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DEREGULATION AND THE ADMINISTRATIVE ROLE: LOOKING AT DIETARY SUPPLEMENTS

Margaret Gilhooley*

I. INTRODUCTION

As anyone who watches television or shops in a supermarket or drugstore knows, claims of dietary supplements which “support mood” or achieve other effects have expanded in recent years. This expansion is attributable to the 1994 enactment of the Dietary Supplement Health and Education Act (DSHEA).¹ This statute represents the most important example of deregulation of a federal health and safety program.

This article examines the statutory scheme and the regulatory measures taken by the Clinton Administration to implement federal health and safety program deregulation. The article begins by describing the earlier pre-market approval system for drug claims on supplements and the reasons for the statutory change. The law now permits claims to be made for drug-like effects of supplements on the “structure and function” of the body, but not for disease claims.² The Food and Drug Administration’s (FDA) recent regulation recognizing a wide scope for structure and function claims will be assessed, along with the adequacy of the substantiation model that has now

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1. Pub L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U.S.C.). See discussion in Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663 (1997) [hereinafter *Herbal Remedies*], and in the Comm’n on Dietary Supplement Labels, Comm’n on Dietary Supplement Labels Report to the President, Congress and the Secretary of Health and Human Services (Nov. 24, 1997) [hereinafter *Commission Report*], available at <<http://www.health.gov/dietsupp>>.

2. 21 U.S.C. § 321(g) (1994) (structure and function claims exempt from drug definition).

replaced prior review.³ The article will also take note of a judicial decision based on constitutional grounds that permits health claims to be made on supplements based on disclaimers, and the FDA's action on remand.⁴ The policy arguments for allowing disease claims, with disclaimers, based on consumer choice are also noted. The policy issues about the role of choice for supplements has a corollary in the debate about the role of alternative medicine in relationship to conventional medical care.⁵

The deregulation of supplements has also replaced the system of prior approval of the safety of food additives found in supplements with a system that places the burden on the agency to prove the supplement poses a significant safety risk.⁶ To understand the agency's present authority, the pending issues concerning the use of ephedrine in supplements for weight control are examined. The article considers whether there are means, other than a return to a pre-market approval system, that would provide adequate assurance of the safety of supplements.

The article also considers the deregulation of supplements in the context of a larger debate about the role of administrative regulation. Regulation is seen as "under attack," with a lack of any "clear vision of the goals of regulatory reform."⁷ The "pragmatic tradition of governance" has been described as providing "a better conception for administrative reform" than earlier models.⁸ Efforts have also been made to identify a "third

3. 21 U.S.C. § 343(r)(6) (1994) (substantiation and disclaimer for structure and function claims), FDA Final Rule, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure and Function of the Body, 65 Fed. Reg. 999 (2000) (hereinafter *Final Rule*) and Part III *infra*.

4. *Pearson v. Shalala*, 164 F.3d 650, (D.C. Cir. 1999); see Part IV *infra*, and Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TUL. L. REV. 815, 841-62 (2000).

5. Kathleen Boozang, *Is the Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567 (2000), Ronald A. Chez & Wayne B. Jonas, *The Challenge of Complementary and Alternative Medicine*, 177 AM. J. OBSTETRICS & GYN. 1156 (1998), and David M. Eisenberg et al., *Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use*, 328 NEW ENG. J. MED. 246 (1993).

6. 21 U.S.C. § 321(s) (1994 & Supp. III 1997) (exemption from food additive provisions); see Part VI *infra*.

7. Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 3-4 (1997).

8. Sidney A. Shapiro, *Administrative Law After the Counter-Reformation: Restoring Faith in Pragmatic Governance*, 48 U. KAN. L. REV. 689 (2000). The paper reviews the writings of a range of commentators, and notes different patterns in viewpoints about the government's role over the past thirty years. These approaches

way” of regulation distinct from conservative or traditional democratic approaches.⁹ Measures to regulate less are also likely to be of special interest to the Administration of the new President.

An “alternative conception” of administration has also been proposed, that it should be seen as “a set of negotiated relationships,” which reflects the extent of “public/private interdependence” and the need to “grapple with private power.”¹⁰ That approach encourages agencies to participate in “collaborative governance” through measures such as negotiated rulemaking and voluntary self-regulation, but also recognizes a need to assess the regulatory regimes that are a product of these interactions.¹¹

Others view collaborative techniques as having only a limited role.¹² The negotiation model has also been criticized as giving the agency the role of being just another participant in the process, seeking consensus, rather than as having an

include the concern for beneficiaries and the public interest in the 1970's as described, e.g., in Richard S. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669 (1975) (emergence of administrative law as a pluralistic decision-making process that gave attention to regulatory beneficiaries and public interest group representatives), the criticism of government failure in the Reagan era, described, e.g., in CASS R. SUNSTEIN, *AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE* 74 (1990) (while regulatory statutes are not a failure, some regulatory strategies produce costs that “dwarf” benefits and have “unanticipated side effects”), and the current effort at restoration or reconciliation, described, e.g., in IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* 38-39 (1992) (responsive regulation should seek to cooperate with regulated entities as the first strategy before commanding solutions). See also Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1180 (1986) (tracing developments beginning in the Populist era and New Deal).

9. Shapiro, *supra* note 8, at 689 (citing President Clinton and Prime Minister Blair's proposal for a “third way” of government). See also Robert B. Reich, *Where Clinton's Third Way Went Wrong*, HARPER'S MAGAZINE April 1999, at 5 (describing the Third Way as having gone beyond finding a middle ground between capitalism and communism to seeking policies equidistant from Margaret Thatcher conservatism and pre-New Democrat approaches; while there is “no formal statement of principles,” this program includes “deregulation and privatization” and a belief that economic growth and free trade can provide security and make the economically displaced “winners”).

10. Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 545 (2000).

11. *Id.* at 199; See also Jody Freeman, *Private Parties, Public Functions and the New Administrative Law*, 52 ADMIN. L. REV. 813, 857 (2000).

12. Mark Seidenfeld, *Empowering Stakeholders: The Limits on Collaboration as the Basis for Flexible Regulation*, 41 WM. & MARY L. REV. 411 (2000); cf. Barry Boyer & Errol Meidinger, *Privatizing Regulatory Enforcement: A Preliminary Assessment of Citizen Suits under Federal Environment Laws*, 34 BUFF. L. REV. 833, 836-37 (1985) (potential for a “major—perhaps permanent realignment of roles and powers with respect to private and public enforcement of the law”).

independent responsibility to implement the statute, a responsibility for which it is accountable.¹³ Delegation to agencies has also been seen as having a positive role, with the agency having the power to participate actively in an ongoing process of constructing legislative meaning.¹⁴

This article does not deal with the overall direction of administrative reform or regulatory theory, nor with the collaborative role that private parties have or might have in the general area of food and drug regulation with respect to drug approvals and agency review of food additives.¹⁵

Instead the focus is on dietary supplements because they represent an important example of how changes, mandated by Congress, have affected the rationale and form of regulation for a major category of consumer products. The substantive deregulation has fundamentally shifted the public and private roles with respect to the availability of supplements. The supplements represent a test of the public's acceptance of deregulation and the role of individual choice. The experience with supplements may lead to a further unraveling of the pre-

13. William Funk, *Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest*, 46 DUKE L.J. 1351, 1356 (1997) (the principles of negotiated rulemaking "subtly subvert the basic underlying concept of American administrative law"). See also Daniel A. Farber, *Democracy and Disgust: Reflections on Public Choice*, 65 CHI.-KENT L. REV. 161, 163, 174 (1989) (criticizing an early version of the public choice theory that views the political process as solely self-seeking).

14. Jerry L. Mashaw, *Greed, Chaos and Governance* at 148, 204 (1997). While public choice can offer insights, some theorists have a bleak vision in which legislators use the administrative process to deliver on deals that maintain them in office. *Id.* at 109. Agencies, though, are constrained by legal rules and rationality review, and are expected to be responsive to the policy issues of a nationally-elected President. *Id.* at 152-57. Moreover, game theorists view preferences as static, but the agency implementation can influence the way legislators view their actions and preferences. *Id.* at 204.

15. There has been an active debate about giving third party reviews presumptive weight in drug approvals. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1857-64 (1996); Margaret Gilhooley, *The Administrative Conference and the Progress of Food and Drug Reform*, 30 ARIZ. ST. L. J. 129, 133-41 (1998). Regulated entities can also make their own determination, subject to the risk of enforcement action, that a food additive does not need prior review by the agency because it is generally recognized as safe (GRAS). See Lars Noah & Richard A. Merrill, *Starting From Scratch: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 441-43 (1998). FDA has proposed requiring pre-market notification of genetically-modified foods, but continues to regard transferred genetic material as presumptively GRAS and not subject to pre-market approval. FDA Proposed Rule, *Premarket Notice Concerning Bioengineered Foods*, 66 Fed. Reg. 4706, 4709 (2001); *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000) (upholding FDA presumption).

market approval system for foods and drugs, and possibly other consumer products. Out of a concern of “being DSHEA’ed” in other areas by Congress, the FDA may be more willing to pursue collaborative measures with regulated entities and alternative approaches. Moreover, this study of how dietary supplements have been regulated can serve as a benchmark in judging the impact of the new Administration from a different party.

The examination of the regulation of supplements concludes with some reflections on the wider debate about regulation and the administrative role in this context. Dietary supplement manufacturers are required to substantiate their claims for the products, but need not obtain any pre-market approval. Can substantiation be a “third way” of regulation that provides an intermediate model to ensure that the supplements work? The safety of supplements is an even more basic concern. Would the substantiation model be better at ensuring the safety of supplements than the present provisions which put the burden on the agency to demonstrate risks? What is needed to make the substantiation process an effective one? How does the deregulation of supplements affect the agency’s mission under its delegated authority?

II. STATUTORY DEREGULATION OF SUPPLEMENTS CLAIMS BEFORE DSHEA

A. Pre-market Approval Model for Drug Claims

Before DSHEA, a dietary supplement could only make a drug claim if the manufacturer obtained pre-market approval from the FDA showing that the product was safe and effective.¹⁶ That licensing process is a lengthy one that involves establishing that the claims are supported by “adequate and well-controlled investigations.”¹⁷ Thus, supplements were subject, in theory, to one of the most rigorous models for regulation.

Drug claims fall into two categories. The first, and most familiar category, relates to therapeutic claims to prevent or treat disease. The second category covers claims to “affect the structure or function of the body.”¹⁸ The drug definition was

16. 21 U.S.C. § 355(d) (1994).

17. 21 U.S.C. § 355(d) (1994). See Merrill, *supra* note 15.

18. 21 U.S.C. § 321 (g)(1)(C) (1994 & Supp. III 1997).

broadened in 1938 to cover these additional claims in order to reach weight reduction products. At that time, obesity was not considered a disease, and the expansion was necessary to reach claims for slenderizing effects, and “to make possible the regulation of a great many products” that do not treat disease.¹⁹ Claims to affect the structure and function of the body also include products concerned with physical difficulties, such as sleep-aids, or tranquilizers, as well as products that produce recreational effects.²⁰

B. Supplements Sold As Foods: Scope of Food Claims and Pre-market Approval

1. Limits of Food Structure and Function Claims

Dietary supplements were typically sold as foods. Foods and supplements could not make disease claims without complying with the requirements for pre-market approval of drugs.²¹ Whether they could make structure and function claims was more complicated. Foods are exempt from being considered drugs when they claim to effect the structure and function of the body. Foods inherently have these effects.²² Supplements could only get the benefit of the food exemption, however, if these claims related to uses of foods, such as taste, aroma, or nutrition.²³ As a result, supplements, like the familiar vitamins and minerals, could make claims about their nutritional effects (e.g. calcium builds strong bones), but other claims about the effects of supplements, such as to reduce weight by blocking absorption of starch, were considered drug claims.²⁴ This nutritional test for food claims limited the scope

19. *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983) (weight control products), quoting Hearings on S.1944 before a Subcommittee of Senate Comm. on Commerce, 73rd Cong., 2d Sess. 15-16. (Statement of Walter G. Campbell, Chief of FDA, 1933). See *infra* Part III.B.3 for FDA’s current position that some weight reductions are not disease-related.

