

United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

Office of Commissioner Terrell McSweeny

TO: Don Clark
FROM: Christine DeLorme
DATE: October 11, 2017
RE: Contact Lens Rule: Comments to be placed on the public record

On October 6, 2017, representatives of 1-800 CONTACTS, Inc. met with FTC Commissioner Terrell McSweeny and other agency staff¹ to discuss proposed amendments to the FTC's Contact Lens Rule (Rule).

I. Avalon Survey

1-800 CONTACTS expressed support for the proposed amendments in the Notice of Proposed Rulemaking and urged the Commission to move forward with the rulemaking. 1-800 CONTACTS noted that there has been significant pushback against the proposal from the American Optometric Association (AOA), but opined that AOA is relying on a survey of AOA members (Avalon survey) that is not credible.

1-800 CONTACTS stated that the Avalon survey is not reliable for a number of reasons, including that the survey asked *prescribers* about how *consumers* would react to certain situations, instead of asking consumers themselves. Further, 1-800 CONTACTS emphasized that the entire framing of the Avalon survey was problematic because the survey respondents, who were AOA's members, knew the survey was being conducted by the AOA and therefore the responses may not have been neutral. Further, several questions were posed with binary yes/no answer choices (e.g., do you expect that patients would have questions about the acknowledgment or not?) when a range of responses would likely be possible (*e.g.* that only *some* patients would have questions). Some closed-ended questions had answer options that may have suggested particular intervals of time, all of which were too high. Further, the Avalon survey question about how much time it takes prescribers to comply with rules and regulations did not ask specifically about the *incremental* amount of additional time it would take to comply with the proposed Rule amendment requiring a signed acknowledgement — and instead would likely elicit an answer about how much time prescribers take to comply with *all* applicable rules and regulations. Therefore, the Avalon survey responses are not a reliable estimate of the costs of the proposed Rule amendment.

¹ In attendance on behalf of 1-800 CONTACTS were John Graham (President), Cynthia Williams (General Counsel), Professor Laurence Baker (Professor of Health Research and Policy, Stanford University), Lisa Kimmel (Crowell & Moring, LLP), Kate Watkins (Crowell & Moring, LLP), and Megan Wolf (Crowell & Moring, LLP).

In attendance from the FTC were: Commissioner Terrell McSweeny, Christine DeLorme, Beth Freeborn, and Morgan Kennedy.

II. Survey Sampling International (SSI) Survey Prepared for 1-800 CONTACTS

1-800 CONTACTS hired SSI to conduct a survey of 500 contact lens wearers (SSI survey) to measure consumer reactions to the proposed Rule amendment (survey report attached). According to the SSI survey, the average time required to read the suggested text for the proposed acknowledgement was only 12 seconds, and 90% of respondents read it in 20 seconds or less. In addition, 90% of respondents indicated comprehension of the proposed acknowledgement and 94% of respondents indicated that they had no questions about the meaning of the statement. By contrast, the Avalon survey concluded that explaining the purpose of the acknowledgement would require 3 minutes for every patient, every single year, and estimated that answering questions about the statement would require 3.5 minutes for every patient, every year.

1-800 CONTACTS stated that SSI survey respondents indicated that "getting the best price" was the single most important consideration in deciding where to purchase contact lenses, and that 59% of wearers would "stretch" lenses (*i.e.*, wear them longer than recommended) to save money. Also, SSI survey respondents indicated that they were very interested in having a copy of their prescription to be able to buy lenses from a location other than their prescriber; of the 500 survey participants, only one indicated no interest at all in having a copy of a prescription.

According to the SSI survey, only 5% of respondents indicated they would be more likely to pay attention to a posted sign (regarding their right to a prescription) than to an acknowledgement form. 1-800 CONTACTS stated that a requirement to post a sign does not provide any additional incentives to prescribers to comply with the Rule, since it does not incorporate any recordkeeping requirement.

III. Costs and Benefits Analysis of the Proposed Rule

1-800 CONTACTS discussed a written report by Professor Laurence Baker (attached) that analyzes the likely economic benefits and costs of the proposed requirement that prescribers obtain a signed acknowledgment from consumers after providing them a copy of their prescription, and maintain the acknowledgements for three years.

Dr. Baker walked through his assumptions and calculations in his cost-benefit analysis (*see* Tables 1 and 2 of the attached report). He explained how the estimated cost of the proposed acknowledgment (\$10.8 million) was based on the labor estimates the FTC published in its Paperwork Reduction Act analysis in 2015, updated and adjusted upwards with 2016 wage and salary data. Dr. Baker explained how he attempted to calculate how many prescription verifications would need to be avoided to offset the \$10.8 million estimated cost of the acknowledgement requirement.

Dr. Baker stated that if verifications are handled on the prescriber side by an optometrist, each avoided verification would save a total of \$5.77 (4 minutes on the seller side with a \$1.06 incremental cost, and 5 minutes on the prescriber side with a \$4.71 incremental cost). If verifications are handled on the prescriber side by office staff at a lower hourly wage rate, then each avoided verification would save \$2.38. In the former case, 1.88 million verifications would need to be avoided each year (8.8% of total annual verifications) to break even on the costs of

the proposed Rule, and in the latter case, 4.56 million verifications would need to be avoided each year (21.4% of total annual verifications) in order to break even. These calculations are based on the assumption that each contact lens wearer orders a six-month supply of lenses at a time, or requires two verifications per year — an assumption that is consistent with 1-800 CONTACTS' actual experience.

Dr. Baker estimates that about 70% of consumers do obtain a copy of their prescription from their prescriber, either automatically or upon request. According to the FTC, 27% of consumers purchasing from a third-party seller submit a prescription for the purchase. From these figures, he estimates that 38.6% of consumers who buy from third-party sellers and have a prescription, actually use that prescription for the purchase. If you assume that the proposed acknowledgement requirement results in 100% compliance with the Rule, *i.e.*, 100% of consumers actually obtain a copy of their prescription, then you can assume that an additional 4.38 million consumers who purchase from third-party sellers will get their prescription. If you also assume that 38.6% of them will use the prescription to purchase lenses twice a year, that will be another 3.38 million verifications avoided per year, or 15.9% of the total annual volume of verifications. This figure falls within the range of estimated avoided verifications described above (between 8.8% and 21.4%) that would be required to offset the costs of the acknowledgment requirement. Dr. Baker stated that changes to the underlying assumptions for his calculations would result in small changes around the margins, but emphasized that they would not affect the calculations dramatically.

Dr. Baker also stated that his analysis did not take into account other benefits, such as benefits to competition, quality, and price of contact lenses.

Clark, Donald S.

To:Clark, Donald S.Subject:FW: Analysis of Costs and Benefits of Proposed Amendment to the Contact Lens RuleAttachments:Professor Baker Report on CLR 9.25.17.pdf

From: Kimmel, Lisa [mailto:LKimmel@crowell.com]
Sent: Monday, September 25, 2017 11:13 AM
To: DeLorme, Christine Lee
Cc: Wolf, Megan
Subject: Analysis of Costs and Benefits of Proposed Amendment to the Contact Lens Rule

Christine, attached please find an analysis of the costs and benefits of the proposed amendment to the Contact Lens Rule, prepared by Professor Laurence Baker, a healthcare economist at Stanford.

Please note in particular the SSI survey he references at Exhibit B, which provides information on consumer reaction to the proposed acknowledgment form.

Please let me know if Commissioner McSweeny has any question or other issues she would like us to address at the meeting.

Here are the attendees for the meeting. If there are any last minute changes, will let you know.

John Graham, President, 1-800 CONTACTS Cynthia Williams, General Counsel, 1-800 CONTACTS Professor Laurence Baker, Professor of Health Research and Policy, Stanford University Lisa Kimmel, Crowell & Moring, LLP Megan Wolf, Crowell & Moring, LLP Kate Watkins, Crowell & Moring, LLP

Best, Lisa

Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule

Laurence C. Baker, Ph.D. Stanford University

September 25, 2017

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A. Qualifications

1. My name is Laurence Baker. I am a Professor of Health Research and Policy at the Stanford University School of Medicine and Professor (by courtesy) of Economics at Stanford University. I also serve as Chair of the Department of Health Research and Policy, am a core faculty member of Stanford Health Policy, and hold appointments as a Senior Fellow of the Stanford Institute for Economic Policy Research, and Research Associate of the National Bureau of Economic Research. I have been on the faculty at Stanford for more than 20 years.

2. At Stanford, I teach undergraduate and graduate level courses on the U.S. health care system that cover a range of health policy issues, including costs of health care in various segments of the health care system such as hospitals and physician practices, payments to hospitals, physicians, and other health care providers, competition in health care, and the effects of regulations and policies on the health care system. I have conducted research on a wide variety of health economics topics, with a focus on the economic performance of the health care system and of elements of the system, including payments for medical services, competition in health care, and the adoption of medical equipment and technologies. My research work has included analysis of the costs and benefits of regulations impacting the healthcare system, including those affecting patient access to medical records. I have authored or co-authored numerous works published in peer-reviewed journals, books, and other contexts, and given many academic and public presentations on topics in health care economics and financing.

3. I received my B.A. degree with majors in Economics and Mathematics from Calvin College in 1990, and my M.A. and Ph.D. degrees in Economics from Princeton University in 1994. I have been awarded the ASHEcon medal from the American Society of Health Economists, which annually recognizes the top American health economist under age 40. A more complete description of my qualifications may be found in my CV, which is included as Exhibit A to this report. My rate of compensation in this matter is \$775 per hour.

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B. Assignment

4. I have been asked by 1-800 CONTACTS Inc. ("1-800 CONTACTS") to analyze the likely economic benefits and costs of the proposed acknowledgment and recordkeeping amendment ("Proposed Amendment") to the Contacts Lens Rule ("Rule"). I have also been asked to analyze and provide my opinion on the value of certain evidence that the American Optometric Association ("AOA") provided to the FTC, including a report by Avalon Health Economics sponsored by the AOA.

C. Summary of Opinions

5. Based on the evidence I have reviewed and my expertise in healthcare economics, I reach the following conclusions:

- As described in this report, the evidence I have reviewed supports the FTC's conclusion that eye care provider ("prescriber") compliance with the Rule's automatic prescription release requirement is deficient.
- The number of consumers who have complained to the FTC after not receiving a copy of their contact lens prescription from their prescriber is unlikely to be a reliable measure of prescriber compliance with the Rule.
- By creating a more credible threat of enforcement actions and fines for failing to release prescriptions, the Proposed Acknowledgment will increase prescriber incentives to comply with the Rule.
- Prescribers and third-party sellers spend significantly more time to comply with the Rule when consumers buy lenses from third-party sellers but do not have a copy of their prescription at the time of the transaction, requiring verification through a direct communication with the prescriber. For that reason, a relatively modest reduction in verifications could be expected to have a significant impact on compliance costs for both prescribers and sellers.
- As described in more detail below, using the FTC's estimates of the time prescribers and sellers spend to verify orders, it is possible to estimate the reduction in the number of verifications needed to completely offset the estimated annual cost of the Proposed Amendment. I estimate that a reduction in verifications of between 9% and 21% would be sufficient, depending on the estimation assumptions.
 - Moreover, if I assume that with the Proposed Amendment (1) consumers who are not receiving a prescriptions today were to receive

prescriptions and (2) they were to use the prescriptions when purchasing lenses in the same way that consumers receiving prescriptions do so today, verifications would fall by 16%, an amount consistent with my estimates of the range of reductions needed to offset the costs of the Proposed Amendment, and possibly an amount sufficient to produce a net reduction in the costs for prescribers and sellers to comply with the Rule.

