not place an absolute prohibition on ... potentially misleading information . . . if the information also may be presented in a way that is not deceptive."[19] *Pearson* at 655 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)). The government may not presume that health claims will mislead but must meet its burden of proof with empirical evidence documenting that, in fact, consumers will be misled. *Id.* (citing *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994)).

In *Pearson v. Shalala*, the Court held that FDA may not ban health claims that it deems are potentially misleading and not scientifically proven, where the misleading nature of the claim can be cured with a corrective disclaimer.[20] In reaching its decision, the *Pearson* Court quoted at length from *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977). *Bates* involved the State Bar's discipline of several attorneys who advertised their fees for certain legal services in violation of the Bar's rule. In that case, the Arizona Bar justified its decision on the ground that such advertising was inherently misleading. Ruling for the attorneys, the Court refused to credit the notion that "the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information." *Id.* at 374-75. Accordingly, the Court held that the "incomplete" attorney advertising was not inherently

[19] FDA may only restrict claims that are inherently misleading. An inherently misleading claim conveys no scientific information and may be prohibited outright. If the claim is not inherently misleading, it will either be truthful and non-misleading or it will be potentially misleading. As will be explained below, a health claim can be truthful, accurately reflecting the current state of scientific knowledge, but not scientifically proven. Such claims must be allowed without disclaimers if they are not potentially misleading. A potentially misleading claim is one that can be rendered non-misleading through the addition of a disclaimer. Such claims must also be allowed accompanied by mandated disclaimer language that the agency reasonably believes will eliminate the misleading connotation. In every instance of speech restriction, FDA carries the First Amendment burden of proof and must marshall empirical evidence to support the restriction. Moreover, the restriction must be no more extensive than necessary to achieve the goal of eliminating the misleading connotation.

[20] *Pearson v. Shalala*, 164 F.3d 650, 659 (1999).

misleading and that "the preferred remedy is more disclosure, rather than less."[21] *Id.* at 376. The Court has repeatedly reaffirmed this principle holding that disclaimers are constitutionally preferable to outright suppression. *See Peel,* 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206, n.20; *Shapero,* 486 U.S. at 478.

Consumers have a constitutional right to receive information and ideas.[22] Where consumer confusion exists, the proper remedy is more disclosure, not less. The restriction of health claims, including qualified health claims altered or censored based on consumer survey data, violates the First Amendment when the claim is protected speech. The solution is to disabuse the public of misconceptions through disclosure of more information, not suppression of heretofore "incomplete" information. It is axiomatic that complex speech, if true, may not be lawfully suppressed if few, or any, members of the public comprehend the message. That is because the First Amendment affords protection to the content of the speakers' communication and does not permit abridgement of that content on the plea that listeners or readers lack an adequate understanding of the message. *See, e.g.*, *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974)*; see also New York Times Co*. v. *Sullivan*, 376 U.S. 254, 279 (1964). The editorial prerogative of the speaker, the speaker's control over his or her own message, is absolute and cannot be censored on the argument that one or more who receive the message

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[21] The Supreme Court has continuously affirmed that its solution to consumer confusion is more speech, not less.

> "[T]he argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefits of public ignorance. [citation omitted]… the preferred remedy is more disclosure, rather than less. If the naiveté of the public will cause advertising . . . to be misleading, then it is the [Government's] role to assure that the populace is sufficiently informed as to enable it to place advertising in its proper perspective." *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-375 (1977).

[22] *Stanley v. Georgia,* 394 U.S. 557, 564 (1969)

