FDA EFFORTS TO CONTROL THE FLOW OF INFORMATION AT PHARMACEUTICAL INDUSTRY-SPONSORED MEDICAL EDUCATION PROGRAMS: A REGULATORY OVERDOSE†

*Charles J. Walsh**
*Alissa Pyrich***

TABLE OF CONTENTS

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* Charles J. Walsh is a member of the firm of Sills Cummis Zuckerman Radin Tischman Epstein & Gross, P.A. Newark, N.J. B.S. 1964 and M.A. 1972 (Economics), Fordham University; L.L.B. 1967, University of Pennsylvania.

** Alissa Pyrich is an associate at the firm of Sills Cummis Zuckerman Radin Tischman Epstein & Gross, P.A., Newark, N.J. B.A. 1989, Fordham University; J.D. 1992, Harvard Law School.

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I. INTRODUCTION

Pharmaceutical companies traditionally have spent significant amounts of money promoting and advertising their products in formats such as medical journals.[1] These advertisements are regulated by the United States Food and Drug Administration (FDA), which also regulates the sale of the drug products themselves. This control of both product and information gives the FDA a unique degree of regulatory authority over pharmaceutical companies.[2]

The past decade, however, has seen substantial changes in both the prescription drug market and the advertising media. Pharmaceutical companies, for example, have begun to use several vehicles for disseminating product information which do not fall within the traditional spheres of FDA regulation.[3] Partly as a reaction to this trend, the FDA has become increasingly aggressive in

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[1] Since the 1970s, the money spent by pharmaceutical companies to promote and advertise their products has increased substantially, to an estimated $5 billion per year. *Advertising, Marketing and Promotional Practices of the Pharmaceutical Industry: Hearing Before the Senate Comm. on Labor and Human Resources*, 101st Cong., 2d Sess. 1 (1990) [hereinafter *Advertising, Marketing and Promotional Practices*] (statement of Senator Edward M. Kennedy). For a survey of pharmaceutical industry marketing expenses, *see also* Alexa Boer, *Pharmaceutical Advertising in Medical Journals*, 268 JAMA 147 (1993); W. Benjamin Fisherow, *The Shape of Prescription Drug Advertising: A Survey of Promotional Techniques and Regulatory Trends*, 42 FOOD DRUG COSM. L.J. 213 (1987); Keith B. Leffler, *Persuasion or Information? The Economics of Prescription Drug Advertising*, 24 J.L. & ECON. 45, 52-53 (1981); Richard B. Ruge, *Regulation of Prescription Drug Advertising: Medical Progress and Private Enterprise*, 32 LAW & CONTEMP. PROBS. 650, 651 (1967).

[2] *See* Richard T. Kaplar, *The FDA and the First Amendment*, *in* BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION 43, 45-47 (Richard T. Kaplar ed., 1993) [hereinafter BAD PRESCRIPTION]; Fisherow, *supra* note 1, at 231. Advertising for products other than prescription drugs is regulated by the Federal Trade Commission (FTC).

[3] *See* Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 FOOD & DRUG L.J. 309, 309 (1992). The increasing competitiveness in pharmaceutical advertising has also af-

asserting its authority to control all statements about prescription drugs.[4] Activities by pharmaceutical companies which previously had not been thought to be labeling or advertising have come under increased scrutiny from the FDA in the past few years.[5]

Among such activities are scientific and educational symposia or forums funded or otherwise sponsored by pharmaceutical companies. While the pharmaceutical industry always has been involved in such endeavors, its involvement has increased significantly in recent years.[6] FDA officials and medical professionals have increasingly expressed concern that industry-sponsored educational and scientific programs are no more than thinly-veiled advertising fairs, presenting biased or inaccurate information.[7]

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fected the content and tenor of print advertising to physicians. Fisherow, *supra* note 1, at 229.

4 Although the FDA has no direct statutory authority to regulate statements that are not within the definitions of labeling or advertising, the agency "has defined its own authority in this area to cover virtually any material issued by or sponsored by a drug manufacturer." David A. Kessler & Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising and Promotion*, 264 JAMA 2409, 2409 (1990).

5 The FDA has afforded closer regulatory attention to various practices, which include: the promotion of medical devices, see Sandra J.P. Dennis, *Promotion of Devices: An Extension of FDA Drug Regulation or a New Frontier?*, 48 FOOD & DRUG L.J. 87 (1993); statements by company detailers (local sales representatives), see Noah, *supra* note 3; and product health claims, see Peter B. Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSM. L.J. 3 (1986); Elisabeth A. Sachs, *Health Claims in the Marketplace: The Future of the FDA and the FTC's Regulatory Split*, 48 FOOD & DRUG L.J. 263, 264-68 (1993). *See generally* Richard M. Cooper, *Marketing "Violations,"* 47 FOOD & DRUG L.J. 155 (1992). In addition, the FDA has also increased pressure on physicians to avoid off-label uses of prescription drugs. William L. Christopher, *Off-Label Prescriptions: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 250-52 (1993).

6 In 1975, the pharmaceutical industry spent approximately $6 million, adjusted for inflation, in funding and sponsoring educational or scientific programs. By 1988, studies revealed that the pharmaceutical industry contribution had increased to nearly $86 million. Lisa A. Bero et al., *The Publication of Sponsored Symposiums in Medical Journals*, 327 NEW ENG. J. MED. 1135, 1135 (1992); *see also* Teri Randall, *Kennedy Hearings Say No More Free Lunch—Or Much Else—From Drug Firms*, 265 JAMA 440, 442 (1991); Andrew A. Skolnick, *FDA Issues Draft 'Concept Paper' on Drug Company Funding of CME*, 266 JAMA 2947, 2947 (1991). Further, the number of educational and scientific symposiums being presented has increased markedly in recent years. In the five-year period between 1966 and 1971, 71 papers based on symposiums were published in leading medical journals. Comparatively, during the five years between 1984 and 1989, 307 similar papers were published in the same journals. Bero, *supra*, at 1136.

7 *See, e.g.*, Kessler & Pines, *supra* note 4; Marvin Moser et al., *Who Really Determines Your Patients' Prescriptions*, 265 JAMA 498 (1991); Teri Randall, *New Guidelines Expected in 1991 for Relationship of Continuing Education, Financial Support*, 264 JAMA 1080 (1990); Michael D. Rawlins, *Doctors and the Drug Makers*, 1984 LANCET 276.

