IN DEFENSE OF THE *PFIZER* FACTORS

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I. INTRODUCTION

The Federal Trade Commission's ("FTC") 1972 *Pfizer*[1] decision established the principle that an advertiser must possess and rely on a "reasonable basis" to substantiate advertising claims. By 1977 the Commission viewed this principle as "well-established."

> [I]t is now well-established that in the absence of a contrary disclosure, a product claim necessarily carries with it a representation that 'the party making it possesses a reasonable basis for so doing, and that the assertion does not constitute mere surmise or wishful thinking on the advertiser's part.'[2]

The 1983 Advertising Substantiation Policy Statement reaffirmed the "reasonable basis" doctrine. It concluded: "Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers."[3]

In 1984, the Commission faced a major challenge when Kellogg developed a marketing campaign for its high fiber All Bran cereal built around the recommendation of the National Cancer Institute ("NCI") that diets higher in fiber could reduce the risk of some kinds of cancer. Under *Pfizer*, the FTC permitted health claims in advertising if those claims are adequately

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[1] Pfizer, Inc., 81 F.T.C. 23 (1972).

[2] Porter & Dietsch, Inc., 90 F.T.C. 770, 866 (1977) (quoting Nat'l Comm'n on Egg Nutrition, 88 F.T.C. 89, 191 (1976), *modified*, 605 F.2d 294 (7th Cir. 1979)). The failure to possess a reasonable basis for objective claims was first held to be deceptive in *National Dynamics Corp.*, 82 F.T.C. 488 (1973), *modified*, 492 F.2d 1333 (2d Cir. 1974).

[3] FTC Policy Statement Regarding Advertising Substantiation, *appended to* Thompson Med. Co., 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

substantiated. In contrast, in 1984, the Food & Drug Administration (FDA) regarded any label claim about the relationship between diet and disease as a drug claim. Unless a seller wished to file for approval as a drug, such claims were therefore illegal. In the 1960s, for example, FDA seized packages of Quaker Oatmeal as a misbranded drug, because the label discussed the relationship between fiber and serum cholesterol. Although some health claims were made in advertising, they were relatively infrequent until claims were also permitted on food labels.

Although the Kellogg campaign clearly violated existing FDA regulations, the FTC, in a highly publicized event, joined the NCI in supporting the ads. The FTC argued that Kellogg had the necessary level of substantiation. The FDA ultimately declined to take action.

The Kellogg episode illustrates the centrality of the substantiation doctrine to the Commission's consumer protection mission. Numerous cases are based entirely on allegations that the respondent did not have a reasonable basis to support its claims. Even when the Commission alleges that the claims are false, frequently it also alleges that the claims are unsubstantiated. State Attorneys General use the doctrine under their baby FTC acts, and substantiation is used in self-regulatory proceedings before the National Advertising Division of the Council of Better Business Bureaus. It has also influenced private litigation between competitors under the Lanham Act.

From the beginning in *Pfizer*, a hallmark of the substantiation doctrine, and a key to its great utility, has been its flexibility. In general, the Commission has not attempted to use the doctrine to prescribe specific types of tests as the basis for particular classes of advertising claims. Moreover, the Commission has always recognized that the amount of evidence required depends on what the advertiser has said about the evidence.

In recent consent agreements, however, the Commission replaced that flexible standard with the same kinds of evidence that the FDA has traditionally required to approve new drugs. These orders require two well controlled clinical trials to substantiate certain claims, including weight loss,[4] the duration of diarrhea and children's absence from school,[5] and reducing temporary irregularity or improving intestinal transit time,[6] regardless of what experts generally accept as reliable. Moreover, some orders require prior FDA approval of certain claims,[7] which the press releases specifically designate as a "fencing in" provision to facilitate compliance and enforcement rather than a requirement of Section 5 of the FTC Act. Although the Analysis to Aid Public Comment accompanying the Nestle order leaves open the possibility that a more limited claim might require more limited substantiation, it also cautions that the Commission's "experience and research show that it is very difficult to adequately qualify a disease risk-reduction claim in advertising to indicate that the science supporting the claimed effect is

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[4] FTC v. Iovate Health Sciences USA, Inc., File No. 072 3187 (W. Dist. NY, July 14, 2010); Beiersdorf, Inc., File No. 092-3194 (June 29, 2011).

[5] Nestle HealthCare Nutrition, Inc., File No. 092 3087 (July 14, 2010).

[6] The Dannon Company, Inc., FTC File No. 0823158 (December 15, 2010).

[7] Nestle HealthCare Nutrition, Inc., File No. 092 3087 (July 14, 2010) (claims of preventing or reducing the risk of upper respiratory tract infections).; The Dannon Company, Inc., FTC File No. 0823158 (December 15, 2010) (claims that covered products reduce the likelihood of getting a cold or the flu). These recent cases are inconsistent with the Commission's 1983 decision to modify an order prohibition to allow claims that a household disinfectant could reduce the incidence and spread of colds if supported by competent and reliable scientific evidence. See Sterling Drug, Inc. et al, 101 F.T.C. 375 (1983). They are also difficult to square with the Commission's recognition " … that there may be certain limited instances in which carefully qualified health claims may be permitted under Section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support." See Enforcement Policy Statement on Food Advertising, May, 1994. Interestingly, claims that a vacuum cleaner or an air cleaner reduce the chances of getting the flu are subject to the traditional "competent and reliable scientific evidence" standard. *See* Oreck Corporation, File No. 102 3033 (April 7, 2011). Another order has an even broader scope of claims that require prior FDA approval. FTC v. Iovate Health Sciences USA, Inc., File No. 072 3187 (W. Dist. NY, July 14, 2010) (claims that a product "is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease").

limited."[8] Recent cases also indicate that the Commission is increasing the stakes for failing to have a reasonable basis, seeking monetary relief (even in administrative orders) for conventional substantiation cases.[9]

If followed, these cases represent a significant ossification of a formerly flexible standard. To date, the cases setting a more rigid standard are consent agreements, although the notice order for one case currently in administrative litigation seeks an FDA prior approval requirement.[10] In its litigated district court cases, the Commission is not universally adopting the new approach. For example, the stipulated preliminary injunctions in its cases involving weight loss claims for acai berry products use the traditional "competent and reliable scientific evidence" standard for substantiation.[11]

This paper discusses the role of the substantiation doctrine in protecting information in the marketplace. It then examines why the flexibility inherent in the doctrine is both appropriate and crucial to its utility as a consumer protection tool. Section IV addresses why "competent and reliable scientific evidence" is the appropriate standard for health-related claims about foods, and Section V discusses applying the standard to dietary supplements. Section VI explains why

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[8] Nestle HealthCare Nutrition Inc., Analysis of Proposed Consent Order to Aid Public Comment (*available at* http://www.ftc.gov/os/caselist/0923087/100714nestleanal.pdf) (July 14, 2010) at 2.

[9] Oreck Corporation, File No. 102 3033 (April 7, 2011) ($750,000); Beiersdorf, Inc., File No. 092-3194 (June 29, 2011) ($900,000); NBTY, INC., Naturesmart LLC, and Rexall Sundown, Inc; Docket No. C-4318, File No. 1023080 (December 13, 2010) ($2.1 million); FTC v. Iovate Health Sciences USA, Inc., File No. 072 3187 (W. Dist. NY, July 14, 2010) ($5.5 million).

[10] POM Wonderful LLC et al., File No. 082-3122 (September 27, 2010). Shortly before the Commission issued its administrative complaint, the respondents filed a declaratory judgment action, arguing that the Commission was making substantive changes in the substantiation doctrine without following proper procedures, and that the new standard restricts nondeceptive speech and thus exceeds the Commission's authority in violation of POM's First Amendment rights. See *POM Wonderful, LLC v. FTC***,** No. 1:10-CV-01539 (D.D.C.) (filed September 13, 2010).

