

777 Beltone, R8/1652-53. Dahlberg outlined two purposes for the interview - a "professional method" of eliciting information to aid the fitting, and a "motivational tool." Dahlberg, R8/7039.

778 Kuptz, TR 5644.

among them, "Will a hearing aid help me?," cannot be answered without tests. "Without waiting for a response," the salesperson should "take the initiative" and get the testing equipment. Upon return, the salesperson is to "assume consent" to begin the test.⁷⁷⁹

The manuals also advised salespersons to use family members to complete a sale. Audivox explained that the wife of a hard-of-hearing man, for example, was tired of constant repetition, and may be "more eager to see her deafened husband buy an aid than the poor fellow is himself."⁷⁸⁰

During the presentation, the salesperson will jump back and forth between questioning and testing. At the end, the sale must be closed, and

A good close is an automatic close. There is no clearly recognizable point at which you stop and ask for the sale. Actually, your close started with your very first contact with the prospect. The entire sale is a series of closes . . . There is no difficulty in making the buying decision that solves a hearing problem. When a prospect agrees step-by-step that he wants help in solving his problem and he agrees that Beltone is the answer, he has closed the sale.

The prospect has made a series of positive decisions through the body of the sale, so the final decision to sign the order and give a

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R8/1647-49. The record shows that the manual was in use in 1975 - Staff Rebuttal on HAIC (Barnow), R13/1940.

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R13/1160. Beltone advised to use a third party, but to try to get the prospect to make his own decision, R8/1661. Maico advised that the case history will reveal if the third person will be a help or hindrance at the time of closing. Maico, R13/897.

deposit is almost automatic.⁷⁸¹

One way to do this, the manual advised, was to by-pass the decision to buy; and simply ask about color or style. "Any question which gives the prospect an alternative choice is a proven method of getting him to make up his own mind."⁷⁸² Another was to ask the prospect to get water so the ear mold can be made; the physical act will show consent to the sale.⁷⁸³

The Dahlberg Manual similarly advised the dealer to "assume control," first, by telling people where to sit (in their own home).⁷⁸⁴ Maico advised that, when a woman belittles her role as housewife, there is "a great opportunity to gain COMPLETE CONTROL of the prospect," by pleasantly "bawling her out" and "then building her up as the 'Home Engineer' she truly is."⁷⁸⁵

781 Beltone, R8/1659.

782 R8/1662. Dahlberg similarly advised that the dealer should select an aid, say he will set a schedule, and ask for a promise that the buyer will stick to the schedule. The manual noted,

Draw a firm commitment from him because when he agrees to wear the instrument as you have scheduled it, he is indicating that he will BUY the instrument."

R8/7053. In one instance in the record, a salesman asked his customer's wife, whether she wanted her husband to hear better. When she said yes, he began to make the earmold, and the customer felt he had committed himself. AARP, R10/4214.

783 Beltone, R8/1663.

784 R8/7038.

785 R13/891.

A Beltone dealer advised, that, where a prospect misses sentences on a test "criticize him, and ask him to try harder." Later, the same manual advised

ELATE. Thank God we got to you in time. I wouldn't have believed we could help you from your audiogram, but it looks like we can.⁷⁸⁶

5. Extent of Home Sales

The discussion above indicates substantial abuse and deception in practices used in homes sales. Such practices can apply in office sales as well.

The record contains evidence about the extent of home sales. Approximately 650,000 hearing aids were sold in the United States in 1975.⁷⁸⁷ In-home sales often accounted for between 60 and 90 percent of a dealer's business.⁷⁸⁸

With regard to in-home sales, industry stated that door-to-door "cold" canvassing was virtually non-existent in the hearing aid

786 HX158/6-7.

787 Burris, TR 2521; Plotkin, TR 6027; Sullivan, R8/1188W²; ASHA, R8/1188E²; Hecker, R10/4817; HAIC, R3/3560-61.

788 Bowen, TR 1908 (citing 1968 industry study showing 60% of sales made at home); Elliott, R10/3184 (90%); Leale, TR 11715 (70% of his sales); Beltone, R13/2033, 2036 (based on guarantee registration cards, 62.6% of 1971 sales, 64.0% of 1972 sales, and 62.8% of first six months of 1973 sales; the "top 10" dealers made 75.9% of first six months of 1973 sales in home); Tremmel, TR 8332 (63.7% of his sales); Tryba, R10/6746 (68.6% of his sales); Samole, TR 6660 (substantial proportion, and perhaps a majority, of sales are in home). But see Fortner, TR 2870 (35% of his sales); Campagna, TR 2621 (5% of RCI Inc.'s, sales; RCI makes most sales in Montgomery Wards stores).

industry;⁷⁸⁹ that in-home sales provide a needed service for many of the elderly who live in rural areas,⁷⁹⁰ and that "there is no basis for finding significant abuses in home hearing aid sales."⁷⁹¹

However, there was substantial evidence as to the frequency with which consumers were approached directly at their door,⁷⁹² and there was also evidence that this often resulted in surprise⁷⁹³ and abuse.⁷⁹⁴

6. Commission Precedent: The Cooling-Off Rule⁷⁹⁵

The Commission has previously focused on practices similar to

789 NHAS Final Comments, R9/1739-40.

790 Id., R9/1742, 1747. Keyes, TR 10692; Gunter, TR 8202; Samole, TR 6716; Scheuler, TR 11424; Hearing Aid Specialists of Maryland, Washington, D.C. and Delaware, Inc., R10/407.

791 NHAS Final Comments, p. 160.

792 Hardick, R10/6407; Loavenbruck, TR 1558; Schaefer, TR 8267; Beltone (Boston), R13/1384; Rompala, TR 9138; Lankford, TR 8001; Franks, TR 9816; NCSC, R10/4490, 4459, 4538, 4496; R10/4643, 4647, 4750, 4725; Doucette, TR 4434; Conlin, TR 7760; Nevells, TR 4425; NHAS complaint analysis, R13/3007; Kady, R8/2933; Ohio Department of Consumer Protection, R8/2991, 2994; Graham, S., R8/7539; Wimmer, TR 6519; AARP, R10/3953.

793 Hardick, R10/6407; Schaefer, TR 8267; Brakebill, TR 1334; Nevells, R10/4594; Graham, S., R8/7539. But see Norris, TR 6876 (consumers who send in these cards expect salesman might come to their door).

794 Platt, TR 6462; Loavenbruck, TR 1555-56; Tobin, TR 4094; Fennema, TR 1753; Franks, R10/6521; Gunterman, TR 9721; Powers, TR 9845. See RPAG, R8/2780 (consumer at psychological disadvantage at home).

795 Cooling-Off Period for Door-to-Door Sales, 16 C.F.R. § 429 (1982).

those outlined above. In the cooling-off rule proceeding, the Commission found practices similar to those in hearing aid sales, and noted that they set the stage for high-pressure tactics which lay behind the cooling-off rule. The Statement of Basis and Purpose said

The record contains evidence of wide-spread use of deception to obtain the person-to-person contact between the salesman and the consumer which is essential to the door-to-door salesman.

The various schemes and devices used to open the door for the salesman are almost limitless in number. All of these devices are designed to convey to the consumer, at least initially, that the visitor is not going to attempt to sell him anything. Thus, the salesman may say that he is conducting a survey, is engaged in a brand identification program, or is connected with an advertising or other promotional program. Some companies seek to pave the way for the salesman's admission into the home by advertising free gifts or a free demonstration, always without obligation, provided the consumer answers an advertisement or responds favorably to a telephone offer of information. Others use the cold canvass method wherein the salesman makes the initial contact on the doorstep. By its terms, most "door openers" must be misleading to a degree or the salesman will simply not get into the home.

Once the salesman has made the person-to-person contact with the consumer the stage is set for the use of high pressure sales tactics and the other practices which the purchasers in the homes have found to be so objectionable. 37 Fed. Reg. 22937 (1972).

More broadly, high pressure practices were described, and condemned, in the cooling-off rule. The Statement of Basis and Purpose said,

High pressure sales tactics are the leading cause for consumer complaints about door-to-door selling. The use of such tactics is of course present to a degree in all forms of selling. The door-to-door sale, however, seems to be particularly susceptible to the use of these tactics. While various forms of misrepresentation

may be utilized in the door-to-door sale, high pressure sale techniques are almost always used. This explains the high degree of success of the glib fast-talking, and persistent door-to-door salesman in selling a product which the customer often does not want, or does not need, or cannot afford.

The high-pressure tactics used are not restricted to persistence and argumentativeness. Often subtle psychological techniques are used to instill in the consumer a desire for the product and to persuade him to purchase it. Moreover, the circumstances under which a door-to-door sale is made is another reason for the success of high-pressure tactics and accounts for the frequency of their use. Although he may not have previously considered the need for the merchandise or service, the consumer by admitting the salesman into his home has placed himself in a position of consenting to listen to a practiced, skilled, and almost hypnotic sales pitch which has been scientifically designed to create his desire for something he may not need, or cannot afford." 37 Fed. Reg. 22937-38.

The Commission also noted that misrepresentations of quality, price, or characteristics of a product often accompany this pressure;⁷⁹⁶ these deceptions have been shown have specifically been shown in the hearing aid industry.

Thus, except for problems specific to hearing aid sales (particularly the mingling of purportedly "scientific" testing with a sales pitch), the Commission has already noted the prevalence in home

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37 Fed. Reg. 22938. See also Horizon Corp., 97 FTC 464, 841 (1981). ("Horizon's high pressure sales tactics violated Section 5 because they occurred in the context of pervasive deception as to material facts.")

sales of the precise practices shown here, and expressed its concern.⁷⁹⁷

⁷⁹⁷. However, as detailed infra., Sec. XL. L. the cooling-off period adopted in that proceeding is inadequate here.

V. Prevalence of Problems

There is record evidence that many buyers are not satisfied with their hearing aids.

An HEW study, although based on 1962-63 data, is the most technically rigorous study in the record. The study sampled the binaurally impaired. It found that approximately 30% of this population had used hearing aids -- but approximately 6% to 9% had rejected them.⁷⁹⁸ In other words, at least 1 in 5 binaurally impaired users who tried an aid abandoned it. In addition 6% of current users said their use was negligible.⁷⁹⁹ Over 36% of all those who tried an aid reported that they either were not satisfied or had abandoned the aid.⁸⁰⁰

The Market Facts study, conducted with a consumer mail panel in 1971, suggests a higher rate of dissatisfaction. While the study showed that 94% of consumers were satisfied with the service they received when tested⁸⁰¹, only 71% were satisfied with their ability

798 HEW, R8/D219ip10. A comparison of data in this study with a prior study of both monaurally impaired persons and binaurally impaired persons indicates that binaurally impaired persons are somewhat more likely to use aids. Id., R8/D219ip9.

799 Id., R8/D219ip33

800 Id., R8/D219ip12.

801 Market Facts, R8/630. 91% were satisfied with the service at time of purchase and 87% with post-fitting service.

to hear; 12% were somewhat dissatisfied, and 5% were very dissatisfied.⁸⁰² It seems reasonable that, at the least, many of the 5% who were "very dissatisfied" would have returned their aids if they had had a trial. Moreover, in a Market Facts sample of hearing impaired persons who did not use aids, fifteen percent said they had tried amplification -- and rejected it.

John Corso cites three relevant studies. A 1968 study examined 604 patients over age 65. Three months after getting their aids 20 returned them. (The summary does not indicate if the consumers had to pay for the aids.) The other two studies involved binaural amplification. In a 1974 study, 972 presbycusis patients, aged 70 to 80 years were given free binaural aids. One-fourth of them abandoned one of the aids, and 2% abandoned both of the aids. In a 1968 study of 48 subjects over age 65, 4 abandoned binaural amplification, and 2 abandoned both of their binaural aids.⁸⁰³

Indeed, there are over 500 consumer letters in the record where consumers indicated that they had failed to receive any significant benefit from their amplification system. This was generally attributable to fitting the wrong aid, making an unnecessary fitting, or selling an aid to an individual who required medical attention

802 Market Facts, R8/658. 16% of those who only saw a dealer were dissatisfied, as were 19% of those who only saw a physician, 13% of those who only went to a clinic, 15% of those who went to a dealer as well as an MD or clinic, and 18% of those who saw an MD or clinic.

803 Corso, R10/186-88.

instead of an amplification device.⁸⁰⁴

The serious level of problems in this industry is also evidenced by the number of state agencies from across the country who supported the right to cancel. These include attorney general's offices, consumer protection officials, and state licensing boards.⁸⁰⁵ Only

804 See Supplement to Section V.

805 Wisconsin Attorney General, R6/D71, TR 5590 (Jeffries); Office of the Alabama Attorney General, R6/D58; Legal Counsel, Consumer Advocate's Office, Office of the Governor of Illinois, TR 6463, 6495 (Platt); Ohio Division of Consumer Protection, R10/6505 (Leber); Georgia Office of Consumer Affairs, R6/2; South Dakota Department of Commerce and Consumer Affairs, R6/D11, D28; Maine Bureau of Consumer Protection, R6/D18; Wisconsin Bureau of Consumer Protection, R6/D37; Bureau of Consumer Protection, Office of the Pennsylvania Attorney General, R6/D46, D101; Massachusetts Office of Consumer Affairs, R6/D37; Michigan Consumers Council, R6/D50; Office of the Ohio Attorney General, R6/D72; California Hearing Aid Dispensers Examining Committee, TR 11923-24; Division of Professional Registration, Missouri Department of Consumer Affairs, Regulation and Licensing, R6/D17; Antitrust and Consumer Protection Division, Office of the Texas Attorney General, R6/D16; Consumer Affairs Division, Nevada Department of Commerce, R6/D60; California Department of Consumer Affairs, R6/D76, C165; Illinois Department of Public Health, R6/D103; Nebraska Attorney General, C94; Wisconsin Department of Regulation and Licensing, C60; Division of Drugs, Devices, and Cosmetics, Pennsylvania Department of Health, C67; Office of Consumer Affairs, Orange County, California; R6/D21; Consumer Affairs Unit, Syracuse, New York, R6/D29; Department of Consumer Affairs, New York City, R6/D54; Department of Weights & Measures, and Consumer Affairs, San Bernadino County, California, R6/D33; Department of Consumer Affairs, Long Beach, California, R6/D36; Consumer Affairs Coordinator, Monterey County, California, R6/D38; Bureau of Consumer Protection, Allegheny County, Pennsylvania, R8/4730; Health Department, Prince George's County, Maryland, C284; and Illinois Consumer Advocate Office, TR 6460 (Platt).

This list includes several post-record comments. See Section IX for an explanation of the citations.

one state consumer protection official testified in opposition to the rule,⁸⁰⁶ although several state licensing boards opposed the rule.⁸⁰⁷

Various experts attributed some of the dissatisfaction with aid performance to their understanding that many persons with hearing impairments can not receive effective treatment from amplification. This was based on evidence of the percentage of users who were dissatisfied with amplification,⁸⁰⁸ as well as testimony of clinicians, discussing the percentage of hearing impaired for whom they would not recommend amplification.⁸⁰⁹

Despite the problems discussed in previous sections and these figures, industry contends that hearing aids have a smaller risk of failure than other products. They claimed that the incidence of consumer complaints was low, showing there was little risk.⁸¹⁰

HAIC had marketing experts review record testimony regarding the

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- 806 Gunter, TR 8205-06 (Director of the Consumer Protection Agency in the Office of the Governor of Alabama).
- 807 Tennessee, R6/D10; Georgia, R6/D8; Nevada, R6/D13; Virginia, R6/D25; Louisiana, R6/D59; and North Carolina, R6/D81. See Section VI.B., for a discussion of these industry-dominated boards.
- 808 Corso, TR 1223 (30%); Wiley R8/7629 (25%); Hill, R8/728 (30%); Kasten, R8/6978 (25% of repeat purchasers).
- 809 Kasten, TR 755 (30%); Urban, TR 1811; Loavenbruck; TR 1661-2 (40%); Rupp, R8/7112 (25%); Butts, TR 4158; Olsen, R8/4436 (40%).
- 810 Zelnick, TR 435; Kojis, TR 2003, 2004, 2094-95; Payne, James, TR 2133; 2138; Gerstram, TR 2441; Fortner, TR 2850; Gunter, TR 8202, 8204; Clinkscales, TR 10622.

percentages of hearing aids returns. Based on the testimony of 30 witnesses, one expert affidavit reported that the return rates varied from 1% to 17%; the median percentage of returns was 4.5%, with over half reporting rates between 2.5% and 7%.⁸¹¹ The HAIC experts indicated that these return rates were substantially lower than those reported for a large number of consumer products; for example, the median rate of general returns of merchandise for all large department stores was 7.4%.⁸¹²

However, the HAIC analysis failed to consider a critical fact. The sample was drawn from dispensers who voluntarily offered a return option. These dispensers had an incentive, because of the trial period, to use both fitting and counseling procedures, so as to maximize adjustment to the hearing aid. Consequently, the statistics reflecting low rates of return, while consistent with the optimum in hearing aid testing and fitting practices, are not generalizable to transactions where optimum incentives do not exist.

For its rebuttal submission, NHAS contacted federal and state consumer protection agencies.⁸¹³ It reported that 36 states received a total of 722 complaints in 1975. The total hearing aid

811 Id., R13/2226-27, 2228, 2237; See generally Section VI.D.3.a.

812 HAIC (May), R13/2228-29; HAIC (McGann), R13/2249-50. With respect to other product lines, the rate of return for television (11.0%), radio and audio appliances (9.6%), photo and other audio-visual goods (7.3%), was also higher than the return rate for hearing aids. HAIC (McGann), R13/2249-50.

813 NHAS Rebuttal, R13/2717-33.

sales in those states during that year were 325,066, providing a ratio of complaints to sales of 0.2%.⁸¹⁴

However, the record indicates that these reported complaints do not indicate the real rate of dissatisfaction. NHAS did not survey local consumer protection offices⁸¹⁵, for example, and many state and federal agencies did not keep the requested data.⁸¹⁶

Moreover, there is substantial evidence that even a more comprehensive survey would scarcely have measured real consumer discontent. Although a number of witnesses confirmed that they received a low number of complaints regarding hearing aids,⁸¹⁷ many indicated that the number of formal complaints lodged was only a small percentage of the numbers of actual complainants.⁸¹⁸ This is

814 Id., R13/2720-23.

815 The NHAS exhibit contains a directory of consumer protection offices. In California alone, there were 18 county offices (plus 8 branch offices) and 4 city offices. Id., R13/2755-72.

816 E.g., R13/2815 (Alaska attorney general); R13/2017 (Arizona attorney general); R13/2819 (Arkansas attorney general).

817 ASHA, R13/4164; Murphy, R10/4941; Griesel, R10/6803; Zumbunnen, R10/7269-70; Leale, TR 11777; Penalver, TR 4972-73 (Florida); Waters, R8/3987; Byrne, R8/6459; Herrink, R8/8363; ASHA, R13/3654; NHAS, R8/4032; Stockler, R10/3189; Yudkin, R10/3086; Kennedy, TR 11170-71.

818 Rassi, TR 5745; ASHA, R13/4199, 4124, 4203, 4147, 4166, 4158, 4156, 4131, 4162, 4155, 4145, 4140, 4135, 4128, 4217, 4211, 4209, 4201, 4192, 4184, 4181, 4176, 4166, 4164, 4161.

"Moreover, the number of complaints filed . . . is hardly representative of the total since hundreds more flow into
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even suggested by some of NHAS' figures.⁸¹⁹

The witnesses who indicated that few dissatisfied users complain cited several reasons. They indicated that as a group, the elderly and hearing impaired are less likely to complain.⁸²⁰ Some cited lack of awareness of the proper grievance mechanism,⁸²¹ a fear of intimidation or testifying at trial, reprisals from the dealer,⁸²²

818 (FOOTNOTE CONTINUED)

the FDA, FTC, congressional offices, local consumer protection offices and the industry sponsored Better Hearing Institute from purchasers who are not aware of or feel they cannot count on their state licensing boards."; Percy Report, R8/3823.

See also, Griesel, TR 9375; Warland, R8/5765, 5775; Penalver, TR 4972-73; NCSC, R13/4251; Yudkin testimony R10/3086; ISPIRG, R8/1384; Brown (Ohio Attorney General), R6/303; Longley, TR 11340; NHAS Complaint Analysis, R13/3519; P.O. Report, R9/Dlip93;

819 Several agencies reported complaints for different industries. In the first half of 1975, for example, the Iowa Department of Justice had 12 complaints about hearing aids, but only 4 concerning funeral homes and cemetaries, and 10 concerning health spas and weight salons. R13/2932.

820 See Section II.

821 Kole, R13/4145; Skeen, R13/4135; Roland, R13/4220; Alton, R13/4209; Mitchell, R13/4201; Kramer, R13/4192; Greenwell, R13/4176; Sattler, R13/4159; Lundberg, R13/4156; Garcetti, R13/4131; Griesel, TR 9375, R10/6023, 6024, 6034; ASHA, R10/2576A; Kelly, TR 7564; Byrne, R8/6444; Schmitz, R8/7265; Bailey, et. al., HX103/2; Jeffries, TR 5586; Kasten, TR 782; Schreiber, TR 4059; Finkel, TR 4466-67; P.O. Rpt., R9/Dlip93; Lynch, TR 1459; Sypniewski, TR 1604, 1606, 1616-18; Penalver, TR 4910; Soos (Mass. AG), R13/4149; Doelling (Dept. Cons. Aff., Missouri), R13/4153

822 See n.458.

or embarrassment at having been taken advantage of or being considered senile.⁸²³ Others cited poor health, and lack of transportation and money to pursue their claim.⁸²⁴

The Percy committee stated, of its own findings

The fact that there had been 2,383 complaints lodged with state licensing agencies in a universe of only 5,700 dealers over a 5 year period, in view of the obstacles many boards have placed in the past of filing a grievance, suggests the extent and intensity of user unhappiness with many dealers.⁸²⁵

Another suggested reason as to why the statistics understate the problems are that state boards and consumer protection agencies often settle disputes informally and do not record the complaints.⁸²⁶ Moreover, disputes may be dropped when meeting resistance at the dealer level.⁸²⁷

Nevertheless, various witnesses testified that the documented number of complaints accurately represents the incidence of dealer abuse,⁸²⁸ based on their belief that the elderly are not

823 . See n.459.

824 See n.460.

825 Percy Report, R8/3823.

826 PIRGIM, R8/1334-jj; MPIRG, R8/1269; Senate Staff Study, R8/3820; Wiley, R8/7632; Lentz, R8/8002. See also Section VI.B, supra.

827 Fennema, R8/4209; Mastricola, TR 8661; Warland, R8/5765; Lentz, R8/8195, 8002, R10/6535; Graham, S., R8/7467; Corso, TR 1201, 1239, 1258; Brickfield, TR 1459; Gunterman, TR 9726, NCSC, R13/4251; ISPIRG, R8/1385 ASHA, R13/3639; Schreiber, TR 4064, 4072; NCSC, R10/4582-83.

828 Gunter, TR 8238; Teter, TR 10284.

vulnerable⁸²⁹ and will complain about unsatisfactory aid performance.⁸³⁰ In fact, numerous witnesses testified that the elderly are more likely to complain.⁸³¹

Supplement: Consumer Letters.

Corbett, R10/14 (TR 172-75); Brennan, R10/45, (TR 245); GaNun, R10/472; Healet, R10/684; Wheaton, R10/747; AARP: R10/875, 914, 916, 917, 924, 926, 937-38, 939, 949, 953, 955, 956, 957-58, 960, 962, 963, 965, 967, 969, 971-74, 977, 988, 990, 1005-06, 1008, 1021-22, 1026, 1227, 1229, 1031, 1042-43, 1045, 1050-52, 1055, 1090, 1098-1100, 1117, 1119, 1133-34, 1194, 1204, 1219, 1224, 1228, 1229, 1234, 1238, 1242, 1250, 1257, 1259, 1260, 1271, 1272, 1274, 1276, 1300, 1303, 1306, 1312, 1318, 1321, 1335, 1336, 1337, 1347, 1356, 1359, 1362, 1364, 1370, 1371, 1400, 1402, 1408, 1410, 1413, 1418, 1419, 1421, 1422, 1424, 1432, 1436, 1441, 1447, 1450, 1454, 1461, 1463, 1470, 1481, 1482-84, 1488, 1493, 1496, 1501; ASHA: R10/1908, 1909, 1910; McDowell, R10/2615; Knecht, R10/3073; Gordon, R10/3079; AARP: R10/3883, 3885, 3889, 3942, 3953, 3955, 3965, 3967, 3975, 3979, 3982, 3992, 3993, 3994, 3997, 3998, 3999, 4002, 4004, 4013, 4023, 4025, 4044, 4046, 4062, 4064, 4081, 4083, 4087, 4089, 4091, 4097, 4102, 4104, 4108, 4115-16, 4117, 4118, 4120, 4122, 4124, 4126, 4139, 4171, 4173, 4188, 4195, 4208, 4213, 4216, 4218, 4221, 4224, 4486; NCSC: R10/4488-89, 4492-93, 4500, 4503-04, 4505, 4509, 4512, 4519, 4515-16, 4524, 4526-28, 4529-31, 4532-34, 4535-36, 4539-40, 4545, 4553-55, 4557, 4559-60, 4561-62, 4564, 4573, 4582; Getchell, R10/4585; Diogo, R10/4597; Nevells, R10/4594, TR 4429; Burt, R10/4589, TR 4422; Doucette, R10/4591-92; NCSC, R10/4608-16, 4643, 4646, 4655, 4658-59, 4667, 4669, 4673, 4677, 4680, 4687-91, 4694, 4696, 4707, 4709, 4714, 4715, 4719, 4720, 4722-23, 4724, 4725-26, 4734, 4737, 4739, 4741, 4742, 4744, 4746, 4750, 4755; Schwartz, R10/4802;

829 See Section II.

830 Stutz, TR 9001-03; Splansky, TR 9022; Gunter, TR 8221; Harris, TR 10438-39; Teter, TR 10284-89; Perrill, TR 11629-30; Zumbrunnen, TR 12007; Berkove, TR 11002, 11047; Gower, R13/4133; Hall, TR 11062; Shuford, TR 699-700.

831 ASHA, R13/4166, 4133, 4173; Shuford, TR 637-639, 699 (not reluctant); Kojis, TR 2000, 2017; Payne, James, TR 2185; Corso, TR 1200; Fortner, TR 2950; Plotkin, TR 6056; Gunter, TR 8221; Teter, TR 10284-85; Vick, TR 10585, R10/6596; Clinkscales, TR 10629; Taub, R13/4195; Gardner, TR 10352; Hall, TR 11062.

Stutz, R10/5275; Hayden, R10/5366; Erickson, R10/5414; Gierach, R10/5421-25; Hughes, R10/5429; Orr (Starks), R10/5430; Wolski, R10/5441, 5443, 5445; Jeffries (Wolff), R10/5448; Peterson, TR 6111; Jeffries (Dederick), R10/5451; Jeffries (Jones), R10/5458; Jeffries (Breutzmann), R10/5467; Minnesota Kelly, R10/5661, 5666, 5671; Hylla, R10/5683; Minnesota Kelly, R10/5654; Chuba, R10/5685; Abraham, R10/5686-87; Campbell, R., R10/5688; Hanson, R10/5690; Brede, R10/5693-97; Wuizer, R10/5698; Haberman, R10/5699; Yantz, R10/5703; Koessler, R10/5709; Pete, R10/5708; Dienst, R10/5714; Anonymous, R10/5721; Herman, R10/5722-23; Lilja, R10/5726; Sheppard, R10/5730, 5731; Nyman, R10/5737-39; Mattson, R10/5742-43; Salveson, R10/5745; Brown, R10/5751; Monaghan (Sheldon), R10/5753; Hawthorne, R10/5759; Sha, R10/5761-64, 5766; Anderson (Levin), R10/5767-69; Siegler, R10/5773; Just, R10/5775; Norrell, R10/5780-82; Heiss, R10/5783; Feaster, R10/5792; Nelson (Jensen), R10/5796, 5797; Zeininger, R10/5798; Moen, R10/5816; Lapham, R10/5818-19; Nichols, R10/5820; Herrud, R10/5821; Hays, R10/5823; Yatchoski, R10/5824; Clausson, R10/5826; Perleberg, R10/5827; Maemberg, R10/5831; Aigner, R10/5837; Kohler, R10/5839; Miller, R10/5833; Daniels, R10/5840; Halls, R10/5841; Flaten, R10/5842; Foster, R10/5843; Giedt, R10/5844; Halvorson, R10/5846; Tebben, R10/5847; Sauve, R10/5848; Peach, R10/5857, 5858; Korkowski, R10/5860; Johnson, A., R10/5861; Hurst, R10/5862; Fuller, R10/5866; Gingrey, R10/5872; Althoff, R10/5877; Vollman, R10/5884-85; Duncan, R10/5887; Potter, R10/5894; Stenger, R10/5896; Boggs, R10/5908; Olson, R10/5914; Myhre, R10/5916; Nyberg, R10/5917; Johnson, R10/5920-24; (Evanson), R10/5927; (Craig), R10/5932; (Hummel), R10/5941-42; (Abbott), R10/5948; (Boucher), R10/5958; (Grabish), R10/5960; (Renstrom), R10/5966; (Ginsvikz), R10/5967; Anonymous, R10/5977; (Dingman), R10/5978; (Cooper), R10/5979; (Vornbrock), R10/5988; (Watt), R10/5998; (Olstad), R10/6000, 6002; Moody, R10/6007; Anonymous, R10/6026; Hash, R10/6032; Van Horne, R10/6045; Catlin, R10/6051; Lugar, R10/6127; Goltra, R10/6142; Bell, R10/6144; Baker, R10/6148; Moomaw, R10/6149; Bennett, R10/6155-58, 6162; Landers, R10/6175; Spruyt, R10/6191; Foster, R10/6192; Wichman, R10/6204; Jacobs, R10/6216; Fiske, R10/6223; Ingram (Gorrell), R10/6232-33, R8/290; Spangler, R10/6237; Thomas, R10/6243-47; Alexander, R10/6261; Davidson, R10/6282; Harmon, R10/7284-90; Berberich, R10/8292; Wilburn, R13/409-10; Gathercoal, R13/425; Fite, R13/670; Burk, R13/823; Cain, R13/820; Kaufman, R13/1425-27; Berzina, R13/1439; Galbraith, R13/1445-48; Hamilton, R13/1466; Buenting, R13/1477; Tyler, R13/1478; Moser, R13/1481; O'Neill, R13/1491-1512; Gale, R13/1523; Latinir, R13/1543; Surrect, R13/1576; Schwerdtfeger, R13/1585; Pigg, R13/1588-90; Dietz, R13/1599-1605; Schmidt, R13/1602; Bicksler, R13/1623-28; Morrison, R13/1632; Crumpler, R13/1643; Sewell, R13/1653; Benenson, TR 883; Murray, TR 4843-44; Wortzel, TR 4859-62; Schwartz, TR 4878; Varga, TR 6367-88; Davis, TR 8534; Rupert, R8/4; Percy, R8/8; Schenz, R8/20; Thorne, R8/23-26; Viscount, R8/27; Banner, R8/34; Peterson, R8/39; Heilan, R8/40; Norris, R8/45; Ludwig, R8/61; McAllister, R8/62; Percy, R8/64; Sawyer, R8/71; Heyduck, R8/81; Percy, R8/84, 90; Routh, R8/95; Lenald,

R8/103-05; Cagan, R8/115; Makasiar, R8/121-22; Fischer, R8/128; Percy, R8/147; Culp, R8/148; Meyer, R8/152; Kobat, R8/170; Fields, R8/171; Stone, R8/174; Gandmann, R8/186; Seaver, R8/189; Feeney, R8/195; Morris, R8/205; Moses, R8/208; Landauer, R8/209; Lyons, R8/217; Bauserman, R8/224; Petrie, R8/232; Beach, R8/240; Giller, R8/253; Adelstein, R8/254; Suter, R8/255; Rhodes, R8/258; Nelson, R8/264; Lazier, R8/274; Bodenhorn, R8/279; Percy, R8/280; Williams, R8/282; Tilton, R8/292; Wildman, R8/293; Percy, R8/298, 301; Hadorn, R8/303; Newmiller, R8/309-12; Lininger, R8/317; Percy, R8/305; Mosse, R8/324; Otto, R8/325; Percy, R8/334; Reyburn, R8/341; Percy, R8/342; Needham, R8/346; Griggs, R8/347; Van Kerrybrook, R8/349; Jenkins, R8/357; Cross, R8/364; Percy, R8/365; Moody, R8/370; Percy, R8/378; Comings, R8/380; Lancaster, R8/384; Percy, R8/385; Nelson, R8/387; Percy, R8/390-92; Phillips, R8/396; Ireland, R8/397; Caforelli, R8/399; Shenberger, R8/400; Roberts, R8/402; Verzuh, R8/405; Percy, R8/409; Seldon, R8/416; Peiffer, R8/434; Carlesco, R8/438, Percy, R8/440; Marquardt, R8/442; Smith, R8/445; Tillman, R8/447; Cooper, R8/461; Ohio Consumer Protection, R8/2942, 2943, 2944, 2945, 2946, 2991, 3015, 3021, 3032; Rossie, R8/7507-08; Stoll, R8/7636-37; King, R8/7841-46; Gawron, R8/8284; Davenport, R8/8288; McGurk, R8/8543.

VI. Existing Consumer Protection Framework

A. FDA Regulation

The Food and Drug Administration has issued regulations regarding medical pre-clearance; FDA requires a medical examination but allows anyone over 18 years of age to waive it.⁸³³ FDA has also issued labeling requirements, which disclose certain technical data, and other material; various information is required on the aid itself, in packaging, and in an User Instruction Brochure;⁸³⁴ the brochure includes a short statement about trial periods. These are detailed in Appendix D.

B. State Laws

Virtually every state regulates hearing aid sales and dispensers, generally with licensing statutes.⁸³⁵ Some states also provide

833 21 C.F.R. 801.421.

834 21 C.F.R. 801.420.

835 44 states have licensing statutes. Of the other states, New York requires hearing aid dispensers to register (and provides additional protection with a mandatory trial period and limitations on home sales). Vermont law requires a trial period and certain disclosures, and Massachusetts and requires certain disclosures. (Massachusetts and Vermont also had medical pre-clearance requirements which, unlike FDA's, did not allow a waiver. FDA has announced that the Massachusetts law has been pre-empted, however, 45 Fed. Reg. 67325 (1980); in light of FDA's position, the Vermont law is also probably unenforceable). Of the three remaining states, Illinois and Alaska have not regulated dispensers; Minnesota law relied on a non-waivable pre-clearance requirement, which FDA has pre-empted.

additional protections for consumers.⁸³⁶

Several witnesses testified that these laws adequately regulate dispensers and protect consumers.⁸³⁷ Some testified that the volume of complaints dropped following passage of state licensing laws.⁸³⁸

A staff study by the Percy Committee, however, found state training and licensure efforts to be inadequate protection for hearing-impaired consumers.⁸³⁹ Witnesses testified that licensing laws have been a step in the right direction, but did not sufficiently protect consumers. Others criticized the effectiveness of specific state laws.⁸⁴⁰

Furthermore, some held that far from correcting the abuses in hearing aid selling, licensing has served merely to cloak the dispenser with an "aura of quasi-professionalism" and that this has

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- 836 Ten states and the District of Columbia, for example, provide a right to cancel. Some provisions of these laws are detailed in Section IX.
- 837 Cooper, TR 10771, 10774; Mettler, TR 11371-72; Scheurer, TR 11433; NHAS, R8/1188M⁷; Payne, James, R8/1520; Zenith, R3/3399; See Teter, TR 10293.
- 838 Murphy, TR 7953-59; Schaefer, TR 8253; Wilson, TR 10037; Capano, R8/6968; Wallace, R10/3399. Others testified that state regulations have helped practically to eliminate bait and switch advertising. Schiff, R8/1188E⁷; Anderson, R8/1159-60.
- 839 Percy Report, R8/3809, 3872. Specific criticisms in the report are debated below.
- 840 Kasten, R5/1434; Franks, R10/6518; Morgan, R10/7327, HX158 and TR 9507; ASHA, R10/2593, 2576, 2816; Harford, R5/852; Shattuck, TR 6772; Byrne, R8/6445; Stahl, TR 5537; Komer, R8/6614; Schiavetti, R8/5683; Penalver, TR 4954; HEW Final Report, R8/3218; Woodard, HX 65, R8/3390; Rose, R5/710; Griesel, R10/6803; Platt, TR 6459-66; Chaney, R8/5345.

resulted in a greater capacity to deceive consumers who rely upon apparent expertise.⁸⁴¹ Others said that state licensing laws protected dispensers from undesirable competition, instead of protecting consumers from unfair sales practices.⁸⁴²

One question about state laws is whether they insure adequate preparation for testing; this is detailed in Section I.B.5.b.(1). Other questions, which deal with other protection which state laws might afford consumers, are summarized below.

1. Dispenser Control

In many states, hearing aid dispensers comprise a majority of the licensing board. Thus the Board is essentially a device of self regulation.⁸⁴³

NHAS indicated that dispenser control serves a valid purpose, in that "professionals" are particularly suited to understand their own

841 ASHA, R10/1650; Hardick and Gilmore, R8/6687; Graham, S., R8/5288.

842 Rose, TR 500; Shattuck, TR 6772; Palmquist, TR 6565-66; Platt, TR 6459-66; Chaney, R8/5345; Nygren, SPXC/257; Franks, R10/6518; Hecker, R10/4806; Graham, R8/5288; Longley, TR 11354-55; Jeffries, TR 5593.

843 This was a major criticism by the Percy study. Percy Report, R8/3816, 3823. The report challenged control by dispenser-members who were themselves often grandfathered (see below) and who were "often responsible for the drafting of loophole-ridden laws in the first place." See Palmquist, TR 6563-64; Platt, TR 6459-66; Shattuck, TR 6772; RPAG Report, R8/2657. This research has been updated by staff.

technical and ethical problems.⁸⁴⁴ However, there is also evidence indicating problems with dispenser control. For example, many statutes do not provide procedures for handling complaints, and the record shows that most complaints have been handled informally; the dispenser involved can settle with the consumer after some intervention by the board.⁸⁴⁵ In consequence, it was asserted, complaints against a particular dispenser may not always be handled by official action of the board --even if the conduct involved warrants investigation to determine dispenser competency. The process was criticized because the dispenser might not be deterred from repeating the act.⁸⁴⁶ Another problem cited concerning dispenser control involved Kentucky board member's participation in questionable activities.⁸⁴⁷

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R8/4031.

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Ott, R8/8354; Kenney, R8/8369; Leslie, R8/8379; Herrink, R8/8387-90; Winston, R8/7394; Byrne, R10/3282.

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RPAG, R8/1188S⁴, R8/2657. Sharon Graham, President of Arkansas State Board of Hearing Aid Dispensers, charged that a board member had screened complaints sent from the state attorney general, and did not pass them onto the other board members. Graham characterized this as an effort to protect the dealers complained about. Graham also testified that the board refused to take disciplinary action against two large Arkansas dealers (one a current board member, the other a past board member) who had employed a salesperson who had not even applied for a temporary license. The dealers pleaded a misunderstanding of board regulations even though according to the witness, a clear letter had been sent to each dispenser explaining the requirements. Graham, S., R8/7469.

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In Kentucky, several board members organized a "college of otometry." The "college" was to grant a "Doctor of

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2. Sanctions

The primary, and often exclusive, function of state licensing boards is to regulate and restrict certain activities of licensed dispensers. Their primary sanction is to deny or revoke a license, and with it the right to sell hearing aids.⁸⁴⁸

There were two problems cited with this approach. First, it was often considered too heavy-handed. Perhaps because the penalty is so severe, in many states it was seldom invoked.⁸⁴⁹ Second, the use

847 (FOOTNOTE CONTINUED)

Otometry" degree. At the end of the three-day seminar, the college awarded a "certified otometrist degree." They attempted to secure Board approval of the college, although no vote was taken. The attorney general sued and defendants ceased their activities pursuant to a consent order. Percy Report, R8/3817-18. The consent decree contained no admission of wrongdoing by board members. Id., R13/2277.

848 RPAG Report, R8/2792; P.O. Report, R9/Dlip238-39. Updated by staff.

849 The Percy Committee did a survey which found that 16 out of 34 states responding had suspended no licenses between 1970 and 1974. There were 126 revocations or suspensions in the other states; however, 41 of these were simply for failure to renew a license, and only 26 were for unethical behavior. There were 23 prosecutions, 7 civil and 16 criminal, of which 10 cases resulted in fine or imprisonment. Percy, R8/3821. NHAS cites these same statistics as proof of the highly ethical behavior of dealers. R8/4031.

of sanctions often failed directly to benefit the aggrieved customers;⁸⁵⁰ in this it is unlike informal mechanisms, which benefit the consumer but have limited impact on the dispenser's overall behavior.

3. Financing

According to the record, boards are also constrained by limited financial resources.⁸⁵¹

The 1975 Percy Report surveyed the states and found

Few of the States employ full-time professional staff members to oversee the dealers. Most board budgets are miniscule and sometimes nonexistent. In most States, boards transact business only infrequently.

In all, only nine States employ full-time professional staff to serve the boards. Only seven States--Florida, Michigan, Mississippi, Ohio, Oregon, Texas, and California--spend more than \$20,000 a year administering the dealer licensing laws. Eight states spend between \$10,000 and \$20,000; 15 spend between \$5,000 and \$10,000; seven spend less than

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The following incident is recounted in the PIRGIM Report: A 72-year-old man was sold binaural aids with the guarantee that either he would hear or he would receive a full refund. Receiving little benefit, he complained to the dealer repeatedly. The dealer adjusted the aids and told him to try them again. After more than a year of trying to wear the aids, he was tested at a hospital, and told that no hearing aid could help him. He asked the dealer for a refund and was refused. In November 1971, he complained to the Michigan Board of Hearing Aid Dealers. In February 1972, the Board said that it could do nothing because the complaint had not been filed within 1 year of the date of purchase. The Attorney General ruled in July 1972 that the Board had misinterpreted the statute of limitations. The hearing was scheduled in March, 1973. A decision was rendered in August. At the end of all this, the consumer received nothing -- the dealer's license was suspended for 15 days. PIRGIM, R8/1334 - hh to ii.

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ASHA, R10/1656.

\$5,000 and six have no separate operating budget.⁸⁵²

Out of sixteen state licensure boards and agencies that completed RPAG survey forms, only six (Florida, Texas, Ohio, Montana, Georgia and Oregon) had any employees who were working full-time in matters relating to licensure. None had field investigators.⁸⁵³

4. Consumer Knowledge

There is evidence that some states have attempted to inform the public about complaint mechanisms. Arizona, for example, had a special telephone number which could be called to initiate a complaint, and publicized this to county attorneys, the Attorney General's office, Better Business Bureau offices and consumer bureaus.⁸⁵⁴

Other evidence indicated that knowledge of complaint procedures was the exception, rather than the rule. Dr. Michael Winston, a hearing aid dispenser in Arkansas, commented that practically no one in Arkansas seemed to know of the existence of the Board of Hearing Aid Dispensers; even physicians, social workers, and nurses had

852 Percy Report, R8/3819.

853 RPAG, R8/2657; Percy, R8/2657; Brakebill, TR 1326-27 (Texas); Jeffries, TR 5031; Munger, TR 4504; Platt, TR-6459-66; Metcalfe, R8/8480; Tyszka, R8/5656; Drain, R8/8500-03; ASHA, R10/1677.

854 West, TR 10471-72. Nebraska also asserts that its board's activities are well-publicized. Murphy, TR 7958.

called his clinic asking where to complain.⁸⁵⁵ Other witnesses and commentators reinforced the view that consumers simply do not know where to complain.⁸⁵⁶

C. Industry Self-Regulation

The National Hearing Aid Society, composed of hearing aid dispensers, has initiated some self-regulation. They adopted a Code of Ethics in 1960, subsequently developed a certification program, and adopted a Four-Point Consumer Protection Plan in 1975.

Many dispensers are not NHAS members, and thus are not subject to its sanctions. Luke Fortner, the President of NHAS, testified that he believed that NHAS dispensers sold 75% of the aids in the country; by his estimate, 25% of aids are sold by non-NHAS members. The number of dispensers beyond NHAS' reach, however, may well be substantially higher; Fortner indicated that there are between 10,000 and 12,000 dispensers in the country, but only 3,600 are NHAS members (and only 2,300 of these are certified by NHAS).⁸⁵⁷

855 Winston, R8/7392.

856 Anderson, R13/403; Stroup, TR 941-47; RPAG, R8/1188S⁴; Shattuck, TR 6772; Fennema, TR 1751; Kasten, TR 782; Jeffries, TR 5593; Graham, R8/7467.

857 Fortner, R13/1070, TR 2873-75. See also HEW Task Force Final Report, R8/3349, 3486-87. In Dallas 5 of 12 hearing aid dealers are members of NHAS, but those 5 may be selling 90% of the hearing aids in that area. Anthony, TR 8487-88. In Maryland, less than half the dealers are members. Hamburger, TR 5359. As of May 27, 1976, Michigan had 59 NHAS members and 252 non-members. Hardick, R10/6408. Fortner, R13/1079-82.

1. Industry Programs

a. NHAS Code of Ethics

NHAS' code of ethics prohibits numerous misrepresentations and abusive sales practices.⁸⁵⁸ The evidence in the record, however, shows that many of these practices continue; in fact, they provide much of the basis for the Rule.

The code provides for a Grievance Committee, which is empowered to take various actions, including expulsion from membership.⁸⁵⁹

b. The Certification Program

The certification program was developed as an extension of a basic education course. Its purpose was to encourage dispensers to meet and maintain requirements for experience, education, examination, ethics, endorsement, and evaluation.⁸⁶⁰ Details of the program are discussed in Section I.B.5.a.

858 These include (1) advertising (or any other form or representation) which has the effect of misleading or deceiving hearing aid purchasers or prospective purchasers; (2) "bait" advertising; (3) misrepresentations regarding the character or type of business of the industry member; (4) false medical claims or misleading terms with medical connotations; (5) misrepresentations that a hearing aid is a new invention or incorporates a new scientific principle; and (6) misrepresentations that a hearing aid is new, unused, or rebuilt and failure to disclose that an aid is used or rebuilt; R6/51a-51e; R10/1871-76.