20. The wider recreational effects were the basis for FDA’s effort to regulate tobacco as a drug and medical device. FDA regulation of tobacco was found statutorily invalid in *Food and Drug Admin. v. Brown & Williamson*, 590 U.S. 120 (2000). The Supreme Court found tobacco not to be a drug relying on Congressional intent to exclude tobacco from regulation, in the absence of disease claims, rather than any general limitation of the scope of the drug definition.

21. 21 U.S.C. § 321(g)(1)(B) (1994).

22. 21 U.S.C. § 321(g)(1)(C) (1994 & Supp. III 1997).

23. *Nutrilab*, 713 F.2d at 335.

24. *Id.*

of claims which could be made by supplements without meeting the drug approval requirements.

2. *Scope of Food Additive Pre-Market Approval Requirements*

With respect to safety, supplements sold as foods were subject to pre-market approval as food additives if an ingredient was added to other foods, and if it was not generally recognized as safe (GRAS).²⁵ Obtaining approval for food additives is also a lengthy process and approval can be difficult to obtain.²⁶ Nutritional supplements such as vitamins and minerals are ordinarily considered GRAS, and can be sold without the need for prior agency review. Other dietary supplements sold as foods were potentially subject to the need for prior agency approval.

The scope of the food additive provisions was tested when the FDA challenged as an additive a supplement containing only black currant oil in a capsule made of gelatin, an inert food substance. The court rejected the FDA effort and described as “Alice-in-Wonderland” the position that putting the black currant oil in a gelatin capsule constituted the addition of foods to each other.²⁷ Rather, the oil should be considered as a food sold in its individual form, making it subject to the less-rigorous safety standards governing raw agricultural products and other “non-added” foods.²⁸

C. Enforcement Discretion Model: Non-Regulation and the Portent of Increased Regulation

Notwithstanding the theoretical rigor of the regulatory scheme applicable to supplements, in practice, the FDA’s enforcement was limited in scope.²⁹ In the 1970’s, the FDA

25. 21 U.S.C. § 321(s) (1994).

26. Lars Noah & Richard A. Merrill, *supra* note 15.

27. *United States v. Two Plastic Drums*, 984 F.2d 814, 819 (7th Cir. 1993), For a similar result *see United States v. 29 Cartons of . . . An Art. of Food*, 987 F.2d 33 (1st Cir. 1993). FDA’s position may have had merit, nonetheless, since packaging a food in a capsule affects the palatability of the contents, and thus affects that characteristic of the food, an element of the food additive definition. 21 U.S.C. § 321(s) (1994).

28. 21 U.S.C. § 342(a)(1) (1994); *United States v. 1232 Cases American Beauty Brand Oysters*, 43 F. Supp. 749 (W.D. Mo. 1942).

29. General Accounting Office Report to Senator Kennedy, at 4 (B252966, July 2, 1993) [hereinafter GAO Report] reprinted in I. SCOTT BASS & ANTHONY L. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* 297, 300 (1996) (published by the Food and Drug Law Institute).

sought to regulate high doses of nutritional supplements and “irrational combinations” as drug products implicitly intended to treat or prevent diseases.³⁰ The FDA’s effort led to a Congressional repeal of the agency’s authority to classify supplements as drugs based on dose or combinations.³¹ Thereafter, the FDA did not “systematically” regulate supplements; the agency acted in response to safety problems or express drug claims, rather than insisting on prior proof of lack of harm.³² Over time, non-food products also came to be sold as dietary supplements, some of which may have had a history of use in traditional medicines.³³

The FDA’s regulatory approach changed when 38 deaths and 1500 adverse effects were attributed to the use of the non-essential amino acid, L-tryptophan.³⁴ Commissioner David Kessler of the FDA had a Task Force consider options for dealing not only with L-tryptophan but also with the range of issues presented by dietary supplements.³⁵ The Task Force considered the amino acid to be an unapproved food additive because of its safety risks, one which needed to be addressed by FDA regulatory action.³⁶ In addition, the Report viewed the supplement as an unapproved drug based on its marketing claims to support the immune function, to be “nature’s tranquilizer,” and to treat schizophrenia and senility.³⁷

The Task Force also discussed “issues of concern” about herbal supplements, and identified the FDA’s immediate goal as ensuring removal of hazardous products and products marketed for drug uses in accordance with the agency’s health fraud program.³⁸ The Task Force may have intended only selective enforcement to deal with major frauds and safety risks, since it sought to provide “some accommodation of the desire of a substantial segment of the public to obtain dietary supplements,

30. *Herbal Remedies*, *supra* note 1, at 673-75.

31. 21 U.S.C. § 350 (1994).

32. GAO Report, *supra* note 29, at 4.

33. FDA Advance Notice of Proposed Rulemaking, Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, at 33,698-99 [hereinafter Advance Notice].

34. *Id.* at 33,690-92.

35. *Id.* at 33,694-99.

36. *Id.* at 33,698; *Herbal Remedies*, *supra* note 1, at 677-78 (1997).

37. See Advance Notice, 58 Fed. Reg. at 33,697. The claims to support the immune system, and claims to reduce stress or support mood would now be permissible under DSHEA. See *infra* Part III.B.2, III.B.3.

38. See Advance Notice, 58 Fed. Reg. at 33,698.

including ones with little or no documented nutritive value.”³⁹

The dietary supplement industry portrayed the FDA approach in terms of its broadest possible reach as having the potential to take vitamins and minerals away from the public.⁴⁰ A national blackout day was organized in which retailers covered in black crepe all the supplements that might be removed from sale if the FDA pursued an expansive view of its regulatory authority.⁴¹ The public reaction “galvanized support” for the legislation that became DSHEA.⁴²

D. Reasons for DSHEA and Lessons for Regulatory Reform

DSHEA was enacted, not by a Republican Congress, but by a Democratically controlled Congress, and was signed by a Democratic President on the eve of the 1994 election.⁴³ The principal spur for the law was public reaction to the FDA Task Force’s plans to address safety problems posed by L-tryptophan and other supplements, a plan which could be read to impose the rigors of pre-market review to broad numbers of supplements.⁴⁴

There were other factors. The FDA’s regulations on health claims allowed claims for foods, but no claims for nutritional supplements, furthering the perception that the FDA was prejudiced against supplements.⁴⁵ The cases the FDA had brought against dietary supplements complicated the agency’s position. The categorization of the FDA’s position on the scope of the food additive provisions as “Alice-in-Wonderland” contributed to a perception of an overzealous agency.⁴⁶ The FDA’s judicial success in establishing that supplements sold as food had to have nutritional value concerned the industry

39. *Id.* at 33,691.

40. Bass & Young, *supra* note 29, at 28.

41. *Id.* See also Michael Weisskopf, *In the Vitamin Wars, Industry Marshals an Army of Citizen Protesters*, WASH. POST, Sept. 14, 1993, at A7 (reporting on campaign, the slogan of “Don’t Let Health Freedom Follow the Dinosaur,” role of Senator Hatch, and industry lobbying).

42. Bass and Young, *supra* note 29, at 7.

43. DSHEA was enacted on Oct. 25, 1994, Pub. L. No. 103-417. The Republican Party won a majority in Congress in the November election. See Adam Clymer, *G.O.P. Celebrates Its Sweep to Power, President Clinton Vows to Find Common Ground*, N. Y. TIMES, Nov. 10, 1994, at A1.

44. Bass and Young, *supra* note 29, at 7, 26-28. See also FDA Advance Notice, 58 Fed. Reg. 33,690.

45. Food Labeling; General Requirements for Health Claims 59 Fed. Reg. 395 (1994) (to be codified at 21 C.F.R. 101.4).

46. See *supra* note 21 and accompanying text.

because it narrowed the scope of permissible claims.⁴⁷

The passage of DSHEA has been described as Commissioner Kessler's "greatest failure" as the head of the FDA. He viewed supplements as being one of the "problems you are not going to solve."⁴⁸ The problem, on the one hand, is that the agency had concerns with preventing safety risks from supplements like L-tryptophan, and, in pursuit of its protective public health mission, identified how its authority, if exercised fully, could be used to limit the supplement as a food additive and as a drug. This authority, if pursued and fully applied to that and other supplements, would end the truce provided by the FDA's enforcement discretion, allowing supplements to be sold simply as supplements in the absence of express drug claims of some identified specific safety risk.

The dietary supplement industry, though, probably wanted more than a return to a state of truce. Herbal remedies had a potential for a greater market, as demonstrated by their popularity in Europe as well as Asia.⁴⁹ To broaden the appeal of the products and to advertise effectively to a mass audience, the manufacturers needed to be able to make express claims about the usefulness of the products for drug purposes. Some supplement proponents sought to have Congress allow express disease claims to be made for supplements, so long as there was substantiation.⁵⁰ While Congress expanded the claims for supplements, it did not go as far as allowing disease claims.⁵¹

Perhaps the agency could have made greater commitments

47. See *supra* note 18.

48. Marion Burros, *F.D.A. Commissioner Is Resigning After 6 Stormy Years in Office*, N. Y. Times, Nov. 26, 1996, at A1.

49. Edgar R. Cataxinos, Note, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561; Commission Report, *supra* note 1, at 49-54.

50. *Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?* Hearing before the House Comm. on Gov't Reform, 106th Cong. 58 (1999) (remarks of ranking Democratic member Cong. Waxman) [hereinafter Hearings]:

When we drafted this legislation, there were some people who argued a manufacturer ought to be able to sell a product and make any claim that he wants to if he has some substantiation . . . And let the marketplace operate. On the other hand, other people felt, well, that is just too wide open. And we made a distinction in the law between disease claims. . . And we said those products are drugs and they ought to be reviewed by FDA to be sure they are safe and effective. But if it is a product that simply is intended to affect the structure and function of the body, we said the manufacturer can make claims in that regard.

51. 21 U.S.C. § 343(r)(6) (1994).

about the limited scope of its regulatory intentions. Perhaps regulatory negotiations or compromises might have forestalled Congressional action. One lesson may be that when enforcement discretion is used as an “accommodation” to those resistant to greater regulation, the agency needs to provide advice clearly not only on the high priorities for enforcement action, but also on those matters of lesser regulatory concern.⁵²

Most relevant now is that Congress has rewritten the regulatory scheme for supplements. The agency has to implement the law mindful of the Congressional decision to allow more scope for supplement claims. Still, Congress has kept supplements within the framework of FDA regulation. The agency needs to reexamine and reformulate how its public health mission relates to the expanded scope for claims. If agency regulation is to be seen as an effort at problem-solving, the deregulation of supplements provides a challenge in how to reconcile the expansion of claims with the agency’s traditional core responsibilities of preventing harm and deception from personal use products.

III. SCOPE OF REGULATION OF SUPPLEMENT CLAIMS UNDER DSHEA

A. DSHEA Provisions on Claims

A major change made by DSHEA is to allow dietary supplements to make statements about the role of a “dietary ingredient” in affecting “the structure or function of the body” without the statement being considered a drug claim.⁵³ To be permitted, the claim has to be accompanied by a disclosure that the “statement has not been evaluated by [the FDA]” and the product “is not intended to diagnose, treat, cure, or prevent disease.”⁵⁴ The statement has to be substantiated, but no prior FDA approval is needed, as would be necessary for a drug claim.⁵⁵ The claims can be made not only for nutrients, but also for “dietary ingredients.”⁵⁶ This language indicates that claims

52. See *infra* Part II.A.3 and Part V.B.6. However, firm commitments by the agency not to take enforcement action necessitates the use of rulemaking procedures. See *Community Nutrition Institute v. Young*, 818 F.2d 943 (D.C. Cir. 1987).

53. 21 U.S.C. § 343(r)(6)(A) (1994).

54. 21 U.S.C. § 343(r)(6)(C) (1994).

55. 21 U.S.C. § 343(r)(6)(B) (1994).

56. 21 U.S.C. § 343(r)(6)(A) (1994).

for supplements are permitted even though the claim does not relate to nutrition. Thus, nutritional value, the prior test for an appropriate food supplement claim, is no longer a restraint.⁵⁷ The effect of DSHEA is to allow herbs, botanical and other products to be sold as dietary supplements and to make claims about their effects even though they are not foods in any nutritional sense and even though they may have had a history of use in traditional medicine in other countries.