Several studies have attempted to determine the extent of the pharmaceutical companies' influence over physician prescribing practices. *See, e.g.*, Jerry Avorn et al., *Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73

In October 1991, the FDA took the first steps toward developing a comprehensive policy to regulate industry-sponsored educational activities by publishing guidelines.[8] The FDA's Draft Concept Paper[9] proposed that those programs funded or otherwise supported by pharmaceutical companies be regulated as if they were advertisements made by or on behalf of the industry under the Federal Food Drug and Cosmetic Act (FDCA). This proposal met with strong negative responses from the pharmaceutical and health care industry.[10] A revised version appeared for comment as a Draft Policy Statement in November 1992.[11] As of now, no final rule has been promulgated.[12]

If implemented, this Draft Policy Statement would severely limit the ability of pharmaceutical companies to sponsor scientific forums, academic speakers, or other educational activities relating to their products. More significantly, the FDA's proposed rules would in most instances prohibit discussion of any new treatments, uses, or therapies which have not already been approved by the FDA. While proponents of this proposal claim that regulating industry-sponsored scientific and educational activities will curb the dissemination of false or misleading information under the cover of a seemingly objective scientific format,[13] others believe the FDA's efforts will restrict unnecessarily the flow of

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AM. J. MED. 4 (1982); Bero, *supra* note 6 (studying content and treatment of articles based on industry-sponsored symposiums published in medical journals).

8 Prior to the promulgation of these guidelines, the FDA had announced no identifiable regulatory position on industry-sponsored educational programs. Rather, the FDA's position had to be gleaned from speeches, writings, and public statements by individuals within, or closely connected with, the agency. *See, e.g.*, Kenneth R. Feather, Acting Director of the FDA Division of Drug Advertising and Labeling, Speech at Annual Meeting of Pharmaceutical Manufacturers' Association Marketing Section (Mar. 13, 1989), *reprinted in* FOOD & DRUG LAW, CASES & MATERIALS at 462 (Peter Barton Hutt & Richard A. Merill eds., 2d ed. 1991); David A. Kessler, *Drug Promotion and Scientific Exchange*, 325 NEW ENG. J. MED. 201 (1991). *See also* Cooper, *supra* note 5, at 158-59 (complaining about the lack of clear rules and "official general guidance" in this field from the FDA).

9 Food and Drug Administration, Drug Company Supported Activities in Scientific or Educational Contexts: Draft Concept Paper (Oct. 26, 1991) [hereinafter Draft Concept Paper].

10 *See, e.g.*, John E. Calfee, *The FDA vs. The First Amendment*, WALL ST. J., Feb. 13, 1992, at A18; Cooper, *supra* note 5; Arthur N. Levine, *FDA's Expanding Control Over Drug Promotion*, *in* BAD PRESCRIPTION, *supra* note 2, at 23-24; Greg Tobias, *Regulation of Drug Advertising—A Violation of Free Speech?*, SCRIP MAGAZINE, Mar. 1993, at 22.

11 Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412 (1992) [hereinafter Draft Policy Statement].

12 Reaction to the Draft Policy Statement was so significant that the FDA extended the time for comments. 58 Fed. Reg. 6,126 (1993).

13 Kessler & Pines, *supra* note 4, at 2412.

scientific information.[14]

FDA attempts to regulate industry-sponsored scientific and educational activities raise serious questions about the extent of its authority to control statements about drug products, particularly by those who are not the agents or employees of a pharmaceutical company. Moreover, the FDA's proposal has serious implications for the First Amendment rights both of companies to speak about their products and of health care professionals to receive information about them.

This Article discusses the FDA's proposed regulation of industry-sponsored scientific and educational activities in light of the history and purpose of advertising regulation. It examines the scope and nature of the agency's authority to regulate statements about prescription drug products, and discusses whether the FDA has overstepped its regulatory authority. Finally, it considers whether, even if the FDA's proposal does not exceed its authority, such regulations would violate the First Amendment and unduly restrict socially valuable scientific discourse.

II. THE REGULATION OF PRESCRIPTION DRUG ADVERTISING

A. *Justifications for the Regulation of Advertising*

1. Product Information and Consumer Protection

Advertising regulation primarily is intended to protect consumers from false, misleading, or deceptive product claims. Truthful product information is helpful to consumers because it allows them to make informed, efficient choices about which products to purchase or use.[15] By providing information about their products to consumers, manufacturers reduce the costs of decision-making and promote the efficient functioning of a market economy. Inaccurate or deceptive product information, on the other hand, undermines the functioning of the market. Misinformation can lead consumers to make incorrect choices, and ultimately lower public confidence in all product claims.[16] False claims about the efficacy

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[14] Tobias, *supra* note 10, at 22; Paul H. Rubin, *From Bad to Worse: Recent FDA Initiatives and Consumer Health*, *in* BAD PRESCRIPTION, *supra* note 2, at 87, 92.

[15] *See, e.g.*, Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 670-71 (1977); Jeffrey P. Singdahlsen, Note, *The Risk of Chill: A Cost of the Standards Governing the Regulation of False Advertising Under Section 43(a) of the Lanham Act*, 77 VA. L. REV. 339, 340 (1977).

[16] J. Howard Beales, III, *What State Regulators Should Learn From FTC Experience in Regulating Advertising*, 10 J. PUB. POL'Y & MARKETING 101, 102 (1991) ("Misinformed consumers will make inappropriate choices, misdirecting economic activity and reducing consumer welfare."); Pitofsky, *supra* note 15, at 671. In addition, some argue

or safety of a product also can cause injury to individuals in much the same manner as a defective product, by encouraging improper uses or by failing to provide adequate instructions for the product's use.[17]

In a properly functioning marketplace, many argue that deceptive or false claims are self-defeating.[18] The falsity of the claims are discovered by consumers after they purchase or use the product, thereby undermining confidence in that advertiser's products. Obviously, the chance of repeat purchases in such circumstances is reduced.[19] Hence, it is in the economic self-interest of most advertisers to avoid false or misleading advertising claims or to correct any inaccuracies promptly. When the marketplace fails or consumers are unable to detect false claims, however, regulation of advertising may become necessary.[20]

Prescription drugs represent the type of products where the marketplace may fail to adjust properly for false and misleading claims. Prescription drugs are classic examples of "credence goods"—products whose qualities cannot be assessed by the consumer through normal use.[21] Hence, information about the proper use of such products is often as valuable to health care professionals as the actual product itself.[22] Even sophisticated health

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that false or misleading advertising impairs fair competition in the market by unfairly diverting customers from truthfully advertised goods. *See, e.g.*, FTC v. Winsted Hosiery Co., 258 U.S. 483, 493-94 (1922). The prevention of unfair competition was the original rationale advanced for the regulation of advertising by the FTC in the 1920s.