859 Kenwood, TR 9352-54, 9288-89.

860 Fortner, R13/1045.

c. The Consumer Protection Plan

NHAS announced a 4-Point Consumer Protection Program on May 7, 1975. The plan was developed upon recommendations made by Payne and Payne Consultants, on the basis of its industry survey.⁸⁶¹ Two other studies also contributed to the development of NHAS's new policies: The Market Facts Report and a 1973 study by the Retired Professionals Action Group (RPAG), an offshoot of Ralph Nader's Public Citizen organization.⁸⁶² The purpose of the program is "to protect the consumer and provide improved service to the hearing aid user."⁸⁶³

The plan includes a medical evaluation by a licensed physician, preferably a medical ear specialist, for first-time users prior to purchase. However, an exemption is made where the consumer signs a written waiver because of religious or personal reasons.⁸⁶⁴ This is similar to FDA's subsequently adopted pre-clearance requirements, except that FDA's regulations treat repeat users the same as first-time users⁸⁶⁵ (NHAS would also require a non-waivable medical

861 Presiding Officer's Report, R9/Dlip243; Fortner, R13/1045. See generally, Appendix B. Part III.

862 Fortner, R10/1045-46.

863 NHAS press release, May 11, 1975, R8/1613.

864 NHAS, R3/3237-38; Pigg, R8/3482; Presiding Officer's Report, R9/Dlip45; HEW Task Force Final Report, R8/3354.

865 See Appendix D, Part II.

examination if users showed one of seven specified symptoms.)⁸⁶⁶

The second provision of the four-point plan is a 30-day trial and rental program. The trial must be given on request, unless a specific hearing aid is recommended by someone other than an NHAS member (such as a physician or audiologist).⁸⁶⁷ This provision was seen as an alternative to a mandatory 30-day trial.⁸⁶⁸ It is described in detail in Section VI.D.

The third element in the NHAS program is a consumer grievance handling procedure.⁸⁶⁹

The last provision of the Consumer Protection Plan is a training/educational program for its dealers. In 1975, the NHAS formed the Hearing Instruments Institute to establish advanced courses for new and experienced dealers. NHAS was to provide the

866 These are: (1) Visible congenital or traumatic deformity of the ear; (2) history of or active drainage from the ear within ninety days; (3) history of sudden or rapidly progressive hearing loss within ninety days; (4) acute or chronic dizziness; (5) unilateral hearing loss of sudden or recent onset within ninety days; (6) significant air bone gap; and (7) visible evidence of cerumen accumulation or foreign body in ear canal. NHAS, R3/3238.

867 Hardick, R10/6408; Griesel, R10/6854; HEW Task Force Hearings, Pigg, R8/3483; NHAS, R3/3240.

868 Pigg Letter, R3/275.

869 The hearing aid industry has established toll-free hot-lines to receive complaints and to forward those complaints to designated NHAS officials authorized to initiate investigations and resolve cases. The industry indicated that they also work with local Better Business Bureaus and local authorities to provide third party arbitration. HEW Task Force Final Report, R8/3361; NHAS, R3/3241.

initial financing.⁸⁷⁰

2. Impact of Self-Regulation

Several witnesses questioned whether the NHAS plan could work. A critical factor was that many hearing aid dispensers are not NHAS members.⁸⁷¹ Witnesses also suggested that the maximum penalty for violations (expulsion or withdrawal of NHAS certification) was ineffective⁸⁷² and rarely used.⁸⁷³ Others felt that the NHAS plan developed too slowly.⁸⁷⁴ Even a full year after the plan was announced, no steps had been taken to implement significant portions-- including trial periods.⁸⁷⁵

However, Marvin Pigg, past President of NHAS, felt that the NHAS plan would provide strong safeguards for the hearing impaired.⁸⁷⁶

870 HEW Task Force Hearings Pigg, R8/3483-84; Hearing Aid Journal, May 1975 at 22, R8/4367.

871 See the introduction to Section VI.C.

872 ASHA, R13/3639-40; HEW Task Force Hearings (Frink), R8/3519 ("if it is as successful as the rest of their voluntary measures it will fall flat on its face"); Rich, TR 3026.

873 The President of NHAS knew of one suspension and no reprimand during his presidency. Fortner, TR 2925-26.

874 One witness said it had only come about because they "feel the heat and not because they have seen the light." Frink, R8/3518-19; Kasten, TR 708; McPherson, TR 5114.

875 Fortner, R13/1070.

876 HEW Task Force Final Report (Pigg), R8/3348.

Others felt that this plan should be given a fair chance to work.⁸⁷⁷

D. The Existence and Mechanics of Current Trials

This section discusses voluntary and state-mandated trial arrangements for hearing aid users. As used in this discussion, the term "trial" means any arrangement whereby a dissatisfied user of a hearing aid can return the aid for all or part of his purchase price. It includes, as will be detailed below, arrangements of varying durations and costs. The most common arrangement allows consumers 30 days to use an aid; during those 30 days, they can return the aid and pay only a portion of the purchase price. Sometimes trials are offered to all buyers, sometimes they are offered selectively, and sometimes buyers are not told of a trial period, but will be given a refund upon request. The availability of trials, and the details of trial arrangements, are discussed below. The discussion below serves two purposes. It details the prevalence of current arrangements similar to the proposed trial period proposed. In addition, it provides details about the mechanics of trials, and thus insight into appropriate "fine tuning" of the trial period. A chart summarizing state laws appears at the end of this section.

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Kojis, TR 2024; Heisse, TR 3285; Anthony, TR 8454; NHAS, R3/3221; Winslow, R10/6942; HEW Task Force Final Report, R8/3354; Giglia, R10/2923; HEW Task Force Hearings (Pigg), R8/3484.

1. Existence of Trials

Ten states and the District of Columbia require trial periods, although two condition the right on a physician or audiologist.⁸⁷⁸

The testimony in the record indicates that, elsewhere, trials are often (but not always) offered. This is shown by surveys of consumers, prescribers, and dispensers. Thus, a survey of Utah consumers showed that 73 out of 144 hearing aid purchasers were given trials.⁸⁷⁹ In an informal survey of dispensers at a meeting of the North Carolina Hearing Aid Specialists, 95% indicated that they offer trials.⁸⁸⁰ Another brief and informal survey of dispensers suggested that 25% of the dispensers in Michigan offered trials.⁸⁸¹

Another study, the most extensive in the record, surveyed prescribers. One hundred and sixty-five clinics responded to a questionnaire which asked how often they recommend trials. Thirty-two percent said they recommended trials to over 95% of their

878 See the chart in this section. California implies a warranty of fitness in every purchase of an "assistive device." A hearing aid is an "assistive device," and California's mandatory implied warranty might allow dissatisfied users to return aids.

879 Powers, R13/969.

880 Cato, R13/2284. Cato's statement was offered in rebuttal to a statement by Bartels (audiologist/dispenser) at TR 6320, that while many North Carolina dealers offered trials, many do not.

881 This was based on interviews and information conveyed by 5 of the 190 dealers in Michigan. Conlin, TR 7847 (Michigan PIRG). See generally, AHSA, R10/1727.

patients, although 56% recommended trials to fewer than 40% of their patients.⁸⁸² As noted in the previous section, the National Hearing Aid Society requires that its members offer trials upon request (under most circumstances).⁸⁸³ The record also contains the testimony of dealers who offer trial periods, as well as advertisements which note trial periods.⁸⁸⁴

Some consumers are informed about the importance of trials. Many physicians and audiologists recommend⁸⁸⁵ or even insist

882 In full, the data showed that 33% of clinics recommended trials to over 95% of their patients; 39% to over 60% of their patients; 44% to over 40% of their patients; and 93% to at least 5% of their patients. This was published in a 1972 article. Burney, R8/4788. The study included V.A. hospitals, which dispense aids without cost.

883 See e.g., NHAS, R8/1613 (press release); Pigg, R3/275 (letter to members). The plan requires that trials should be made available upon request -- except where someone has already "prescribed" a particular make and model of an aid. Failure to comply would be a violation of the NHAS Code of Ethics, and would subject members to disciplinary action. The impact of the plan is discussed infra, at Section VI.C.

884 E.g., Starkey, R8/4374, R8/4877; Fidelity, R8/4350, R13/96, 97, 98, R8/4881; Mastercraft, R8/4921; Winston, R8/7454 (1975 yellow pages with an advertisement); Wyley, R8/7673 (Starkey advertisements); Zenith, R8/1960, R8/3691; Byrne, R10/3099 (from Radioear and Tinder-Kraus-Tinder Hearing Aid Center); Wood, R13/2357-58; New Hope, R13/1925; Maico, R8/1410, 3694, 3063, 3071, 3082; Sears, R8/3115; Dahlberg, R8/4394; HX/37 (3 out of 17 boxed advertisements in 1975 D.C. Yellow Pages); HX/53; HX/54; ASHA, R10/2690, 2700; HX/172; Vicon, R8/2230.

885 E.g., Noffsinger, TR 7659-60, 7688-89 (Northwestern University clinic); Ruben, R8/1189ww; Alpiner, R8/5460; Madell, R8/4343; Bartels, TR 6293-94; Burke, M., TR 6426; Yantis, R8/4399; Kasten, TR 708; Ventry, TR 1741; Sullivan, R8/911; Butts, TR 4170; Lentz, TR 11238; Schiavetti, R8/5682 (statement by Miller, audiologist); Harvey, R8/6890;

(CONTINUED)

on⁸⁸⁶ trials. Publications directed to consumers also advise potential users to get a trial period.⁸⁸⁷ (A discussion of an FDA mandated disclosure appears in Appendix D.)

The evidence, however, also indicates that many consumers do not get trials. Some dispensers, for example, offer trials selectively; They may be offered to most of a dispenser's patients⁸⁸⁸ or to a smaller number.⁸⁸⁹ Physicians and audiologists, similarly, may recommend trials selectively.⁸⁹⁰

Where trials are used selectively, they may be granted or

885 (FOOTNOTE CONTINUED)

Mastricola, TR 8614, 8670; Franks, TR 9774-75, 9800 (audiologist, testified that 25-30 colleagues encouraged them); Harford, TR 88-90.

886 Capano, R8/6964; Hecker, R10/4836; Syfert, R10/816-17; Mastricola, TR 8634; Griesel, R10/6821 (describing Mayo clinic practice); Willeford, R8/7974; Wilson, TR 10224; Kasten, R8/6978, TR 708; Stroup, TR 969.

887 Consumers Union, R8/1039; Noffsinger, R8/5420; RPAG, R8/2847; AARP/NRTA, TR 1453-54; Alpiner, R8/5460; Griesel, R10/6896.

888 Butts, TR 4170; Leale, TR 11714; Zelnick, TR 430.

889 A representative of Audiotone indicated that the manufacturer accepts returns so the dealer can offer it to the "rare bird" who needs it. Keyes, TR 10750. One dispenser indicated that 8% of his patients take advantage of his trial plan. Vreeland, TR 3850. Another dispenser said he gives trials to about half of his patients. Giglia, TR 2747.

890 Graham, S., TR 7446; Norris, TR 6831, 6879 (a "select few"); Costello, R8/4794; Harris, TR 10424 ("once in a great while"); Rupp, R8/7112 (30% of recommendations); Rickenberg, TR 3536; Johnson, E., R8/4490 (25% of recommendations); Vreeland, R13/106; Wilber, R8/5330.

recommended on the basis of a variety of criteria. A primary criterion is the dispenser's evaluation of client motivation.⁸⁹¹ Some dispensers, moreover, grant a trial where a consumer⁸⁹² or prescriber⁸⁹³ requests it; the NHAS plan only requires a trial on request.⁸⁹⁴ It may be offered to convince a reluctant customer to purchase an aid.⁸⁹⁵ It may be granted or recommended when there is doubt about amplification;⁸⁹⁶ on the other hand, it might be denied precisely where such doubt exists, and increased risk that the aid will be returned.⁸⁹⁷

Moreover, several witnesses indicated that they gave trials to first-time users, but not to repeat users (purchasers of a replacement aid).⁸⁹⁸ Others said that repeat users also needed

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- 891 Zumbunann, TR 11951; Fortner, TR 2936; Leale, TR 11714; Vreeland, TR 3851-52.
- 892 Stahl, TR 5573-74. See Kenwood, TR 9299.
- 893 Gerstman, TR 2389; Kemker, R8/6935 (says he can get a satisfactory adjustment for his referrals when an aid proves unsatisfactory); Martinucci, TR 8397-98; Kenwood, TR 9299; Loavenbruck, TR 155; Ross, R8/4327; ASHA, R8/5366.
- 894 The requirement of a trial period would be waived, moreover, if the consumer came with a prescription for a particular make and model of aid.
- 895 Mitchell, TR 9005; Fortner, TR 2965.
- 896 Butz, R10/5203; Stabb, TR 7042; Campagna, TR 2602.
- 897 Leale, TR 11714.
- 898 Zelnick, TR 439; Eichelberger, TR 8697. See Section IX.D.

trials.⁸⁹⁹

While trials are sometimes offered to selected potential users, some dispensers never offer them.⁹⁰⁰ Some sales manuals portraying a request for a trial as an obstacle for the dispenser to overcome.⁹⁰¹

Moreover, the record contains numerous specific instances where consumers could not get a trial period, even though they tried, before purchasing an aid.⁹⁰² Some consumers or prescribers were unable to secure a trial period, even though they contacted several dealers.⁹⁰³ In yet other cases, consumers said they were promised

899 Harford, TR 88-90 (indicating he had changed his position, expressed previously). Other witnesses noted trials for "all patients," e.g., Teter, TR 10272. Presumably "all patients" included repeat users.

900 Kasten and Warren, R8/6978 (audiologists indicating that 13 of the 15 dispensers they could use refuse to give trials); MPIRG, R8/1257 (survey showing that few trials are offered in Minnesota); Masticola, TR 8650 (audiologist who has had to stop dealing with certain dispensers because they would offer trials).

901 Audivox, R13/1163 (manual which advises that a trial period is one of the worst tactical errors a dispenser can commit -- because the dispenser places himself on trial and the hearing-impaired is a poor judge of what constitutes a proper fitting for himself). See also Maico, R13/872; Beltone, R8/1835.

902 AARP, R10/914, 953, 960, 1021, 1436, 3934, 4025; Butts, TR 4219-20 (experience of several consumers); Brewer, TR 3970 (experience of several consumers).

903 Thus, in 23 Southern counties of Illinois, there are no dispensers who will offer a trial. Mosely, TR 7755. One
(CONTINUED)

a trial period, but refused a refund when they requested it.⁹⁰⁴

Finally, some dispensers indicated that they would grant a refund to a dissatisfied user, but did not inform consumers of a right to cancel.⁹⁰⁵ Certain witnesses even indicated that any responsible dealer would offer a refund for an unsatisfactory aid.⁹⁰⁶ The suggestion that consumers can rely upon such an unstated right to cancel, however, is at odds with evidence that many consumers have been denied requested refunds.⁹⁰⁷ While the evidence does not permit an evaluation of how common unannounced rights to cancel really are, it is clear that the consumer who is not promised a right

903 (FOOTNOTE CONTINUED)

audiologist testified that he recommends trials when the consumer can get them -- but that in Southern New Mexico, the consumer is often unable to get them. Dalton, TR 8745. See also Butts, TR 4219 (some Virginia consumers who seek trials can not get one); AARP, R10/4034.

904 E.g., Willeford, R8/7980; Byrne, R8/6464 (three complaints to the Kentucky Department of Consumer Affairs); Jeffries, R13/5434 (Wisconsin Attorney General's Office); Kelly, R10/5666 (practice of Mr. Flake, with other complaints against the same dispenser at R10/5676, 5788, 5842, 5843, 5845, 5847, 5864, 5866), R10/5942, 5955; NCSC, R10/4655, 4677, 4673; AARP, R10/1274 Texas State Audio, R13/681, 689, 735, 738, 747; HX172, HX212; Staff, R13/1473.

905 See Section VI.D.2.a., infra.

906 Kleiman, TR 6959; Fechheimer, TR 7008. See also Harris, TR 10429.

907 Brennan, TR 245-47 (witness received \$225 when he returned a \$420 aid, balance received six months later only after he filed a complaint with county, Department of Consumer Affairs); Staff Rebuttal, R13/1366-67 (four complaints where promised refund honored only after threat of official action); Kasten, R8/6987; Stutz, TR 8997, R10/5275; Leber, R10/6507; Epstein, TR 4600.

to cancel will often be unable to return an aid which proves unsatisfactory. Thus, while trials are not uncommon, some consumers do not and cannot get them.

2. Nature of the Arrangement

A "trial period" has been defined as any arrangement which permits dissatisfied purchasers to return their aids. These arrangements go by a variety of names: "adjustment period,"⁹⁰⁸ "lease,"⁹⁰⁹ "money back guarantee,"⁹¹⁰ "test use arrangement,"⁹¹¹ and "evaluation,"⁹¹² for example. The record as summarized below indicates that whatever they are called, they are often similar; they generally give the buyer a fixed amount of time, most often 30 days, to return the aid for a substantial refund. Even though there are some arrangements which vary from this norm in significant respects, a thirty-day trial is so common that several witnesses described the proposed remedy under the rule as essentially the 30-day trial period now in extensive use.⁹¹³

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- 908 Resnick, TR 5451. See Capano, R8/6969.
- 909 Schaeffer, TR 8297; Tremmel, TR 8335, 8371; Williams, TR 3782-83.
- 910 Johnson, J., TR 2300-01.
- 911 Payne, John, TR 9209. See also Penalver R10/4447 (a "testing" period).
- 912 Keyes, TR 10711. See also McShane, TR 8107; Schnackel, R8/4790; Krebs, TR 11845.
- 913 Rassi, TR 5737. See Brewer, TR 3915; Curran, TR 10893; Kasten, R5/1435.

a. Customer Knowledge

The most critical distinction among trials was whether consumers were told of their right to cancel. A dissatisfied consumer who does not know of a right to cancel might not return to or contact the dispenser to seek a refund. Nevertheless, the record indicates while consumers were often told of trials, and while many dispensers even advertised them, other "trial periods" were not disclosed; consumers were sometimes given refunds even where they were not told of a trial period.⁹¹⁴ For example, Montgomery Ward gave a right to cancel, but did not tell the customer unless asked.⁹¹⁵ Other sellers also affirmed that they offered or knew of unmentioned rights to cancel.⁹¹⁶ Another indicated that he "doesn't always emphasize" the trial.⁹¹⁷ A manufacturer whose firm would accept a return indicated that they made no effort directly to inform

914 But see n. 904, supra., indicating that many consumers who are not given a trial period and request a refund are denied it.

915 Campagna, TR 2640-42. The witness indicated that this implemented Ward's policy for all merchandise, and that customers would know it applies to hearing aids.

916 Delk, TR 10953; Dunlavy, TR 3440; Resnick, TR 5395-97; Keyes, TR 10707; Tremmel, TR 8336; Jerger, R8/5339 (audiologist/dispenser who says that this is their practice because of an excess of caution for the small proportion of buyers who might lose motivation.)

917 Vreeland, R10/3420.

consumers.⁹¹⁸ Some audiologists indicated that their clients could get refunds even where dispensers have not promised a trial.⁹¹⁹

b. Time

The record indicates that 30 days is the most common trial period offered.⁹²⁰ Today, all the state laws which require some sort of trial period have a 30-day period, except for Oregon's 45-day provision and Maine's 20-35 day provision.

Some trials were shorter.⁹²¹ Other arrangements lasted for a longer time.⁹²² Several reports even indicated trials lasting a

918 Keyes, TR 10712 (Audiotone).

919 Kemker, R9/6935.

920 Rassi cited a study of 60 patients, which found that the most common trial period was 30 days (the average was 36 days). R8/5368. See also Bailey, HX 103 ip325; Payne, John, TR 9209-10; Kenwood, TR 9298; Ehritt, R8/4799; Nygren, R8/4938; Holmes, TR 8614; Keyes, TR 10710; Willett, R8/4426; Greene, R8/4742; Powell, R8/4467; Brewer, TR 3918; Burris, TR 2578; Harford, TR 146; Vreeland, TR 3834-35; Fennema, TR 1747; Kasten, R5/1434; Price, R8/2017; Owens, R8/6485; Schmitz, R8/7261; Leber, R10/6509; AARP, R8/4790; Stroup, R5/55; Teter, TR 10224; Wilber; TR 1367; Graham, S., R8/5286.

921 AARP, R10/1368 (20 days); Ugoretz, R8/8345 (4 weeks); Borst, R8/1950 (10 days); Hull, R8/6167; Holloway, R13/775; Miller, TR 4814 (one to two weeks); AARP, R10/1436 (3 hours).

922 Teter, TR 10229 (30-45 days); Scott, TR 2339 (45 days); Leale, TR 11714, 11720 (60 days); Starkey, R13/1108 (60 days); Stein, TR 8970 (several months); Custom Aids of Houston, R8/2395 (up to 3 months); Lentz, R8/8267 (up to 3 months; practice of Brogan, dispenser); Fowler, R8/1983 (90 days).

full year,⁹²³ and one witness even pointed to an arrangement which lasted for 30 months.⁹²⁴ Moreover, however long the trial arrangements were initially arranged for, they were sometimes extended by mutual agreement.⁹²⁵

c. Cost

The record indicates a range of pricing techniques for trial arrangements, and substantial price variations under each technique. Most state laws allow a percentage of the selling price; 10% is the most common figure.⁹²⁶

According to the record, some dealers charged nothing for a trial.⁹²⁷ Others charge a single bundled fee⁹²⁸ under

923 Lentz, R8/8258 (practice of Hurt); AARP, R10/1449.

924 Schaefer, TR 8264, 8300. The witness offers an open-ended lease, with charge starting at \$10 per month, and with payments made for a period of 30 months. The aid can be returned at any time. The witness describes this as a lease arrangement for the purpose of operating as a financing plan.

925 Stein, TR 8976; Brakebill, R8/4333.

926 The District of Columbia however, only allows 5 %, while New Hampshire allows 20%, substantially more than any other state. Tennessee and Vermont do not fix a fee. Chart on page 264-65.

927 Kasten, R8/6978 (citing experience with a dealer).

928 The record is not always clear, when a witness cited a total price for an aid, whether customers are given this as a set ("bundled") total, or whether the consumer is given an unbundled breakout, e.g., of how much of the price is for the use of the aid for 30 days, how much for the ear mold, how much for services. Thus, the figures below -- particularly the estimates by non-dispensers -- may represent unbundled prices as well as bundled prices.

\$50.⁹²⁹ Many charged exactly \$50.⁹³⁰ Others charged between \$50 and \$100.⁹³¹ Yet, others charged even more -- ranging up to \$300.⁹³² One dispenser set his fee at 30% of the cost of the aid.⁹³³

Sometimes fees are "unbundled." For example, there may be a specified charge for the use of the aid. Numerous dispensers charge \$1.00 per day,⁹³⁴ although lower daily charges were noted by some

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- 929 Graham, S., R8/5279 (\$30); Masticola, TR 8633-34 (\$30 - \$45); Rassi, R8/5359 (\$30 - \$50); Alpiner, R8/5429 (\$25 - \$50 range in Denver); Tremmel, TR 8335 (\$35 - \$40); Lentz, R5/1291 (\$45/month); Loavenbruck, TR 1574 (\$15 - \$45/month); Bartels, TR 6296 (\$40 - \$50).
- 930 Willett, R8/4426, R3/817 (includes weekly check-ups); Brakebill, R8/4333; Kenwood, TR 9298-99; Norris, R8/4336, TR 6884 (typical fee around University of Nebraska); Mynders, TR 1156; Williams, TR 3810 (\$30 - \$35 for rental, \$15 for mold).
- 931 Carter, R., TR 3664 (\$50 to \$55); Fortner, TR 2894 (\$65); Payne, John, TR 9211 (\$84); Winston, R8/7462 (\$95, including \$50 for medical and hearing evaluation, \$30 for use of the aid, and \$15 for the ear mold).
- 932 E.g., MPIRG, R8/1258 (citing one \$140 experience); Graham, S., R8/5275 (\$200); Winston, R8/7395 (citing an experience where he heard of a dealer who charged \$300-\$150 for an aid and \$150 for services rendered). One witness said he would only recommend patients to dealers who charged a maximum of \$225 for trial. Schiavetti, R8/5682 (statement by Miller).
- 933 Fowler, R8/1983.
- 934 Fennema, TR 1761 (plus ear mold); Wilson, TR 10045; Kasten, R5/1435; Freeman, R8/4050 (plus ear mold and battery); Dahlberg, R8/1975 (example given in Deltagram to its dealers); Giglia, TR 2749 (plus ear mold and batteries); Holmes, TR 9614; New Hope for Hearing, Inc., R13/1925; Urban, R10/76 (referring to dealers she knows); Shannon, R5/666 (referring to dealers in the Baltimore area).

witnesses,⁹³⁵ and higher charges by another.⁹³⁶

Other common charges are for ear molds, batteries, and CROS or BICROS wiring. These are sometimes imposed in conjunction with other costs, e.g., a total price of \$10 plus the ear mold cost,⁹³⁷ or \$15 plus the ear mold,⁹³⁸ or \$25 plus the ear mold.⁹³⁹ Sometimes the ear mold costs are the only costs imposed.⁹⁴⁰ The ear mold costs cited in the record ranged from \$10 to \$20, with the most common figure cited being \$15.⁹⁴¹ Ten of the jurisdictions which require trials allow earmold charges; five allow charges for batteries.⁹⁴²

With regard to CROS wiring, one witness indicated that few CROS

935 Kojis, R8/899-900 (Chicago area); Kasten and Warren, R8/6978 (a range of 50 to 75 cents per day); Rassi, R8/5368.

936 Lentz, R5/1291 (\$1.50 per day).

937 Lentz, R8/8116 (letter from a dealer).

938 Teter, TR 10229.

939 Palmquist, TR 6588.

940 Nygren, R8/4938 (plus batteries); Greene, R8/4742; Owens, R8/6485.

941 E.g., Kuptz, TR 5719; Owens, R8/6485; Winston, R8/7387 (\$15); Freeman, R8/4045 (\$15); Lentz, R8/8267 (practice of a dispenser) (\$15); Fennema, TR 1768 (\$12.50 to \$17.50); Tremmel, TR 8335 (\$15 to \$20); AARP, R10/1277 (\$20); Ohio Department of Consumer Protection, R8/2971 (\$20). Winston indicated that the mold cost him \$7.50 to \$8.00, and the remaining charge was for taking the impression and for professional time and services. R8/7387.

942 See pp. 264-65. Eight of these establish a maximum charge.

aids require wiring now,⁹⁴³ and another witness indicated that the dispensers he worked with made temporary CROS fittings when an aid is on trial.⁹⁴⁴ However, there are sometimes charges made for wiring. Thus, one witness charges \$20 -- but he noted that some factories charge as much as \$50.⁹⁴⁵ Only two states which require trials allow this charge.

A separate question concerns the charge where two aids are sold. Only two state laws address the issue: Maine allows a charge based on the cost of one aid; New York based on both aids. The one witness who discussed binuaral aids indicated that he charges the same for one aid or two.⁹⁴⁶

3. Returned Aids

a. Rate of Return

Numerous witnesses referred to the rates of return of hearing aids under current trial arrangements. Few of these return rates were over 10% and none was over 20%.⁹⁴⁷ Several witnesses cited

943 Nygren, R8/4938.

944 Kasten, R8/6989.

945 Freeman, R8/4046.

946 Harvey, R8/6893 (dispenser) (charges same maximum of \$40 per month for one or two aids).

947 One witness indicated that Denver, Colorado dispensers believe the return rate to be 20%. Lentz, R5/1291. Another cited a return figure of 10-15%. Holmes, TR 9597. One audiologist/dispenser indicated that he had had 5-7 aids returned out of 60 dispensed (7-13%). McShane, TR 8110.

figures of exactly 10%, although it is clear that many of these figures are estimates.⁹⁴⁸ Numerous witnesses cited return rates under 10%.⁹⁴⁹ Indeed, while some estimates were in the 5-10% range,⁹⁵⁰ most were 5% or under, often well under.⁹⁵¹

It thus appears that typical rates of return are under 10%, and are frequently well under 5%. An attempt was made to generalize from this data by E. Goodard, who concluded that the average return rate of 26 witnesses who discussed returns was 4.5% - and over half of the

948 Hecker, R10/4836; Wilson, TR 10090-91; Rassi, TR 5738; Dahlberg, R8/1975 (minimum description of experience according to its dealers); Urban, R13/4226 (updating prior figures of 17%, at R10/76); Ehritt, R8/4799 (estimates that of the 10% who are dissatisfied with the aid, 9% take another aid and only 1% take no aid); Peterson, R8/3953.

949 Several witnesses referred generally to rates under 10%. Keyes, TR 10756; Harford, R8/4550.

950 The figures were 9% [Owens, R8/6485 (citing experience with 241 patients)]; 8-10% [(Schnackel, R8/4790)]; Vreeland, TR 3852; Rassi, TR 5738 (experience with 65 patients); Leale, TR 11744 (dispenser)]; 6% [Rompala, TR 9088 (4 returns out of 67 aids)]; Burris, TR 2578; 5-10% (Hopmeier, TR 3343).

951 The figures were 5% [Rassi, R8/5359; Fowler, R8/1983; Willett, R8/4424; Kojis, TR 1973 (reporting a Zenith survey); Stroup, TR 962 (5 out of 120 aids)]; under 5% [Mastricola, TR 8650; Greene, R8/4742]; 4% [Winston, R8/7462 (based on almost 300 aids dispensed by clinic over 20 months); Campagna, TR 2660 (Montgomery Ward Stores); Fortner, TR 2896; Baesemann, TR 7361 (citing experience of Zenith Corporation)]; 3% [Freeman, R8/4044]; 3-5% [Lankford, TR 8040]; 2-3% [Bartels, TR 6296; Radioear, R8/1972]; 2% [Butz, TR 6626; Fennema, TR 1749; Griesel, TR 9391; Norris, TR 6873; Lentz, R8/8262]; and under 1% [Schaeffer, TR 8300]. One audiologist indicated that he had had no returns among users who chose to keep an aid after a one week "evaluation period," although they could have returned it subsequently. Traynor, R8/6807 (statement of Hall, audiologist).

rates discussed were between 2.5% and 7%.⁹⁵²

b. Use of Returned Aids: Manufacturer's Practice

Several witnesses discussed the use of returned aids.⁹⁵³ The record indicates that manufacturers often limited the dealer's loss. One dealer, for example, indicated that almost all of the 15 manufacturers he worked with took back aids returned under trial arrangements.⁹⁵⁴ Zenith has offered a money back guarantee since the 1940's, it charges dispensers a 15% restocking fee.⁹⁵⁵ Starkey Laboratories offered a free trial for several years.⁹⁵⁶ Maico, too, offered a 30 day trial.⁹⁵⁷ Qualitone sent all aids to dispensers on a 30-day return option, charging a percentage for the return if the aid is not in good shape.⁹⁵⁸ Telex charged \$28 to restock an aid.⁹⁵⁹ Dahlberg accepted used aids in good condition

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- 952 May, R13/2227. See also P.O. Report, R9/Dlipl19-22.
- 953 Projections of what would happen with used aids under a federally mandated right to cancel are discussed in Section VII.
- 954 Fennema, R10/21.
- 955 The trial period was extended from 10 days to 30 in 1975. Johnson, J., TR 2299.
- 956 Starkey, R13/1108.
- 957 Kojis, R8/899-900.
- 958 Curran, TR 10840. Sometimes an undamaged aid will be taken back after a longer period. None of this is advertised to the public. Id., TR 10860.
- 959 Kleiman, TR 6932-33.

and gave a replacement for \$25, or alternatively refurbished it at no cost.⁹⁶⁰ Audiotone offered trials.⁹⁶¹ On the other hand, Radioear⁹⁶² and Sonotone⁹⁶³ had no policy on returns. A witness for Fidelity said the company would not accept a returned aid.⁹⁶⁴

c. Use of Returned Aids: Dispenser's Practices

Several witnesses addressed specific dispenser practices with returned aids other than reconditioning. Dispensers indicated that returned aids were used as demonstrators,⁹⁶⁵ "loaners,"⁹⁶⁶ or donated to charities or clinics.⁹⁶⁷ Others were simply sold as used aids.⁹⁶⁸

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- 960 Dahlberg, R8/1975.
- 961 Keyes, TR 10711 (Audiotone). This is not promoted to consumers.
- 962 Talum, R8/1970.
- 963 ASHA, R10/1926.
- 964 Samole, TR 6675. But see Fidelity, R13/96, 98.
- 965 Nygren, R8/4940. See Borst, R8/1956; Hopmeier, TR 3346-47.
- 966 Fortner, TR 2962; Noffsinger, R8/5405; NHAS, R8/1188T³; Capano, R8/6969; Barwell, TR 5185; Vreeland, TR 3878.
- 967 Nygren, R8/4940; NHAS, R3/3299; HAIC, R3/3687.
- 968 NHAS, R3/3389.

STATE STATUTES WHICH MANDATE
TRIAL PERIODS

State	Who Is Entitled	Written Disclosure Required ¹	Length of Trial ²	How Buyers Cancel	Condition of Cancelled Aid	Return of Trade-In Aid to Buyer Required
California ³ Cal. Code § 1791 et. seq.	All buyers	Yes	30 days	returns aid	N.S.	Yes
Connecticut Conn. Gen. Stat. Ann. § 20-402a	All buyers	Yes	30 days	returns aid	S.C.	N.S.
District of Columbia DC Code Ann. § 29-4004 et. seq.	All buyers	Yes	30 days/d.o.p.	returns aid	S.C. ⁴	N.S.
Kentucky KY. Rev. Stat. § 334-210	All buyers (with exceptions: see note ⁵)	Yes	30 days	written notice (returns aid after dispenser returns money)	Buyer must take "reasonable care"	Yes ⁶
Maine Me. Rev. Stat. Ann. Tit. 32 § 1653-B	All buyers	No	20-35 days ⁷ /d.o.p.	Oral or written notice ⁷	N.S.	Yes
New Hampshire N.H. Rev. Stat. Ann. § 137-F11 et. seq.	All buyers	Yes	30 days/d.o.p.	returns aid	S.C.	N.S.
New York N.Y. Business Law §§ 784	All buyers	Yes	30 days/d.o.p.	returns aid	S.C.	N.S.
Oregon Or. Rev. Stat. § 694-042	Buyers advised against using aid (see note ⁸)	No	45 days	written notice certified mail ⁹	S.C.	Yes ¹⁰
Tennessee Tenn. Code Ann § 23-1513	First-time buyers	Yes	30 days	returns aid	satisfactory condition	N.S.
Texas ¹¹ Vernon's Civil Stat- utes, Art. 4566, § 123	All buyers	Yes	30 days	returns aid	good working order, ordinary wear and tear excepted	N.S.
Vermont Vt. Stat. Ann Tit. 90 § 4581	All buyers	Yes	30 days	returns aid	S.C. ^{4, 12}	N.S.
Washington Washington Rev. Code Ann. § 18.35.190	Buyers advised against using aid (See note 13)	No	30 days/d.o.p.	written notice, certified mail ⁹	S.C.	Yes ^{11, 14}

NOTES:

1. No state requires oral disclosure.
2. Trial period begins upon receipt of aid unless otherwise specified.
3. California statute requires that all "assistive devices" sold be accompanied by a written warranty by the retail seller that the device is specifically fit for the buyer's particular needs. If the device is not specifically fit for the buyer's particular needs, the devices may be returned to the seller within 30 days of the date of actual receipt by the buyer and the buyer must promptly refund the total amount paid.
4. Ordinary wear and tear is not explicitly excluded.
5. Trial periods are not required in a) sales made pursuant to a written recommendation of a specific hearing aid by a physician or audiologist who is financially independent of the dispenser; or b) sales of identical aids made to replace a damaged or unworkable one.
6. If the trade-in is not returned, dispenser must make payment to consumer equal to trade-in allowance. Return of trade-in or payment must be made within 15 days of receipt of cancellation notice.
7. The Maine Statute requires that dispensers personally contact purchasers of hearing aids between 20 and 35 days after purchase. Up to or during this time, the buyer may cancel the purchase by "notifying" the dispenser. If this occurs, the buyer is obligated to return the cancelled aid at the time of the visit and at this time, the dispenser is required to refund the customer's money, minus the cancellation fee, and also return any trade-in aids to the consumers.
8. Hearing aid purchasers can only be cancelled if the purchaser consults with a licensed medical physician specializing in diseases of the ear or an audiologist and a licensed medical physician and either the physician or audiologist advises against using a hearing aid and specifies the reason in writing.
9. Consumer can return aid or request dispenser pick it up.
10. Dispenser can charge reasonable costs incurred in making goods ready for sale.
11. The specifics of Texas' trial period are set by regulations promulgated by the Texas Board of Examiners in the Fitting and Dispensing of Hearing Aids under statutory mandate. Tex. Admin. Reg., Vol. 7, No. 17, 3/5/82.
12. Dispenser can charge for damage.
13. Aid can be returned only if physician advises against using aid.
14. Dispenser must refund trade-in within 10 days of receiving written cancellation and cancelled aid.

d.o.p. = date of purchase

S.C. = same condition as purchased, ordinary wear and tear excepted unless otherwise noted.

N.S. = not specified.

MAXIMUM CANCELLATION CHARGES
PERMITTED UNDER STATE STATUTE

Additional Cancellation Charges Permitted

State	Maximum Cancellation Charge Permitted ¹	Earmold(s)	Batteries	Services	CROS/BICROS	Binaurals: charge for second aid?
California Cal. Code §1791 et. seq.	None allowed	No	No	No	No	No
Connecticut Conn. Gen. Stat. Ann. §20-402a	12% of p.p.	Yes-regular selling price	Yes-regular selling price	No	No	N.S.
District of Columbia D.C. Code Ann. §28-4004 et. seq.	5% of p.p.	No	No	No	No	N.S.
Kentucky ² Ky. Rev. Stat. §334-210	\$15.00 plus 5% of p.p.	Yes-lesser of dispenser's reg- ular selling price or twice his cost	Yes-lesser of dispenser's reg- ular selling price or twice his cost	No	No	N.S.
Maine Me. Rev. Stat. Ann. tit. 32 §1658-B	10% of p.p.	Yes-regular selling price	No	No	No	No
New Hampshire N.H. Rev. Stat. Ann. §137-F11 et. seq.	20% of p.p.	Yes-regular selling price	No	No	No	N.S.
New York Business Law	Lesser of \$30 per aid ³ or 10% of p.p.	Yes-lesser of dispenser's reg- ular selling price or twice his cost	Yes-lesser of seller's regular selling price or twice his cost	Yes-regular charge if specified on bill	No	Yes
Oregon Or. Rev. Stat. §694-042	10% of p.p.	Yes-regular selling price	No	No	NO	N.S.
Tennessee ⁴ Tenn. Code Ann. §63-1513	"reasonable charge"	Yes	Yes	Yes	Yes	N.S. ?
Texas ⁵ Tex. Admin. Reg. Vol. 7. No. 17, 3/5/82	Amount N.S.	Yes-regular selling price	Yes-regular selling price	Yes	Yes	Yes
Vermont ⁴ Vt. Stat. Ann. tit. 90 §4581	None allowed, except for earmold and service	Yes	No	Yes	No	N.S.
Washington ² Washington Rev. Code Ann. §18.35.190	10% of p.p.	Yes-regular selling price	No	No	No	N.S.

Notes

1. If additional cancellation charges are permitted, the cost of these items (earmold(s), batteries, services, CROS/BICROS) are not included in the purchase price.
2. Dispenser must refund payment within 15 days of receiving cancellation notice.
3. This \$30 cancellation charge is adjusted annually to account for the annual percentage adjustment in the U.S. City Average All Items Consumer Price Index (1976 = 100) published by the Bureau of Labor Statistics of the U.S. Department of Labor.
4. Cancellation charges must be specified on bill.
5. The specifics of Texas' trial period are set by regulations promulgated by the Texas Board of Examiners in the Fitting and Dispensing of Hearing Aids under statutory mandate. These regulations require that the consumer must agree to the cancellation charges prior to sale. If no agreement exists, a limit of \$2.00 per aid per day can be charged.

n.s. = not specified
p.p. = purchase price

VII. Economic Consequences of Trial Periods

The proposed rule was criticized on various grounds. Some witnesses said that trials will be abused, for example, by consumers who use numerous trial periods,⁹⁶⁹ or who return aids with undetected damage.⁹⁷⁰ Most of the criticism, however, went to two points: the impact of the rule on ability to adjust to amplification⁹⁷¹ and predictions of adverse economic effects.

The record debate on the economic consequences of the proposed rule revolved around certain critical issues. These primarily involved projected consequences of the rule: How many aids will be returned? Will there be a market for the returned aids? What will be the broad effect on industry and consumers? Will the rule stimulate new sales?

Several economic experts offered evidence on the impact of the rule: Dr. Kenneth Baesemann, a HAIC witness; Dr. Dennis Murphy, of the Commission's Bureau of Economics; and Dr. Paul Ginsburg, a NCSC witness. In addition to the analyses by these three economists, numerous other commentators addressed one or more of the economists' concerns.

969 E.g., Baird, TR 3636; McMahon, R8/4308. Instances of such dispenser shopping are discussed in the record. Franks, R10/6526; Krebs, TR 11845.

970 E.g., Carter, R., TR 3661; Fennema, TR 1783-84; Joseph, TR 4235; O'Brecht, R8/3876; Williams, TR 3780; Samole, TR 6682; Teter, TR 10238-40.

971 See Section III.D.

A. Percentage of Returns

The forecast of the numbers of consumers who will return their aids is central to the economic analysis of mandatory trial periods. As discussed above, experience in the market indicates that dispensers offering a return privilege have generally experienced return rates of under 10%, commonly between 2.5% and 7%.⁹⁷² Some witnesses noted that this has not proved burdensome.⁹⁷³ Some witnesses and commenters feel that the institution of the proposed rule will not lead to a large number of returned aids, at least not for reputable dispensers,⁹⁷⁴ while others believe it will result in an increase in the number of returns.⁹⁷⁵

Drs. Baesemann, Murphy and Ginsburg all relied upon record evidence. Dr. Baesemann assumed 10% as the appropriate return rate.⁹⁷⁶ Dr. Murphy utilized a 10% return rate, which he viewed as a maximum figure. Dr. Ginsburg argued that the percentage of aids

972 See Section VI.D.3.a.

973 ASHA, R10/1730; Leber, R10/6509; Urban, TR 1814, 1809; Brakebill, TR 1291; Rassi, TR 5787, (asserting that no dealers he knows of who offers trials has had their income adversely affected.)

974 E.g., ASHA, R13/3647-48; Byrne, R10/3064; Loavenbruck, TR 1597; Pratt, TR 3699; Schmitz, R8/7267.

975 E.g., Kleiman, TR 6911-12; McGann, R13/2250; Vreeland, R10/3420-21; Samole, TR 6656; Shuford, TR 686.

976 Baesemann states that he relied on the testimonies of Drs. Harford and Kasten for this figure. TR 7356.

returned might be reduced as a result of the proposed rule.⁹⁷⁷ Ginsburg suggested that this could occur because in a market in which all dispensers do not offer a return privilege, the consumers most likely to return an aid will purchase from dispensers who offer trials. Ginsburg asserted that this presented a real economic barrier to being the dispenser offering a return privilege in an area where others do not. If all dispensers provided the right to return, the consumers most likely to return an aid should be spread among all dispensers in a market area.⁹⁷⁸

B. The Market for Returned Aids

Opinions about the prospects for a market for returned aids vary. The FDA's hearing aid labeling rule requires that a used aid, including those used during a trial period, be labeled as such.⁹⁷⁹

Many indicated that there is no used aid market or, at best, a very limited market.⁹⁸⁰ This is Dr. Baesemann's position.

977 Ginsburg, TR 4667-70.

978 And, accordingly, the percentage of returns experienced per dispenser may drop. Id., TR 4668-70. This argument assumes that dispensers currently may not attempt or be able to screen customers to whom they offer a right to return.

979 21 CFR 801.420. Staff no longer recommends a parallel FTC Rule. See Section IX.M.

980 E.g., Anthony, TR 8494-95; Burris, TR 2499; Dunlavy, TR 3403; Freshley, R10/6653; Kleiman, TR 6952; Kojis, TR 2027, 2107; Loavenbruck, TR 1602; NHAS, R3/3389-90; Payne, James, R10/858; Percy, R8/136; Scott, TR 2327; Stroup, TR 985; Tremmel, TR 8322-23; Vreeland, R10/825-26; Waters, R8/3990, 4013, 4016; Zumbrennen, TR 12002.

Baesemann said that 50% of the hearing aids sold each year are sold to previous users. This, he said, indicates that the used aids resulting from the institution of the trial would over-saturate the used aid market; the reason, Baesemann implies, is that dispensers already have large inventories of old, worn aids which have been traded in by existing users.⁹⁸¹ In addition, Baesemann stated that he had surveyed the Chicago phone book, and did not observe advertisements for used hearing aids; this, he said, confirms that no used aid market exists.⁹⁸²

Other witnesses agreed that there is no market for used aids. The primary reasons cited were that a hearing aid is essentially a personal, or intimately worn, item which people do not like to purchase used;⁹⁸³ and that the discount which would be reasonable for dispensers to offer on used aids would not be great enough to induce buyers to purchase used aids.⁹⁸⁴ There was also testimony that aids were so individualized that use of a hearing aid by a

981 Baesemann, TR 7322, 7347, 7349-50.

982 Id., TR 7406. Baesemann also stated that, as far as he knows, hearing aid manufacturers have very little interest in cultivating a used aid market; Id. See also Griesel, TR 9469.

983 E.g., Campagna, TR 2610; Maloney, R10/6332; Mynders, TR 11597-98; NHAS, R3/3255-56, 3299-3300; Vreeland, TR 3878, R10/3420-21. Although it was suggested that this might be solved by replacing the exterior case of the aid. See Platt, TR 6463. It was also noted that a client might resist purchase of an instrument which has previously been rejected by another. Vreeland, TR 3878.