misunderstand it or find it incomprehensible. Truth is defended even if it is beyond the comprehension of every listener or reader. It has been said repeatedly by the Court that our First Amendment depends on a free and open idea and information exchange. Edification depends not on a single statement but on the contest of statements in the idea marketplace. Truth arises from the dross of conflicting opinions; the government's duty is to keep itself out of this robust and wide-open exchange except in the most extraordinary circumstances. *See Miami Herald Publishing Co.* at 252-253; *New York Times Co*. at 270. FDA has a history of frequently overstepping its statutory and constitutional bounds, censoring speech that is beyond its lawful authority to suppress (*Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999) *reh'g denied,* 172 F.3d 72 (D.C. Cir. 1999); *Washington Legal Foundation v. Shalala,* 13 F. Supp. 2d 51 (D.D.C. July 30, 1998); 880 F. Supp. 26 (D.D.C. 1995), and *Pharmanex, Inc. v. Shalala,* 35 F.Supp. 2d 1341 (C.D.UT. 1998)). The public is in the best position to judge the validity of scientific information and ideas if only the public is well enough informed.[23] Given the opportunity, contest in the market will permit assessment of the credibility of every qualified health claim and will yield a better understanding of the claim's meaning and utility.

C. ANALYSIS CONSUMER CONFUSION CONCERNING HEALTH CLAIMS CANNOT BE MEASURED BY AN INTERNET SURVEY

[23] "There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." VA State Board of Pharmacy v. VA Citizens Consumer Council, 425 U.S. 748, 770 (1976).

1. Consumers have a constitutional right to receive truthful and nonmisleading scientific health-related information at the point-of-sale.

The First Amendment protects the publication of truthful and nonmisleading speech. Consistent with Congressional intent under NLEA and the decision in *Pearson*, FDA is required to establish and maintain a system that permits truthful and non-misleading claims on a product's label and in product labeling.

Economic literature confirms that the exercise of informed consumer choice hinges on the availability of accurate information at the point of sale in the consumer marketplace. *See generally* John E. Calfee & Janis K. Pappalardo, How Should Health Claims for Foods Be Regulated? 26-27 (Bureau of Economics, Federal Trade Commission 1989) *cited in Pearson*, 164 F.3d at 658, n.7 (explaining that channels other than the label and labeling impose higher search costs on consumers and reach them less effectively than claims directly on the label); *see also* The Hartman Group, "Organic Products—How do consumers choose?" *Natural Sensibility* 1999, 2:1-2; "Branding in the V[itamin]M[ineral and]H[erbal]S[upplement] marketplace," *Natural Sensibility*, 1998, 1:1-2 (presenting data from a survey of 4,000 households revealing that consumers most depend upon the information contained on labels of food and food products for nutrition information). In a 1998 study, Alan Mathios demonstrated that suppression of health claims and health benefit information "stifles the flow of useful information to consumers especially less-educated consumers" and results in consumers changing their purchasing habits to make less healthy food purchases.[24]

Qualified health claims provide dietary supplement consumers with access to truthful and nonmisleading scientific health information at the point of sale. The

[24] Mathios, A., 'The Importance of Nutrition Labeling and Health Claim Regulations on Product Choice: An Analysis of the Cooking Oil Market," *Agricultural and Resource Economics Review*, 1998

information allows consumers to make better informed dietary choices. It also serves to counteract fraud while raising public awareness of the importance of nutrition and healthy eating habits.

a. Rather than assessing consumer confusion, FDA should be fostering the dissemination of more scientific information on the nutrient-disease relationship at the point-of-sale.

Rather than attempting to discern consumer confusion regarding the scientific weight afforded recently allowed qualified health claims, the agency should start with the assumption that the claims are too new, that consumer understanding of the truthful content of them is likely primitive and incomplete, and that FDA ought to permit disclosure of more scientific information to the public by allowing its regulatees to send consumers scientific articles, abstracts, and accurate summaries of the scientific evidence concerning the relationship and by educating the public of the science through its own public service announcements, via its website, and via press releases and consumer information bulletins. That would maximize to the fullest extent possible the opportunity for public appreciation of the science. FDA has a history of denying consumers access to scientific information at the point of sale when it concerns nutrient-disease relationships.[25] FDA has repeatedly denied consumers access to health-related scientific literature, even truthful scientific government reports, and products at the point-of-sale.[26] There is substantial evidence that denying consumers access to truthful and nonmisleading health information at the point-of-sale contributes to a widespread failure

[25] *Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51 (D.D.C. 1998); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999)); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). *See also Pearson v. Leavitt*, No. 8:04-cv-3600 (S.D.Md. 2004)(pending).