B. FDA Regulations on Structure and Function Claims

DSHEA poses a challenge, indeed an enigma, on how to distinguish disease claims from structure and function claims. As the FDA has stated, diseases, "by definition, adversely affect some structure and function of the body, and it is possible to describe most products intended to treat or prevent disease in terms of their effects on the structure and function of the body."⁵⁸ While distinguishing between disease and structure and function claims matters little for purposes of drug regulation, since both claims are subject to pre-market approval, the passage of DSHEA has necessitated a difficult feat of line-drawing for supplement claims.⁵⁹

In its rulemaking, completed in January 2000, the FDA identified several major factors for drawing the boundary between disease claims and permissible structure and function claims for dietary supplements.⁶⁰ The FDA rules are complicated and deal with a great variety of claims. This discussion highlights the major themes. The examples used are often as illuminating as the tests in understanding the overall pattern.

1. Implied References to Specific Diseases Versus Broad References to Body Systems

The supplement industry argued that a claim is a disease

57. Cf. *Nutrilab, Inc.*, 713 F.2d at 335.

58. Proposed Rule, *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 82 Fed. Reg. 23624 (1998) (proposed April 29, 1998) [hereinafter Proposed Claims Rule].

59. The 1962 Drug Efficacy Amendments required pre-market approval for drug claims in the wake of the thalidomide crisis. The Act extended to both therapeutic and structure and function claims.

60. FDA Final Rule, *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure and Function of the Body*, 65 Fed. Reg. 999 (2000) (to be codified at 21 C.F.R. pt. 101)[hereinafter Final Claims Rule].

claim only if it makes an express reference to a disease. In support, the industry maintained that Congress required a disclaimer on supplements because Congress understood that the effects of specific diseases “can also be described” as structure and function effects and resolved the “tension” by requiring the disclaimer, leaving it to the consumer to decide.⁶¹ The FDA rejected that position and found implied disease claims are precluded for supplements, since implied claims would contradict and eviscerate the disclaimer and cause confusion.⁶²

On the other hand, the FDA regards as disease claims statements that refer to *specific* diseases, but not statements that “refer broadly to body systems or functions without *sufficient* reference to specific abnormalities or symptoms to be understood as references to particular diseases.”⁶³ As a result, the FDA accepts as permissible structure and function claims statements that a product “helps maintain cardiovascular function”, or “promotes relaxation.”⁶⁴

2. Changing Abnormal Function Versus Maintaining Function.

Under another test, the FDA regards as an implicit disease claim references to abnormal conditions, or to the “characteristic signs or symptoms” of a specific disease. The agency gives the following examples of disease claims: “lowers cholesterol,” “reduces joint pain” (a characteristic of arthritis), or “improves urine flow in men over 50” (a characteristic of benign prostatic hypertrophy).⁶⁵

On the other hand, the FDA regards as non-disease claims statements that a product maintains bodily functions, such as “helps maintain a healthy lung function,” “reduces stress and frustration,” or “improves absentmindedness.”⁶⁶ The FDA’s rationale is that some signs and symptoms, such as absentmindedness, “may be associated with a number of diseases, but are not, by themselves, sufficient to characterize

61. *Id.* at 1012-13.

62. *Id.* at 1013-14.

63. Proposed Claims Rule, 82 Fed. Reg. at 23,626; *see generally* Final Claims Rule, 65 Fed. Reg. at 1015, § 37 (emphasis added).

64. These claims were recognized as appropriate in the Proposed Claims Rule, 82 Fed. Reg. at 23626, a recognition not changed by the Final Claims Rule.

65. Final Claims Rule, 65 Fed. Reg. at 1016; 21 C.F.R. § 101.93(g)(2)(ii).

66. Proposed Claims Rule, 82 Fed. Reg. at 23,626; Final Claims Rule, 65 Fed. Reg. at 1018-19; 21 C.F.R. § 101.93(g)(2).

specific diseases.”⁶⁷

Under this approach, while claims to lower cholesterol are a disease claim, maintaining cholesterol is a supplement claim. In the case of cholesterol, though, in response to comments, the FDA believes that the maintenance claim should say, “helps to maintain cholesterol levels that are already within the normal range.”⁶⁸

The final rule also deleted, as too vague, the proposal’s identification of disease in terms of signs and symptoms recognizable to professionals and consumers. The final rule looks at whether the labeling refers to signs and symptoms of disease, in lay or professional language, without considering recognizability.⁶⁹ The change seems to make consumer confusion about the scope of the labeling claim less significant.

3. *Substitutes for Drug Therapy versus Other Functions*

A claim is a disease claim if it suggests that the product is a substitute for a recognized drug use, such as a claim to be an Herbal Prozac or an antibiotic or antiviral.⁷⁰

However, a claim that a supplement “supports the immune function” is not a disease claim. This is because it does “not identify a specific drug. . . action,” and makes “general references to an effect on a body system that has several functions, only one of which is resistance to disease.”⁷¹ The other functions include the role of white blood cells in disposing of aging red blood cells and damaged cells.⁷²

The FDA also found that an “appetite suppressant” claim or a claim for “use in your weight loss plan” is a structure and function claim. Even though obesity is a disease, merely being overweight is not, and the claims are permissible when the context makes clear it is for ordinary weight loss.⁷³

A claim to “help increase muscle mass” falls in the structure

67. Proposed Claims Rule, 82 Fed. Reg. at 23,626. *See also* Final Claims Rule, 65 Fed. Reg. at 1016.

68. Final Claims Rule, 65 Fed. Reg. at 1019. The author made comments supporting this change. Letter to FDA Dockets Management Branch, on Docket 98N-0044, Dietary Supplements, July 29, 1999 (on file with the author).

69. Final Claims Rule, 65 Fed. Reg. at 1016; 21 C.F.R. § 101.93(f)(2)(ii).

70. Final Claims Rule, 65 Fed. Reg. at 1015.

71. Proposed Claims Rule, 82 Fed. Reg. at 23,627. *See also* responses to comments in Final Claims Rule, 65 Fed. Reg. at 1028, including comments of author.

72. Final Claims Rule, 65 Fed. Reg. at 1029.

73. Final Claims Rule, 65 Fed. Reg. at 1026-27.

and function category. However, the effect implied may be one for an anabolic steroid, and thus be subject to the Controlled Substances Act.⁷⁴

4. *Natural States*

The FDA's final rule is significantly more expansive than its proposal because it permits claims about "common, mild symptoms associated with normal life stages." Supplements can now claim usefulness for conditions associated with aging such as "hot flashes," "wrinkles," "mild memory problems," "hair loss," and "inability to change eye focus from near to far (or vice versa)."⁷⁵ Also acceptable is a claim for "decreased sexual function associated with aging."⁷⁶ The claims are considered disease claims only if they affect an abnormal condition that "is uncommon or can cause significant or permanent damage."⁷⁷

5. *OTC Nonspecific Conditions and Various Causes*

The FDA's final rule also accepted as non-disease claims a number of claims made for over-the-counter drugs. Acceptable claims include "occasional heartburn," "for relief of occasional sleeplessness," and for "nausea. . . associated with motion."⁷⁸ On the other hand, in a tougher call, the FDA did not consider nasal decongestant claims to be permissible because they relate to the characteristic symptoms of diseases such as colds, flu and hay fever.⁷⁹

6. *Disease Definition*

The FDA's final rule adopted a different definition of disease than the proposal, which had relied on a medical dictionary definition.⁸⁰ The final rule accepted the position

74. *Id.* at 1030, § 84 (citing 21 U.S.C. § 802(41) (1994)). FDA has also recently issued guidance that claims to be alternatives to illicit street drugs and for recreational purposes to affect psychological states, such as "to get high," are not dietary supplement claims since the claims do not relate to supplementing the diet. *Notice, Availability of Guidance, Street Drug Alternatives*, 65 Fed. Reg. 17,512 (Apr. 3, 2000).

75. Final Claims Rule, 65 Fed. Reg. at 1020.

76. *Id.* at 1020. A claim to be an herbal Viagra would not be permissible under the criteria stated.

77. 21 C.F.R. § 101.93 (g)(2)(iii), as added by Final Claims Rule, 65 Fed. Reg. at 1050.

78. Final Claims Rule, 65 Fed. Reg. at 1031.

79. *Id.*

80. Proposed Claims Rule, 82 Fed. Reg. 23,624, 23,625 (1998).

urged in the comments and relied, instead, on a regulatory definition used in implementing the statute on health claims for foods. The FDA's final rule discusses the differences between the definitions in considerable detail.⁸¹ The principal significance seems to be that the definition adopted in the final rule uses the term "damage" to identify a disease, a term the proposal did not use because of a concern that the term could limit diseases to those which were "serious or long-term."⁸² The FDA intended the final rule to be more permissive than the proposal, and the change in the definition seems related to the decision to allow claims about natural states which are mild and that do not cause significant or permanent harm.⁸³

C. Right Line?

1. Dietary Role As Test

One question is whether the FDA Rule draws an appropriate line between permitted and unpermitted claims. Previously I suggested that structure and function claims should be "dietary" in some meaningful sense, such as being a claim to have a food-like effect on the body, like providing energy, or an alertness effect, similar to that from coffee, but that the claims not be for drug-like effects such as improving absentmindedness.⁸⁴ The FDA rejected that distinction.⁸⁵

DSHEA is an ambiguous statute, and it is understandable, if not entirely satisfactory, that the FDA took a more expansive approach. The FDA received over 235,000 comments on its proposed rule, most urging expanding the permitted claims.⁸⁶ Congress also held hearings to consider whether the FDA was misinterpreting DSHEA by being too restrictive.⁸⁷ The agency's familiarity with the history of the enactment of DSHEA also provides support that "dietary" has a wider meaning, and that Congress indeed intended to split the drug definition in half. There remains, though, something odd and unsettling about

81. Final Claims Rule, 65 Fed. Reg. at 1009-10.

82. *Id.* at 1009-10 (disease definition).

83. *Id.* at 999 (intent to expand permitted claims).

84. Herbal Remedies, *supra* note 1, at 690-92; *see also* Testimony of Margaret Gilhooley at Hearings, *supra* note 50, at 138,140.

85. Final Claims Rule, 65 Fed. Reg. at 1011.

86. *Id.* at 1000.

87. Hearings, *supra* note 54.

calling products and claims “dietary” when they do not relate to foods. The “dietary supplement” designation now serves largely to mark out a special category of non-foods whose claims need special evaluation by consumers.

2. *Seriousness and Consumer Ability to Evaluate*

The FDA’s rule was influenced by another test that makes sense in this context, whether the claim suggests use for “a serious health condition that is beyond the ability of the consumer to evaluate.”⁸⁸ That test was identified in the report of a Presidential-appointed Commission on Dietary Supplement Labels (Commission) on which I served, and in my comments on the rule.⁸⁹ The FDA stated it paid “particularly close attention” to claims which relate to “serious health conditions that patients cannot safely evaluate on their own.”⁹⁰

The FDA also viewed safety as one of the “major purposes” of its rule. The FDA wanted to ensure supplements did not make disease claims because such claims can harm consumers if they induce substitution of “ineffective or less effective treatments for a proven one, especially if the disease involved is serious or life-threatening.”⁹¹

3. *Application Difficulties*

a. *Effects Beyond Consumer Assessment*

While the tests used by the FDA seem justifiable, in trying to make sense of the puzzle, the FDA has not always applied the principles correctly. Some claims seem inappropriate, such as the FDA’s initial acceptance of claims to treat “morning sickness.” The FDA is reconsidering this claim, in view of the potential for safety risks to the baby, an effect that is beyond the ability of the mother to evaluate.⁹²

Moreover, claims to “help maintain cardiovascular function”

88. Final Claims Rule, 65 Fed. Reg. at 1018; Commission Report, *supra* note 1 at 38, 39.

89. See Commission Report, *supra* note 1, at viii and 38; and Letter of Margaret Gilhooley to FDA Dockets Management Branch (July 29, 1999) (available from the author).

90. Final Claims Rule, 65 Fed. Reg. at 1011.

91. *Id.* at 1003.