17 Charles G. Geyh, *The Regulation of Speech Incident to the Sale or Promotion of Goods and Services: A Multifactor Approach*, 52 U. PITT. L. REV. 1, 19-24 (1990); Allan Tannanbaum, Comment, *"New and Improved": Procedural Safeguards for Distinguishing Commercial Speech from Noncommercial Speech*, 88 COLUM. L. REV. 1821, 1827, 1831-32 (1988).

18 *See, e.g.*, Charles J. Walsh & Marc S. Klein, *From Dog Food to Prescription Drug Advertising: Litigating False Scientific Establishment Claims Under the Lanham Act*, 22 SETON HALL L. REV. 389, 399 (1992); Howard Beales et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 502 (1981); R.H. Coase, *Advertising and Free Speech*, 6 J. LEGAL STUD. 1 (1977). *But see* Pitofsky, *supra* note 15, at 663-67 (arguing that the marketplace often generates insufficient incentives to control deceptive product claims).

19 Singdahlsen, *supra* note 15, at 388-91 ("[A] producer generally has no incentive to promise the customer something she cannot deliver, because there is no reason to believe that a consumer will continue to buy a product in the face of the manufacturer's deceit."). *See also* Leffler, *supra* note 1, at 54-55; Cooper, *supra* note 5, at 156-57.

20 For a full discussion of various failures in the information market, see Beales et al., *supra* note 18, at 503-13.

21 Walsh & Klein, *supra* note 18, at 399-400; Kaplar, *supra* note 2, at 50; Singdahlsen, *supra* note 15, at 389.

22 John E. Calfee, *Free Speech, FDA Regulation, and Market Effects on the Pharmaceutical Industry*, *in* BAD PRESCRIPTION, *supra* note 2, at 63, 64 ("The main difference between a chemical entity and a marketable drug is information about what the chemical does

care professionals depend on pharmaceutical manufacturers to provide accurate and reliable information about when and how to use their products.[23] Further, the consequences of false or misleading information when dealing with drug products can be particularly severe—death or serious injury. Consequently, significant government regulation of drug advertising has long been thought necessary in order to ensure that accurate information about these products is provided.[24]

2. The Economic and Societal Value of Advertising

Though now considered integral to a properly functioning marketplace, advertising was not always viewed in this light. Rather, advertising generally was thought of as a waste of social resources.[25] In fact, as late as World War II, advertising was thought to have so little value that it was afforded no protection under the First Amendment.[26]

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under various conditions. Information is therefore the linchpin of pharmaceutical markets."); Cooper, *supra* note 5, at 156 ("[O]ver the years of the life of a drug, *the drug* changes very little if at all; but the information about it may change considerably. Whether information developed and disseminated newly is positive or negative, if it is accurate it improves the use of the product and thereby makes the product more valuable."); Kaplar, *supra* note 2, at 50.

23 Physicians are particularly dependent on the pharmaceutical industry for receiving information on new drug products because they are held responsible for keeping up with new scientific and medical developments. Gary L. Boland, *Federal Regulation of Prescription Drug Advertising and Labeling*, 12 B.C. INDUS. & COM. L. REV. 203, 206 (1970).

Some have argued, however, that physicians, being more sophisticated, will seek out information about credence goods from other sources than advertisements by the manufacturers. *Hearings on H.R. 11581 and H.R. 11582 Before the House Comm. on Interstate and Foreign Commerce*, 87th Cong., 2d Sess. 269-71 (1962) [hereinafter *House Hearings*] (statement of George R. Cain, President of Abbott Laboratories); *House Hearings*, 597-98 (statement of F.J.L. Blasingame, M.D., on behalf of the American Medical Association). However, recent studies of physician prescribing practices reveal that physicians do, in fact, receive a significant amount of their information about drug products from advertisements and other commercial sources. Rebecca K. Schwartz et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 SOC. SCI. & MED. 577, 579-82 (1989); Avorn et al., *supra* note 7, at 7-8. *See generally* Moser et al., *supra* note 7.

24 Lloyd G. Millstein, *FDA Policy on Comparative Prescription Drug Advertising*, 17 DRUG INFO. J. 63, 65 (1983) ("Because of the sensitive nature of medical and pharmaceutical information, the need to adhere to strict government regulations is vital. There is no room for disputed or less-than-factual information."); *see also* Walsh & Klein, *supra* note 18, at 399-400; Kaplar, *supra* note 2, at 50; Pitofsky, *supra* note 15, at 663-65, 667-68.

25 *See* Singdahlsen, *supra* note 15, at 372; Coase, *supra* note 18, at 8-9.

26 Valentine v. Chrestensen, 316 U.S. 52 (1942). This case involved a challenge by an entrepreneur to a local ordinance prohibiting the distribution of commercial handbills. The Court ruled on his constitutional argument in one sentence: "We are . . . clear that the Constitution imposes no . . . restraint on government as respects

By the early 1960s, economists discovered that advertising provides much of the essential information needed for an efficiently functioning marketplace.[27] Resources in a market economy ultimately are allocated through multiple individual economic choices. Consumers depend on information to help them differentiate among competing products.[28] Because information is not free, consumers often are unwilling to spend sufficient amounts of money or time to educate themselves properly. Product manufacturers, on the other hand, have a strong incentive to finance the provision of information about their respective products. Consumers, seeing this as low-cost information to them, often look to advertising as the major source for product information. By educating the public about product choices, truthful advertising has considerable social utility. It can lead to improvements in products and lower prices, as well as lowering barriers to entering new marketplaces.[29]

Soon after economists began to recognize the value of advertising so too did the courts. Beginning in the early 1960s, a number of Supreme Court Justices, in concurring and dissenting opinions, started to reconsider the constitutional status of advertis-

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purely commercial advertising." *Id.* at 54. This decision was reached "[w]ithout citing any cases, without discussing the purposes or values underlying the [F]irst [A]mendment, and without even mentioning the [F]irst [A]mendment except in stating Chrestensen's contentions." Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 628 (1990).

27 The first definitive article about the social and economic value of advertising was George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213 (1961). Theories about the value of information to the functioning of a market economy have since been incorporated into various legal doctrines impacting advertising. Beales et al., *supra* note 18, at 492-95.

28 Singdahlsen, *supra* note 15, at 339-40; Beales, III, *supra* note 16, at 101-02. This modern view of consumers as sophisticated appraisers of product information is in marked contrast to the older view of consumers, prevalent in the 1930s, which presumed that they were naive and easily deceived by advertising ploys. *See, e.g.*, Milton Handler, *The Control of False Advertising Under the Wheeler-Lea Act*, 6 LAW & CONTEMP. PROBS. 91, 98 (1939) ("It is because consumers are unsophisticated, because they unreasonably attach importance to baseless claims, because they are lured by exaggerations, half-truths, ambiguities and emotional appeals—in short because consumers do *not* always act wisely or reasonably—that legislative protection is required."). This same perception of consumers is apparent in the "fool's rule" applied in early FTC advertising cases. *See, e.g.*, Charles of the Ritz Distrib. Corp. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944) (requiring that advertising be sufficiently clear so that even less-than-reasonable persons would not be misled); Beales, III, *supra* note 16, at 105.