[11] See e.g. Federal Trade Commission v. IMM Interactive, Inc., Case No. 1:11-cv-02484, Northern Dist. Ill., Eastern Division (April 19, 2011); Federal Trade Commission v. DLXM LLC, Case No. CV 11-1889, Eastern District of New York (May 6, 2011).

repudiation of the *Pfizer* factors cannot be justified as fencing in relief. A final section offers our conclusion.

II. INFORMATION IN MARKETS

Policing deceptive advertising is vital because of the critical role of information in competitive markets. Advertising, in the words of Nobel Laureate George Stigler, is "an immensely powerful instrument for the elimination of ignorance."[12] When more accurate information is available to consumers, competition operates more effectively to guide producers to the types of products that consumers most prefer. Consumers are more aware of alternatives across product categories, as well as within a particular market. The result is more competition to attract consumers, leading to enhanced competition for their business on both price and non-price dimensions.

We begin with a discussion of the importance of the free flow of information to producing market outcomes that benefit consumers in Section A. Advertising also leads to product improvements, as we describe in Section B. Of course, advertising must be truthful and non-misleading. Allowing information that may be misleading will reduce consumer welfare, because consumer choices will then misdirect market outcomes. As is so often the case, the specifics of regulation matter. We consider how advertising regulation can provide the most benefit to consumers in Section C.

A. Advertising Often Enhances Competition, Reducing Prices.

Much of what we know empirically about the impact of advertising on market competition and consumer welfare stems from studies of restrictions on advertising. The first

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[12] George J. Stigler, *The Economics of Information*, 64 J. POL. ECON. 213, 220 (1961).

restrictions studied were relatively crude, often involving complete prohibitions on advertising obtained by professional groups seeking to limit competition among their members and thereby raise prices. One of the earliest studies examined state prohibitions on advertising of eyeglasses, and found that prices were significantly higher in states with such prohibitions.[13] Subsequent studies found that the adverse effects of restrictions on advertising were greatest for less advantaged consumers: the least educated paid the highest increase in prices from restrictions on advertising.[14] Similarly, states that prohibited advertising of the retail prices of prescription drugs had higher prices.[15] Such blanket prohibitions on advertising were overturned when the United States Supreme Court extended First Amendment protection to commercial speech.[16]

More subtle restrictions on advertising also have adverse effects on consumers. Attorney advertising restrictions, for example, varied considerably, with restrictions on broadcast advertising in some states, prohibitions on the use of pictures in others, and requirements for "dignified" advertising elsewhere. States with more restrictions on advertising had higher prices for routine legal services.[17] Other studies have also found that restrictions on the media where advertising is permitted are associated with higher prices. The ban on broadcast advertising of cigarettes, for example, increased cigarette prices.[18] The introduction of television toy advertising was associated with significant price declines, both over time as advertising was

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[13] Lee Benham, *The Effect of Advertising on the Price of Eyeglasses*, 15 J.L. & ECON. 337, 342-45 (1972).

[14] Lee Benham & Alexandra Benham, Regulating Through the Professions: A Perspective on Information Control, 18 J.L. & ECON. 421 (1975).

[15] John F. Cady, Restricted Advertising and Competition: The Case of Retail Drugs (1976).

[16] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

[17] John Schroeter, et al., Advertising and Competition in Routine Legal Service Markets: An Empirical Investigation, 36 J. INDUSTRIAL ECON. 49 (1987); William Jacobs, et al., Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising, FTC Staff Report (1984).

[18] Robert Porter, *The Impact of Government Policy on the U.S. Cigarette Industry, in* EMPIRICAL APPROACHES TO CONSUMER PROTECTION 447 (Pauline Ippolito & David Scheffman eds., 1986).

introduced and withdrawn, and across geographic markets comparing areas where toys were advertised with those where they were not.[19] Similarly, Quebec's ban on television advertising to children raised the price of children's cereals in Quebec, compared to other provinces. Prices for adult or family cereals, however, which could still advertise, were no higher in Quebec than elsewhere.[20]

Price advertising has been found to lower prices in studies of retail gasoline markets,[21] prescription drugs,[22] and retail liquor stores.[23] Restrictions are also associated with higher prices even when advertising rarely, if ever, includes price information, as in the studies of cereals, toys, and cigarettes discussed above. Thus, the critical factor appears to be the general competitive effects of advertising, rather than the specific effects of advertising price.

B. Advertising Leads To Product Improvements.

Following the All Bran cereal advertising campaign discussed in the introduction, in 1987 the FDA proposed a rule change (later withdrawn) that would have permitted any health claim that was truthful and not misleading. Health claims (statements about the specific health effects of nutrients or foods) rose from approximately three percent of food advertising in magazines to a peak of just over 11 percent of such advertising in 1989.[24] In response, Congress passed the Nutrition Labeling and Education Act of 1990, which authorized health claims, but

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[19] Robert Stiner, *Does Advertising Lower Consumer Prices?*, 37 J. MARKETING 19 (1973).

[20] C. Robert Clark, Advertising Restrictions and Competition in the Children's Breakfast Cereal Industry, 50 J.L & ECON. 757, 759-60 (2007).

[21] Alex Maurizi & Thom Kelly, Prices and Consumer Information: The Benefits from Posting Retail Gasoline Prices (1978).

[22] CADY, *supra* note 7.

[23] Jeffrey Milyo & Joel Waldfogel, The Effect of Price Advertising on Prices: Evidence in the Wake of 44 Liquormart, 89 AM. ECON. REV. 1081 (1999).

[24] Pauline Ippolito & Janice Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising, 1977-1997*, FTC Staff Report (2002), *available at* http://www.ftc.gov/opa/2002/10/advertisingfinal.pdf.

only with prior FDA approval of the claim's substance.

The changing rules governing permissible claims have provided a rich environment to study the impact of the content of seller-provided information on markets, as well as the impact of regulations on seller incentives to discuss certain product attributes. Studies of the impact of claims about the relationship between fiber and cancer, which launched the health claims era, found a significant market response. These advertising messages led to a demonstrable increase in fiber consumption. In part, the increase was the result of changes in purchasing patterns, but it also stemmed from product changes. Although the weighted average fiber content of breakfast cereals had been essentially constant for several years preceding the introduction of health claims, there was a positive and significant trend toward increased fiber content after the advertising began. There was no significant trend in fat or sodium content; the product improvements on the fiber dimension were *not* at the expense of deterioration on other aspects of nutrition. The increases in fiber consumption were greatest for economically disadvantaged groups. Although fiber consumption increased for all demographic groups, it increased more among racial minorities and female-headed households.[25]

One particularly common health claim concerned the relationship between diet and heart disease or serum cholesterol. Until 1984, such claims appeared in under two percent of magazine food advertising. After health claims began in earnest, they rose to appear in just over eight percent of advertising in 1989.[26] Most such claims concerned the relationship between fat, particularly saturated fat, and heart disease risk. Again, significant consumption change

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[25] Pauline Ippolito & Alan Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market, FTC, (1989), *available at* http://www.ftc.gov/be/econrpt/232187.pdf; Pauline Ippolito & Alan Mathios, Information, Advertising and Health Choices: A Study of the Cereal Market, 21 RAND J. ECON. 459 (1990).

[26] Ippolito & Pappalardo, *supra* note 16.

accompanied the increase in advertising claims. Although fat and saturated fat consumption declined slightly between 1977 and 1985, both measures fell far more sharply between 1985 and 1990.[27] Again, information provided through advertising had a significant and positive impact on the marketplace.

The Nutrition Labeling and Education Act of 1990 again changed the regulatory environment for health claims. Under the statute and its implementing regulations, which became effective in 1993 (for health claims) and 1994 (for nutrient content claims), health claims were only permitted after prior FDA approval of the substance of the claim. The regulations authorizing certain health claims included detailed "model claims" with large amounts of information about the relationship and which population groups were most at risk for the particular condition.