984 E.g., Fortner, TR 2858-59, 2959; Freshley, R10/6640; Hopmeier, TR 3346-47; Payne, James, TR 2144, 3602.

different person was impractical;⁹⁸⁵ however, this was contested by comments that performance characteristics among many aids vary little and that hearing aids are not that highly individualized.⁹⁸⁶

Other witnesses said that there were actual or potential markets for returned aids. In a survey by the Minnesota Hearing Aid Industry, for example, 27% of the respondents said they would purchase a renovated aid if offered at a discount.⁹⁸⁷ A variety of possible uses have been proposed and used. Many believed, some on the basis of their own experience,⁹⁸⁸ that returned aids could be resold at a reduced price.⁹⁸⁹ The record also suggests that a used aid might also be purchased for a second, or spare, instrument by a current user.⁹⁹⁰ They could be used as trial or rental aids for

985 E.g., Beltone, R3/3147; Freshley, R10/6653; Harford, R5/5854; Keyes, TR 10738, 10762-65.

986 ASHA, R8/1188I²; Lentz on Keyes, R13/1972-74; BPAG, R8/2663-64, 1188U; Resnick, R8/1188D⁶-E⁶, Y⁵-Z⁵; Rose, R8/4184; Shuford, TR 664; Sullivan, R8/921.

987 Minnesota H.A.S., R8/1310; AARP/NRTA, TR 1476 (testimony of Lynch), R10/880; Alpiner, R8/5432; ASHA, R13/3647-48; Fennema, TR 1749; Harford, R8/4550; Hattler, R8/4728; Johnson, K., TR 4369-70; Lentz on Keyes, R13/1972-74; Loavenbruck, TR 1574-75; Michigan Hearing Aid Board, R8/6574; Pasiewicz, TR 8944; Pratt, TR 3753; Stutz, TR 8939; Urban, TR 1810, R10/75.

988 See Section VI.D.3.

989 ACO (Meyers), TR 3753-55; Fennema, R10/21; Israel, TR 926, 933-34; Rose, R8/4184; Traynor, R8/6807. Several witnesses said these aids should be reconditioned.

990 Harford, R8/4550; Vreeland, TR 3878.

future customers.⁹⁹¹ They could be (and have been) used as demonstrator aids or loaners for customers who are waiting for an aid which may be on order or in repair.⁹⁹² Others raised the option of donating used aids to financially needy hearing impaired individuals, charitable organizations or public service agencies, for which the donator would receive tax benefits.⁹⁹³

Dr. Murphy challenged Dr. Baesemann's forecast about a used aid market.⁹⁹⁴ Murphy noted that the trade-ins Baeseman considered were hearing aids over three years old. Murphy said that aids returned after a short trial period would be more highly valued by prospective purchasers than these older, heavily worn aids.⁹⁹⁵

C. Effect on Consumer and Industry Behavior

Dr. Baesemann described the buyer's right to cancel as a government-mandated insurance policy guaranteeing satisfaction to all

991 Harford, R5/853-54; Hecker, R10/4840; Zumbrunnen, TR 12003.

992 Barwell, TR 5185; Capano, R8/6969; Fortner, TR 2962; Lentz (Weeks), R8/8263; McPherson, TR 5158; Rose, R5/711; Schnackel, R8/4791; Stephens, R5/1104; Vreeland, TR 3878; ACO (Meyers), TR 7753-55.

993 See Capano, R8/6969; Harford, R5/853-54; Israel, TR 925-26, 934-35; Johnson, K., TR 4369-70; Lentz, R8/7993; Pratt, TR 3753.

994 Murphy on Baesemann, R13/2062. The Presiding Officer has found that increased efforts to sell reconditioned aids to consumers unable to afford new ones could and should result in an increased market for used aids. P.O. Report, R9/Dlip274. See n. 64, infra.

995 Murphy on Baesemann, R13/2067.

purchasers, regardless of whether or not they desire such an insurance policy.⁹⁹⁶ Baesemann considered this an unnecessary mechanism which would raise prices and reduce consumer welfare.⁹⁹⁷

Since Baesemann assumed that there would be no market for returned aids, he concluded that firms will realize no income on returned aids. Furthermore, he said that the income lost on these sales would be made up through higher prices to consumers. Building from this analysis, Baesemann contended that many purchasers may not desire this return privilege.⁹⁹⁸ Furthermore, he asserted, 90% of hearing aid consumers are as certain of their need for hearing aids as they are in the case of almost any other durable consumer product,⁹⁹⁹ and this diminishes the need for a trial

996 Baesemann, TR 7324.

997 Id., TR 7329-30. See also Barnow, TR 1649-50; Briskey, TR 7247-49; Clinkscales, TR 10623; Cooper, TR 10789; Dunlavy, TR 3402-03; Franks, TR 9811; Gunter, TR 8203; Hamburger, TR 5323 (discussing the response of Maryland dealers to proposed right to cancel legislation in that state); Hopmeier, TR 3346-49; Joseph, TR 4238; Kojis, TR 1986; McGann, R13/2247; Menzel, R8/4205; NHAS, R3/3261, 3393; Payne, James, TR 2144; Platt, TR 6463; Samole, TR 6656, 6663-64; Shuford, TR 686; Scott, TR 2314; Vreeland, R10/3420-21; Waters, R8/3995; West, R10/7364; Westfall, R7/175; Zenith, R2/11. Contra, Bartels, TR 6321-24; Fennema, TR 1800; Jeffries, TR 5621-22; Newby, R5/426; Resnick, R8/4774; Rompala, TR 9089, 9144; Ross, R8/4726.

998 Baesemann, TR 7328, 7315.

999 Id., TR 7329, 7352, 7354-61. The witness bases this assertion on his reading of statements by Drs. Harford and Kasten in the record concerning cancellation rates and National Retail Merchants Association data concerning percentage of returns experienced in retailing. Id.

period.¹⁰⁰⁰ Basemann believed that the hearing aid purchaser is as capable a shopper as any other; if there is sufficient demand for trials, the market will provide trials.¹⁰⁰¹ Baesemann said a government mandated return privilege would lead to price increases for all buyers, including those who do not want such an insurance policy, thus causing the subsidization of one group of hearing aid users by another.¹⁰⁰²

As noted previously, Murphy disputed the underlying assumption that used aids would be worthless. He also criticized Baesemann's contention that hearing aids are like other consumer durables and that hearing aid purchasers are like other consumers.¹⁰⁰³ Murphy cited the record as establishing that hearing aid purchasers are neither certain of their needs nor aware of the importance of determining the benefit of an aid under real life conditions. Furthermore, Murphy said that many consumers cannot effectively comparison shop for the package of product performance, service, and price best suited to their needs.¹⁰⁰⁴

Because of these special circumstances, Murphy said, the unassisted market has failed to appropriately safeguard hearing aid

1000 Id., TR 7351.

1001 Id., TR 7358, 7364, 7395-97.

1002 Id., TR 7330, 7401-7404.

1003 Murphy on Baesemann, R13/2069.

1004 Id., R13/2068-71. See also Section II.D.

customers.¹⁰⁰⁵ Murphy said that, if the hearing impaired were more aware of the risks associated with buying an aid, the demand for a buyer's right to cancel would be greater. He said that the proposed rule attempts to compensate for these market imperfections.¹⁰⁰⁶

Murphy acknowledged that a mandatory right to return may increase producer costs and consumer prices. He agreed that such a cost increase would serve as an insurance policy. However, he concluded that this result is appropriate.¹⁰⁰⁷

Dr. Ginsburg also considered the trial period to be a form of insurance, or guarantee,¹⁰⁰⁸ but believed that cancellation fees might indeed prevent losses occasioned by the returned aids.¹⁰⁰⁹ Furthermore, he asserted that, should this not be the case and the price of all hearing aids increase, consumers would still be benefitted by a mandated return privilege.¹⁰¹⁰ Ginsburg maintained

1005 Murphy on Baesemann, R13/2068.

1006 Id., R13/2072.

1007 Id., R13/2062, 2072.

1008 Ginsburg, TR 4633, 4649.

1009 See generally Section IX.D.

1010 Ginsburg, TR 4633-38, 4649. The Presiding Officer has found that major costs associated with the reconditioning or replacement of returned aids will probably be borne by the manufacturers and passed along to dealers and consumers, although such costs should be diminished by efforts to create a market for reconditioned aids. P.O. Report, R9/Dlip274. See n. 49, supra. Furthermore, the Presiding Officer has concluded that any cost increase to consumers associated with the proposed rule "will be more than offset by the benefits that will be received by those who formerly

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that, given the uncertainty of receiving benefits from a hearing aid, the "purchase of a hearing aid is a type of gamble".¹⁰¹¹ This witness maintained the trial period would mitigate the financial consequences to the consumer should the aid not perform effectively;¹⁰¹² consequences which would be highly significant, especially to an elderly consumer.¹⁰¹³

In addition to producing price increases, Baesemann seemed to suggest that returns might increase concentration among dispensers. Even a conscientious dispenser may randomly experience high returns.¹⁰¹⁴ Since the cancellation fee will be less than the lost wholesale price of the aid, Baesemann concluded, dispensers will lose revenue.¹⁰¹⁵ Since hearing aid dispensers tend to be small enterprises,¹⁰¹⁶ he asserted that even a small term loss resulting

1010 (FOOTNOTE CONTINUED)

would have purchased hearing aids from which they derived no significant benefits and who will, by virtue of the rule, be in a position in the future to recoup a large part of the purchase price." P.O. Report, R8/Dlip274.

1011 Ginsburg, TR 4627-28, 4686. Ginsburg discusses, in this context, the issues addressed in Parts A and B of this summary of evidence.

1012 Id., TR 4629.

1013 Id., TR 4625-27. See also Fleming, R10/593.

1014 However, the rate will also be affected by other factors, such as competence and ethics. Baeseman, TR 7362-64.

1015 Id., TR 7339, 7318, R10/5148.

1016 Id., TR 7318-19. Baesemann states that the average dispenser sells 100 hearing aids per year.

from too many return aids could lead to bankruptcy.¹⁰¹⁷ He further predicted that manufacturers would assume the burden of random cancellations, because their larger size would enable them to better absorb random losses. However, the manufacturers would not protect many dispensers, Baesemann said, because manufacturers would choose to deal with fewer dispensers to eliminate their own risk.¹⁰¹⁸

Baesemann also set forth several other factors which, he said, would lead to a more concentrated hearing aid market.¹⁰¹⁹ He said trial periods would necessitate establishing procedures and facilities for processing returns.¹⁰²⁰ These procedures would have to conform to the specifics of each manufacturer's operation and, consequently, would have costs associated with them; the most important cost, Baesemann said, is learning the procedures for various manufacturers.¹⁰²¹ The more manufacturers with whom dispensers do business, he concluded, the more procedures they would

1017 Id., TR 7318-19, 7364-65.

1018 Id., TR 7319. The dispensers most likely to be cancelled, however, would be unethical or imprudent dealers. Id., TR 7371.

1019 See also Cooper, TR 10789; Freshley, R10/6656; HAIC, R3/3683-84; Hopmeier, TR 3346-47; Horne, R10/106; Kleiman, TR 6911-12; Payne, James, TR 2144.

1020 Baesemann, TR 7331.

1021 Id., TR 7374.

have to accommodate and, concomittantly, the greater their cost.¹⁰²² Baesemann believed that the rule would, therefore result in a closer relationship between existing manufacturers and dispensers. Furthermore, the costs associated with arranging for a return mechanism unique to each manufacturer would make it difficult for new firms to enter the market.¹⁰²³ The witness speculated that this might increase concentration.¹⁰²⁴

Staff economist Murphy disagreed.¹⁰²⁵ He believed that manufacturers would have a strong incentive to design simple return procedures.¹⁰²⁶ In addition, since the return rate would be less than ten percent,¹⁰²⁷ Murphy did not foresee that a dispenser would cancel an otherwise profitable line of aids over a small number of cancellations.

In a second argument involving industry concentrations, Baesemann contended that the uncertainty in level of returns resulting from the buyer's right to cancel would cause all firms to reduce output. He reasoned that the more aids a firm sold, the more likely that an aid would be returned and cause the firm to incur the associated costs. Manufacturers would tend to produce less, and dispensers sell less,

1022 See McGann, R13/2247.

1023 Baesemann provides no estimate of cost.

1024 Baesemann, TR 7332, 7374-76.

1025 Murphy on Baesemann, R13/2067-68.

1026 See also Bartels, TR 6321-24.

1027 See Section VI.D.3.a.

to minimize the risk of a return. These firms would accept reduced profits to avoid some of the risk of return. The consequence, Baesemann predicted, would be to reduce the supply of hearing aids and increase their price.¹⁰²⁸ Small firms would be the most risk-adverse, moreover, and will most reduce output.

Murphy again disagreed. He argued that, rather than cutting back production, a more effective means of insuring against high return rates would be to increase the chance that aids were used successfully.¹⁰²⁹ Murphy also maintained that the actual experience of new entrants into the industry and his reading of the record evidence indicated that the proposed right to cancel would not disadvantage smaller firms.¹⁰³⁰

Murphy also argued that the economic theory concerning risk avoidance, relied on by Baesemann, pertains to consumer behavior rather than the behavior of producers, whose response to uncertainty is considered to be far more complex and uncharted.¹⁰³¹ Overall,

1028 Baesemann, TR 7333-34.

1029 This might include the use of more accurate promotional materials reflecting the actual performance capabilities of hearing aids and the exercise of more control by firms over the sales practices of dispensers. See also ASHA, R10/1696. The Presiding Officer has stated that the costs to dispensers associated with the right to cancel will cause them to exercise greater care that aids are not sold to individuals who do not need them and that aids which are sold are fitted properly. P.O. Report, R9/Dlip274.

1030 Murphy on Baesemann, R13/2064-65; See also ASHA, R10/1741; Brakebill, TR 1298-1307; Kasten, R8/6690.

1031 Baesemann associates this principle with the work of Kenneth Arrow and John Pratt. Baesemann, TR 7334, 7379-80.

Murphy believed that the economic theory on producer behavior is not sufficiently advanced to allow any meaningful speculation as to how, if at all, producers might alter their output due to uncertainties in cancellation rates.¹⁰³²

The third argument Baesemann made concerning concentration was that coping with uncertainty--such as that which would the proposed rule would cause--require certain expenditures.¹⁰³³ Large firms might be able to distribute these costs over a larger volume of output than small producers. The firms with the largest stock of wealth would be better able to survive a run of bad luck than small firms. Baesemann would expect a higher concentration in the market and barriers to entry to result.¹⁰³⁴

His fourth argument is that the proposed rule would cause new uncertainty about future profits, which would increase the cost of entry. Lenders would view the prospects for return on capital to be reduced as a result of this regulation and, accordingly, would raise interest rates. The resulting capital barrier might completely bar

1032 Id., TR 7334-35, 7381-84. Murphy contends that Baesemann has misapplied the theories of Kenneth Arrow and John Pratt. Murphy on Baesemann, R13/2063.

1033 Baesemann states that this argument concerns stochastic scale economics. Baesemann, TR 7335.

1034 Id., TR 7335-36. Murphy does not respond directly to Baesemann's third and fourth points, although he does conclude, generally, that the rule is unlikely to affect the industry's capital structure. Murphy on Baesemann, R13/2068.

the entry of small firms.¹⁰³⁵

D. The Ability Of The Proposed Rule To Stimulate Sales

Countervailing the predictions of substantial costs, several witnesses and commenters contended that trial periods would generate an increase in sales.¹⁰³⁶ Witnesses indicated that trial periods benefit those consumers in need of amplification but unwilling to risk the full purchase price of an aid until they can determine that an aid would help them.¹⁰³⁷ Dr. Murphy shared the belief that the institution of a buyer's right to cancel might stimulate sales to hearing-impaired individuals previously unwilling to try an aid. Murphy pointed to testimony of dispensers and manufacturers which, he believed, revealed that trials were being offered voluntarily by members of the industry, partly in an attempt to gain sales to consumers who otherwise would not purchase an aid or to gain sales of newer, more technologically advanced aids to existing hearing aid

1035 Baesemann, TR 7337, 7413.

1036 See e.g., ASHA, R10/1696; Brakebill; R8/4333; Corbett, R10/6024; Fennema, TR 1784-86, 1801; Johnson, K., TR 4369; Kemker, R8/6935; Rose, R10/86-87; Schmitz, R8/7267.

1037 See, e.g., Griesel, R10/6765, TR 9381; Conlin, TR 7776; Rose, TR 494, 454; Harford, TR 141; Schmitz, R8/7267; Ruben, TR 4000; Brewer, TR 3915; Rassi, TR 5737; Fennema, R10/6018-21; Butz, TR 6621; Schaie, R8/6237; Brakebill, TR 1281-83, 1291, R8/4333; Syfert, R10/0813; Smith, B., TR 324-25. The Presiding Officer has concluded that, as a result of the rule, "many who were previously reluctant to risk a large financial loss will now be willing to try a hearing aid for the first time, or to try a second or newer aid. Certainly, this will stimulate sales." P.O. Report, R9/Dlip275.

users.¹⁰³⁸ The record does contain numerous comments indicating that the use of trials had spread because dispensers had found them to have a positive impact on their business.¹⁰³⁹

VIII. The Deception and Unfairness: Staff's Analysis

The legal authority for the recommended rule is Section 5 of the FTC Act, which prohibits unfair and deceptive acts or practices, and Congress's recognition of the Commission's authority to issue rules involving such acts or practices, in the Magnuson-Moss Act.¹⁰⁴⁰ The definitive legal basis for the provisions of a trade regulation rule will be set forth by the Commission in its Statement of Basis and Purpose, which would be issued along with any final rule. General principles are summarized below.

1038 Murphy on Baesemann, R13/2064-66.

1039 Urban, TR 1814; Giglia, TR 2704-06-9; Anderson, R13/2455; Conlin, TR 7776; Harford, TR 141; Wilber, TR 1406; Leber, R10/6509; Fennema, TR 1748, R10/6018-21 (who indicates that his sales increased 35% in the first year he offered trials); Brakebill, R8/4333, TR 1281, 1298-1307; Rose, TR 454, 458; Samole, TR 6739-6756; Kasten, TR 708; Butz, R10/5203, TR 6621; Pigg, R3/274; Johnson, K., TR 4380; Keyes, TR 10693, TR 8902-69, R10/6299; Vleck, TR 903; Loavenbruck, TR 1555; Johnson, J., TR 2301; Burris, TR 2579; Hopmeier, TR 3342; Wilson, L., TR 10091; Harris, TR 10414; Curran, TR 10893; Byrne, (letter) R10/3120; P.O. Report, R9/Dlip112. As a corollary matter, record statements indicate that voluntarily offered trials have not adversely affected sales and indeed, have increased business. See e.g., Brewer, TR 3915; Fortner, TR 2096; Giglia, TR 2768; Plotkin, TR 6018-20; Rassi, TR 5787.

1040 P.L. 93-637, § 202(a)(1)(B) (January 4, 1975).

A. Deception

An act or practice is deceptive under Section 5 if it has the tendency or capacity to deceive the "average" or ordinary consumer, whether or not the deception is intended.¹⁰⁴¹ Deceptive and misleading representations are defined by the nature of their overall message and their foreseeable effect on target consumers;¹⁰⁴² if the claim, directly or indirectly, creates an erroneous or misleading impression, it is deceptive.

Further, deception can occur not only by what is affirmatively represented, but by what is left unsaid. A long line of cases holds that failure to disclose material information can violate Section 5.¹⁰⁴³ When a seller's silence harms the consumer's economic interest, the Commission has required affirmative disclosure of

1041 See e.g., Charles of the Ritz Dist. Corp. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944); Goodman v. FTC, 244 F.2d 584, 602 (9th Cir. 1957); U.S. Retail Credit Ass'n, Inc. v. FTC, 300 F.2d 212, 221 (4th Cir. 1962); Indiana Quartered Oak Co. v. FTC, 26 F.2d 340, 342 (2d Cir. 1928); Exposition Press, Inc. v. FTC, 295 F.2d 869, 872 (2d Cir. 1961); Simeon Management Corp. v. FTC, 579 F.2d 1137 (9th Cir. 1978).

1042 See e.g., FTC v. Hires Turner Class, 81 F.2d 362 (3d Cir. 1935); Bockenstette v. FTC, 134 F.2d 369 (10th Cir. 1943).

1043 See e.g., Chrysler Corp. v. FTC, 561 F.2d 357 (D.C. Cir. 1977); Tashof v. FTC, 437 F.2d 707 (D.C. Cir. 1970); Double Eagle Lubricants, Inc. v. FTC, 360 F.2d 268 (10th Cir. 1965). See also, The Meaning of "Unfair Acts of Practices" in Section 5 of the Federal Trade Commission Act, 70 Geo. L. J. 225, 257-65 (1981).

material information.¹⁰⁴⁴ The Commission has also taken steps to insure that information is presented in a fashion that consumers can understand and utilize.¹⁰⁴⁵

Under these standards, each of the representations detailed in Part IV is deceptive: the performance claims, therapeutic claims, and claims about sellers. In addition, staff believes that failure to disclose the risk of no significant benefit is deceptive. Even incompetence and the related "avoidable" risk of no benefit are the basis for deception which violates Section 5. This is because the testers and fitters necessarily make a representation that they are competent to use the technical equipment they employ.

B. Unfairness

In addition to its regulation of deceptive practices, Section 5

1044 See e.g., Warner-Lambert Co., 86 FTC 1398 (1975), aff'd, 562 F.2d 749 (D.C. Cir. 1977), cert. denied 435 U.S. 950 (1978); J.B. Williams Co., 68 FTC 481 (1965), enforced 381 F.2d 884 (6th Cir. 1967); Bantam Books, Inc., 55 FTC 779 (1958), aff'd, 275 F.2d 680 (2d Cir. 1960); Mohawk Refining Corp., 54 FTC 1071 (1958), enforced, 263 F.2d 818 (3d Cir. 1959); Haskelite Mfg., 33 FTC 1212 (1941), review denied, 127 F.2d 765 (7th Cir. 1942); Encyclopedia Britannica, Inc. v. FTC, 605 F.2d 964 (7th Cir. 1979), cert. denied, 445 U.S. 934 (1980). Failures to disclose material information have been the subject of other Commission rules. See e.g., Incandescent Lamp Light Bulb Industry Rule, 16 C.F.R. Part 409 (1977).

1045 In various cases and rules issued by the Commission, specific language and formats have been mandated to ensure that the information required would be provided in a manner that would be most understandable and useful to consumers. Recent examples include, Grolier, Inc., 91 FTC 315 (1978); Cooling-Off Period for Door-to-Door Sales, 16 C.F.R. 429.

outlaws practices which violate the "elusive, but Congressionally mandated" standard of unfairness.¹⁰⁴⁶ The concept of unfairness is a dynamic one. In a 1980 letter to Senators Ford and Danforth, the Commission set out a "Statement of Policy on the Scope of Unfairness Jurisdiction."¹⁰⁴⁷

The Commission discussed three previously recognized criteria for unfairness: consumer injury, violation of public policies, and unethical or unscrupulous behavior. While these criteria had all been cited with apparent approval by the Supreme Court,¹⁰⁴⁸ the Commission explained that subsequent refinements show that consumer injury is the critical factor. Indeed, consumer injury is itself sufficient to warrant a finding of unfairness. Public policy plays a secondary role; it may provide a dispositive determination that consumer injury exists, but it usually is used only to test the validity and strength of other evidence of injury.¹⁰⁴⁹

On the key criterion of injury, the Commission set out three tests: the injury must be substantial, it must not be outweighed by any countervailing benefits to consumers or competition, and it must

1046 FTC v. Sperry & Hutchinson, 405 U.S. 233, 244 (1972).

1047 Letter from Federal Trade Commission to Senate Committee on Commerce, Science, and Transportation (Dec. 17, 1980), 49 U.S.L.W. 2429.

1048 FTC v. Sperry & Hutchinson, 405 U.S. 233, 244-45 n. 5 (1972).

1049 The policy statement indicated that the final S&H criterion, unethical or unscrupulous conduct, has never been an independent basis for a finding of unfairness, and will not be used in the future.

be an injury that consumers themselves could not reasonably have avoided.

Because there is an inherent risk of no significant benefit in every hearing aid sale, staff believes that every sale without a trial period is unfair. Our analysis is presented below, in the context of the Commission's Policy Statement on Unfairness.

1. Consumer Injury

Consumers are injured when they purchase an aid which does not provide significant benefit. The analysis above explained some of the reasons, both avoidable and unavoidable, for the injury. The record also provides some evidence of the magnitude of the injury.

The record shows that many dispensers offer trial periods, and virtually all said that some aids are returned. As NHAS concluded, common rates were between 2.5% and 7%.¹⁰⁵⁰

There were approximately 650,000 hearing aids sold in 1975.¹⁰⁵¹ These figures suggest a minimum of from 16,250 to 45,500 unsuccessful sales annually. At a cost of \$300 to \$400 per aid,¹⁰⁵² this in turn suggests an annual loss to consumers of between \$4.9 million and \$18.2 million. The figures are for dealers who offer trials -- and who therefore have incentives not to deceive

1050 See Section VI.D.3.a.

1051 Burris, TR 2521. See also Johnson (ASHA) R8/1188EE (600,000 in 1973); Sullivan, R8/1188ww (600,000 in 1973).

1052 Bartels, TR 6321 (\$320 average); Fleming, TR 609 (\$300 to \$450); Pratt, TR 3698 (\$400); Ginsberg, R10/429 (\$350).

consumers. Presumably, the failure rate is far higher for dispensers who do not offer trials. They are more likely to introduce deception and other avoidable risk factors into the sale. 1962-63 data collected by HEW suggests that this conclusion is accurate: it indicates that over one-fifth of hearing aid purchasers abandoned their aid.¹⁰⁵³ More recently, in the portion of the 1971 Market Facts study which surveyed hearing impaired people who did not use an aid, 15% had tried amplification and rejected it. Other data indicates that the group sampled -- hearing-impaired not using aids-- include 80% of all hearing impaired. This suggests that, as late as 1971, many of the 15 million hearing impaired had tried an aid and rejected it.¹⁰⁵⁴

In measuring actual harm, however, these figures need to be discounted to account for buyers who already receive trials. For example, approximately one-fourth of the population lives in states

1053 Industry indicated that one-half of all sales annually are to new users. Baesemann, TR 7322. Thus, approximately 325,000 sales were to new users in 1975. If 20% of these users rejected amplification, this suggests 65,000 sales to new users alone provided no significant benefit.

1054 If 80% of the hearing-impaired do not use amplification, and if 15% of them had rejected amplification, this suggests that 12% of the hearing-impaired rejected amplification. However, only 20% of the hearing-impaired use amplification. These figures suggest that over one-third of those who try an aid reject it. Assuming, as in n. 1053, supra., that 325,000 aids were sold to new users in 1975, this suggests that over 100,000 sales were to new users who rejected amplification.

which currently mandate trials.¹⁰⁵⁵ In other states, trials are presumably offered by those sellers who would have the lowest rates of return; even so, voluntary trials would obviously reduce consumer injury, perhaps significantly.

However they are adjusted, these aggregate figures do tell a significant part of the story - but only a part. Staff also urges the Commission to consider how the loss will be distributed. A useless hearing aid imposes a substantial loss, on the order of \$400 (and twice that for binaural aids). Annually, tens of thousands of consumers suffer this loss. Moreover, the hearing-impaired tend to be older and poorer than the rest of the population, and therefore experience more severe personal hardship from a \$400 loss than the average consumer.

In sum, staff believes that the evidence shows substantial consumer injury.

2. Off-setting Benefits

Under the policy statement, the second relevant inquiry is whether consumer injury is offset by benefits of the challenged practices.

The off-setting benefits of the challenged practice (failure to offer a trial period) are equivalent to the costs of offering a trial period. According to industry, there will be substantial costs. The

¹⁰⁵⁵ See pp. 264, 265, supra. and 1970 U.S. Census. See also section VI.D.

first category of suggested costs is that users will be deterred from using an aid which could benefit them. According to some witnesses, a trial period will impair a consumer's motivation to adjust to an aid.

Staff believes that the record establishes that hearing-impaired consumers want to hear, and will not abandon amplification for frivolous reasons. Moreover, there will be some financial cost to a consumer who returns an aid, perhaps on the order of \$100. This, too, should discourage frivolous cancellations.

Industry also suggests that the mere knowledge that a hearing aid might fail could adversely impair a consumer's motivation. However, staff believes that this argument should be dismissed. First, record evidence shows that the argument is unsound; consumers actually have greater difficulty adjusting to an aid when they have unrealistic expectations about the aid. Second, public policy shows that, where providers of sales or service who have special knowledge (which hearing aid dispensers claim to possess), they must not withhold material facts because they believe that the consumer should not have the facts. For example, many cases hold that physicians have a particularly high duty to apprise their patients about material facts concerning their conditions and possible treatments;¹⁰⁵⁶ there is

1056 The current trend is to require disclosure of any information necessary for the consumer to judge the need for treatment. (Absent such disclosure, the physician faces a malpractice action for negligence or assault.) Cobbs v. Grant, 502 P.2d 1 (Cal. 1972); Canterbury v. Spence, 464 F.2d 772, (D.C. Cir.) cert. denied, 409 US 1064

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only a very narrow exemption for information which the provider deems inappropriate to disclose.¹⁰⁵⁷

The second broad category of costs is financial. Industry claims that trials will impose severe economic hardship on dispensers. This argument is immediately suspect, staff believes, because many dispensers do successfully offer trials. The argument assumes that a substantial number of aids will be returned, and that they will be worthless. The record shows, however, that current return rates tend to be between 2.5% and 7%. Presumably one reason they are so low is that dispensers who offer trials have reduced incentives for deceptions and sales abuses. In other words, where aids are appropriately dispensed, the average return rate will be reasonably small.

Of course, many sellers would consistently have substantially

1056 (FOOTNOTE CONTINUED)

(1972); Parker v. St. Paul Fire & Marine Insurance Co., 335 So.2d 725, cert. denied, 38 So.2d 700 (La. Ct. App. 1976); Cooper v. Roberts, 286 A.2d 647 (Pa. Super. Ct., 1971); Wilkinson v. Vessey, 295 A.2d 676 (RI. 1972); Small v. Gifford v. Gifford Memorial Hospital, 349 A.2d 703 (Vt. 1975); Getchell v. Mansfield, 489 P.2d 953 (Or. 1971); Sard v. Hardy, 379 A.2d 1014 (Md. 1975). Older standards look to the customary practices of physicians, or to reasonable physicians standard. See "Modern Status of Views as to General Measure of Physician's Duty to Inform Patients of Risks of Proposed Treatment," 88 A.L.R. 3d 1008.

1057 Small v. Gifford Memorial Hospital, supra., Getchell v. Mansfield, supra. Canterbury v. Spence, supra. at 789, held that the privilege of non-disclosure was limited to cases where the patient would become "so ill or emotionally distraught as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage..."

higher cancellations -- these are the sellers who sell aids to consumers who do not need them. These business, often small retail operations, would suffer. However, the mere fact that dispensers consistently have high cancellation rates, would indicate they are selling aids inappropriately. One purpose of the rule is to deter deceptions and sales abuses leading to sales that provide no significant benefit. If a dispenser's revenue has been based on market abuses, the elimination of those abuses is appropriately counted as a benefit -- and not a cost -- of the rule.

3. Could Consumers Reasonably Avoid the Injury?

Finally, the last question is whether consumers can reasonably avoid injury. Absent any Commission action, in staff's view, the answer is clear-cut. Confronted with unrealistic performance claims presented as "expert" advice, a consumer can not avoid the risk that a hearing aid will provide no significant benefit. If anything, the claims minimize the chance that a consumer will take steps to avoid injury. Moreover, staff believes that FDA's limited disclosure about trials does not provide adequate protection.¹⁰⁵⁸

The more difficult question is whether a less restrictive remedy would enable consumers to avoid risk. Specifically, suppose the consumer is clearly and conspicuously told that there is an unavoidable risk of no benefit in every sale. Would that be adequate to eliminate the risk? Staff believes it would not.

1058 See Appendix D., Section II.

First, consumers might be unable to get a trial period; the record indicates that some consumers have been unable to get trials. This is particularly true in rural areas.

Moreover, the value of the information itself is limited. Consumers cannot fully determine the value of a trial period if they cannot evaluate their own risk of receiving no significant benefit.

However, the Commission could not provide more precise information to let individual consumers actually evaluate their own risks. For example, as a practical matter, the Commission could not force dispensers to disclose that one reason for trials is seller abuses--but without this information, the consumer could not make an informed choice.

Moreover, the risk depends on factors individual to each sale. For example, users with very severe or very mild losses are less likely to benefit from an aid than users with moderate losses. The risk is also a function of various avoidable factors which vary from sale to sale; these include the quality of testing and the extent of deception and pressure in the sale. A disclosure, therefore, could not meaningfully disclose the risk in an individual sale.

To a certain extent, consumers themselves can evaluate the risk in a sale. If they wear an aid during the fitting process, for example, they will have some idea of how much it increases their ability to understand speech. However, the information is limited, perhaps misleadingly so. In the tester's office, they will not be able to evaluate their ability to understand speech in the presence of normal background noise. Moreover, even if they encountered some

background noise in testing, they could not evaluate a dispenser's assurances that they will adjust to the noise in time.¹⁰⁵⁹ With the best testing, consumers cannot get adequate pre-sale information about this major purchase. With poor testing, they may get even less information. If tested with a master hearing aid, they may never encounter the poorer performance of a real aid until after their purchase.

Thus, a purely informational remedy would alert consumers to the fact that there is some risk of no significant benefit. But even having been alerted, the consumer would have at best limited ability to evaluate the risk. Only a trial period would allow adequate evaluation of the risk.¹⁰⁶⁰

1059 Indeed, because they are deseparate to hear and may view the seller as an "expert," they may be open to exaggerated promises of an adequate adjustment.

1060 The "risk of no benefit" is not the only issue premised primarily on unfairness. The sales tactics described in Section IV are also unfair. As noted previously, the Commission recently confirmed that high-pressure sales tactics in the presence of substantial deception, are unfair. See Horizon Corp., 97 FTC 464 (1981). The practices include various forms of pressure, and the intermingling of "science" and sales in a matter which lends to make the sales presentation appear to be "scientific."

In the context of its three-part test, these practices cause substantial consumer injury. This is shown by the evidence of the size of the market, see n.1051, the extent of home-sales (which are most subject to abuse), see Section IV.B.5., and the extent and variety of deceptions.

There are scant off-setting benefits to the specific practices defined. This is in part a function of how the unfair practices are defined: It is high-pressure tactics, and not merely aggressive salesmanship, which is unfair.

(CONTINUED)

C. The Remedy Will Cure Most Section 5 Violations

In staff's view, a mandatory trial period would most effectively remedy the various unfair and deceptive practices, although it substantially intrudes into the market place.

The basis for staff's conclusion that the Commission can mandate a trial is set forth in the introduction. The rationale for a mandatory trial period is set forth, in part, in the preceding analysis, which explains why - in staff's view - every hearing aid sale without a trial is unfair.

The trial would directly remedy this central unfairness. It would also indirectly remedy deceptive performance claims, which the consumer could evaluate during the trial. It would similarly remedy deceptive "new" or "unique" claims, in part, because repeat users would be able to evaluate the claimed advance against the performance

1060 (FOOTNOTE CONTINUED)

Arguably, any cost of prohibiting the unfair practice would be a benefit of allowing the practice to continue, and the chilling effect of a rule on legitimate aggressive salesmanship would be such a cost. However, the problem is mitigated here because of the remedy used to prohibit the practice - the trial period - will specifically focus on the worst sales. Legitimate salesmanship can be used to motivate the consumer without deception. If accompanied by appropriate counselling, there is likely to be a relatively low return rate, on the order of 2.5% - 7%. Hence, there are few costs which the rule would impose on legitimate salesmanship.

Finally, consumers are unlikely to avoid the injury. As noted in text, these very practices minimize the chance that consumers will get the only fully effective remedy--a trial period.

of their prior aid. It would similarly remedy deceptive claims of expertise, because the consumer could evaluate the end product of that expertise. It would remedy high-pressure sales tactics, because the consumer could evaluate the end product of the presentation.¹⁰⁶¹ It would thus provide disincentives to virtually all of the deceptive claims and marketing abuses in the record.¹⁰⁶²

1061

While the Cooling-off Rule already applies to home hearing aid sales, the special problems of the hearing aid market require that the consumers at least receive the product before they can evaluate the purchase decision that was made under pressure. A three-day cooling-off period, beginning on the date of contract, simply cannot address the myriad problems in hearing aid sales -- either home or office.

1062

Indeed, the only demonstrated problem a trial will scarcely address is therapeutic claims. A consumer is unlikely to discover, within 30 days, that an aid provides no long-term therapeutic benefit. However, the record shows that these claims also contribute to a pressurized buying decision. To the extent that a consumer can evaluate the aid unhurriedly, the trial period at least partially addresses the harm from the claim. (This claim might be addressed separately in the rule, but staff has excluded it to keep the rule focused on the trial itself.)

IX. Evidence Concerning Definitions, Format, and Mechanics of Rule

This section examines evidence about the definitions in the Rule, the format of the Rule, and the mechanics of the proposed trial period. The Rule was initially proposed in 1974; the 1974 "Proposed Rule" appears in Appendix A-3. The 1978 staff report offered a "Recommended Rule," which appears in Appendix A-2. Following a post-record comment period in which over 500 comments were received, the original staff proposed a Revised Rule in 1979, which appears in Appendix A-1.

The current proposal follows, and is built upon the 1979 proposal. It is re-numbered, but specifies the section numbers contemplated in the 1978 version in parenthesis.

1982 PROPOSED RULE
(RE-NUMBERED, WITH NUMBERS FROM 1978 VERSION IN PARENTHESIS)

§ 440.0 [New] Unfair or Deceptive Acts or Practices

Following is a list of unfair or deceptive acts or practices which the Federal Trade Commission has found in the hearing aid industry:

- (1) Misrepresentations about the ability of a hearing aid to enable users to hear, including misrepresentations about the quality of sound produced by an aid; misrepresentations that an aid is certain to correct hearing loss; misrepresentations that an aid is individually designed to correct each user's hearing loss; misrepresentations that sounds heard through a master hearing aid during testing are the same as those which will be heard through a regular hearing aid; misrepresentations that an aid will eliminate background noise; misrepresentations that an aid has new or unique features; misrepresentations that a CROS aid enables users to hear with a dead ear; claims about telephone options which are misrepresentations because they fail to disclose that the aids will not work on all telephones; and claims about bone conduction aids which are misrepresentations because they fail to disclose that the aids are only advised for a small percentage of consumers.
- (2) Misrepresentations about the therapeutic quality of hearing aids.
- (3) Claims which are misrepresentations because they disclaim or fail to disclose the dispenser's sales intent.
- (4) Misrepresentations about seller's expertise.
- (5) High-pressure sales tactics, which also embed sales pressure in a purported "scientific" presentation.
- (6) Failure to offer a trial period.

§ 440.1 [new] Violations of the Rule

The Commission has adopted this rule in order to prevent the unfair or deceptive acts or practices defined in section 440.0. It applies to the sale or rental of hearing aids to consumers, in or affecting commerce.

It is an unfair or deceptive act or practice, and a violation

of this rule, to fail to offer a trial period as required by the rule. If you offer a trial period and comply with Sections 440.3 and 440.5 through 440.12, you do not violate the rule.

§ 440.2 [§ 440.3] Penalties

The Federal Trade Commission Act sets forth the penalties for violating the rule. In general, this means that the Commission can sue dispensers who violate the rule in Federal District Court. Dispensers who the court finds to be in violation of the rule could be required to pay a civil penalty of up to \$10,000 to the U.S. Treasury for each violation. In appropriate cases, the Commission can also obtain an order from the court to require the dispenser to make redress to buyers.

§ 440.3 [§ 440.36] Trial period.

When you sell a hearing aid to a consumer or rent one to a consumer for more than 30 days, you must give him or her 30 days from the date of delivery to cancel the sale or rental, return the hearing aid, and get a refund. A "consumer" is the person who actually uses the aid. You must give the trial even if a third party is the "buyer" who pays for the aid.

The details of the refund policy appear in §440.6 and §440.7.

Do not mislead the consumer or buyer about the trial period, or keep a consumer from exercising it fully and freely.

§ 440.4 [new] Exception for identical aid.

You need not offer a trial where a consumer has previously purchased an identical aid, or rented or used an identical aid for at least 30 days. An identical aid must be of the same make and model.

§ 440.5 [§ 440.37] Notice on contract or receipt.

After [date one year from the effective date of the rule] include the following notice in each contract or receipt, for a sale or rental of over 30 days, covered by § 440.36:

30-DAY TRIAL PERIOD

You can get a full or partial refund if you return this aid within 30 days. The attached notice tells you how.

The notice must be printed in medium weight 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The heading must be printed in 12-point boldface.

The notice must be boxed in lines at least 2 points thick. It must be next to the space for the buyer's signature. If there is no signature space on a receipt, the notice must be on the front page.

If the oral sales presentation is principally in a language other than English, the notice must be in that other language. If the buyer's contract or receipt is in a language other than English, the notice must be in that other language. A notice in a foreign language, however, may be written and need not be printed.

§ 440.6 [§ 440.38] Separate notice.

- (a) At the time the buyer pays or promises to pay, give that person the following notice. If there is more than one buyer, give a copy to each of them. If the buyer is not the consumer who will actually wear the aid, give a separate notice to the consumer. Keep a signed copy for your files.

Your 30-Day Trial Period

What You Should Do.

You have a 30-day trial period. Your trial will end on _____ . To get a refund you can do one of these three things on or before this date.

- (1) Bring us the aid. Ask us for a receipt; OR
- (2) Send us the aid. Include a copy of the attached notice, or a note. Send it "Certified mail, Return Receipt Requested" and fully insure it. Be sure you get to the Post Office before closing time on the last day of the 30-day period; OR
- (3) If we tested you at your home and delivered or mailed the hearing aid to your home, you can send us the note or form without the aid, and ask us to pick it up. Then you must make it available to us in a reasonable manner. Ask for a receipt when we pick it up.

When you return the hearing aid, it must be in about the same condition as when you got it. We don't have to take it back if you damage it. But marks of normal wear and tear like scratches on the casing are OK. Defects that were in it when you got it are not your responsibility. You don't have to return the earmold and batteries.

If you don't return the hearing aid or make it available to us in a reasonable manner, or if you damaged the hearing aid, you will owe us the full price of the hearing aid.

If you bought or rented two hearing aids, you can return one or both.

What We Will Do. As soon as we get the hearing aid we will return your old hearing aid, if you traded it in. Within 30 days of the date you cancelled we will give you a refund. However, we will keep a cancellation fee. The fee will be \$ _____. This covers _____

_____. (Don't return the earmolds.) There will be no other charges.

Replacements. If you get a replacement aid for the one you return, we will give you another 30-day trial. But we can also charge you the cancellation fee for this trial.

Your other rights. If you bought or rented the hearing aid in your home, you have an additional right. You can cancel the sale or rental and get a full refund of all your money, with no cancellation charges, if you tell us within three business days from now. Check your contract or receipt for details.

If you have a problem with a refund, contact the Federal Trade Commission, Washington, D.C. 20580.

(Seller's Signature)

(Seller's Address)

Buyer's Acknowledgement: I have received a copy of this form.

I Want to Return My Hearing Aid

(Please fill in the date and check the proper boxes.)

Date _____

To _____
(Name and Address of Seller)

I've changed my mind about the hearing aid(s) I got from you. I want to return:

- The hearing aid for my right ear.
- The hearing aid for my left ear.
- A hearing aid for each ear.

Please send my refund.

- I am returning the hearing aid(s) along with this notice.
- You sold me the hearing aid(s) at home, and you delivered the hearing aid(s) to my home. Please pick it (them) up there.

(Buyer's Signature) _____

(Buyer's Address) _____

(b) The text of this notice must be printed in medium weight 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The headings must be printed in 12-point extra boldface.

(c) Before you give the buyer the notice,

- (1) Fill in the correct date after the words "your trial will end on." If you do not know exactly when the consumer will get the hearing aid(s) in usable condition, make sure the date is at least 30 days after the probable delivery date. It should not be a Saturday, Sunday, or holiday.

If unavoidable circumstances delay delivery, you can provide a new form when you deliver the aid. Fill in the date 30 days after the actual delivery date. Write the word "corrected" at the top of the page.

- (2) Fill in the cancellation charges. Maximum charges you can list are described in section 440.7. You may specify details of the charges on the blank lines.
- (3) Sign the form and fill in your address.

§ 440.7 [~~§440.40~~] Maximum cancellation fee.

You can deduct a cancellation charge for each hearing aid returned. The cancellation fee should not be higher than 10% of the purchase price of the aid or aids. You can also deduct any open charges for earlier rentals.

In addition you can deduct charges for custom earmolds and a 30-day supply of batteries, if the buyer got them. You cannot charge more than what you charge all buyers for them.

You can also deduct charges for any services you performed before the sale. You can only deduct charges for services if the buyer signs a form before the services are performed. The form should explain:

- the amount charged for each service
- the fact that these charges are not refundable upon cancellation
- the sentence "I read and signed this form before any services were provided." This sentence shall appear next to the space for the buyer's signature.

§ 440.8 [~~§ 440.45~~] Extra rights and extensions.

You can give extra rights. If you do so, make the proper changes

in all of the documents.

You can also extend the 30-day cancellation period. Even if you do extend the cancellation period, however, you must still allow the buyer to cancel within the first 30 days and pay cancellation charges no greater than those listed in section 440.7.

§ 440.9 [§ 440.46] Short rentals.

In rentals for 30 days or less, do not charge more than the total cancellation charges that would be allowed under section 440.7, if you sold the aid.

At the time the buyer pays or signs, give the buyer a form or contract that contains these three items:

- your full name and address
- the dates when the rental period begins and ends
- all rental charges.

§ 440.10 [§ 440.47] No waivers.