92. *FDA Statement Concerning Structure/Function Rule and Pregnancy Claims*, (visited Feb. 9, 2000) <<http://www.fda.gov>>.

or “maintain lung function” are beyond the consumer’s ability to assess and they relate to important physical functions. Claims of this type are more appropriately considered a disease claim. As a disease claim, agency approval would be needed, thus providing an added assurance of reliability and adequate testing.⁹³ Supplement labeling of “non-disease” claims has been described as having risen to “an art form of doublespeak,” with medical uses “merely insinuated” but, nonetheless, still clear as in the case of claims to “promote prostate health.”⁹⁴

It may be thought that claims like maintaining cardiovascular health do not need the additional assurances of reliability required for disease claims since the claim relates only to the continuation of a normal state of functioning. However, the line between maintenance and disease prevention overlaps in this context. Consumers may view the product as needed to maintain the function and prevent deterioration. The claim may divert consumers from other proven means of maintaining the function, and thus increase risks of harm.

Even if an adverse safety impact cannot be established, allowing the claim is objectionable, if unsupported, because of its ability to deceive lay users about a matter they view as important to their health but which is beyond their ability to assess. Providing the safeguards of pre-market approval and testing simply to prevent deception, even if a safety impact cannot be proven, is an appropriate and traditional regulatory role. Whether the alternative of substantiation provided by DSHEA is adequate to protect the public with respect to such implied disease prevention claims is open to debate. The impact on the public is also affected by the criteria for and priority given to the implementation of the substantiation requirement.⁹⁵

Consumers would also be better protected if the labeling for these maintenance supplement claims indicated the product should be used when there is assurance the body function is normal, and the types of symptoms which indicate the need for

93. It is true that other claims about important functions, such as cholesterol reduction, are made directly to consumers on foods, but, by statute, the claim can only be made based on scientific acceptance and agency approval. 21 U.S.C. § 343(r). See *infra* Part IV and *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) for a discussion of the allowance of health claims on supplements, based on constitutional grounds, without that level of support, based on disclaimers.

94. Editorial, *Alternative Medicine—The Risk of Untested and Unregulated Remedies*, 339 NEW ENG. J. MED. 839, 841 (1998).

95. See *infra* Part III.D. The adequacy of disclaimers and labeling to prevent deception is discussed *infra* Parts IV.A.3 and V.B.

further medical advice. Claims to maintain cholesterol functioning, for example, have less risk of deception now that the claim is to indicate that the product is for use by those with normal cholesterol levels.⁹⁶ Whether labeling can adequately communicate the range of normal use for the various health function claims permitted for supplements is another question.

Supplements may be popular because some consumers find the effort to uncover an off-label “real” use as empowering and providing access to a hidden means to affect their health. Other consumers may be wary of claims that are not clearly stated on the label, and, for them, the generality of supplement claims may serve indirectly as a caution and safeguard. The FDA’s acceptance of generality in supplement claims can be seen as simply needed to accommodate the Congressional intent of permitting expanded uses for consumers. The generality has its drawbacks though, in leading to consumer confusion and the risk of inappropriate use of supplements. Whether consumers would be better off if supplements could expressly make disease claims with adequate disclosures about the basis for the claims, as some maintain, is discussed later, along with the difficulties in identifying what is an adequate disclosure.⁹⁷

b. Generality and Need for Better Labeling

The generality of some of the permissible claims is unsettling in other ways. For example, FDA considers claims to be non-disease claims if the claim relates to several functions which include disease and non-disease functions. On this basis, the FDA recognizes a claim to “support the immune function” as appropriate. The claim may still suggest usefulness for infections, colds, or possibly for immune deficiency diseases like AIDS. An ingredient sold with the immune support claim, for example, is recognized in a World Health Organization monograph “as an immunostimulant, supportative therapy for colds and infections. . . .”⁹⁸ When an ingredient has dual functions, the supplement claim should be stated in terms that are specifically limited to the non-disease use. The non-disease

96. See *supra* note 53 (discussion of cholesterol maintenance claims and author’s comments).

97. See *infra* Part V on traditional medicines and disclosures.

98. World Health Organization Draft Monographs on Botanical, Geneva, Switzerland, 1996, as cited in Commission Report, *supra* note 1, at 50 (effects of echinaceae).

function involved in the immune system claim seems to relate to supporting white blood cells in their ordinary function of removing damaged blood cells.⁹⁹ The immune system claim for supplements should not be a general claim but one that identifies the limited role. The claim should state the product maintains the immune system by supporting the ordinary role of white blood cells in removing damaged blood cells.

Better labeling may also help in some cases to prevent confusion about the generality or other aspects of supplement claims. For example, the general claim to “improve absentmindedness” should indicate that it relates to “ordinary minor absentmindedness” to avoid an implication that it helps with more serious conditions, including Alzheimer’s disease. The claim to help eye focus should alert consumers, with some specificity, when they need to seek professional advice about the condition. Claims for conditions related to life-stages should relate to relief of symptoms recognizable to consumers when the condition occurs, rather than prevention, a matter beyond ready appraisal by the user, and one that leads to long-term use with its greater implications for safety.

c. Congestion Claim as Illustrative of Choices

The FDA’s restrictive treatment of nasal congestion as a disease claim seems puzzling and problematic, and warrants some discussion, notwithstanding the mundaneness of the claim, because it illustrates the choices underlying the various tests. The FDA considers the claim to be a disease claim because congestion is a characteristic symptom of diseases like colds, flu and hay fever.¹⁰⁰ This criteria focuses on medically recognized symptoms. If one focuses on a different criteria, the seriousness of the condition, and the role of lay judgment, the result could be different. While claims to prevent colds can be considered a disease claim, treating the symptoms of colds, once

99. Compare *supra* notes 55-56. Food manufacturers also maintain that they should be able to make the same structure and function claims that are permitted for dietary supplements, without the claim being considered a disease claim. FDA has advised that it is likely to interpret the line in a similar way, although the claims may only be permissible for foods with respect to their nutritional value. Final Claims Rule, 65 Fed. Reg. 999, 1034 (2000); *Nutrilab v. Schweiker*, 713 F. 2d 335, 338 (7th Cir. 1983), discussed in Part II.A. Compare *Jeannie Perron & Eugene I. Lambert, DSHEA and Structure and Function Claims for Animal Feed*, 555 FOOD & DRUG L. J. 151, 153 (2000) (discussion of claims for sterol esters).

100. Final Claims Rule, 65 Fed. Reg. at 1031.

the condition occurs, seems within the ordinary ability of consumers to judge, and something which could be a supplement claim. The ability of the consumer to assess the claim from experience provides some justification for believing that pre-market approval is less necessary.

The congestion claim might also seem permissible based on FDA's willingness to accept generality as a mark of a supplement claim. A claim for "maintaining clear nasal function" is similar to the maintenance claims the FDA has recognized.¹⁰¹ Relying on generality as a factor permits a measure of compromise under the FDA tests and permits a wider recognition of structure and function claims. A claim for temporary relief of "nasal stuffiness" would also seem to be a supplement claim if the FDA were willing to view stuffiness as due not solely to colds or other diseases, but related as well to more general causes. How to deal with the classification of this claim reflects choices on whether the determination turns on traditional medical criteria (disease symptoms), the seriousness of the effect in light of the consumer's ability to judge its effects, or a test that considers claims stated in a more general way as having non-disease functions. The tests vary in their ability to permit compromise and adapt themselves to a more pragmatic or conciliatory approach.¹⁰² Which is appropriate involves judgments about how important the health consequences are and how important conciliation is on its own as a regulatory goal.

An additional factor may also have played a role. The FDA later announced plans to withdraw the use of phenypropanolamine, an ingredient used in decongestant over-the-counter drugs (OTC), for safety reasons, and the OTC drugs were reformulated using another ingredient.¹⁰³ If the decongestion claim had been recognized as an appropriate supplement claim, it is possible there would have been a market for herbal supplements making this claim. There would, however, have been safety concerns if ephedrine was used in

101. See *supra* notes 55-56.

102. See *Shapiro*, *supra* note 8, and *Freeman*, *supra* note 9.

103. See FDA Talk Paper, FDA Issues Public Health Warning on Phenylpropanolamine, Nov. 6, 2000 (available at <fda.gov/bbs/topics/ANSWERS/ANS01051.html>), and Jeff Gerth & Sheryl Gay Stolberg, *Another Part of the Battle: Keeping Drugs on the Shelves of Stores*, N. Y. TIMES, p. 31, Dec. 13, 2000.

supplements to achieve the decongestion effect.¹⁰⁴ Ephedrine may also have a use in relieving congestion, since claims for traditional Asian medicines include relief of cold symptoms.¹⁰⁵ Moreover, the FDA has proposed restricting use of ephedrine in OTC drugs, at the request of the Drug Enforcement Administration, because of its illicit use as a precursor in making controlled substances like methamphetamine.¹⁰⁶ Whether those factors played a role in the FDA's not allowing a congestion claim for supplements is not clear, but these considerations demonstrate choices regulators may sometimes face.

D. Adequacy Of The Substantiation Model For Claims

Supplement claims are required to have substantiation, by law, but no FDA prior approval of the claims is needed.¹⁰⁷ Thus, DSHEA provides a test for whether substantiation is an appropriate model for products which make a claim that would ordinarily fall within the drug definition. Whether the substantiation model can be sufficient if the claims truly are non-disease claims relates to the criteria for substantiation testing, and the means to enforce the requirement.

1. Enforcement Difficulties

To start with the last point, a major difficulty is that the FDA has no express authority to obtain the records and studies of food and supplement manufacturers. Without this authority, the FDA has no routine way to check what studies the manufacturers have done to substantiate their claims for supplements. The FDA could try to seek access to the records under its general authority to conduct "reasonable" inspections.¹⁰⁸ When the FDA relied on this theory in a rulemaking in the late 1960's, the Supreme Court found the issue was not ripe until the FDA sought enforcement in a specific context that permitted a judgment about the need for

104. See *infra* Part VII.B.3.

105. *Dietary Supplements Containing Ephedrine Alkaloids*, Proposed Rule, 62 Fed. Reg. 30,677, 30,691 (1997) [hereinafter *Proposed Ephedrine Rule*].

106. *Proposed Ephedrine Rule*, 62 Fed. Reg. at 30,691.

107. 21 U.S.C. § 343(r)(6)(B) (1994).

108. 21 U.S.C. § 374 (1994). See also *Herbal Remedies*, *supra* note 1, at 695-96; Commission Report, *supra* note 1, at 44 (author's individual views on need for FDA to have access to files through administrative interpretation or legislation).

the authority.¹⁰⁹ To avoid the prolonged litigation that would ensue if the FDA sought to obtain access to substantiation records under its existing authority, Congress should give FDA authority to obtain access to the records.

2. *Substantiation Criteria*

The substantiation model originated with the FTC's efforts to regulate misleading advertising claims. An advertising claim is considered misleading if the advertiser does not have adequate substantiation for all objective claims before disseminating the advertisement.¹¹⁰ Thus, the maker of the claim has the affirmative obligation to employ studies which are adequate to support the claim. The use of substantiation for these products is new, despite the FTC precedents, since there is no separate FDA prior review of the claims on the label, and the products are ingested, presenting more significant issues for safety substantiation.

In determining what is adequate support, the FTC considers what constitutes "competent and reliable scientific evidence" in the overall context, including the amount of substantiation experts in the field consider reasonable.¹¹¹ Determining the level of substantiation needed involves a balancing test that calls for consideration of the type of product, type of claim, the benefits of a truthful statement, the ease of developing substantiation, the consequences of a false claim and the amount of substantiation the experts in the field believe is necessary.¹¹² The FTC would accept significant scientific agreement as needed for substantiation, when other agencies or authoritative bodies recognize the standard, as in the case of health claims, but the FTC does not expressly call for this level of support for other

109. *Toilet Goods Ass'n v. Gardner*, 387 U.S. 167 (1967).

110. FTC, *Dietary Supplements: An Advertising Guide to the Industry*, <www.ftc.gov/bcp/online/pubs/dietsupp.htm> [hereinafter *Advertising Guide*]. See generally C. Lee Peeler & Susan Cohn, *The Federal Trade Commission's Regulation of Advertising Claims for Dietary Supplements*, 50 FOOD & DRUG L. J. 349 (1995).