[26] In 1995, FDA took substantial measures to ensure the safety of imported fish products. *See* 60 Fed.Reg. 65096 (December 18, 1995). The Final Rule was applied not only to fish but also to fish oil. 60 Fed.Reg. 65110. .

to address and prevent a number of illnesses and diseases responsive to nutrition.[27] FDA's aim, consistent with the First Amendment mandate *Pearson* places upon the agency, must be to disclose scientific information, not suppress it.

Consumers have the right to receive truthful information, regardless of their comprehension of it.[28] They have no constitutional right to understand truthful speech nor is there any constitutional power in government to suppress truthful speech because listeners or readers fail to comprehend it or comprehend it in a way that the government finds displeasing. *See Western States Medical* at 375; *44 Liquormart* at 503. The Courts have continuously rejected the paternalistic notion that the government has the authority to restrict the publication of truthful and nonmisleading speech when the government bases suppression on the notion that consumers will misunderstand the truth.[29]

b. If FDA proceeds with its proposed study, the information collected will be insufficient to prove consumer confusion.

Data obtained from the proposed survey will fail to prove the existence, degree, or character of any consumer confusion. This is especially true in light of the fact that the agency has predicted an estimated response rate of 0.2%.[30] This is prima facie evidence of massive response bias, as nonresponders (here 98.8% of the participants) may have

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[27] *See* discussion of the folic acid health claim, *supra at* footnote 7. The consequences of the agency's ill-advised rule were both tragic and resulted in thousands of preventable serious birth defects.

[28] *Stanley v. Georgia*, 394 U.S. 557, 564 (1969)

[29] *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002)("We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (The court rejected the "State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely . . . ." The court also noted that "bans on truthful and non-deceptive advertising usually rest solely on the offensive assumption the public will respond 'irrationally' to the truth…The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." (citing *Linmark Assoc.*, 431 U.S. at 96), *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 505 (1981)("A State may not completely suppress the dissemination of truthful information about an entirely lawful activity merely because it is fearful of that information's effect upon its disseminators and its recipients.")

[30] 70 Fed.Reg. 16291, 16292 (March 30, 2005)

very different views. The proposed survey is, thus, an unwarranted exercise, a waste of tax dollars.

FDA cannot be sure that perception of the qualified health claim is based on the claim itself or on undisclosed preconceived notions concerning the underlying nutrient-disease relationship arising from inaccurate media reports or other sources. The claims are too new and, thus, not yet vetted through the idea marketplace such that the complexities and nuances of them are largely unfamiliar to the public. Any attempt to interpret data suggesting misunderstanding will be fraught with great risk of error because there are a myriad of reasons why comprehension may be lacking, most of which may arise not from the claim language itself but from inadequate information in the idea marketplace on the nature of the relationship (i.e., from the paucity of science this agency allows to be disseminated concerning the nutrient-disease relationship). Moreover, the claims are by their very wording based on less than conclusive evidence. They, thus, beg differences in comprehension based on relative weight assigned by each reader of the claim. The far better approach is to assume limited public understanding of the science on the nutrient-disease relationship and to use agency resources not to study that limited understanding but to disseminate widely scientific information concerning the relationship so that greater public understanding is achieved. Disclosure over suppression is this agency's First Amendment mandate.

Because the FDA bears the First Amendment burden of proof, it may not deem disclaimers infeasible because it *lacks* conclusive evidence of their perfect comprehension or that few, if any, consumers understand the plain meaning of all qualified claim language.

Consumer confusion does not make a health claim or qualified health claim inherently misleading. Even where confusion is shown, so long as the disclosed information is truthful, the disclosure is protected speech under the First Amendment, regardless of consumer understanding of it. It is only through greater disclosure, not less, that consumer confusion will be reduced over time.