- The Proposed Amendment can be expected to provide additional economic benefits that will flow directly to consumers.
 - In a competitive market, at least some amount of any net cost savings from a reduction in the cost of compliance is likely to be passed on to consumers.
 - As described below, an August 2017 survey of contact lens wearers shows that a large fraction of respondents are interested in receiving a copy of their prescription so they can use it to buy lenses from someone other than their current prescriber or to be able to more easily comparison shop among sellers. The Proposed Amendment would thus help to align prescriber behavior with consumer preferences. The same survey indicates that responding consumers themselves believe that having a copy of their prescription facilitates comparison shopping and choice.
 - Consumers who choose to purchase lenses from third-party sellers will usually receive their lenses faster if they are able to submit a copy of their prescription.
 - Eliminating obstacles to comparison shopping will allow consumers to search for sellers that offer them their most preferred mix of product attributes including price, reliability, convenience, and service. In the long run, increased competition among sellers of contact lenses can be expected to put downward pressure on price and upward pressure on quality of service for all contact lens wearers.
- While total direct consumer benefits are difficult to quantify, if verifications decline sufficiently to offset the cost of the Proposed Amendment, the total expected benefits of the Proposed Amendment, including the additional economic benefits, are likely to exceed the expected costs.

- The Avalon Health Economics survey and analysis of the costs of the Proposed Amendment (sponsored and submitted by the AOA) are fundamentally flawed and unreliable.
 - The AOA had repeated communications with optometrists about the Proposed Amendment before fielding the survey and participants were aware of the sponsor and purpose of the survey. Such communications can easily influence members' decisions to participate in the survey and are likely to bias their responses in the direction of overestimating the cost of compliance.
 - As discussed in detail below, many of the survey questions reflect improper assumptions that are likely to bias responses to questions regarding the time for, and cost of, compliance with the Proposed Amendment.
 - The Avalon Report misuses the flawed survey results to grossly overestimate the costs associated with the Proposed Amendment. Most importantly, the Avalon Report conflates the total cost of compliance with the existing Rule *and* the Proposed Amendment (*and* all other rules, regulations, and policies) with the *incremental* cost of the Amendment.

D. FTC's Review of the Contact Lens Rule and the Proposed Amendment

6. Nearly 41 million U.S. consumers, or 16% of the adult population, wear contact lenses.¹ The Rule requires that prescribers of contact lenses, nearly always an optometrist or ophthalmologist, automatically provide these patients with a copy of their contact lens prescription after completing a contact lens fitting (regardless of whether the patient requests one).² Prescribers are also required to provide or verify a patient's contact lens prescription as directed by a third-party seller acting on behalf of a patient.³ Prescribers

¹ According to the FTC, approximately 40% of contact lens sales in the U.S. are made by independent eye care professionals, 19% by conventional retail chains, 25% by mass merchants and wholesale clubs, and about 16% by online sellers that do not have a physical retail presence. Notice of Proposed Rulemaking and Request for Comment, 81 Fed. Reg. 88526, 88528 (Dec. 7, 2016) ("NPRM"), https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_f rn12716.pdf.

² Contact Lens Rule, 16 C.F.R. § 315.3 (a) (2004), <u>https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=e4b29336cdda80fda942b265b6f47049&ty=HTML&h=L&n=16y1.0.1.3.39&r=PART.</u>

³ *Id*.

have the option to passively verify an order by simply not responding to a seller's verification request within eight business hours.⁴ The Rule bars third parties from selling contact lenses without either obtaining a copy of a customer's prescription (from either the customer or the prescriber) or verifying the order through a direct communication with the prescriber.⁵ The Rule also requires sellers to maintain records for each order they verify.⁶

7. Based on its review of available evidence, the FTC has concluded that compliance with the Rule's automatic prescription release provision could be substantially improved.⁷ To that end, the FTC has proposed an amendment to the Rule that would require prescribers to request that patients acknowledge receipt of their prescription by signing a short form. The form must be entitled "Patient Receipt of Contact Lens Prescription," and include the following additional language: "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice."⁸ Prescribers would be required to retain a copy of that signed acknowledgment form for at least three years, to be made available to the FTC for inspection upon request.⁹

E. The Proposed Amendment Would Increase Prescriber Compliance with the Contacts Lens Rule

8. Approximately 60% of optometry office revenue flows from the sale of corrective lenses: 16% from contact lenses and 43% from eyeglasses. Healthcare services account for just 40% of optometric office revenue.¹⁰

⁴ *Id.* § 315.5 (c).

⁵ *Id.* § 315.5 (a).

⁶ *Id.* § 315.5 (f).

⁷ NPRM, *supra* note 1, at 88532.

⁸ *Id.* at 88535.

⁹ Id.

¹⁰ HARRIS WILLIAMS & CO., VISION INDUSTRY OVERVIEW at 3 (Jan. 2015) (citing data from *Optometrists in the US*, IBISWorld (Nov. 2015)) ("Harris Williams Report"), <u>http://www.harriswilliams.com/system/files/industry_update/vision_industry_overview.pdf</u>. Revenue breakdown for ophthalmologists was not available. However, given that ophthalmologist treat a broad range of medical conditions, a larger fraction of revenue is likely derived from the provision of healthcare services. *Id.* at 4 ("Higher average revenue per patient visit – provide premium, specialized services.").

9. Prescribers have an economic incentive to use their control of a contact lens prescription to keep the sale of contact lenses in-house. Research in other medical contexts shows that economic incentives can influence healthcare providers just as they do other sellers. For example, physicians who buy MRI machines and can profit from ordering MRI scans tend to increase the number of scans their patients receive after they obtained the machine. ¹¹ It is thus not surprising that prescribers who can profit from contact lens sales would take steps to increase the number of sales, such as refusing to release prescriptions. Limiting the release of prescriptions can have negative effects on purchasers of contact lenses by limiting their options and reducing the amount of competition among sellers of lenses. It is my understanding that Congress passed the Fairness to Contact Lens Consumers Act to deal with this very dynamic and to promote competition in the retail sale of lenses through prescription portability.¹²

10. However, the mere adoption of a law or regulation does not guarantee compliance. A useful way to understand the approach firms take to regulatory compliance decisions is to apply a cost/benefit framework, and in the context of this matter it is reasonable to assume that prescribers, at least implicitly, weigh the costs and benefits of compliance with the Rule's automatic prescription release mandate.¹³ Violating the Rule provides a benefit to prescribers in the form of a greater likelihood of retaining a profitable in-house sale. The expected cost of a violation can be understood as, roughly, the probability of detection

http://shea.senate.ca.gov/sites/shea.senate.ca.gov/files/ca_senate_self-referral_baker.pdf; Shankar Vedantam, *Doctor Self-Referrals Part of Health-Care Cost Trend*, WASH. POST (July 31, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073004285.html; Laurence C. Baker, *Acquisition of MRI Equipment by Doctors Drives Up Imaging Use and Spending*, HEATH AFFAIRS (Dec. 2010), http://content.healthaffairs.org/content/29/12/2252.full.pdf+html.

¹¹ Laurence C. Baker, Physician Self-Referral: Research & Health Spending Issues, Testimony before the Cal. Senate Health Comm. (Mar. 18, 2015),

¹² FED. TRADE COMM'N, THE STRENGTH OF COMPETITION IN THE SALE OF RX CONTACT LENSES: AN FTC STUDY 1 (2005), <u>https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf</u>.

¹³ Gary S. Becker, *Crime and Punishment: An Economic Approach*, J. POL. ECON., Mar.–Apr. 1968, at 169, <u>http://www.journals.uchicago.edu/doi/abs/10.1086/259394</u>; *see generally* ROBERT COOTER & THOMAS ULEN, LAW & ECONOMICS, 6TH EDITION 462 (Berkeley Law Books 2016), <u>http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1001&context=books</u>.

multiplied by the amount of a fine.¹⁴ More precisely, the following equations describe the prescriber's expected incremental cost and benefit of violating the Rule:

(1) E[cost] = P[detection] * F

(2) $E[benefit] = (P[sale|violation] - P[sale|no violation]) * \pi$

Where:

- *P*[*detection*] is the probability that the FTC will detect the violation and pursue enforcement,
- *F* is the dollar amount of the fine and any other cost to the prescriber associated with the violation,
- *P*[*sale*|*violation*] is the probability that the purchaser will buy contact lenses from the prescriber given that the prescriber did not release the prescription,
- *P*[*sale*|*no violation*] is the probability that the purchaser will buy lenses from the prescriber given that the prescriber did release the prescription,
- π is the profit from the sale.

Note that if the P[detection] and/or the F are too low,¹⁵ and P[sale|violation] is sufficiently greater than $P[sale|no \ violation]$, then the expected incremental benefit of violating the rule will be greater than the expected incremental cost.

11. Surveys conducted by different organizations and provided to the FTC in connection with its review of the Rule indicate that, for many prescribers, the benefits of a violation outweigh the costs.¹⁶

¹⁴ For simplicity, this framework assumes that the incremental cost associated with compliance that would be eliminated by non-compliance is negligible (for example, the likely small cost of writing down or printing out the prescription to give to the purchaser).

¹⁵ I understand that violations of the Rule are treated as unfair acts of practices under the Federal Trade Commission Act. Maximum penalties are set by Commission rules and adjusted periodically for inflation. I understand that as of January 12, 2017, the maximum fine for each violation of the Rule is \$40,654. *FTC Publishes Inflation-Adjusted Civil Penalty Amounts*, FTC (Jan. 12, 2017), <u>https://www.ftc.gov/newsevents/press-releases/2017/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts</u>.

12. In 2008, *Contact Lens Spectrum Magazine*, an industry trade publication, surveyed prescribers regarding compliance with prescription release. Only 50% of responding prescribers reported that they released contact lens prescriptions to every patient.¹⁷

13. More recently, in an October 2015 consumer survey conducted by Survey Sampling International ("SSI") and commissioned by 1-800 CONTACTS, just 35% of responding contact lens wearers reported that they received a copy of their prescription automatically on the day of their office visit.¹⁸ The survey also found that while 28% of patients were provided with a copy of their prescription upon request (either during the same visit or after being required to return a second time), 36% of patients did not receive a copy at all.¹⁹ This same survey also indicated that 46% of responding contact lens wearers were not aware of their right to receive a copy of their prescription.²⁰

14. In January 2017, SSI conducted an additional consumer survey, also commissioned by 1-800 CONTACTS, that yielded similar results.²¹ The January 2017 survey found that 37% of respondents were automatically provided with a copy of their contact lens prescription; approximately 35% of respondents requested a copy and received it the day of their visit or were told to call or return for a copy at a later time; 24% of respondents reported that they did not receive a copy of their prescription at all.²²

¹⁸ Comments of 1-800 CONTACTS, Inc. on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995) (Comment #568), at Exhibit B, p. 3 (Oct. 26, 2015), <u>https://www.ftc.gov/policy/public-</u> comments/2015/10/26/comment-00568 ("1-800 October 2015 Comments") ("SSI October 2015 Survey").

¹⁹ *Id.* at 3.

 20 Id. at 5.

https://www.ftc.gov/system/files/documents/public_comments/2017/01/03898-138466.pdf ("1-800 January 2017 Comments") ("SSI January 2017 Survey").

¹⁶ One would not expect the costs and benefits to be identical across prescribers. Some prescribers may be more or less averse to the risk of either legal action or losing trust with patients. Others may not offer certain lenses or sell lenses at all.

¹⁷ Carla J. Mack, *Contact Lenses 2007: A Look Back at Contact Lens Events of 2007 Including Prescribing Trends, Product Recalls and Launches, Compliance Issue, Mergers and Corneal Staining*, CONTACT LENS SPECTRUM (Jan. 1, 2008), <u>http://www.clspectrum.com/issues/2008/january-2008/contact-lenses-2007</u>.

²¹ Comments of 1-800 CONTACTS, Inc. on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995) (Comment #3898), Exhibit A at 3 (Jan. 30, 2017),

²² SSI January 2017 Survey, *supra* note 21, at 3.

15. Also in January 2017, Consumer Action commissioned a survey of contact lens wearers and found that approximately 31% of survey respondents were not provided with a copy of their contact lens prescription and 60% were unaware of their right to automatic receipt of a copy.²³

16. While few surveys are beyond criticism, the fact that multiple surveys conducted by different sources over a span of nearly ten years reach similar conclusions bolsters the credibility of each individual survey and the collective conclusion that prescriber compliance with automatic release is far from universal. In addition, I am not aware of any surveys that suggest prescriber compliance is substantially more widespread.