111. *FTC Enforcement Policy Statement on Food Advertising*, 59 Fed. Reg. 28,388, 28,393 (1994) [hereinafter *FTC Enforcement Policy*]; *FTC Policy Statement on Advertising Substantiation*, 48 Fed. Reg. 10,471 (1984), reprinted in *Thompson Medical Co.*, 104 F.T.C. 648,839 (1984), aff'd, *Thompson Medical Co. v. F.T.C.*, 791 F.2d 189 (D.C. Cir. 1986), cert. denied. 479 U.S. 1086 (1987).

112. *Advertising Guide*, supra note 110, at 6 (substantiation will vary depending on the product and claim, the consequences of a false claim and benefits of a truthful one, the cost/feasibility of developing substantiation, and the amount of substantiation that experts in the field believe reasonable). See also *Commission Report*, supra note 1, at 43.

supplement claims.¹¹³ Whether this level of support is needed is affected by whether claims such as maintaining cardiovascular function are viewed as claims that relate to matters of health importance.

3. Application of Criteria to Supplement Claims

The FDA has stated that it agrees with the Commission's report which made recommendations for substantiation after considering the FTC's criteria.¹¹⁴ How the criteria will apply remains to be tested in particular cases involving the new types of labeling claims for supplements. Since the claims recognized by the FDA as permissible supplement claims vary in their health importance, with some relating to minor matters, like hair loss, the need to have significant scientific agreement to support claims would seem to vary.

Another concern is the extent to which public disclosure of the substantiation data is needed in order to make it available to the wider medical and scientific community. The public availability permits independent scientific evaluation of the supporting material.¹¹⁵ Moreover, public availability provides a way for doctors to know more about the basis for claims and to be in a better position to advise patients.

Some supplement manufacturers may regard the testing and data relied on for substantiation to be proprietary and trade secrets. If they do, it increases the importance of the FDA having access to the test records. Some general summary of the type of test results used for substantiation should still be made publicly available.¹¹⁶ Moreover, when the data is not fully available, experts may find the claim to be adequately supported

113. FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, at 28,393 ("principal guide" for the support for advertisements for health claims); *Advertising Guide*, *supra* note 110, at 6-7. See also *Herbal Remedies*, *supra* note 1, at 694 (that significant scientific agreement should be needed for claims of health importance).

114. Final Claims Rule, 65 Fed. Reg. 999, 1032 (2000), (*citing* Notice, 63 Fed. Reg. 23,624, at 23,633 (1998)). See Commission Report, *supra* note 1, at 43. See *infra* note 131 (FDA's criteria for significant agreement to support health claims).

115. FDA has stated that it "would expect" a manufacturer to provide those who request copies of the substantiation data contrary and supporting studies. FDA Final Claims Rule, 65 Fed. Reg. at 1032.

116. The FTC will consider unpublished proprietary studies in connection with the substantiation of claims, but recognizes that publication in a peer-reviewed journal provides some measure of scrutiny. *Advertising Guide*, *supra* note 110, at 9. While the test data for new drugs is confidential, FDA has developed policies to release summaries of the basis for approval. See 21 C.F.R. § 314.430(e)(2) (2000); HUTT & MERRILL, FOOD AND DRUG LAW 531 (1991); 39 Fed. Reg. 44,602, at 44,635-36 (1974).

only if the claim has been subject to an in-depth independent evaluation by expert review panels with strong credentials.

The difficulty in doing studies is a factor under the FTC's criteria.¹¹⁷ This factor has the most pertinence when the claim relates to prevention and the support necessitates long-term studies. The issue also arises for health claims, and the discussion below explores if there are ways to permit preliminary claims in a way that provides an incentive for needed research.¹¹⁸

E. Is There A Need for Substantiation of Supplement Claims?

On a policy basis, some may question the need for any substantiation requirement for supplement claims, and concomitantly the need for rigorous enforcement. If supplement claims deal with non-diseases and nonserious conditions within the ability of the consumer to evaluate, is there any real need to have the government heavily involved in reviewing how much testing supports the claim? If, for example, a supplement claims to reduce hair loss but it does not produce, won't consumers realize this, therefore the product fails in the marketplace? If a supplement is safe but makes vague claims, does it matter whether the claim is proven?

Supplement claims vary under the FDA rule, and some are harder for consumers to evaluate than others. The absentminded, for example, may have special difficulty in knowing whether the product works. Furthermore, can consumers know whether a product helps maintain the immune system or the cardiovascular system? Those suffering from hair loss may let their hopes for improvement cloud their judgment while they spend time and money on the product. Allowing false or unproven claims to be made routinely on commercial products, as a matter of policy, breeds distrust and cynicism about the commercial market.

The consumer's ability to judge the results, while it does not eliminate the need for regulation, has an important relevance to

117. See *supra* note 88.

118. See *infra* Part IV.D. The FTC weighs the cost and feasibility of studies against the other factors to ensure that the valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive. *Advertising Guide*, *supra* note 110, at 6. An advertiser cannot "make any claim it wishes simply because the cost of research is too high." See also Commission Report, *supra* note 1, at 70 (difficulties of long-term studies), and 69 (need for placebo studies and challenges for claims such as those for enhancing well being or the immune function).

the priorities for enforcement. The FDA's enforcement efforts sensibly should be focused first on safety, and next on claims beyond ready consumer evaluation. Effects which consumers can assess need less attention, but should still be subject to the possibility of enforcement action when circumstances warrant, especially for claims with complete lack of support.

The claims for supplements also indirectly affect their safety. The claims induce consumer use. If the product has no usefulness it needlessly leads consumers to be exposed to whatever risk the product has. While this may be considered to be solely a safety matter, the FDA views the safety and efficacy issues as interconnected in a risk-benefit determination of safety.¹¹⁹

The lack of effectiveness may affect the priority for enforcement action, as a way of forestalling needless risks, even if the safety risks are unknown or not well-documented.

IV. DISCLOSURE MODEL: HEALTH CLAIMS AND COMMERCIAL FREE SPEECH

A. Judicial Determination on Health Claims

1. Constitutional Basis for Disclosures

A different regulatory model, based on disclosures, has recently received acceptance in a court decision relating to supplements on constitutional grounds based on commercial free speech. Under this approach, Congress cannot "suppress" claims by requiring studies or scientific acceptance, but must instead allow the claim with disclosures qualifying it, unless there is a showing that such disclosures would be insufficient to prevent consumers from being misled. The Court of Appeals for the District of Columbia Circuit applied this "preference for disclosure over outright suppression" to health claims for dietary supplements in *Pearson v. Shalala*.¹²⁰

Health claims are claims for foods, about diet-related disease factors, such as the claims on breakfast cereals for the usefulness of fiber in relationship to heart disease.¹²¹ By law,

119. See Final Claims Rule, 65 Fed. Reg. at 1003; see also *infra* Part VI.B.3.b.

120. 164 F.3d 650, 657 (D.C. Cir. 1999) (rejecting the government's argument and relying on *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977)).

121. 21 U.S.C. § 343(r)(1) (1994); 21 C.F.R. § 101.81 (2000) (soluble fiber and

disease claims for foods can be made only with FDA approval, based on publicly available evidence and significant scientific agreement.¹²² While Congress gave the FDA the discretion to determine the tests and procedures to be applied to health claims for supplements, the FDA decided to use the same tests as those statutorily applicable to foods.¹²³

In *Pearson*, the supplements sought to make claims based on preliminary studies performed solely on foods. The court thought the FDA could not preclude the claims since the potential for deception could be dealt with by disclosures about the inconclusiveness of the studies and lack of agency approval.¹²⁴ The court remanded to the FDA to determine what specific disclaimers are needed to prevent deception. A claim may be barred if it is against the weight of the evidence and disclaimers would be confusing. The FDA could also seek to show consumers would be bewildered by disclaimers about the inconclusiveness of the supporting studies, but the court believed that the FDA would have to have “empirical evidence” that consumers would be confused.¹²⁵ On remand, the agency also has to provide better criteria for what constitutes “significant scientific agreement.”¹²⁶

2. Role of Significant Scientific Agreement

Health claims involve long-term effects in preventing diseases. Whether the effect occurs may not be determinable from controlled studies, for ethical and practical reasons, and may depend instead on the results of large-scale epidemiological studies or other evidence.¹²⁷ Epidemiological studies are often expensive and complex to interpret. In assessing claims in this context, experts rely on the strength, consistency and preponderance of data, and the degree of concordance of the evidence.¹²⁸ Having significant scientific agreement to support

coronary heart disease).

122. 21 U.S.C. §§ 321(g)(1), 343(r)(1)(B) & 343(r)(3)(B) (1994).

123. 21 U.S.C. § 343(r)(5)(D) (1994) (FDA can determine the “procedure and standard” for claims on nutritional supplements).

124. *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999).

125. *Id.* at 659

126. *Id.* at 660-61.

127. *Commission Report*, *supra* note 1, at 31.

128. Committee on Diet and Health, Nat’l Research Council, *Diet and Health: Implications for Reducing Chronic Disease Risk 5* (1989); *Commission Report*, *supra* note 1, at 31 vii and 35 (standard is appropriate and serves the public interest); Peeler & Cohen, *supra* note 110 (significant scientific agreement as principal guide for

the claim provides a high standard of evidence for claims that promote the public health and that have health importance. The FDA's guidance for significant scientific agreement indicates it is met "when the validity of the relationship is not likely to be reversed by new evolving science."¹²⁹

3. Remands, Disclaimers and the Lack of Scientific Agreement

On remand, the FDA adopted an "interim enforcement policy" pending consumer research and reconsideration of the general health claims regulation.¹³⁰ Under this policy, the FDA will not take enforcement action against supplement claims for which there is no significant scientific agreement if the claim is supported by the weight of the evidence and the claim can be qualified in a non-misleading way.¹³¹

Under the interim enforcement policy, when claims are permitted, no disclaimer is needed about the lack of significant scientific agreement. An illustration of the qualifying language FDA considers sufficient is provided by the agency's policy toward supplement claims for omega-3 fatty acids.¹³² The claim is to indicate that the studies on fish, while suggestive, are not conclusive, and that it is not known what effects the supplement "may or may not have" on the risks of coronary heart disease in the general population. While this qualifying language helps consumers, a disclaimer that the claim is not supported by significant scientific agreement (once the criteria is established) is better because it alerts consumers to the type of support that is missing.¹³³

advertisement of health claims under FTC's substantiation criteria in light of health importance of claims).

129. *Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, page 16, (visited Dec. 22, 1999) <<http://vm.cfsan.fda.gov/~dms/ssaguide.html>>. While significant agreement does not require "consensus in the sense of unanimity," or an "arbitrary quantitative criteria," it "represents more than an initial body of emerging evidence." The information relating to the claim needs to be available to the scientific community.

130. Notice, Food Labeling; Health Claims and Label Statements; Update to Strategy for Implementation of the Pearson Court Decision, 65 Fed. Reg. 59,855, 59,857 (Oct. 6, 2000).

131. *Id.* at 59,856.

132. Letter Regarding Dietary Supplement Health Claims for Omega-3 Fatty Acids and Coronary Heart Disease to Jonathan W. Emord, Esq., Oct. 31, 2000, available at <<http://vm.cfsan.fda.gov/dms/ds-ltr11.html>>.

133. *Constitutionalizing*, *supra* note 4, at 849, 851. Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress? Hearings Before the House Comm. On Gov't Reform, 106th Cong. (1999)

The FDA recently took another approach by requiring that a disclaimer for folic acid claims state that “FDA does not endorse this claim,” along with a succinct statement of the reasons.¹³⁴ This type of disclaimer makes it clear for consumers how a claim lacks the support an expert agency considers needed.