These changes caused the incidence of health claims in advertising to plummet. From the peak of just over 11 percent of magazine food advertisements making some health claim in 1989, health claims fell to under three percent of advertisements in 1992-1994. Claims about heart disease and serum cholesterol were most dramatically affected, falling from 8.2 percent of all advertising in 1989 to zero percent in 1994.[28] A significant part of the decline was apparently due to the belief that claims must include the entire, burdensome model claims. When the FDA proposed in 1994 to clarify that the full model claim was not required, and the FTC clarified the relationship between the labeling rules and advertising in its 1994 policy statement on food

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[27] Pauline Ippolito & Alan Mathios, Information and Advertising: The Case of Fat Consumption in the United States, 85 AM. ECON. REV 91-95 (1995); Pauline Ippolito & Alan Mathios, Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990, FTC (1996).

[28] Ippolito & Pappalardo, *supra* note 16.

advertising, health claims again began to increase.[29] By 1997, the end of the sample period, health claims again appeared in eight percent of ads, and heart and serum cholesterol claims had returned to just under four percent.[30]

Undoubtedly the new rules most heavily affected advertising for fats and oils. In 1988 and again in 1990, 45 percent of all advertising for fats and oils included a disease related claim. These claims provided information about the importance of fat composition, particularly saturated fats, to the risk of heart disease. But by 1994, these claims had entirely disappeared from advertising for fats and oils, as the regulations required.[31]

With less ability to explain to consumers why fat composition mattered, there was also less incentive for fats and oils manufacturers to discuss fat composition at all. The total number of advertisements for fats and oils declined, as did the number of ads that included saturated fat content information. From a peak of 20 ads discussing saturated fat in 1992, the number of ads fell to only one in 1997.[32] Crucially, the shift in the informational content of advertising resulted in changes in the marketplace. With less information about both saturated fat content and its importance to health, consumer choices unfortunately shifted toward cooking oils with more saturated fat and less monounsaturated fat.[33]

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[29] Federal Trade Commission, *Enforcement Policy Statement on Food Advertising*, FTC (1994), *available at* http://www.ftc.gov/bcp/policystmt/ad-food.shtm.

[30] Ippolito & Pappalardo, *supra* note 16.

[31] *Id.*

[32] *Id.* at E-28. In percentage terms, 51 percent of advertising for fats and oils discussed saturated fat in 1992, compared to 8.3 percent in 1997. *Id*. at 157-8.

[33] Alan Mathios, The Importance of Nutrition Labeling and Health Claim Regulation on Product Choice: An Analysis of the Cooking Oils Market, 27 AGRIC. & RESOURCE ECON. REV. 159 (1998).

C. Advertising Regulation Is Vital To Protect Consumers, And Must Consider The Costs of Mistakes.

Changes in advertising and consumer choices do not necessarily mean an improvement in consumer well-being. To best protect consumers, the government must consider the costs of both mistakenly prohibiting and allowing particular claims. Government should err on the side of protecting consumers, but doing so depends on which risk is more serious – mistakenly prohibiting truthful claims or mistakenly allowing false ones.

Consider, for example, the Kellogg claim about the relationship between diets high in fiber and the risk of colon cancer. Although the FDA believes that there is "substantial scientific agreement" that the claim is correct, uncertainty remains. There are, after all, no randomized clinical trials measuring the incidence of cancer at different levels of fiber intake, and such trials would surely increase our confidence in the truth of the claim. If the claim is true, however, waiting for the results of such trials would impose substantial costs on consumers, who would lose an important source of information about the likely relationship between fiber consumption and cancer risk. Before such claims were allowed, consumers ate less fiber, and as a result incurred a higher risk of cancer than necessary. On the other hand, if the claim turns out to be false, the consequences to consumers are relatively small. They may give up the better taste of another cereal, or pay a little more for a higher fiber product.[34] It seems clear that, in this case, the far more serious error is mistakenly to prohibit truthful claims. Such a mistake is worth avoiding, even though it means an increased risk of the far less serious error of allowing a false

[34] Preventing economic injuries such as these is important, and at the core of the Commission's consumer protection mission. Rarely, if ever, however, has the Commission been willing to risk public health consequences to avoid economic injuries.

claim to continue.[35]

Indeed, the FTC has made this very argument. Carol Crawford, the Bureau Director at the time, in a speech before the American Advertising Federation, praised the Kellogg claim, stating:

> Caution, however, does not necessarily mean prohibiting a claim until all possible doubts have been resolved. Rather, caution requires that we carefully consider the consequences of both action and inaction. If we act to prohibit the Kellogg ad, few consumers will find out about the National Cancer Institute's recommendation.
>
> If the N.C.I. is right, the result of prohibiting the ad may be that consumers will be ignorant about a possible way to reduce the likelihood of their contracting some types of cancer. If it turns out that the N.C.I.'s recommendation is wrong, the result may be that consumers may have eaten All-Bran when they otherwise might not have done so, perhaps giving up a better-flavored or a lower-priced cereal to do so. Caution dictates that we avoid the more serious mistake.

III. FROM THE BEGINNING, APPLICATION OF THE SUBSTANTIATION DOCTRINE HAS RELIED CORRECTLY ON A FLEXIBLE STANDARD

The substantiation doctrine is a critical part of the Commission's efforts to police deceptive advertising. As one of us noted elsewhere, "protection of consumers against advertising fraud should not be a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable competitive market process."[36] The flexible reasonable basis standard is just such a

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[35] Typically, more is at stake in decisions about approving new drugs than in decisions about whether to allow diet and health claims. The critical issue, however, is the *relative* risk of the two potential mistakes, because reducing the risk of one mistake necessarily increases the risk of the other. It is not that foods offer greater benefits than new prescription drugs; rather, unlike prescription drugs, the potential benefits of allowing claims about diet and health even in the face of some uncertainty are vastly greater than the potential costs of allowing mistaken claims.

[36] Robert Pitofsky, Beyond Nader: Consumer Protection and the Regulation of Advertising, 90 HARV. L. REV. 661, 681-83 (1977).

practical tool.

Beginning with the original *Pfizer* decision that created the substantiation doctrine, the Commission has always considered various factors to determine the amount of substantiation necessary to constitute a reasonable basis for a particular claim. In *Pfizer*, the Commission identified:

> (1) the type and specificity of the claim made, – e.g., safety, efficacy, dietary, health, medical; (2) the type of product – e.g. food, drug, potentially hazardous consumer product, other consumer product; (3) the possible consequences of a false claim – e.g., personal injury, property damage; (4) the degree of reliance by consumers on the claims; and (5) the type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims.[37]

In the Advertising Substantiation Policy Statement, the Commission reiterated that

> The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.[38]

The type of claim is critical in evaluating the required level of substantiation, because it determines the kind of support that consumers are likely to expect. As the Commission noted in *Firestone*, "the appropriate test depends on the nature of the claim made. Thus a road or user test may be an adequate scientific test to substantiate one performance claim, whereas a laboratory

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[37] *See Pfizer, Inc.*, 81 F.T.C. at 64.

[38] FTC Policy Statement Regarding Advertising Substantiation, *supra* note 3.

test may be the proper test to substantiate another claim."[39] Similarly, the Commission has long recognized that advertisers can reduce the burden of substantiation by making claims that acknowledge the limitations of the evidence available to support them. In *Litton,* for example, the Commission noted that the company "could have cured the defect [in its surveys] by use of a representative sample, or by accurately and conspicuously disclosing the identity of the population that was actually surveyed."[40] As the Substantiation Policy Statement states, "the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers."[41]

Linking the required level of substantiation to the claim made also comports with First Amendment protection for commercial speech. The courts have overturned FDA decisions to ban health claims not supported by "substantial scientific agreement" because disclosures of the limitations of the evidence could achieve the goal of preventing misleading claims.[42]

When an advertisement is unclear about the nature of the supporting evidence, the Commission has sought to determine the optimal amount of evidence that is needed to support a particular claim. For most claims, different forms of evidence may exist that provide varying levels of confidence for assessing the likely truth of the claim. Even when only one form of testing is possible, the truthfulness of the claim can be made more certain by increasing the sample size, requiring the product to pass two or more independent repetitions of the test, or in other ways. In any substantiation case, the critical question is how much confidence in the likely

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[39] Firestone Tire & Rubber Co., 81 F.T.C. 398, 463 (1972).