17. It is my understanding that the FTC has never issued a fine to a prescriber for failing to release prescriptions. Instead, the FTC has made efforts to improve compliance by issuing warning letters to noncompliant prescribers, accompanied by an agency press release to publicize its actions. The agency issued warning letters with an associated press release in 2004 and again in 2007.²⁴ Then in April 2016, the FTC issued warning letters with an associated press release to 45 contact lens prescribers, who, among other things, failed to release contact lens prescriptions to patients.²⁵ The survey evidence noted above suggests that, even after these warning letters were sent, compliance with the Rule remains far from complete.

18. In fact, there is evidence that the warning letters did not even impact the behavior of the specific prescribers who received the warning letters. I understand that, to investigate the effects of the letters, 1-800 CONTACTS obtained through a Freedom of

 ²³ Comments of Consumer Action on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995)
 (Comment #3721) (Jan. 30, 2017), <u>https://www.ftc.gov/policy/public-comments/2017/01/30/comment-03721</u>
 ("Consumer Action January 2017 Comments") ("Consumer Action January 2017 Survey").

²⁴ Press Release, Contact Lens Rule (16 C.F.R. Part 315) and Eyeglass Rule (16 C.F.R Part 456), Oct. 22, 2004, <u>https://www.ftc.gov/news-events/press-releases/2004/10/contact-lens-rule-16-cfr-part-315-and-eyeglass-rule-16-cfr-part;</u> Press Release, FTC Warns Ten Contact Lens Prescribers to Provide Patients With Prescriptions, Sept. 14, 2007, <u>https://www.ftc.gov/news-events/press-releases/2007/09/ftc-warns-ten-contact-lens-prescribers-provide-patients</u>.

²⁵ Press Release, FTC Issues Warning Letters Regarding the Agency's Contact Lens Rule: Prescribers Must Provide Patients with Their Prescriptions; Sellers Must Obtain or Verify Valid Prescriptions before Dispensing Lenses, Apr. 7, 2016, <u>https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-</u> warning-letters-regarding-agencys-contact-lens-rule.

Information Act request the names of the 45 prescribers receiving the 2016 letters and conducted a "secret shop" of 21 of the 45 prescribers after they had received the letters. Shoppers were not informed of the purpose of the exercise or that their assigned prescriber had previously received an FTC warning letter. Shoppers were instructed to complete the eye examination and contact lens fitting process and were instructed that they should not ask for a copy of their contact lens prescription. I understand that of those 21 prescribers who had recently received a warning letter from the FTC, 18 failed to automatically release a prescription to the secret shopper after they had completed a contact lens fitting.²⁶

19. Interpreted in light of the underlying economic framework for prescriber compliance, as set forth in the discussion of equations (1) and (2) above, the evidence presented to the FTC strongly suggests that the current enforcement regime, including repeated warning letters, results in insufficient incentives to comply with the automatic release requirement for many prescribers.

20. According to the FTC, an important goal of the Proposed Amendment is to provide the agency with the evidence it has concluded is necessary to adequately enforce the Rule.²⁷ With a "paper trail," as required by the Proposed Amendment, the FTC could more credibly threaten an enforcement action, raising the expected cost of a violation relative to the benefits, and in turn increasing the incentive for prescribers to comply.

E.1. The Number of Individual Consumer Complaints Filed with the FTC Is Unlikely to be a Reliable Measure of Compliance with the Rule

21. The AOA claims that relatively few consumers have complained directly to the FTC regarding prescription release and argues that few consumer complaints is good evidence of adequate prescriber compliance. In particular, the AOA claims to have reviewed consumer complaints related to Rule compliance submitted to the FTC over the past five years. It reports that less than half of those complaints were "directly related to

²⁶ It is my understanding that this information has been provided to FTC staff.

²⁷ The FTC recognizes the need for greater enforcement of the Rule's automatic release mandate, but explains, "[t]he absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription as required, in any particular case." NPRM, *supra* note 1, at 88533.

prescription release," and that 18% "were related to confusion regarding the contact lens evaluation and fitting process," concluding that 123 consumers filed "potentially valid complaint[s] regarding contact lens prescription release" with the FTC over the past five years.²⁸ The AOA asks the FTC to conclude that 123 complaints in five years is evidence of adequate prescriber compliance.

22. That would be a mistake. Even if the AOA were able to accurately evaluate the content of these consumer complaints, there are important reasons to believe that the number of consumer complaints is not a reliable measure of prescriber violations. Studies of complaints to businesses show that consumers often do not submit complaints when they are dissatisfied with a product or service, particularly if the cost (in time, money, or other things) is larger than the economic benefit of remedying their dissatisfaction.²⁹ There are many reasons why patients who are not provided with a copy of their prescription would not submit a complaint to the FTC as a regulatory agency. First, many simply do not know that they have the right to automatically receive a copy of their prescription.³⁰ Second, those who are aware of such a requirement may not know that the FTC enforces the Rule or that they can complain to the FTC, or how to do so. Third, patients may be reluctant to offend their prescriber by filing a legal complaint. Finally, consumers, at least implicitly, make some determination about the costs and benefits of taking an action they are considering. There is an opportunity cost associated with submitting a complaint and some may simply assume that the benefit to them is smaller than the cost, or that other patients and organizations will complain and they can rely on those efforts. For all these reasons, it is plausible, even likely, that many patients would not file a complaint when they do not receive a prescription automatically.

²⁸ The AOA claims that .0003% of the 41 million contact lens wearers filed what it determines to be a valid complaint with the FTC regarding prescription release (.000003 x 41,000,000 = 123). Comments of The AOA on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995) (Comment #3830) at 4 (Jan. 30, 2017), <u>https://www.ftc.gov/policy/public-comments/2017/01/30/comment-03830</u>.

²⁹ John Goodman & Steve Newman, *Understanding Customer Behavior and Complaints*, QUALITY PROGRESS (Jan. 2003), <u>http://web.ist.utl.pt/~ist11038/CD_Casquilho/PRINT/qp0103goodman.pdf</u>.

³⁰ SSI October 2015 Survey, *supra* note 18, at 5; Consumer Action January 2017 Comments, *supra* note 23, at 1.

23. For these reasons, I would not interpret the number of consumer complaints submitted to the FTC regarding prescription release as a reliable measure of prescriber compliance with the Rule.

F. Estimated Cost of the Proposed Amendment

24. In its proposed rulemaking, the FTC estimated a total labor cost for paperwork requirements related to the Proposed Amendment of \$10,475,495.³¹ This calculation assumes that all prescribers would comply with the Proposed Amendment, that maintaining records of the Acknowledgment form will take one minute per visit for each of the approximately 41 million contact lens wearers, and that each wearer has one visit per year. The one-minute estimate is based on an assumption that all prescribers will present a paper form to the patient for signature and then scan the signed Acknowledgment to maintain it as an electronic document. The FTC recognizes that for offices that obtain signatures electronically or store records in hard copy, the recordkeeping time may be just a few seconds per patient, so an average of one minute per form is likely an overestimate.³² The FTC's estimate is based on 2015 wage and salary data. Using the same methodology and 2016 wage and salary data, the total paperwork cost would be \$10,844,495.³³

25. Recent survey evidence suggests that patients can be expected to readily understand the form and will have few questions. In August 2017, SSI conducted a consumer survey, commissioned by 1-800 CONTACTS, to measure consumer reactions to the Proposed Acknowledgment.³⁴ They report that this online survey collected data on 500 U.S. adult contact lens wearers who were blind to the sponsor and purpose of the study. The findings of the survey most relevant to this report are as follows:

³¹ NPRM, *supra* note 1, at 88557.

³² *Id*.

³³ *Id.* at 88558.

³⁴ Exh. B. Consumer Survey of Proposed FTC Contact Lens Prescription Acknowledgment, Report Prepared by Survey Sampling International for 1-800 CONTACTS, August 31, 2017 ("SSI August 2017 Acknowledgment Survey").

- First, responding consumers were presented with the suggested text for the Proposed Amendment. Respondents were asked to read the statement and click through to the next question when they had finished reading, allowing SSI to directly measure the time they needed to read the statement. The survey found that the average time to read the statement was 12 seconds and the median time was 10 seconds; 90% percent of respondents read the statement in 20 seconds or less.³⁵
- Second, the survey measured respondents' comprehension of the statement and collected data on the number reporting that they would have questions before signing the proposed statement. The survey found that 90% of respondents correctly identified the meaning of the statement immediately after reading it, and 94% of respondents would not have any follow-up questions.³⁶
- Third, the survey asked about respondent interest in receiving a copy of their prescription. 85% of consumers said they were interested or extremely interested in receiving a copy of their prescription to use to purchase lenses from a seller other than their current eye care provider. 73% indicated being interested or extremely interested in receiving a prescription to use to facilitate comparison-shopping among sellers. The survey also covered lens wear habits, showing that 56% of respondents will wear lenses longer than the manufacturer recommendation and that the most common reason for stretching lenses was "to save money."³⁷

26. The complete set of data needed to arrive at an estimated cost of the Proposed Amendment to providers that incorporates recordkeeping time as well as other provider time for things such as showing consumers the form and answering questions is not available. However, it seems reasonable to use the FTC estimate described above of approximately \$10.8 million. This estimate incorporates what the FTC recognizes is

³⁵ *Id.* at 7.

³⁶ *Id.* at 8.

³⁷ *Id.* at 5–6.

probably an overestimate of the recordkeeping time. It does not incorporate additional time needed to have customers read the form and answer any questions, but, as described above, consumer survey evidence indicates that such additional time is not likely to be substantial.

G. The Proposed Amendment Would Decrease the Number of Verifications and Verification Time

27. To determine if the Proposed Amendment is efficient, the expected costs should be weighed against the expected benefits. One straightforward economic benefit would flow from a decline in the costs to prescribers and sellers associated with time consuming verification requests.³⁸ As described in more detail below, the combined time that a prescriber and third-party seller must spend to comply with the Rule and verify an order is much higher when the patient does not provide the seller with a copy of his or her prescription. If the Proposed Amendment increased the number of patients able to provide their prescription, it would reduce verification costs.

28. The FTC recognizes that verification requests are likely to decline and at least partially offset any costs associated with the Proposed Amendment, but states that it does not have the data it needs to calculate that benefit.³⁹ While the exact percentage by which verifications would decline is unknown, one can calculate the percentage drop in verifications that would be necessary to fully offset the estimated costs of the Proposed Amendment and compare that to a reasonable prediction of the extent to which verifications could fall if the Proposed Amendment improves compliance.

29. As described in more detail below, using the FTC's estimates of the time prescribers and sellers spend to verify orders, a reduction in verifications of between 9% and 21% (depending on specific assumptions) would completely offset the estimated annual cost for the Proposed Amendment.

³⁸ For example, 1-800 CONTACTS places approximately 5.2 million calls annually to prescribers to verify prescriptions.

³⁹ NPRM, *supra* note 1, at 88557.

30. Moreover, if we assume that with the Proposed Amendment (1) the approximately 30% of consumers who never receive a prescription (either automatically or upon request) were to receive a prescription and (2) they were to use it when placing an order at the same rate that consumers receiving a prescription today use it when placing an order with third-party sellers, verifications would fall by 16%, consistent with the range of verification reduction needed to offset the cost of the Proposed Amendment.⁴⁰

31. Information from prior FTC regulatory filings provides most of the information needed to perform these calculations. The FTC estimates that prescribers spend approximately five minutes per verification request.⁴¹ Similarly, the FTC estimates that sellers spend five minutes on tasks related to verifying an order. For orders placed with a copy of the prescription, the FTC estimates that sellers spend one minute to store the patient's prescription.⁴² Prescribers who release prescriptions as required do not spend any additional time if the patient uses that prescription to place an order with a third-party seller. Thus the incremental cost of verification is five minutes for prescribers, and four minutes for third-party sellers.