4. *Research Incentives and Preliminary Claims: Considering Alternative Non-Constitutional Grounds*

Congress gave the FDA discretion to determine the standards for health claims on supplements.¹³⁵ This delegation to the agency offered a way to resolve the issues without having to reach the constitutional issues.¹³⁶ In addition, this delegation allows the agency to consider whether there are ever circumstances which could justify allowing preliminary health claims. These circumstances can encompass the difficulties of doing long-term studies, and the need to provide research incentives.¹³⁷

One of the criteria which affects the testing needed to substantiate claims is the difficulty of doing studies. Long-term epidemiological studies to support health claims are particularly difficult and expensive. Supplement manufacturers also report they have difficulty in protecting their research investment because claims for a generic product are difficult to patent.¹³⁸

These factors do not, though, eliminate the need for a disclaimer about the lack of scientific support for preliminary claims, but they may make it appropriate to permit labeling claims that an acceptable research program is being undertaken to determine whether the preliminary claims can be

<http://www.house.gov/reform/hearings/healthcare/supplementn3_25_99/Gilhooley.htm>

134. Letter Regarding a Health Claim for Folic Acid and Neural Tube Defects to Jonathan W. Emord, Esq., April 3, 2001 (available at <<http://cfsan.fda.gov/~dms/ds-ltr22.html>>). The agency developed the disclaimer on remand from a District Court decision that FDA was incorrect in placing on the marketer the burden to show that a claim was supported by the weight of the evidence, and that once credible evidence exists for a claim, it should be allowed with disclaimers. *Pearson v. Shalala*, 2001 U.S. Dist. LEXIS 1253 (D. D.C. 2001)

135. 21 U.S.C. § 343(r)(5)(D) (1994).

136. *Constitutionalizing*, *supra* note 4, at 858.

137. KEYSTONE CENTER, *The Keystone National Policy Dialogue on Food, Nutrition and Health 77-84* (1996) (means for providing research incentives for foods and generic products include exclusivity, and royalties as well as increases public and private funding). *See also Herbal Remedies*, *supra* note 1, at 714-15.

138. Commission Report, *supra* note 1, at 69; *Constitutionalizing*, *supra* note 4, at 855, n. 211 and 214.

scientifically established. Approval of a “research-in-progress” claim could encourage manufacturers to undertake, individually or cooperatively, research programs eligible for the claim.¹³⁹

The FDA would need to identify the criteria for what makes a research program acceptable. The FDA might allow the claim only if scientists believe the preliminary claim is probably valid. The label should also indicate the expected duration of the research program to provide some impetus to finish the research. Such a program is an alternative to having a research limbo of preliminary claims which never get further tested.

B. Applicability of Disclosure Model to Other Supplement Claims

The *Pearson* decision has created uncertainty about whether there are other areas of food and drug regulation that are now constitutionally beyond Congressional control when the manufacturer provides disclaimers instead of meeting the statutory requirements. Arguably, for example, Congress could not require substantiation for structure and function claims on supplements.¹⁴⁰ Instead, manufacturers might claim they need only make a disclosure that the claim is based on inconclusive studies unless the FDA can show the claim is against the weight of the evidence. To be adequate, though, at a minimum, such a disclosure should indicate there is a lack of adequate scientific substantiation.

Some comments on FDA’s recent rule even maintained, based on *Pearson*, the First Amendment permits express disease claims to be made for supplements when accompanied by non-misleading disclosures about the basis for the claim and lack of FDA approval. The FDA rejected that comment, and pointed out:

If companies could avoid the time and expense of complying with the new drug provisions of the act merely by attaching a disclaimer to a disease treatment or prevention claim, the long-standing system of drug regulation in this country would be eviscerated, with serious public health consequences.¹⁴¹

The *Pearson* court also stated that drugs “appear to be in an entirely different category—the potential for harm presumably

139. See *Constitutionalizing*, *supra* note 4, at 854-57, n. 218, for a discussion of such a program based on legislative, and possibly administrative, grounds. The alternative of simply disclosing whether the manufacturer or others are conducting any tests is not as satisfactory, especially for claims that have health importance or that are beyond consumer assessment.

140. 21 U.S.C. § 343(r)(6) (1994). See also *infra* Part III.D.

141. Final Claims Rule, 65 Fed. Reg. 999, 1040 (2000).

is much greater.”¹⁴² This distinction in risk of harm is strongest for prescription drugs and claims that would divert consumers from more effective treatment for a serious condition.¹⁴³

A different question arises, though, if supplements are safe and claim to treat diseases in a way that does not pose serious harm, such as by treating mild disease conditions like those treated by OTC drugs for relief from fever. If commercial free speech permits claims to be made for mild disease conditions, with disclaimers, the claims for supplements would be expanded beyond the limits of the scope permitted by Congress in DSHEA. Whether the courts would go this far is uncertain, as well as what would be considered a claim for a mild and non-harmful condition. Would claims to prevent colds or treat arthritis be protected? The disclaimers needed and the means to ensure that the products are safe are important questions given this possible expansion on constitutional grounds of the opportunity for claims for supplements and other products.

V. TRADITIONAL MEDICINES AND A DISCLOSURE MODEL

A. Policy Proposal for Traditional Medicines

What constitutes adequate disclaimers for disease claims on supplements is a policy issue that the Commission extensively discussed. This discussion indicates the difficult issues involved and the importance of the type of disclaimers. Similar issues would also arise if the courts were to consider recognizing disease claims for mild conditions as constitutionally protected under commercial free speech.

Most Commission members believed supplements should be able to make express disease claims about their traditional uses, provided there was other support and the label bore a disclaimer that the support is based on traditional use. They believed this would be better and less confusing than the system created by DSHEA under which dietary supplements are sold with

142. *Pearson v. Shalala*, 164 F.3d 650, 656, n. 6 (D.C. Cir. 1999).

143. While the *Pearson* court considered drugs to be different, there has been inconclusive litigation on whether commercial free speech protects the promotion of new claims for prescription drugs by manufacturers to doctors through the distribution of medical journal reprints and continuing medical education programs. See *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000), dismissing the appeal from *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), and *Constitutionalizing*, *supra* note 4, at 815-44.

structure and function claims which can indirectly suggest disease use to consumers, and which “may also create a climate of deception that serves neither the industry nor consumers.”¹⁴⁴

B. Disclaimers Needed and Scientific Standards

The Commission agreed that this approach deserved more study as a policy matter in light of international models. However, in my view, a disclaimer is not adequate if it merely says the support is based on use as a traditional medicine. Instead, if disease claims are to be made, the disclosure should say “not based on adequate and well-controlled studies and not generally recognized as effective.”¹⁴⁵ This approach to disclaimers is like the one suggested earlier: the disclaimer needs to clearly state whether or not the claim is based on scientific testing and standards.¹⁴⁶ Whatever role tradition may have in identifying potential effective ingredients, scientific testing is needed to have reliable proof. The effort to regulate disclosures tests whether science and medical expertise sets the standard for what makes a claim reliable and what the consumer needs to know.

If disease claims are to be allowed on scientifically unproven “safe” products or supplements, it should not be on the basis that they really work, but that the consumer should have the freedom-of-choice to use even unproven products when consumers are adequately informed of the choice being made.¹⁴⁷ This requires clear disclosures. The directness and bluntness of disclosures, if adequate, may lessen the appeal of making these claims.

C. Dietary Supplements and Freedom of Choice

Dietary supplements have become the way in practice to

144. Commission Report, *supra* note 1, at 55-56.

145. *Id.* at 52-54; *Herbal Remedies*, *supra* note 1, at 709-22.

146. *See infra* Parts III.C.3.d, IV.A.3.

147. *Herbal Remedies*, *supra* note 1, at 715-22. *See also* J. Richard Crout, *The Nature of Regulatory Choices*, 33 *FOOD DRUG COSM. L. J.* 413, 422 (1978) (stating:

The drug regulatory laws deal with science and to risk its essential features in the political arena over relatively innocuous product is to court a serious long-term setback in the rational control of powerful chemicals in our society. . . . [T]he choice is between competing good values—do we want scientific rationality or personal freedom? And if we want the latter, are we willing to pay the price of a few frauds here and there?)

See also Herbal Remedies, *supra* note 1, at 716, 719-21.

provide consumers with the opportunity to choose a product which may be used for disease purposes without the type of scientific testing needed for approval of claims. DSHEA allows non-food products to be sold as supplements, and the supplement claim may indirectly suggest these broader uses. While imperfect, DSHEA may continue to have this indirect role of providing choice to consumers on an off-label basis about unproven disease uses. While other approaches may be better, it is doubtful that there would be agreement on the disclaimers needed or the willingness of Congress to permit disease claims based on disclaimers.¹⁴⁸

VI. SAFETY OF SUPPLEMENTS

A. *Changes Made By DSHEA's Safety Standard*

Whether the safety of supplements under the deregulatory scheme established by DSHEA provides adequate means to protect consumers from unsafe products needs evaluation. Consumers experiment with the new uses of dietary supplements because consumers assume they are safe. The "dietary" designation may lead consumers to believe the supplements are as safe as foods.

Dietary supplements are not, though, subject to any pre-market approval for safety. DSHEA exempted supplements from being considered "food additives."¹⁴⁹ The food additive provisions ordinarily necessitate FDA approval of the safety of substances added to foods, unless the substance is generally recognized by experts as safe based on scientific testing or use in food before the adoption of the statute in 1958.¹⁵⁰ Before DSHEA, judicial decisions had narrowed the applicability of the food additive provisions by the finding that single ingredient supplements sold in gelcap form were not food additives and were subject only to the requirements governing non-added foods.¹⁵¹ However, the judicial decisions were made at a time when supplements had to be foods in a nutritional sense. The exemption in DSHEA from the food additive requirements includes herbal supplements with no nutritional value or history

148. See *Herbal Remedies*, *supra* note 1, at 721-24.

149. 21 U.S.C. § 321(s)(6) (1994).

150. 21 U.S.C. §§ 321(s), 348 (1994).

151. *United States v. 29 Cartons of an Article of Food*, 987 F.2d 33 (1st Cir. 1993); *United States v. Viponte Ltd. Black Currant Oil*, 984 F.2d 814 (7th Cir. 1993).

of use in food, a far broader category.

Under DSHEA, the FDA has the burden of showing that a supplement poses “significant or unreasonable risk” under the doses stated on the label before use can be limited.¹⁵² The test is similar to the one that applied to foods under the first FDA Act passed in 1906, at the turn of the last century.¹⁵³ Now, though, the FDA can use rulemaking as well as court proceedings to enforce the provision.¹⁵⁴

B. Need for Safety Substantiation Requirement

1. Drawbacks of DSHEA Safety Provisions

An important problem with supplements is the unknown. According to the FDA, the safety and benefits of “many” supplements has not been proven by adequate testing.¹⁵⁵ There also have been a number of reports of adverse reactions from supplements.¹⁵⁶ Some relate to contamination with drugs or heavy metals.¹⁵⁷ Some involve interactions with drugs, including the possible interaction of St. John’s Wort with anesthesia used for surgery.¹⁵⁸ Some involve quality control problems.¹⁵⁹ Confusion about the name of a Chinese herb led to

152. 21 U.S.C. § 342(f) (1994).

153. 21 U.S.C. § 342(a) (adding that substances in foods violate the law if the substance “may render [the food] injurious to health”). The Supreme Court interpreted the standard as not applying if the substance “cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer.” *United States v. Lexington Mill Co.*, 232 U.S. 399, 411 (1914).

154. 21 U.S.C. § 371(a) (1994). This provision was recognized as giving the agency the authority to issue substantive rules in *National Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975).

155. *Final Claims Rule*, 65 Fed. Reg 999, 1003 (2000). See also Laurie Tarkan, *Natural Remedies for Menopause Gain Popularity, But Self-Treatment to Alternatives to Hormone Replacement Therapy carries Risk, Experts Warn*, N. Y. TIMES, June 20, 2000, at F7.

156. M. Angell & J.P. Kassirer, *Alternative Medicines—The Risks of Untested and Unregulated Remedies*, 339 NEW ENG. J. MED. 839 (1998).

157. Guy Gugliotta, *Health Concerns over Herbal Aids; As Industry Booms, Analysis Suggests Rising Toll in Illness and Death*, WASHINGTON POST, March 19, 2000, at A O1 (reporting its own “first national survey” including reports from poison control centers, and findings by California investigators in ‘1998 that one-third of imported Asian herbals were “spiked with drugs not listed on the label or contained lead, arsenic or mercury.”) (Heavy metals may be viewed as beneficial in traditional medicines).