2. FDA's Proposed Survey Is an Inadequate Tool to Measure Consumer Confusion

Focusing on the Omega-3 fatty acids and monounsaturated fatty acids from olive oil health claims, FDA intends to study consumer confusion in the context of the public's understanding of the relative significance of the scientific evidence supporting qualified health claims. Silent as to the methodology or design of the proposed survey, the Notice simply states that "data will be collected using participants of an Internet panel …"[31] No specific information is provided as to the survey's design, format, questions, sampling pool, or how the collected data will be measured, analyzed and used. The agency has only said that the experimental study data will be collected using voluntary participants of an Internet panel of approximately 600,000 people.[32] Considering the importance of the study to consumers and the food and dietary supplement industries, the precise study questions, the precise study design, and the precise study methodology must be revealed to permit meaningful opportunity for comment, as required by the APA. 5 U.S.C. § 553. The agency's failure to explain the proposed study with specificity denies the public, and, here, the "Joint Commenters," the opportunity to comment fully on the subject of the Notice.

[31] *Id*.
[32] 70 Fed. Reg. 16292 (March 30, 2005).

1. Methodology

Well designed web-based surveys offer researchers many advantages over traditional methods of data collection including, but not limited to, more design options, the use of graphics, greater control over respondents' behavior, reduced costs and faster response times.[33] However, for each of those advantages, there are technical challenges and potential limitations that must be considered by the researcher including presentation, hardware (different browser settings and user preferences), diversity of the sample pool, and distribution and data measurement. A poorly designed web-based survey encourages web-users to break off the survey process early, making it less effective than more traditional methods of surveying, such as mail, telephone or email.[34] The agency has provided no information regarding the structure or format of the proposed survey, denying commenters their APA right to a meaningful opportunity for comment. *See* 5 U.S.C. § 553.

2. Questions

The Notice does not say what type of questions will be asked.[35] No examples of sample questions have been provided. How the questions are written and the language used will directly affect the quality of the scientific data obtained. The questions must be designed to avoid bias. Consumer confusion cannot possibly be determined based on quantifiable data alone.

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[33] Andrews, D., Nonnecke, B., Preece, J. (2003) Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines. International Journal of Human-Computer Interaction, page 4.

[34] Andrews, D., Nonnecke, B., Preece, J., Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines. International Journal of Human-Computer Interaction. Page 5 (2003).

[35] Will the questions be "adaptive" (questions are individualized according to a respondent's answer to an earlier question) or in "batch form" (consumers complete a series of predetermined questions).

3. Sampling

Sampling is the process by which a survey pool is selected. The Notice only states that participation will be voluntary. No other information is provided about how the participants will be selected. Meaningful opportunity for comment has thus been denied in violation of the APA. *See* 5 U.S.C. § 553.

Generally, there are two main methods for selecting a sample pool: probability and non-probability based approaches (frequently referred to as "random" and "nonrandom" approaches to surveys).[36] Because FDA is silent as to the approach it will use, the "Joint Commenters" are unable to comment on the actual survey to be used, and the Notice violates the APA as a consequence. *See* 5 U.S.C. § 553.

FDA has not stated how it intends to create the sample pool. The public is not told whether the agency intends to use a probability or non-probability-based approach. Additionally, the agency has not said who will be included in the sample pool, and

[36] Probability-based approaches ("nonrandom") involve having prior knowledge of a sample frame, most often through pre-recruitment or prior demographic identification of the sample pool. Prior knowledge affords the researcher greater control over recruiting while providing them with greater understanding of data collected and the nonresponse rate. *See* Couper, Mick P., *Web Surveys: A Review of Issues and Approaches*. Public Opinion Quarterly, Vol. 64: 464-494, 484 (2000). Some of the most commonly used probability based approaches include intercept (targeting web users on a particular website and inviting every nth person to participate in the survey), list-based coverage (invitations are sent out to potential respondents from pre-selected weblists asking them to participate in the survey), mixed-mode surveying (data is collected from a sample group using different methods such as mail, email, telephone and web-based surveys), pre-recruitment (respondents selected by researcher prior to the survey) and probability samples of full populations (subjects are provided with the equipment and tools needed to participate). Using a probability based approach, a risk of bias exists considering that participants are pre-selected from a predetermined website or based on a specific characteristic. However, one advantage to such an approach is that the nonresponse rate is measurable.