32. Based on comments submitted by the AOA, the FTC assumes optometrists handle verifications, at an average wage estimated by the Bureau of Labor Statistics, which in 2016 corresponded to \$56.53.⁴³ The cost of verification through direct communication is

⁴⁰ Survey evidence indicates the fraction of patients who do not receive a prescription either automatically as required by the Rule, or upon request, ranges from 24-36%. SSI October 2015 Survey, *supra* note 18 (36%); SSI January 2017 Survey, *supra* note 21 (24%); Consumer Action January 2017 Survey, *supra* note 23 (31%).

⁴¹ Agency Information Collection Activities, Submission for OMB Review, 81 FR 175, Sept. 19, 2016, ("FTC September 2016 PRA Notice"),

https://www.ftc.gov/system/files/documents/federal_register_notices/2016/09/frn_contact_lens_rule_p05451 0.pdf. The FTC's estimate of the time prescribers spend to verify an order is based on information that the AOA provided and claims to be based on a 2016 "survey of approximately 300 optometric practices to gather more information from prescribers regarding the passive verification system." Comment of the American Optometric Association, Contact Lens Rule: File No. P054510, July 19, 2016, https://www.ftc.gov/system/files/documents/public_comments/2016/07/00004-128575.pdf.

⁴² *Id*.

⁴³ *Id.* The FTC assumes an average wage of \$55.65 based on Bureau of Labor Statistics ("BLS") May 2015 estimate. *News Release: Occupational Employment and Wages—May 2015*, BLS (Mar. 30 2016) <u>https://www.bls.gov/news.release/archives/ocwage_03302016.pdf</u>. The BLS 2016 hourly optometrist salary is from *Economic News Release: Table 1. National Employment and Wage Data from the Occupational Employment Statistics Survey by Occupation, May 2016*, BLS (Mar. 31, 2017),

thus \$4.71 per event.⁴⁴ For sellers, assuming that the hourly wage of the employees performing verifications is \$15.87, the implied incremental cost is \$1.06 per verification.⁴⁵ Thus, the incremental cost is an estimated \$5.77 per verification event.⁴⁶ Using the additional costs that prescribers and sellers incur when an order must be verified, one can determine that a decline in verification requests of 8.8% would completely offset the expected cost of the Proposed Amendment.⁴⁷ This calculation is illustrated in Figure 1 and Table 1. Table 2 illustrates an alternate break-even calculation, assuming that staff at prescribers' offices perform verifications, in which case a decline in verifications of 21.4% would completely offset the expected cost of the Proposed Amendment.

33. Also using data from the FTC's regulatory filings, I can investigate circumstances in which a decline in verifications in this range could occur. I estimate that approximately 14,596,000 consumers buy from third-party sellers.⁴⁸ According to the FTC, 73% percent of those orders are verified. So for the remaining 27%, consumers must be submitting a prescription, that is, around 3,940,920 consumers who buy from third-party sellers provide the seller with a prescription. I also estimate from survey evidence that about 70% of consumers ultimately receive a prescription, either automatically (as the Rule requires) or

<u>https://www.bls.gov/news.release/ocwage.t01.htm</u>. I understand that the AOA claimed in comments to the FTC on the paperwork costs of the Rule that it takes a prescriber five minutes to verify a prescription, and that verifications are handled by optometrists and ophthalmologists themselves. Comment of the American Optometric Association, *supra* note 41.

 $^{^{44}}$ (\$56.53 per hour) x (.083 hours), (where .083 hours is 5/60 hours or five minutes).

 $^{^{45}}$ (\$15.87 per hour) x (.066 hours), (where .066 hours is 4/60 hours or four minutes).

⁴⁶ (incremental cost for prescriber = 4.71) + (incremental cost to seller = 1.06) = (5.77).

⁴⁷ The estimated cost of the Proposed Amendment is 10,844,495. The added cost for each order that requires verification is 5.77. Thus, the decline in verifications needed to offset the cost is 10,844,495/55.77 = 1,879,842. The FTC estimates that 35.6% of orders are placed with third-party sellers that must verify the order either through receipt of the prescription or a direct communication with the prescriber. The FTC also estimates that 73% of orders placed with third-party sellers are verified. Evidence indicates that consumers make two orders per year on average. If the sellers do not have a copy of the consumer's prescription, both orders must be verified. Thus, given 41 million contact lens wearers, a reasonable estimate of the total number of verifications per year is 21.3 million (41 million x .356 x .73 x 2). The percentage decline in verifications needed to offset the costs of the Proposed Amendment is 1,879,842 / 21,310,160 = .088. Table 1 describes this calculation in more detail and provides references for data sources.

⁴⁸ 41,000,000 x 0.356. FTC September 2016 PRA Notice, *supra* note 41.

upon request.⁴⁹ Thus, I estimate that approximately 10,217,200 consumers who buy from third-party sellers receive their prescription.⁵⁰ From this, I infer that 38.6% of consumers who buy from third-party sellers and have a prescription use the prescription.⁵¹

34. The FTC (and Avalon) estimates of the cost of the Proposed Amendment assume that all prescribers comply with it. I thus assume that, with the Proposed Amendment, all of the 30% of patients who are not receiving prescriptions today will start receiving them, so that an additional 4,378,800 of consumers buying from third-party sellers will get their prescription.⁵² If I further assume that, like today, 38.6% of consumers will use it when they place an order, then approximately 1,688,966 more consumers would use a prescription when placing an order if the Proposed Amendment were to take effect.⁵³ Therefore, with two verification events per year per patient, the Proposed Amendment would reduce the number of verifications by 3,377,921 per year,⁵⁴ which corresponds to 15.9% of the estimated total number of verifications.⁵⁵ This decline in seller verification requests is in the middle of the range of 8.8% to 21.4% shown in Figure 1 that would completely offset the expected cost of the Proposed Amendment.

H. Other Potential Economic Benefits of the Proposed Amendment

35. The Proposed Amendment can be expected to generate other benefits for consumers as well. Because I understand that there is robust competition among suppliers of both eye care services and contact lenses, at least some part of any drop in the net compliance costs is likely to be passed on to consumers. In addition, consumers who purchase lenses from third-party sellers will typically receive their lenses faster if they submit a copy of their prescription. I understand that 1-800 CONTACTS' internal

⁴⁹ The estimated fraction of patients who do not get a prescription varies from 24% to 36%. See *supra* note 38.

⁵⁰ 14,596,000 x 0.70.

⁵¹ 3,940,920 / 10,217,200.

⁵² (0.70 + 0,30) x (14,596,000 - 10,217,200).

⁵³ 0.386 x 4,378,800.

⁵⁴ 2 x 1,688,966.

⁵⁵ 3,377,921 / 21,310,160.

customer satisfaction surveys show that customers place a high value on quick delivery; consumer satisfaction suffers a meaningful decline if customers must wait five days to receive an order.⁵⁶ Even with overnight delivery, a customer who places an order with an online seller on a Friday afternoon without submitting a prescription may not be able to receive their lenses until the following Tuesday, or even later over a holiday weekend.⁵⁷ If that consumer were able to submit her prescription, she could receive her order sooner, the next day with overnight delivery and even the same day in certain markets or regions. In addition, survey evidence indicates that 65% of consumers will over wear lenses if they are down to their last pair.⁵⁸ Based on its review of the medical evidence, the FTC has stated that overwearing lenses presents a health risk for contact lens wearers.⁵⁹

36. Survey evidence also shows that consumers value having a copy of their prescription. The SSI August 2017 Patient Acknowledgment Survey reports that 85% of respondents said they would be interested or extremely interested in receiving a copy of their prescription to use if they choose to buy lenses from somewhere other than their current eye doctor.⁶⁰ The same survey indicates that respondents believe that having a copy of their prescription facilitates comparison shopping: 73% of respondents said they would be interested or extremely interested in receiving their prescription so that they could more easily comparison shop among sellers.⁶¹ Since approximately 50% of respondents appear to not fully understand their rights under the Rule,⁶² the Proposed Amendment could easily increase the pool of consumers who comparison shop for lenses.

⁵⁶ 1-800 October 2015 Comments, *supra* note 18, at 14. 1-800 CONTACTS also reports that if they have a prescription on file, they can ship an order within 14 minutes of placement. *Id.*

⁵⁷ If a seller places a verification request and does not receive a quick affirmative verification, the seller must wait at least eight business hours before even shipping lenses. 16 CFR 315.5 (c) (3).

⁵⁸ SSI January 2017 Survey, *supra* note 21, at 4–5.

⁵⁹ NPRM, *supra* note 1, at 88549 ("The failure to replace lenses is a well-documented cause of many contact lens-related health issues.").

⁶⁰ SSI August 2017 Acknowledgment Survey, *supra* note 34, at 6.

⁶¹ *Id*.

⁶² SSI October 2015 Survey, *supra* note 18, at 5; Consumer Action January 2017 Comments, *supra* note 23, at 1.

37. Eliminating obstacles to comparison shopping will allow consumers to search for sellers that offer them the price, reliability, convenience, and service they prefer.⁶³ In the long term, increasing automatic prescription release can be expected to enhance competition, drive down prices, expand choice, improve customer service, and ultimately benefit the entire population of contact lens wearers, not only those patients who decide to switch providers of contact lens. That is, patients who did not switch would also benefit from lower prices and better services in the marketplace.⁶⁴

I. Response to the Avalon Report and Survey

I.1. Overview of the Avalon Report and Survey

38. At the AOA's request, Avalon conducted a survey of AOA members to examine the potential costs of implementing the FTC's Proposed Amendment.⁶⁵ The AOA solicited members to participate in the survey, and a total of 130 responses were recorded during the survey period.

39. The survey consists of 16 questions that relate to the administrative time staff members spend on various tasks at optometric practices, including patient interactions, patient engagement practices, and staff training, among others.

40. Based on the survey responses, Avalon analyzed the potential financial impact of the Proposed Amendment on optometric practices across the United States. Avalon's survey and analysis are both fundamentally flawed. The survey design is methodologically unsound, and the survey questions are misleading and incorporate improper assumptions, likely biasing the resulting data set. Avalon then combines the flawed survey results with entirely unsupported assumptions not even drawn from its own survey to reach wildly

⁶³ Independent survey data found that 63% of consumers would identify "Getting the best price" as an extremely important factor when considering to purchase contact lenses. 47% would identify "Good customer service" and "Convenience of speed of ordering my lenses" as extremely important factors when considering to purchase contact lenses. SSI August 2017 Acknowledgment Survey, *supra* note 34, at 4.

⁶⁴ Joseph Farrell & Paul Klemperer, Coordination and Lock-in: Competition with Switching Costs and Network Effects, in HANDBOOK OF INDUSTRIAL ORGANIZATION 1967 (Mark Armstrong & Robert Porter eds., 2007).

⁶⁵ Economic Evaluation of FTC Ruling on Contact Lens Prescriptions, AVALON HEALTH ECONOMICS at 3–4 (Jan. 27, 2017) ("2017 Avalon Report").

inflated estimates for the incremental costs to prescribers of the Proposed Amendment, as discussed in greater detail below.

I.2. The Survey Conducted by Avalon Health Economics Has Methodological Flaws

I.2.a. The Administration of the Avalon Survey Is Flawed

41. Best practices for survey design dictate that respondents should be blind to the purpose and sponsorship of a survey to minimize the bias that results from respondents giving the answers that they *think* the surveyor wants to find.⁶⁶ It is my understanding that the AOA had repeated communications with optometrists about the Proposed Amendment before fielding the survey, including a press release urging its members to submit comments opposing the Proposed Amendment that included a link to a sample letter describing the burden prescribers would face, including the need for "ongoing staff training."⁶⁷ The AOA itself also directly contacted its members and requested their participation in the survey.⁶⁸ Thus, survey participants were aware of the sponsor and purpose of the survey, which evidence suggests can influence respondents' answers.