158. Eric Nagourney, *A Warning Not to Mix Surgery and Herbs*, N.Y. TIMES, July 6, 1999, at F5.

159. FDA has the express authority to establish good manufacturing practices for supplements, and these rules could provide an alternative way to deal with some safety-

a manufacturing error and the inadvertent use in a weight loss supplement of a different herb which not only caused renal failure but also cancer.¹⁶⁰

2. *Safety Substantiation as Preferable to DSHEA*

A major weakness in DSHEA is that it does not impose on all dietary supplements the burden and obligation to affirmatively substantiate their safety. DSHEA imposes a requirement for safety substantiation, but limits it to new ingredients sold after 1994, and defines “new” in a narrow way to exclude “any” dietary ingredient marketed before DSHEA, apparently even if for a different use.¹⁶¹ While not without ambiguity, no substantiation seems required when new claims are made. All the supplements, whether sold before or after 1994, should have to substantiate their safety.¹⁶²

If manufacturers had to substantiate safety, they would have to perform tests, in accordance with scientific standards, to determine risks and establish a safe level. They would have a responsibility to follow-up on adverse reaction reports, and undertake whatever testing or changes scientists would consider necessary to assure safety.

Because of the health importance of safety risks, significant scientific approval is also relevant in determining whether the product has been substantiated.¹⁶³ There may be times, though, in which a process of a publicly disclosed independent evaluation of the testing by highly qualified experts could be viewed as tantamount to scientific acceptance. A proxy system needs consideration because there can be difficulties in achieving actual scientific acceptance when new adverse reactions occur, or if peer-reviewed journals do not publish studies for these products.¹⁶⁴

related problems. 21 U.S.C. § 342(g)(2) (1994).

160. J.L. Nortier et al., *Urothelial Carcinoma Associated with the Use of a Chinese Herb*, 342 NEW ENG. J. MED. 1686 (2000).

161. 21 U.S.C. § 350(b) (1994). Perhaps when the level of use recommended has changed significantly, the supplement might be considered new, but this is debatable. *Herbal Remedies*, *supra* note 1, at 704.

162. The Report of the FDLI Futurist Task Force on Dietary Supplements projected that it is “not unlikely” that the law may be amended to impose some additional safety-related requirements for supplements, which might take the form of an obligation to substantiate safety. 55 FOOD & DRUG L.J. 17, (2000).

163. See criteria for safety substantiation in Part III.D.2.

164. Manufacturers may also have concerns about protecting trade secrets. See *infra* Part III.D.3.

3. *Ephedrine, Weight Control and Safety Determinations in Practice*

a. *Effort Needed to Regulate*

Under the present safety provisions of the DSHEA, the difficulty and resource burdens of regulating supplements is demonstrated by the FDA's inconclusive effort to limit the amount of ephedrine in supplements. This effort also is a case-study of some issues which can arise in determining the safety of supplements, no matter what model of safety regulation is used, including how to identify the use, how to deal with overuse, how to make warnings adequate and how to determine acceptable risk.

The proposed rule took 55 pages in the Federal Register, and identified 800 adverse events, and some deaths, associated with supplements containing ephedrine. These reports amounted to half of all adverse reactions reported for all forms of supplements.¹⁶⁵ Ephedrine is an "amphetamine-like compound."¹⁶⁶ The proposal limited the levels of ephedrine in individual doses, the length of use to no more than 7 days, and provided for warnings that exceeding the limits "may cause heart attack, stroke, seizure or death."¹⁶⁷

The proposal would have allowed claims for short-term use such as for alertness or increased energy.¹⁶⁸ However, the proposal precluded any claim for weight loss, because weight loss cannot be safely or effectively achieved in a short period of time, and use beyond seven days posed unreasonable risks.¹⁶⁹ The proposal thus viewed any weight loss claim as one implicitly for an intended use for a long period that created risks, rather than as a matter of misuse by the consumer in excess of the labeling instructions. Under the DSHEA, safety is determined based on the dose levels "recommended or suggested in the labeling."¹⁷⁰

Before the election, the FDA partially withdrew its proposal

165. *Proposed Ephedrine Rule*, 62 Fed. Reg. 30,677, 30,678 (1997).

166. *Proposed Ephedrine Rule*, 62 Fed. Reg. at 30,678. See *infra* note 87 for concerns about diversion of OTC ephedrine products. The ephedrine in some weight control products is claimed by the manufacturer not to be susceptible to diversion.

167. *Proposed Ephedrine Rule*, 62 Fed. Reg. at 17,476.

168. *Id.* at 30,718. 21 C.F.R. § 111.100(f)(1).

169. *Proposed Ephedrine Rule*, 62 Fed. Reg. at 30,697.

170. 21 U.S.C. § 342(f) (1994).

to limit ephedrine use, pending further consideration in light of a recommendation by the General Accounting Office that the FDA “provide stronger evidence” for the proposal and greater “transparency” in its cost-benefit analysis.¹⁷¹ The FDA is considering information on 270 additional adverse events not known at the time of the proposal and has invited public comment on whether the proposed limits or alternatives are needed.¹⁷² The effect of the FDA’s re-consideration of the proposal is to leave the issue of how to regulate ephedrine to the new Administration.

b. Determining Safety: Risk / Benefits, and Acceptable Risks

One alternative which may be raised is whether use for ordinary weight loss claims can be considered safe under some conditions that limit the length and amount of use.¹⁷³ In an effort to understand the choices regulators face, one might hypothetically consider whether the permissible dose could be reduced to a quarter of the amount to allow use for a month for ordinary minor weight reduction. If any weight loss claims are allowed for ephedrine products, however, there remains a risk consumers will exceed the label limits. That risk is greater, if, as is often the case, increasing the dose increases effectiveness, but also the risks.

The FDA’s authority with respect to safety is based on the “conditions of use recommended or suggested” in the labeling.¹⁷⁴ When the agency’s authority is restricted to claims about intended uses, the labeling needs to be especially clear about the use intended and the consequences of overuse.¹⁷⁵ Furthermore,

171. Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, 65 Fed. Reg. 17,474, at 17,475 (2000) (proposed Apr. 3, 2000) [hereinafter Ephedrine Rule Withdrawal].

172. *Id.* See also 65 Fed. Reg. 17509 (2000) (providing for availability of additional adverse reaction reports).

173. The FDA’s proposed and final rule on supplement claims recognizes that supplements can claim to be for ordinary weight loss, since that condition is different from treating obesity, and is not itself a disease. Final Claims Rule, 65 Fed. Reg. 999, 1027 (2000). The use of ephedrine for weight loss may expand because of FDA’s plans to propose the withdrawal use of phenylpropanolamine (PPA) in over-the-counter drugs because of risk of stroke. While OTC marketers are switching to pseudoephedrine as a replacement for PPA in OTC decongestants, there is no alternative OTC ingredient for use as an appetite suppressant, and manufacturers may market the product using the herbal ephedrine. See Jeff Gerth & Sheryl Gay Stolberg, *Another Part of the Battle: Keeping Drugs on the Shelves of Stores*, N.Y. TIMES, Dec. 13, 2000, at 31.

174. 21 U.S.C. § 342(f) (1994).

175. The type of labeling to alert consumers about risks can be regulated by the

as the ephedrine proposal illustrated, the use of the supplement can be identified in a way that attributes the risk to the intended use rather than to overuse. The possibility of redefining and limiting the claim to make the use safe, if the limits are observed, also illustrates the tension between claims and misuses, and the opportunities for compromise and pragmatic judgments under DSHEA that some may bemoan and some may accept.

To pursue the analysis of a possible dosage reduction, if the product poses significant risks for ordinary limited weight loss, even when used at one-quarter of the dose or other restrictions, it should not be permitted. Such a product should be viewed as posing a significant risk not permissible under DSHEA.¹⁷⁶ The adequacy of the risk information and scientific evaluations, in light of the comments, will be key in making that determination. The effectiveness of the product in achieving its claimed effects on a limited basis also has relevance. If the effectiveness of the claim cannot be substantiated, there is a separate reason for precluding it.¹⁷⁷ Whether to allow time for additional studies to substantiate its effectiveness with the dose restrictions also needs to be considered.

In addition, the FDA has stated that the safety of supplements has to be determined on a risk-benefit basis in light of the health benefits claimed.¹⁷⁸ This type of risk-benefit balancing is used for determining drug safety, but is not typically used for foods, nor, until now, for supplements. As a result, there is an interconnection between the substantiation of the effectiveness of supplements and the determination of the acceptability of the risks it poses. If the product is ineffective for limited weight loss under its labeling restrictions, its ineffectiveness may also tempt users to exceed the dose restrictions and incur greater risks that are unreasonably high.

The acceptable level of risk from the intended dose raises a different issue. The appropriate benchmark test for determining acceptable risk would seem to be the scale of risks associated with OTC drugs. This approach would seem to lead to permitting only fairly limited risks in the interest of furthering consumer safety.

FDA based on its authority to prevent deceptive labeling, 21 U.S.C. § 343(a)(1) (1994).

176. 21 U.S.C. § 342(f) (1994).

177. 21 U.S.C. § 343(r)(6) (1994) (substantiation requirement).

178. Final Claims Rule, 65 Fed. Reg. at 1003.

c. Risks from Misuse: Labeling and Distribution Limits

When prescription drugs pose risks, the matter is typically dealt with by providing additional warnings to physicians that limit the use of the drug, and redefine the approved and appropriate use of the drug.¹⁷⁹

Supplements are used by ordinary consumers, though, and when overuse poses serious risks, the label needs to identify clearly to lay users the parameters of the appropriate use, and the dangers of exceeding these limits. The FDA-proposed warning for ephedrine seems blunt, referring as it does to risks of “heart attack, stroke, seizure, or death.”¹⁸⁰ Still, to ensure consumer awareness, the warning may need to be a boxed warning, like those used in prescription drug labeling for serious warnings. This type of prominence would seem especially necessary if any type of weight loss claim were to be allowed because of the risk that the label restrictions will be exceeded to enhance the effects.

More study is also needed on ways to make information on the labeling about risks more real and understandable for lay users. The labeling may need to convey information to consumers about risk factors associated with increased risk.¹⁸¹ Perhaps, package inserts should provide real-life examples of the harm suffered by typical users (without names) who used the product at doses in excess of the labeling. The FDA proposed rule provided reports of harm to individuals from the use of ephedrine in various products.¹⁸²

Finally, if the revised labeling and warnings are insufficient to prevent a widespread overuse of a product that causes a substantial number of deaths and serious harm, other measures may need to be considered, including possible limits on distribution. Perhaps users should be required to consult a physician before using supplements for a purpose which leads to wide, harmful overuse. The advice from physicians can make consumers better able to understand the risks and intended use, and help ensure there is a medical justification for exposure to greater risks.

Whether the FDA could impose such limits under the

179. See 21 CFR § 201.57(e) (2001) (requiring label revisions “as soon as there is reasonable evidence of an association of a serious hazard” with the drug).

180. Proposed Ephedrine Rule, 62 Fed. Reg. at 30,718.

181. *Id.* at 30,687, 30,692.

182. *Id.* at 30,718-24.

existing law is uncertain. The FDA's effort to restrict the distribution of prescription drugs to prevent harm when physicians failed to comply with labeling restrictions has been judicially rejected.¹⁸³ Removal of a drug to prevent risks has been upheld, though, notwithstanding there may have been some safe uses for which the drug could have been labeled.¹⁸⁴ The FDA has also conditioned approval of drugs on distribution limits, based on the manufacturer's voluntary acceptance of the restrictions, or the approval of the drug on an expedited basis.¹⁸⁵ Thus, the FDA might seek to have the manufacturer accept voluntary limits on the distribution of supplements. The agency might also test whether distribution limits can be required to make a product sold to consumers safe with respect to risks of overuse which foreseeably occur under the suggested labeling. This position has added strength when consumers are using the product for the use indicated on the labeling but regularly exceed the stated dose.¹⁸⁶

4. Need for Legislative Action

a. Authority, Inspections and Adverse Reaction Reporting

The FDA could use the existing law to induce manufacturers indirectly to substantiate the safety of all supplements, by requiring a warning if there is inadequate substantiation of the safety.¹⁸⁷ Legislative action to require safety substantiation for

183. *American Pharm. Assoc. v. Weinberger*, 377 F. Supp 824 (D.D.C. 1974), *aff'd sub nom American Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam).