29 Kaplar, *supra* note 2, at 56; Beales, III, *supra* note 16, at 102; Cooper, *supra* note 5, at 156; Walsh & Klein, *supra* note 18, at 394-98; Singdahlsen, *supra* note 15, at 374-75; Noah, *supra* note 3, at 331. There is general agreement, however, that false advertising has no such beneficial effects for consumers. Singdahlsen, *supra* note 15, at 340.

ing.[30] By 1976, the Supreme Court pronounced that truthful advertising was protected by the First Amendment.[31] The Court's holding in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* was premised in substantial part on advertising's value as a means of conveying useful information about products.[32] False advertising, because it has no utility, remains unprotected.[33] Advertising, however, continues to be treated differently than other forms of speech. Advertising is viewed as "commercial speech," and is afforded a lesser degree of constitutional protection.[34] The Supreme Court found that because commercial speech is engaged in for profit it is presumed to be more durable than

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[30] *See* Lehman v. City of Shaker Heights, 418 U.S. 298, 314-15 (1974) (Brennan, J., dissenting, joined by Stewart, Marshall & Powell, JJ.); Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 401, 404 (1973) (Stewart, J., dissenting); *id.* at 404 (Blackmun, J., dissenting); Cammarano v. United States, 358 U.S. 498, 514 (1959) (Douglas, J., concurring).

[31] Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976). This case involved a challenge to a ban on advertising of prescription drug prices by pharmacists. The Court held that the state's interest in prohibiting such advertising was outweighed by the strong public interest in obtaining information about the cost and availability of prescription medications. *Id.* at 769-70.

[32] As noted by Justice Blackmun:

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

Id. at 765 (citations omitted); *see also* Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 561-62 (1980) ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information.").

[33] As the *Central Hudson* Court explained:

> The First Amendment's concern for commercial speech is based on the informational function of advertising. . . . Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it, . . . or commercial speech related to illegal activity . . . .

Central Hudson, 447 U.S. at 563 (citations omitted).

[34] *See, e.g.*, Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 64-65 (1983); *Central Hudson*, 447 U.S. at 562-63; *Virginia Pharmacy*, 425 U.S. at 771-72. A regulation on commercial speech will be upheld if the government can show that: (1) it has a substantial interest in regulating the speech; (2) the regulation directly advances that interest; and (3) there is a "reasonable fit" between the regulation and the asserted government interest. Board of Trustees of the State Univ. of New York v. Fox, 492 U.S. 469, 475 (1989); *Central Hudson*, 447 U.S. at 564-66. This test is more easily met than the test applied to political expression or other forms of speech.

noncommercial speech.[35] The distinction between commercial speech and fully protected speech, however, remains murky and continues to trouble courts and commentators.[36] What may safely be said is that any speech which truthfully discusses a product at least qualifies as commercial speech, and is entitled to some First Amendment protection.

As the economic and legal communities have accepted advertising's value and have begun to provide legal protection for it, the regulatory atmosphere has changed. Regulators increasingly are weighing the economic impact of restrictions on product advertising, a task which was ignored in the past. A brief view of history shows this progression.

B. A Brief History of Drug Advertising Regulation

By the second half of the nineteenth century, large-scale production of drugs by pharmaceutical companies had replaced the preparation of such products by the local pharmacist.[37] Companies began to use and promote brand names to differentiate their products.[38] During the same time the United States saw a dramatic increase in advertising for patent medicines which were being

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[35] Kozinski & Banner, *supra* note 26, at 634; *see also* Geyh, *supra* note 17, at 29.

[36] The line between fully protected speech and less-protected commercial speech is hazy and necessarily fact specific. The United States Supreme Court has yet to formulate a workable definition of "commercial speech." Rather, it falls back on a "common sense" definition: commercial speech is speech which does "no more than propose a commercial transaction." Pittsburgh Press Co. v. Human Relations Comm'n, 413 U.S. 376, 385 (1973), *quoted in Virginia Pharmacy*, 425 U.S. at 762; *Bolger*, 463 U.S. at 66; *Board of Trustees*, 492 U.S. at 473-78. The "mere fact" that statements are intended to promote or advertise a product "clearly does not compel the conclusion that they are commercial speech." *Bolger*, 463 U.S. at 66 (citation omitted). In fact, the best guidance has been phrased in terms of what does not constitute commercial speech. *Id.* at 66-68. Not surprisingly, this essentially ad hoc approach to defining commercial speech has met with a great deal of criticism. *See, e.g.*, Kozinski & Banner, *supra* note 26, at 638-41; Tannanbaum, *supra* note 17, at 1836-38.

[37] Leffler, *supra* note 1, at 48; Charles W. Dunn, *The Federal Food and Drugs Act of June 30, 1906: Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297, 305 (1946). As one writer explained:

> [D]uring the quarter of a century when the 1906 act was developed, our country was emerging from a rural into an industrial nation; the food and drug industries were beginning to be organized on the basis of mass production and distribution; the science of food and drug manufacture had reached the point where it could be constructively used to improve these products or destructively to debase them; and the uncontrolled forces of competition were working for the sophistication of these products, in order to secure the commercial advantage of a lower price.

Id.

[38] Leffler, *supra* note 1, at 48.

heavily marketed as cures for all sorts of ailments.[39] Public concern about exaggerated and outright false claims grew as a consequence.[40] Various groups lobbied heavily for legislation restricting such fraudulent claims. Attempts at imposing federal controls on the drug industry, however, were unproductive until after the turn of the century.[41]

In 1906, Congress finally passed the Pure Food and Drugs Act,[42] banning the manufacture and distribution of adulterated and misbranded food and drugs.[43] Although the Pure Food and Drugs Act did ban false and misleading labeling as well as require complete disclosure of a drug's ingredients,[44] it contained no proscriptions against false or misleading product claims.[45] No federal law regulated the advertising of drug products until 1914, when Congress created the Federal Trade Commission (FTC)[46] and gave it authority to regulate false and misleading advertising.

1. Regulation of Prescription Drug Advertising by the FTC

The Federal Trade Commission Act (FTC Act)[47] empowered the FTC to regulate "unfair methods of competition in commerce."[48] The FTC interpreted this general mandate to include

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39 Wallace F. Janssen, *The U.S. Food and Drug Law: How It Came; How It Works*, 35 FOOD DRUG COSM. L.J. 132, 133-34 (1980).