[40] Litton Indus., Inc., 97 F.T.C. 1, 76 (1981). *See also* Kroger Co., 98 F.T.C. 639, 737 (1981) ("Where the demands of the purse require such compromises, the advertiser must generally limit the claims it makes for its data or make appropriate disclosures to insure proper consumer understanding of the survey's results.").

[41] FTC Policy Statement Regarding Advertising Substantiation, *supra* note 3.

[42] *See* Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999); Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002).

truth of the claim should be required before the claim is allowed.

Viewed as part of the practical enterprise to ensure reliable data, the Commission's focus on the optimal level of support for claims is sound. As the Pfizer factors recognize, the optimal amount of support for a particular claim is the amount that makes the expected gains from relying, or not relying, on the claim as large as possible, after considering the costs of more information. For example, consumers will purchase if the expected benefits of truthful claims outweigh the expected costs of a false claim.[43] This approach assures that consumers receive the largest possible expected gain from relying on the claim. Additional testing enables consumers (or the Commission) to estimate better the likely truth of the claim, and therefore to determine better the expected gain from relying on the claim. Testing is worthwhile as long as it increases the expected gains from relying on the claim by more than the cost of the test. More evidence than optimal reduces the expected gain, i.e., it increases the costs more than it reduces the risks of mistaken consumer decisions. Less evidence than optimal also reduces the expected benefits, because the increased costs of more testing are less than the decreased risk of mistakenly relying on false claims.

If the possible costs of a false claim are high and the possible benefits from a truthful claim are slight, the government should require more evidence before allowing the claim. Claims about the safety of a drug that is substantially similar to other drugs on the market offer a clear example. The benefits of using the drug are limited to its therapeutic advantage over other products, but the potential costs if the claim of safety is false are substantial.

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[43] Thus, rational consumers will purchase if the probability that the claim is true, multiplied by the benefits if the claim is true, exceed the similarly weighted costs if the claim is false. The difference is the expected gain from relying on the claim. Other things equal, consumers will purchase if the expected gain from relying on the claim is positive; they will not purchase otherwise.

The Commission should require relatively less evidence of the probable truth of a claim, however, if the benefits of relying on the claim if it is true greatly exceed the costs of relying on it if it is false. Claims that products low in saturated fat help reduce the incidence of heart disease, for example, may enable consumers to reduce their risk of death from heart attack significantly. If the claim is false, consumers pay a few cents more or give up only an alternative product with more saturated fat that is perhaps better tasting. Because preventing such losses is important, the Commission should require substantiation for claims about the relationship.[44] Because allowing claims that are likely true even in the face of some uncertainty is also important, it should avoid requiring *too much* substantiation.

Decisions about how much evidence to require also depend on the likely usefulness of additional testing. If additional testing will most likely confirm the results of previous tests, then additional testing is not very useful. Moreover, additional testing will at least delay the availability of the information to consumers, and may chill the claim entirely. If, on the other hand, the result of the initial evidence is unexpected or inconsistent with prior work, then additional testing is more likely to contradict it, and is therefore more valuable.

Consider, for example, a statistical test that indicates at the conventional 95 percent confidence level that there is a significant difference between two products. With such a test, there is by definition a five percent chance that the result is due solely to the peculiarities of the particular sample. Repeating the test would reduce that risk even further, but most likely, it will simply achieve the same result.

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[44] Of course, we do not suggest that an advertiser should be able to use an analysis of the relevant costs and benefits to support having no or nominal substantiation for a claim.

Just as a peculiar sample may find a difference that is not really there, the sample may also fail to detect a relationship that actually exists. Although larger sample sizes could increase the chance of detecting a real difference, they are more costly and the tests frequently take more time. As a practical compromise between these competing objectives, statistical tests and sample sizes are frequently chosen to have an 80 percent chance of detecting a difference (of a specified size) if it really exists.[45] That is, 20 percent of the time a test will fail to detect a real difference that in fact exists.

There is relatively little value in simply repeating a test. Repeating the test can reduce the five percent chance that the original result was simply due to the particular sample, because it is unlikely that both tests would find the difference statistically significant.[46] Unfortunately, however, it increases the chance that the pair of tests will fail to find a real difference that actually exists. That is, in the second test there is a 20 percent chance of failing to find a real difference because of the particular nature of the second sample. *Both* tests will only confirm the

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[45] A frequent criticism of clinical trials of drugs, for example, is that the sample sizes are too small to find differences statistically significant, even when the differences are clinically important. Indeed, this problem is a significant factor behind the rise of meta-analyses, which pool the results of individual trials to determine more accurately whether an effect exists. *See e.g.*, Douglas G. Altman & J. Martin Bland, *Absence of Evidence is Not Evidence of Absence*, 311 B.M.J. 485 (1995); NATIONAL ACADEMY OF SCIENCES, SMALL CLINICAL TRIALS: ISSUES AND CHALLENGES (2001). For example, in a meta-analysis of 21 trials of long term use of beta blockers following a heart attack, the median samples size was 119 patients; one third of the studies had fewer than 90 patients. *See* Yusuf S, Peto R, Lewis J, Collins R, Sleight P. Beta blockade during and after myocardial infarction: An overview of the randomized trials. Prog Cardiovasc Dis 1985; 27: 335-371. Similarly, a review of 24 studies of intravenous use of clot dissolving drugs to treat heart attack found a median sample size of 114; one third had fewer than 60 patients. *See* Yusuf S, Collins R, Peto R, Furberg C, Stampfer MJ, Goldhaber SZ, Hennekens CH. Intravenous and intracoronary fibrinolytic therapy in acute myocardial infarction: Overview of results on mortality, reinfarction and side-effects from 33 randomized controlled trials. European Heart J 1985; 6:556-585

[46] The likelihood that both tests find a significant difference when in fact there is no difference is .05 times .05, or .0025. That is, only in one quarter of one percent of cases will both tests find a statistically significant difference that does not in fact exist.

difference in 64 percent of cases.[47] That is, there is a 36 percent chance that at least one of the two tests will fail to find a difference, when the difference in fact exists. Repeating the test is therefore more likely to reject truthful claims than to detect a result that only arose because of chance in the first place.[48]

Finally, it is important to consider the cost of testing. One cost of testing is obvious – it consumes scarce resources that could be used somewhere else, including other tests that may be more valuable. Consumers, of course, pay these costs in the form of higher product prices.

A more important cost, however, is the potential for changes in the kinds of claims that advertisers make. If it is too costly to substantiate certain types of claims, advertisers may simply choose to make other types of claims, instead of providing information that would be more valuable to consumers. It is easy to sell food products, for example, based on taste, even if products that are better tasting also have more nutritional drawbacks. If the Commission requires excessive testing to substantiate claims about nutritional characteristics, advertisers can simply talk about something else. As discussed above, that is precisely the experience with health claims. Requirements for too much proof and too much information prevented consumers, particularly the poorer and less educated, from receiving valuable information to improve their health.

Evaluating the factors that go into determining the appropriate balance between the benefits and costs of testing can be difficult. Experts in the field, however, are familiar with the

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[47] When there is a real difference, the chance of finding the difference statistically significant is .8. The chance of finding it significant in both tests is .8 times .8, or .64.

[48] A second test is more likely to reject truthful claims even if the chances of failing to detect a difference are the same as the chances of mistakenly finding one. If the chance of either mistake (significance when there is no difference or failure to find significance when one exists) is 5 percent, the chance that both tests will find the difference is 90.25 percent (i.e., .95 times .95). Thus, there is almost a 10 percent chance of mistakenly rejecting a truthful claim. With only one test, there was only a 5 percent chance of mistakenly allowing a false one.

different methodologies that might be used to develop evidence about particular claims, and can be extremely useful in determining the appropriate level of substantiation. As FTC publications have noted, "the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines."[49] Numerous FTC orders require that advertisers must substantiate claims with "competent and reliable scientific evidence," defined as "tests, analyses, research studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[50] This definition recognizes that different types of evidence may be required for different claims. The relevant question is whether those in the profession regard the evidence as an appropriate way to obtain accurate and reliable results.