42. It is survey best practice to ensure that the sample approximates the relevant population.⁶⁹ The Avalon Survey does not describe how it defined the relevant population, but it appears to have excluded a significant portion of prescribing eye care providers. Eye

https://www.aoa.org/documents/secure/advocacy/FTC Comments Letter Template 120716.pdf.

⁶⁶ "[A]ny potential bias is minimized by having interviewers and respondents blind to the purpose and sponsorship of the survey and by excluding attorneys from any part in conducting interviews and tabulating results." Shari S. Diamond, *Reference Guide on Survey Research, in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 238 (2011), ("*Reference Guide on Survey Research*").

⁶⁷ FTC Proposes Contact Lens Rule Changes; AOA Warns of Inaction, AOA (Nov. 17, 2016), <u>http://www.aoa.org/news/advocacy/ftc-proposes-contact-lens-rule-changes;</u> Proposed Contact Lens Rule Misguided: AOA Encourages Doctors' Comments to FTC, AOA (Dec. 8, 2016) (providing link to sample letter to then Chairwoman Ramirez), <u>https://www.aoa.org/news/advocacy/proposed-contact-lens-rulemisguided</u>. The sample letter included specific language on the burden prescribers would face ("while the FTC seems to dismiss the potential burden on physicians for complying with this requirement, the proposal would undoubtedly add new costs for doctors and patients. It would require an additional step in the patient engagement process, which would necessitate ongoing staff training to ensure that doctors are meeting this unprecedented requirement."),

⁶⁸ 2017 Avalon Report, *supra* note 65, at ¶ 2.5.

⁶⁹ "The definition of the relevant population is crucial because there may be systematic differences in the responses of members of the population and nonmembers" *Reference Guide on Survey Research, supra* note 66, at 240.

care providers include both optometrists and ophthalmologists, but Avalon surveyed only optometrists, omitting 15% of prescribers.⁷⁰ Additionally, Avalon surveyed only those optometrists who were also members of the AOA, omitting roughly a quarter of optometrists.⁷¹ As a result, the surveyed population will not represent the relevant population.

43. A low response rate is often taken to indicate the potential for biased results and care must be taken when interpreting results from surveys with low response rates.⁷² The Avalon Report appears to have recorded a total of 130 survey responses but does not provide any information on the response rate. Assuming that the survey was sent to all of the AOA's approximately 28,000 members, this is a response rate of less than 0.5%.⁷³ With an apparently very low response rate, and since the purpose of the survey was known in advance to those surveyed, there is a significant risk that those who self-selected into participation are more likely than average to oppose the Proposed Amendment and thus more likely to estimate a high cost of compliance.

44. Finally, it should be noted that the Avalon survey asked *prescribers* to predict how patients would handle the information and whether they would comprehend a form prescribers have no experience with, rather than try to gauge *patient* reaction and comprehension directly.

I.2.b. Survey Questions Are Flawed

45. A number of survey questions related to the Proposed Amendment include improper implicit assumptions, are vague, prime respondents in such a way that they may not truthfully answer, and at times require the respondent to perform subjective

⁷¹ According to the Bureau of Labor Statistics, there were 36,430 optometrists in practice in 2016. *Occupational Employment and Wages, May 2016*, BUREAU OF LABOR STATISTICS, <u>https://www.bls.gov/oes/current/oes291041.htm</u>. The AOA claims reports that it has 28,000 members. *About the American Optometric Association (AOA)*, AOA, <u>https://www.aoa.org/</u>.

⁷⁰ The FTC estimates that 85% of prescribers are optometrists, and 15% ophthalmologists. Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315 (OMB Control # 3084-0127), <u>https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201609-3084-001</u>.

⁷² *Reference Guide on Survey Research, supra* note 66, at 245.

⁷³ About the American Optometric Association (AOA), supra note 71.

calculations, all of which are likely to bias the data and the resulting calculation of compliance costs.

46. **First,** a number of the survey questions incorporate unsupported assumptions that are likely to bias the data collected. For example:

- Question 5 asks, "When you introduce a new patient engagement process into your office workflow (e.g. the requirement for patients to sign additional paperwork) how much staff training does this require?"⁷⁴ This question incorporates an assumption that staff training is necessary for each new patient engagement process, and that all processes involve the same amount of time and complexity. Additionally, the provided response options ("Less than 5 minutes per staff member," "5–10 minutes per staff member," . . . "20 or more minutes per staff member") assume that all staff members must receive the training, rather than just the relevant staff members.
- <u>Question 7</u> asks, "How much time do periodic assessments of new policies and protocols generally take?"⁷⁵ It incorporates the assumption that periodic assessments of different policies and protocols are the same length. Moreover, when performing its cost analysis, Avalon arbitrarily assumes that all respondents interpreted the question to refer to time per assessment per staff member,⁷⁶ and that four assessments per year are necessary, conclusions that cannot be drawn from responses to the actual survey questions or any of the reported summary statistics.
- <u>Question 8</u> asks, "How much time do you anticipate it would take to explain to a patient the purpose of [the FTC Acknowledgment] . . . ?"⁷⁷ This question improperly incorporates the assumption that all patients will require an

⁷⁴ 2017 Avalon Report, *supra* note 65, Appendix at 6.

⁷⁵ Id.

⁷⁶ In contrast, a previous question (Question 5) explicitly provided response options "per staff member," which would have then created further confusion around the unclearly defined response options for this subsequent question (Question 7). *Id*.

⁷⁷ Id.

explanation. The SSI August 2017 Acknowledgment Survey, which surveys patients directly, found that more than 90% of respondents understand the meaning of the Proposed Acknowledgment and do not require an explanation.⁷⁸

<u>Question 9</u> asks, "Do you anticipate that patients would have questions before signing this type of Acknowledgment?"⁷⁹ This question only allows respondents a binary yes/no response, implicitly assuming that either all patients would have questions or all patients would not. Respondents are not allowed to report how many, or what fraction, of their patients would have questions. As noted above, the SSI 2017 Patient Acknowledgment survey reports that the vast majority of respondents say they would not have questions.⁸⁰

47. **Second**, some of the survey questions are open to multiple interpretations by respondents, likely leading to biased results. For example:

• Question 10 asks, "If patients have questions regarding this Acknowledgment, how much time do you anticipate would be necessary to answer these questions?" and offers respondents the option to answer, "Less than 1 minute," "2 minutes," "3 minutes," "4 minutes," or "More than 5 minutes."⁸¹ There is no indication that the response alternatives provided were appropriate given the two-sentence length of the acknowledgment (which in the SSI survey reported above took respondents an average of 12 seconds to read). Moreover, the question is open to multiple interpretations by respondents, for example whether they should report the time for a representative patient who had a question as opposed to an average for all patients incorporating those who had no questions as well as those who did.

⁷⁸ SSI August 2017 Acknowledgment Survey, *supra* note 34, at 8.

⁷⁹ 2017 Avalon Report, *supra* note 65, Appendix at 7.

⁸⁰ SSI August 2017 Acknowledgment Survey, *supra* note 34, at 8.

⁸¹ 2017 Avalon Report, *supra* note 65, Appendix at 7.

• Question 16 asks, "What is the total administrative time associated with adhering to the rules, regulations and policies regarding the operations of your practice? (per week)."⁸² This question is unclear and is open to multiple interpretations of "rules, regulations and policies regarding the operations of [their] practice." Lack of clarity in survey questions can be a substantial problem.⁸³ In this case, it is not clear that all providers would know or easily be able to think through the types or numbers of rules, regulations, and policies to which a given practice is subject. If they could, coming up with a response would require possibly substantial calculations. As a result, any reliance on responses to this question as basis for calculating the cost of all aspects of the Rule, let alone the incremental cost of the Proposed Amendment, should be suspect.

48. <u>Third, many questions improperly prime the respondents with the appropriate</u> <u>answer and disincentivize the respondent to truthfully answer the question</u>. For example, Question 6 asks, "When a new patient engagement process is introduced into your office, do you conduct periodic assessments to determine if protocols are being appropriately followed?"⁸⁴ This question is likely to lead the respondent to believe that periodic assessments are necessary in order to ensure that staff members are following new protocols, priming the respondent with the value of periodic assessments, which in turn is likely to affect how truthfully they answer this and the subsequent question.⁸⁵

⁸² Id., Appendix at 8.

⁸³ "When unclear questions are included in a survey, they may threaten the validity of the survey by systematically distorting responses if respondents are misled in a particular direction, or by inflating random error if respondents guess because they do not understand the question. If the crucial question is sufficiently ambiguous or unclear, it may be the basis for rejecting the survey." *Reference Guide on Survey Research*, *supra* note 66, at 248.

⁸⁴ 2017 Avalon Report, *supra* note 65, Appendix at 6.

⁸⁵ The subsequent question, Question 7, asks: "How much time do periodic assessments of new policies and protocols generally take?" *Id.*

49. Fourth, certain survey questions present inappropriate response alternatives that are likely to bias the results.⁸⁶ Almost none of the questions include a "don't know" or "no opinion" option. Including these options and/or using filter questions is good practice in survey design to remove respondents who are not qualified to answer and reduce guessing.⁸⁷

I.3. The Analysis Performed by Avalon Health Economics Overestimates the Cost of Compliance with the Proposed Amendment

50. Using its flawed survey data, combined with unsupported assumptions, Avalon concludes that "the annual cost associated with various aspects of the implementation of the new Rule will total to at least \$743,905,990 if we assume that only optometrists are providing an explanation of the rule"⁸⁸ and \$543,106,326, assuming that "only staff members are providing an explanation of the rule. This cost analysis, which is summarized in Table 1 to the Avalon Report, is based on biased data, unsupported assumptions, and does not specifically calculate the *incremental* cost of the Proposed Amendment, though that is what Avalon purports to be measuring.

51. For example, the first cost item in Avalon Table 1 is the cost of "All staff time per new patient engagement training. Annual assumption of four trainings."⁸⁹ The underlying survey question that provides the data for this calculation does not account for the fact that patient engagements vary in complexity; it is not specific to the Proposed Amendment. Additionally, there is no support for an assumption that an optometric office will need four trainings a year to properly handle a two-sentence form. The second cost item ("Periodic

⁸⁶ *Reference Guide on Survey Research, supra* note 66, at 252 ("Precoded responses . . . in addition to reminding respondents of options that they might not otherwise consider, may direct the respondent away from or toward a particular response.").

⁸⁷ "Some survey respondents may have no opinion on an issue under investigation, either because they have never thought about it before or because the question mistakenly assumes a familiarity with the issue.... By signaling to the respondent that it is appropriate not to have an opinion, the question reduces the demand for an answer and, as a result, the inclination to hazard a guess just to comply." *Id.*, at 249–50.

⁸⁸ 2017 Avalon Report, *supra* note 65, at ¶ 4.3.

⁸⁹ *Id.*, Table 1.

assessment of new patient engagement policies. Assumption of quarterly review") suffers from the same defects.⁹⁰

52. The third cost item ("Explanation of new FTC ruling at every patient visit") appears to be based on survey Question 8, which incorporates the unsupported assumption that *every* patient will require an explanation at *every* visit. ⁹¹

53. Similarly, the fourth cost item ("Answering questions in regards to new FTC ruling for each patient") is based on an unsupported assumption that *every* patient will have questions about the Proposed Amendment *every* year, year after year. Even their own survey reported that only 84% of respondents expected patients to have questions about the Proposed Acknowledgment.⁹²

54. The fifth cost item ("Administrative time associated with adhering to rules") is completely irrelevant to measuring the incremental cost of the Proposed Amendment.⁹³ As discussed above, survey Question 16 is not specific to the Proposed Amendment and instead solicited an aggregation of all time spent "adhering to the rules, regulations and policies" ⁹⁴ Responses to that question have no relationship to the incremental cost of administrative aspects of the Proposed Amendment.

55. In sum, I find the Avalon Report to be fatally flawed, unreliable and irrelevant to predicting the likely incremental cost of the Proposed Amendment.