40 Journalists known as "muckrakers" published numerous articles describing patent medicine frauds. Janssen, *supra* note 39, at 134. C.C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3, 6-7 (1933). As the patent medicine producers were also some of the largest print advertisers, however, they also wielded substantial influence over the press. *Id.*

41 One author commented that "[a]t first there was very little interest in this sort of legislation. It was regarded as the work of cranks and reformers." Regier, *supra* note 40, at 4. More than 103 bills were proposed in Congress for the national regulation of food and drugs between approximately 1880 and 1906. Of these bills, only 19 were given serious consideration. For a comprehensive history of these early efforts at regulation, *see* Dunn, *supra* note 37, at 297-303; James F. Hoge, *The Drug Law in Historical Perspective*, 1 FOOD DRUG COSM. L.Q. 48, 48-55 (1946).

42 Pub. L. No. 59-384, 34 Stat. 768 (1906), *repealed by* Federal Food Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 (1938).

43 Myron L. Marlin, *Treatment INDs: A Faster Route to Drug Approval?*, 39 AM. U. L. REV. 171, 175 (1989).

44 Leffler, *supra* note 1, at 49; Marlin, *supra* note 43, at 175. The labeling of subject products was monitored by the Bureau of Chemistry, part of the Department of Agriculture and the forerunner to the FDA. In 1927, the Bureau of Chemistry became the Food, Drug and Insecticide Administration which, in turn, was renamed as the FDA in 1931. Janssen, *supra* note 39, at 134; Michael Brannon, *Organizing and Reorganizing the FDA*, *in* FOOD & DRUG LAW 113, 115 (Richard M. Cooper ed., 1991).

45 Leffler, *supra* note 1, at 49.

46 Dunn, *supra* note 37, at 299.

47 15 U.S.C. §§ 41-58 (1914).

48 15 U.S.C. § 45.

the prohibition of false and misleading advertising,[49] and a substantial amount of the FTC's enforcement work in its early life was devoted to the prosecution of such advertising.[50]

In 1931, however, the FTC's ability to regulate false advertising suffered a setback when the Supreme Court decided *FTC v. Raladam Co.*[51] There the Court ruled that the FTC lacked power under the FTC Act to prohibit false advertising unless there was evidence that the advertising harmed a competitor. Although recognizing the potential harm to the public from false and misleading advertisements, the Court held that harm to the public was not actionable by the FTC in the absence of competitive injury.[52]

The holding in *Raladam* was overruled by Congress in 1938 with the enactment of the Wheeler-Lea Act.[53] The Wheeler-Lea Act clarified the FTC's authority to regulate not only unfair competitive practices, but also "unfair or deceptive acts or practices in commerce."[54] In addition, the Wheeler-Lea Act specifically declared false advertisements of food, drugs, and cosmetics unlawful, and it empowered the FTC to stop them.[55]

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[49] FTC v. Winsted Hosiery Co., 258 U.S. 483, 493-94 (1922) (interpreting the powers of the FTC to include the regulation of false and misleading advertising); *see also* Milton Handler, *The Jurisdiction of the Federal Trade Commission Over False Advertising*, 31 COLUM. L. REV. 527 (1931); Ira M. Millstein, *The Federal Trade Commission and False Advertising*, 64 COLUM. L. REV. 439, 451-52 (1964). Enforcing the prohibition of false advertisements was one of the primary functions of the FTC in the 1920s. Millstein, *supra*, at 452-53.

[50] Of the 144 complaints issued by the FTC in 1923, 53 concerned false advertisements. Further, most of the cease and desist orders issued by the FTC in false advertising cases were upheld by the courts. Millstein, *supra* note 49, at 452-53 & n.56.

[51] 283 U.S. 643 (1931).

[52] *See also* Legislation, *The Federal Trade Commission Act of 1938*, 39 COLUM. L. REV. 259, 261-62 (1939) (discussing the *Raladam* case in the context of the Wheeler-Lea Act).

[53] Ch. 49, 52 Stat. 111 (1938). The provisions of the Wheeler-Lea Act are incorporated throughout the FTC Act, 15 U.S.C. §§ 41-58. For a coherent contemporary perspective on the Wheeler-Lea Act, see Handler, *supra* note 28.

The false advertising provisions of the Wheeler-Lea Act were enacted in large part to reverse the holding of *Raladam*. H.R. Conf. Rep. No. 1774, 75th Cong., 3d Sess. (1938), *reprinted in* CHARLES W. DUNN, THE WHEELER-LEA ACT 339-400 (1987).

[54] 15 U.S.C. § 45. This change permitted the FTC to "act under its legislative mandate whenever deception of the public was involved, regardless of the effect upon competition." Millstein, *supra* note 49, at 453.

[55] 15 U.S.C. § 52. For the FTC's purposes, a "false advertisement" was defined as "an advertisement, other than labeling, which is misleading in a material respect . . . ." 15 U.S.C. § 55. This definition encompassed not only affirmative representations, but also omissions of material facts. *Id.* The FTC was empowered to obtain injunctions against false advertisements of food, drugs, or cosmetics where such injunctions were in the interest of the public. 15 U.S.C. §§ 53(b) & 55(a); *see also* Note, *The FTC's Injunctive Authority Against False Advertising of Food and Drugs*, 75 MICH. L. REV. 745 (1977) [hereinafter Note, *Injunctive Authority*].

The Wheeler-Lea Act, however, created a loophole for prescription drug advertisements disseminated solely to the medical profession. These advertisements enjoyed a "safe harbor" from FTC regulation so long as they contained no false representations of material facts, were made available only to doctors, and were accompanied by a truthful, quantitative disclosure of the particular drug's formula.[56] Only those drug advertisements distributed to the general public were subject to action by the FTC.[57] Further, although the FTC had the power to prevent false or deceptive statements in drug advertisements, it lacked the authority to require an affirmative disclosure of information. For example, it could not compel drug manufacturers to list a drug's side effects or even contraindications in drug advertisements.[58] Considering these limitations, it is not surprising that there were few litigated cases involving the FTC's regulation of prescription drug advertising.[59]

2. FDA Regulation of Drug Labeling

During the 1930s, Congress considered several bills designed to improve the existing federal regulation of food and drugs.[60] However, it was not until several incidents involving unsafe medicines which sparked public and legislative concern over the safety of drug products, that reform efforts began in earnest.[61] The

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It appears, however, that the FTC could regulate only expressions of fact in advertisements, not opinions. *See* Koch v. FTC, 206 F.2d 311, 317 (6th Cir. 1953) (holding that a book by a physician expressing opinions about the therapeutic value of a prescription drug was not an advertisement regulated by the FTC); Handler, *supra* note 28, at 99-102.