IV. SUBSTANTIATING HEALTH AND NUTRITION CLAIMS REGARDING FOODS

For decades, the FTC has required that most health or efficacy related claims for foods must be substantiated by competent and reliable scientific evidence. Occasionally, however, the agency and the staff have considered whether more stringent standards, modeled on the FDA's approach to regulation of new prescription drugs, should be adopted. Such standards might require clinical trials to substantiate certain types of claims, rather than allowing other methods that use "procedures generally accepted in the profession to yield accurate and reliable results." Moreover, multiple clinical trials addressing the same proposition might be required before claims are allowed. Except in very limited circumstances (e.g., "establishment" claims that

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[49] Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry* ("Guide"), FTC, p. 9 (1998).

[50] *Id*.

certain benefits have been scientifically proven),[51] however, the Commission has not required FDA-like standards. In fact, for decades the FTC has urged that the FDA should approach health related claims as the Commission does, seeking to prevent misleading claims without unduly restricting the flow of truthful information.[52] Both public policy and the law support this conclusion.

A. The Costs of Mistakes.

Many have questioned whether the economic costs of the drug approval process are worth the benefits.[53] The costs of producing substantial evidence are themselves substantial. Recent estimates place the cost of developing a successful new drug at over $800 million[54] – a figure that is likely comparable to the total revenues of many food products that make health-related claims. Only the potentially large public health impact of mistakenly allowing dangerous drugs on the market can justify such costs, and only the high prices that patented drugs command can support them.

For health-related claims about foods, the situation is completely reversed. The potential

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[51] *See e.g.*, American Home Prods. Corp., 98 F.T.C. 136 (1981).

[52] *See e.g.* Federal Trade Commission, *In the Matter of Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements*, FTC Staff Comments (2006), *available at* http://www.ftc.gov/os/2006/04/v060014FTCStaffCommentstotheFDAReDocketNo2006-0066.pdf; Federal Trade Commission, *In the Matter of Request for Comment on First Amendment Issues*, FTC Staff Comments (2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf; Federal Trade Commission, *In Response to Request for Comments on Proposal to Amend the Rules Governing Health Messages on Food Labels and Labeling*, FTC Staff Comments (1988), *available at* http://www.ftc.gov/opp/advocacy/1987/V870027.PDF.

[53] *See, e.g.*, Kip Viscusi, Regulatory Reform and Liability for Pharmaceuticals and Medical Devices, *in* Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century, The Progress and Freedom Foundation (1996), 79–102 (Viscusi notes: "There is a widespread consensus in the literature that the current FDA drug approval process establishes safety incentives that are excessive. … This imbalance in the emphasis for these two types of errors has led to excessive deterrence of new risks that may be created by pharmaceutical products and inadequate weight on reducing existing risks that patients now experience.")

[54] Joseph DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

risks from foods are surely orders of magnitude less than the potential risk from even the most thoroughly tested new drug. There is simply nothing akin to the risk of unknown drug side effects that might conceivably arise from mistaken reliance on nearly any claim about the nutritional benefits of a food product, and there is no plausible evidence – certainly none that would meet FDA standards – that consumers would forego effective alternative treatments in favor of dietary modifications. In fact, the available evidence is to the contrary: consumers do not ignore effective treatments when they alter their diet.[55] Indeed, the underlying rationale for the statutory distinctions between the regulatory standards for foods and the more stringent controls on drugs is the intuitive principle that the consequences of errors in deciding what to eat are far less than the costs of erroneous decisions about drugs.

In contrast to the relatively low risks of using a particular food, the risks of mistakenly prohibiting information about the health effects of dietary changes can be far more significant. If sellers cannot tell consumers about the potential health benefits of diets high in fiber, low in cholesterol, or of reducing trans fatty acids, many consumers will simply continue dietary habits that may in fact create significant health risks. Overly stringent regulation, which would result from applying drug standards to food claims, would inhibit or prevent truthful claims about the relationship to disease. Doing so creates risks to public health, because fewer consumers will hear or know of important information, and manufacturers will have greatly reduced incentives to improve products to reflect the implications of that information. When opportunities to reduce the incidence of disease are foregone because of mistaken and excessive regulatory requirements, the public's health suffers.

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[55] John E. Calfee & Janice K. Pappalardo, *Public Policy Issues in Health Claims for Foods*, 10 J. PUB. POLICY & MARKETING 33, 37-38 (1991) .

The risks of discouraging truthful claims with excessive testing requirements are particularly great for claims about the relationship between diets and disease. Because there are many dietary sources for any particular nutrient related to disease, other sellers will likely benefit when one company makes a claim. Because no one seller can capture all of the benefits of providing information, there is less incentive to provide the information in the first place. Moreover, if product-specific testing is required, producers of substantially similar products can rely on the same tests. Unlike patented new drugs, the company that incurs significant testing costs cannot prevent imitation by competitors. Thus, other producers can "free ride" on the results of the test, undercutting the advantage to the seller who actually paid for the test.[56]

Of course, exaggerated or misleading claims about the health benefits of particular foods can harm consumers. The harm, however, is essentially economic. Consumers might pay more for a product or might purchase one brand instead of another that tastes better. Sound regulation should prevent such injuries, and therefore benefit consumers. Drug regulation incurs substantial economic costs in pursuit of important public health benefits. In contrast, applying similar approaches to health related claims for foods risks incurring significant public health costs in pursuit of economic benefits that are comparatively minor.

B. The Limitations of Clinical Trials.

The randomized, double blind, placebo controlled clinical trial is the gold standard of medical research, with good reason. For some specific questions, it is the only methodology that experts in the field accept as yielding accurate and reliable results. Under the competent and reliable scientific evidence standard, the Commission has challenged some claims as

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[56] Calfee & Pappalardo, *supra* note 47 at 36.

unsubstantiated because no reliable controlled trials were conducted.[57] Thus, when experts believe that clinical trials are the only acceptable methodology to support a particular claim, the competent and reliable scientific evidence standard in effect requires clinical trials.

Some have suggested that clinical trials should be required more frequently, or for broader categories of product claims. Such an approach would require more elaborate substantiation for such claims. If there are alternative methods, however, that experts accept as yielding accurate and reliable results, what would be the value of requiring a clinical trial in addition to, or in lieu of, a presumably cheaper alternative? A clinical testing requirement in these circumstances would suppress exactly the kind of information that is highly likely to have significant value to consumers. Although test methodologies that experts in the field accept yield reliable results, an advertiser cannot tell consumers about the result until clinical trials are concluded. At best, such a provision would spare the Commission the burden of establishing that other methods actually are *not* reliable. In numerous cases, that has not been a significant burden.

Despite the value of clinical trials, there are claims for which clinical trials are simply not necessary. A systematic review of randomized trials of parachutes, for example, was not able to locate any clinical trials of the device, but few would recommend jumping out of an airplane without one. The authors concluded:

> As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think

[57] *See e.g.*, F.T.C. v. QT, Inc., 512 F.3d 858, 860 (7th Cir. 2008).

> that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.[58]

Of course, some aspects of parachutes, such as different designs or different deployment mechanisms, might be subject to randomized testing. Any trial, however, takes time. As one author noted, "waiting for the results of randomised trials of public health interventions can cost hundreds of lives, especially in poor countries with great need and potential to benefit. If the science is good, we should act before the trials are done."[59]

An across-the-board requirement for clinical trials for health-related claims ignores products like parachutes. It assumes that the "best" methodology is the only acceptable methodology, even when experts in the field generally agree that other methods yield accurate and reliable results.