J. Conclusion

56. For these reasons, I agree with the FTC that compliance with the Rule's automatic release mandate is incomplete, and the Proposed Amendment is a reasonable, cost-effective approach to improving compliance. My analysis supports the conclusion that the

⁹⁰ Id.

⁹¹ *Id*.

⁹² *Id.* at 4.

⁹³ *Id.*, Table 1.

⁹⁴ Id., Appendix at 8.

benefits associated with the Proposed Amendment could easily be commensurate with, and might exceed, any modest additional cost.

Camere C. Sale

Laurence C. Baker

EXHIBIT A

Exhibit A Laurence C. Baker, PhD

Professor of Health Research and Policy Chair, Department of Health Research and Policy Stanford University School of Medicine HRP Redwood Building, Rm 110 150 Governors Lane Stanford, CA 94305-5405 650-723-4098

ACADEMIC HISTORY

- 1990 B.A. (Mathematics and Economics), Calvin College, Grand Rapids, MI
- 1994 M.A. (Economics), Princeton University, Princeton, NJ
- 1994 Ph.D. (Economics), Princeton University, Princeton, NJ
 - (Principal advisor: Alan B. Krueger, Ph.D.)

EMPLOYMENT HISTORY

Academic Appointments:

August 1, 1994 – August 31, 2001	Assistant Professor, Department of Health Research and Policy
	Stanford University School of Medicine, Stanford, CA
August 1, 1995 – August 31, 2002	Assistant Professor, by courtesy, Department of Economics
	Stanford University, Stanford, CA
September 1, 2001 – August 31, 2007	Associate Professor, Department of Health Research and Policy
	Stanford University School of Medicine, Stanford, CA
September 1, 2001 – Sept. 30, 2015	Chief of the Division of Health Services Research
	Department of Health Research and Policy
	Stanford University School of Medicine, Stanford, CA
September 1, 2002 – August 31, 2007	Associate Professor, by courtesy, Department of Economics
	Stanford University, Stanford, CA
September 1, 2007 – Present	Professor, Department of Health Research and Policy
-	Stanford University School of Medicine, Stanford, CA
September 1, 2007 – Present	Professor, by courtesy, Department of Economics
	Stanford University, Stanford, CA
May 1, 2014 – September 30, 2015	Associate Chair, Department of Health Research and Policy,
	Stanford University School of Medicine, Stanford CA
October 1, 2015 – Present	Chair, Department of Health Research and Policy
	Stanford University School of Medicine, Stanford CA

Other Appointments

1994-2002 H	Faculty Research Fellow
ľ	National Bureau of Economic Research, Cambridge, MA
2000-present H	Fellow
- (Center for Primary Care and Outcomes Research and Center for Health Policy
S	Stanford University, Stanford, CA
2001-2002 A	Acting Director

	Health Services Research Interdepartmental Masters Degree Program
	Stanford University, Stanford CA
2002 - present	Research Associate
	National Bureau of Economic Research, Cambridge, MA
2007 - present	Director of the Scholarly Concentrations Program
_	Stanford University School of Medicine, Stanford, CA
2015 - present	Senior Fellow
_	Stanford Institute for Economic Policy Research, Stanford University, Stanford CA
2016 - present	Kennedy-Grossman Faculty Fellow, Human Biology Program, Stanford University, Stanford CA
2016 - present	Core Faculty, Stanford Health Policy

Non-Academic Employment

1993-1994 Research Economist The Robert Wood Johnson Foundation, Princeton, NJ

PUBLIC AND PROFESSIONAL SERVICE

University, School, and Departmental Committees

1994 – present 1994 – 2000	Member, Health Services Research Masters Program, Admission Committee Member, Health and Safety Committee, Department of Health Research and Policy
1996-1997	Member, Computer Committee, Department of Health Research and Policy
1997-2003	Elected Departmental Representative, Stanford University School of Medicine Faculty
	Senate
1997-1999	Member, Health Services Research faculty search committee
2003	Member, HIPAA compliance committee, Department of Health Research and Policy
2003	Member, Faculty search committee, Center for Primary Care and Outcomes Research
	and Center for Health Policy
2003-2007	Member, Courses and Curriculum Committee, School of Medicine
2005-2007	Member, Committee on Medical Student Scholarship
2007-2008	Chair, Courses and Curriculum Committee, School of Medicine
2007-present	Chair, Committee on Medical Student Scholarship, School of Medicine
2010-present	Member, Bing Overseas Studies Program Oversight Committee, Stanford University
2012-present	Member, Committee on Curriculum and Academic Policy, School of Medicine
2012-2013	Member, PCOR faculty search committee
2012-2013	Member, General medical disciplines faculty search committee
2012-2014	Member, Appointments and Promotions Committee, School of Medicine
2013-present	Member, Committee on Faculty Staff Human Resources, Stanford University
2014	Chair, Bing Overseas Studies Program, Madrid Center Review Committee
2014-present	Member, Executive Committee, Human Biology Program, Stanford University

Other Public and Professional Service

1993	Consultant, The White House Task Force on Health Care Reform, Washington DC
1994-1998	Member, Evaluation team for the Robert Wood Johnson Foundation Minority Medical
	Education Program," (Joel Cantor, principal evaluator).
1996-2001	Freshman advisor, Stanford University
1997-1999	Member, Health Economics Committee,
	Medical Care Section, American Public Health Association
1997-1999	Member, Health Economics Annual Meeting Program Committee
	Medical Care Section, American Public Health Association
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1998-present	Member, Editorial Board, Health Services Research
1999	Special Member, AHCPR Health Services Research Study Section
1999-2000	Member, State of California Universal Health Care Technical Assessment Committee
	(charged with overseeing studies of the effect of health reforms on health care in
	California)
1999-present	Advisory Committee Member, Center on the Demography and Economics of Health and
	Aging, Stanford University
2001-2003	Member, State of California Universal Health Care Technical Assessment Committee
	(charged with overseeing studies of the effect of health reforms on health care in
	California)
2002	Invited Contributor, Economic Report of the President
2002-2003	Member, Local Organizing Committee, International Health Economics Association
	2003 Annual Meeting
2002-2004	Member, AcademyHealth Alice S. Hersh New Investigator Award Selection Committee
2002-2004	Advisor, RWJF Scholars in Health Policy Research Program, UC Berkeley
2002-present	Member, Editorial Board, Medical Care Research and Review
2003	Organizer and Chair, NBER Health Care Program Fall meeting
2003-2004	Member, Planning Executive Committee and Planning Committee, AcademyHealth 2004
	Annual Research Meeting
2003-2004	Proposal Reviewer, Office of Technology Licensing, Stanford University
2003-2007	Co-founder and Co-organizer, Annual Bay Area Health Care Quality and Outcomes
	Research Conference (with Hal Luft, UCSF; and Tom Rundall, UC Berkeley)
2004-2006	Member, Advisory Board, Health Economics, Policy, and Law (new Journal)
2004-2008	Member, Advisory Board for NIH funded project "Advanced Neuroimaging: Ethical,
	Legal and Social Issues" (Principal Investigator Judy Illes)
2005	Chair, Panel Selection Committee, AcademyHealth 2005 Annual Research Meeting
2005	Member, Planning Committee, AcademyHealth Annual Health Policy
	Conference
2005-2007	Guest Editor, special issue of Medical Care Research and Review on Markets and
	Managed Care
2005-2008	Member, Scholarship Oversight Committee for Pediatrics Fellow Henry Lee
2006-2008	Member, Editorial Board, Health Economics, Policy, and Law
2006	Special Member, NIH HSOD Study Section
2007-present	Member, Research Award Selection Committee, National Institute for Health Care
1	Management (chair 2009-present)
2007-2015	Senior Associate Editor, Health Services Research
2008-2011	Member, AcademyHealth board nominating committee
2008-2009	Member, Planning committee, and Abstract Reviewer, AcademyHealth Annual Research
	Meeting
2009-present	Member, Board of Directors, American Society of Health Economists (ASHEcon)
2010	Abstract Reviewer, AcademyHealth Annual Research Meeting
2010	Member, CMS Geographic Variation Special Study Technical Expert Panel
2010-2011	Annual Meeting Chair, AcademyHealth 2011 Annual Research Meeting
2010-2016	Member, Board of Directors, International Health Economics Association
2012	Reviewer for IOM report on the California Institute for Regenerative Medicine
2012-present	Member, Board of Directors, AcademyHealth
2013-2015	Member, Alice Hersh Award selection committee, AcademyHealth
2013	Member, host committee, ASHE annual meeting
2013-2016	Member, National Advisory Council, Robert Wood Johnson Foundation Scholars in
	Health Policy Research Program
2015	Chair, AHRQ Review Committee, Comparative Health System Performance in
	Accelerating PCOR dissemination RFA

2015	Testimony before the California Senate Committee on Health (Informational Hearing
	"Making Health Care Affordable: Impact on Consumers," March 18)
2016-present	President Elect, American Society of Health Economists
2016-present	Member, Technical Expert Panel, AHRQ/Coordinating Center for the Study of Health
_	System Performance

HONORS AND AWARDS

Individual Career Awards

2000	Alice S. Hersh Young Investigator Award, AcademyHealth
	(recognizes one individual per year for excellence in Health Services Research, among
	individuals within 6 years of entering the field)
2008	ASHE Medal, American Society of Health Economists. ("awarded biannually to the economist age 40 or under who has made the most significant contributions to the field of health
	economics.")

Other Honors and Awards

1990-1993	International Finance Section Fellowship, Department of Economics, Princeton University
1997	National Institute for Health Care Management Research Award
	(recognizes one article per year; this award for "The Effect of HMOs on Fee-For-Service Health
	Care Expenditures: Evidence from Medicare")
1999	National Institute for Health Care Management Research Award
	(recognizes one article per year; this award for "Managed care, Consolidation Among Health
	Care Providers, and Health Care: Evidence From Mammography")
1998-2003	Letter of Excellence in Education for HRP 205, "Introduction to Health Care Systems and Health
	Policy," Stanford University School of Medicine
1999	Henry J. Kaiser Award for Excellence in Preclinical Teaching, Stanford University School of
	Medicine
2000	Most Outstanding Abstract, Academy for Health Services Research and Health Policy Annual
	Meeting
	(recognized about 6 best from all submitted abstracts, this for "Is it health plans of providers that
	influence the quality of care?")
2001	Most Outstanding Abstract, Academy for Health Services Research and Health Policy Annual
	Meeting
	(recognized 3 best abstracts from all submitted abstracts (about 500), this for "Managed Care,
	Technology Adoption, and Health Care: The Adoption of Neonatal Intensive Care")
2001	Advisor of Merit, Stanford University Undergraduate Advising Program
2006	Henry J. Kaiser Award for Excellence in Preclinical Teaching, Stanford University School of
	Medicine
2007	Most Outstanding Abstract, AcademyHealth Annual Meeting
	(recognized 28 best abstracts from all submitted abstracts, this for "Hospital Safety Culture:
	Relationship to Organizational Characteristics")
2007	Best Paper Proceedings, Academy of Management Annual Meeting (for Singer and Baker,
	"Relationship of Safety Climate and Safety Performance in Hospitals")
2009	Best Paper for the Health Care Management Division and Best Paper Proceedings, Academy of
	Management Annual Meeting (for Singer, Rosen, Gaba, Meterko, Baker, and Hartmann
	"Identifying Organizational Cultures that Promote Patient Safety"

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- Baker LC, Afendulis CC, Heidenreich PA. Managed Care, Information, and Diffusion: The Case of Treatment for Heart Attack Patients. *American Economic Review Papers and Proceedings* 94:2 (May 2004) 347-351
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- 44. Wagner TH, **Baker LC**, Bundorf MK, Singer SJ. Use of the Internet For Health Information By the Chronically Ill. *Preventing Chronic Disease* 1:4 (October 2004). PMID: 15670445

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- Hsia R, MacIsaac D, Baker LC. Decreasing Reimbursements for Outpatient Emergency Department Visits Across Payer Groups from 1996 to 2004. *Annals of Emergency Medicine* 51:3 (March 2008) 265-274. Epub November 13, 2007. PMID: 17997503
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EXHIBIT B

Consumer Survey of Proposed FTC Contact Lens Prescription Acknowledgment: August 31, 2017 Executive Summary

Overview:

In August 2017, Survey Sampling International – on behalf of 1-800 CONTACTS – conducted an online survey of 500 U.S. adult contact lens consumers. The primary purpose of this study was to gauge consumer reaction to the FTC's proposed amendment to the Contact Lens Rule requiring that eye care providers ("prescribers") ask patients to review and sign a short form to acknowledge receipt of their contact lens prescription.¹ The survey also measures the value consumers place on receiving a copy of their prescription and the factors they consider when choosing a contact lens seller.