Do not include in any contract or receipt a waiver of any right granted to the buyer by this Regulation. Also, do not include any waiver of notice, hearing, or trial.

§ 440.11 [§ 440.49] Requirements concerning employees.

If you have any employees, agents, salespersons, and representatives who deal with your customers, give them each a copy of this regulation. Get a signed, dated receipt. If one of them breaks a rule, both of you may face the penalties set out in Section 440.3.

§ 440.12 [§ 440.50] Recordkeeping.

Keep the following records:

- copies of all sale or rental contracts
- copies of a "Your 30-Day Trial period" notice signed by each buyer.
- all "I Want to Return my Hearing Aid" forms or other cancellation notices returned by buyers.
- copies of the disclosure forms for pre-sale services required by section 440.7
- the receipts required by section 440.11.

Keep these records at least three years. Federal Trade Commission staff members can check these records at any time, but they must give you reasonable notice first.

§ 440.13 [§ 440.51] Other laws, rules and orders on hearing aids.

- (a) These rules do not replace outstanding FTC Cease and Desist Orders unless the orders themselves state otherwise. If a Cease and Desist Order applies to you and it differs from the rules given here, you can petition to amend the order.
- (b) Current state laws and local regulations in this field are changed as follows:
 - (1) Parts of those laws and regulations that grant consumers at least the same rights stay in force. So do parts that fix fines and duties for you if you break one of the rules given here.
 - (2) Parts that do not grant at least the same rights to consumers are replaced.
 - (3) Parts that are not replaced stay in force.
 - (4) The cancellation notice required by this Regulation must be used in all hearing aid sales or rentals. However, if a state law or local regulation grants greater rights to buyers, the FTC notice can be changed to reflect those greater rights.
- (c) These rules do not supersede the provisions of the Federal Trade Commission's Trade Regulation Rule Concerning a Cooling-Off Period for Door-to-Door Sales, 16 C.F.R. Part 429.

§ 440.14 [new] FDA Regulations Concerning Returned Hearing Aids.

According to the Food and Drug Administration Regulations, if an aid has been used or rebuilt, you must disclose this on a tag attached to the aid, and on the container. An aid is used if it has been worn for any period of time by a user. There is one exception. An aid is not used if it was only worn as part of an evaluation, "in the presence of the dispenser or a professional selected by the dispenser to assist the buyer in making . . . an evaluation."

§ 440.15 [§ 440.52] Severability.

The provisions of this Regulation are severable. If any part of it is held invalid in any way, the rest of the Regulation will stay in force.

The discussion which follows contains a section-by-section analysis of the rule. The discussion analyzes comments made about both the 1974 and 1978 proposals.

For purposes of citation, commentators have been divided into categories. These are: Audiologists (A); Physicians (MD); Hearing Aid Sellers (S); Consumers (C); Manufacturers (M); National Hearing Aid Society (NHAS), which represents sellers; Hearing Industries Association (HIA), which represents manufacturers [name subsequently changed to Hearing Aid Industry Conference (HAIC)]; American Speech and Hearing Association (ASHA), which represents audiologists; and

National Council of Senior Citizens (NCSC), which represents elderly consumers.¹⁰⁶³

1063 Other organizations which commented are labelled as follows:

ACRONYMS

A: Audiologist
ACO: American Council of Otolaryngology
ADA: Academy of Dispensing Audiologists
ASHA: American Speech and Hearing Association:
Comment Number 450
Asst. D.A.: Assistant District Attorney
C: Hearing Aid Consumer
CAIS: Consumer Assistance and Information Service
ADHA: Chief Legal Officer, California Department of
Health Services
CRLA: California Rural Legal Assistance
EE: Electrical Engineer
FCA: Federal Council on the Aging
Ga.SHA: Georgia Speech and Hearing Association
GP: General Public
H: Director or Manager of Hospital Audiology or
Hearing Aid Program
HAIC: Hearing Aid Industry Conference (previously
the Hearing Industries Association)
HIA: Hearing Industries Association: Comment
Number 432
IBOL: Chief, Idaho Bureau of Occupational Licenses
ISPIRG: Iowa Student Public Interest Research Group
M: Manufacturer
Mass.HAS: Massachusetts Hearing Aid Society
MD: Medical Doctor
MPIRG: Minnesota Public Interest Research Group
NCSC: National Council of Senior Citizens
NHA: Nursing Home Administrator
NHAS: National Hearing Aid Society: Comment Number
431
NIRE: National Institute for Rehabilitation
Engineering
NRTA/AARP: National Returned Teachers Association/
American Association of Retired Persons
NYDS: New York Department of State
NYGHAD: New York Guild of Hearing Aid Dealers
NYSHAS: New York State Hearing Aid Society
NYSSHA: New York State Speech and Hearing Association
OCL: Oregon Consumer League

(CONTINUED)

All written comments received during the comment period were given a comment number before being placed in Section IX of the record. Comments are identified by an acronym as well as this number. For example, an audiologist who sent in a comment numbered by staff as comment number 234 will be referenced as A-234. An exception to this system occurs when NHAS, HIA, or ASHA is the commentator; for these three submissions, the page number rather than

1063 (FOOTNOTE CONTINUED)

Oh.HADFLB: Ohio Hearing Aid Dealers and Fitters
Licensing Board
OUT: Organization for the Use of the Telephone
P: College or University Professor in a
discipline related to hearing, such as
audiology or otolaryngology
Pa.St.Rep.: Representative, Pennsylvania State Legislature
PDDDC: Director, Division of Drugs, Devices and
Cosmetics, Pennsylvania Department of Health
PE: Professional Engineer
PGCHD: Chief, Speech and Audiology, Prince George's
County, Maryland Health Department
PIRG: Public Interest Research Group
PIRGIM: Public Interest Research Group in Michigan
PMSLHA: President, Minnesota Speech-Lanugage-Hearing
Association
POHAS: President, Ohio Hearing Aid Society
RPAG: Retired Professional Action Group
S: Hearing Aid Seller
SCDCA: South Carolina Department of Consumer Affairs
SNHADA: Secretary, Nevada Hearing Aid Dealers
Association
SLP: Speech-Language Pathologist
T.Ala.: Alabama State Treasurer; formerly the
Director of the Alabama Consumer Protection
Agency
Tenn.HAS: Tennessee Hearing Aid Society
Tex.St.Rep.: Representative, Texas State Legislature
VA: Veterans Administration
VRC: Vocational Rehabilitation Counselor
WAGHOH: Washington Area Group for the Hard of Hearing
Wash.HAS: Washington Hearing Aid Society
Wis.HAS: Wisconsin Hearing Aid Society

the comment number is used, e.g., NHAS(308).

The discussion analyzes all sections relating to trials, and does not address either advertising prohibitions in the prior rule, or definitions which pertained only to these section.¹⁰⁶⁴

A. Sections 440.0, 440.1: Specification of Unfair or Deceptive Acts or Practices and Description of Violations of the Rule.

Section 440.0 sets out the unfair and deceptive acts or practices which constitute the basis for the rule. Section 440.1 specifies that hearing aid sellers violate the rule if, and only if, they fail to offer the trial period specified by the rule. Thus, for example, sellers who misrepresent their expertise, a deceptive practice specified in 440.0(4), do not violate the rule, so long as they offer the required trial period.¹⁰⁶⁵

B. Section 440.2: Penalties.

Section 440.2 sets out the statutory penalties for rule violations. It is more specific than previous language proposed, which merely referred to potential for heavy fines.

1064 § 440.5, for example, defined "say or imply" and "explain." The rule no longer prohibits claims, expressed or implied. See n.1067; Introduction, section C.3.f.4. , supra. It does require an "explanation" (of trial periods) but prescribes the precise language of the explanation. Hence, these definitions are no longer needed.

1065 While they do not violate the rule, however, they do violate Section 5.

C. Section 440.3: Trial Period.

Section 440.3 specifies the basic requirement for a trial period. Most of the mechanical aspects of the trial requirement appear in the consumer notice, specified by Section 440.6. To simplify the text of the rule, those details are not repeated in Section 440.3.

Section 440.3 does forbid dispensers from misleading buyers about trials, or keeping buyers from exercising their trials fully or freely. Several commentators were concerned that the provision would prevent dispensers from doing anything to encourage buyers to come for counseling before returning a hearing aid.¹⁰⁶⁶ However, staff believes that this provision is important and should be retained. Dispensers can encourage buyers to adjust to an aid in a manner consistent with the provision. They simply cannot encourage a reluctant buyer to keep an aid beyond the trial period --unless they offer to extend the trial period.¹⁰⁶⁷

Section 440.3 also defines who must give a trial, and who is entitled to a trial. All consumers are entitled to get trials --

1066 See Mynders, TR 11589; McPherson, TR 5130-33; see also HAIC, R2/56.

1067 Staff does recommend one change, however. The original rule stated, "do not do, say, or imply" anything to mislead the consumer about trials. The terms "say" and "imply" were defined in § 440.4 of the 1978 text. In staff's view, the use of the terms "say or imply" add little to the rule, which now says "do not mislead the buyer about this right." Rather than use and define the terms (which previously appeared throughout the rule), staff has simply dropped the language.

even if a third party pays for their aid. Anyone who sells an aid to a consumer, or rents to a consumer for more than 30 days, must give a trial.

Prior versions of the rule applied to a wider range of "sellers". The 1975 proposal said that all "sellers" were covered, and broadly defined "seller."¹⁰⁶⁸ The 1978 text replaced the definition of "seller" with a similarly broad section entitled "Who is Covered." It stated that the rule "applies to you if you rent or sell [hearing aids], or if you offer to do so, whether for profit or not."

The current recommendation is substantially narrower; it only applies to those who rent or sell aids "to consumers," and it does not set out a detailed list of who is covered.¹⁰⁶⁹ This is because the current version of the rule only provides for a trial period, and other "sellers," such as manufacturers,¹⁰⁷⁰ need not offer

1068 Proposed Rule § 440.2(c).

1069 The list led to comments suggesting, e.g., that "trainees" be added, A-106; and that the term "salesperson" be excluded, NHAS (308).

1070 Under previous proposals, there was substantial question as to whether manufacturers should be covered. Several stated that they should not be covered by the entire rule. See Staab, TR 7037; Saad, R3/2184; Stultz, R3/836-37; NHAS, R2/96, R3/3142; Maico, R2/127; Kleiman, TR 6907; Campagna, TR 2605-06; HAIC, R2/44, R3/3646; Radioear, R2/28, 32a; Zenith R2/D2ipl, R3/3393-94; Bowen, HX35/9-10; ASHA R10/1700. Zenith said that they should be completely excluded, Zenith, R3/3091. Two commentators said they should not be required to offer trials. ASHA, R10/1700, Stultz, R3/836-37.

trials.¹⁰⁷¹

The 1975 text also provided for who gets a trial. The rule defined a "buyer" as

Any person, partnership, corporation, or association assuming a financial obligation in connection with a "sale," either for its personal use or for the use of a person on whose behalf the financial obligation is assumed.¹⁰⁷²

A "buyer" was entitled to a trial. All of the comments on this definition centered around issues raised when the "buyer" is not the user. Comments called the definition "unreasonably broad, vague and ambiguous"¹⁰⁷³ and said that the definition could be interpreted to include, for example, creditors from which the hearing aid user has borrowed money to finance the purchase.¹⁰⁷⁴

The 1978 text deleted the definition of "buyer" in the

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- 1071 Note, however, that Dr. Baesemann, an economist who testified for industry, said manufacturers would bear much of the cost in any event. See Section VIII.C.
- 1072 Proposed Rule § 440.2(d).
- 1073 HAIC R2/45.
- 1074 Id., R3/3647-48, R2/45; NHAS R3/3243, R2/96; Zenith, R2/9, R3/3091-92. The Washington Area Group for the Hard of Hearing stated their concerns that the definition of "buyer" creates the potential for abuse of nursing home patients whose finances are controlled by the home's administrators. Washington Area Group for the Hard of Hearing, R10/244. They recommended that the Rule state that when an institution acts as a financial agent for an individual the user be designated as the "buyer". Where a patient cannot act for himself, as in the case of senile patient, they recommended that a family member or close friend be authorized as the "buyer". Id. see Paschell, TR 858-60. One commentator was concerned that the definition of "buyer" would not include federal and state agencies who purchase hearing aids. Brakebill, TR 1280-81, 1333.

Recommended Rule.¹⁰⁷⁵ It provided that the right to cancel had to be given (and disclosed) to the "consumer";¹⁰⁷⁶ the separate notice must be given to the "one(s) who pay(s)." Staff now recommends that trials be given to consumers and that "consumer" be defined as the "person who uses the aid". The notice has to be given to the consumer and, where a third party pays, to that third party.

D. Section 440.4: Exception for Identical Aid.

The rule proposed in 1975 contained two exemptions to the requirement that dispensers offer trials: one exempted sales of identical aids sold to previous users, and the other exempted sales by a dispenser where a physician or audiologist recommended a specific aid.

The previous recommended rules, from 1978 and 1979, did not include either exemption. The current staff recommends that the Commission include an identical aid exemption, but not an exemption for aids recommended by a third party.

1. Identical Replacement Aids Exemption, as Now Recommended by Staff

The Proposed Rule provided that the dispenser would not have to grant a trial period in the sale of an identical replacement aid of a damaged or worn out hearing aid.¹⁰⁷⁷ Virtually everyone who

1075 Recommended Rule § 440.38.

1076 Recommended Rule § 440.36.

1077 Proposed Rule § 440.4(i)(2).

commented on this section opposed the specific exemption proposed, either as too broad or too narrow. Staff recommends an "identical replacement exemption" somewhat different than was initially proposed.¹⁰⁷⁸

The hearing aid industry objected that the original exemption did not go far enough.¹⁰⁷⁹ NHAS and HAIC expressed concern that the exemption might deter sales of different or technologically improved aids, even if warranted.¹⁰⁸⁰ Both recommended that the sale of all replacement aids be exempted from the trial period.¹⁰⁸¹

Most commentators, however, felt the exemption was already too broad.¹⁰⁸² They indicated that due to certain product variance factors, an "identical" aid may in fact function quite differently from the aid it is replacing.¹⁰⁸³ Dr. Roger Kasten, a clinical

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- 1078 Critics included the International Association of Parents of the Deaf, Woodward, TR 4142; the Ohio Division of Consumer Protection, R8/2927; the Illinois Department of Health (Shattuck), TR 6777; and numerous audiologists opposed the exemption. See Kasten, R5/1434; Rose, R5/709; Warren, R8/5313; Brewer, TR 3916-17; Shannon, TR 1865; Urban, TR 1814; Franks, R10/6518; Syfert, R10/818-19; Barwell, TR 5168.
- 1079 See NHAS, R2/117; HAIC, R2/54; see also Zenith, R3/3406.
- 1080 See NHAS, R3/3280; HAIC, R2/54. NHAS stated, "the exemption will deter persons from recommending improved models, to the detriment of the hearing impaired." NHAS, R3/3280.
- 1081 NHAS, R2/117; HAIC, R2/54; see Zenith, R3/3104.
- 1082 See generally, ASHA, R10/1754; Bowen, HX35/5-6.
- 1083 See ASHA, R13/3632; Wilber, TR 1350; Woodard, TR 4142; Eichelberger, TR 8674; Ruben, TR 3976; Shattuck, TR 6778; Griesel, TR 9408-09; Warren, R8/5813; Graham, S., R8/5275; Kasten, R5/1434; RPAG, R8/2747-48; Traynor, R8/6804.

audiologist, stated:

I feel it is important that the proposed rule not exempt sellers when a so-called identical hearing aid is sold to replace a given model. At the present time there are no standards detailing product uniformity and the buyer actually has no assurance that the identical model will be similar to the one it is replacing. Previously published research conducted by myself has demonstrated the high variability that can be seen within models for hearing aids.¹⁰⁸⁴

ASHA agreed,¹⁰⁸⁵ and others also raised the question of what would constitute an "identical" aid.¹⁰⁸⁶ Dr. Dorothy Shannon, Chief of the Speech and Hearing Section of Sinai Hospital in Baltimore, Maryland stated:

This term [identical] seems to imply an aid of the same make and model as the original. Since that definition is not stated, it may lead to problems if the same make and model is not available and term is extended to encompass aids of similar characteristics. This might include a new model of an outdated aid, or an aid whose frequency response is similar to the replaced, whether it is made by the same or different manufacturer. If these exceptions are allowed, it would be possible to justify almost any new purchase by a hearing aid user as a "replacement" which is exempt from the right to cancel.¹⁰⁸⁷

Another commentor wondered whether an aid that was internally identical to the one being replaced but had different controls would

1084 Kasten, R5/1434.

1085 ASHA, R10/1754.

1086 See Shannon, TR 1864-65, R10/120-21; Kojis, TR 2073; Krebs, TR 11837.

1087 Shannon, TR 1865.

be considered "identical".¹⁰⁸⁸ NHAS noted that due to technological changes, fitting a hearing aid user with an "identical" aid may be impossible.¹⁰⁸⁹ Because of these potential problems, it was suggested that the definition of "identical" be more specific.¹⁰⁹⁰ Staff recommends a somewhat more specific definition, requiring that the aid be of the same make and model. Staff recognizes the complex issues raised in these comments, some of which are not addressed by this definition. However, FDA now requires that accurate specification sheets accompany every aid. This has substantially addressed the problem that nominally identical aids may differ substantially.¹⁰⁹¹ While problems with the standard may still remain, staff recommends that purchasers of "identical replacements" should not be covered by the rule. We also note that the exemption may encourage the use of returned aids as "demonstrators;" consumers could be given a trial with a demonstrator

1088 Kojis, TR 2073.

1089 NHAS, R3/3280.

1090 Shannon, R10/120. One commentor, arguing against the exemption, noted that no aid can be "identical" to the one it is replacing, if for no other reason than one is old and used while the other is new and untried, and hence, an adjustment and trial period may be necessary. Rassi, TR 5733.

1091 A manufacturer with poor quality control can create a separate specification sheet for each aid. However, staff has rejected a definition of "identical" which requires identical specification sheets. Manufacturers with good quality control may provide individual specification sheets as a service to dealers. This practice would be discouraged by a narrow definition of "identical" which required identical specification sheets.

aid and, if satisfied, could be sold an identical aid without trials. To ensure that the exemption applies for a demonstrator aid, we have eliminated previous language requiring the new aid be a replacement for a "damaged or worn out" hearing aid. The language now recommended would specifically include a replacement for an aid which the consumer had rented for at least 30 days. This would lessen the burden the rule imposes on dispensers.

2. Proposed Exemption for Aids Sold Pursuant to an Audiologist's or Physician's Recommendation, Not Recommended by Staff

The Proposed Rule contained a provision which would have exempted the dispenser from offering a trial if the buyer had a written recommendation of a physician or audiologist for a specific hearing aid.¹⁰⁹²

Very few witnesses supported this provision¹⁰⁹³, and the current staff does not recommend it. Opposition to this exemption was broad-based and almost universal.¹⁰⁹⁴

1092 Proposed Rule § 440.4(i)(1).

1093 See Byrne, R8/6455; Byrne and Stockler, R10/3195-96; Jerger, R8/5338; Meci, R3/1239; Simms, R3/126.

1094 See Barwell, TR 5168-69; Beiter, R10/5267, TR 9034, 9068-69; Benenson, TR 888; Bowen (NCLD), HX35/5-6; Brewer, R10/271, TR 3916; Eichelberger, TR 8673-74; Epstein, TR 4593; Fennema, TR 1796; Eglit, HX93/351; Franks, R10/6518; NCSC/Hamburger, TR 5349; Harford, R5/844, 851-52; Ill. Dept. of Health, R10/5471; Jeffries, R10/5364, TR 5590; Kasten, R8/1447; Lankford, TR 8010; Levy and Tuttle, TR 11655; Madell, R10/5584, R8/4343; McPherson, TR 5130; Marcus, TR 5524; Mass. Eye and Ear Infirmary, R5/1163; Masticola, TR 8621; Mowry, R13/1122; Resnick, TR 5424,

(CONTINUED)

There were a variety of reasons for this opposition. Many objected that the premise behind the exemption was that hearing aids can be "prescribed."¹⁰⁹⁵ However, physicians and audiologists cannot prescribe aids, and cannot even recommend them with anywhere near the precision that, for example, eyeglasses can be "prescribed."¹⁰⁹⁶

Several witnesses felt that the exemption would unfairly penalize consumers who sought a physician's or audiologist's advice,¹⁰⁹⁷ and discourage such evaluations.¹⁰⁹⁸ It was also stated that the

1094 (FOOTNOTE CONTINUED)

R10/6495; Shannon, TR 1863, R10/120; Silverman, R8/7326; Stein, R10/6306; Stephens, TR 4995; Woodward (IAPD), TR 4141-42; AARP, R10/878; ASHA, R10/1751; NHAS, R3/3568-69; Marlin, TR 4551; Graham, S., R8/5275; Brakebill, TR 1283; Loavenbruck, TR 1552-53; Knox, R3/1447; Miragliotta, R3/1056; Pitts, R3/192; Griesel, TR 9384-85; McCurdy, R8/4404; Schein, TR 241; Dalton, TR 8724; Gardner, R5/1564; Ruben, TR 3976; Lentz, R5/1291; Brickfield, TR 1432; R10/878; Shattuck, TR 6777, R10/5471; Chasen, R7/522; Nygren, R8/4940.

1095 See Benenson, TR 888; Brakebill, TR 1292; Elia, TR 7492; Gerstman, TR 2406-07; Stephens, R10/109; Ohio Div. of Con. Prot., R8/2927; James Payne, TR 2142, HX39/9; NHAS, R2/115, R3/3268-69; 3577; Glasgow, R3/1391; Beltone, R3/53; Ruben, TR 3976; Loavenbruck, TR 1553; Woodard (IAPD), TR 4141. NHAS said, "if the Commission is relying on the inherent nature of hearing loss and/or hearing aids, there can be no exceptions for the consumers' right to a 30-day trial. NHAS, R3/3173. See also Id., R3/3577.

1096 See Section IV.A.4. See also NHAS, R3/3516.

1097 See ASHA, R10/1751; Zenith, R3/3103; Shannon, TR 1863; Ill. Dept. of Pub. Health, R10/5471; Ill. Speech and Hearing Association, R10/4907.

1098 See Dalton, R10/5206, TR 8724; ASHA, R10/1751; Menzel,

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exemption might discourage audiologists and physicians from making specific recommendations for hearing aids.¹⁰⁹⁹

NHAS also suggested that the proposed exemption might encourage "unlawful schemes in order to obtain the benefit of continuing referrals."¹¹⁰⁰ Various persons commenting on this exemption expressed a similar concern about kickbacks and similar schemes.¹¹⁰¹

NHAS and other members of the hearing aid industry, expressed concern that it would be inequitable to require hearing aid dealers to take back aids that were recommended by someone else.¹¹⁰² It was suggested that audiologists or physicians who recommend specific hearing aids that are later returned should be required to refund a part of their professional fees.¹¹⁰³ However, others noted that

1098 (FOOTNOTE CONTINUED)

R8/4201; Colongo, R3/203; Shattuck, TR 6777; Nygren, R8/4940; Ill. Speech and Hearing Assoc., R10/4907.

1099 Nygren, R8/4940.

1100 NHAS, R3/3578.

1101 See Brakebill, TR 1283, R8/4438; Graham, R8/5276; NHAS, R3/3578-79; Rose, R5/709; Palmquist, R8/3513; Samole, TR 6709; Shuford, R10/65; RPAG, R8/2635; ASHA, R10/1777; Shattuck, TR 6777.

1102 See NHAS, R3/3275-76, 3279-80; see also Byrne and Stockler, R10/3198.

1103 See NHAS, R3/3275-76, 3279-80; Skadegard, R3/176; Byrne and Elliott, R10/3183.

the physician or audiologist sells a service rather than a product;¹¹⁰⁴ indeed, the rule now recommended would allow anyone who provided a service, including a dispenser, with a means to retain charges for the service.

Staff notes that dispensers could verify that a recommended aid works, if they have doubt about a recommendation. They need not rely entirely on the audiologist or physician.

E. Sections 440.5 and 440.6: Notice Provisions and Mechanics of Trial Periods

1. Notice

The original rule would have required that notice be given in three ways.

a. Oral Explanation Not Recommended

Both the Proposed and Recommended Rules would have required the dispenser to orally apprise the buyer of any mandatory trial period.¹¹⁰⁵ The Recommended Rule would have excused a dispenser from this requirement if it were physically impossible to carry it out.¹¹⁰⁶ In light of possible enforcement difficulties, however,

1104 Bowen (NCLD), TR 1927-28.

1105 Proposed Rule § 440.4(e); Recommended Rule § 440.25

1106 Recommended Rule § 440.48. HAIC argued that oral disclosure was unnecessary and redundant in light of the written disclosures required. HAIC, R2/55. It also expressed concern that enforcement of this provision would put the dispenser's word against the consumer's word. *Id.* R2/56. NHAS said the physical impairment exclusion in the

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staff recommends that this oral disclosure requirement be eliminated.

b. Notice on Contract

Prior versions of the rule required a precise notice of the trial on the contract or receipt, and staff again recommends this notice. Both set out the exact language required and also set out a required format (e.g., type size).¹¹⁰⁷

The 1975 text would have required the following statement:

THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE OR RENTAL FOR ANY REASON AT ANY TIME PRIOR TO MIDNIGHT OF THE 30TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID(S). SEE THE ATTACHED "NOTICE OF BUYER'S RIGHT TO CANCEL" FOR AN EXPLANATION OF THIS RIGHT.¹¹⁰⁸

The 1978 rule also required a notice to the buyer, in plain English, that you have "30 days to change your mind."¹¹⁰⁹ Both rules set out requirements as to the notice's type size.¹¹¹⁰

Several post-record comments stated that the 1978 notice was too simplistic.¹¹¹¹ Some commentators recommended that sellers be

1106 (FOOTNOTE CONTINUED)

Recommended Rule raised the question of who would determine that a seller is physically unable to make the oral disclosure. NHAS (349).

1107 Proposed Rule § 440.4(a); Recommended Rule § 440.37.

1108 Proposed rule § 440.4(a).

1109 Recommended Rule § 440.37.

1110 Proposed Rule § 440.4(a); Recommended Rule § 440.37.

1111 (S,A)-191; (S)-303; (S,A)-396; S-330; M-378; S-442.

permitted to compose their own notices.¹¹¹²

Staff believes that a prescribed notice on the contract is valuable. Since the consumer must receive a copy of the contract, moreover, it makes the rule more self-enforcing, assuring that there will be some access to information about the trial period. Moreover, the rule now contains a provision which applies where sales are not conducted in English: it requires the notice to be written or printed in the language of the transaction. Thus, this notice also insures that persons who cannot speak English will learn of the trial.

However, in light of comments objecting to the language used,¹¹¹³ staff has re-drafted the disclosure.

Finally, because there will be costs associated with the use of new contracts, staff recommends that implementation of this provision be delayed for a year, during which dispensers may continue to use existing contract forms.

c. Separate Consumer Notice

Section 440.4(b) of the Proposed Rule required dispensers to provide buyers with two copies of a detailed separate notice at the time the buyer assumed any financial obligation. This separate notice contained details about the trial period, including a standard form which the buyer could use to notify the dispenser of a cancellation. The 1978 text had a similar provision.

1112 S-447; S-283; S-313; S-393.

1113 See n. 1117-1119.

Staff believes that a separate notice setting out details of the trial period is needed, although we recommend modifications. The notice is intended to do two things: first to insure that the consumer knows about the trial, and second, to provide details of the trial if the consumer chooses to cancel.

While many persons considered the consumer notice, as originally proposed, to be both clear and adequate,¹¹¹⁴ others criticized it as being too difficult for many hearing-impaired consumers to comprehend.¹¹¹⁵ The 1978 text addressed this problem through its Plain English format, discussed generally in section IX.N. Specific comments on the 1978 text, however, asserted that it was still too complicated.¹¹¹⁶

There was also substantial comment on specific phrases, and the general tone, of the texts. Numerous comments criticized the alleged negative tone of each draft separate consumer notice.¹¹¹⁷ They asserted that the notice implied that aids were likely to be

1114 See Harford, R5/852; Kasten, R5/1434; Franks, R10/6518; Beiter, R10/5266; Ohio Div. C.P., R8/2927.

1115 See Liversidge, TR 1085; James Payne, TR 2143; Bowen, TR 1906-08, 1919, 1938-39; Jeffries, TR 5590; Tobin, TR 4091-93; Woodard, TR 4141; NHAS, R2/115. The New York League for the Hard of Hearing, in a test utilizing 50 volunteers, found that only 30% understood the notice's "effective content." See Madell, TR 5858-59, R10/5583, 5587-89; Sullivan, R8/8569-70.

1116 S-292; S-242; S-430; S-221; S-304; S-329; C-418; S-373.

1117 Staab, TR 7038; see Stallons, TR 7864-65; Curran, TR 10894.

unsatisfactory¹¹¹⁸ and that the dispenser was dishonest.¹¹¹⁹ Several persons said that this language would deter purchases¹¹²⁰ and impair consumer motivation.¹¹²¹ Staff has endeavored to be sensitive to these issues in drafting the notice, even though we do not accept all of the criticisms in the current proposal.

In the 1975 text, for example, much of the specific criticism focused on the phrase "right to cancel." The record indicates that other names are generally used with existing arrangements.¹¹²² There was specific testimony by some witnesses that the term "right to cancel" was negative but other words were not.¹¹²³ NHAS preferred the term "trial,"¹¹²⁴ although even this word was

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- 1118 Staab, TR 7038; see Payne, John, TR 9232; HAIC, R3/3681; Zenneth, R2/10.
- 1119 See Krebs, TR 11831, 11855; Payne, James, TR 2143; Fennema, TR 1773, 1781; Leale, R3/1614; Dahl, R3/2792; Beltone, R3/3439; Zenith, R2/10; S-386; (Wis. HAS-248), A-250; S-423; S-257; S-352; S-427.
- 1120 Krebs, TR 11836, 11838, 11854-55; see Staab, TR 7038; HAIC, R2/57. But see Freeman, R8/4046; Link, TR 1144-46; S-221; S-419; S-426; S-439; S-442; S-187; S-382; S-385; (Wis. HAS)-248.
- 1121 Payne, James, TR 2143-44; S-242; S-382; HAI-II (239); M-236(40-41); (S,A)-191; M-378; see also S-430; S-428; S-227; S-44; S-299; S-329; S-257; S-366; M-378; S-447; M-236 (40-41). See Beltone, R3/3443. See generally Section III.D .
- 1122 See Section VI.D., supra.
- 1123 Scott, TR 2375 (favored "right to return" or "trial privilege"); Oberhand, TR 3088-89 (favored "rental option").
- 1124 Fortner, TR 2856.

challenged as negative in connotation.¹¹²⁵ While the 1978 notice used neither term (referring instead to the opportunity to "change your mind"), criticism of the 1978 notice persuades staff that "trial period" is the best term to use.

Some comments on the 1978 notice also focused on other phrases. Some criticized the language, "If you damage the hearing aid, we can sue you for the fair market value,"¹¹²⁶ and staff has dropped this language. Several sellers criticized the advice that the consumer contact a lawyer, stating that it would undermine reliance on the right to cancel, was an unnecessary "scare tactic" and will unreasonably "bait litigation." Staff agrees that this language may be unduly strong, and therefore has dropped it.¹¹²⁷

In recommending these revisions, staff has carefully considered the criticism as to the tone of the notice. The correct tone should strike a balance. If the notice makes consumers more wary, they are more likely to comparison shop and take other rational market precautions; in staff's view, this is desirable. However, even though staff believes that every sale without a trial is unfair, this certainly does not mean that every dispenser who does not offer trials is dishonest. The text obviously should not imply this, and, in staff's view, it does not. Moreover, staff agrees that language

1125 Fechheimer, TR 7007; Keyes, TR 10711; Tremmel, TR 8371; Krebs, TR 11845.

1126 See M-378; S-447; S-220.

1127 S-227; S-430; (S,EE)-435; S-366.

of the text should not encourage frivolous cancellations. Although the record indicates that few, if any, cancellations are frivolous, staff has nevertheless reviewed the text with this concern in mind.

Staff's current proposal incorporates certain changes already made in the 1979 text, and further changes appear in response to general and specific comments.

One other change has been made concerning the notice. The notice has a number of blanks that the seller must fill in (indicating, for example, the actual or probable delivery date).¹¹²⁸ HAIC questioned whether a seller can reasonably make such estimates.¹¹²⁹ Staff agrees this is a problem, and recommends that the dispenser be allowed to revise an estimate which proves incorrect.

2. Buyer's Responsibilities in Cancelling

a. Giving Notice and Returning Aid

The 1975 text and the 1978 text both specify how the buyer can cancel.¹¹³⁰ In both texts, the details appear in the separate consumer notice. The steps are similar. First, the buyer had to give written notice. The cancellation notice, which could be personally delivered or mailed, had to be received or postmarked by

1128 See Proposed Rule §§ 440.4(b) and (c).

1129 HAIC, R2/60.

1130 Proposed Rule § 440.4(b); Recommended Rule § 440.38. In the Recommended Rule, the term "proper cancellation" is further defined in § 440.39.

the deadline. The buyer then had 7 days to return the aid or mail it back;¹¹³¹ if the seller had delivered the aid, however, the buyer could request that it be picked up at the same place.¹¹³²

Several commentators supported the use of written cancellations to avoid misunderstandings and to provide clear evidence of the cancellation.¹¹³³ However, other commentators suggested that there would be no misunderstanding if the buyer just returned the aid and obtained a receipt.¹¹³⁴ Several commentators said that for some consumers writing a cancellation notice might be difficult or impossible.¹¹³⁵ Staff believes that written notice serves a valuable function, but agrees that it is unnecessary where a consumer personally returns the aid and gets a dated receipt. The dated receipt will establish the date when the seller's 30 day period to

1131 The separate notice advised the buyer either to get a receipt for the cancellation notice if he personally delivered it, or to mail it by "certified mail, return receipt requested. Id.

1132 Id. If the buyer elects to have the aid picked up at his home, the dispenser is required to do so within 20 days. The buyer is obligated to make it available to him. If the dispenser fails to claim the aid within the 20-day period, the dispenser forfeits the aid. Id.

1133 See Selger, R5/815; McGargill, R5/51; Suty, R5/1257; Kasten, R5/1439; Wright, R5/1197; Moyer, R4/181; Michaelis R5/945; Fariss, R5/320; Barrager, R5/1269; Ainsworth, R5/753; Dolowitz, R8/1615; Byrne, R10/3127, 3260, R8/6427.

1134 See ASHA, R10/1736; Fennema, R3/215; Lovering, R5/1054.

1135 Galleher, R5/43. For example, some cited users who could not read the language of its notice. Stroup, R5/59; Madell, TR 5866-67.

return payment begins.¹¹³⁶

Several comments addressed the Rule's provisions for return of the aid. Two commentators stated that consumers should be required to return their hearing aids at the same time they submit their cancellation notices.¹¹³⁷ Staff agrees. It was suggested that if consumers choose to return their aids by mail, they should be required to insure the aids in order to prevent controversy if the aid is damaged or lost in the mails.¹¹³⁸ Staff again agrees.

One dispenser stated it was unreasonable to require dispensers to pick up cancelled hearing aids at the buyer's home.¹¹³⁹ Staff believes there is a problem, because there is a possibility of limited mobility. The customer might be unable to go the dealer's place of business, or even reach the post office; and the consumer must go to the post office to adequately insure the aid. However, this problem would be adequately addressed if the provision only covered users who had aids delivered to them and were tested at home. Staff proposes limiting the provision accordingly.

b. Condition of the Aid

1136 See Section IX.E.3.

1137 (S,A)-191; (S,EE)-435. It was stated that this will reduce the chance that aids will be lost and also reduce the work that consumers must perform with respect to cancellations.
Id.

1138 Knox, R3/1445; Staab, TR 7040.

1139 (S,EE)-435.

The 1975 text stated that a returned aid must be:

in substantially as good condition as it was when [the buyer] received it. However, the seller cannot refuse to accept a cancelled hearing aid because it shows signs of normal wear and tear such as scratches on the casing. Nor can the seller refuse to accept a cancelled hearing aid because of its defects, unless those defects were caused by [the buyer's] mistreatment of it.¹¹⁴⁰

The 1978 text's provisions concerning damaged hearing aids were substantively the same.¹¹⁴¹ Both texts informed the buyer of these conditions in the consumer notice.¹¹⁴² Staff recommends that this provision be retained, and set out in the consumer notice.

Several commentators questioned the meaning of "normal wear and tear."¹¹⁴³ Some sellers felt it would be unfair to require them to accept returned aids that showed any sign of wear and tear,¹¹⁴⁴ while others expressed concern that they would be required to accept returned aids no matter how mistreated.¹¹⁴⁵ One commentator

1140 Proposed Rule § 440.4(b).

1141 Recommended Rule § 440.41.

1142 Proposed Rule § 440.4(b); Recommended Rule § 440.38(a).

1143 See O'Brecht, R8/3876; Joseph, TR 4235; see also Radioear, R2/29. NHAS felt the phrase "in about the same condition as when you got it" is too ambiguous. NHAS(303).

1144 See Joseph, TR 4235; O'Brecht, R8/3876; see also NHAS, R2/112; but see AARP/NRTA, TR 1432. One manufacturer disagreed that scratches on the casing can result from normal wear and tear, stating "scratches can only be caused by mistreatment." Zenith, R2/11. (emphasis in original); see also S-362.

1145 See Williams, TR 3780; West, TR 10483; Carter, TR 3661-62; Gillies, R4/84; Warren, R3/2923.

suggested that aids bought on trial are more likely to be abused than those bought outright,¹¹⁴⁶ but there was disagreement on this.¹¹⁴⁷ Staff believes there is little likelihood of abuse, and that buyers should not be denied a right of return because of minor scratches.

Dispensers expressed concern that internal damage caused by abuse may not be immediately apparent.¹¹⁴⁸ However, the seller has 30 days to return most payments, and can have the aid evaluated during that time.

Several commentators wanted to establish procedures for resolving disputes over whether damage was actually caused by consumer abuse.¹¹⁴⁹ One dispenser was concerned that disputes would arise over whether a defect was caused by buyer mistreatment, and suggested that all aids be classified as "free of defects" upon purchase and then all defects subsequently discovered would be the buyer's responsibility.¹¹⁵⁰ Staff believes this would unnecessarily complicate the rule.

The Proposed Rule also provided that if buyers cancelled but

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- 1146 Samole, TR 6662-63. It was suggested that these provisions should contain a stronger emphasis on the buyer's responsibility to care for the aid during the trial. See M-236 (42).
- 1147 See Fennema, TR 1783-84.
- 1148 See West, TR 10483; Teter, TR 10239-40; Walden, R5/1152.
- 1149 Goodwin, R5/165-66; see also Hamburger, R6/403; Zenith, R2/1.
- 1150 See, S-352.

failed to fulfill their responsibilities,¹¹⁵¹ the dispenser could recover "the fair market value of the cancelled hearing aid(s) and the services the [the buyer had] in fact received."¹¹⁵² Similar language appeared in the consumer notice of the 1978 text. One commentator felt problems might arise if buyers refused to pay for damaged aids,¹¹⁵³ while another objected that this provision would not permit the seller to recover the full contract price.¹¹⁵⁴ Given the difficulty of establishing fair market value, staff agrees that the full contract price is the appropriate charge.

3. Dispenser's Obligations Upon Cancellation

When the buyer cancelled a sale, the 1975 text would have required the dispenser to refund all payments made towards the purchase price (less any cancellation charges specified in the separate notice), to return any traded-in aids, and to terminate all

1151 For example, if buyers who do return the aid, or return it in unsatisfactory condition, would fail to fulfill their responsibilities.

1152 Proposed Rule § 440:4(b).

1153 Williams, TR 3780. Presumably this refers to instances where the buyer is paying in installments.

1154 Knox, R3/1447. Mr. Knox' comment asserted that the "extent of the buyer's liability would not be the fair market value of the hearing aid, but the contract price." Id. This suggests that the buyer should be liable for services provided under the contract, but never received.

security interests. This had to be done within 15 days of the notice.¹¹⁵⁵

Several changes were made in the 1978 text. One comment had suggested that the applicable period of time should begin on the date the cancellation notice was personally delivered or mailed; the prior staff agreed, and the current staff similarly agrees.¹¹⁵⁶

Other comments suggested that the proposed 15 day period was too short if the hearing aid was returned by mail¹¹⁵⁷ or if the hearing aid had to be picked up at the buyer's home.¹¹⁵⁸ This comment, too, was incorporated in the 1978 rule; except for traded-in aids, discussed below, the seller was given 30 days to return payment. Again, the current staff agrees.

With regard to traded-in hearing aids, comments suggested that the 15 day time period was too long. The Proposed Rule would have required the buyer to return a cancelled aid within 7 days of the cancellation notice, while the dispenser had 15 days to return any trade-ins;¹¹⁵⁹ the buyer might therefore have had no aid for 8

1155 Proposed Rule § 440.4(g)(2) and (3) (ii). These requirements were also reflected in the "Notice of Buyers Right to Cancel." See id. §440.4(b).

1156 Knox, R3/1445.

1157 Knox, R3/1444-45 (should be 30 days); Zenith, R3/3099; see ASHA, R10/1738; NHAS, R2/114; HAIC, R2/59. But see Freeman, R8/4046.

1158 Knox, R3/1445. This was particularly stated as a problem in rural areas. Id.

1159 Proposed Rule §§ 440.4(b) and (g)(2).

days, a substantial hardship.¹¹⁶⁰ On the other hand, other comments said that dispensers were unduly burdened by the mere requirement that would have to keep the aids at all, so they could return them on cancellation.¹¹⁶¹

In staff's view, the seller should be required to keep the traded-in aid during a trial, and to return it upon cancellation. (The buyer, too, must now return the new aid at the time of cancellation). If the traded-in aid were sold, there would be at least a substantial inconvenience for the consumer. It might even prevent the rule from working, if the consumer were deterred from cancelling. The dispenser's inconvenience -- keeping the aid in stock, and then returning it before fully evaluating damage to the returned aid -- is far outweighed by the potential harm to the buyer.

Consequently, staff recommends the language of the 1978 text; the trade-in must be returned "as soon as possible" after cancellation. This language is now set out in the consumer notice.

1160 See Harford, TR 64-65, 109-10; R5/855; Bowen, TR 1930.

1161 See Brill, R5/973; Zenith, R3/3097; Kasten, R5/1439. But see Willett, R3/818; Madell, R5/1691; Galleher, R5/43; Cull, R5/1089; McPherson, R5/632; Noon, R5/692. One suggestion was to allow a value to be placed on the trade-in at the time of the sale, so that the dealer could have the option of either returning the trade-in or refunding the value in cash. Brill, R5/973; see Sullivan, R6/373. Others that the value to the buyer of a traded-in hearing aid in the event of a cancellation usually far exceeds its value to anyone else. ASHA, R10/1749-50; Shannon, R5/669; Noon, R5/693; McGargill; R5/51; Zerbe, R5/1109; Lovering, R5/1054; Selger, R5/815.

4. Substitution of Hearing Aids During the Trial

The Proposed Rule and Recommended Rule both would have required a new 30-day trial whenever the dispenser substituted hearing aids during the initial trial period.¹¹⁶² The current staff recommends this, as well.

However, the prior proposals also contained other aspects which we do not recommend. As discussed in detail in Section IX.F., staff recommends the Commission fix a maximum cancellation fee for trials. Prior proposals would have provided that dispensers could not collect cancellation charges at the time of the substitution (although they could collect any difference in price between the aids),¹¹⁶³ and that, if the substitute aid were cancelled, the cancellation charges could not exceed the cancellation charges specified for the initial aid.¹¹⁶⁴

On the issue of whether a new trial is required for a replacement, NCSC supported granting the consumer a new 30-day period whenever the dispenser substituted hearing aids, because the consumer might otherwise only have a short period of time in which to evaluate

1162 Proposed Rule § 440.4(h); Recommended Rule §§ 440.38, 440.44. The dispenser is not required to substitute aids.

1163 Proposed Rule § 440.4(b); Recommended Rule §§ 440.38 and 440.44.

1164 Proposed Rule §§ 440.4(b) and (h); Recommended Rule §§ 440.38 and 440.44.

the replacement aid.¹¹⁶⁵ Dr. Rose agreed with the NCSC, stating that otherwise "the protection of the buyers' right to cancel could unfairly be lost in situations in which it is needed most."¹¹⁶⁶

Several commentators objected, however, that the accompanying cost limitation was unfair,¹¹⁶⁷ and that dealers would lose money by substituting aids without charge.¹¹⁶⁸ Some suggested that dispensers would hesitate to substitute aids,¹¹⁶⁹ to the detriment of consumers.¹¹⁷⁰ Other commentators felt the lack of a substitution charge would encourage consumers to behave "capriciously."¹¹⁷¹ ASHA, however, said that if dispensers could collect cancellation charges every time an aid was substituted, the total amount might be excessive.¹¹⁷²

In staff's views, the dispenser's potential burden on a substitution would be significant, if the provision were retained. However, it would not be as great as the comments suggest, because: (1) the the dispenser need not offer the buyer a replacement aid, and

1165 NCSC, TR 4550.

1166 Rose, R8/4187.

1167 See (S,A)-191; S-379; S-426; S-352; S-241; S-447. See also NHAS, R2/115, R3/3282-83; S-314; S-363 ("provision is price-fixing"); S-442 (provision is "unconstitutional").

1168 NHAS, R2/115; (S,A)-191; M-378; see also S-286, NHAS R3/3283.

1169 S-352.

1170 See Joseph, TR 4236; S-309; M-378.

1171 (S,A)-191; S-352; see also NHAS, R2/115.

1172 ASHA, R10/1750-51.

the fact that the buyer has failed once may suggest that a dispenser should be cautious in recommending a replacement; and (2) the dispenser might minimize the risk by offering a used aid as a replacement -- so that if the buyer again fails, the dispenser will not encounter any costs incurred when a new aid becomes used.

On the other hand, there is little likelihood of abuse by sellers if two cancellation charges are allowed. The dispenser will still have strong incentives to act cautiously with a client who has failed, merely because there is some maximum cancellation charge on the second aid.