There are also instances in which clinical trials would be unethical or impractical. For obvious reasons, there are no randomized clinical trials establishing the adverse effects of tobacco consumption on humans, nor are there randomized controlled trials of any of a number of workplace chemicals regulated as hazardous. In other circumstances, clinical trials might be possible conceptually, but would be wildly impractical. It would be possible, for example, to imagine a randomized clinical trial of whether increasing calcium intake in young adulthood actually reduces the risk of osteoporosis, but the trial would have to follow participants for 50 or 60 years to determine the result.

There are other ways of learning about the real world, beyond the randomized clinical

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[58] Gordon C.S. Smith & Jill P. Pell, Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: Systematic Review of Randomized Controlled Trials, 327 B.M.J. 1459 (2003).

[59] Malcolm Potts, et al., *Parachute Approach to Evidence Based Medicine*, 333 B.M.J. 701 (2006).

trial. Much of what we know about the relationship between diet and disease is based on epidemiology,[60] not randomized trials. Trials are frequently a useful supplement, as, for example, with feeding studies that document the short term effect of diets with different fat compositions on serum cholesterol, but the crucial knowledge base about the relationship between serum cholesterol and heart attack risk is epidemiological. Reliance on epidemiology is also common in other areas for which clinical trials are difficult or impossible. Often, for example, the "best evidence" of workplace hazards is derived from epidemiologic studies of workers exposed to different levels of suspect chemicals. Moreover, the Commission's "Dietary Supplements: An Advertising Guide for Industry" explicitly recognize the possibility that epidemiological evidence alone may suffice to substantiate efficacy claims for dietary supplements.[61]

The FDA has also approved health claims relying on basic science and epidemiology. For example, it approved a health claim regarding dietary noncariogenic carbohydrate sweeteners and dental caries in 1996. The FDA did not have clinical evidence, reasoning that it would be virtually impossible to isolate a control group that consumed no foods containing sugars or sugar alcohols. Instead, the FDA relied on evidence from human epidemiological, animal, and in vitro studies related to the association between an individual's consumption of

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[60] Epidemiology uses sophisticated statistical techniques to analyze a relationship of interest while holding constant other factors that may influence the result. Epidemiological studies controlling for other possible risk factors, for example, establish that smoking causes cancer in humans.

[61] Guide, *supra* note 41, at 11, example 14.

sugar alcohols in chewing gum and plaque pH, acid production, plaque quantity and quality, bacteria levels, and the incidence of caries.[62]

Similarly, the FDA approved a health claim regarding folate and neural tube defects relying on only one clinical trial. Even though the study was difficult to generalize to the population as a whole because it only included women with a history of neural tube defects in pregnancy, it was sufficient for the FDA to conclude that there was a significant reduction in risk when women supplemented their diets with high levels of folic acid. Most of the evidence the FDA considered consisted of non-clinical human studies, including four intervention trials with women at a high risk of a having a pregnancy with a neural tube defect because they had a personal history of having had such a pregnancy in the past.[63]

One clear illustration of the value of non-experimental evidence is knowledge about the side effects of drugs. Common side effects are discovered in clinical trials, but relatively rare side effects that may still pose a significant public health risk often do not occur until a drug has been on the market and used by millions. Under current FDA policy, a drug with a 1 in 1,000 chance of killing the patient would be barred from the market for anything other than an illness with a very high risk of fatality. Even in a clinical trial of 3,000 patients on such a drug, however, there is nearly a five percent chance that the side effect will not occur at all.[64] Even if it occurs, it may not be recognized as an effect of the drug. Yet, most clinical trials are nowhere

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[62] Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries, 60 Fed. Reg. 37,507 (July 20, 1995) (codified at 21 C.F.R. § 101.80 (2009)).

[63] Folate and Neural Tube Defects, 61 Fed. Reg. 8,752 (Mar. 5, 1996) (codified at 21 C.F.R. § 101.79 (2009)).

[64] The probability that any one patient avoids the side effect is .999. The probability of all 3,000 patients avoiding it is .999 raised to the power of 1000, or 4.97 percent. In the standard clinical trial design, which allocates half of the patients to the treatment and half to the control, this would require a trial of 6,000 patients. In most circumstances, this "balanced" design is most efficient from a statistical perspective. In practice, individual trials with much smaller sample sizes are pooled to analyze the risk of side effects.

near this large. Instead, identifying rare side effects and warning patients and their physicians about them relies heavily on adverse event monitoring after a drug is on the market. This is essentially uncontrolled, observational evidence of the results of using a particular drug. It would not substantiate a claim of drug efficacy, but it is often the only evidence available about side effects.

C. Testing Products Versus Testing Ingredients.

As a matter of logic, virtually every individual product is a unique combination of ingredients. Both the ingredients and the process of combining them may substantially affect the characteristics of the final product. Eggs, for example, are the foundation ingredient of both soufflés and custards, but the final products are substantially different. Because different combinations of ingredients can produce different effects, it is tempting to conclude that all tests must use the actual product that is making the claim.

That conclusion, however, is not a sensible basis for regulatory policy. To continue the egg example, in both soufflés and custards, eggs contribute cholesterol and saturated fat to the final product. We can test the final product to measure how much of each is present, but we have no basis other than inference and assumption for concluding that the effects of the same amount of cholesterol and saturated fat is the same in each product. As a matter of logic, there could be other idiosyncrasies of the products and their ingredients that lead to different effects. Nonetheless, the fundamental premise of nutritional labeling is that saturated fat is saturated fat – it is likely to have the same effects on the human body in all of its manifestations, without regard to the other ingredients in the product. Abandoning that assumption would require us to abandon nutritional labeling as well.

Of course, for a particular product and a particular claim, there may be reason to suspect

an interaction that would invalidate the results of studies on the ingredient in a different context. If there is a sound reason to think that the particular combination of ingredients may undermine the applicability of studies demonstrating the ingredient's effects, then studies of the product itself would appear necessary to support a claim. The logical possibility that interactions *could* exist is not sufficient to warrant the costs of additional testing, however, any more than that same logical possibility would lead us to test for possible differences in the effects of saturated fat in custards and soufflés. Absent a good reason, relying on the normal assumption that the same ingredient is likely to have the same effects regardless of the other ingredients with which it may be combined is surely more reasonable. We could test to determine whether that conclusion is correct, but unless there is some reason to doubt it, there is no reason to do the test.

In fact, even the FDA relies on the ingredients approach. When it began the review of efficacy of "grandfathered" over-the-counter drug products under the 1962 Amendments to the Food, Drug, and Cosmetic Act, it concluded that a product-by-product review was neither feasible nor desirable. Many of these products had been on the market for decades, and their risks and benefits were relatively well known. Rather than rely on testing specific products, the agency decided to review the far smaller number of active ingredients, assuming that the effect of the active ingredient is the same regardless of the vehicle used to deliver it. The monograph process considered combinations of ingredients, but it retained the basic assumption that ingredients would determine the effects of the product and allows considerable leeway for combinations of active ingredients.[65] Moreover, manufacturers can use any inactive ingredients,

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[65] *See e.g.* 21 C.F.R. 341.40 (Permitted combinations of active ingredients for cold cough, allergy, bronchodilator, and antiasthmatic drugs). For example, 341.40 (a) allows the combination of any single ingredient antihistamine active ingredient with any safe and effective single analgesic active ingredient, or any combination of acetaminophen with other analgesics, or any aspirin and antacid combination.

as long as they do not interfere with the effectiveness of the active ingredients.[66] Thus, over the counter ("OTC") drugs do not require premarket approval if they meet the applicable requirements of the OTC drug monograph.[67]

Even for prescription drugs, the ingredient assumption is the basis of regulation. Generic versions of prescription drugs can be approved under an abbreviated new drug application, which only needs to show that the product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use to a previously approved product.[68] Despite potential differences in formulations, additional clinical testing is not required.