56 15 U.S.C. § 55(a)(1). The rationale for this "safe harbor" was that physicians were experts capable of evaluating the accuracy and reliability of drug claims by themselves. H.W. Chadduck, *'In Brief Summary': Prescription Drug Advertising, 1962-1971*, 6 FDA PAPERS, Feb. 1972, at 14; Ruge, *supra* note 1, at 651; Boland, *supra* note 23, at 206.

57 *Koch*, 206 F.2d at 316-17 (holding that an advertisement in a journal which was distributed both to medical professionals and to the general public did not fall within the safe harbor provision).

58 Boland, *supra* note 23, at 207; Handler, *supra* note 28, at 102-03.

59 James M. Johnstone, *Prescription Drug Advertising and the FDA: A Brief History*, *in* BAD PRESCRIPTION, *supra* note 2, at 1, 3. The sole case may be *Koch v. FTC*. *Koch*, 206 F.2d at 317 (holding that a prescription drug advertisement in a general circulation journal was regulable by the FTC).

60 A prior effort at reforming the federal food and drug laws had been rejected in 1933, due to industry pressure on Congress. Marlin, *supra* note 43, at 175-76; *see also* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2 (1939).

61 The most famous of such incidents involved the deaths of at least 73 persons from a drug known as Elixir of Sulfanilamide, and the paralysis of several others from poisoned Jamaican Ginger. *See* Cavers, *supra* note 60, at 20; Marlin, *supra* note 43, at 176; *House Hearings*, *supra* note 23, at 95 (statement of Rep. Leonor K. Sullivan); *Report*

end result of these efforts was the Food Drug and Cosmetic Act (FDCA), enacted in 1938.[62]

During the initial drafting of the FDCA, there was lengthy debate over whether food and drug advertising should be regulated by the FTC or by the recently created FDA.[63] Ultimately, however, the Senate rejected a provision which would have given the FDA jurisdiction over such advertising,[64] electing to deal with the problem through the Wheeler-Lea Act.[65]

The FDCA, however, gave the FDA comprehensive authority to regulate the labeling of prescription drug products. Drug labels were required to bear "adequate directions for use,"[66] as well as be "informative and accurate and neither promotional in tone nor false and misleading in any particular."[67] Failure to comply with these requirements would result in the drug product being misbranded, in violation of the FDCA.[68]

The FDA has always expansively interpreted its power over labeling. As defined by the FDCA, labeling includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying any such

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of the Secretary of Agriculture On Deaths Due to Elixir Sulfanilamide, S. Doc. No. 124, 75th Cong., 2d Sess. 1 (1937); Note, *Injunctive Authority*, *supra* note 55, at 761 n.102.

62 The FDCA required for the first time that all drugs be tested for safety prior to marketing. Marlin, *supra* note 43, at 176 n.43.

63 *See* Note, *Injunctive Authority*, *supra* note 55, at 757-60.

The FDA was created in 1927 as part of the Department of Agriculture. Prior to the creation of the FDA, food and drug laws were overseen by the Bureau of Chemistry, also part of the Department of Agriculture. Originally called the Food, Drug, and Insecticide Administration, the agency acquired its present title in 1931. The FDA is now part of the Department of Health and Human Services. *See* Marlin, *supra* note 43, at 176 n.44.

64 CHARLES W. DUNN, FEDERAL FOOD DRUG AND COSMETIC ACT 621-33 (1938). *See* Note, *Injunctive Authority*, *supra* note 55, at 757-60.

65 The bill which became the Wheeler-Lea Act was introduced while the debates over the proper regulation of drug advertising were still ongoing. Note, *Injunctive Authority*, *supra* note 55, at 760.

66 21 U.S.C. § 352(f) (Supp. IV 1993); *see also* 21 C.F.R. § 201.56(a) (1993) (requiring that labeling contain the "essential scientific information needed for the safe and effective use of the drug"). Labeling is also required to contain specific factual information, including the manufacturer's name, 21 C.F.R. § 201.1 (1993), a statement of the identity of the drug, 21 C.F.R. § 201.50 (1993), and the usual or recommended dosage, 21 C.F.R. § 201.55 (1993).

67 21 C.F.R. § 201.56(b) (1993).

68 21 U.S.C. § 352(a) (1988). Misbranded drugs may be subject to seizure, *id.* § 334, or enjoined from distribution, *id.* § 332. Companies or individuals responsible for marketing or distributing misbranded drugs may be criminally prosecuted. *Id.* § 333.

article."[69] Throughout the 1940s and 1950s, the phrase "accompanying any such article" was interpreted by the FDA to include any written or printed materials which supplemented or explained the use of the product.[70] If any such materials suggested or mentioned uses of the drug for which adequate instructions were not provided on the label, the drug was considered misbranded.[71] As a result, nearly every form of drug company promotional material not explicitly within the FTC's definition of advertising was regulated as labeling by the FDA.[72]

This distinction between drug labeling and advertising persisted until 1962, when Congress amended the FDCA. As part of these amendments, jurisdiction over the regulation and enforcement of prescription drug advertising was transferred from the FTC to the FDA.[73]

C. *The 1962 Amendments to the Food Drug and Cosmetic Act*

In the years following World War II, the prescription drug industry experienced enormous growth. New drug products were introduced at a greater pace than in the past. Drug company profits also rose substantially, and with increased profits came an increase in the promotion of prescription drug products.

In 1959, Senator Estes Kefauver began a lengthy congressional investigation into the practices of the pharmaceutical industry as part of a campaign to reform the industry and to lower prescription drug prices. In the wake of a growing consumer protection movement and the strong public reaction to the thalidomide trag-

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69 *Id.* § 321(m). A "label" was defined as "a display of written, printed, or graphic matter upon the immediate container of any article." *Id.* § 321(k).

70 Kordel v. United States, 335 U.S. 345, 350 (1948) ("One article or thing is accompanied by another when it supplements or explains it, in the manner that a Committee Report of Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant."); Alberty Food Products v. United States, 185 F.2d 321 (9th Cir. 1950).

71 *See, e.g,* United States v. Hohensee, 243 F.2d 367, 369-71 (3d Cir.), *cert. denied,* 353 U.S. 976 (1957) (finding that product was mislabeled where written materials and lectures by company president suggested medicinal uses for which no instructions were provided on label).

72 *See e.g.*, United States v. Vitamin Indus., Inc., 130 F. Supp. 755 (D. Neb. 1955) (holding that posters distributed with the drug products as part of the manufacturer's marketing program were labeling). *See also* Boland, *supra* note 23, at 205; Ruge, *supra* note 1, at 651.