From the buyer's perspective, if this provision is dropped, there is a risk of substantial costs from multiple cancellations -- but even after multiple cancellations the amount returned would also be substantial.

On balance, staff recommends that separate cancellation fees should be allowed.

F. Section 440.7: Cancellation Charges

The record contains substantial debate on the desirability of setting cancellation charges for trials, and on the appropriate formula if charges are set. Each prior version of the rule proposed to specify maximum cancellation charges.¹¹⁷³

1173

Proposed Rule § 440.4(g)(1); Recommended Rule § 440.40. The Commission's power to set a cancellation fee is discussed in Section C.3.e of the Introduction.

Many commentators supported a set maximum.¹¹⁷⁴ Some stressed that the trial remedy could be effectively negated by high cancellation fees, which could even equal the total cost of the aid.¹¹⁷⁵

Other commentators, however, objected to any limits on cancellation charges.¹¹⁷⁶ NHAS and others objected to "price-fixing,"¹¹⁷⁷ and concern was expressed that every dispenser would charge the maximum permissible charge, reducing competition.¹¹⁷⁸ Others objected that a uniform formula did not take into account individual differences in operating expenses.¹¹⁷⁹ In response to the charge that unreasonably high cancellation fees might result if maximum limits were not set, HAIC and others responded that the

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- 1174 See Kasten, TR 775; Rose, R5/710; Graham, S., R8/5277; Yamashiro, R8/3707; Griesel, R10/6768; ASHA, R10/1738-39, 1746; Syfert, R10/818; Jeffries, TR 5590-91; Franks, R10/6519; Ohio Div. of Con. Prot., R8/2927; Conlin, TR 7776; Luzi, TR 7714, R10/5214.
- 1175 See Rose, R8/4184; Yamashiro, R8/3707; see also ; Bowen (NCLD), HX35/5; AARP/NRTA, TR 1431.
- 1176 See Staab, TR 7038; HAIC, R2/60; Zelnick, TR 439; Freshley, R10/6638; Zenith, R3/3404; Byrne, R10/3176; NHAS, R3/3256; Schaefer, R10/6473; Teter, TR 10230; Payne, John, R10/5592.
- 1177 See NHAS, R2/113; O'Brecht, R8/3876; Zenith, R3/3100-01; Byrne and Stockler, R10/3198.
- 1178 See O'Brecht, R8/3876; Zenith, R3/3100.
- 1179 See Byrne, R10/3176; Holmes, TR 9595-96; Zenith, R3/3100-01; HAIC, R2/61; Campagna, TR 2610; Schaefer, R10/6473; Fortner, TR 2857; Burriss, TR 2507; Payne, John, TR 9187; Teter, TR 10230.

market would produce fair and reasonable cancellation charges.¹¹⁸⁰

Staff disagrees. Competition has not compelled all dispensers to offer trials absent a rule.¹¹⁸¹ Given this, we cannot agree that competition will set a reasonable fee for a mandatory trial. Moreover, as a practical matter, it is difficult to envision how the Commission could challenge any fee short of a 100% "cancellation fee" unless the rule sets a maximum.

If a charge is needed, however, there was fundamental disagreement among the witnesses as to the purpose of the cancellation charges. Many commentators felt that its primary purposes should be to encourage consumers to make a good faith effort to adjust to the aid, and to discourage casual or frivolous cancellations.¹¹⁸² Other witnesses said users were generally well-motivated and would not casually cancel.¹¹⁸³ At the same time, it was stated that the charge should not deter consumers from returning

1180 HAIC, R2/60; Zelnick, TR 439.

1181 See Section VI.D.1.

1182 See NY League for the Hard of Hearing, R8/4312; AARP, R10/877; Harford, R5/853; Oberhand, TR 3041; Ill. Speech and Hearing Assoc., R10/4891; Urban, TR 1810; Jerger, R8/5339; HEW Task Force Final Report, R8/3377; Moneka, R8/5391; Rassi, R8/5359; Noffsinger, R8/5405; Schrieber, TR 4051; Horne, R10/105; Keyes, TR 10713; Rupp, R8/7120; HEW Task Force Final Report, R8/3377; Rose, TR 478, R8/4184; Kasten, R5/1534-35, R8/6978.

1183 Harford, R8/4550; Schmitz, R8/7267; Munger (NCSC), TR 4511; Rose, TR 503; Vlcek, TR 896; Link, TR 1149; Masticola, TR 8634; Stein, TR 8987. See also, Splansky, TR 9012 (even a small fee might appear substantial to the elderly).

an aid, or from trying an aid in the first place.¹¹⁸⁴

On the other hand, many commentators felt that the primary purpose of the cancellation charges should be to compensate dispensers for their costs, including service costs as well as material costs.¹¹⁸⁵

Many commentators felt that these two views of the purpose of the cancellation charges were not mutually exclusive, and that the cancellation charges should both encourage a good faith effort by the consumer, and compensate the dispenser for costs incurred.¹¹⁸⁶ In staff's view, the focus should be on both the consumer's and dispenser's needs, but the dispenser need not be fully compensated in each individual transaction. Consistently high return rates indicate that a seller is deliberately or negligently selling inappropriate aids -- a pattern of behavior which scarcely justifies full recovery of costs.

1. The Cancellation Charge Formulas

Four possible alternative formulas for determining the maximum permissible 30-day rental cancellation charges served as vehicles for focusing public comment. They were:

1184 See Krebs, TR 11839-40; Bowen (NCLD), HX35/5; AARP/NRTA, TR 1431. Splansky, TR 9012.

1185 See HAIC, R3/3658; NHAS, R3/3301; Samole, TR 6663; Freshley, R10/6640, 6652.

1186 See Stabb, TR 7038-39; Byrne, R10/3064; Fowler, R8/1983; AARP/NRTA, TR 1431; Bowen (NCLD), HX35/5.

Alternative 1: \$15 plus 5 percent of the purchase price;¹¹⁸⁷

Alternative 2: \$30 per cancelled hearing aid (with an annual inflation adjustment) or 10 percent of the purchase price, whichever was the lesser.¹¹⁸⁸

Alternative 3: 10 percent of the purchase price;¹¹⁸⁹

Alternative 4: \$30 adjusted annually in accordance with the Consumer Price Index.¹¹⁹⁰

Staff recommends Alternative 3, a percentage formula similar to that used by most states which mandate trials. A chart summarizing state law appears in Section VI.B.

Several commentators said fees under these formulas would meet one of the tests above: they would adequately motivate consumers.¹¹⁹¹ NHAS and others disagreed.¹¹⁹²

There was also disagreement over whether the cancellation charges were adequate to compensate the dispenser. Again, some commentators felt they were adequate,¹¹⁹³ others

1187 Proposed Rule § 440.4(g)(1)(i)(A).

1188 Id. § 440.4(g)(1)(i)(B).

1189 This alternative was suggested in Commission Question (q), 40 Fed. Reg. 26653 (1975).

1190 Id.

1191 Rose, R5/710; Harford, R5/853; Kasten, R5/1434-35; Krebs, TR 11840; Franks, R10/6519; Ill. Speech and Hearing Assoc., R10/4891; Jerger, R8/5339; Rassi, R8/5359; Moneka, R8/5391; Schrieber, TR 4051; Noffsinger, R8/5405; Bowen (NCLD), HX35/5.

1192 See Section III.D, supra.

1193 Ginsburg, R10/433; Kasten, R5/1434-35; Rose, R5/711; Harford, R5/853; Graham, R8/5277; Leber, R10/6509; Bowen (NCLD), HX35/5.

disagreed,¹¹⁹⁴ and a few even felt they overcompensated the dispenser.¹¹⁹⁵ Part of this disagreement arose from differing concepts of "adequate compensation," with some commentators advocating "full" reimbursement for materials and/or labor,¹¹⁹⁶ while others felt less would be sufficient.¹¹⁹⁷ Much of the disagreement grew out of differing perceptions of the resale value of a cancelled hearing aid; would there be a market for these used aids?¹¹⁹⁸ Although there were differing opinions as to what constitutes "adequate compensation," and as to whether the proposals provide adequate compensation, staff notes that the maximum permissible charges allowed by any of the alternative formulas are similar to those charged in existing trial periods.¹¹⁹⁹

Several commentators expressed a specific preference for one of

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- 1194 HAIC, R2/62, R3/3658; Zenith, R3/3100; NHAS, R2/112; Holmes, TR 9583, 9633; Mynders, TR 11151-52; Byrne, R10/3127; Freshley, R10/6640, 6652; Samole, TR 6663; Staab, TR 7039.
- 1195 Peterson, TR 6116; Ginsburg, R10/433.
- 1196 Samole, TR 663; Vreeland, R10/3420; NHAS, R3/3301; ACO, TR 3699, 3715 (dispenser should be reimbursed, but this should not include a profit margin).
- 1197 Dr. Donald Krebs stated that if the cancellation charges were to fully compensate the dispenser, they would be "unreasonable." Krebs, TR 11840. Dr. Robert Baesemann stated that instead of the dispenser receiving full compensation in the event of a cancellation, he should raise his hearing aid prices slightly, so that each purchaser would, in effect, be purchasing "cancellation insurance." Baesemann, TR 7320-21.
- 1198 See Sections VI.D.3, VII.B.
- 1199 See Section VI.D.3.

the alternative methods of calculating cancellation charges. Some favored Proposed Rule alternative 1 as simpler,¹²⁰⁰ or because they felt it would result in lower cancellation charges.¹²⁰¹ Others preferred alternative 2¹²⁰² or 4.¹²⁰³ Two commentators recommended a dollar-a-day cancellation charge,¹²⁰⁴ but another said a daily charge might encourage consumers to return their aids before they had a chance to adjust.¹²⁰⁵

Alternatives 2 and 4 would have annually adjusted the maximum permissible cancellation charges based on the Consumer Price Index (CPI). Several commentators supported the idea of an annual CPI adjustment for inflation.¹²⁰⁶ Others said the CPI as unnecessarily complex,¹²⁰⁷ and that it might not accurately reflect the actual inflation for hearing aids.¹²⁰⁸

Others expressed support for the percentage formula of alternative

1200 AARP, R10/877.
1201 Drew/Eiler, R10/5195.
1202 Jeffries, TR 5591.
1203 Rompala, R10/5280; Splansky, TR 9012.
1204 Fennema, TR 1780; Rose, R5/710. See also ADA-420 (\$1.50 per day).
1205 Jerger, R8/5340.
1206 Jeffries, TR 5591.
1207 ASHA, R10/1747.
1208 NHAS, R2/113.

3,¹²⁰⁹ and the concept of a straight percentage fee was supported by others.¹²¹⁰ Still others, however, objected that a percentage fee might encourage higher prices¹²¹¹ or penalize dispensers who sold less expensive aids.¹²¹² Several audiologists stated that a percentage cancellation charge would penalize audiologists who sold hearing aids "at cost."¹²¹³

The 1978 staff recommended a flat fee of \$30. As with the original formulas, there was disagreement as to whether this charge was reasonable and adequate. The National Retired Teachers Association, American Association of Retired Persons, American Speech and Hearing Association, National Council of Senior Citizens, Federal Council on the Aging, and others felt the charge was appropriate,¹²¹⁴ but many industry members objected that it would not cover their costs,¹²¹⁵ even the cost of reconditioning the

1209 Franks, R10/6519; see also Byrne (Silverman), R10/3127.

1210 Syfert, R10/818.

1211 See ASHA, R10/1747-48; Hardick, R5/575; Davis, R5/566; DeVoe, R5/293; Gerstman, R5/1169; Owens, R5/1042; Cabeza, R5/497; Joyner, R5/501; Graunlie, R5/473; Menzel, R5/12; Ivey, R5/938.

1212 See Nygren, R8/4939; Kasten, R8/6989; ASHA, R10/1747-48; Fennema, R3/216; Pollard, R5/679; Harford, R5/853.

1213 Madell, R10/5584; Manel, R5/437.

1214 See (NRTA/AARP)-164; ASHA (36); A-74; A-137; (A,P)-486; NCSC-398; FCA-156.

1215 See S-309; S-382; S-240; S-367; S-242; S-386; S-422; M-378; AOA-420.

cancelled aid.¹²¹⁶ Several commentators complained because the flat fee did not take inflation into account.¹²¹⁷

The current staff recommends a percentage formula, which will automatically adjust for inflation. We further recommend that the fee be set at 10% of the selling price. This comports with record evidence that cancellation fees (excluding earmold and battery charges) were commonly \$30 or less for aids which cost at least \$500.¹²¹⁸ Moreover, this figure is used by several states; indeed, only two states allow a higher fee.

2. Binaural Aids

Both the Proposed Rule and Recommended Rule provided that two 30-day rental cancellation fees could be charged if binaural aids were sold and then cancelled.¹²¹⁹ The Initial Notice, however, asked whether the Rule should limit the cancellation fee further in binaural sales, in order to discourage inappropriate fittings¹²²⁰ (Maine has adopted this approach).¹²²¹

Despite potential abuse, staff recommends that cancellation fees

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- 1216 See (S,A)-191; S-196; S-329; M-378; NHAS (304), (S,A)-250.
1217 See A-223; S-407; S-423; S-426; S-270; S-274; S-345; M-378.
1218 See Section VI.D.
1219 Proposed Rule §§ 440.4(b) and (g)(1)(i); Recommended Rule §§ 440.38 and 440.40.
1220 40 Fed. Reg. 26652-53 (1975).
1221 See Section VI.D.

be allowed for both aids. Many commentators favored limiting this charge.¹²²² Earl Harford, Ph.D., for example, noted that the time spent on a binaural fitting is comparable to the time on a monaural fitting.¹²²³ Some felt that the charge for the second aid should be one-half of that of the first.¹²²⁴ However, others said that any limit would discourage sellers from making appropriate fittings.¹²²⁵ Any decision on this matter is complicated by the current disagreement about the value of binaural amplification.¹²²⁶ The current record does not permit a conclusion that binaural aids should not be fit simultaneously, and staff believes there is no basis to single out these sales for a special limit on fees.

3. Accessories

a. Earmolds and Batteries

In addition to the cancellation charge for the hearing aid, both

1222 See Kasten, R5/1435, R8/6986, TR 716; Bowen (NCLD), HX35/5; Harford, R5/853; Eichelberger, TR 8715; ASHA, R10/1744-45; Rose, R5/711, R8/4183; Ohio Div. of Cons. Prot., R8/2928.

1223 Harford, R8/4549.

1224 See Skadegard (Oticon), R3/177; Franks, R10/6520; Hardick, R5/575; Brickfield, R7/459-60. Others suggested that the 30-day rental cancellation charge should be less for the second aid than for the first, but did not suggest what the difference should be. Willett, R3/817; Hahn, R5/763.

1225 See Zelnick, TR 441-42; Hopmeier, TR 3355; Vreeland, R10/3422-23; Freshley, R10/6653; HAIC, R2/55; Zenith, R2/11-12.

1226 See Section I.B.7

the Proposed Rule and Recommended Rule would have allowed an additional cancellation charge for a custom earmold and a 30 day supply of batteries.¹²²⁷ Both rules set the maximum cancellation charge for these items at the lesser of the dispenser's regular selling price or twice the actual cost.¹²²⁸ In the interest of simplicity and enforceability, and following the example of state law,¹²²⁹ staff recommends that a fee be allowed, but that it be limited only by a single criterion: the regular selling price of the item.¹²³⁰

ASHA and others supported these maximum charges.¹²³¹ NCLD supported the Rule's maximum charges on batteries, but recommended that the dispenser only be permitted to charge the "direct" cost on earmolds.¹²³² AARP and NRTA recommended that the limit be material

1227 Proposed Rule § 440.4(g)(1)(ii); Recommended Rule § 440.40.

1228 Id.

1229 Ten "trial period" laws, for example, allow earmold charges. Two of them say nothing to limit those charges. Two use staff's proposed formula. The other six specify "regular selling prices."

1230 Several dispensers specifically objected to the provision further limiting the price by reference to "actual selling costs. S-422; S-241; S-242; S-329.

1231 ASHA, R10/1749. Yamashiro, R8/3707; see also Rose, R8/4187. ASHA further recommended that the dispenser only be allowed to charge consumers for batteries actually used. ASHA, R10/1749.

1232 Bowen (NCLD), HX35/5.

costs plus labor.¹²³³

Several dispensers opposed any limits, repeating the charge of unjustified "price fixing." Some addressed complications in the meaning of "actual cost."¹²³⁴

b. CROS Fittings

Both the Proposed Rule and Recommended Rule would not have permitted a separate cancellation charge for the costs of imbedding CROS wiring into eyeglass frames. Although several comments recommended that such a charge be allowed,¹²³⁵ staff disagrees.

A non-returnable charge is sometimes made for this custom wiring. However, most eyeglass aids now come with a fitting for easily installed CROS wiring. Due to the availability of this inexpensive alternative,¹²³⁶ a cancellation charge is inappropriate.¹²³⁷ It was noted that wires could be imbedded, if

1233 See AARP/NRTA, TR 1432-33; AARP, R10/878.

1234 See Zenith, R3/3102; S-314; see also FIBP-102; S-291; S-296; S-313; S-381; S-419; S-426; S-298; S-382; S-335; S-340; S-345; S-363; S-371; S-380; S-415; S-345.

1235 See H-188; Staab, TR 7039; Franks, R10/6520.

1236 See Nygren, R8/4939; Kasten, R8/6989; Harford, R5/854-55; ASHA, R10/1748-49; Rose, R5/711; see also McPherson, R5/630; Lovering, R5/1052; Atkins, R5/477; Eckel, R5/521. One manufacturer sells a wireless CROS aid. Freeman, R8/4046. Such a development obviously obviates the need for any wiring.

1237 Harford, R5/854-55. See Rose, R5/711; Kasten, R5/1435; ASHA, R10/1749; Patrick, R3/1435; Loovis, R5/343.

necessary, after the expiration of the trial period.¹²³⁸

c. Pre-Sale Services

The Proposed Rule prohibited dispensers from charging a cancellation fee for services unless (1) such charges were separately stated in the contract, (2) the "buyer" was given the option of not purchasing such services, and (3) these services were rendered prior to the date of cancellation.¹²³⁹ NHAS objected that these provisions were unfair to dispensers.¹²⁴⁰

The original staff, based on evidence in the record, recognized a potential problem that might arise from this provision: dispensers who wish to charge separately for pre-sale testing would have to offer these services optionally; but for obvious reasons, reputable dispensers would not sell a hearing aid without appropriate testing.¹²⁴¹ The 1978 staff therefore recommended a provision that would allow these dispensers to retain a cancellation charge for pre-sale services. The 1978 proposal required

You can also deduct charges for any services you performed before the sale, as long as you charge everyone who gets those services the same amount. However, you can do this only if you clearly and conspicuously explain the following two things to the buyer before the services are performed:

1238 See ASHA, R10/1748; Rose, R5/711; Harford, R5/854; Kasten, R8/6989.

1239 Proposed Rule § 440.2(e).

1240 NHAS, R2/97, R3/3243-44, 3281.

1241 See Carmel, R5/1306A.

- the amount charged for each service
- the fact that these charges are not refundable upon cancellation.¹²⁴²

The 1979 proposal required the disclosure be in writing and added another clause:

- the sentence "I read and signed this form before any services were provided." This sentence shall appear next to the space for the buyer's signature.

Thus, while the 1975 Proposed Rule would have required that any pre-sale service that the dispenser wished to separately charge for be "optional," subsequent proposals instead would have required that (1) the seller charge all customers who receive these services, whether or not they decided to purchase a hearing aid after receiving them,¹²⁴³ and (2) the charge for everyone had to be the same. Finally, while the 1975 Proposed Rule specified that dispensers could charge separately for services provided that were performed prior to the time of cancellation, the 1978 Recommended Rule required that such services be rendered prior to the sale.

The 1978 staff noted that these requirements were similar to the standard practice of many reputable dispensers who offered trial rental periods.¹²⁴⁴ They also noted that, by allowing dispensers

1242 Proposed Rule § 440.40.

1243 Consequently, the dispenser cannot offer to waive the fees charged for pre-sale services if the buyer keeps the aid beyond the trial period (i.e., does not cancel). Such activity would, in any event, violate § 440.36 of the Proposed Rule.

1244 See Section VI.D.2.b.

to charge for pre-sale services, the rule reduced the competitive burden on dispensers who did their own testing vis-a-vis dispensers who only sold hearing aids.

NHAS objected that these provisions would not allow a dispenser to reduce charges for customers in poor financial condition¹²⁴⁵; staff recommends eliminating the provision requiring that everyone who get the services pay the same amount. Even if there were merit to NHAS's contention, it is now moot. One seller stated that these provisions would add an "exorbitant amount" to hearing aid prices.¹²⁴⁶

Several commentators objected that dispensers should always be allowed to charge for services if a cancellation occurs.¹²⁴⁷ Staff disagrees, because of the potential abuse; the dispenser could claim that an unreasonable portion of the cost was for services.¹²⁴⁸

NRTA and AARP expressed concern that the provision would allow abuse: dispensers could charge for services that they were not qualified to perform.¹²⁴⁹ In staff's view, however, the market could limit the charges under this provision. The reason that competitive forces often fail to operate in the hearing aid market is

1245 NHAS(296); see also S-329.

1246 S-352; see also A-159; NHAS (295).

1247 Kojis, TR 2088; see also (A,S)-130.

1248 In addition, an incompetent dispenser might not have provided any service of value.

1249 (NRTA/AARP)-164; see also (A,M.D.)-43; A-49; A-72.

that many buyers do not comparative shop. In many cases, these buyers respond to "free test" offers or are surprised at their home by a salesman who, to gain entry, promises a "free test."¹²⁵⁰ Thus, the dispensers responsible for the most substantial deception, and the dispensers most likely to be trained in salesmanship in place of testing, could not charge everyone for their services (because they would thereby preclude access to customers). The dispensers who could charge everyone for pre-purchase services are likely to have established that their services have real value.

Staff has made one significant change in the provision: As noted above, we propose to eliminate the requirement that everyone be charged the same for a service. All price differentiation is not bad. A dispenser might, for example, want to reduce charges for a poor customer. The only price differentiation with a serious potential for abuse involves differentiating between consumers who buy an aid, and consumers who do not (e.g., charging consumers \$250 for a test if they do not buy an aid, but only \$25 for the test if they buy a \$400 aid.) However, this abuse is unlikely to arise so long as the rule requires disclosure of the price before testing. Hence, no further restriction on differential pricing is needed.

Staff has also made one minor change: to simplify the rule, we have eliminated the requirement that the disclosure be "clear and conspicuous." The 1979 addition, which required a statement signed by the buyer, renders this language unnecessary. Moreover, this

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See Section IV.B.

would be the only provision to use the phrase, which has proved nettlesome in prior "plain English" rules.¹²⁵¹

G. Section 440.8: Extra Rights and Extensions

Prior texts would have allowed dispensers to grant greater rights than provided in the Rule¹²⁵²--for example, to extend the trial rental period beyond the initial 30 day cancellation period. The current staff recommends this provision.¹²⁵³

The 1978 text added a provision which limited the charge on extensions to \$1 per day.¹²⁵⁴ Several commentators objected to this ceiling,¹²⁵⁵ and staff believes it is unnecessary. After 30 days, the consumer's need for protection is less and, in staff's view, too little to warrant government intervention.

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- 1251 See Labeling and Advertising of Home Insulation, 44 Fed. Reg. 50234 (1979) (merely appended existing enforcement policy statements, whose inclusion was subsequently stayed; See 45 Fed. Reg. 54702).
- 1252 Proposed Rule § 440.6. This provision would have also allowed dispensers to amend appropriate documents to reflect such expansion.
- 1253 Comments suggest that it is reasonable to expect that dispensers and buyers will make mutually agreeable extensions of the cancellation period when, despite a good faith effort by both, the buyer has not decided whether sufficient benefit is being derived from the aid. See ASHA, R10/1737-38; Hayes, R8/4952; Hull, R8/6137; Jerger, R8/4568; Kasten, R8/6989; Rose, R8/418; Harvey, R8/5332; See also McPherson, TR 5152; Masticola, TR 8649; Anthony, TR 8503-04; Brakebill, R8/4333; Pasiewicz, TR 8930-31.
- 1254 Recommended Rule § 440.45.
- 1255 S-291; S-423; S-363; S-345; M-378; S-447.

H. Section 440.9: Short Term Rentals and Leases

Prior texts limited charges on rentals and leases of 30 days or less. In the first 30 days, they could not exceed cancellation charges for trial periods. Sellers had to orally disclose these charges and provide consumers with a form disclosing their name and address, the dates of the rental/lease period and all charges.¹²⁵⁶ The purpose of the provision was to prevent dispensers from using "rentals" to circumvent the Rule's limits on cancellation charges. Except for the oral disclosure requirement, the current staff recommends that this provision be included in the rule.

The AARP, NRTA, ASHA, and others supported these limits.¹²⁵⁷ Others, however, opposed the provision for the same reasons they opposed a fixed cancellation fee: that it was beyond the Commission's authority,¹²⁵⁸ and incorporated price fixing.¹²⁵⁹

One commentator urged that the Rule be modified to require dispensers to disclose whether the rental charges could be applied to the purchase price if the rental instrument was purchased,¹²⁶⁰

1256 Proposed Rule § 440.5; Recommended Rule § 440.46.

1257 See AARP/NRTA, TR 1433; ASHA, R10/1756; AARP, R10/879-80; Rose, R5/712; Harford, R5/856, see also Ohio Division of Consumer Protection, R8/2928.

1258 HAIC, R3/3654. But See Introduction, Section C.3.e.

1259 See HAIC, R3/3654-58, (A,S)-130; S-299, HAIC, R3/3955, S-299.

1260 Drew and Eiler, R10/5194.

while another argued that such application should be mandatory.¹²⁶¹

Since the consumer need not buy the aid, however, staff believes this is unnecessary. ASHA recommended that a written contract be required for all rentals/leases beyond 30 days and that the written contract disclose what the total charges will be per year.¹²⁶²

ASHA also recommended clarifying language, which has been adopted in the Recommended Rule.¹²⁶³ Again staff believes this is unnecessary.

I. Section 440.10: No Waivers

Section 440.10 simply provides that a dispenser should not include any waiver of the trial period, or of notice, hearing, or trial, in a contract or receipt for a hearing aid.

J. Section 440.11: Requirements Concerning Employees

The 1975 Rule would have required dispensers to provide each employee, agent, salesperson, or representative with a copy of the Rule and receive a signed receipt back.

The hearing aid industry objected to having to distribute copies

1261 Zerbe, R5/1108; see also Drew and Eiler, R10/5194.

1262 See ASHA, R10/1756.

1263 ASHA, R10/1756-57. ASHA stated that the introductory language of Proposed Rule § 440.5, "when leasing or renting a hearing aid for a period of up to 30 calendar days," was ambiguous as to whether the 30th day of the rental was covered and recommended clarifying this to clearly state that the 30th day is covered, hence making this period compatible with the Buyer's-Right-to-Cancel period. Id. The 1978 Staff clarified this in the Recommended Rule § 440.46 states "In rentals for 30 days or less."

of the Rule to employees who were not directly affected,¹²⁶⁴ and the 1978 staff limited the scope of the distribution requirement. The Recommended Rule would have required dispensers give notice only to employees who dealt with customers or prepared advertisements.¹²⁶⁵ Since provisions directly affecting deceptive claims have been eliminated from the remedy, the current staff recommends that the requirement be further limited, to those who deal with consumers.

The Proposed Rule would have also required dispensers to establish and maintain a disciplinary system including fines, suspension or dismissal for employees who willfully and/or repeatedly violate the Rule.¹²⁶⁶ Numerous commentators objected to this provision on various grounds,¹²⁶⁷ and the 1978 text deleted the

1264 See NHAS, R2/123, R3/3652; see also HAIC, R3/3644-45; Joseph, TR 4240-41; O'Brecht, R7/551.

1265 Recommended Rule § 440.49.

1266 Proposed Rule § 440.12(c).

1267 It was stated that it would be unfair to hold dispensers liable both for violations of the Rule and for not disciplining employees who created the infraction. See Kojis, R3/2171; O'Brecht, R8/3878; Joseph, TR 4240; HAIC, R3/3644. See also NHAS, R3/3652; NHAS (349); Johnson, TR 2270; Kojis, R3/2171-72; O'Brecht, R7/551. It was argued that the Commission was abrogating its enforcement responsibilities by requiring dispensers to conduct the discipline of employees for violations of the Rule. See Kojis, R3/2171-72; Durbin, R3/1649; Kelly, R3/1456; Persiano, R3/1476; Hampton, R3/1492; Mayes, R3/3022; Moorcroft, R3/2260. Several dispensers expressed the concern that if an employee contested a particular disciplinary measure, the dispenser would not be entitled to immunity from civil suit normally accorded government

(CONTINUED)

requirement. However, a reminder was added that if employees violate the Rule, both they and their employers may be fined.¹²⁶⁸ A similar reminder appears in the current text.

K. Section 440.12: Recordkeeping Requirements

The Proposed Rule would have required hearing aid dispensers to maintain and retain, for a three year period, accurate records of all hearing aid sales, as well as all documents required by the Rule.¹²⁶⁹ The recordkeeping requirements in the Recommended Rule were substantively the same.¹²⁷⁰ Both Rules would have required these records to be made available to FTC staff for inspection upon reasonable notice.¹²⁷¹

Staff believes that recordkeeping provisions are necessary. We note that the recordkeeping burden has been reduced, because several provisions which would have generated records have been eliminated.

1267 (FOOTNOTE CONTINUED)

agencies in such situations. Radicchi, R3/2348; Moorcroft, R3/2260; Davis, R3/972; Mayes, R3/3334; Kelly, R3/1456; Canary, R3/2776.

1268 Id. State law governs the extent to which employers are liable for the actions of their employees. In practice, dispensers will in all likelihood be responsible for virtually all violations of the Rule which their employees commit.

1269 Other recordkeeping requirements involve sections subsequently deleted from the rule.

1270 See Recommended Rule § 440.50.

1271 Proposed Rule § 440.13; Recommended Rule § 440.50.

The rule requires that the sales contract be retained, but this is already prudent business practice. Between one and three documents will be required for other sales, and they can easily be retained with the sales contract. Under industry's estimate, that the average dispenser sells 100 aids annually, the average dispenser will have to maintain records for 300 sales over three years.

Industry comments suggested that the additional recordkeeping, record storage, and mailing expenses would increase costs, resulting in higher retail prices for consumers.¹²⁷² It was also suggested that these forms will so fatigue consumers that they will reject amplification and consequently it might be better just to orally appraise the buyer of his right to cancel.¹²⁷³ Staff does not consider these arguments credible.

A number of persons stated that these provisions allow the FTC to invade the privacy of the hearing aid customers because these records are "confidential".¹²⁷⁴ However, there is no right of confidentiality in these sales; moreover, staff would treat any records examined under these provisions with appropriate care.

1272 See Kuhl, R3/2523; Baer, R3/2367; NHAS, R2/123, R3/3353; S-101; S-302; S-313; S-322; S-390; S-391; S-438; NHAS (344); S-347; S-371; S-380; S-285; S-442; S-294; S-367; S-326; see also S-329; S-340; S-393; S-410.

1273 See (Tenn. HAS)-201; S-350; S-329.

1274 See Hampton, R3/1394; Canary, R3/2776; Mayes, R3/3035; Bruner, R3/2717; Campbell, R3/1220; Jones, R3/2142; C-331; see also Clinkscapes; TR 10626; S-101.

L. Section 440.13: Effect on Other Rules and State Laws

Section 440.14 of the 1975 Rule, and Section 440.15 of the 1978 Rule, involved the impact of the Rule on other Rules, Orders, and Laws.

The two principle issues raised by this section involve the impact of the rule on the FTC's own Cooling-Off Rule, and on state law. The Cooling-Off Rule establishes a three-day cooling off period in every home sale, for hearing aids or other purchases. Unlike the thirty-day trial period, the Cooling-off period lasts for three days after the date of contracting. It can expire, in other words, before the product is even delivered. However, it also provides for a full refund.

Several witnesses suggested that two FTC rules applicable to home hearing aid sales would lead to confusion,¹²⁷⁵ and therefore opposed the continued application of the Cooling-Off Rule for home hearing aid sales. Others, however, believed the hearing aid rule and the cooling off rule provided cumulative protection to the consumer, and that both should apply.¹²⁷⁶ Staff agrees. The Cooling-Off Rule does provide substantial additional protection to consumers: a full, rather than a partial refund. Moreover, since

1275 Harford, R5/855; Rose, R8/4184.

1276 E.g., ASHA, R10/1716, 1840; AARP, TR 1432, Krebs, TR 11840.

hearing aids are rarely delivered within three days of a home sale,¹²⁷⁷ this extra protection for consumers is paralleled by reduced cost for dispensers; since they have not yet delivered the aid (whose value will presumably be reduced by the trial), they will be less burdened by the cancellation.

The previous rules also provided for pre-emption of state law, and staff endorses this pre-emption. The 1982 version, like the previous versions, pre-empts inconsistent state laws, if those laws provide consumers with lesser rights.

Insofar as the current rule only involves trial periods, the impact of the pre-emption provisions has been limited. The current rule thus provides that inconsistent state laws involving trial periods are pre-empted, if they provide consumers with less protection than the rule.¹²⁷⁸

Industry criticism suggested that pre-emption would unduly limit the rights of states. Given the narrow scope of the current rule, however, these limits would be slight.¹²⁷⁹

M. Section 440.14: FDA Regulations Concerning Returned Hearing Aids

Both the Proposed Rule and Recommended Rule contained

1277 AARP, TR 1432; Luzi, TR 7714.

1278 E.g., Maico, R8/6888.

1279 Another provision of the 1974 and 1978 proposals involved FTC Trade Practice Rules for the industry; these rules, however, were rescinded on September 28, 1978.

substantively identical provisions which would have prohibited dispensers from selling used hearing aids as new.¹²⁸⁰ These provisions would have required dispensers to clearly and conspicuously disclose when an aid is used.¹²⁸¹ Both rules defined a hearing aid as "used" if it has been worn "for any length of time." Hearing aids that have been returned after a trial are "used," although hearing aids that have only been "tried on" in the presence of a salesperson or professional are "new".¹²⁸²

FDA has already enacted the most critical parts of this rule.¹²⁸³ Staff therefore does not recommend that it be included in a FTC rule. Rather, we recommend a reference to FDA's rule.

N. Plain English Format

The Proposed Rule was written in technical legal terminology and

1280 Proposed Rule § 440.7(c); Recommended Rule § 440.33.

1281 The dispenser could use words such as "loaned," "reconditioned," "refurbished," or "rebuilt" if these more accurately describe the status of the aid. Proposed Rule § 440.7(c); Recommended Rule § 440.33.

1282 Proposed Rule § 440.2(j); Recommended Rule § 440.33. This distinction between a "new" and a "used" hearing aid is consistent with the distinction adopted by the Food and Drug Administration. See 21 C.F.R. § 801.420(a)(6) for the definition of a "used hearing aid" which had been adopted by the Food and Drug Administration.

1283 The Food and Drug Administration has adopted labeling requirements for hearing aids which require packages containing, and tags physically attached to, used or reconditioned hearing aids to disclose that the aid is used. 21 C.F.R. § 801.420(c)(5).

style which many commentators found difficult to understand.¹²⁸⁴

NCLD expressed concern that consumers would not be able to understand the separate consumer notice explaining their rights under the Rule.¹²⁸⁵

In an effort to make the Proposed Rule more easily understandable to both hearing aid dispensers and consumers, the prior staff, with the help of Rudolf Flesch, Ph.D., rewrote the Rule in a "plain English" format.¹²⁸⁶

The current staff endorses this format. On August 27, 1977, a copy of this draft rule was sent to all designated group representatives for comment, and the rule was later included in the original staff report.¹²⁸⁷ NCSC applauded the new "plain English" version, stating that it would make both consumers and sellers more aware of their rights and responsibilities under the Rule.¹²⁸⁸ The Federal Council on Aging,¹²⁸⁹ and the Academy of Dispensing Audiologists also supported the "plain English" version. ASHA stated that the original Proposed Rule was not that difficult to understand, but

1284 See Jeffries, TR 5590; Bowen, TR 1906-08, 1919; Tobin, TR 4091-93; Woodard, TR 4141; Payne, James, TR 2143.

1285 See Bowen, TR 1919; NCLD, R7/685-86.

1286 Dr. Flesch is the author of How to Write Plain English: A Guide for Lawyers and Consumers, (New York; Harper Row, 1981).

1287 Staff memorandum dated Aug. 22, 1977.

1288 Marlin letter dated Sept. 30, 1977 at 1; NCSC-398.

1289 FCA-156; ADA-420

urged that the consumer notice be put in "plain English."¹²⁹⁰
HAIC, however, stated that the plain English redraft sacrificed
precision, and was vague and ill-drafted.¹²⁹¹ NHAS
concurred.¹²⁹²

Staff recommends a "plain English" format. The Commission has
previously recognized the importance of writing understandable
regulations and has promulgated two previous trade regulation rules
in a "plain English" format.¹²⁹³ Staff believes that the "plain
English" version of the Proposed Rule will be more comprehensible to
both dispensers and consumers, and will give them a better
understanding of their rights and responsibilities under the Rule.

1290 Dowling letter dated Sept. 22, 1977 at 1.

1291 See Vakerics letter dated Nov. 14, 1977. HIA-II (189-198).

1292 See Waters letter dated Nov. 2, 1977.

1293 See Labeling and Advertising of Home Insulation, 16 C.F.R.
460 (1981); Proprietary Vocational and Home Study Schools, 16
C.F.R. 438 and Statement of Basis and Purpose 43 Fed. Reg.
60812 (1978).

APPENDIX A
PRIOR VERSIONS OF THE RULE
A-1: 1979 VERSION

NOTE: In order to facilitate comparisons between the Rule as recommended in the 1978 Staff Report and the Rule as revised, the 1979 Staff retained the numbering system used in the Staff Report.

§ 440.1 Preamble.

This Regulation deals with the advertising, promotion, offering for sale, sale, marketing, or distribution of hearing aids in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act. If you are covered by this Regulation and break one of its rules, it is an unfair and deceptive act or practice and an unfair method of competition within the meaning of sections 5 and 12 of the FTC Act.

§ 440.2 Who is covered.

Hearing Aids are portable instruments worn to help one's impaired hearing. This Regulation applies to you if you rent or sell them, or if you offer to do so, whether for profit or not. It applies to all of the following:

- manufacturers
- wholesalers
- retailers
- owners
- partners
- corporations
- associations
- employees
- salespersons
- agents
- representatives
- physicians
- audiologists

§ 440.3 Acts and practices that are covered.

You must follow these rules whenever you:

- promote
- sell
- offer to sell

- rent
- offer to rent
- market, or
- distribute

hearing aids. You must follow them whenever you prepare, approve, place, or pay for ads. You can be fined heavily each time you break one of these rules.

§ 440.4 "Clearly and conspicuously".

The words "clearly and conspicuously" are used often in these rules. They describe the way you must explain additional information whenever you say or imply certain things. These words are important. Be careful to see that explanations really are both clear and conspicuous. An explanation is clear if people will easily understand its meaning. An explanation is conspicuous if it catches the eye or ear and attracts as much attention as the statement that it relates to.

A disclosure is not clear and conspicuous unless it is in the same language as the rest of the statement.

§ 440.5 "Say or imply" and "explain".

When one of these rules says that you cannot "say or imply" something, it means that you cannot do so in ads or written materials covered by these rules. When a rule says not to "imply" something, it means not to let people get that idea from anything you say or do in ads or written materials.

When one of these rules says that you must "explain" something, it means that you must tell consumers about it clearly and conspicuously.

§ 440.6 Say you are a seller.

In all signs, ads, and other written materials, clearly and conspicuously explain that you sell hearing aids. If your firm's name clearly refers to hearing aid sales, using its name will serve this purpose.

§ 440.7 Your firm's name.

Do not use a name that says or implies that your firm is something it is not. If you are in business for profit, your name must not say or imply that you are a nonprofit group or service, or a government or educational agency, or that you do public service or research. Do not call your firm an "institute" unless it

regularly does research or teaching. Do not call it a "bureau" if it is not a government agency. Do not call it a "clinic" if it does not regularly offer medical services supervised by a physician. Do not call it a "hearing and speech center," or any similar name if it does not regularly offer hearing services supervised by a physician or audiologist.

§ 440.8 Your title.

Do not say or imply that you or anyone in your firm is a physician or an audiologist unless it is true. An audiologist is someone who:

- has been certified as an audiologist by the American Speech and Hearing Association (ASHA)

or

- currently meets, or at one time met, all of the educational, experience and testing requirements for an ASHA certificate

or

- has a graduate degree in audiology and is qualified as an audiologist under state law.

Do not use the word "audiologist" in advertising or other written materials, even with other words, in describing anyone who does not meet one of these three definitions.

§ 440.9 Professional advice.

Do not say or imply that a physician or an audiologist helps or advises you unless it is true.

§ 440.11 "Normal" or "natural" hearing.

Do not say or imply any of the following.

- that any hearing aid will help people get their normal hearing back
- that any hearing aid will make or help people hear as well as someone with normal hearing
- that the sounds heard through a hearing aid will sound natural.

§ 440.12 "Act now."

Do not say or imply that any hearing aid will stop a hearing

loss or slow it down. For example, do not say any of the following:

- "Act now before it's too late."
- "Delay may be harmful."
- "I caught your loss just in time."

§ 440.17 "Unique," "special," "revolutionary," or "superior."

Do not say or imply that a hearing aid is "unique," "special," "revolutionary," or "superior" without clearly and conspicuously explaining exactly how it differs from all other hearing aids on the market and what good this difference will do for consumers. However, if you only say or imply it is "unique," "special," "revolutionary," or "superior" with respect to some other brands or models, you must clearly and conspicuously explain only how it differs from those brands or models, and what good this difference will do for consumers.

§ 440.19 Proof for claims.

You must have reliable proof that you trusted whenever you do either of the following:

- explain what good a feature of a hearing aid will do for consumers.
- explain how your hearing aid is different from others and what good this difference will do for consumers.

If you are not a manufacturer, you can rely on the manufacturer's material unless:

- you know or should know that the manufacturer's claims are false or are not backed up by good evidence

or

- you could check the claims yourself quickly and easily.

§ 440.21 "Prescribe" and "prescription."

Do not say or imply that a hearing aid is "prescribed" or is a "prescription hearing aid."

§ 440.22 "CROS" hearing aids.

Do not say or imply that a hearing aid that routes sound from one ear to the other lets people hear with or through the ear the sound is routed from.

§ 440.23 Bone conduction hearing aids

Do not say or imply that a bone conduction hearing aid can help people unless you clearly and conspicuously explain that very few people can benefit from bone conduction aids.

§ 440.28 Phone options.

If your product has a phone option that does not work on all phones, do not advertise the option without clearly and conspicuously explaining that fact.

§ 440.32 Testing devices.

Do not say or imply that a consumer's experience with a testing device demonstrates the way he or she can expect to hear with a hearing aid, if those two experiences differ noticeably.

§ 440.33 Used hearing aids.

Do not sell or rent used hearing aids as new. A hearing aid is used if it has been worn for any length of time. This includes new hearing aids that have been returned. However, if a hearing aid was only tried on in front of a salesperson or professional, it is still new.

If a hearing aid is used, you must clearly and conspicuously explain this:

- in any ad for the hearing aid,
- on the outside of the container or package,
- on a tag attached to the hearing aid itself, and
- in the contract or receipt for a sale or rental.

Instead of the word "used" you can use words like "demonstrator," "loaned," "reconditioned," "refurbished," or "rebuilt." The word you choose must accurately describe the hearing aid.

§ 440.34 Testing programs.

If the main purpose of a hearing aid market testing or evaluation program is to sell people the hearing aids they will be trying out, you must clearly and conspicuously explain that to them in all ads or written materials that solicit participation in such programs.

§ 440.35 Buyer's right to cancel

When a consumer buys a hearing aid or rents it for more than 30 days, you must give him or her 30 days from the date of delivery to cancel the sale or rental, return the hearing aid, and get a refund. At the time of the sale or rental, orally explain in a clear and conspicuous manner that he or she has 30 days to cancel the sale or rental, return the hearing aid and get a refund. Do not do, say, or imply, either orally or in writing, anything that may mislead the buyer about this right, or keep him or her from exercising it fully and freely.

However, you need not make the oral disclosure required by this section when a sale or rental is made through the mail.

§ 440.37 Notice on contract or receipt.

Include the following notice in each contract or receipt for a sale or rental of over 30 days:

You have 30 Days to Change Your Mind

If you change your mind about this sale or rental, you have 30 days from the date when you got the hearing aid to let us know you want a refund. The attached notice tells you how.

The notice must be printed in medium 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The heading must be printed in 12-point boldface.

The notice must be boxed in lines at least 2 points thick. It must be next to the space for the buyer's signature. If there is no signature space on a receipt, the notice must be on the front page.

If the oral sales presentation is principally in a language other than English, the notice must be in that other language. If the buyer's contract or receipt is in a language other than English, the notice must be in that other language.

§ 440.38 Separate notice.

- (a) At the time the buyer(s) pay(s) or promise(s) to pay, give him or her (each of them) two copies of the following notice. If someone other than the user pays or promises to pay, give the notice to the one(s) who pay(s). Keep a third copy for yourself.

You Have 30 Days to Change Your Mind

If you change your mind about this sale or rental, you have 30 days from the date when you got the hearing aid to let us know you want a refund. Simply take the attached "I've Changed My Mind" form, put in the date, check the proper boxes and sign it. If you can't find the "I've Changed My Mind" form, send a written notice of your own. Just say you want to return the hearing aid and get a refund. If the hearing aid was sent to your home, tell us whether you want us to pick it up there.

Take the notice to our office and have it postmarked by _____.

Ask for a receipt if you bring us the notice yourself. If you mail us the notice, send it "certified mail, return receipt requested." Be sure you get to the Post Office before closing time on the last day of the 30-day period.

Returns. You have 7 days from the date you delivered or mailed your notice to return the hearing aid.

