

Testimony of Dr. Mario F. Teisl, Assistant Professor, Department of Resource Economics and Policy, University of Maine, at the FDA Public Meeting on Implementing the PEARSON Court Decision and other Health Claim Issues. Washington, DC, April 4, 2000

Good afternoon, before continuing I want to thank the Food and Drug Administration for inviting me to this important forum.

Today, I am going to answer the main question with some specific recommendations based upon results from a variety of consumer research. Although many of these studies do not focus on dietary supplements, the recommendations I make are based on findings that are relatively consistent across studies. However, one should note that consumer reactions to labeling programs often differ based upon product specific factors. I would recommend that more research be performed to gauge consumer reactions to specific examples of dietary supplement labeling.

1. *Disclaimers should be simple, direct and strongly worded.* The wording of disclaimer messages can greatly influence their effectiveness. Disclaimers that provide background or general information are often ineffective; consumers often view general disclaimers as simply a tool the manufacturer uses to protect themselves legally. Further, general disclaimers may be counterproductive, leading the consumer to misinterpret the meaning of the disclaimer. In addition, the effectiveness of a disclaimer is greater if it is intensely worded. In fact, weakly worded messages, even from a highly credible source, are ineffective in changing consumer perceptions. However, disclaimers appearing alarmist will be discounted or ignored.
2. *Disclaimers will have to be claim specific to indicate to the consumer that the substantiation of different health claims will vary.* Previous to Pearson, FDA set one uniform standard of substantiation for all health claims on dietary supplements. However, after Pearson it seems that there will no longer be one unifying standard. As a result, different health claims will have different standards; consumers will need to be informed about this for several reasons. First,

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TS 7

consumers need to understand the particulars of each product's level of substantiation to more correctly evaluate the credibility of the claim. A second reason for clearly delineating across claims is to maintain the credibility of more highly substantiated claims. Meagerly supported claims, that may change repeatedly across time as new health-related research is performed, are likely to generate higher levels of skepticism for all health-related claims. In addition, the reputation of agencies seen as regulating the health claims is also likely to diminish. This could lead to a situation where many consumers who could actually benefit from the consumption of a particular well-researched product would end up not purchasing the item due to a general skepticism of all health claims.

3. *Disclaimers should focus on providing information that is new to the consumer.* Telling the consumer what they already know is not particularly useful. When possible, the disclaimer messages should be rotated to increase their effectiveness.
4. *Disclaimer items should be physically separated from other non-disclosure items, preferably through the use of a 'box' around the disclaimer.* There are two reasons to separate the disclaimer from other information. First, reducing the amount of informational 'clutter' around the disclaimer increases their readability and ease of use. Second, the disclaimer should be understood by consumers as a regulatory mechanism, not as part of the marketing information provided by firms. Consumers see regulated information mechanisms as more credible than firm-provided information. As a result, physically separating disclaimers from non-disclaimer information enhances consumer trust in the disclaimer.
5. *The actual disclaimer should be placed on the back of the product container.* In general, consumers view the front of the container as the area that the manufacturer uses to sell their product whereas the back of the container is the area where regulated information is placed.

6. *A reference to the disclaimer should be located close to the claim and clearly refer to the presence of a disclaimer.* In general, the presence of a health claim tends to reduce the likelihood that consumers will continue their information search onto the back of the container. Thus, an asterisk or footnote-type reference is not enough because consumers may mistakenly think that the footnote refers to material that directly supports the claim.
7. *To enhance readability and increase effectiveness, the font size for the disclaimer and for the reference to the disclaimer should be at least as large as the font used in the health claim.*
8. *Definitions of all terms should be consistent with common understanding and usage.* Consumers must be able to understand and use the information provided; research should ensure that consumers' perceptions of any important information are the same as those that the agency intends.
9. *The disclaimer label should provide references to disclosures of supporting documentation available at off-label locations.* Informed consumers should have access to detailed information about a health claim's level of substantiation. The label does not have the room needed to provide this detail, thus necessitating an off-label disclosure. Supporting documentation should be reviewed by the agency for truthfulness and its potential to mislead.
10. *If the disclaimer is to have supporting documentation, then this documentation should be placed prominently at the point of purchase and be made available on a secure FDA website to permit consumers to examine and easily compare different products. Each product's disclaimer should refer to the availability of this supporting documentation.* Linking the disclosed information to an official website of a regulatory body will enhance the credibility of the information.
11. *All disclaimer and disclosure information should be presented in a standardized format to decrease consumer confusion and increase credibility.* Where possible, this includes