With non-probability based approaches ("random" sampling), researchers are unfamiliar with the background of the survey group beforehand. The two most popular approaches are self-selection and volunteer response. With self-selection, web postings are located on a number of different websites inviting respondents to participate in the survey by going to the survey. This approach involves no attempt to statistically sample the online population and depends exclusively on online traffic. *See* Andrews, D., Nonnecke, B., Preece, J., *Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines*. International Journal of Human-Computer Interaction. Page 8 (2003). The second approach relies on demographic information to randomly select participants.

whether that demographic pool will include dietary supplement buyers and consumers. Again, the APA has been violated. 5 U.S.C. § 553.

4. Demographic Data

The American Herbal Products Association reports that in 2003, consumers spent approximately $12.5 billion on vitamins and other dietary supplements.[37] Of that amount, $6.2 billion was spent on dietary supplements alone, the fastest growing subsector in the health foods market.[38] 2003 sales (in dollars) increased 2.6% from 2002.[39]

According to data from the 1999-2000 National Health and Nutrition Examination Survey, a total of 52% of adults reported taking a dietary supplement in the past month.[40] Of the adults surveyed, 35% took a multivitamin or multimineral supplement. Prevalent characteristics among dietary supplement users include: female gender, older age, more education, non-Hispanic White race/ethnicity.

In the United States, 59% of males and 54% of females use the Internet. Teenagers and young adults use the Internet more than any other age group.[41] Seventy-six percent of people ages 18 to 24 and 72% of people ages 25 to 34 use the Internet, while only 66% of people ages 35 to 44, 61% of people ages 45 to 54, 46% of people

[37] Euromonitor, *Vitamins And Dietary Supplements in the USA*, page 72 (July 2004)
[38] *Id* at 83.
[39] *Id*.
[40] The information is from a nationally representative, cross-sectional survey of U.S. health and nutrition conducted to assess prevalence of dietary supplement use overall and in relation to lifestyle and demographic characteristics.
[41] Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf. *See also* U.S. Department of Commerce, *A Nation Online: How Americans are Expanding Their Use of the Internet*, Executive Summary (February 2003) at http://www.ntia.doc.gov/ntiahome/dn/html/toc.htm ("Children and teenagers use computers and the Internet more that any other age group. Ninety percent of children between the ages of 5 and 17 (or 48 million) now use the Internet.").

ages 55 to 64 and 15% of people ages 65 and over use the Internet.[42] Lower income homes are less likely to have Internet access. Only 38% of households making $30,000 or less have access to the Internet while 61% of households that make $30,000 to $50,000, 77% of households making $50,000 to $75,000, and 86% of households making over $75,000 have Internet Access.[43] 59% of non-Hispanic Whites, 42% of non-Hispanic Blacks, 54% of Hispanics, and 60% of people listing themselves as "Other" use the Internet.[44] Only 22% of people with less than a high school degree use the Internet, while 45% of people with a high school degree, 70% of people with some college education, and 82% of college graduates or people with further education use the Internet.[45]

Based on the above demographics, the following conclusions can be drawn: mostly older Americans, and particularly women, use dietary supplements.[46] That group is underrepresented among those who use the Internet most and are to be subjects of the proposed survey. A recent study reported that only 15% of American adults over the age of 65 use the Internet, and when the federal government last studied American Internet use in 2003, it reported that that "[c]hildren and teenagers use computers and the Internet more than any other age group."[47]

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[42] Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf.
[43] *Id*.
[44] *Id*.
[45] *Id*.
[46] R. Bethene Ervin, et al, *Prevalence of Leading Types of Dietary Supplements Used in the Third National Health and Nutrition Examination Survey*, 1988-94, Advance Data/Centers for Disease Control and Prevention, Nov. 9, 2004, at 3 at http://www.cdc.gov/nchs/data/ad/ad349.pdf (reporting that roughly 57% of women use supplements compared with 47% of men; reporting approximately 63% of adults over the age of 60 take supplements, only 43% of adults between the ages of 20 and 39 take supplements); Kathy Radimer, et al., *Dietary Supplement Use by US Adults: Data from the National Health and Nutrition Examination Survey, 1999-2000*, American Journal of Epidemiology, Feb. 27, 2004, at 341.
[47] Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf; U.S. Department of Commerce, *A Nation Online: How Americans are Expanding Their Use of the Internet*, Executive Summary (February 2003) at http://www.ntia.doc.gov/ntiahome/dn/html/toc.htm.