Again, if you bring the hearing aid to our office, ask for a receipt. If you mail it to us, insure it. Be sure you mail it before closing time on the last day of the 7-day period.

If you bought or rented two hearing aids, you can return one or both.

If we delivered or mailed the hearing aid to your home, you can ask us in your notice to pick it up there. Then you must make it available to us in a reasonable manner. Ask for a receipt when we pick it up.

When you return the hearing aid, it must be in about the same condition as when you got it. We don't have to take it back if you damage it. But marks of normal wear and tear like scratches on the casing are OK. Defects that were in it when you got it are not your responsibility.

If you don't return the hearing aid or make it available to us in a reasonable manner, or if you damaged the hearing aid, you will owe us the fair market value of the hearing aid.

Refunds. Within 30 days of date you delivered or mailed your notice, we'll give up all our rights from the sale or rental and refund what you paid. We can keep \$_____. This covers \$_____ for testing, \$_____ for each hearing

aid returned, \$ _____ for each custom earmold and \$ _____ for batteries. (Don't return the earmolds or batteries.) We can also keep any money you may owe us for earlier rentals. There'll be no other charges.

As soon as we get the hearing aid from you, we'll return your old hearing aid or anything else you traded in.

Replacements. You don't have to accept a replacement instead of a refund. If you do, we'll give you another notice like this one. You'll have another 30 days from the day you got the replacement to change your mind and let us know you want a refund. If the replacement is more expensive than the first hearing aid, you'll have to pay the difference.

If you return the replacement aid, we can deduct the charges listed earlier in this notice. But there'll be no charge for the hearing aid you returned the first time.

If you bought or rented the hearing aid in your home, you have an additional right if you change your mind. You can cancel the sale or rental and get a full refund of all your money, with no cancellation charges, if you tell us within three business days from now. Check your contract or receipt to find out how to cancel within three business days if you bought or rented the aid in your home.

Your other rights. If we don't pay your refund or live up to our other obligations, you should report this to the Federal Trade Commission, Washington, D.C. 20580. You should also get in touch with a lawyer.

(Seller's Signature)

(Seller's Address)

I've Changed My Mind

(Please fill in the date and check the proper boxes.)

Date _____

To _____
(Name and Address of Seller)

I've changed my mind about the hearing aid(s) I got
around _____ . I want to return:
(Estimated Delivery Date)

- the hearing aid for my left ear.
- the hearing aid for my right ear.
- both hearing aids.

Please send me my refund.

- I am returning the hearing aid(s) along with
this notice.
- I will return the hearing aid(s) within 7 days.
- You delivered the hearing aid(s) to my home.
Please pick it (them) up there.

(Buyer's Signature) X _____

(Buyer's Address) _____

- (b) The text of this notice must be printed in medium weight 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The two headings and four subheadings must be printed in 12-point extra boldface.
- (c) Before you give the buyer the notice, fill in the copies like this:
- (1) Fill in the date after the words "have it postmarked by." If you do not know exactly when the consumer will get the hearing aid(s) in usable condition, make sure the date is at least 30 days after the probable delivery date.
 - (2) Fill in the cancellation charges. They are listed in section 440.40.
 - (3) Sign the form and fill in your address.
 - (4) On the form headed "I've Changed My Mind," fill in the date after the words "I got around." If you do not know when the consumer will get the hearing aid(s) in usable condition, make sure the date is not earlier than the probable delivery date.
- (d) If the oral sales presentation is principally in a language other than English, the notice must be in that other language.

§ 440.39 "Proper cancellation."

The words "proper cancellation" are used in sections 440.40 and 440.43. There has been a proper cancellation when these two things happen:

- a buyer's "I've Changed My Mind" form is personally delivered or postmarked in time
- the canceled hearing aid is returned in time or made available to you in a reasonable manner.

§ 440.40 Refunds.

If there has been a proper cancellation, you must make a refund. You have 30 days from the date the "I've Changed My Mind" form was personally delivered or postmarked to refund all payments made for the returned hearing aid(s), including finance charges and taxes. You can deduct a cancellation charge of up to \$30 for each hearing aid returned. You can also deduct any open charges for earlier rentals.

In addition to the cancellation charge for the hearing aid itself, you can deduct charges for custom earmolds and a 30-day supply of batteries, if the buyer got these things too. You can charge up to twice what the earmolds and batteries actually cost you, but no more than what you charge all buyers for them. In figuring your actual cost, deduct all rebates, discounts, and similar allowances.

You can also deduct charges for any services you performed before the sale, as long as you charge everyone who gets those services the same amount. However, you can do this only if you clearly and conspicuously provide the following information to the buyer in writing before the services are performed:

- the amount charged for each service
- the fact that these charges are not refundable upon cancellation
- the sentence "I read and signed this form before any services were provided." This sentence shall appear next to the space for the buyer's signature.

You must also have the buyer sign and date the disclosure form that you use.

§ 440.41 Damaged hearing aids.

You need not refund any money to the buyer if he or she is responsible for any damage to the cancelled hearing aid. However, the buyer is not responsible for marks of normal wear and tear, like scratches on the casing. Nor is the buyer responsible for defects that were in the aid(s) when he or she first got it(them).

§ 440.42 Trade-ins .

As soon as possible after you get the cancelled hearing aid(s), return any hearing aid or other item that was traded in for it (them). Any item you return must be in the same condition it was in when you got it.

§ 440.43 Papers to be returned.

Within 30 days of a proper cancellation, cancel and return any security interest that you got from the buyer for the purchase of the returned hearing aid(s). Also, take the cancellation notice that you got and attach it to your copy of the buyer's contract or receipt.

§ 440.44 Replacements.

If the consumer agrees to accept a replacement hearing aid within the 30-day period of the right to cancel, you cannot collect the cancellation charges from the original sale or rental. Instead, you must treat the replacement sale or rental like the original one. Give the buyer a new notice and another 30 days from the date of delivery to cancel the replacement sale or rental. The cancellation charges filled in must be the same as those in the first notice. If the replacement hearing aid is more expensive than the one being returned, you can charge for the difference in price. However, you cannot charge anything else for the replacement.

§ 440.45 Reduced charges, extra rights, and extensions.

You can reduce the cancellation charges or give extra rights. If you do so, make the proper changes in all of the documents.

You can also extend, but not shorten, the 30-day cancellation period. However, if you do this, you cannot charge more than \$1 for each extra day. Even if you do extend the 30-day cancellation period, you must allow the buyer to cancel within the first 30 days and pay the cancellation charges listed in section 440.40. Make sure the buyer understands this.

§ 440.46 Short rentals.

In rentals for 30 days or less, do not charge more than the total cancellation charges allowed under section 440.40. Clearly and conspicuously explain to the buyer exactly what these charges will be. Do not let the buyer pay or sign before you have done this.

At the time the buyer pays or signs, give the buyer a form or contract that contains these three items:

- your full name and address
- the dates when the rental period begins and ends
- all rental charges.

§ 440.47 No waivers.

Do not include in any contract or receipt a waiver of any right granted to the buyer by this Regulation. Also, do not include any waiver of notice, hearing, or trial.

§ 440.49 Requirements concerning employees.

Give a copy of this Regulation to all employees, agents, salespersons, and representatives who deal with your

customers or prepare your ads. Get a signed, dated receipt. If one of them breaks a rule, both of you may have to pay heavy fines.

§ 440.50 Recordkeeping.

Keep the following records:

- copies of all sale or rental contracts
- copies of all "You Have 30 Days to Change Your Mind" notices given to buyers
- all documents showing the proof you relied on in making claims required by section 409.19
- copies of the disclosure forms required by section 440.40
- the receipts required by section 440.49.

Keep these records for at least three years. For the documents showing proof for claims, the three years will begin again each time you make the claim.

Federal Trade Commission staff members can check these records at any time, but they must give you reasonable notice first.

§ 440.51 Other rules and orders on hearing aids.

- (a) These rules do not replace outstanding FTC Cease and Desist Orders unless the orders themselves state otherwise. If a Cease and Desist Order applies to you and it differs from the rules given here, you can petition to amend the order.
- (b) Current state laws and local regulations in this field are changed as follows:
 - (1) Parts of those laws and regulations that grant consumers at least the same rights stay in force. So do parts that fix fines and duties for you if you break one of the rules given here, and parts that are more strict as to the words you can use in referring to yourself or your firm.
 - (2) Parts that do not grant at least the same rights to consumers are replaced.
 - (3) Parts that are not replaced stay in force.
 - (4) The cancellation notice required by this Regulation must be used in all hearing aid sales or rentals. However, if a state law or local regulation grants greater rights to buyers, the FTC notice can be changed to reflect those greater rights.

- (c) These rules do not supersede the provisions of the Federal Trade Commission's Trade Regulation Rule Concerning a Cooling-Off Period for Door-to-Door Sales, 16 CFR Part 429.

§ 440.52 Severability.

The provision of this Regulation are severable. If any part of it is held invalid in any way, the rest of the Regulation will stay in force.

APPENDIX A- 2

1978 Version

Rule Recommended by Staff for Final Adoption

§ 440.1 Preamble.

This Regulation deals with the advertising, promotion, offering for sale, sale, marketing, or distribution of hearing aids in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act. If you are covered by this Regulation and break one of its rules, it is an unfair and deceptive act or practice and an unfair method of competition within the meaning of sections 5 and 12 of the FTC Act.

§ 440.2 Who is covered.

Hearing aids are portable instruments worn to help one's impaired hearing. This Regulation applies to you if you rent or sell them, or if you offer to do so, whether for profit or not. It applies to all of the following:

- manufacturers
- wholesalers
- retailers
- owners
- partners
- corporations
- associations
- employees
- salespersons
- agents
- representatives
- physicians
- audiologists

§ 440.3 Illegal acts and practices.

You must follow these rules whenever you:

- promote
- sell
- offer to sell
- rent
- offer to rent
- market, or
- distribute

hearing aids. You must follow them whenever you prepare, approve, place, or pay for ads. You can be fined heavily each time you break one of these rules.

§ 440.4 "Clearly and conspicuously."

The words "clearly and conspicuously" are used often in these rules. They describe the way you must explain additional information whenever you say or imply certain things. These words are important. Be careful to see that explanations really are both clear and conspicuous. An explanation is clear if people will easily understand its meaning. An explanation is conspicuous if it catches the eye or ear and attracts as much attention as the statement that it relates to.

A disclosure is not clear and conspicuous unless it is in the same language as the rest of the statement.

§ 440.5 "Say or imply" and "explain."

When one of these rules says that you cannot "say or imply" something, it means that you cannot do so in ads, written materials, or conversations covered by these rules. When a rule says not to "imply" something, it means not to let people get that idea from anything you say or do.

When one of these rules says that you must "explain" something, it means that you must tell consumers about it either orally or in writing. Explanations must always be clear and conspicuous.

§ 440.6 Say you are a seller.

In all signs, ads, and other written materials, clearly and conspicuously explain that you sell hearing aids. If your firm's name clearly refers to hearing aid sales, using its name will serve this purpose. Also, when you start to talk to potential customers, make sure they understand that you sell hearing aids.

§ 440.7 Your firm's name.

Do not use a name that says or implies that your firm is something it is not. If you are in business for profit, your name must not say or imply that you are a nonprofit group or service, or a government or educational agency, or that you do public service or research. Do not call your firm an "institute" unless it regularly does research or teaching. Do not call it a "bureau" if it is not a government agency. Do not call it a "clinic" if it does not regularly offer medical services supervised by a physician. Do not call it a "hearing and speech center," "speech and hearing center," "speech and hearing aid center," or any similar name if it does not regularly offer hearing services supervised by a physician or audiologist.

§ 440.8 Your title.

Do not say or imply that you or anyone in your firm is a physician or an audiologist unless it is true. An audiologist is someone who:

- has been certified as an audiologist by the American Speech and Hearing Association (ASHA)

or

- currently meets, or at one time met, all of the educational, experience and testing requirements for an ASHA certificate

or

- has a graduate degree in audiology and is qualified as an audiologist under state law.

Do not use the word "audiologist", even with other words, in describing anyone who does not meet one of these three definitions.

§ 440.9 Professional advice.

Do not say or imply that a physician or an audiologist helps or advises you unless it is true.

§ 440.10 "Counselor" and "consultant."

Do not call yourself or anyone in your firm a "counselor" or a "consultant." Do not use any similar terms that say or imply that anyone in your firm will give financially disinterested advice.

§ 440.11 "Normal" or "natural" hearing.

Do not say or imply any of the following:

- that any hearing aid will help people get their normal hearing back
- that any hearing aid will make or help people hear as well as someone with normal hearing
- that the sounds heard through a hearing aid will sound natural.

§ 440.12 "Act now."

Do not say or imply that any hearing aid will stop a hearing loss or slow it down. For example, do not say any of the following:

- "Act now before it's too late."
- "Delay may be harmful."
- "I caught your loss just in time."

§ 440.13 Background noise.

Do not say or imply that any hearing aid can shut out all unwanted background noise. You can explain that a hearing aid with a telephone option can reduce background noise while the wearer is using the telephone, but only if this is true.

§ 440.14 "Features."

In this Regulation, a "feature" is something that a hearing aid has or can do. For example, if a hearing aid is custom fitted or has a directional microphone, that is a feature. It is also a feature if a hearing aid can reduce background noise in some circumstances.

Physical characteristics like the color and size of a hearing aid are not considered features.

§ 440.15 Explanation of features.

If you say or imply anything about any feature of a hearing aid, clearly and conspicuously explain what the feature is and what good it will do for consumers.

There is one exception to this rule. If you merely list the types of hearing aids that you carry, such as in-the-ear or body aids, you need not list their features or explain what good they will do for consumers.

§ 440.16 Comparisons.

If you compare a feature of a hearing aid to one of other brands or models, clearly and conspicuously explain which ones you are comparing it to. For example, do not say that a hearing aid is "better" without explaining what it is better than. You need not name specific brands as long as it is clear to consumers which other hearing aids you mean. For example, you can compare your directional hearing aid to "all other directional aids," but not just to "other directional aids."

When you make comparisons, clearly and conspicuously explain exactly what the compared features enable your hearing aid to do that others cannot do. For example, if you say that a hearing aid has a new feature, explain what this feature does that other hearing aids cannot do.

§ 440.17 "Unique," "special," or "revolutionary."

Do not say or imply that a hearing aid is "unique," or "special," or "revolutionary" without clearly and conspicuously explaining

exactly how it differs from all other hearing aids on the market and what good this difference will do for consumers.

There is one exception to this rule. You can say that a hearing aid is unique, special, or revolutionary if you make it clear that you are comparing it only to certain other brands or models. However, when you do this, you must follow the rule on comparisons. For example, if you say that a hearing aid is "unique among bone conduction aids," it is a comparison with all other bone conduction hearing aids.

§ 440.18 "Smaller."

Do not say or imply that a hearing aid is smaller than other models unless:

- it provides about as much power and produces sounds of about the same quality as those other models

or

- you explain clearly and conspicuously that it does not do so.

If you do say that a hearing aid is smaller than other models, clearly and conspicuously explain which models you are comparing it to. You need not name specific brands as long as it is clear which other models you mean.

§ 440.19 Proof for claims.

You must have reliable proof that you trusted whenever you do any of the following:

- explain what good a feature of a hearing aid will do for consumers
- explain how your hearing aid is different from others
- say or imply that a hearing aid is smaller than others but provides about the same power and quality of sound.

If you are not a manufacturer, you can rely on the manufacturer's material unless:

- you know or should know that the manufacturer's claims are false or are not backed up by good evidence

or

- you could check the claims yourself quickly and easily.

§ 440.20 New models or features.

Do not say or imply that a hearing aid model or feature is new if it was first marketed in the United States over a year ago. Keep a record of when all models and features were first marketed in the United States. Make sure that if you prepare, approve, place, or pay for ads dealing with new models or features, the ads will be changed or withdrawn after one year.

§ 440.21 "Prescribe" and "prescription."

Do not say or imply that a hearing aid is "prescribed" or is a "prescription hearing aid."

§ 440.22 "CROS" hearing aids.

Do not say or imply that a hearing aid that routes sound from one ear to the other lets people hear with or through the ear the sound is routed from.

§ 440.23 Bone conduction hearing aids.

Do not say or imply that a bone conduction hearing aid can help people unless you clearly and conspicuously explain that very few people can benefit from bone conduction aids.

§ 440.24 "Invisible."

Do not say or imply that a hearing aid or any part of it is hidden or cannot be seen unless it is true.

§ 440.25 "Cordless."

Do not say or imply that a hearing aid is "cordless" or can be worn without any visible cord or wire unless it is true. You can use the word "cordless" or similar expressions if a plastic tube or similar device runs from the instrument to the ear, but only if you explain that clearly and conspicuously.

§ 440.26 "No button."

Do not say or imply that a hearing aid has "no button" or that it can be worn without a button or receiver in the ear, unless it is true. You can use "no button" or similar expressions if an earmold or plastic tip is put into the ear, but only if you explain that clearly and conspicuously.

A-21 "Blank"

§ 440.27 "No batteries."

Do not say or imply that a hearing aid works without batteries.

§ 440.28 Phone options.

If your product has a phone option that does not work on all phones, do not advertise the option without clearly and conspicuously explaining that fact.

Before a customer pays or signs up for a phone option that does not work on all phones, clearly and conspicuously explain the following two things:

- whether the option will work on phones in your selling area
- which types of phones the option will work on.

§ 440.29 Soliciting leads.

Do not solicit the names or addresses of potential customers without clearly and conspicuously explaining that a salesperson may phone or write for an appointment to see them.

You need not explain this if there is no plan to set up appointments with the people whose names and addresses you get. However, you must have a system to make sure that these names and addresses are never actually used to contact the people for an appointment.

§ 440.30 Sales visits.

Do not make hearing aid sales visits to people's homes or places of business without an appointment. You can make the appointment with the potential buyer or with the consumer. If you want to visit the consumer's home, you can also make the appointment with someone who lives with him. You can make the appointment orally or in writing. When you make appointments, clearly and conspicuously explain when you will be coming and that you may want to sell a hearing aid.

If you make an appointment orally, keep a record of these three things:

- the name and address of the person you spoke to
- the date you spoke to the person
- the date of the appointment.

Also, if someone sends you a written consent to a sales visit, keep it on file.

§ 440.31 Service calls.

You can make a service call to the home or place of business of a current customer without an appointment. However, if you plan to sell the customer a hearing aid, it is a sales visit and you must follow the rule on sales visits.

§ 440.32 Testing devices.

Do not say or imply that a consumer's experience with a testing device demonstrates the way he or she can expect to hear with a hearing aid, if those two experiences differ noticeably.

§ 440.33 Used hearing aids.

Do not sell used hearing aids as new. A hearing aid is used if it has been worn for any length of time. This includes new hearing aids that have been returned. However, if a hearing aid was only tried on in front of a salesperson or professional, it is still new.

If a hearing aid is used, you must clearly and conspicuously explain this four times:

- in any ad for the hearing aid
- on the outside of the container or package
- on a tag attached to the hearing aid itself
- orally, before the customer pays or signs.

Instead of the word "used" you can use words like "demonstrator," "loaned," "reconditioned," "refurbished," or "rebuilt." The word you choose must accurately describe the hearing aid.

§ 440.34 Testing programs.

If the main purpose of a hearing aid market testing or evaluation program is to sell people the hearing aids they will be trying out, you must clearly and conspicuously explain that to them.

§ 440.35 Ads that do not look like ads.

Make sure that your ads do not look like something else, such as news items or public service announcements.

§ 440.36 Buyer's right to cancel.

At the time a consumer buys a hearing aid or rents it for more than 30 days, orally explain in a clear and conspicuous manner that he has 30 days to cancel the sale or rental, return the hearing aid and get a refund. Do not do, say, or imply anything that may mislead the buyer about this right, or keep him from exercising it fully and freely.

§ 440.37 Notice on contract or receipt.

Include the following notice in each contract or receipt for a sale or rental of over 30 days:

You have 30 Days to Change Your Mind

If you change your mind about this sale or rental, you have 30 days from the date when you got the hearing aid to let us know you want a refund. The attached notice tells you how.

The notice must be printed in medium weight 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The heading must be printed in 12-point boldface.

The notice must be boxed in lines at least 2 points thick. It must be next to the space for the buyer's signature. If there is no signature space on a receipt, the notice must be on the front page.

§ 440.38 Separate notice.

(a) At the time the buyer(s) pay(s) or promise(s) to pay, give him (each of them) two copies of the following notice. If someone other than the user pays or promises to pay, give the notice to the one(s) who pay(s). Keep a third copy for yourself.

You Have 30 Days to Change Your Mind

If you change your mind about this sale or rental, you have 30 days from the date when you got the hearing aid to let us know you want a refund. Simply take the attached "I've Changed My Mind" form, put in the date, check the proper boxes and sign it. If you can't find the "I've Changed My Mind" form, send a written notice of your own. Just say you want to return the hearing aid and get a refund. If the hearing aid was sent to your home, tell us whether you want us to pick it up there.

Take the notice to our office or have it postmarked by _____.

Ask for a receipt if you bring us the notice yourself. If you mail us the notice, send it "certified mail, return receipt requested." Be sure you get to the Post Office before closing time on the last day of the 30-day period.

Returns. You have 7 days from the date you delivered or mailed your notice to return the hearing aid.

Again, if you bring the hearing aid to our office, ask for a receipt. If you mail it to us, insure it. Be sure you mail it before closing time on the last day of the 7-day period.

If you bought or rented two hearing aids, you can return one or both.

If we delivered or mailed the hearing aid to your home, you can ask us in your notice to pick it up there. Then you must make it available to us in a reasonable manner. Ask for a receipt when we pick it up.

When you return the hearing aid, it must be in about the same condition as when you got it. We don't have to take it back if you damage it. But marks of normal wear and tear like scratches on the casing are OK. Defects that were in it when you got it are not your responsibility.

If you don't return the hearing aid or make it available to us in a reasonable manner, or if you damaged the hearing

aid, we can sue you for the fair market value of the hearing aid and the services already given.

Refunds. Within 30 days of the date you delivered or mailed your notice, we'll give up all our rights from this sale or rental and refund what you paid. We can keep \$ _____. This covers \$ _____ for testing, \$ _____ for each hearing aid returned, \$ _____ for each custom earmold and \$ _____ for batteries. (Don't return the earmolds or batteries.) We can also keep any money you may owe us for earlier rentals. There'll be no other charges.

As soon as we get the hearing aid from you, we'll return your old hearing aid or anything else you traded in.

Replacements. You don't have to accept a replacement instead of a refund. If you do, we'll give you another notice like this one. You'll have another 30 days from the day you got the replacement to change your mind and let us know you want a refund. If the replacement is more expensive than the first hearing aid, you'll have to pay the difference.

If you return the replacement aid, we can deduct the charges listed earlier in this notice. But there'll be no charge for the hearing aid you returned the first time.

Your other rights. If we don't pay your refund or live up to our other obligations, you should report this to the Federal Trade Commission, Washington, D.C. 20580. You should also get in touch with a lawyer.

(Seller's Signature)

(Seller's Address)

I've Changed My Mind

(Please fill in the date and check the proper boxes.)

Date _____

To _____
(Name and Address of Seller)

I've changed my mind about the hearing aid(s) I got around

_____, I want to return:
(Estimated Delivery Date)

- the hearing aid for my left ear.
- the hearing aid for my right ear.
- both hearing aids.

Please send me my refund.

- I am returning the hearing aid(s) along with this notice.
- I will return the hearing aid(s) within 7 days.
- You delivered the hearing aid(s) to my home. Please pick it (them) up there.

(Buyer's Signature) X _____

(Buyer's Address) _____

(b) The text of this notice must be printed in medium weight 12-point roman type, in an easily readable style, not all capitals, not condensed, and on a contrasting background. The two headings and four subheadings must be printed in 12-point extra boldface.

(c) Before you give the buyer the notice, fill in the copies like this:

- (1) Fill in the date after the words "have it postmarked by." If you do not know exactly when the consumer will get the hearing aid(s) in usable condition, make sure the date is at least 30 days after the probable delivery date.
- (2) Fill in the cancellation charges. They are listed in section 440.40.
- (3) Sign the form and fill in your address.
- (4) On the form headed "I've Changed My Mind," fill in the date after the words "I got around." If you do not know when the consumer will get the hearing aid(s) in usable condition, make sure the date is not earlier than the probably delivery date.

§ 440.39 "Proper cancellation."

The words "proper cancellation" are used in sections 440.40 and 440.43. There has been a proper cancellation when these two things happen:

- a buyer's "I've Changed My Mind" form is personally delivered or postmarked in time
- the canceled hearing aid is returned in time or made available to you in a reasonable manner.

§ 440.40 Refunds.

If there has been a proper cancellation, you must make a refund. You have 30 days from the date the "I've Changed

"My Mind" form was personally delivered or postmarked to refund all payments made for the returned hearing aid(s), including finance charges and taxes. You can deduct cancellation charges of up to \$30 for each hearing aid returned. You can also deduct any open charges for earlier rentals.

In addition to the cancellation charge for the hearing aid itself, you can deduct charges for custom earmolds and a 30-day supply of batteries, if the buyer got these things too. You can charge up to twice what the earmolds and batteries actually cost you, but no more than what you charge all buyers for them. In figuring your actual cost, deduct all rebates, discounts, and similar allowances.

You can also deduct charges for any services you performed before the sale, as long as you charge everyone who gets those services the same amount. However, you can do this only if you clearly and conspicuously explain the following two things to the buyer before the services are performed:

- the amount charged for each service
- the fact that these charges are not refundable upon cancellation.

§ 440.41 Damaged hearing aids.

You need not refund any money to the buyer if he or she is responsible for any damage to the canceled hearing aid. However, the buyer is not responsible for marks of normal wear and tear, like scratches on the casing. Nor is the buyer responsible for defects that were in the aid(s) when he or she first got it (them).

§ 440.42 Trade-ins.

As soon as possible after you get the canceled hearing aid(s), return any hearing aid or other item that was traded in for it (them). Any item you return must be in the same condition it was in when you got it.

§ 440.43 Papers to be returned.

Within 30 days of a proper cancellation, cancel and return any security interest that you got from the buyer for the purchase of the returned hearing aid(s). Also, take the cancellation notice that you got and attach it to your copy of the buyer's contract or receipt.

§ 440.44 Replacements.

If the consumer agrees to accept a replacement hearing aid within the 30-day period of the right to cancel, you cannot collect the cancellation charges from the original sale or rental. Instead, you must treat the replacement sale or rental like the original one. Give the buyer a new notice and another 30 days from the date of delivery to cancel the replacement sale or rental. The cancellation charges filled in must be the same as those in the first notice. If the replacement hearing aid is more expensive than the one being returned, you can charge for the difference in price. However, you cannot charge anything else for the replacement.

§ 440.45 Reduced charges, extra rights, and extensions.

You can reduce the cancellation charges or give extra rights. If you do so, make the proper changes in all of the documents.

You can also extend, but not shorten, the 30-day cancellation period. However, if you do this, you cannot charge more than \$1 for each extra day. Even if you do extend the 30-day cancellation period, you must allow the buyer to cancel within the first 30 days and pay the cancellation charges listed in section 440.40. Make sure the buyer understands this.

§ 440.46 Short rentals.

In rentals for 30 days or less, do not charge more than the total cancellation charges allowed under section 440.40. Clearly and conspicuously explain to the buyer exactly what these charges will be. Do not let the buyer pay or sign before you have done this.

At the time the buyer pays or signs, give the buyer a form or contract that contains these three items:

- your full name and address
- the dates when the rental period begins and ends
- all rental charges.

§ 440.47 No waivers.

Do not include in any contract or receipt a waiver of any right granted to the buyer by this Regulation. Also, do not

include any waiver of notice, hearing, or trial.

§ 440.48 When oral disclosures are not required.

You need not make the oral disclosures required by sections 440.33 and 440.36 of this Regulation if it is physically impossible for you to do so.

§ 440.49 Requirements concerning employees.

Give a copy of this Regulation to all employees, agents, salespersons, and representatives who deal with your customers or prepare your ads. Get a signed, dated receipt. If one of them breaks a rule, both of you may have to pay heavy fines.

§ 440.50 Recordkeeping.

Keep the following records:

- copies of all sale or rental contracts
- copies of all "You Have 30 Days to Change Your Mind" notices given to buyers
- all "I've Changed My Mind" forms or other cancellation notices returned by buyers
- all written consents to sales visits, as required by section 440.30
- a record of all oral consents to sales visits, as required by section 440.30
- all documents showing the proof you relied on in making claims, as required by sections 440.15 through 440.19
- the receipts required by section 440.49.

Keep these records for at least three years. For the documents showing proof for claims, the three years will begin again each time you make the claim.

Federal Trade Commission staff members can check these records at any time, but they must give you reasonable notice first.

§ 440.51 Other rules and orders on hearing aids.

(a) These rules do not replace the Trade Practice Rules for the Hearing Aid Industry, published July 20, 1965, by the Federal Trade Commission (16 C.F.R. Part 214). However, note the following exceptions:

- Section 440.7 replaces Rule 10 [214.10].

- Section 440.8 replaces Rule 6(a) [214.6(a)].
- Section 440.21 replaces Rule 6(c) [214.6(c)].
- Section 440.23 replaces Rule 7(d) [214.7(d)].
- Section 440.24 replaces Rule 7(a) [214.7(a)].
- Section 440.25 replaces Rule 7(b) [214.7(b)].
- Section 440.26 replaces Rule 7(c) [214.7(c)].
- Section 440.32 replaces Rule 14(a) and (b) [214.14(a) and (b)].

(b) These rules do not replace outstanding FTC Cease and Desist Orders unless the orders themselves state otherwise. If a Cease and Desist Order applies to you and it differs from the rules given here, you can petition to amend the order.

(c) Current state laws and local regulations in this field are changed as follows:

- (1) Parts of those laws and regulations that grant consumers at least the same rights stay in force. So do parts that fix fines and duties for you if you break one of the rules given here, and parts that are more strict as to the words you can use in referring to yourself or your firm.
- (2) Parts that do not grant at least the same rights to consumers are replaced.
- (3) Parts that are not replaced stay in force.
- (4) The cancellation notice required by this Regulation must be used in all hearing aid sales or rentals. However, if a state law or local regulation grants greater rights to buyers, the FTC notice can be changed to reflect those greater rights.

(d) These rules do not supersede the provisions of the Federal Trade Commission's Trade Regulation Rule Concerning a Cooling-Off Period for Door-to-Door Sales, 16 CFR Part 429.

§ 440.52 Severability.

The provisions of this Regulation are severable. If any part of it is held invalid in any way, the rest of the Regulation will stay in force.

26616

NOTICES

FEDERAL TRADE COMMISSION
[16 CFR 440]

HEARING AID INDUSTRY

Proposed Trade Regulation Rule; Notice of Proceeding

Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., the provisions of Part I, Subpart B of the Commission's procedures and rules of practice, 16 CFR 1.7, et seq., and section 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code (Administrative Procedure) has initiated a proceeding for the promulgation of a Trade Regulation Rule for the Hearing Aid Industry.

In accordance with the above notice the Commission proposes the following Trade Regulation Rule and to amend Subchapter D, Trade Regulation Rules, Chapter I of 16 CFR by adding a new Part 440:

PART 440—PROPOSED TRADE REGULATION RULE FOR THE HEARING AID INDUSTRY

Sec.	
440.1	Preamble.
440.2	Definitions.
440.3	Form and manner of making required disclosures in television, radio and print advertisements.
440.4	Buyer's right to cancel.
440.5	Leases or rentals.
440.6	Seller may grant greater rights.
440.7	Selling techniques.
440.8	Prohibited representations concerning hearing aid sellers.
440.9	Prohibited representations concerning hearing aids.
440.10	Advertising representations that must be qualified.
440.11	Required disclosures concerning telephone options.
440.12	Necessary steps to insure compliance with this Part.
440.13	Record maintenance and retention.
440.14	Effect on prior Federal Trade Commission actions and on State laws and ordinances of State political subdivisions.

AUTHORITY: 38 Stat. 717, as amended (15 U.S.C. 41, et seq.)

§ 440.1 Preamble.

In connection with the advertising, promotion, offering for sale, sale, marketing, or distribution of hearing aids in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, it is an unfair and deceptive act or practice and an unfair method of competition within the meanings of sections 5 and 12 of that act for any seller to fail to comply with the following provisions of this Part.

§ 440.2 Definitions.

For the purposes of this Part the following definitions shall apply:

(a) "Hearing aid." Any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing.

(b) "Sale" or "purchase." A sale or purchase, or lease or rental for a period

of more than 30 calendar days, of a hearing aid to a member of the consuming public.

(c) "Seller." Any person, partnership, corporation, or association engaged in the sale, lease or rental of hearing aids, or any employee, agent, salesperson and/or representative of same, whether made to a "buyer" or to another "seller."

(d) "Buyer." Any person, partnership, corporation, or association assuming a financial obligation in connection with a "sale," either for its personal use or for the use of a person on whose behalf the financial obligation is assumed.

(e) "Purchase price." The total price paid or to be paid for a hearing aid, including all interest charges, taxes, and charges for services rendered in connection with a sale; *Provided however*, That "purchase price" shall not include the pro rata portion of any charges for services:

(1) When such charges are separately stated in the contract for sale; and

(2) When the "buyer" has been given the option of not purchasing such services; and

(3) When such services have been rendered prior to the date of the buyer's exercise of his right to cancel under § 440.4.

(f) "Represent" or "representation." Any direct or indirect statement, suggestion or implication, including but not limited to one which is made orally, in writing, pictorially, or by any other audio or visual means, or by any combination thereof, whether made in an advertisement or otherwise.

(g) "Advertisement" or "advertising." Any written or verbal statement, illustration, or depiction, other than a label or in the labeling, which is designed to effect the sale of any hearing aid, or to create interest in the purchase of any hearing aid, whether the same appears in a newspaper, magazine, leaflet, circular, mailer, book insert, catalog, sales promotional material other literature, billboard, public transit card, point-of-purchase material, or in a radio or television broadcast or in any other media. "Advertisement" or "advertising" does not include:

(1) Signs which only identify the name of a seller and are located at the seller's place of business; or

(2) A listing in a telephone directory which gives only the seller's name, address and telephone number, and the brand(s) of hearing aids offered for sale; or

(3) Representations directed solely to physicians or audiologists.

(h) "Audiologist". A person who:

(1) Possesses the Certificate of Clinical Competence in audiology granted by the American Speech and Hearing Association (ASHA); or

(2) Meets the educational and experience requirements for ASHA certification in audiology and has successfully completed the examination required for ASHA certification in audiology; or

(3) Meets the requirements of any applicable State law which defines the term "audiologist".

(i) "Clearly and conspicuously disclose" or "clear and conspicuous disclosure." Disclosing in a manner which (or a disclosure which):

(1) Can easily be understood (in the case of television and print advertising, also easily seen and read) by the casual observer, listener, or reader among members of the public; and

(2) Occurs each time the representation which creates the requirement for the disclosure is made, and in immediate conjunction with such representation, except that the disclosure required by § 440.8(a) need be made only once, in immediate conjunction with the major theme of an advertisement and at the outset of any other communication; and

(3) Is made in the same language, e.g., Spanish, as that principally used in communicating with the person(s) to whom the disclosure is addressed; and

(4) In any television advertisement, is made in the manner and form prescribed by § 440.3(a); and

(5) In any radio advertisement, is made in the manner and form prescribed by § 440.3(b); and

(6) In any print advertisement, is made in the manner and form prescribed by § 440.3(c).

(j) "Used hearing aid." A hearing aid which has been worn for any period of time by a buyer or potential buyer. *Provided however*, That a hearing aid shall not be considered "used" merely because it has been worn by a buyer or potential buyer as part of a bona fide evaluation conducted to determine whether to select that particular hearing aid for that buyer, if such evaluation has been conducted in the presence of the seller or a hearing health professional selected by the seller to assist the buyer in making such a determination.

(k) "Telephone option." An option available on hearing aids which enables the wearer to hear the electrical signal on the telephone line rather than the acoustic signal produced by the telephone.

§ 440.3 Form and manner of making required disclosures in television, radio and print advertisements.

(a) Disclosures in television advertisements. (1) Except for a disclosure required by § 440.8(a), any disclosure shall be made clearly and conspicuously and at least as clearly and conspicuously as any representation which creates a requirement for such disclosure.

(2) Except for a disclosure required by § 440.8(a) or § 440.10(a) (which shall be made simultaneously in the audio and video portions of the advertisement), any disclosure shall be made in the same portion (audio or video) of the advertisement in which the representation which creates the requirement for the disclosure is made.

(3) The video portion of any disclosure shall contain letters of sufficient size so that it can be easily seen and read on all television sets, regardless of the picture tube size.

(4) The video portion of any disclosure shall contain letters of a color and shade that readily contrast with the back-

ground, and the background shall consist of only one color or shade.

(5) No other sounds, including music, shall occur during the audio portion of any disclosure.

(6) The video portion of any disclosure shall appear on the screen for a sufficient duration to enable it to be completely read by the viewer.

(b) *Disclosures in radio advertisements.* Except in connection with § 440.8 (a), any disclosure in any radio advertisement shall be made clearly and conspicuously, and at least as clearly and conspicuously as the representation which creates the requirement for such disclosure. No other sounds, including music, shall occur during the disclosure.

(c) *Disclosures in print advertisements.* Except in connection with § 440.8 (a), any disclosure in any print advertisement shall be made clearly and conspicuously and at least as clearly and conspicuously as the representation which creates the requirement for such disclosure.

[See § 440.2(1).]

§ 440.4 Buyer's right to cancel.

(a) A seller shall include in every receipt or contract pertaining to a sale, in immediate proximity to the space reserved for the signature of the buyer, or on the first page if there is no space reserved for the signature of the buyer, a clear and conspicuous disclosure of the following specific statement in all capital letters of no less than twelve point bold face type of uniform font and in an easily readable style:

THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE OR RENTAL FOR ANY REASON AT ANY TIME PRIOR TO MIDNIGHT OF THE 30TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID(S). SEE THE ATTACHED "NOTICE OF BUYER'S RIGHT TO CANCEL" FOR AN EXPLANATION OF THIS RIGHT.

(b) A seller shall furnish each buyer, at the time such buyer assumes any financial obligation with respect to the purchase, a completed form in duplicate, captioned "Notice of Buyer's Right to Cancel," which shall contain in no less than ten point type (twelve point bold face type for words in the "Notice of Buyer's Right to Cancel" which appear below entirely in capital letters) of uniform font and in an easily readable style, a clear and conspicuous disclosure of the following specific statements in the following format. A copy of such completed form shall be retained by the seller in accordance with § 440.13(a)(2).

NOTICE OF BUYER'S RIGHT TO CANCEL

This notice is for the buyer and each person who has assumed a financial obligation on the buyer's behalf: **YOU HAVE THE RIGHT TO CANCEL THIS PURCHASE OR RENTAL.** Here is information on:

- Your right to cancel,
- How to cancel,
- What happens if you cancel, and
- Other things you should know.

YOUR RIGHT TO CANCEL.

Any time before the end of -----
(30 calendar days from the date you received the hearing aid(s))

you can cancel this purchase or rental for any reason and get most of your money refunded. If you purchased or rented two or more hearing aids in this transaction, you can cancel your purchase or rental of any or all of them. Upon cancellation, the seller can keep the following cancellation charges: \$----- (for 30 days rental, for each cancelled hearing aid) \$----- (for each custom ear mold made for the cancelled hearing aid(s)) \$----- (for batteries) No other cancellation charges, penalties or fees are legal. However, the seller can keep the charges for any lease or rental period which ran prior to this transaction.

If, before the end of -----
(30 calendar days from the date you received the hearing aid(s))

the seller substitutes any other hearing aid(s) for the one(s) you originally purchased or rented, then the seller is required to provide you with a new "Notice of Buyer's Right to Cancel" and an additional 30 day period in which you can cancel the purchase or rental of the substitute hearing aid(s). The seller is not entitled to keep any of the cancellation charges listed above when such a substitution is made, but you will have to pay the additional cost involved if a more expensive hearing aid is being substituted. If you cancel the purchase or rental of the substitute hearing aid(s), the seller can keep only the cancellation charges listed above.

HOW TO CANCEL.

To cancel this purchase or rental, your cancellation must be actually delivered to the seller or postmarked no later than the end of -----

(30 calendar days from the date you received the hearing aid(s))

You may cancel by giving the seller any form of written notice of your cancellation, so long as you make it clear to the seller that you are cancelling and, if you received the hearing aid at your home, whether you want the seller to pick it up there. If you wish, you may use the "Cancellation Notice" form provided at the end of this notice. Keep a copy of your cancellation notice for your records.

WHAT HAPPENS IF YOU CANCEL.

The seller's responsibilities if you cancel are as follows: Within 15 calendar days after the date of your written cancellation notice he must:

- (1) Actually return to you anything you traded in on the cancelled hearing aid(s) (including your old hearing aid(s)); and
- (2) Cancel all financial obligations you assumed, as part of the purchase or rental, to cover the purchase or rental of the cancelled hearing aid(s); and
- (3) Cancel all security interests (such as a mortgage) which were created in your property, as part of the purchase or rental, to cover the purchase or rental of the cancelled hearing aid(s); and
- (4) Refund all payments you made toward the purchase or rental price of the cancelled hearing aid(s), less the cancellation charges listed in this notice and the charges for any lease or rental period which ran prior to this transaction.

Your responsibilities if you cancel are as follows:

(1) If you picked up the hearing aid at the seller's place of business, then you must return it there, either by actually delivering it or by having it postmarked (you must pay the postage) no later than 7 calendar days from the date of your written notice of cancellation; or

(2) If the hearing aid was delivered to your home, then you have a choice of what to do:

(i) You may return the hearing aid to the seller's place of business, either by actually delivering it or by having it postmarked (you must pay the postage) no later than 7 calendar days from the date of your written cancellation notice; or

(ii) If you notified the seller that you will make the hearing aid available at your home, you must do so. Then, if the seller does not pick it up within 20 calendar days from the date of your notice, you may keep it.

OTHER THINGS YOU SHOULD KNOW.

The seller is entitled to receive a cancelled hearing aid back in substantially as good condition as it was when you received it. However, the seller cannot refuse to accept a cancelled hearing aid because it shows signs of normal wear and tear such as scratches on the casing. Nor can the seller refuse to accept a cancelled hearing aid because of its defects, unless those defects were caused by your mistreatment of it.

To protect yourself at the time you cancel, you should do the following: If you deliver a cancelled hearing aid to the seller's place of business or the seller picks it up at your home, you should obtain a receipt from him. If you mail a cancelled hearing aid to the seller, the hearing aid should be sent "registered mail, return receipt requested."

If you cancel but do not fulfill your responsibilities, the seller will be entitled to sue you for the fair market value of the cancelled hearing aid(s) and the services you have in fact received.

If the seller refuses to honor a valid exercise of your right to cancel this purchase, or does not fulfill his other responsibilities, you have a right to sue him to make him fulfill all his responsibilities. In addition to giving you a right to sue the seller, such a refusal or failure would be a violation of a Federal Trade Commission Rule. Such violations should be reported promptly to the Federal Trade Commission, Washington, D.C. 20580.

The granting of this right to cancel does not deprive you of any of the other rights given to buyers under the law. Nor does it limit any rights you have concerning warranties made by the seller or provided by law.

CANCELLATION NOTICE*

(Date of cancellation)

To: -----

(Seller)

(Seller's address)

I hereby cancel my purchase or rental of the hearing aid(s) which I received on -----

(Date you received the hearing aid(s))

(If two or more hearing aids were purchased or rented at the same time, the buyer must check the appropriate box so that the seller will know how much of the purchase or rental is being cancelled)

I am cancelling the purchase or rental of:

- both hearing aids
- the hearing aid for my left ear
- the hearing aid for my right ear
- other (explain)

(If you received the cancelled hearing aid(s) at your home and you want the seller to pick it (them) up there, then check this box:)

(Buyer's signature)

(Buyer's address)

*If you do not use this form you may still provide written notice to the seller by any other means, as long as you make it clear to the seller that you are cancelling and, if you received the hearing aid at your home but you cannot or do not want to return it to the seller's place of business, that the seller should pick up the hearing aid at your home.

(c) Before furnishing copies of the "Notice of Buyer's Right to Cancel" to the buyer, a seller shall complete both copies of each such notice by entering:

(1) The date which is "30 calendar days from the date on which the buyer received the hearing aid(s)", in each of the three blanks provided for it. If the seller does not or cannot know the exact date on which the buyer's receipt of the hearing aid(s) will take place, then the appropriate blanks shall be completed so as to reasonably insure that the 30 calendar day period does not begin to run before receipt by the buyer has actually taken place; and

(2) The cancellation charges allowed under § 440.4(g)(1); and

(3) The seller's full name and address (in the "Cancellation Notice" form); and

(4) The date the buyer received the hearing aid(s) (in the "Cancellation Notice" form). If the seller does not or cannot know the exact date on which the buyer's receipt of the hearing aid(s) will take place, then the date of receipt by the buyer shall be estimated so as to reasonably insure that it does not precede the actual receipt of the hearing aid(s).

(d) A seller shall not include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the buyer is entitled under this Part, including but not limited to the buyer's right to cancel the sale in accordance with the provisions of § 440.4.

(e) At the time the buyer purchases a hearing aid, a seller shall inform him orally of the existence of the buyer's right to cancel.

(f) A seller shall not misrepresent in any manner the buyer's right to cancel; nor shall the seller make any representation or perform any act or practice which in any way negates, contradicts, detracts from or is inconsistent with a full understanding or a proper exercise of such right to cancel.

(g) A seller shall honor any valid notice of cancellation by a buyer and within 15 calendar days after the date of such notice:

(1) Refund all payments made toward the purchase price of the cancelled hearing aid(s), less any lease or rental charges applied as payments toward the purchase price of the cancelled hearing aid(s) and only those "cancellation charges" which are properly set forth in the "Notice of Buyer's Right to Cancel"

as required by § 440.4(c) and are within the following limits:

(i) [Following are two mutually exclusive formulas for the "cancellation charge" for 30 days rental]

(A) *Alternative 1.* The cancellation charge for 30 days rental for each cancelled hearing aid shall not exceed the total of \$15 plus 5 percent of the purchase price (excluding any "cancellation charges" for any custom ear mold or batteries).