If there are valid reasons to suspect that ingredients may interact in ways that undercut the effects of one or more of them, tests of the product itself may be essential to provide "competent and reliable scientific evidence." Under the "competent and reliable scientific evidence" standard, such product-specific tests would be required when experts in the field believe that the possibilities for interactions are significant. If so, tests on ingredients alone would not yield "accurate and reliable results." If not, there is no benefit from tests on the particular combination of ingredients found in an individual product.

V. SUBSTANTIATING HEALTH AND NUTRITION CLAIMS REGARDING DIETARY SUPPLEMENTS

Frequently, dietary supplements make claims about the effects of their product on the

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[66] Stan Stringer, *What Has Been Happening With Over-the-Counter Drug Regulation*, 53 FOOD DRUG L.J. 633, 637 (1998); *See also* 21 C.F.R. § 330.1(e).

[67] Dana Ziker, What Lies Beneath: An Examination of the Underpinnings of Dietary Supplement Safety Regulation, 31 AM. J. L. & MED. 269, 272 (2005).

[68] *Id.* at 279.

structure or function of the body.[69] Moreover, a relatively large number of small companies exist. The Commission has been aggressive in pursuing cases against companies that make dubious product claims, alleging both falsity and a lack of substantiation.[70] Moreover, it has repeatedly urged the FDA to increase its own enforcement efforts against dubious claims, and has closely coordinated certain enforcement actions. Challenging deceptive claims under the "competent and reliable scientific evidence" standard set forth in the Dietary Supplements guide has not proved difficult in such cases.[71]

Like foods, however, many dietary supplements are also lower risk products than new drugs. Most have been used for hundreds, if not thousands, of years. As a result, we have a far larger base of experience than even the most extensively studied new drug accumulates before it is marketed.[72]

In some cases, dietary supplements are virtually indistinguishable from foods from a risk perspective. A bread or cereal fortified with vitamins and minerals is regulated as a conventional

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[69] Although such claims are not drug claims by law, they raise some of the same issues inherent in drug regulation. The risk-benefit profile of products like ephedra or certain forms of comfrey, for example, which pose significant health and safety risks for users, are closely akin to the risks and benefits of drugs. In recent years, the FDA has removed such dangerous products from the market entirely, an approach that is far more likely to protect consumers from safety risks than simply regulating the kinds of claims the sellers can make about product efficacy.

[70] *See e.g.*, F.T.C. v. Trudeau, 579 F.3d 754 (7th Cir. 2009).

[71] We recognize that the Commission has recently experienced some difficulties in a few isolated federal district courts. Nevertheless, altering the long-standing definition of "competent and reliable scientific evidence" simply to avoid a handful of litigation defeats in federal court is unwise. It imposes too high a cost, as discussed above, and is premature given the dearth of other courts, particularly appellate courts, applying the standard in a manner that the Commission believes to be incorrect.

[72] Although safety-related withdrawals of dietary supplement ingredients have occurred, far more common are contamination or impurity problems with particular products, risks that are much more akin to the risks that a food will be recalled because of bacterial contamination. They are problems in the manufacturing process, rather than problems with the use of the supplement itself.

food. Take away the cereal, however, and the product is a dietary supplement.[73] It might be somewhat easier to overdose on the supplement than on the food, but there is no other meaningful difference. Indeed, product-specific testing requirements are particularly inappropriate for claims about the effects of vitamin and mineral fortification, because the basic science for the effects of such supplements on the structure and function of the body is clear and well understood. Unlike foods, dietary supplements are prohibited if they present a significant or unreasonable risk of illness or injury, and the FDA can ban any supplement that presents an imminent hazard to public health or safety.[74] Because the risks for supplements are usually low and because of the substantial experience base, there is simply no reason to invoke the elaborate premarket safeguards of the drug approval process.

As it has in other areas, the Commission has always relied on the flexibility of the reasonable basis standard to tailor substantiation requirements to particular claims for dietary supplements. When the Pitofsky Commission issued "Dietary Supplements: An Advertising Guide for Industry" in 1998, it noted that "the FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science."[75] The Guide also stated that efficacy or safety claims for supplements must be supported with "competent and reliable scientific evidence." It stated:

> This is the same standard the FTC applies to any industry making health-related claims. There is no fixed formula for the number or type of studies required or for more specific parameters like

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[73] Peter Barton Hutt, FDA Statutory Authority to Regulate the Safety of Dietary Supplements, 31 AM. J. L. & MED. 155, 159 (2005).

[74] *Id.* at 170.

[75] Guide *supra* note 41 at 8.

sample size and study duration.[76]

In 2000, the Commission unanimously denied a petition for rulemaking to set more specific substantiation requirements for dietary supplement claims. The agency reviewed the principal questions the petition raised regarding the types and amount of substantiation required, in each case relying on the Guides to address the question. It concluded:

> The Commission is committed to providing clear and specific guidance on its enforcement policies to dietary supplement marketers and to all other industries it regulates. For this reason, the agency has engaged in extensive efforts to define its substantiation standard and to illustrate, through its Supplement Advertising Guide, how that standard applies to supplement advertisers.[77]

The FTC explicitly rejected more specific substantiation standards. It noted:

> the Commission's substantiation doctrine allows for some flexibility in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified. The Commission has determined that further refinement of the standard through rulemaking might result in a more rigid standard that, in some instances, could be higher than necessary to ensure adequate scientific support for certain specific claims.[78]

VI. REPUDIATION OF THE *PFIZER* FACTORS CANNOT BE JUSTIFIED AS FENCING IN.

The likelihood of setting a standard that is "higher than necessary to ensure adequate scientific support" is no different when the Commission imposes a more rigid standard as an order provision, rather than through rulemaking. The scope of the potential damage is formally

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[76] Guide *supra* note 41 at 9.

[77] Letter from Donald S. Clark to Jonathan W. Emord Denying Petition for Rulemaking, November 30, 2000 *available at* http://www.ftc.gov/os/2000/12/dietletter.htm.

[78] *Id*.

limited to the covered claims and a particular respondent, but incorporating more rigid standards will surely signal to others in the industry what the Commission expects as adequate substantiation. Indeed, the "competent and reliable scientific evidence" standard itself emerged from a series of orders incorporating that provision. Unless the Commission expressly disavows the applicability of a "two clinical trials" provision to companies that have not made unsubstantiated claims, responsible companies will have little choice but to follow that requirement, creating exactly the problems the Commission sought to avoid when it refused to engage in rulemaking.[79]

The FTC staff has argued that the Lane Labs decision[80] provides evidence of the need for a more specific substantiation standard to enhance enforceability of Commission orders. In that case, a contempt action to enforce a previous consent agreement, the judge characterized the claims for two diet supplements as claims they "are good products that will most likely help the people who take them."[81] He characterized the evidence as "credible medical testimony that the products in question are good products and could have the results advertised."[82] Because the company had made a good faith effort to comply with the order, he denied the Commission's motion for contempt. Not surprisingly, the Commission appealed.

The Circuit Court remanded, because "the able District Judge did not provide sufficiently detailed findings or sufficient rationale to allow us to perform effective appellate review."[83] It

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[79] The large number of small companies in the dietary supplement business suggests that, as the Commission has found in fighting fraud, there will always be companies that overstep the boundaries. Changing the boundaries will not address that fundamental problem.

[80] FTC v. Lane Labs-USA, INC., No. 00-cv-3174, 2009 WL 2496532 (D.N.J. Aug. 11, 2009).

[81] *Id*. at *7.

[82] *Id*. at *9.