The survey provides a direct measure of the time it takes consumers to read the proposed acknowledgment form and tests whether they understand what they have read. The survey establishes that consumers quickly read and understand the meaning of the proposed acknowledgment and few have any questions after reading the form. The survey also shows that the vast majority of consumers are interested in receiving a copy of their prescription to use to purchase lenses from the seller of their choice or to make comparison shopping easier.

Key Findings:

1. Consumers read the proposed acknowledgment in an average of 12 seconds, and consumer comprehension of the meaning of the statement is near-universal.

¹ The proposed amendment to the Contact Lens Rule would require that prescribers present patients with an acknowledgment form for signature that would state: **"My eye** care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice."

- a. Respondents were asked to read the proposed acknowledgment on their screen and click to continue when finished. The survey measured the amount of time it took respondents to move from the proposed acknowledgment screen to the "next" button. It took an average of 12 seconds for respondents to read the proposed acknowledgment, with a median time of 10 seconds; 90% of respondents read the statement in 20 seconds or less.
- b. Immediately after being presented with the proposed acknowledgment, respondents were asked to identify the purpose of the statement. Nearly all respondents (90%) correctly identified the purpose of the statement.
- 2. The proposed acknowledgment is clear and self-explanatory. Very few consumers would have questions about its meaning. The survey asked respondents if they would need to ask any questions about the meaning of the statement before signing the form. Nearly all respondents (94%) reported that they would not have any questions.
- 3. Consumers are far more likely to pay attention to a notice of their rights that is presented to them for signature than a posted sign. 74% of respondents reported that they are more likely to pay attention to a document presented directly to them, while only 5% reported that they are more likely to pay attention to a posted sign.
- 4. The vast majority of consumers are interested in receiving a copy of their contact lens prescription.
 - a. 85% of respondents were interested or extremely interested in receiving a copy of their prescription to use if they want to purchase lenses from someone other than their current prescriber.
 - b. 73% of respondents were interested or extremely interested in receiving a copy of their prescription to more easily comparison shop among sellers.

- c. 71% of respondents were interested or extremely interested in receiving a copy of their prescription to provide to a preferred retailer to make ordering easier.
- d. Only <u>one</u> respondent out of 500 sampled indicated s/he was not interested in receiving a copy of the prescription for any reason.
- 5. Consumers value price, selection, reputation and service in choosing a contact lens seller.
 - a. 63% of respondents reported that "getting the best price" was "extremely important" when deciding where to purchase lenses.
 - b. 47% or respondents reported that "convenience or speed of ordering my lenses" was "extremely important"; 46% reported that "getting my lenses quickly" is "extremely important."
- 6. Many consumers stretch their lenses to save money. 56% of respondents reported that they wear lenses longer than the manufacturer's recommendation. The most common reason for stretching (59% of consumers who stretch) is "to save money."

Survey Design:

The survey was independently administered by Survey Sampling International and was conducted among U.S. adult contact lens wearers who purchased soft contact lenses for personal use in the past 6 months. The sample was fielded between August 3– 8, 2017 and was representative of the overall market makeup by location of last retail purchase and by gender and modality. Sample size of 500 respondents yielded a confidence level of 95%.



Consumer Survey of Proposed FTC Contact Lens Prescription Acknowledgment

Report prepared by Survey Sampling International for 1-800 CONTACTS

August 31, 2017

1800 contacts



Overview

Objectives

- Understand how contact lens consumers would use a copy of their prescription
- Analyze the following regarding the proposed FTC acknowledgment:
 - Length of time to read FTC statement
 - Degree of understanding of FTC statement
 - Whether patients pay more attention to a particular notification method

Methodology

- Independently administered online study conducted among U.S. adult contact lens wearers who purchased soft contact lenses for personal use in past 6 months
- Data collected August 3-8, 2017
 - Sample size of 500 respondents yielded confidence level of 95%
- Representative of overall market makeup by location of last retail purchase type:
 - Independent Eye Care Professional = 40%
 - Discount Retailer = 25%
 - Optical Chain Retailer = 19%
 - Online Retailer = 16%

ISSI

Sample demographics





U.S. Geographic Region



Age



Contact Lens Modality



63% of consumers believe "getting the best price" is extremely important



Factors identified as "extremely important" when considering where to purchase contact lenses

(% of total respondents)



Q3. How important are the following factors to you when considering where to purchase contact lenses? Response options were a 5-point importance scale (1="Not at all important," 5="Extremely important"). Total Respondents, n=500

56% of consumers wear lenses longer than recommended

The most common reason for stretching lenses is to save money





Q4. Do you ever wear your lenses longer than the manufacturer's recommended duration (e.g., wearing a 2-week lens for 3 weeks)? (Total Respondents, n=500)

Q5. Which of the following are reasons why you might wear your lenses longer than recommended? (Non-compliant respondents, n=282)

85% are interested in a copy of their Rx so they can have the freedom to choose where to buy lenses



Consumers are also highly interested in Rx to keep for their records (77%), to know if their Rx has changed (75%), so that they can comparison shop (73%), and to make it easier for a retailer to keep Rx on file (71%)

Reasons consumers are interested in receiving their Rx (% of total respondents)



Q10. How interested would you be in having a copy of your prescription for the following reasons? Response options were a 5-point interest scale (1="Not at all interested," 5="Extremely interested") Total Respondents, n=500 Note: Only one respondent out of total sample of 500 (0.2%) selected "Not interested at all" for all reasons.

It takes consumers an average of 12 seconds to read the proposed FTC prescription acknowledgment



90% of consumers read the statement in 20 seconds or less

Time to read statement page:

"My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice."



90% of consumers initially understand the purpose of the proposed acknowledgment



Only 4% of consumers have a question or comment about the statement



Q12. Which of the following describes the main purpose of the statement you just read? (Total respondents, n = 500)

Q13. Would you need to ask any questions about the meaning of the statement (see below) before signing the form? (Total Respondents, n=500)

Q14. What questions do you have about the meaning of this statement? (Total Respondents, n=128; 106 selected "I do not have any questions about the meaning of the statement")



Q15. Which type of notice would you be more likely to pay attention to? (Total Respondents, n=500)



1-800 CONTACTS US Adult Contact Lens Wearers n=500 Survey conducted over the internet Fielded: Aug 03, 2017 – August 08, 2017

Question S1 Are you	
	Total
Male	44%
Female	56%
Question S2 What is your age?	
	Total
Under 18	Terminate
18-24	13%
25-29	14%
30-34	18%
35-39	12%
40-44	11%
45-49	9%
50-59	13%
60+	11%
Question S3 Do you or anyone else in your household work for any of the following types of businesses?	
	Total
Marketing research	Terminate

Marketing research	Terminate
Advertising or public relations	Terminate
An eyewear manufacturer, distributor or retailer	Terminate
A financial institution such as a bank, brokerage house or insurance company	2%
A telephone or telecommunications firm	0%
An automobile manufacturer or dealership	1%



An optometrist or ophthalmologist

None of the above

Question S4 In which state do you currently reside?

	<u>Total</u>
Northeast	21%
Midwest	20%
South	33%
West	26%

Question S5

Which, if any of the following products do you regularly use? Check all that apply

	<u>Total</u>
Soft contact lenses	97%
Prescription eyeglasses	80%
Prescription Sunglasses	23%
Readers	16%
Non-prescription Sunglasses	42%
Hard contacts / gas permeable contacts	6%
None of the above	3%

Question S6

n = 487

Which, if any have you purchased for your own use in the past six months? Check all that apply

	<u>Total</u>
Soft contact lenses	100%
Prescription eyeglasses	44%
Prescription Sunglasses	13%
Readers	9%
Non-prescription Sunglasses	23%
Hard contacts / gas permeable contacts	4%

None of the above



Question S7

Which of the following best describes where you last purchased contact lenses for your personal use?

	<u>Total</u>
An eye doctor such as an ophthalmologist or optometrist	40% Quota n = 200
A discount retailer such as Walmart or Target or wholesale club such as Sam's or Costco	25% Quota n = 125
An internet, online or mail order retailer such as 1-800 CONTACTS	16% Quota n = 80
An optical retail chain such as LensCrafters or Pearle Vision	19% Quota n = 95
Somewhere else	Terminate
l don't know / l don't recall	Terminate

Introduction: For the first set of questions for this survey, we are interested in knowing some things about your general contact lens use.

Question 1 What type of contact lenses do you wear?

	<u>Total</u>
Dailies/one day	24%
1-2 week	26%
Monthlies/one month	43%
Frequent replacement/2-3 months	4%
Conventional/non-disposable/6 months or longer	2%

Question 2

Select all of the places where you have purchased contacts lenses for personal use over the last 3 years. (Check all that apply.)

<u>Total</u>



An eye doctor such as an ophthalmologist or optometrist	54%
A discount retailer such as Walmart or Target or wholesale club such as Sam's or Costco	37%
An internet, online or mail order retailer such as 1-800 CONTACTS	33%
An optical retail chain such as LensCrafters or Pearle Vision	28%
Somewhere else	2%

Question 3 (Top box summaries)

How important are the following factors to you when considering where to purchase contact lenses?

[5 point scale from "Not at all important" to "Extremely important"]

	<u>Total</u>
Getting the best price	63%
Making sure my prescribed brand is available	60%
Seller has a good reputation	49%
Good customer service	47%
Seller is my eye doctor	19%
Getting my lenses quickly	46%
Convenience or speed of ordering my lenses	47%
Other	40%

Question 4

Do you ever wear your lenses longer than the manufacturer's recommended duration (e.g., wearing a 2 week lens for 3 weeks)?

	<u>Total</u>
Yes	56%
No	42%
I don't know/don't recall	2%

Question 5 If Q4=yes n=282 Which of the following are reasons why you might wear your lenses longer than recommended?

<u>Total</u>



<u>Total</u>

To save money	59%
I am low on lenses/ran out of lenses	43%
To save time	19%
I sometimes forget when I last replaced my lenses	51%
It's inconvenient to order more lenses	12%
Other [specify]	6%
None of the above	2%

For the next set of questions, we are interested in knowing some things about your eye exam experiences.

Question 6
Approximately how often do you have an eye exam?

More than once every 6 months	4%
Once every 6 months to one year	18%
About once every year	55%
Once every year to 1 1/2 years	10%
Once every 1 ¹ / ₂ to 2 years	6%
About once every 2 years	5%
Once every 2 to 3 years	2%
Less than once every 3 years	1%

Question 7 Approximately how long ago was your last eye exam?

	<u>Total</u>
Less than one month ago	8%
Between 1 and 3 months ago	22%
Between 3 and 6 months ago	27%
Between 6 months and 1 year ago	33%
Between 1 and 2 years ago	8%
Between 2 and 3 years ago	1%
3 or more years ago	0%



Question 8 Where did you go for your last eye exam? (Select the best option.)

	<u>Total</u>
An independent eye doctor's office	40%
The eye department of a multidisciplinary medical clinic or group eye care practice (optometrist or ophthalmologist)	12%
A local optical retailer that offers eye exams	9%
A national optical retailer that offers eye exams (like LensCrafters, Pearle Vision or America's Best)	20%
A large retailer that has an optical department (like Walmart, Costco, or Target)	19%

Question 9

Thinking about the last place where you had an eye exam, how long have you been visiting this place for your eye exam?