(B) *Alternative 2.* The cancellation charge for 30 days rental shall not exceed the sum of \$30 per cancelled hearing aid or 10 percent of the purchase price (excluding any "cancellation charges" for any custom ear mold or batteries), whichever is the lesser. This \$30 maximum shall be adjusted annually after the effective date of this part to account for the annual percentage adjustment in the United States City Average All Items Consumer Price Index (1967=100) published by the Bureau of Labor Statistics of the United States Department of Labor. The computation of this annual adjustment shall be as follows: The Index for the month in which this part becomes effective shall be the Base Index. The Index for that same month in subsequent years shall be divided by this Base Index and the result of that division shall be multiplied by the sum of \$30 to arrive at the maximum which shall obtain until the publication of the Index in the next subsequent year.

(ii) The cancellation charge for any custom ear mold and a 30 day supply of batteries shall not exceed twice the actual cost of such ear mold and/or batteries to the seller or the seller's regular selling price for such ear mold and/or batteries, whichever is the lesser. In computing the actual cost, all rebates, discounts, and any other similar allowances provided to the seller must be considered; and

(2) Return any goods or property traded in on the cancelled hearing aid(s), in substantially as good condition as when they were received by the seller; and

(3) Take all action necessary or appropriate to terminate:

(i) All financial obligations assumed by the buyer as part of this transaction to cover the purchase of the cancelled hearing aid(s); and

(ii) All security interests created in connection with this transaction to cover the purchase of the cancelled hearing aid(s).

(h) If, within 30 calendar days from the buyer's receipt of a purchased hearing aid, a seller substitutes another hearing aid for the originally purchased one, the seller shall treat such a substitution as a "sale" of a hearing aid for the purposes of § 440.4 by providing each buyer with a new "Notice of Buyer's Right to Cancel" and an additional 30 calendar day period in which to cancel. The cancellation charges set forth in the subsequent "Notice of Buyer's Right to Cancel" shall remain the same as those indicated in the original "Notice of Buyer's Right to Cancel."

(i) The provisions of paragraphs (a) through (h) of this section shall not apply to a sale:

(1) Made pursuant to a written recommendation of a specific hearing aid, by serial number or by model, made by a physician or an audiologist who receives no direct or indirect financial compensation from the seller for such recommendation or for services rendered in connection with such recommendation; *Provided, however,* That § 440.4(i)(1) shall not be construed to prevent any physician or audiologist from requesting or requiring as a condition of his referral to a seller that a patient be offered a trial period prior to a purchase; or

(2) Made to replace a damaged or worn out hearing aid when the replacement hearing aid which is sold is identical to such damaged or worn out hearing aid.

§ 440.5 Leases or rentals.

When leasing or renting a hearing aid for a period of up to 30 calendar days, a seller shall:

(a) Limit any lease or rental charges for any trial period(s) of up to 30 calendar days to only the total dollar amount of cancellation charges permitted to be retained by the seller under § 440.4(g)(1); and

(b) Clearly and conspicuously disclose such lease or rental charges orally to the potential buyer before any financial obligation relating to the lease or rental is assumed by the potential buyer; and

(c) Furnish each potential buyer, at the time any financial obligation relating to the lease or rental is assumed by the potential buyer, a form or contract which clearly and conspicuously discloses, in no less than ten point type of uniform font and in an easily readable style:

(1) The complete name and address of the lessor or renter; and

(2) The dates on which the trial period begins and ends; and

(3) All lease or rental charges.

§ 440.6 Seller may grant greater rights.

The seller may accord a buyer greater or more extensive rights than those to which the buyer is entitled under the provisions of this Part. In such instances, a seller may make suitable amendments in all appropriate documents to reflect the granting of such rights.

§ 440.7 Selling techniques.

(a) No seller shall utilize any device to demonstrate the performance which a consumer can expect from a hearing aid, when the performance of such a device differs in any material respect from that of said hearing aid.

(b) No seller shall visit the home or place of business of a potential buyer for the purpose of inducing a sale without having obtained, prior to any such visit, the express written consent of such potential buyer to such a visit. Such consent shall clearly and conspicuously state that such potential buyer is aware that the seller may attempt to sell a hearing aid during such a visit.

(c) If a hearing aid has been used, loaned, rented, leased, reconditioned, re-

furnished, repaired or rebuilt, that fact shall be clearly and conspicuously disclosed:

(1) In the oral sales presentation, before the buyer assumes any financial obligation with respect to the purchase; and

(2) In any advertisement relating to such hearing aid; and

(3) On the container in which such hearing aid is packaged; and

(4) On a tag which is physically attached to such hearing aid.

(d) No seller shall represent that a person can or may be able to participate in a hearing aid testing or evaluation program if the primary and/or ultimate purpose of such program is to sell hearing aids to persons who participate unless such purpose is clearly and conspicuously disclosed.

(e) No seller shall prepare, approve, fund, disseminate or cause the dissemination of any advertisement which, because of its form and/or content, cannot be easily understood as being designed to effect the sale of hearing aids, or to create interest in the purchase of hearing aids, by the audience to whom such advertisement is directed.

§ 440.8 Prohibited representations concerning hearing aid sellers.

(a) No seller shall make any representation to members of the consuming public without clearly and conspicuously disclosing that it is a seller of hearing aids. The disclosure requirement of § 440.8(a) will be satisfied by a clear and conspicuous statement of the name of the seller's business, if that name includes the words "hearing aid center" or other words which clearly identify that the establishment is a seller of hearing aids.

(b) No seller shall represent that it is a governmental or other public service establishment or a nonprofit medical, educational or research institution unless such is the fact. Such a representation is made by the use of names such as "hearing center" (but not "hearing aid center"), "hearing institute," "hearing aid institute," "hearing bureau," "hearing aid bureau," "hearing clinic," "hearing aid clinic," "speech and hearing center," "speech and hearing aid center," and "senior citizen surveys."

(c) No seller shall represent that it or any of its employees, agents, salespersons and/or representatives is a physician or an audiologist, unless such is the fact. One example of a violation of § 440.8(c) is the use of the term "audiologist" to describe one who is not an audiologist as defined in § 440.2(h); and

(d) No seller shall represent that the service or advice or a physician or an audiologist will be used or made available in the selection, adjustment, maintenance or repair of a hearing aid, unless such is the fact.

(e) No seller shall represent that it or any of its employees, agents, salespersons and/or representatives is a "counselor" or a "consultant."

§ 440.9 Prohibited representations concerning hearing aids.

(a) No seller shall represent that any hearing aid will restore or help restore normal or natural hearing or will enable or help enable wearers to hear sounds normally or naturally.

(b) No seller shall represent that any hearing aid will in any way reverse, halt, or retard, or in any way help to reverse, halt or retard the progression of hearing loss, including but not limited to the use of expressions such as "Act now before it's too late," "Delay may be harmful," or "I caught your hearing loss just in time." Section 440.9(b) does not prohibit, however, a clearly stated and adequately qualified representation as to the difficulties which a consumer may encounter in adjusting to a hearing aid if he gets out of practice in using his hearing.

(c) No seller shall represent that a hearing aid model or feature is new for a period greater than one year from the date on which it was first marketed in the United States.

(d) A seller shall maintain an adequate system for insuring that all advertising it prepares, approves, funds or disseminates is in compliance with § 440.9(c).

(e) No seller shall represent that any hearing aid brand or model possesses any general or specific feature or characteristic or embodies any concept or principle (hereinafter referred to as a "characteristic") unless:

(1) Each such characteristic is clearly and conspicuously disclosed; and

(2) Each such disclosed characteristic provides some significant benefit(s) to the wearer of a hearing aid; and

(3) There is a clear and conspicuous disclosure of each such specific benefit; and

(4) There is a clear and conspicuous disclosure of the specific condition(s) under which or the category or categories of hearing aid wearers by which each such disclosed benefit will be received; and

(5) At the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes that each benefit is significant and will be received by a significant number of buyers under the condition(s) disclosed; *Provided, however*, That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

(i) That the manufacturer did not possess such evidence; or

(ii) That the representation could not be substantiated by such evidence; or

(iii) That the representation was false; and

(6) If the represented characteristic(s) is (are) compared generally or specifically to the comparable characteristic(s) possessed by any other hearing aid brand(s) and/or model(s), including but not limited to any representation of newness (other than a representation that a hearing aid is not "used" as described in § 440.2(j)):

(i) There is a clear and conspicuous disclosure of the hearing aids with which such comparison is made; i.e., so that the comparison is not in the form of a dangling comparison; and

(ii) There is a clear and conspicuous disclosure of each particular characteristic with respect to which such comparison is being made; and

(iii) Each such compared characteristic provides a significantly greater benefit than the benefit provided by the comparable characteristic in the disclosed hearing aid brand(s) and/or model(s) with respect to which the advertised hearing aid(s) is (are) being compared; and

(iv) At the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes that each compared characteristic provides a significantly greater benefit than the benefit provided by the comparable hearing aid brand(s) and/or model(s); *Provided, however*, That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

(A) That the manufacturer did not possess such evidence; or

(B) That the representation could not be substantiated by such evidence; or

(C) That the representation was false.

(f) For purposes of § 440.9(e)(5), a general or unqualified representation that a hearing aid is unique, revolutionary or special will be deemed to be a comparison to all other hearing aid brands and models; *Provided, however*, That a representation that a hearing aid is revolutionary or special will not be deemed to be a comparison to all other hearing aid brands and models if it is clearly and conspicuously disclosed that the comparison being made is to less than all other hearing aid brands and models.

(g) No seller shall represent that a hearing aid model is smaller than other hearing aid models unless, in addition to making all disclosures prescribed by § 440.9(e):

(1) The quality and range of sounds produced by representative samples of such hearing aid model are at least of

substantially the same quality and range as the sounds produced by representative samples of each of the different brand(s) and/or model(s) of hearing aids with which it is being compared, and, at the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes the relative quality and range of sounds produced by such hearing aids; *Provided, however*, That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

- (i) That the manufacturer did not possess such evidence; or
- (ii) That the representation could not be substantiated by such evidence; or
- (iii) That the representation was false; or

(2) It is clearly and conspicuously disclosed that such hearing aid does not produce sounds which are at least of substantially the same quality and range as the sounds produced by the hearing aid brand(s) and/or model(s) with which it is being compared.

(h) No seller shall use the words "prescribe" or "prescription" or any other word(s) or expression(s) of similar import.

(i) No seller shall represent that a hearing aid which routes the signal from one ear to the other ear enables the wearer to hear out of the ear from which the signal is being routed.

(j) No seller shall represent, through the use of words or expressions such as "invisible," "hidden," "hidden hearing," "completely out of sight," "conceal your deafness," "hear in secret," "unnoticed even by your closest friends," "no one will know you are hard of hearing," "your hearing loss is your secret," "no one need know you are wearing a hearing aid," "hidden or out of sight when inserted in the ear canal," or by any other words or expressions of similar import, that any hearing aid or part thereof is hidden or cannot be seen, unless such is the fact.

(k) No seller shall represent, through the use of words or expressions such as "no cord," "cordless," "100 percent cordless," "no unsightly cord dangling from your ear," "no wires," "no tell-tale wires," or other words or expressions of similar import, that a hearing aid can be worn without any visible cord or wire, unless such representation is true and it is clearly and conspicuously disclosed that a plastic tube (or similar device) runs from the instrument to the ear. If such is the fact.

(l) No seller shall represent, through the use of words or expressions such as "no button," "no ear button," "no buttons or receivers in either ear," or other words or expressions of similar import,

that a hearing aid can be worn without any button or other receiver in the ear, unless such representation is true and unless it is clearly and conspicuously disclosed that an ear mold or plastic tip is inserted in the ear, if such is the fact.

(m) No seller shall represent that any hearing aid can eliminate unwanted noise; *Provided, however*, That it shall not be a violation of § 440.9(m) to represent accurately the ability of a hearing aid with a telephone option to attenuate acoustical background signals, if such is the fact.

(n) No seller shall represent that any hearing aid can operate without batteries, unless the power source for such a hearing aid can be recharged from a household electric outlet.

§ 440.10 Advertising representations that must be qualified.

No seller shall prepare, approve, fund, disseminate or cause the dissemination of any advertisement:

(a) Which makes any general or specific representation that a hearing aid will or has the capacity to affect hearing capability or hearing quality, unless it is clearly and conspicuously disclosed that many persons with a hearing loss will not receive any significant benefit from any hearing aid; *Provided, however*, That nothing herein shall prohibit a truthful representation that hearing aids can help many persons with a hearing loss.

(b) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in noisy situations, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in noisy situations by using any hearing aid.

(c) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in group situations, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in group situations by using any hearing aid.

(d) Which makes any representation that the use of two hearing aids, one in each ear, will be beneficial to persons with a hearing loss in both ears, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss in both ears will not receive greater benefits from the use of two hearing aids, one in each ear, than from the use of one hearing aid.

§ 440.11 Required disclosures concerning telephone options.

(a) No seller shall prepare, approve, fund or disseminate any advertisement which represents that a hearing aid has a telephone option, unless it is clearly and conspicuously disclosed that the telephone option will not work on all telephones.

(b) Before a buyer assumes any financial obligation with respect to a hearing aid which has a telephone option, a seller shall clearly and conspicuously disclose the limitations of the telephone option orally to the buyer. Such disclosure shall include the following information:

(1) A statement that the telephone option will not work on all telephones; and

(2) A statement which indicates whether or not the telephone option will work on the telephones in the seller's trade area. If the telephone option will work on some, but not all, of the telephones in the seller's trade area, a statement indicating the types of telephones on which it will work shall be included in this disclosure; and

(3) A statement which indicates whether or not the approximate percentage of telephones in the seller's trade area on which the telephone option will work is increasing, decreasing, or remaining about the same.

§ 440.12 Necessary steps to insure compliance with this Part.

Every seller shall take such steps as are necessary to reasonably insure full compliance with the provisions of this Part by its employees, agents, salespersons, and/or representatives. At a minimum, such steps shall include:

(a) Furnishing each employee, agent, salesperson and/or representative with a copy of the Rule in this Part, either at the time of its promulgation or at the time their employment is commenced; and

(b) Obtaining from each employee, agent, salesperson and/or representative a signed and dated receipt for the copy of the Rule in this Part provided in accordance with § 440.12(a); such receipt to state that the recipient is aware that the seller is required to and will take appropriate disciplinary action for violations of this Part, which shall, in the event of willful violations or repeated violations, consist of the imposition of a fine, suspension, or dismissal of the employee, agent, salesperson and/or representative involved; and

(c) Establish and maintain a disciplinary system which will include, in the event of willful violations or repeated violations, the imposition of a fine, suspension, or dismissal of the employee, agent, salesperson and/or representative involved.

§ 440.13 Record maintenance and retention.

A seller shall maintain accurate and adequate records which may be inspected by Commission staff members upon reasonable notice and which pertain to the activities listed below. Such records shall be retained for a period of no less than three years. In the case of records covered by § 440.13(d), the three year period shall commence each time a representation supported by such records is made.

(a) All hearing aid sales. Documents which must be maintained and retained include but are not limited to:

- (1) Copies of all contracts of sale; and
- (2) Copies of all "Notices of Buyer's

NOTICES

Right to Cancel" provided to buyers in accordance with § 440.4(b); and

(3) Copies of all cancellation notices of any kind received from buyers exercising the right to cancel; and

(b) All hearing aid leases or rentals. Documents which shall be maintained and retained include but are not limited to copies of all contracts or forms provided in accordance with § 440.5; and

(c) All home sales visits. The prior express written approval required for each home sales visit by § 440.7(b) shall be maintained and retained; and

(d) Substantiation of representations. Documents which must be maintained and retained include but are not limited to all evidence required by §§ 440.9 (e) through (g); and

(e) All steps taken in accordance with the requirements of § 440.12.

§ 440.14 Effect on prior Federal Trade Commission actions and on State laws and ordinances of State political subdivisions.

(a) Sellers in compliance with this Part are exempt from the provisions of the Federal Trade Commission Trade Regulation Rule Concerning a Cooling-Off Period for Door-to-Door Sales, 16 CFR Part 429.

(b) This Part shall not be construed to supersede the Trade Practice Rules for the Hearing Aid Industry, promulgated July 20, 1985, by the Federal Trade Commission (16 CFR Part 214) except in the following instances:

(1) section 440.7(c) of this Part supersedes Rule 14 (a) and (b) (§ 214.14 (a) and (b)).

(2) section 440.8(b) of this Part supersedes Rule 10(a) (§ 214.10(a)).

(3) section 440.8(d) of this Part supersedes Rule 6(a) (§ 214.6(a)).

(4) section 440.9(h) of this Part supersedes Rule 6(c) (§ 214.6(c)).

(5) section 440.9(j) of this Part supersedes Rule 7(a) (§ 214.7(a)).

(6) section 440.9(k) of this Part supersedes Rule 7(b) (§ 214.7(b)).

(7) section 440.9(l) of this Part supersedes Rule 7(c) (§ 214.7(c)).

(c) This Part shall not be construed to supersede any of the provisions of any outstanding Federal Trade Commission Cease and Desist Orders. The method for resolving any inconsistencies between this Part and such Cease and Desist Orders shall be by a petition to amend the provisions of such Orders.

(d) By taking action in this area, the Federal Trade Commission does not intend to preempt action in the same area, which is not inconsistent with this Part, by any State, municipal, or other local government. This Part does not annul or diminish any rights or remedies provided to consumers by any State law, municipal ordinance, or other local regulation, insofar as those rights or remedies are equal to or greater than those provided by this Part. In addition, this Part does not supersede those provisions

of any State law, municipal ordinance, or other local regulation which impose obligations or liabilities upon sellers, when sellers subject to this Part are not in compliance therewith. This Part does supersede those provisions of any State law, municipal ordinance, or other local regulation which are inconsistent with this Part to the extent that those provisions do not provide a buyer with rights which are equal to or greater than those rights granted a buyer by this Part. This Part also supersedes those provisions of any State law, municipal ordinance, or other local regulation requiring that a buyer be notified of a right which is the same as a right provided by this Part but requiring that a buyer be given notice of this right in a language, form, or manner which is different in any way from that required by this Part. In those instances where any State law, municipal ordinance, or other local regulation contains provisions, some but not all of which are partially or completely superseded by this Part, the provisions or portions of those provisions which have not been superseded retain their full force and effect.

(e) This Part is not intended to supersede any State law, municipal ordinance, or other local regulation which more strictly limits the terminology by which hearing aid sellers may legally refer to themselves.

APPENDIX B
METHODOLOGY OF SURVEY EVIDENCE

The record contains many surveys and reports, by industry consultants, public interest research groups, and the Department of Health, Education, and Welfare. The public interest group studies used primarily investigative techniques. These reports, which generally support the rule, are cited in the report as evidence of the specific instances they relate; staff does not claim that they are entitled to greater weight than other evidence of specific instances. Another study, the NHAS Complaint Analysis, claims to be a comprehensive analysis of consumer dissatisfaction.¹

The three remaining studies claim to use some sort of scientific sampling techniques. While they do not claim to be comprehensive, they do claim to have particularly broad implications because of the methodology employed. These are:

- Characteristics of Persons with Hearing Impairment, 1962-1963 (HEW, 1967);²
- The Hearing Aid Industry: A survey of the Hard of Hearing (1971)³ (commissioned by NHAS and HAIC) (hereinafter "Market Facts Survey"); and
- "A National Survey of the Hearing Aid Delivery System in the United States"⁴ (1974) (commissioned by NHAS) (hereinafter "Payne & Payne").

1 See Section V.

2 R8/511.

3 R8/616-82.

4 R8/1436-1512.

Each of these studies is cited extensively in the report. The conclusions reached in the studies are discussed elsewhere. The discussion below concerns only the survey methodology.

This section focuses on a narrow question. Are the three cited studies actually "scientific," and thereby entitled to increased evidentiary weight? When 8 out of 21 doctors interviewed by Payne & Payne say that dealers are not competent to give hearing tests, what does this mean? Is this only the opinion of 8 doctors? Does it represent the opinion of 38% of all physicians nationwide? Or does its meaning lie somewhere in between these extreme positions?

I. HEW Survey

The HEW study was published by the Public Health Service of HEW as one of a series of statistical reports prepared by the National Health Survey. It is based on information collected in 1962, in a continuing nationwide sample of households in the Health Interview Survey, a part of the National Health Survey program.⁵ The report includes data on the social, economic, and demographic characteristics of persons with a binaural loss of hearing (a little over 4 million persons in 1962). The report also includes information regarding this group's use of, and satisfaction with, hearing aids and training and testing received.

5 R8/D219/ip. 45.

Method.⁶ The information contained in this report was collected in two parts and is based on the data obtained in each. First, trained interviewers of the Bureau of the Census for the Health Interview Survey, National Center for Health Statistics, conducted household interviews (of one or more persons) in the respondents' homes.⁷ Respondents' answers were recorded on a "basic" questionnaire. Second, a follow-up supplementary questionnaire, edited and coded by Gallaudet College, was mailed to those individuals identified by the basic questionnaire as hearing impaired.

Sample. For purposes of the household interview, conducted from July 1962 through June 1963, the sample population consisted of about 134,000 persons from 42,000 households. The "universe" population consisted of the civilian, non-institutional population of the United States living at the time of the interview. The sample population is representative of the universe population in terms of age, sex, color and residence.⁸

The supplemental questionnaire was mailed to all persons identified in the basic interview as having a binaural hearing

6 Details regarding the statistical design (general plan, sample size, data collection, estimating methods, reliability, etc.) of the Health Interview Survey are given in Appendix I of the report and are not summarized here (see R8/D219/ip. 45 et seq.).

7 Copies of the basic and supplemental questionnaire are provided in Appendices III and IV (R8/D219/ip. 55 et seq.).

8 R8/D219/ip.45-46.

problem. Thus, current, former and non-users of hearing aids were included in the sample. Parents or guardians were asked to fill out the questionnaire for children. The number of persons receiving a supplemental questionnaire was not given. About 93% of the supplemental questionnaires were returned.⁹

II. Market Facts

Purpose/Objectives. The Market Facts Survey was commissioned by the National Hearing Aid Society and the Hearing Aid Industry Conference to "propose a program of research to evaluate how well" the two organizations were achieving the "rehabilitation of the hard of hearing." Market Facts conducted a pilot survey in September and October of 1970 to evaluate data collection techniques and the feasibility of obtaining such information. After completion of the pilot study a full scale study was authorized by NHAS.¹⁰

Method and Sample. The study, conducted in February 1971, was done by mail. Users and non-users were sampled. The respondents--hearing aid users and hard of hearing non-users--were all members of Consumer Mail Panels, a division of Market Facts.¹¹ Twenty-eight

9 Id. at ip.2.

10 R8/618.

11 Consumer Mail Panels is comprised of 70,000 households. From these households 45 panels of 1,000 households each has been formed based on 1) age of panel member, 2) income, 3) population density, and 4) geographic region. The samples are purported to match US Census Information and thus each comprises a representative sample of US households (R8/620).

thousand households were screened to locate 717 users and 2,511 non-users. Survey questionnaires were sent to all 717 users and to 700 non-users.¹² Ninety percent (646) of the users and 85% (593) of the non-users returned the questionnaire. Former users of hearing aids were included in the non-user category.

Appendix C to the Market Facts report is entitled "Qualifications of Market Facts, Incorporated." These include:

- 1) The company was established in 1946 and employed over 250 people full-time.
- 2) To help insure objectivity, the company was publicly owned and officers were not permitted to become directors of other companies.
- 3) The company conducted primarily consumer attitude and/or behavior studies, covering a "wide range" of subjects and techniques.

III. Payne & Payne

The Payne and Payne Study occasioned the most record debate. James Payne appeared as a witness in the hearings. Hal Kassarian testified to criticize the study.

Purpose/Objectives. This study was commissioned in spring 1974 by the National Hearing Aid Society "[t]o satisfy the need for information "regarding the practices and attitudes of ear specialists, audiologists, and dealers and the attitudes, needs and experiences of users" and to provide insights which might be useful

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A different survey was mailed to each group. Copies are provided in Appendix B of the study (R8/670 et seq.).

in improving the hearing aid specialist's¹³ services to the hearing impaired" The survey was "conceived, planned, and carried out" by Payne & Payne Consultants. Chilton Research Services developed the sample and served as a consultant.¹⁴ According to this report, NHAS had no input in planning the survey, and exercised no censorship over the findings (R8/1439).

The survey's "notable features" were listed by Payne and Payne to include:

- 1) It was national in scope, covering a systematic cross section of the population.
- 2) The survey sample included ear specialists, audiologists, dealers, and users.
- 3) The survey technique (i.e., "depth interviews" built around a standard questionnaire which elicited comparable and measurable data, and . . . provided free association stimuli leading to broader data on attitudes") (R8/1439).¹⁵

However, Payne testified that the study was not an opinion poll. "We were not attempting to generalize it for the four populations

13 Hearing aid dealers are consistently referred to as hearing aid specialists in this report.

14 Background on James E. and Majorie Payne and a description of Chilton Research Services are provided in Appendix I to the Payne & Payne report (R8/1505-07). Payne & Payne is described as a company specializing in "attitude research, and analysis of problems involving business and industry, science and society" (R8/1439).

15 Appendix II is entitled "Samples of Core Questionnaires" and includes a list of questions asked of users, dealers, ear specialists and audiologists (R8/1508 et seq.). It is not clear if these lists include every question asked (i.e., if the lists are an exact copy of the questionnaires used).

studied."¹⁶

Sample: The researchers identified primary sampling units (PSU's), from cities or towns with at least one NHAS member. Seventeen PSU's were randomly selected. (The cities used were not revealed.) Two to six NHAS members were selected in each PSU; a total of 73 were interviewed: audiologists and dispensers were located from the Yellow Pages, according to the report.¹⁷ Up to three audiologists and three doctors were interviewed in each city. However, because many would not co-operate, only 21 doctors and 17 audiologists were interviewed. Users were selected from the dealer files; 184 users were interviewed.¹⁸ 37% of the interviews were not completed; Payne did not consider incomplete interviews.¹⁹

The sampling was criticized by Hal Kassarian, a marketing professor at UCLA. He asserted, among other criticisms of the survey, that the sample could at most be projected to NHAS members.²⁰ Moreover, he criticized the small sample size for

16 R13/2617 [emphasis in original].

17 R8/1440 (In subsequent testimony, Payne said that universities and hospitals were consulted to add to the list.); R13/2614.

18 R8/1440-41.

19 HX38/ip5 (173 incomplete interviews; 295 complete interviews).

20 TR 9924, see also Melnick, R10/153. Payne indicates that the intent of the study was to focus on this limited population. R13/2613.

audiologists and doctors.²¹

Methodology. In using "depth interviews," a questionnaire served as a starting point. The interviewer used follow-through questions to explore the answers.

Kassarjian acknowledged the value of depth interviews, but criticized the Paynes' use of the technique. He noted great potential for abuse with the technique, because "a well-turned phrase, the intonation of the voice, the raising of one eyebrow" can influence the response. Kassarjian said it is considered poor practice for the experimenter to conduct interviews himself, as the Paynes did. Moreover, the Paynes' were "fully aware of the client's wants and needs."²² Even absent these special circumstances, he noted, verbatim responses, not produced here, must be available to analyze for possible bias.²³

Kassarjian cites several specific examples where he said, Payne & Payne's questionnaire indicated deficiencies. Question 2, for example, asks "In addition to the hearing aid specialist, whom did you consult about your hearing loss?" (Payne & Payne called the dispensers "hearing aid specialists"). The results, he notes, indicate that all respondents gave clear answers; e.g., general

21 Kassarjian called this sample size "silly." TR 9926. Payne later described the sample as "adequate for an exploratory study." R13/2615.

22 TR 9936.

23 Payne said that only the sponsor had the right to request verbatims for such verification.

practitioner or ear specialist.

"Not one of them confused an M.D. with a hearing aid specialist, not one of them said ear doctor when he meant audiologist. Based on my knowledge of questionnaire construction and research, the question as worded could not have produced [these] results. . . ."24

He concludes that the questions had to be paraphrased and the survey results without a transcript would be meaningless. In response Payne said that he never repeated anything but respondent's own answers. He denied any guidance, bias, or paraphrasing in any question in any of the interviews.²⁵

The record thus indicates that the most serious questions raised any of about these three studies concerned Payne and Payne.

24 TR 9932.

25 R13/2620-21.

APPENDIX C
THE MEDICAL DEVICE AMENDMENTS OF 1976

The purpose of the Medical Device Amendments of 1976 (P.L. 94-295) as described in its title, was "[t]o amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices." 90 Stat. 539 (1976) (emphasis added). In addition to various provisions designed to ensure the safety and effectiveness of medical devices, the Amendments empowered the Secretary of Health, Education and Welfare (now Health and Human Services) to classify certain medical devices as restricted if, because of "its potentiality for harmful effect or the collateral measures necessary to its use," it is determined that its safety and effectiveness cannot otherwise be assured. 21 U.S.C. § 360j(e).¹ The statute specifies that a device may be restricted as to sale, distribution, or use either (1) upon authorization of a licensed practitioner, or (2) upon other conditions the Secretary prescribes. 21 U.S.C. § 360j(e)(1).

The Medical Device Amendments made a further, special provision for restricted devices by amending section 502 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 352, which defines when a drug or device is misbranded. Subsection (q) thereof provides that a restricted device is misbranded "if (1) its advertising is false or misleading in any particular. . . ." Subsection (r) provides that a restricted device is misbranded unless the manufacturer, packer, or

¹ The Secretary immediately classified hearing aids as restricted devices. 41 Fed. Reg. 16758 (1976).

distributor includes in any advertisement or other descriptive printed matter the device's established name and "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications² Subsection (r) further states that

no advertisement of a restricted device . . . shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of Title 15. (15 U.S.C. 52-55).

21 U.S.C. § 352(r) (emphasis added). There is no comparable language in subsection (q).

The repeal of FTC jurisdiction in section 502(r) of the FDCA refers only to sections 52 through 55 of Title 15 (sections 12 through 15 of the Federal Trade Commission Act), and does not refer to section 5. However, NHAS and HAIC argue that all FTC authority under section 5 is implicitly repealed. Moreover, while Subsection (r) limits its withdrawal of FTC jurisdiction to "the matters specified in this paragraph" (i.e., the specified affirmative disclosure requirements), they contend that FTC jurisdiction is implicitly repealed with respect to the regulation of any aspect of the sale, distribution, or use of hearing aids.

The FDA, however, disagrees. In the Statement of Basis and Purpose to its 1977 regulation dealing with hearing aids, FDA said,

² In certain cases, the Secretary can also require a full description of the components of a device, or of the formula for a drug.

Section 502(r) gives FDA jurisdiction for regulating certain specified advertising of restricted devices, and the section concurrently removes FTC authority to apply the sanctions of court injunction or criminal penalties under sections 12 through 15 of the Federal Trade Commission Act to prevent [the dissemination of false advertisements]. It is the Commissioner's opinion, however, that section 502(r) limits FTC authority to the extent specifically stated in the section, i.e., section 502(r) applies only to restricted devices and only to possible FTC use of court injunctions or criminal penalties to prevent false advertising relating to the items of information specified in section 502(r). Moreover, section 502(r) does not extend to, or in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to prevent unfair or deceptive acts or practices.

In sum, it is the Commissioner's opinion that the net effect of section 502(r), as of the comparable provision under section 502(n) relating to prescription drugs, is to enable each agency to approach the regulation of restricted devices from the perspective of its particular statutory mandate. It is also the Commissioner's belief that both agencies will continue, as they have in the past, to work together in pursuit of their separate but closely related mandates. The Food and Drug Administration has long been aware of the FTC activities in the regulation of hearing aids that led to the FTC proposed rule, and the Commissioner believes these activities complement, rather than conflict with, this FDA regulation relating to labeling and conditions of sale of hearing aids. The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise.

Staff believes that an examination of the statutes, their legislative histories, and the relevant case law will demonstrate that the view endorsed by FDA is correct.

- I. The Medical Device Amendments of 1976 Do Not Repeal Jurisdiction Over Restricted Medical Devices Under Section 5 of the Federal Trade Commission Act.

The Preamble to the Federal Trade Commission's Proposed Trade Regulation Rule for the Hearing Aid Industry³ states that the Rule would be promulgated pursuant to both Sections 5 and 12 of the Federal Trade Commission Act (FTCA). This report shows that the acts and practices challenged violate Section 5.

Since Section 502(r) of the FDCA omits any reference to section 5 of the FTCA, it is clear that the Commission has retained jurisdiction under Section 5 to prohibit "unfair methods of competition" and "unfair or deceptive acts or practices" involving hearing aids.⁴ Indeed the Commission has also retained jurisdiction under Sections 12 to 15 over matters involving hearing aids not within the ambit of Section 502(r) of the FDCA.

A. Section 5 Jurisdiction Is Not Implicitly Repealed by The Medical Device Amendments

1. Repeals by Implication Are Not Favored

It is

"a cardinal principle of construction that repeals by implication are not favored. . . . It is not sufficient, as was said by Mr. Justice Story, in Wood v. United States, 16 Pet. 342, 363, "to establish that subsequent laws cover some or even all of the cases provided for by [the prior act]; for they may be merely affirmative, or cumulative,

³ See Proposed Rule, § 440.1, 40 Fed. Reg. 26646 (1975).

⁴ As the Supreme Court has declared, when we find the terms of a statute unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances Rubin v. United States, 449 U.S. 424 (1981). The court has also noted "The plain meaning of the words of the Act covers the use. No single argument has more weight in statutory interpretation than this. Browder v. United States, 312 U.S. 335, 338 (1941). See also TVA v. Hill, 437 U.S. 153, 187, n. 33 (1978).

or auxiliary." There must be "a positive repugnancy between the provisions of the new law, and those of the old; . . ."

United States v. Borden Co., 308 U.S. 188, 198-99 (1939) (emphasis added).⁵ See also St. Martin Evangelical Lutheran Church v. South Dakota, 451 U.S. 772, 788 (1981); United States v. United Continental Tuna Corp., 425 U.S. 164, 168 (1976) (collecting cases).

While it is true that the failure to repeal the Commission's authority under Section 5 leaves both the Commission and the FDA with some authority over statements concerning intended uses, warnings, precautions, side effects, and contraindications in the advertising of hearing aids, that fact does not require the implicit repeal of the Commission's Section 5 jurisdiction. Indeed, it is a corollary of the principle that repeals by implication are not favored that

when the legislature has chosen to enact two acts which deal with the same subject matter, the rule is to give effect to both if possible. . . .

Id. at 198. Thus, only if the two acts are impossible to reconcile, or repugnant to one another, can the FDA's new authority over the advertising of restricted devices be construed to divest the FTC of its established jurisdiction under Section 5. No such "positive repugnancy" between the two

⁵ The Borden Court reversed a lower court determination that, because the Agriculture Marketing Agreement Act had committed to the Secretary of Agriculture power over production and marketing in interstate commerce of agricultural products, the Sherman Act was implicitly repealed with respect to such products.

statutes can be found.⁶

To support its assertion that FTC jurisdiction under section 5 was impliedly repealed by the Medical Device Amendments of 1976, NHAS has relied upon the principle that a "specific statute will usually not be controlled or nullified by a general one." (R1/D225ip7). This principle has no application, however, since the existence of FTC jurisdiction under Section 5 does not "nullify or control" the jurisdiction granted to FDA by the Medical Device Amendments.⁷

6 Such a repugnancy could exist only if the two agencies interpreting the acts developed inconsistent regulations, a state of affairs that the FTC and the FDA have steadfastly avoided. See Appendix C, Section II.C.

7 The cases cited by NHAS in support of this contention are similarly inapplicable. Indeed, in Morton v. Mancari, 417 U.S. 535 (1974), the Supreme Court reversed a lower court determination that the 1972 Amendments to the Civil Rights Act had impliedly repealed the Indian Reorganization Act of 1934, which gave preferential treatment to Indians in federal employment. The Court noted

In the absence of some affirmative showing of an intention to repeal, the only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable.

Id. at 550 (emphasis added). On the other hand, the remaining cases cited by NHAS are inapposite because they did involve irreconcilable statutes. In Thielebeule v. M/S Nordsee Pilot, 452 F.2d 1230 (2d Cir. 1971), the two statutes contained conflicting provisions concerning the prepayment of monies as security for expenses incurred in an in rem proceeding. In A.P.W. Paper Co. v. FTC, 149 F.2d 424 (2d Cir. 1945), aff'd, 328 U.S. 193 (1946), the Commission had banned the use of the words "Red Cross" and the Red Cross symbol, holding that they had the tendency to mislead the public into believing that the paper products in question were in some way connected with the American Red Cross. The Second Circuit reversed, but only because the American Red Cross Act of 1905, which created the Red Cross,

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Furthermore, the general policy against implicit repeal is even stronger with respect to remedial legislation such as the FTCA. The general rule is that remedial legislation must be given a liberal construction. FTC v. Mandel Brothers, Inc., 359 U.S. 385, 389 (1957). Even such explicit exceptions as are contained in the remedial legislation itself are to be narrowly construed. Phillips Co. v. Walling, 324 U.S. 490, 493 (1945). Surely these principles indicate that an implicit exception to remedial legislation should not be found absent compelling evidence of congressional intention to create such an exception. The language of the Medical Device Amendments does not suggest any such intention; indeed, Congress described with great particularity the circumstances in which certain provisions of the FTCA should not apply to advertising of medical devices. The legislative history, moreover, is ambiguous as to whether further exception was intended. As noted below, the House even did some fine tuning to specify the precise provisions covered. Under these circumstances, a proper construction of the statutes rests on the rule that

when the legislature has acted to except certain categories from the operation of a particular law, it is to be presumed that it intended to go only so far as it did and that no other exceptions are warranted.

Knapczyk v. Ribicoff, 201 F.Supp. 283, 285 (N.D. Ill. 1962).

⁷ (FOOTNOTE CONTINUED)

specifically allowed organizations that had been using the Red Cross emblem prior to the enactment of the statute to continue to do so.

2. Concurrent Jurisdiction is Common in Our Regulatory System

Under these circumstances concurrent jurisdiction must be applied absent "irreconcilability" of the FDCA and the FTCA. Morton v. Mancari, supra at 550; see United States v. Borden, supra at 198-99. In other words, it must be shown that certain aspects of the advertising of restricted medical devices cannot be regulated simultaneously by two agencies. It is instructive to note in this regard the statement by a Senate Committee in 1958, in a matter involving the FTC, that concurrent jurisdiction by two federal agencies "is a common aspect of our regulatory system." S. Rep. No. 1464, 85th Cong., 2d Sess. 4 (1958).⁸ The fact that concurrent agency jurisdiction is possible, and even common, makes it all the more likely that Congress, in enacting two statutes granting partial jurisdiction over the same subject matter to two agencies, meant the acts to be "cumulative or auxiliary." Indeed, absent affirmative evidence to the contrary, this is the manner in which the courts have interpreted such provisions.

In FTC v. Cement Institute, 333 U.S. 683 (1948), the Supreme Court was presented with the question whether the same conduct could be the basis for separate actions by the Attorney General under the Sherman Act and by the Federal Trade Commission under the Federal Trade Commission Act. The Court noted that

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The committee was concerned with the division of jurisdiction over meatpackers between the Federal Trade Commission and the Department of Agriculture.

the fact that the same conduct may constitute a violation of both acts in nowise requires us to dismiss this Commission proceeding. . . . [T]he Sherman Act and the Trade Commission Act provide the Government with cumulative remedies against activity detrimental to competition.

Id. at 694. See also United States v. W.T. Grant Co., 345 U.S. 629 (1953).

Moreover, the overlap between the FDCA and the FTCA has itself already provided numerous occasions for the courts to determine whether those acts were meant to grant exclusive jurisdiction to one or the other of the agencies. For example, Section 15 of the FTCA, which applies only to food, drugs, cosmetics, and medical devices, contains a "false advertisement" definition that specifically excludes labeling. Since authority over labeling of these items has been granted to the FDA pursuant to the FDCA, the argument has been repeatedly made that the FDA's authority over labeling was meant to be exclusive and that the Commission either could not or should not assert jurisdiction over labeling under Section 5 of the FTCA. In Fresh Grown Preserve Corp. v. FTC, 125 F.2d 917 (2d Cir. 1942), the Second Circuit rejected such an argument and upheld a Commission prohibitory order that extended to the labeling of the food in question.⁹ Similarly, in upholding a Federal Trade Commission

⁹ The court simply noted that "petitioners' conduct . . . amounted to unfair methods of competition in violation of §5 . . ." Id. at 919. The court stated that §§ 12-15 were added to the Federal Trade Commission Act "to give the Commission greater control over the advertising of food, drugs, cosmetics and the like by providing for criminal action as well as injunction" and concluded that only in a

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"cease and desist" order against a perfume manufacturer in Houbigant, Inc. v. FTC, 139 F.2d 1019 (2d Cir.), cert. denied, 323 U.S. 763 (1944), the Second Circuit rejected the contention that the FDCA "vested in the Federal Security Administration exclusive jurisdiction over the labeling of perfumes. . . ." 139 F.2d 1020. See also Charles of the Ritz Distributors Corp. v. FTC, 143 F.2d 676 (2d Cir. 1944). In Warner-Lambert Co. v. FTC, aff'd 562 F.2d 749 (D.C. Cir. 1977), the Commission entered an order affecting drug labels; the case was brought under Section 5 rather than section 12. Most recently, the Commission asserted that it had (but did not exercise) section 5 jurisdiction over drug labels in American Home Products, No. 81-8918, slip op. at 20 (1981).

The reverse issue of whether the exercise of FTC jurisdiction precluded action by the FDA was presented in United States v. Five Cases, Etc., 156 F.2d 493 (2d Cir. 1946). There, the district court had dismissed a condemnation action brought by the Food and Drug Administration for the misbranding of "Capon Springs Water." The FTC had charged claimants false advertising in 1936, based on the same label, and FTC had ordered them to cease and desist from making certain representations concerning the water's curative effects. The court stated that claimants' suggestion that because

they are made subject to a penalty for a violation of a cease and desist order, that remedy is

⁹ (FOOTNOTE CONTINUED)

proceeding under those sections was the definition contained in § 15 relevant. 125 F.2d 919 (emphasis added); see section II of this Appendix.

exclusive and a forfeiture proceeding under the Food, Drug and Cosmetic Act will not lie, is unwarranted. The remedies are plainly cumulative and not exclusive.

Id. at 496. In United States v. Research Laboratories, Inc., 126 F.2d 42 (9th Cir. 1942), the Ninth Circuit reversed the dismissal of a condemnation action brought by FDA against Nue-Ovo, a drug. The court upheld FDA's contention that allegedly false and misleading circulars accompanying the drug constituted advertising under the FTC Act, as well as labeling.

The court characterized the fact that the circulars could also be proceeded against by the Federal Trade Commission as "immaterial."
Id. at 45.¹⁰

The conclusion that section 502(r) of the FDCA was not meant to give FDA exclusive jurisdiction over the advertising of restricted devices is bolstered by analogy to Section 502(n) of the Act, which contains a similar provision with respect to prescription drugs. The provision parallels Section 502(r) quite closely,¹¹ although the

10 Similarly, in United States v. Various Quantities of Articles of Drugs, 83 F. Supp. 882, 887 (D.D.C. 1949), which also involved the label of a drug on the grounds of misbranding contained in accompanying booklets, the court noted that it was

well settled that the action of either of these agencies - that of the Food and Drug Administration relative to misbranding, and that of the Federal Trade Commission relative to false advertising - is not the exclusive remedy afforded to the government in a case where both misbranding and false advertising are present.

11 Section 502(n) states that a prescription drug is misbranded unless the manufacturer, packer or distributor includes in

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analogy to Section 502(n) is not perfect.¹² Thus, it is significant that the Commission has determined that it retains Section 5 jurisdiction over prescription drug advertising, noting that the "Drug Amendments of 1962 were clearly not intended to repeal the Commission's authority under Section 5 to proceed, where appropriate to prevent any regulatory gap, against unfair or deceptive representations in the marketing of prescription drugs." Charles Pfizer & Co., Inc., 66 F.T.C. 1000, 1011 (1964).¹³ Moreover, the FDA itself has adopted this analogous construction of Sections 502(r) and 502(n).¹⁴

The principle that meaning and effect must be given to acts of Congress mandates the conclusion reached by the courts in Warner-

11 (FOOTNOTE CONTINUED)

any advertisement the established name of the drug, its formula, and such information regarding side effects, contraindications, and effectiveness as may be required by the Secretary of HEW. It further provides that no advertisement of a prescription drug shall, with respect to the specified matters, be subject to sections 12-15 of the FTCA.

12 The advertising of prescription drugs has in the past been generally directed toward physicians. In fact, § 15(a) of the FTCA provides that "[n]o advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false misrepresentation of a material fact, and includes . . . the formula showing quantitatively each ingredient of such drug."

13 In Pfizer, the Commission did acknowledge the FDA should have a leading role in the area by declining to proceed with the case once it had been informed by HEW that the regulations it was promulgating pursuant to the Drug Amendments of 1962 covered the false advertising of the drug in question.

14 42 Fed. Reg. 9286 (1977).

Lambert Co. v. United States, 361 F. Supp. 948 (D.D.C. 1973), in which plaintiff sought injunctions against both the FTC and the FDA with respect to what it alleged were overlapping proceedings involving Listerine. Since one of the proceedings was adjudicatory, while the other involved rulemaking, the court concluded that the proceedings were "quite different." Id. at 952. The court noted, however, that even if the two proceedings could be characterized as "simultaneous duplicative proceedings," neither could be enjoined since neither was "unlawful nor arbitrary and capricious." Id. at 953. Since any action of the Federal Trade Commission with respect to hearing aids is pursuant to its statutory authority under Section 5, it too is neither "unlawful nor arbitrary and capricious."