standardizing: the size and location of the displays, font type and size, terms and definitions, and graphical elements. If different products exhibit different disclosure structures then comparisons among products will be difficult. Standardization of the format can reduce the cognitive costs of extracting information thus easing the consumer's primary uses of a product's information, i.e., to make cross-product comparisons of attributes and to verify firm-provided claims made elsewhere. In fact, when consumers are faced with information that is not standardized across products, they often take processing shortcuts, such as eliminating attributes or products for consideration. Finally, consumers want product information standardized so that they can make 'apples to apples' comparisons.

12. *Research should be performed to determine the feasibility of developing methods to summarize or score the level of substantiation for a claim.* Even with the availability of more detailed supporting documentation, time and cognitive constraints will probably not allow many consumers the ability to assimilate the detailed information. One simplifying strategy would be to create some sort of ranking or rating scale that could be used as a signal for the level of support made within a claim. A major difficulty here is that developing a scheme that rates the level of research substantiation for a health claim (both in terms of the number of studies and the quality of those studies) will be highly difficult (and probably highly controversial).
13. *If a scoring mechanism can be developed then providing some sort of benchmark information may provide clarity and increase understanding.* An example would be the inclusion of a minimum acceptable score or descriptive text highlighting whether the level of substantiation for a claim was low or high. Inclusion of a reference value can increase the number of consumers who can correctly identify differences across products.

14. *Disclaimers and other disclosure information should be product specific.* Consumers want to know about the attributes of the product. For example, dietary supplement users may want to know about recommended dosages, possible interactions between the supplement and other medications or supplements they may be taking, the overall safety of the product, any side effects associated with using the product and any special considerations for specific population groups (e.g., children). General information would not allow consumers to differentiate products in the manner they most desire

15. *Dietary supplement labeling should be part of a more general information strategy.* There are two parts to this information strategy, each having its own aim. One part of the information strategy should focus on heightening consumer awareness of the new labeling program. Labeling programs, by themselves, are not always effective in changing consumer behavior. Successful labeling programs are often linked to either a public education campaign or to a heightened exposure of the problem in the media; it is the combination of labeling and off-label education that seems to be most effective in altering consumer behavior. The aim of the second part of the information strategy is to have consumers question their priors. One incorrectly held prior is that some consumers think that after they use a particular product they can independently assess whether the product was effective, which in most cases a consumer truly cannot do. Another incorrectly held prior is that consumers seem to view health claim disclaimers solely as a comment about the reliability of the supporting research. However, the disclaimer is meant as a commentary on both the reliability and the validity of the supporting research. These two priors taken together lead many consumers to believe that the only way to determine the effectiveness of a product is to try it and see. This 'try it and see' attitude complicates matters in the long run because positive perceptions of one product experience can influence how

consumers view similar products. Further, as consumers develop increased experience with the products they are more likely to reduce their level of information search prior to purchasing similar products. The summation of all these effects is that the impact of any disclaimer information will be greatly reduced with more experienced consumers of dietary supplements. Labeling by itself will probably not affect these individuals unless an information campaign successfully makes these consumers question their priors.

To finish I would like to reiterate that the actual implementation of these recommendations will require additional consumer research. Given the low level of scientific and statistical literacy in the U.S. and the complex, probabilistic nature of determining health effects, an expanded health-claim labeling program for dietary supplements will have to be carefully designed. Poorly designed labeling is likely to generate confusion leading to incorrect product choices and to an overall reduction in societal welfare.