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**Dissenting Statement of Commissioner Patricia P. Bailey  
Protein Supplement Trade Regulation Rule,  
16 C.F.R. Part 454**

**December 20, 1984**

By its actions today in voting to terminate the Protein Supplements rulemaking proceeding, the Commission abdicates its responsibility to protect the health and safety of consumers against irresponsible and possibly life-threatening commercial practices by marketers of protein supplements products. Those left not protected by the Commission's inaction are infants, for whom ingestion of excessive amounts of protein can have debilitating or even fatal results. In my view, the record evidence in this proceeding supports at least the infant use warning provisions advocated by the San Francisco Regional Office staff and the Directors of the Bureaus of Consumer Protection and Economics, and I therefore dissent from the Commission's termination of this rule.

Let me first note my dismay at the Commission's somewhat cavalier dismissal of the arguments in favor of a rule to prohibit firms from representing that protein supplements are appropriate for infant use and to warn parents of the dangers of such use. As both Bureau Directors pointed out in their memorandum, the danger to infants under one year of age who are fed highly concentrated protein products is substantial since a diet too high in protein can, in a time as short as one or two days, lead to hypernatremic dehydration. If not arrested, this condition can result in serious neurologic disturbances,

irreversible damage to the nervous system and brain, or death. Experts who participated in this proceeding testified that infants should not be fed a diet with concentrations of protein higher than 20 percent, and that the preferred range is from seven to sixteen percent. By contrast, the protein supplements products that are the subject of this rulemaking have protein concentrations ranging from 43 upwards to 90 percent.

Despite the fact that these products more than double (and some quadruple) the maximum concentrations of protein infants can safely partake, several of these products were explicitly marketed for use by infants. Even more were marketed for use by children, which would well suggest to parents that they could safely be used by children under as well as over the age of one. Unfortunately, most parents are ill-prepared to discount or ignore these ill-advised promotions. The record evidence shows that significant numbers of consumers misperceive the need for supplemental protein in American diets, and more importantly, that many are unaware of the risks of feeding large amounts of protein to very young children. Coupled with the affirmative encouragement some marketers gave, these facts demonstrate that there is a substantial danger that protein supplement products may be fed to infants unless parents are warned otherwise.

The Commission's refusal to promulgate a rule addressing these dangers does not rest on any finding that the practice of marketing protein supplements for use by infants is a legitimate one. Indeed, there can be no doubt that such conduct meets the standards for both deceptive and unfair practices. The bases for

this decision, then, lie in considerations of policy: the concerns, first, that these illegal practices are not sufficiently prevalent to warrant an industry-wide rule, and second, that alternate enforcement efforts will prove equally effective and efficient in protecting consumers. I disagree with both judgments.

With respect to the prevalence of these practices, the Commission narrowly focuses only on nine explicit representations that protein supplements are appropriate for infant use, thereby ignoring the evidence of many supplementary representations that could encourage parents to give their infants these products. These include advertising and label claims for some 40 additional protein supplement products recommending their use by children, and another 18 product claims emphasizing the importance of eating high levels of protein. In an industry the size of this one, the Commission is surely justified in taking action when claims for as many as 65 products may encourage product usage that endangers infants, and where all products fail to warn against that use.

In an increasingly common companion argument, the Commission also criticizes the absence of up-to-date evidence that violations are still prevalent. Since the record in this proceeding closed in 1977 and the Commission has made no effort to supplement it, it is not surprising that the record contains no recent evidence of these practices. Of course, the Commission could, as it has in other instances, conduct a brief re-examination of the industry to determine whether deceptive and

unfair practices still prevail. I am fully prepared to act on the basis of the record before us, but would nevertheless welcome a re-examination since I believe it would establish the continuing and persistent failure of marketers of protein supplements to disclose the danger of feeding those products to infants, even in the face of widespread marketing campaigns encouraging their use by everyone.

I also cannot accept the argument that any abuses can be attacked more efficiently on a case-by-case basis. As a preliminary matter, threats of an aggressive case-by-case law enforcement program in this area sound distinctly hollow emanating from an agency that is unwilling to promulgate even the most basic of regulatory protections. Moreover, the Commission has already invested substantial time and money to establish that highly concentrated protein foods cannot safely be fed to infants. Reaching that conclusion involved the compilation of an array of scientific evidence impressive in its breadth and depth. Carrying that conclusion to regulatory fruition imposes almost no costs on the affected industry, but in any future enforcement actions it saves the agency from having to reprove these points over and over again. If an efficient law enforcement effort is the Commission's primary goal, then the Commission should prohibit outright those practices we now know are unfair and deceptive.

The infant use provisions in the proposed rule are certainly the most critical, but other aspects of this proceeding also deserve consideration. For example, the record describes

extensive use by industry members of unsubstantiated and apparently false claims that protein supplements possess therapeutic properties and are needed to ensure that consumers meet their dietary protein requirements. I will be the first to admit the difficulties the Commission faces in attempting to devise fair but adequate remedies to such abuses. I believe nevertheless that the record supports imposition of a rule regulating these practices and that the Commission could formulate effective provisions to this end.

Finally, let me note the anomaly of the Commission's action in light of the position taken by the industry. Virtually all industry members agree that protein supplements should not be recommended for infant use, and they condemn marketing claims to the contrary. The major industry trade group, the Council for Responsible Nutrition, supported a rule prohibiting infant use representations and requiring warnings on product labels. That group also did not contest the rule provisions recommended in 1981 to prohibit deceptive claims about the therapeutic benefits of and dietary need for protein supplements.

Rather than adopting a course supported by the record and in effect accepted by the bulk of the industry, the Commission today sides with those advocating severely misguided regulatory philosophies (though I do not mean to suggest the Commission shares these views). As described at the oral presentations in September, those philosophies counsel speechmaking and consumer education in lieu of any meaningful industry regulation; reject the detailed scientific evidence amassed in this record in favor

of anecdotal wisdom; dismiss the evidence of infant risk from excessive protein consumption as purely theoretical; and insist that a disclosure rule is not warranted absent evidence that infants have actually suffered injury or death. I cannot accept these contentions. Nor can I agree that, at the conclusion of a responsible rulemaking proceeding that supports modest and moderate rule provisions to regulate known abuses in the marketing of protein supplements, the Commission should stop just short of an effective, low-cost, industry-wide remedy and turn instead to an ephemeral new program of case-by-case law enforcement. Accordingly, I dissent from the decision to terminate this proceeding.