B. Legislative Intent

Where the plain meaning of statute is clear, the courts (and the Commission) need not look to legislative history. Rubin v. United States, 449 U.S. 424 (1981), TVA v. Hill, 437 U.S. 153, 187 n. 83 (1978). The Supreme Court recently noted that "indefinite congressional expressions cannot negate plain statutory language and cannot work a repeal or amendment by implication." St. Martin Evangelical Lutheran Church v. South Dakota, 451 U.S. 772, 798 (1981). As an appeals court recently explained, where meaning is apparent on the face of a statute, an examination of the legislative history is inappropriate. The proper function of legislative history is to solve, and not to create, an ambiguity.

United States v. Rone, 598 F.2d 564 (9th Cir. 1979). See also

Glenn v. United States, 571 F.2d 270 (5th Cir. 1978).¹⁵ The language of this statute is clear. If anything, it is the legislative history which is ambiguous.

While staff thus believes that the courts need not even look to legislative history, we do note here that the legislative history does not show clear Congressional intent to preclude FTC jurisdiction.

The industry first asserts that Gerald Thain, then Assistant Director for National Advertising, told a House Subcommittee in 1973 that the FTC lacked the expertise to monitor "prescription device" advertising. However, Thain's statements clearly referred to "advertising which appears in medical journals;" this was the advertising which "requires more technical input than we have at our immediate disposal."¹⁶ Thain made these remarks in the context of

15 The cases cited by HAIC, Final Comments at Vol. III, p. 107, are inappropriate. Litchfield Securities Corp. v. United States, 325 F.2d 667 (2d Cir. 1963), cert. denied, 377 U.S. 931 (1964), used legislative history to choose between two equally plausible readings of a statute. United States v. Wise, 370 U.S. 405 (1962), found no "substantial support for such an artificial interpretation of a seemingly clear statute" in legislative history. Id. at 407.

16 The Regulation of Medical Devices: Oversight Hearings Before the Subcomm. on Intergovernmental Affairs of the House Committee on Government Operations. 93d Cong., 1st Sess. 392 (1973). HAIC's brief, final comments at Vol. III, p. 110, substantially distorts Mr. Thain's position by significantly omitting several key words from another comment of Thain's:

Just as the regulation of prescription drug advertising requires scientific expertise so too does the regulation of the advertising of "prescription devices." The FTC has not committed its scarce resources to the enormously expensive task of building a scientific staff capable of dealing with the complexities of such "prescription"

(CONTINUED)

testimony about IUD's, moreover, and they advertised exclusively to physicians.¹⁷ It is clear that Thain never intended to disclaim all FTC jurisdiction over any devices FDA might subsequently deem within its ambit.¹⁸

HAIC also cites statements by Congressman L.H Fountain, in particular. Fountain, who conducted the House hearings, subsequently testified before a Senate committee. The Senate bill contained a provision which gave FDA jurisdiction over hearing aid advertising.¹⁹ Fountain asked the Senate committee to amend the provision to preclude FTC jurisdiction under Sections 12-17. His intent was to preclude dual jurisdiction. However, while the Senate bill subsequently did incorporate such language,²⁰ it did not

16 (FOOTNOTE CONTINUED)

device advertising which is directed solely to the physician. It would be, in my judgment, inefficient to attempt to build requisite scientific capability at FTC to challenge the therapeutic claims of these "prescription" devices made in highly technical and complex advertising not directed to consumers.

Id. at 390 (emphasis added). The words emphasized above were precisely the words omitted by HAIC.

17 Id. at 391.

18 Indeed, Thain discussed the specific limitations on prescription drug advertising in Section 502(n), noting the Commission's position that a restriction on Section 12 leaves Section 5 jurisdiction intact. Id. at 388.

19 Section 502(r). This parallels § 502(q) of the final act.

20 Medical Devices Legislation: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare. 93d Cong., 1st Sess. 14 (1973).

incorporate the language into the general provision against false or misleading advertisements²¹ (502(q)), as Fountain recommended. Rather, the limitation appears in a more limited provision addressing affirmative disclosures (502(r)). (The accompanying committee report, however, contains broader language. It indicates that advertising of prescription devices generally will not be subject to Sections 12-17.)²²

The House bill that was eventually passed, H.R. 11124, similarly included a prohibition under 502(r) and not 502(q). Moreover, the House bill differed from the Senate bill in several ways. First, it referred to Sections 12 through 15 (not 17) of the FTC Act. This paralleled 502(n), the prescription drug provision.²³ The fact that Sections 16 and 17 were omitted is not substantively critical. (These Sections deal with FTC's representation by the Attorney General, and with severability.) What is significant is that the House Committee took precautions to specify the precise limitations on FTC jurisdiction -- and did not limit Section 5.

This is particularly critical because of another change made in the House bill. The category of "prescription" devices was broadened to cover "restricted" devices. Most testimony had focused on devices

21 S. Rep. 670, 93d Cong., 2d Sess. 36 (1974).

22 Id. at 17.

23 A provision which, Thain said in 1973, the FTC believed to have left section 5 jurisdiction intact.

such as IUD's, which could actually be life-threatening. These devices were prescribed by physicians, and their advertisements were directed to physicians. The change to "restricted devices," however, was accompanied by a change in § 520(e), which authorized FDA to appropriately restrict the sale of non-prescription devices. This change first brought into the act devices which FDA determined needed some controls, but which could still be sold without a prescription. This involves devices, such as hearing aids, which are advertised directly to consumers (and to sellers without formal medical or other academic training).

Even assuming arguendo that the Senate Bill intended to eliminate FTC jurisdiction over prescription devices, there is thus no evidence that H.R. 11124's narrower restriction was intended to eliminate FTC jurisdiction over the broader class of restricted devices. Certainly nothing in the House Committee Report (or the Conference Report²⁴ which tracked the House Bill in this respect) supports this position. This ambiguity in the legislative history contrasts with the clear language of the statute, and the latter must control.

Further evidence of Congressional intent is that the Congress has closely scrutinized Commission rulemaking since 1976. Indeed, the Federal Trade Commission Improvement Act of 1980 set out specific mandates for the funeral industry and children's advertising proceedings. However, Congress has never questioned the ongoing hearing aid rulemaking.

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H.R. Rep. No. 1090, 94th Cong., 2d Sess. (1976).

II. Rational Reasons for Retaining Jurisdiction Under Section 5 While Partially Repealing Jurisdiction Under Sections 12-15

It has long been established that the FTC retains Section 5 jurisdiction over those items (food, drugs, cosmetics, and devices) governed by the more specific provisions of Sections 12-15. It is nevertheless necessary to examine the purposes Congress sought to accomplish through Section 12 through 15, in order to determine the purpose that Congress intended to effectuate by Section 502(r) of the FDCA. In addition, in assessing whether Congress intended the remedies provided in the FDCA with respect to restricted devices to be exclusive of, or supplemental to, those provided in Section 5 of the FTCA, it is important to determine both the major evils at which those statutes were aimed and the methods that were provided to cure them. Statutes often approach the same subject matter from different points of view, and this may indicate congressional recognition that the agencies that carry out the policies of those statutes can approach the problem simultaneously from different perspectives. As the Fourth Circuit noted in resolving a similar jurisdictional problem in Crosse & Blackwell Co. v. FTC, 262 F.2d 600, 603 (4th Cir. 1959): "It behooves us, therefore, to refer briefly to the problem which the Congress sought to resolve and the purpose to be served" when each of the statutes with which we are concerned was enacted.

A. The Purpose of Sections 12-15 of the Federal Trade Commission Act

In Fresh Grown Preserve Corp. v. FTC, *supra*, the Second Circuit noted that Sections 12-15 were added to the FTCA to "give the

Commission greater control over the advertising of food, drugs, cosmetics and the like by providing for criminal action as well as injunction." 125 F.2d 919 (emphasis added). A review of the legislative history of the Wheeler-Lea Amendments, by which these sections were enacted, affirms this conclusion. Representative Lea, in discussing the proposed bill, noted the inclusion of

a provision relating to advertisements of drugs, foods, cosmetics, and devices. The main purpose of this is to strengthen the jurisdiction that the Federal Trade Commission already has over advertising.

83 Cong. Rec. 392 (1938) (emphasis added). At another point in defending the provisions he reemphasized this view, stating that

the Commission has exercised this control for many years. . . . We are asking for nothing new. We are simply asking . . . for an effective enforcement of these provisions.

Id. at 410.

Senator Wheeler similarly stated that the purpose of the provision in Section 12(b) of the FTCA, which states that a practice violative of that Section is also an "unfair or deceptive" act within the meaning of section 5,

is to retain Federal Trade Commission jurisdiction through its cease-and-desist order procedure over such false advertisements which might not be of such serious character as to warrant criminal prosecution under a later section of the act, section 14.

Id. at 3255. He noted that the new sections of the FTCA simply provided "more effective methods of accomplishing the purposes of the existing law." Id. at 3256.

More effective control over this advertising was deemed necessary

because, as Senator Wheeler pointed out, "their use directly affects the consumer's health rather than his pocketbook." Id.; see H.R. Rep. No. 1613, 75th Cong., 1st Sess. 1 (1937). He described the injunctive provisions contained in Section 13 as enabling the Commission "to give the public adequate protection" from the dissemination of false advertisements "pending the issuance of complaints by the Commission and their review by the courts, whenever the Commission has reason to believe that such injunctive relief is in the interest of the public." 83 Cong. Rec. 3255 (1938). Senator Wheeler noted that this injunctive remedy was justified "where there is a question of the public health, where one may take some medicine as a result of false advertising which might kill him. . . ." Id. at 3293.

Thus, the justification for the special provisions in the FTCA for health-related items, including medical devices, is that false advertising of such items may be particularly dangerous. Viewed against this background, a rationale for the congressional decision to withdraw these extraordinary remedies in the area of restricted medical devices becomes apparent.

Under Section 502(r) any medical device is deemed misbranded if its advertising does not contain the information described in the statute. This amounts to a judgment by Congress that "because of its potentiality for harmful effect or the collateral measures necessary to its use," 21 U.S.C. § 360j(e), the safety and effectiveness of a restricted device cannot be guaranteed unless any advertisement for it contains a statement of its intended uses, relevant warnings,

precautions, side effects, and contraindications. By providing that a restricted device is misbranded if its advertising does not contain these statements, Congress has given the Food and Drug Administration the power to seize and condemn any such devices pursuant to Section 304 of the FDCA, 21 U.S.C. § 334. Thus, Congress' repeal of FTC jurisdiction under Sections 12-15 with respect to certain issues merely represents a determination that potentially dangerous situations can be controlled by FDA seizure and condemnation. Moreover, since FDA also has access to the use of criminal penalties and injunctions with respect to misbranded devices, 21 U.S.C. §§ 332, 333, the extraordinary FTC remedies contained in Sections 12-15 are unnecessary.

This is essentially the view of Section 502(r) expressed by the FDA in its recently promulgated rule concerning hearing aids, as noted at the beginning of this appendix. It is well established that an agency's interpretation of its enabling legislation is entitled to great weight. Udall v. Tallman, 380 U.S. 1 (1965); see Zemel v. Rusk, 381 U.S. 1, 11 (1965). Consequently, it is particularly significant that FDA views the FTC's jurisdiction, and the FTC's proposal, as complementing its own.

The fact that the actions of the agencies do complement each other is explained by the fact that each approaches "the regulation of restricted devices from the perspective of its particular statutory mandate." It is the existence of the FTC's particular perspective which explains why Congress chose to leave untouched the FTC's section 5 jurisdiction over "unfair or deceptive acts or practices" involving

hearing aids and other medical devices.

B. The Particular Perspective of Each Agency

At the time of enactment of the Wheeler-Lea Amendments, there was lengthy debate over the question whether control of the advertising of health-related products (food, drugs, cosmetics, and medical devices) should be given to the FDA, since that agency had special expertise in the area of health. The ultimate decision, as reflected in the Wheeler-Lea Amendments to the FTCA, was to leave control over the advertising of these products with the FTC because of its unique expertise in the regulation of advertising. As the House Report stated:

The Federal Trade Commission has the machinery and trained personnel to investigate in a proceeding against false advertising of all industries and all commodities. The common motive of false advertisement is the same in every line of industry, to gain an economic advantage through defrauding or misleading the purchaser. This method of protecting the public should be harmonized and unified under one organization with consistent and uniform methods of enforcement and penalization.

H.R. Rep. No. 1613, 75th Cong., 1st Sess. 5 (1937) (emphasis added).

The partial repeal of FTC jurisdiction under Sections 12-15 of the FTCA, and the concomitant grant of jurisdiction to FDA, does represent a modification of the scheme established by the Wheeler-Lea Amendments. By repealing some (though not all) FTC authority over the issues described in Section 502(r), Congress has indicated that it wishes the FDA to take a leading role in this area. This is consistent with the perspective of the FDA, since a determination of

what intended uses, warnings, side effects, and contraindications must be included so that an advertisement of a restricted device will promote its safe and effective use is a matter requiring medical expertise of a kind particularly available to the FDA. The FTC's special expertise, on the other hand, consists in ensuring that the information contained in an advertisement helps (and does not hinder) the individual consumer to assess the value of the particular device for him or her. By approaching the matter of advertising from these different perspectives, the FTC and the FDA can "work together in pursuit of their separate but closely related mandates."

Thus, for example, if FDA specifies²⁵ that statements concerning intended uses, warnings, contraindications, and side effects must be included in any hearing aid advertisements, the FTC might determine that an additional statement, a more conspicuous statement, or a corrective for non-advertising sales practices, is necessary. Or the Commission might prohibit certain statements involving these issues, something the FDA is not specifically authorized to do. Thus, the jurisdictional overlap created by Congress' refusal to repeal the FTC's Section 5 jurisdiction leaves room for the Commission to utilize its special expertise directly on advertising -- or indirectly to curb marketing abuses.²⁶

25 The rule adopted by the FDA concerning hearing aids does not specify the statements that will satisfy the requirements of § 502(r).

26 The permissibility of concurrent jurisdiction between the FTC and another agency with particular scientific expertise was
(CONTINUED)

Furthermore, FTC action under section 5 can complement FDA action because the remedy under that Section (i.e., the cease-and-desist order) is more flexible than the usual FDA remedy of condemnation. An advertisement for a restricted device might contain a misstatement or omission about its intended uses, warnings, contraindications, or side effects without necessarily endangering the safe and effective use of the device. Condemnation is a severe remedy; only a cease-and-desist order might be a more appropriate remedy in certain situations.

In addition, a device is misbranded under Section 502 of the FDCA only if "the manufacturer, packer, or distributor thereof" fails to include the relevant material in all advertisements. If an advertising agency should omit the relevant material, however, the devices apparently could not be deemed misbranded. Congress could not have intended that there be a complete "regulatory gap" in the control of

26 (FOOTNOTE CONTINUED)

specifically upheld in Sterling Drug, Inc. v. FTC, No. 73 Civ. 3406 (S.D.N.Y., Dec 20, 1973). In that case the court was asked to stay FTC proceedings with respect to plaintiff's product, Lysol, on the ground that the questioned statement (Lysol "kills . . . germs on environmental surfaces") had been approved as scientifically correct by the Environmental Protection Agency. The court noted that the "E.P.A. merely approved a label statement, which while true, the FTC now claims was used in a deceptive manner." Id. at 6. The court noted that FTC authority "includes the power to investigate deceptive advertising, which by definition includes the misleading use of an approved scientifically correct statement." 15 U.S.C. § 45(a) and (b). Id.

such advertisements. See Crosse & Balckwell Co. v. FTC, supra.²⁷

Thus, the differing perspectives of the FTC and the FDA were recognized by Congress in enacting the Medical Device Amendments of 1976, just as they have been recognized in previous legislation. The relevant statutes therefore authorize an interactive process between the FTC (under Section 5 and, for certain claims, section 12 as well) and the FDA in the regulation of hearing aid advertising.

C. Cooperation Between the Two Agencies

The interactive process envisioned by Congress has, in fact, occurred, both with respect to the regulation of hearing aids and in other areas of overlapping FTC-FDA jurisdiction. The final hearing aid rule propounded by the FDA was changed in several respects from the original FDA proposed rule to prevent any conflict, however minor, with the FTC proposal. Thus, for example, in the definition of hearing aid contained in Section 801.420(a)(1), FDA substituted the word "designed" for the word "designated" so as "to conform to the definition in the regulations proposed by FTC." 42 Fed. Reg. 9289 (1977). Similarly, the final FDA rule, unlike the Proposed Rule,

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Finally, it must be noted that because the primary focus of the FTC is on ensuring adequate information for consumers rather than on ensuring the general safety and effectiveness of a medical device, there are significant provisions of the proposed FTC rule on hearing aids which clearly do not directly involve the intended uses, warnings, contraindications, and side effects. Representations that an aid is "new" scarcely go to these concerns, nor do representations about a seller's expertise.

contains a definition of "used hearing aid." This was to ensure conformity with the FTC Proposed Rule.

The two agencies have a long history of working together to accomplish related goals. The working agreement between the FTC and the FDA, approved on June 9, 1954, contains the following statement: "The two agencies have a common objective of preventing deception of the public through the misrepresentation of food, drugs, devices or cosmetics." 3 CCH Trade Reg. Rep. ¶ 9850.01 (1975).

It can only be assumed that Congress was aware of the long history of cooperation between the FTC and the FDA in those areas where they share concurrent jurisdiction, and that it chose to have them continue to share that jurisdiction with respect to the regulation of medical devices.

III. The Regulatory Scheme Established Under the Medical Device Amendments of 1976 Is Not So Pervasive that Federal Trade Commission Jurisdiction Must Be Withdrawn

In asserting that FDA regulation of restricted medical devices was meant to be exclusive, NHAS has noted that Section 520(e) of the FDCA, 21 U.S.C. § 360j(3), allows the FDA to regulate the sale and distribution of restricted devices. (R1/D225ip5). NHAS further relies on the fact that Section 521, 21 U.S.C. § 360k to some extent prohibits state regulation of medical devices. Id. NHAS argues that these sections evidence "the legislative intent to rest exclusive jurisdiction with respect to the sale and distribution of medical devices with the FDA." Id.

However, as set forth above, there is no indication to overcome the clear statutory language in the Medical Device Amendments Act that

limits the preemption of FTC jurisdiction. As pointed out above, concurrent jurisdiction of two agencies over the same subject matter is a common aspect of our regulatory system and thus provides no support for the assumption that Congress meant to repeal the application of the Federal Trade Commission Act. Moreover, as previously noted, the merits of this particular type of concurrent jurisdiction between the FTC and FDA have been repeatedly noted by the courts and the Congress.

Secondly, the provisions concerning state regulation of medical devices militate against the conclusion that FDA jurisdiction was meant to be exclusive. Thus the states are prohibited under section 521(a) of the FDCA, 21 U.S.C. § 360k(a), from establishing or continuing any requirement for a medical device, relating to matters under the act, which is different from (or in addition to) requirements under the Act. However, the act provides that the Secretary may exempt state regulations from this prohibition.²⁸ Thus, the fact that the Medical Device Amendments do leave room for the enactment of more stringent requirements for medical devices by the states indicates that Congress did not view the regulatory scheme established in the Amendments as an all-pervasive one.

Thus, this scheme is not so all-pervasive that it requires immunity from other regulatory statutes in order to function properly; under this test, applied by courts, it is clear that the statute is

not sufficiently pervasive to preclude other jurisdiction.²⁹

IV. Conclusion

The plain meaning of the Medical Device Amendments and the Federal Trade Commission Act, the legislative history of those acts, and the practical construction given them by the agencies responsible for administering them all lead to the conclusion that the acts grant

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In United States v. Philadelphia National Bank, 374 U.S. 321 (1963), the Supreme Court rejected the argument that the regulatory scheme established by the Bank Merger Act immunized bank mergers from section 7 of the Clayton Act. Under the Bank Merger Act, the Comptroller of the Currency was authorized to approve bank mergers, and he had approved the merger of the two Philadelphia banks involved. The Attorney General nevertheless sought and obtained an injunction against the merger under section 7 of the Clayton Act. The Court, in upholding the injunction, noted that the fact "that the banking agencies maintain a close surveillance of the industry . . . does not make federal banking regulation all-pervasive, . . ." Id. at 352.

Similarly, in United States v. Radio Corporation of America, 358 U.S. 334 (1959), a civil antitrust action under section 5 of the Sherman Act, the Court rejected the argument that the Federal Communications Commission's approval of defendants' agreement to exchange a Cleveland television station for one in Philadelphia was a bar to the action. The Court refused to hold that the regulatory scheme established by the Federal Communications Act required immunization from other regulatory schemes, such as the antitrust laws. Indeed, the Supreme Court noted that the doctrine has been invoked only when competing agency jurisdiction would disrupt one agency's "delicate regulatory scheme." Id. at 348.

The hearing aid industry certainly is not subject to a "delicate regulatory scheme" that would be disrupted by FTC regulation. If anything, the regulatory activities of the FTC and the FDA "complement rather than conflict with" each other. The Food and Drug Administration has already so concluded, and NHAS has given the Commission no reason to dispute the soundness of that conclusion.

concurrent jurisdiction over medical devices to the Federal Trade Commission and the Food and Drug Administration, with the very narrow exception specified in section 502(r) of the Food, Drug, and Cosmetic Act. This conclusion is reasonable since the purposes of the acts, and consequently the major emphasis of each administering agency, are different. Moreover, it has not been unusual in the past for Congress to create this kind of concurrent agency jurisdiction. While care must be taken in such situations to ensure that the two agencies do not inflict conflicting regulations upon the industry, the FDA and the FTC have a long history of maintaining close contact to ensure that their actions are complementary. Thus, it is the view of staff that the Commission has clear jurisdiction over hearing aids and over the specific matters contained in the Recommended Rule.

APPENDIX D
POST-RECORD CHANGES

The record in this proceeding closed over five years ago. During that time, there have been two significant changes of which the Commission should take notice:

- (1) The promulgation of FDA regulations governing hearing aid sales; and
- (2) The entry of six consent orders against hearing aid manufacturers.

Despite these changes, staff recommends that the Commission act on the basis of the existing record. We believe, however, that the question is a close one. Indeed, it poses the most serious hurdle to rulemaking.

I. Legal Standards

This decision involves both legal and policy questions. The law in this area is well-settled: an administrative agency has broad discretion to act on a record, despite circumstances which intervene after the record closes. ICC v. Jersey City, 322 U.S. 503

(1944); U.S. v. Pierce Auto Lines, 327 U.S. 515 (1946); Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281 (1974); Nance v. EPA, 645 F.2d 701 (9th Cir. 1981).

Courts are reluctant to remand an agency's decision on the basis that it relied on evidence which has grown stale due to the passage of time or new legislation while awaiting judicial review. See Air Products and Chemicals v. FERC, 650 F.2d 687, 704 (5th Cir. 1981). The rationale of this reluctance was succinctly stated by the Court

in ICC v. Jersey City, supra, at 514-15:

One of the grounds of resistance to administrative orders throughout federal experience with the administrative process has been the claims of private litigants to be entitled to rehearings to bring the record up to date and meanwhile to stall the enforcement of the administrative order. Administrative consideration of evidence--particularly where the evidence is taken by an examiner, his report submitted to the parties and a hearing held on their exceptions to it--always creates a gap between the time the record is closed and the time the administrative decision is promulgated.... If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening. It has been almost a rule of necessity that rehearings were not matters of right, but were pleas to discretion. And likewise it has been considered that the discretion to be invoked was that of the body making the order, and not that of a reviewing body.

To warrant the occasional remand, the change in circumstances must be "not merely 'material' but [must rise] to the level of a change in 'core' circumstances, the kind of change that goes to the very heart of the case." American Optometric Ass'n v. FTC, 626 F.2d 896, 907 (D.C. Cir. 1980), (quoting Greater Boston Television Corp. v. FCC, 463 F.2d 268, 283 (1971), cert. denied, 406 U.S. 950 (1972)); Air Products and Chemicals, supra, at 705.

For example, in American Optometric Ass'n v. FTC, supra, one of the issues which led to remand was a change in circumstances. (The court also emphasized the breadth of pre-emption of state laws). Most of the provisions of the Eyeglasses I rule limited or abolished states' powers to regulate the advertising of ophthalmic goods and services, and the Commission relied for the most part on evidence of

state laws banning this advertising. After Bates v. State Bar of Arizona, 433 U.S. 350 (1977), held that state prohibitions on advertising were unconstitutional, the need for such a broad preemptory rule diminished, but the Commission failed to consider the resulting changes in state laws.

In Burlington Truck Lines v. U.S., 371 U.S. 156 (1962), an ICC order was issued in response to boycotting activity. The order was remanded because an intervening statute had made illegal the very boycotting activity which precipitated the order.¹

Most changes in circumstances, however, do not justify judicial remand. For example, the courts have declined to remand proceedings for reopening where: 1) the ICC granted applications for motor carrier operations in reliance on five year old evidence "undoubtedly" changed by economic changes. Bowman Transportation v. Arkansas-Best Freight System, 419 U.S. 281, 294 (1974); 2) an ICC order granting a certificate of public convenience and necessity to motor carriers was challenged due to changes wrought by the impact of the war upon transportation facilities. U.S. v. Pierce Auto Freight Lines, 327 U.S. 515 (1946); 3) the EPA approved a redesignation of air quality standards without taking into account pending legislation (signed into law two days after final EPA approval) affecting the redesignation. Nance v. EPA, supra. See also Air Products and

¹ See also Greater Boston Television Corp., supra, at 284. The issue was which of two applicants for a license was better qualified and the FCC found that a critical factor was one individual's credentials. The death of that person, the court said, is a change in 'core' circumstances.

Chemicals, supra.

II. FDA Regulations

This section summarizes the FDA's 1977 regulations and their impact on this proceeding. FDA regulations govern the labeling and sale of hearing aids. Several provisions arguably affect the need for rulemaking. In staff's view, these regulations neither constitute a change in "core" circumstances, nor justify discretionary reopening of the record.

A. The Medical Pre-Clearance Requirements

1. The Requirement and Its Limitations

21 CFR § 801.421(a) requires that a hearing aid buyer have a medical examination within 6 months of a hearing aid purchase. However, a user over 18 years of age may waive the examination in writing.² The medical examination is required because:

an unnecessary or partially effective hearing aid device may be substituted for primary medical or surgical treatment... in a detriment to health. In addition... purchase of a hearing aid device that may not achieve its intended effect involves a high and unnecessary cost to the patient.

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The waiver states:

I have been advised by _____ (Hearing Aid Dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

42 Fed. Reg. 9288 (1977).

The medical pre-clearance requirement, in other words, eliminates some sales which are medically as well as economically unwarranted. However, substantial risk of no significant benefit remains. Some of these risks are unavoidable, and thus clearly unaffected by preclearance.³ Others are avoidable, but our record shows that physicians may limit their role to examining for medical problems;⁴ in other words, a physician's visit may not even eliminate the avoidable risks, other than the risk of receiving a medically inappropriate aid. FDA itself explained:

It should be emphasized that the medical evaluation requirement does not require the physician to prescribe, recommend, or certify that a patient may be helped by a hearing aid. The provision simply requires that the physician provide the patient with a written statement indicating that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid.

42 Fed. Reg. 9288 (1977).

Indeed, FDA requires a consumer notice which explains FDA's limited perception of the physician's role:

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

3 See Section I.B.4.

4 See Section I.B.5.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

21 CFR § 801.420.

2. FDA's Position on the FTC's Rulemaking

Beyond recognizing the limits of a medical examination, FDA has said that the FTC has jurisdiction to require a trial period,⁵ and has endorsed the trial period. FDA said the FTC's

activities complement, rather than conflict with FDA regulation. . . . The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise.⁶

* * *

FDA regulations have been developed in full awareness of the FTC proposed trade regulation rule. .

FDA supported the trial period because it

will afford every prospective hearing aid user the opportunity to wear the selected hearing aid in a variety of uses during which the hearing-impaired user can make an informed judgment on whether a

5 See the Introduction to Appendix C.

6 "Hearing Aid Devices," 42 Fed. Reg. 9286 (1977).

7 Id. at 9287.

benefit is obtained from the use of amplification. The Commissioner believes that in the final analysis the hearing aid user is the person best qualified to determine whether or not a hearing aid is useful and efficacious for its intended purpose.⁸

Even while noting its support of the FTC's efforts, FDA acknowledged the need to avoid "unnecessary economic or psychological barriers to the receipt of quality hearing aid health care."⁹ FDA clearly concluded that a trial period was compatible with these goals.

In a subsequent decision involving state petitions to preempt FDA regulations, the FDA again noted the importance of the proposed FTC rulemaking. The 1980 decision concluded that medical pre-clearance had "reduced some abuses in the industry and that adoption of the FTC rule would reduce these abuses even further."¹⁰

3. The Beltone Decision

8 Id. at 9289. See also Id. at 9289 (in rejecting mandatory audiologic-testing, FDA said "a trial-rental option is better...in determining patient benefit from amplification").

9 Id. at 9287.

10 "Exemption From Preemption of State and Local Hearing Aid Requirements; Applications for Exemption." 45 Fed. Reg. 67326, 67328 (1980). See also Id. at 67330 (mandatory audiologic examination could not be required by states; stricter licensing and the FTC's proposed trial period would more efficiently reduce costs of misfittings). In the 1980 notice, FDA also said that a state-mandated trial period remedy did not "relate to the safety and effectiveness of hearing aids." Consequently, a New York provision was not pre-empted by federal law; moreover, FDA said it was desirable because it would encourage reluctant persons to try an aid and reduce the problems associated with misvaluation of hearing loss. Id. at 67334.

The Commission recently noted the impact of this FDA regulation. In Beltone Electronics Corporation, Docket 8928 (July 6, 1982) the Commission found that 40% of hearing aids were sold through professional referrals in 1980,¹¹ with a higher percentage in urban areas. The Commission also found the FDA regulation provided "significant impetus" for this trend, Beltone slip op. at 6. (The Commission further found that there were few referrals in 1973, when the complaint was brought. Beltone slip op. at 15. However, there was little testimony in Beltone on the extent of the referral market in 1973; the more extensive evidence in our record shows that many consumers had pre-clearance even then).¹²

To the extent that physicians select an aid, continuing growth in pre-clearance suggests caution in the use of our record. This is not because physicians can eliminate the risk of no significant benefit -- as noted above, no one can eliminate the risk without a trial -- however, our record suggests that when third parties (audiologist or physicians) recommend a specific aid, they also recommend, and often secure, trials. Thus, a growth in the referral market implies growth

11 There is some ambiguity in Beltone about the extent of professional referrals. Beltone's President attributed only 7% of the firm's sales to professional referrals--but he defined "professional referrals" as sales where the buyer first went to a physician or audiologist. That is, he excluded cases where a client went to a dealer, received the FDA notice, and then went to a physician. Beltone, TR 18510-11. No other witness took this position, and the Commission appears to consider any specific recommendation as a professional referral.

12 See Section I.B.5.a.

in the use of trials without FTC regulation.

However, the fact that 40% of sales were through professional referrals in 1980 necessarily implies that 60% were not sold through "professional referrals."¹³ In these cases, the buyer may not have seen a physician or audiologist at all. This is most likely to occur in the high-pressure home-sale (where the trial period protection is most needed.)¹⁴ In the home sale, the dispenser is least likely to explain the need to see a physician and most likely to unlawfully encourage the client to sign the medical waiver; as a practical matter, moreover, it would be particularly difficult for FDA to detect these abuses in home sales.

Alternatively, the client might see a physician and get no specific recommendation. As noted above, both our record and FDA's own findings indicate that this may occur.

The growth in the referral market may also indirectly improve consumer welfare. Beltone has not penetrated the growing referral market, the Commission recently found, "in part apparently because audiologists and physicians disfavor companies that sell hearing aids

13 There is some ambiguity in the term "professional referrals." See n. 11, supra.

14 As of 1977, Beltone had a 16% market share, Beltone slip op. at 41, and 25% of these sales were made through lead generation. Id. at 5. The Beltone manual indicates that many of these sales were made in the home. On the other hand, Starkey, which offers a trial (and thus has disincentives to sales abuse) had a 13% market share.

through lead advertising."¹⁵ There might be some further spill-over; companies seeking referrals have incentives to improve their reputation among "professionals." But on the other hand, companies which rely almost entirely on lead generation (including Beltone, the market leader), escape this constraint.

In conclusion, existing medical pre-clearance requirements leave substantial room for marketing abuse. Beltone noted that aggressive pre-sale activity is needed for effective market penetration, Beltone slip opinion at 47, but also recognized that the accompanying practices involve welfare trade-offs. Id. at 48.¹⁶ One rationale of Beltone is to encourage market expansion through aggressive sales tactics. One rationale of this rulemaking is to simultaneously correct the abuses which accompany these practices. Market penetration is desirable, in other words, but not the concurrent marketing abuses.

B. Labeling Requirements

FDA also requires that every buyer receive a User Instructional Brochure. The brochure must contain instructions, technical data, and disclosures 21 C.F.R. § 801.420. According to the regulations a dispenser must orally review the booklet prior to sale, and allow the

15 Beltone, supra at 6.

16 The welfare trade off directly addressed in Beltone was that Beltone's policies created single-line dealerships, the dealer might therefore sell a Beltone aid where another manufacturer's aid would be more appropriate. Id. at 48-49.

user an opportunity to read it. 21 C.F.R. § 801.421(b).

In light of these regulations, staff has made several modifications in our proposals. However, we do not believe that the regulations eliminate the need for broad Commission action.

1. Used Aids

FDA requires a disclosure if an aid is used or rebuilt. 21 CFR § 801.421(c)(5). The regulation substantially parallels a provision of prior staff proposals. Staff therefore no longer recommends this provision. We do recommend that a reference to FDA's regulations be included in any FTC trial period regulation.

2. Quality Control

The FDA rule also requires specifications of technical data. 21 C.F.R. § 801.421(c)(4). FDA monitors to insure the accuracy of this data.

This regulation promotes quality control. Manufacturers can comply with the regulations in one of two ways. They could maintain quality control, to ensure that their aids are within acceptable tolerance levels of a single specification sheet. Alternatively, they can provide a separate specification sheet with each aid, setting forth its individual characteristics.

The former solution would clearly address quality control problems, that latter solution would at least inform the dealer of variations in aid performance. In either event, FDA's direct action on this point makes any FTC reliance on quality control concerns

problematic. Although this has substantial implications for the rule,¹⁷ staff does not believe the Commission can rely on evidence that showed a quality control problem prior to 1977.

3. Disclosures

The FDA regulation compels a number of disclosures in the User Instruction Brochure.

These include

A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

21 C.F.R. § 801.420(c)(viii). This affirmative disclosure closely parallels the basis for both the "normal and natural" claims, and the therapeutic claims, of the sales abuse basis for the rule. However, it does not obviate the need for an FTC rule. The regulation does not expressly forbid claims in advertisement. Moreover the disclosure in the brochure would scarcely remedy prior deceptions made in other advertising. First, this disclosure is only one of the many pieces of information which is required in the User Instruction Booklet. The rule does not specify how prominent the disclosures must be. Even if they were prominent, moreover, they would not cure the prior deception, in part because they might not be read. Indeed, FDA has expressly authorized states to require disclosures on sales

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The quality control issue was a primary justification for imposing the right to cancel on so-called "identical aids." Consequently, staff has reconsidered its position on the need for trial periods in this event. See Section IX.C.

receipts which parellel FDA disclosures, because "the inclusion of the information in both places will increase the likelihood that it is brought to the attention of the consumer." 45 Fed. Reg. 67331 (1980). The FDA's notice, in other words, might not be read by the consumer -- particularly in a home sale.

The regulations also require a notice which discusses trials. The notice can appear anywhere in the User Instructional Brochure, under the title "Important Notice for Prospective Hearing Aid Users." Most of the notices discusses the need for pre-clearance. The fourth paragraph of the notice, however, says

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

21 C.F.R. § 801.420(c)(3).

It is important to understand the context of the FDA regulation. When FDA promulgated these rules, they expected the Commission to mandate a trial period shortly, and they endorsed this action. The disclosure was not intended to be the prime means of addressing the trial issue; indeed, it was probably viewed as an interim measure pending passage of FTC's regulations. On the medical pre-clearance, which was a prime concern of FDA's, they did not rely on a self-enforcing disclosure. Rather, they required that buyers execute a written waiver if they do not have a medical examination. With regard to other disclosures they specifically authorized parellel state laws.

Staff believes that a substantially stronger recommendation than

the FDA disclosure is similarly needed to insure consumers the protection of a trial period, and we therefore continue to recommend a mandatory trial.

Staff believes that there are several specific limitations to FDA's disclosure. First, it does not explain that one reason for a trial is sales abuses. Staff does not suggest that every manufacturer should be required to disclose that there are sales abuses in the industry. The problem is that the need for a trial period cannot be reasonably disclosed.

A second problem with the disclosure is that it suggests that a trial period is not necessary for people who have no reservations about their ability to adapt to amplification. However, the goal of many sales abuses is to dispel precisely such doubt. In other words, a successful salesman may convince a consumer that there is no reason for them to get a trial. Moreover, our record shows, and FDA's own findings confirm,¹⁸ that everyone faces a risk of no significant benefit absent a trial period. The FDA disclosure, however, fails to disclose this.

Third, despite the FDA regulations requiring the dispenser to review the booklet, there are numerous facts in the book, involving instructions for use, instructions on repair service, and other facts. A dispenser who does not offer a trial is certainly unlikely to highlight this aspect of the booklet, and indeed high-pressure salesman otherwise deceive consumers are likely to circumvent a

18 See Appendix D, Section II.A.2.

disclosure requirement.

For these reasons, staff recommends that the Commission adopt a trial period despite FDA's action.

III. The Commission's Consent Orders

In 1976, shortly after the hearings ended in this proceeding, the Commission entered into consent orders with six major hearing aid manufacturers. The orders prohibited specific claims, paralleling the claims in the sales abuse basis for the rule, and provided that these prohibitions remained effective unless the Commission promulgated a final hearing aid trade regulation rule which did not include the prohibitions.

These consents affect some of the advertising claims detailed in Part IV of the report.¹⁹ In staff's view, however, the consents do not undercut the basis for the rule. The record shows an industry-wide pattern; many smaller manufacturers and many dispensers, as well as larger manufacturers, made the challenged claims.

The rulemaking would create disincentives for all manufacturers to cease deceptive claims. It would create an industry-wide solution to an industry-wide problem.

More generally, the Commission should retain the flexibility to pursue simultaneous rulemaking and adjudication.²⁰ Rulemaking is

19 See n. ____, supra.

20 Parallel rulemaking and adjudication action does raise questions about resource allocation, and the Commission

(CONTINUED)

an extended process, and there is no way for the Commission to expedite an industry-wide rule by "settlement." Litigation which in part overlaps the rulemaking may lead to consents, and provide more immediate consumer protection.

Even more generally, the question here is whether the Commission should rely on evidence concerning specific problems which have already been addressed. Staff believes the Commission should rely on such evidence. The Commission might want to focus on industry-wide problems after a major litigation, for example. Certainly evidence of the pre-order practices of a leading firm is at least confirmatory of standard industry practices. Similarly, one fruitful source of evidence of sales abuses may be data from state officials. The most probative evidence collected by the states, however, would be litigated cases with judicial determinations that abuse existed--but the litigation would have addressed the problem. Similarly, evidence from the states might simply include consumer complaints; but if the state became involved, the problem may have been resolved. In other words, the very problems most likely to come to the Commission's attention will be those most likely to have been resolved. Nevertheless, staff believes that this evidence, too, would remain highly probative of industry abuses.

20 (FOOTNOTE CONTINUED)

might not normally choose this path. However, staff believes that the Commission should not tie its hand by suggesting that a parallel adjudication would undercut the basis for simultaneous rulemaking.

APPENDIX E
AN INFORMATIONAL REMEDY

Staff does not recommend an informational remedy. In part, this is because of existing FDA regulations which already require dispensers to make certain oral disclosures to their customers.¹ However, if the Commission finds this the appropriate path, there are several issues to consider: What information should be disclosed? What other mechanical details should be set out in the rule? Are other provisions desirable as well?

I. What Should Be Disclosed

One of the reasons staff does not recommend an informational remedy is the difficulty of developing a meaningful disclosure. If the Commission does consider an informational remedy, staff does not believe the information could disclose the sales abuses in the industry. As a practical matter, it is not feasible to require a dispenser (who may well be honest and competent) to communicate that the industry has substantial sales abuses.

Thus, the disclosure could only go to the risk of no significant benefit. Even if a consumer knows that some people fail with amplification, a disclosure might convey useful information: that the risk is unavoidable, and that even the best dispenser and most

¹ See Appendix D, Section II.

motivated consumer cannot avoid it.

While consumers should be reasonably informed about the risk, however, they should not be unduly discouraged from adjusting to amplification; an informational remedy should not exaggerate the risk. A brief notice, which might convey the risk without exaggerating it, appears at proposed notice #1.

This message is necessarily qualified, perhaps to the point where consumers would not detect the intended message. Moreover, there is another problem with the notice. Consider consumers who do not have a medical examination. They will receive a waiver notice indicating tht FDA has deemed a physical examination to be in their interest,² another notice indicating that only a trial offers full protection, and (for home sales) a disclosure of a 3-day cooling off period. Staff believes this series of notices might be confusing. Therefore, a more complicated notice may prove valuable by putting all of these remedies in perspective. Such a notice is offered as proposed notice #2. If the Commisssion chooses to promulgate an informational rule, staff recommends that the selected form be copy-tested to assure that it can be easily understood.

Whatever form is chosen, no notice should be required in states that mandate trials and prescribe a different form.

II. Other Mechanical Aspects of a Rule

2

See Id.

In staff's view, few other provisions would be needed in an informational rule. The buyer should be given certain additional information about how to exercise the cancellation right. One possible approach follows:

Description of Trial Period.

If you offer a trial period, give each consumer a document which describes in clear and conspicuous language:

- When the trial will end.
- What the consumer must do to return the aid.
- How much money you will keep if the aid is returned and the consumer does not accept a replacement aid.
- Whether you will accept the aid if it is damaged in any way, and if so, what your refund will be. You may not refuse to accept an aid which has only received normal wear and tear.

Sign the document.

The seller can use any form which conveys the information. The Commission might develop an optional form for dispensers to use.³

Staff would also recommend one substantive requirement. If a dispenser accepts an aid as a trade-in for a new aid, staff would require the dispenser to keep the original aid until the end of the trial. Otherwise, a consumer might practically be unable to exercise a cancellation privilege; if the old aid were sold, a consumer could not get it back in exchange for the new aid which provided no significant additional benefit.

³ This could be based similar to disclosure proposed in the current recommendation. See Section IX.

III. Other Requirements

If the Commission does impose an informational remedy, it might want to consider additional advertising restrictions as well. Under no circumstances would staff recommend provisions forbidding oral claims, because of the enforcement difficulties. However, the record does show substantial advertising abuses, and the informational remedy would address those abuses in only the most indirect manner. Therefore, the Commission might consider provisions which forbid deceptive advertising claims, such as claims that a hearing aid user will hear "normally" or "naturally."⁴

Another provision staff would recommend that the Commission consider would involve advertisements for "free" materials. These advertisements are often used as a basis for surprise visits. While prior versions of the rule addressed the question of surprise visits with broad remedies,⁵ staff now would suggest a narrow remedy: Where an advertisement for free tests or materials is designed to collect the names and addresses of prospective customers, this information should be disclosed in the advertisement.

⁴ The Commission might also address therapeutic claims. See Section IV.A.1.a. However, most of the therapeutic claims in the record were made orally, and thus would not be covered. See generally Section A.3.f. of the Introduction.

⁵ The 1978 text required an appointment, orally or in writing. Recommended Rule § 440.30.

PROPOSED NOTICE I

MOST PEOPLE FITTED WITH A HEARING AID GET SIGNIFICANT BENEFIT.
HOWEVER, EVEN THE BEST DISPENSERS MAY SELL AN AID TO SOMEONE WHO
CAN'T BENEFIT.

IF YOU ARE NOT SATISFIED WITH HIS AID, YOU

- CAN
- CANNOT

RETURN IT WITHIN 30 DAYS. WE WILL KEEP \$ _____,
EVERYTHING ELSE YOU PAID IN MONEY OR GOODS WILL BE RETURNED.

SELLER'S SIGNATURE

DATE

PROPOSED NOTICE II
IMPORTANT NOTICES TO HEARING AID BUYERS

MEDICAL EXAMINATIONS - Under federal law, you cannot be sold a hearing aid unless you have had a medical examination within the preceeding 6 months. Only a doctor is fully qualified to tell you whether medical or surgical treatment is what you really need. You may waive the medical examination, but it is not in your best interest to do so. If you do choose to waive the medical examination, sign the separate medical waiver.

TRAIL PERIODS - If you do not have your problem corrected medically or surgically, you may be able to benefit from a hearing aid.

HOWEVER, THERE IS NO FOOL-PROOF METHOD TO INSURE THAT THE AID YOU BUY WILL WORK FOR YOU. THE BEST DISPENSERS FIND THAT MOST OF THEIR CUSTOMERS DO GET SIGNIFICANT BENEFIT FROM THEIR AID. EVEN THEY FIND THAT SOME CONSUMERS DON'T GET THIS BENEFIT, THOUGH.

If you don't get the benefit you want, and want to return you aid within 30 days after you receive it, we (will) (will not) take it back. We will keep \$_____. Everything else you paid will be returned. Details are attached.

SPECIAL NOTICE FOR HOME SALES - IF YOU PURCHASE THIS AID AT HOME, YOU CAN CHANGE YOUR MIND WITHIN 3 DAYS. YOU WILL GET A FULL REFUND. SEE THE CONTRACT FOR DETAILS.

BUYER'S ACKNOWLEDGEMENT: I HAVE READ
THE "IMPORTANT NOTICE TO HEARING AID
BUYER'S" ABOVE (this is not a waiver of
the medical examination).

DATE

SELLER'S SIGNATURE

DATE

NOTE: YOU MUST BE GIVEN THIS STATEMENT BEFORE YOU BUY A HEARING AID. Sign two copies and keep one of them. If you are not given this statement in advance, or have a problem involving a trial period or refund, notify the Federal Trade Commission. If you have a problem involving a sale without a medical examination, notify the Food and Drug Administration.