<u>Total</u>
14%
13%
20%
27%
27%

The next few questions are hypothetical regarding some possible scenarios of what may occur when you have an eye exam.

Question 10_1 How interested would you be in having a copy of your prescription for the following reasons?

TO KEEP FOR MY RECORDS

	<u>Total</u>
(5) - Extremely Interested	46%
(4) - 4	31%
(3) - 3	16%
(2) - 2	4%

(1) - Not at All Interested



<u>Total</u>

Question 10_2

How interested would you be in having a copy of your prescription for the following reasons?

TO KNOW IF MY CONTACT LENS PRESCRIPTION HAS CHANGED

	<u>Total</u>
(5) - Extremely Interested	41%
(4) - 4	34%
(3) - 3	17%
(2) - 2	4%
(1) - Not at All Interested	4%

Question 10_3

How interested would you be in having a copy of your prescription for the following reasons?

TO UNDERSTAND THE INFORMATION REGARDING MY CONTACT LENSES

	<u>Total</u>
(5) - Extremely Interested	34%
(4) - 4	32%
(3) - 3	25%
(2) - 2	5%
(1) - Not at All Interested	4%

Question 10_4

How interested would you be in having a copy of your prescription for the following reasons?

TO USE IF I WANT TO BUY MY LENSES FROM SOMEWHERE OTHER THAN MY CURRENT EYE DOCTOR

(5) - Extremely Interested	56%
(4) - 4	29%
(3) - 3	10%
(2) - 2	3%
(1) - Not at All Interested	1%



Question 10_5

How interested would you be in having a copy of your prescription for the following reasons?

TO GIVE IT TO A PREFERRED CONTACT LENS RETAILER TO KEEP ON FILE TO MAKE ORDERING EASIER.

	<u>Total</u>
(5) - Extremely Interested	41%
(4) - 4	30%
(3) - 3	21%
(2) - 2	4%
(1) - Not at All Interested	3%

Question 10_6

How interested would you be in having a copy of your prescription for the following reasons?

TO BRING TO ANOTHER EYE DOCTOR IF I WANTED TO SWITCH PROVIDERS

	<u>Total</u>
(5) - Extremely Interested	34%
(4) - 4	27%
(3) - 3	24%
(2) - 2	8%
(1) - Not at All Interested	7%

Question 10_7

How interested would you be in having a copy of your prescription for the following reasons?

TO HAVE SO I CAN MORE EASILY COMPARISON SHOP AMONG SELLERS

	<u>Total</u>
(5) - Extremely Interested	42%
(4) - 4	31%
(3) - 3	20%
(2) - 2	5%
(1) - Not at All Interested	3%



Total

Question 10_8 How interested would you be in having a copy of your prescription for the following reasons?

TO KNOW WHEN I NEED TO GO BACK TO THE EYE DOCTOR FOR MY NEXT EYE EXAM

(5) - Extremely Interested	28%
(4) - 4	27%
(3) - 3	26%
(2) - 2	10%
(1) - Not at All Interested	8%

Question 10_9

How interested would you be in having a copy of your prescription for the following reasons?

OTHER

	<u>Total</u>
(5) - Extremely Interested	100%
(4) - 4	-
(3) - 3	-
(2) - 2	-
(1) - Not at All Interested	-

For the next set of questions, you will be shown a statement and asked questions about how you would respond if presented with that statement during a visit to your eye care provider.

Question 11

My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice.

Mean time to read statement = 12 Seconds

Median time to read statement = 11 Seconds

Question 12

Which of the following describes the main purpose of the statement you just read?

(selection frequency)

Total



To acknowledge that I received a copy of my contact lens prescription and understand that I can purchase lenses from someone other than my eye doctor if I wish to do so	90%
To tell me that my contact lenses are ready for pickup	3%
To make me aware that there are health risks associated with contact lens wear	4%
To agree to substitute a private label contact lens if my preferred brand is not in stock	1%
I don't know	1%
None of the above	1%

Question 13

Would you need to ask any questions about the meaning of the statement (see below) before signing the form?

	<u>Total</u>
Yes	25%
No	73%
I don't know	2%

Question 14 n=128 What questions do you have about the meaning of this statement?	
[Open-ended anchored response]	
	<u>Total</u>
I do not have any questions about the meaning of the statement	84%
Question 15 Which type of notice would you be more likely to pay attention to?	
which type of house would you be more likely to pay attention to:	T . (.)
	<u>Total</u>
I would be more likely to pay attention to a document that I am given and asked	
to sign	74%
I would be about as likely to pay attention to a posted sign as a document that I am given and asked to sign	22%
I would be more likely to pay attention to a posted sign	5%



<u>Total</u>

Transition: Finally, just a few more questions for classification purposes only.

Question D1	
What is the last grade of school you completed?	(CHECK ONE ANSWER.)

Less than high school degree	0%
High school graduate	8%
Some college	18%
Completed 2-year college	11%
Completed 4-year college	40%
Some post-graduate	4%
Post-graduate degree	18%
Other technical school beyond high school	2%

Question D2 Which of the following best describes you? (CHECK ONE ANSWER.)

<u>Total</u>
60%
13%
8%
7%
1%
6%
5%
0%

Question D3 Are you of Hispanic origin or descent? (CHECK ONE ANSWER.)

<u>Total</u>

	SS
No	88%
Yes	12%
Prefer not to answer	0%

Question D4

Do you consider yourself... (CHECK ONE ANSWER.)

	<u>Total</u>
African-American	7%
Asian/Pacific Islander	11%
Caucasian	77%
Native American	2%
Mixed ethnic background (Specify)	1%
Other (Specify)	1%
Prefer not to answer	2%

Figure 1 Potential Savings with Verification Reductions



Source: Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16; 1-800 Contacts, "Comments of 1-800 CONTACTS, Inc," 1/30/17; BLS 2016 Wage Data; American Optometric Association, Letter to the FTC "Re: Contact Lens Rule, 16 CFR Part 315, Project No. R511995," 1/30/17

Note: The FTC offset value of \$10,844,495 is the FTC's annual estimated labor cost of maintaining records of the proposed acknowledgement, updated for 2016 wage increases. The FTC cost estimate of \$10,475,495 uses the 2015 BLS wage for office clerk, general of \$15.33. The 2016 BLS wage for office clerk, general is \$15.87, which is a 3.5225% increase. Therefore the 2016 wage labor cost is 10,475,495 * 1.035225 = \$10,844,494. BLS 2016 optometrist wage of \$56.53 is used.

Table 1Description of Break-even CalculationAssuming Optometrist Performs Verification

		Assumption	Source
[A]	5	Time prescribers spend per verification (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 3, citing the American Optometric Association.
[B]	5	Time sellers spend per verification (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 7.
[C]	1	Time sellers spend to keep prescription provided by patient (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 7.
[D]	56.53	Average hourly wage for optometrist (\$)	Bureau of Labor Statistics, "May 2016 National Occupational Employment and Wage Estimates United States," 3/31/17. The FTC uses the 2015 BLS optometrist wage in Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 8.
(E)	15.87	Average hourly wage for office clerk, general (\$)	Bureau of Labor Statistics, "May 2016 National Occupational Employment and Wage Estimates United States," 3/31/17. The FTC uses the 2015 BLS office clerk, general wage in Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 8.
[F]	41,000,000	Number of contact lens wearers in the United States	American Optometric Association, Letter to the FTC "Re: Contact Lens Rule, 16 CFR Part 315, Project No. R511995," 1/30/17, p. 4.
[G]	0.356	Fraction of contact lens orders from a source other than the prescriber	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 6.
[H]	0.73	Fraction of non-prescriber sales that require verification	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 6.
[1]	0.50	Average supply of an online order (years)	1-800 Contacts, "Comments of 1-800 CONTACTS, Inc., Contact Lens Rule, 16 CFR part 315 Project No. R511995," 1/30/17, FN 54.
[J]	10,844,495	Labor cost attributable to the proposed acknowledgement form, updated for 2016 wage increases (\$) $^{\left[1\right] }$	Federal Trade Commission, 16 CFR Part 315, RIN 3084–AB36, "Contact Lens Rule," 12/7/16, p. 88557; Bureau of Labor Statistics, "May 2016 National Occupational Employment and Wage Estimates United States," 3/31/17.

		Estimate	Calculation
[K]	21,310,160	Number of verifications per year	([F] x [G] x [H]) / [I]
[L]	4.7108	Cost per verification for prescribers (\$)	[A] x [D] / 60
[M]	1.0580	Incremental cost per verification for sellers (\$) ^[2]	([B] - [C]) × [E] / 60
[N]	5.7688	Total incremental cost per verification (\$)	[L] + [M]
[O]	1,879,842	Number of avoided verifications required to offset the FTC estimated cost of the Proposed Amendment	[J] / [N]
[P]	0.088	Avoided verifications as fraction of the number of verifications per year	[O] / [K]

Note:

[1] FTC cost estimate of 10,475,495 uses the 2015 BLS wage for office clerk, general of \$15.33. The 2016 BLS wage for office clerk, general is \$15.87, which is a 3.5225% increase. This labor cost is calculated as (10,475,495 * 1.035225).

[2] Assumes salary for seller staff is equivalent to office clerk, general.

Table 2Description of Alternate Break-even CalculationAssuming Office Staff at Prescriber Performs Verification

		Assumption	Source
[A]	5	Time prescribers spend per verification (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 3, citing the American Optometric Association.
[B]	5	Time sellers spend per verification (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 7.
[C]	1	Time sellers spend to keep prescription provided by patient (minutes)	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 7.
[D]	15.87	Average hourly wage for office clerk, general (\$)	Bureau of Labor Statistics, "May 2016 National Occupational Employment and Wage Estimates United States," 3/31/17. The FTC uses the 2015 BLS office clerk, general wage in Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 8.
[E]	41,000,000	Number of contact lens wearers in the United States	American Optometric Association, Letter to the FTC "Re: Contact Lens Rule, 16 CFR Part 315, Project No. R511995," 1/30/17, p. 4.
[F]	0.356	Fraction of contact lens orders from a source other than the prescriber	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 6.
[G]	0.73	Fraction of non-prescriber sales that require verification	Federal Trade Commission, "Supporting Statement for Information Collection Provisions of the Contact Lens Rule, 16 CFR Part 315," 9/8/16, p. 6.
[H]	0.50	Average supply of an online order (years)	1-800 Contacts, "Comments of 1-800 CONTACTS, Inc., Contact Lens Rule, 16 CFR part 315 Project No. R511995," 1/30/17, FN 54.
[1]	10,844,495	Labor cost attributable to the proposed acknowledgement form, updated for 2016 wage increases (\$) ^[1]	Federal Trade Commission, 16 CFR Part 315, RIN 3084–AB36, "Contact Lens Rule," 12/7/16, p. 88557; Bureau of Labor Statistics, "May 2016 National Occupational Employment and Wage Estimates United States," 3/31/17.

		Estimate	Calculation
[J]	21,310,160	Number of verifications per year	([E] x [F] x [G]) / [H]
[K]	1.3225	Cost per verification for prescribers (\$)	[A] x [D] / 60
[L]	1.0580	Incremental cost per verification for sellers $(\$)^{[2]}$	([B] - [C]) x [D] / 60
[M]	2.3805	Total incremental cost per verification (\$)	[K] + [L]
[N]	4,555,553	Number of avoided verifications required to offset the FTC estimated cost of the Proposed Amendment	[I] / [M]
[O]	0.214	Avoided verifications as fraction of the number of verifications per year	[N] / [J]

Note:

[1] FTC cost estimate of 10,475,495 uses the 2015 BLS wage for office clerk, general of \$15.33. The 2016 BLS wage for office clerk, general is \$15.87, which is a 3.5225% increase. This labor cost is calculated as (10,475,495 * 1.035225).

[2] Assumes salary for seller staff is equivalent to office clerk, general.