184. *Forsham v. Califano*, 442 F. Supp 203 (D.D.C. 1977).

185. Margaret Gilhooley, *When Drugs Are Safe for Some Uses But Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927-45 (1999).

186. In the 1950's, the FDA was able to require that certain drugs be sold only by prescription based on the requirement that drugs bear adequate directions for use. *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951) (citing 21 U.S.C. § 352(f) (1994)). The agency found consumers could not understand the proper safe use without medical advice, but there may also have been a concern about protecting consumers from misuse of the products, contrary to the labeling, given that the product at issue was testosterone. *Id.* at 65. The approach suggested here is similar in not being based on a specific statutory authority to limit distribution or require a prescription, and in having a similar rationale that the products are not safe, as labeled, without the additional advice provided by physicians. If the FDA does not have the authority under the existing law to impose additional limits to prevent substantial harm in this setting, change in the law may need to be considered.

187. The warning would be based on the authority to prevent deceptive claims and omissions. 21 U.S.C. §§ 321(n), 343(a) (1994). Based on similar authority, FDA has

all supplements is preferable, though, because the obligation would be direct and the legislation can provide for inspection of records, and other measures to ensure that manufacturers meet their obligation to determine the safety of supplements. These measures also include having a better system for determining adverse reactions from supplements, and a system for registration or identification of establishments making supplements.¹⁸⁸

b. Resources and a Substantiation Assurance Fee

Congress also needs to provide adequate resources to the agency to monitor substantiation. Congress should require those who market dietary supplements to pay a "substantiation assurance fee." When there is no pre-market approval, the government has to determine whether products are safe and whether the claims have been substantiated after the products are marketed. This fee would cover the government's extra costs for monitoring the safety and efficacy of supplements.

To ensure monitoring of the appropriate level for the fee, the authorization for the fee should have a five-year life, like that for user fees for new drugs.¹⁸⁹ Moreover, some type of independent survey should be done to determine the extent of safety problems and inappropriate claims being made for supplements in the market. Congress could use the survey as a barometer to judge the extent and severity of the problem in order to determine the level of resources and fees needed.

The substantiation assurance fees could be based on the notification filed by supplement manufacturers for new claims as required by DSHEA.¹⁹⁰ Although the fee would be flat, there should be some differentiation between the fees charged small businesses and other businesses.

5. Substantiation Model versus Food Additive Model

The substantiation model now seems a more relevant model for determining the safety of supplements than the food additive model of pre-market approval. The risk-benefit determinations

called for warnings about the lack of substantiation for cosmetics. 21 C.F.R. § 740.10 (2000). See also *Herbal Remedies*, *supra* note 1, at 703.

188. David A. Kessler, Editorial, *Cancer and Herbs*, 342 NEW ENG. J. OF MED. 1742, 1743 (2000).

189. 21 U.S.C. § 379(h) (1994 & Supp. III 1997).

190. 21 U.S.C. § 343(r)(6) (1994).

the FDA intends to make for supplements are not typically made for food additives.¹⁹¹ Moreover, if Congress were to repeal the food additive exemption, the legislation would likely provide a transition period, or grandfathering, which would make pre-market approval generally irrelevant.

6. Priorities for Substantiation

The FDA should identify which aspects of safety substantiation need to be addressed first if an obligation to substantiate is established. Presumably, the need for substantiation is greatest with respect to supplements for which serious adverse reactions have occurred, supplements with ingredients that have a potential for risks, supplements used for long periods by large numbers, and supplements for which no regularized substantiation review program has been undertaken. The agency should identify its priorities for taking enforcement action and for investigating whether the substantiation obligation has been met. While only advisory, a clear statement by the agency of its enforcement policy can provide for a transition in the initial years of implementation and reduce resistance to a recognition of the obligation.¹⁹²

7. Commercial Free Speech and Safety Substantiation

When the *Pearson* court found that commercial free speech permitted health claims for supplements with disclaimers, the court took particular notice that there was no dispute about the safety of the supplements.¹⁹³ The supplements at issue in that case were nutritional supplements, the only type eligible by statute to make health claims, and their safety was not an issue.¹⁹⁴ Safety is more problematic when claims are made for herbal supplements, without a history of food use, and safety needs more consideration if commercial free speech were ever extended to disease claims or other claims for herbal non-nutritive supplements.

The safety of supplements clearly constitutes a substantial

191. Diethylstilbestrol: Withdrawal of Approval of New Animal Drug Application, 44 Fed. Reg. 54,851, 54,882-83 (1979) (disavowing earlier FDA position that benefits are considered in determining the safety of food additives).

192. Compare Part II.D.

193. *Pearson v. Shalala*, 164 F.3d 650, 655-56 (1999). See also *infra* Part IV.A.

194. 21 U.S.C. § 343(r)(5)(D) (1994) (providing for health claims for nutritional substances).

government interest. Congress' authority to require pre-market approval to ensure safety does not seem open to challenge.¹⁹⁵ Some may question whether Congress can adopt a safety substantiation model that puts the burden on the manufacturer to have affirmative proof that the product is safe. If raised, that contention should be rejected. Placing the substantiation requirement on the manufacturer directly promotes the government's interest in protecting the public health. The means used must also constitute a reasonable fit in achieving the goal, but the means need not be the least restrictive.¹⁹⁶ While the use of a court enforcement model has lesser burdens for manufacturers, a safety substantiation model provides a better assurance of safety by recognizing the affirmative obligation of manufacturers to determine that the products are safe when ingested. The burden the FDA has in using an enforcement model indicates the need for better means to safeguard the public health and prevent deception.

VII. CONCLUSION

DSHEA is an experiment in deregulation. It creates what the FDA has called "a unique regulatory regime."¹⁹⁷ The products are not regulated as rigorously as either foods or drugs. It is an imperfect law because of the peculiarity of calling herbal products "dietary" when they have no food use, and the claims relate to the effects of drugs. DSHEA is an oblique way of providing freedom-of-choice to consumers who may use the products for unproven disease purposes indirectly suggested by the labeling.

The FDA, by rule, has recognized a wide number of claims as permissible structure and function claims for supplements. Some of the claims are vague, like supporting mood or maintaining cardiovascular function. The FDA recognizes that some claims, such as maintaining the immune system, relate to disease and non-disease functions. Some permitted claims deal with the effects of life stages, like hair loss, absentmindedness, or decreased sexual function. In drawing the disease line, the FDA was influenced by the generality of the claim, the lack of references to specific disease symptoms, and the need to avoid

195. For constitutional test, see *Central Hudson Gas & Elec. Co. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). See also *Constitutionalizing*, *supra* note 4, at 823-28.

196. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989).

197. Final Claims Rule, 65 Fed. Reg. at 1002.

safety risks which arise if a claim deters treatment for serious conditions beyond the ability of the consumer to judge.

The generality of some of the claims permitted can still confuse consumers and indirectly suggest the need for use to prevent disease. Many claims should have been more specific in identifying that the supplement use is for a minor condition or for maintaining a normal physical function which the consumer can ascertain and understand.

The most serious problem with DSHEA is that it is an experiment in the use of supplements when their safety is not well known. The FDA bears the burden of proving that supplements are unsafe. Instead, manufacturers should be required to substantiate the safety of all supplements. The agency's inconclusive effort to regulate ephedrine illustrates the challenges in determining safety and the need to identify and communicate effectively the limits of permissible uses.¹⁹⁸

The substantiation model has a potential for being an appropriate alternative scheme for regulating both the safety of supplements and the validity of non-disease claims. Substantiation involves neither the delays to the industry of pre-market review, nor the drawbacks to the public of making the government, rather than the manufacturer, affirmatively prove a supplement works and is safe. But to make the intermediate substantiation model work, the FDA needs to have clear and enforceable authority to require substantiation. Requiring manufacturers to pay the government a substantiation assurance fee is a way to provide needed resources to help enforce the law. Without adequate resources and authority, the substantiation obligation can be an empty shell.

A disclosure model has been allowed for health claims on supplements on constitutional grounds. Supplements can make the health claim with a disclosure about the inconclusiveness of the studies, and the lack of FDA approval, even if the supplement does not have the support or scientific recognition otherwise required.¹⁹⁹ When disclosures relate to claims which rely on scientific testing and recognition, the disclosure should indicate that the determination goes beyond a lay judgment and needs expert scientific support. Thus, consumers should be informed about the lack of significant scientific approval for the

198. See Part VI.B.3.

199. *Pearson v. Shalala*, 164 F.3d 650 (1999). See also *supra* Part IV.A.

claim. Formulating what needs to be said in disclosures involves a judgment about how important science is as the standard of reliability.

The FDA's efforts to regulate supplements since DSHEA provide some examples of the collaborative approach which has been suggested as a model for administrative governance. The FDA holds public meetings and involves "stakeholders" in developing rules.²⁰⁰ At a more basic substantive level, the expansiveness of the claims for supplements allowed in the FDA rule can be seen as a pragmatic effort at problem solving in light of Congress' interest in broadening the claims allowed. The agency has had to come to terms with a statutory change which permits a greater role for consumer choice for an ambiguous category of supplement claims.

Some vision needs to guide the agency's response to objections to regulatory proposals and collaborative efforts, if the agency's role is to be something more than splitting the difference with the most persistent, or avoiding litigation and trouble with Congress. The agency has a role which goes beyond that of private participants in a negotiation.²⁰¹ The agency has a mission to promote the goals identified by Congress in the law. If the agency's core role becomes that of achieving consensus with private parties and regulated entities, the statutory scheme in practice is likely to be deregulated, without Congress having to assume the responsibility to the public for that decision.

The agency, though, is not simply an implementer of clear statutory directions. The food and drug laws have, for purposes of interpretation, been described "as a constitution", and the agency is to develop "whatever innovative and creative regulatory programs are reasonable and most appropriate to achieve the fundamental objectives laid down by Congress."²⁰² This view of the scope of the delegation is consistent with seeing the agency as a problem-solver whose goal is to consider new approaches to deal with emerging concerns in a way consistent with the overall statutory aims.²⁰³

200. The agency has set forth its "Dietary Supplement Strategy," which included public meetings on the plan, regulations, "FDA's new and continued partnerships with other government agencies, academia, health professionals, industry, and consumers," and continued "outreach to stakeholders." <<http://vm.cfsan.fda.gov/~dms/ds-strat.html>>.

201. Funk, *supra* note 13, at 1356.

202. Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD, DRUG, COSMETIC L.J. 177 (1973).

203. See Mashaw *supra* note 14, at 156 (delegation to expert agencies "becomes a

With respect to dietary supplements, Congress has given an ambiguous and difficult task to the agency. While the agency's power has been reduced, Congress did not adopt a laissez-faire approach. The supplements are still regulated within the framework of FDA responsibilities as a scientific and public health agency. The agency has to sort out how to let consumers have access to supplements while ensuring that supplements do what they claim to do, and do not pose a public health risk.

The agency needs to re-formulate how its core statutory mission is at stake in a way which will have public acceptance. The identification of safety concerns as a major purpose behind the rules on supplement claims helps to provide a useful guide. The safety concerns are strongest when they relate to risks of harm like those associated with prescription drugs, and claims for serious conditions beyond the ability of the consumer to judge without medical advice. Even in a deregulatory statute which promotes consumer choice, the potential to cause serious harm is a risk against which the public needs and, presumably, still wants protection.

Moreover, given the regulatory philosophy which emphasizes consumer choice, more attention needs to be given to the type of specific information consumers need to make informed choices. One challenge is whether it is possible to develop adequate information to educate lay consumers. The other challenge is dealing with resistance to better labeling. The adequacy of labeling, and the adequacy of the agency enforcement resources, promise to be the new battlefield in determining whether there is an adequate "third way" to regulate and deregulate consumer products like dietary supplements.

form of consensus building that, far from taking decisions out of politics, seeks to give political choice a form in which potential collective agreements can be discovered and its benefits realized").