73 In 1962, while the amendments to the FDCA were under consideration, President Kennedy sent a special message to Congress seeking a consumer-oriented regulatory program, sparking the beginning of the modern consumer protection movement. *See House Hearings, supra* note 23, at 94 (statement of Rep. Leonor K. Sullivan); Pitofsky, *supra* note 15, at 661.

edy in Europe, however, Senator Kefauver's price control campaign refocused as an effort to close serious gaps in the FDCA.[74] This ultimately resulted in passage of the 1962 Amendments to the FDCA (1962 Amendments).

The 1962 Amendments made substantial changes in the way prescription drug advertising was regulated.[75] During the course of the congressional hearings many prominent physicians testified, criticizing the practices of drug companies in advertising their products. Pharmaceutical advertising, they testified, often presented information in a misleading manner.[76] In other instances, product claims were either totally unsupported or supported by unreliable evidence.[77] Physicians also criticized advertisements that failed to provide balanced information about drug products, including the mention of negative or contradictory studies.[78]

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74 Daniel D. Adams & William E. Nelson, Note, *The Drug Amendments of 1962*, 38 N.Y.U. L. REV. 1082, 1082-83 (1963); *see also House Hearings*, *supra* note 23, at 61 (statement of Abraham Ribicoff, Secretary of the Department of Health, Education and Welfare).

The sedative thalidomide, which was widely used in Europe in 1961 and 1962 for the treatment of pregnant women, was found to cause serious birth defects in children exposed to the drug *in utero*. Marlin, *supra* note 43, at 177 n.49. The strength and extent of the public reaction to the thalidomide problems can be seen in numerous references in the congressional hearings and debates over the 1962 Amendments. *See, e.g.*, *House Hearings*, *supra* note 23, at 432 (statement of Rep. Seymour Halpern); *id.* at 457 (statement of Andrew J. Biemiller, on behalf of the AFL-CIO). Although the FDA was widely praised for not having approved thalidomide for use in this country, *see, e.g.*, *id.* at 463, the specter of a similar disaster was raised as justification for increasing the FDA's power. *See, e.g.*, 108 CONG. REC. 21,070 (1962) (statement of Rep. Reuss); *id.* at 21,072 (statement of Rep. Yates).

75 In the area of prescription drugs, the other significant change resulting from the 1962 Amendments was a shift in emphasis in the FDA's drug approval process. No longer would drugs be assessed by the FDA only for safety—instead, drug companies would have to present the FDA with evidence that a drug was effective for the purposes for which it was intended to be used. For arguments for and against this change, see *House Hearings*, *supra* note 23, at 76-77 (statement of George P. Larrick, Commissioner of the FDA); *id.* at 80 (statement of Abraham Ribicoff, Secretary of Health, Education and Welfare); *id.* at 229-37 (statement of Theodore G. Klumpp, President of Winthrop Laboratories).

76 *Hearings Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary, pursuant to S. Res. 52 on S. 1552*, 87th Cong., 1st Sess. 177 (1961) [hereinafter *Senate Hearings*] (statement of Dr. Charles D. May, professor of pediatrics, New York University School of Medicine); SUBCOMM. ON ANTITRUST AND MONOPOLY OF THE SENATE COMM. ON THE JUDICIARY, STUDY OF ADMINISTERED PRICES IN THE DRUG INDUSTRY, S. REP. NO. 448, 87th Cong., 1st Sess. 155-222 (1961) [hereinafter SENATE REPORT]; *see also* Chadduck, *supra* note 56, at 14; Leffler, *supra* note 1, at 51; Noah, *supra* note 3, at 313; Ruge, *supra* note 1, at 652-53.

77 *Senate Hearings*, *supra* note 76, at 177 (statement of Dr. Charles May, professor of pediatrics, New York University School of Medicine).

78 SENATE REPORT, *supra* note 76, at 165-69; *Senate Hearings*, *supra* note 76, at 177

Physicians' testimony, however, also revealed that they depended on pharmaceutical company advertising for a substantial amount of their information about these drug products.[79] Consequently, most physicians wanted pharmaceutical advertising to contain the information essential to make proper prescribing choices.[80] The potential threat to public health from the lack of accurate and reliable information being sent to physicians was stressed repeatedly.[81] During the hearings, it became apparent that the FTC had been ineffective in regulating prescription drug advertising.[82]

Thus, the focus of the proposed reforms sought not only to

(statement of Dr. Charles D. May, professor of pediatrics, New York University School of Medicine).

79 Testimony and statements presented before Congress indicated that physicians were generally unable to do independent research to verify claims made in pharmaceutical advertisements. *See Senate Hearings*, *supra* note 76, at 319 (statement of Dr. Walter Modell, associate professor of pharmacology, Cornell University Medical College); *id.* at 181-84 (statement of Dr. Charles D. May, professor of pediatrics, New York University School of Medicine); Charles D. May, *Selling Drugs by "Educating" Physicians*, 36 J. MED. EDUC. (1961), *reprinted in Senate Hearings*, *supra* note 76, at 948, 960-61; *see also* SENATE REPORT, *supra* note 76, at 155-56; 108 CONG. REC. 21,089 (1962) (statement of Rep. Holifield); Boland, *supra* note 23, at 208.

One prominent physician, testifying before the Senate Subcommittee on Antitrust and Monopoly, pointed out that, even if physicians were not actually depending on drug advertisements for information, there was still no excuse for drug companies' purveying misleading information. *Senate Hearings*, *supra* note 76, at 370 (statement of Dr. Julius B. Richmond, President of Physicians' Council and Chairman, Department of Pediatrics, State University of New York).

80 *Senate Hearings*, *supra* note 76, at 319 (statement of Dr. Walter Modell, associate professor of pharmacology at Cornell University Medical College). Dr. Modell stated:

> As matters stand right now, only those who make a career of studying drugs begin to know the essential facts about the new drugs in common use. The busy general practitioner is utterly overwhelmed. He cannot cope with the problem if for no other reason that [sic] the unconscionable amount of time it would take. In his dilemma he succumbs to the attractive and easy to swallow information either brought to him directly by the detail man or served through the mail in elegant brochures.

Id.; *see also* SENATE REPORT, *supra* note 76, at 172-73 (quoting Dr. Heinz Lehmann, clinical director of Verdun Protestant Hospital). Dr. Lehmann stated that:

> [a] good ad, if it really would help the physician to inform him as it should about new drugs, would simply state clearly and in scientific and technical language, not in blown-up dramatic language, it would state in scientific and technical language the indications for the use of the product . . . and should also point out the caution and precautions and side effects that apply to that particular drug.

Id.