5. Demographics of the Sample Pool

Data shows that 1) the web population is not reflective of the overall American population[48] and 2) the web-user population is not reflective of the dietary supplement user population. The demographic data presented above clearly confirms those facts. Dietary supplement buyers and consumers are the proper survey audience but reliance on the web will not likely involve a representative sampling of those buyers and consumers. Surveying people who are unfamiliar with dietary supplements will yield gross and unrepresentative biases and will involve a population far more likely to be unfamiliar with the science supporting any qualified health claims.

6. Nonresponse Rate

In addition to methodology and sampling, the overall response rate is important to a surveys' overall success. The Notice in the Federal Register states that of the 600,000 participants, the agency estimates 1,600 individuals will respond. That represents a response rate of 0.2%.[49] The "Joint Commenters" are concerned that the low response rate will have an adverse impact on the survey's ability to collect statistically significant data. Any evidence contained in a survey with a response rate of 0.2% surely cannot be considered accurate and representative. For this reason, it appears that the proposed survey is unlikely to yield accurate and reliable results and is an entirely unjustified expenditure of tax dollars.

[48] "The online population is not reflective of the offline population distribution, and it is changing continually. To infer for a general population based on a sample drawn from an online population is not yet possible and will not be possible until the online and offline populations reflect each other." Andrews, D., Nonnecke, B., Preece, J. (2003) Electronic survey methodology: A case study in reaching hard to involve Internet users. International Journal of Human-Computer Interaction. 16, 2, 185-210.
[49] 70 Fed.Reg. 16293 (March 30, 2005).

Research shows that the nonresponse rate may be attributed to a number of factors including 1) absence of motivation tools (e.g., pre-notification letters or follow-up letters) encouraging participants to complete the survey; 2) technical difficulties such as slow modem speed, unreliable connections or low-end browsers; 3) cost concerns; 4) perceived difficulty and technical intimidation may discourage some participants from completing the survey; 5) disinterest; 6) privacy and confidentiality concerns; and 7) lack of adequate instructions.[50]

7. Piloting

The Notice provides that prior to distribution the survey will be piloted or tested on thirty individuals. Considering the magnitude of the survey, 600,000 individuals, and the importance of the information being collected, the test group is not large enough to adequately evaluate the strengths and weaknesses of the draft survey. Piloting is commonly used by researchers to discover deficiencies in surveys.[51] Common mistakes most frequently caught through piloting include bias in question/answer wording, requesting inappropriate demographic data, overlapping questions scales or selection options, inaccurate or missing instructions, technical vocabulary with no definitions, insufficient space for open-ended question answers and lack of motivational techniques encouraging respondent to complete the survey.[52] The failure of the Notice to reveal in detail the piloting criteria denies commenters a meaningful opportunity for comment in violation of the APA, 5 U.S.C. § 553.

[50] Couper 473-475.
[51] "Survey piloting is crucial to achieving research goals and ensuring that subjects complete the survey. To quote a leader in survey development, "Survey piloting is the process of conceptualizing and re-conceptualizing the key aims of the study and making preparations for the fieldwork and analysis so that not too much will go wrong and nothing will have been left out." Andrews, D… pg 15.
[52] Id at 17.

IV. CONCLUSION

For the foregoing reasons, FDA should abandon its proposed internet survey and, instead, fulfill its First Amendment mandate by allowing the dissemination (and causing the dissemination) of more scientific information on the olive oil and omega-3 fatty acid/heart disease relationships. Disclosure of information over its suppression is the constitutional requirement. Any attempt to rely on the proposed survey to alter or censor a qualified health claim will violate the First Amendment. If the agency insists on use of a consumer perception survey, it should rely on it solely for the purpose of pinpointing those areas in which greater FDA public information campaigns could be used to improve public understanding and foster greater public debate on the role of the particular nutrients in reducing heart disease risk.

Respectfully submitted,

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