[83] F.T.C. v. Lane Labs-USA, Inc., 624 F.3d 575, 2010-2 Trade Cases P 77,204 (3rd Cir. 2010).

clearly agreed with the Commission, however, on most of the specific claims that were at issue in the proceeding. It found that claims that a calcium supplement offered unique benefits, was more absorbable, and superior to prescription treatments for osteoporosis were violations of the order. Nevertheless, it accepted the District Court's conclusion that claims the product increased hip bone density despite the lack of a test of the product itself, because the evidence was clear that calcium had that effect and the source of the calcium was irrelevant. As discussed above, this recognition that ingredient testing alone may be sufficient is entirely appropriate. The Circuit Court also accepted the District Court's finding that claims that a fertility supplement would cause sperm courts to "skyrocket" in 30 days did not violate the order. The Commission's expert apparently conceded that the product would increase sperm counts, but argued that the process would normally take three months. Moreover, he appeared to agree that there could be effects within 30 days. Although it remanded the Commission's allegation that the company had misrepresented research results, the Court also made clear its view that the claims likely were violations.[84]

Although the Commission does not win every case it brings, it certainly wins the overwhelming majority. That fact alone makes clear that a more specific standard is not necessary to simplify enforcement. Lane Labs is no exception; the Commission prevailed in the Circuit Court where its case was strong, and lost where it was challenging claims about which reasonable experts disagreed. In most instances, Commission orders include "fencing in" relief to cover more products or more claims from a company that has violated the law. There is no

[84] "Some of the representations are unlikely to survive careful factual scrutiny, but we leave the initial resolution of each issue to the District Court." *Id.* at 589.

sound reason, however, to require past violators to meet a higher burden to substantiate the likely truth of their claims. A more specific requirement would not "fence in" proven violators; rather, it would "wall off" truthful claims that would be quite valuable to consumers.

One could argue that the Commission needs tools to increase deterrence regarding claims that it has frequently challenged. That, however, is an argument for increased or different sanctions, not an argument for a different standard of proof. In pursuing fraud, for example, the Commission has increasingly sought to work with the criminal enforcement authorities to achieve stronger sanctions and more effective deterrence; it has not sought to redefine fraud. Prohibiting claims that are truthful and not misleading deters, but it only deters precisely those claims that the Commission should seek to encourage.[85]

A more specific standard, such as "two clinical trials," would also abandon what has always been the Commission's best argument as to why substantiation orders do not violate the First Amendment. The "competent and reliable scientific evidence" standard clearly tailors the substantiation requirement to the claim that is made, including whatever qualifications and

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[85] The Commission may, of course, lose some substantiation cases because a court finds that experts for the respondent are credible and reasonable, even though they disagree with the Commission's experts. When there is legitimate debate among experts about either the truth of a claim or the appropriate methodologies for testing it, the fundamental premise of the First Amendment is that consumers should be able to hear both sides of the argument. The Commission's proper role is to prevent advocates of any point of view from exaggerating their case, not to determine which side of a scientific debate is correct. *See* Nat'l Comm'n on Egg Nutrition, 570 F.3d 157, 161 (7th Cir. 1977) ("The FTC concluded that, impossible though it may be to determine whether consuming eggs in fact increases the risk of heart and circulatory disease, it is possible to determine the existence and amount of evidence on that issue."). *See also* Sterling Drug Inc., 101 F.T.C. 275, 377-78 (1983) (Modifying Order). ("Most of these issues are now controversial, and there are reputable scientists on both sides of the controversy. We believe that an absolute ban on claims for which there may be reputable scientific support is inappropriate. On the other hand, we believe that such claims must not be made in such a way that they assert or imply that the propositions in question have been established to the satisfaction of the scientific community, unless such is the case. Consequently, we have modified the order to allow claims … to be made if they are supported by competent and reliable scientific evidence.")

disclosures the advertiser may include to make clear to consumers the limited nature of the supporting evidence. In rejecting the petition for rulemaking and its First Amendment challenge to the substantiation doctrine, the Commission noted the petition's mistaken presumption that the FTC's basic approach is to ban claims if the scientific evidence does not rise to a certain level of support. As the letter noted,

> In fact, the Commission has a long history of allowing, and even encouraging, the use of disclaimers or qualifiers as a means of curing potential deception. The Commission reiterated this policy in its 1994 Food Policy Statement and again in the 1998 Supplement Advertising Guide. Both documents clearly acknowledge that there is room for carefully qualified claims based on emerging science, provided the claims are expressly qualified to convey effectively the extent of the scientific support.[86]

When the Appeals Court rejected the FDA's ban on health claims that were not supported by "significant scientific agreement" on First Amendment grounds, it did so precisely because it believed that carefully qualified claims could avoid the risk of deception even when significant scientific agreement did not exist. The FTC's own empirical studies of qualified health claims support that conclusion.[87] As the staff noted in its comments to the FDA, "On average, consumers were able to discern clear differences in the level of certainty communicated by these [tested] claims."[88]

From a First Amendment perspective, there is no conceptual difference between "two clinical trials" and "significant scientific agreement" as requirements that must be

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[86] Letter Denying Petition for Rulemaking, *supra* note 71.

[87] Dennis Murphy et al., A Generic Copy Test of Food Health Claims in Advertising, FTC (1998); Dennis Murphy, Consumer Perceptions of Qualified Health Claims in Advertising, FTC, Working Paper No. 277 (2005).

[88] FTC Staff Comments on Assessing Consumer Perceptions of Health Claims, January 17, 2006, at 12 *available at* http://www.ftc.gov/be/V060005.pdf.

met before certain claims are permissible. The requirement for prior FDA approval effectively incorporates into FTC orders the "significant scientific agreement" standard that the courts have rejected on First Amendment grounds. Similarly, the "two clinical trials" standard will likely prohibit carefully qualified truthful claims that do not meet the standard, and thus are not likely to mislead reasonable consumers.[89]

Moreover, in the practical enterprise of day to day decision making, knowing that *precisely one* clinical trial supports an important health related claim is every bit as valuable to consumers as it is to the scientists who examine that study in the continuing pursuit of Truth. In this context, the requirement for a second clinical trial appears unnecessary to insure truthful, useful claims. Certainly, no court has ever suggested that reducing the government's litigation costs or risks is a "substantial governmental interest" justifying restrictions on truthful commercial speech.

As noted above, the adverse effects of the Commission's recent orders on truthful speech are not confined to those who are subject to orders. Responsible companies will have little choice but to conform to the new standards to avoid the risk of Commission challenges, which have substantial adverse effects on capital market values.[90] The risk is compounded by the Commission's apparent recent practice of seeking financial relief in

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[89] By its nature, "competent and reliable scientific evidence" requires different amounts of evidence depending on the specifics of the covered claim, because the kinds of evidence that experts would think necessary to support a qualified claim will frequently differ from what is needed to substantiate unqualified claims. Thus, the standard permits claims that appropriately describe the available evidence even when that evidence would not support an unqualified claim. With a clinical testing requirement, however, any covered claim must be supported by clinical testing, regardless of how it might be qualified and regardless of whether it is misleading.

[90] Sam Peltzman, *The Effects of FTC Advertising Regulation*, 24 J.L & Econ. 403 (1981) ("The story the stock market appears to be telling is that an FTC complaint implies essentially a wiping out of the brand's advertising capital."); Alan Mathios & Mark Plummer, *The Regulation of Advertising by the FTC: Capital Market Effects*, 12 Res. L. & Econ. 77 (1989).

routine substantiation cases. The result is likely to be an undue chilling effect on truthful commercial speech, even for those not subject to an FTC order.

VII. CONCLUSION

There has been no significant change in the basis for retaining the flexible substantiation standard in the nearly 40 years since the Commission first adopted it. There has been no significant change since the Commission reiterated that standard in the Advertising Substantiation Policy Statement in 1983. Nor has there been any significant change in the basis for the "competent and reliable scientific evidence" standard for health-related claims in the decade since the Commission specifically refused to abandon it. In the intervening years, the Commission has successfully prosecuted numerous cases involving health-related claims for both foods and dietary supplements. There is nothing in that record of enforcement success that would remotely suggest the need for more specific standards to ease the Commission's burden in proving an advertiser's substantiation inadequate. As the Commission has recognized from the beginning of the substantiation doctrine, an arbitrary, inflexible standard would deny important information to consumers. That conclusion is as applicable today as it was in 1972.

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