81 108 CONG. REC. 16,074 (1962) (statement of Sen. Kefauver); *id.* at 21,052-53 (statement of Rep. Harris); *id.* at 21,072 (statement of Rep. Yates); *id.* at 21,088 (statement of Rep. Moss).

82 *See, e.g.*, *House Hearings*, *supra* note 23, at 88 (statement of Abraham Ribicoff, Secretary of Health, Education and Welfare); *id.*, *supra* note 23, at 461 (statement of

effectively restrict false advertising but also to ensure full disclosure of information concerning the side effects and limitations of drug products.[83] The amendments debated by Congress sought to require that manufacturers provide a full, accurate, and conspicuous statement of all necessary information, which would allow physicians and prescribers to make fully informed judgments about when and how to use a drug product.[84]

The pharmaceutical industry argued before Congress that physicians depended on advertising not as a source of information, but merely as a reminder of the existence and applications of certain products.[85] Rather than relying on advertisements, they contended that physicians did independent research on drug products before prescribing them.[86] The industry argued that it should not have to provide complete prescribing information which was then reflected in the drug product's labeling. Such a course, in the view of the industry, would actually discourage physicians from doing further research about drugs before prescribing them.[87] Moreover, the industry argued that complete disclosure would be impractical, because the required information could not both fit in the usual one-page advertisement and still be readable.[88] Only siza-

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Andrew J. Biemiller, on behalf of the AFL-CIO); 108 CONG. REC. 21,052 (1962) (statement of Rep. Harris).

83 107 CONG. REC. 5640 (1961) (statement of Sen. Kefauver); 108 CONG. REC. 16,073 (1962) (statement of Sen. Kefauver); *id.* at 21,064 (statement of Rep. Dingell); *id.* at 21,072 (statement of Rep. Yates); *id.* at 21,084 (statement of Rep. Blatnik); *see also* Adams & Nelson, *supra* note 74, at 1115; Johnstone, *supra* note 59, at 4-5.

84 H.R. 11,581, 87th Cong., 2d Sess. (1962); *see also* Fisherow, *supra* note 1, at 215. Such disclosures would now be required regardless of the level of sophistication of the audience or the individual advertisement's actual capacity for deception. Chadduck, *supra* note 56, at 15.

85 At this time, pharmaceutical companies themselves thought of advertising only as a means of promoting a specific product. Any informational content was secondary to the purpose of placing a drug name or company name in the consumer's mind. *See, e.g.*, John G. Searle et al., The Pharmaceutical Industry, *reprinted as Exhibit 33 in Senate Hearings, supra* note 76, at 688, 689-90.

86 *See House Hearings, supra* note 23, at 269-70 (statements of George R. Cain, President of Abbott Laboratories) ("The physician understands the distinction between reminder advertising and the wide range of informational and educational materials available to him."); *id.* at 327-28 (statement of Theodore G. Klumpp, President of Winthrop Laboratories); *id.* at 523-24 (statement of Philip Jehle, National Association of Retail Druggists); *id.* at 597-98 (statement of F.J.L. Blasingame, M.D., on behalf of the American Medical Association).

87 *Id.* at 272-73 (statements of George R. Cain, President of Abbott Laboratories); *id.* at 239 (statement of Theodore G. Klumpp, President of Winthrop Laboratories); *id.* at 597-98 (statement of F.J.L. Blasingame, M.D., on behalf of the American Medical Association).

88 *Id.* at 272-73 (statements of George R. Cain, President Of Abbott Laboratories); *id.* at 328-29 (statement of Theodore G. Klumpp, President of Winthrop Laborato-

ble advertisements—which were more expensive—could comply with the disclosure requirements. Industry representatives predicted that print advertising would decline.[89] This decrease in print advertising would, in turn, decrease financial support to medical and scientific journals, which depended on advertising revenues.[90] As an alternative, the pharmaceutical industry proposed that advertisements carry instructions to physicians to consult the physician package insert accompanying the drug product for further information on efficacy, side effects, and contraindications.[91]

This suggestion was rejected.[92] In its stead Congress mandated the provision of information about contraindications, side effects, and limitations on uses in a shortened form and left the task of precisely defining the content of the "brief summary" to the FDA.

In the original draft of the amendments, the FTC rather than the FDA was given expanded authority to deal with misleading prescription drug advertising.[93] As the legislative debate progressed, however, it was decided that the FDA, because of its expertise, was in a better position to regulate prescription drug advertising.[94] To effectuate that judgment, the 1962 Amendments gave the FDA exclusive jurisdiction over prescription drug advertising, and the FTC Act was amended to exempt prescription drug advertisements.[95]

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ries); *see also id.* at 523-24 (statement of Philip Jehle, National Association of Retail Druggists); *id.* at 597-98 (statement of F.J.L. Blasingame, M.D., on behalf of the American Medical Association).

89 *Id.* at 328-29 (statement of Theodore G. Klumpp, President of Winthrop Laboratories).

90 *Id.* at 273 (statement of George R. Cain, President of Abbott Laboratories); *id.* at 329 (statement of Theodore G. Klumpp, President of Winthrop Laboratories).

91 *Id.* at 273 (statements of George R. Cain, President of Abbott Laboratories); *id.* at 329-30 (statement of Theodore G. Klumpp, President of Winthrop Laboratories).

92 108 CONG. REC. 21,070, 21,083-91 (1962).

93 H.R. 11,581, 87th Cong., 2d Sess. (1962).

94 *See generally House Hearings, supra* note 23, at 463-64 (statements of Andrew J. Biemiller, on behalf of the AFL-CIO, recommending transfer of jurisdiction over drug advertising to the FDA); National Academy of the Sciences—National Research Council, *Report of Special Committee Advisory to the Secretary of Health, Education and Welfare to Review the Policies, Procedures, and Decisions of The Division of Antibiotics and the New Drug Branch of The Food and Drug Administration* (Sept. 27, 1960), *reprinted in Senate Hearings, supra* note 76, at 459, 461.

95 In 1971, the FDA and the FTC concluded a liaison agreement clarifying their respective responsibilities in the fields of food, drugs, and cosmetics. *Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs*, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1988).

D. FDA Regulation of Advertising

1. Definition of Advertising

Although the FDCA does not define "advertisement," FDA regulations list materials the administration will regulate as advertisements. This list includes "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems."[96] Essentially, any industry promotional materials that do not fall within the FDCA definition of labeling are classified as advertising by the FDA.[97]

By its terms, the FDA's definition of advertising encompasses only those materials that are printed, published, or broadcast.[98] Early versions of the 1962 Amendments had included oral statements in the statutory definition of advertising.[99] However, this provision was deleted before enactment without explanation.[100] Efforts to include oral statements within the definition of advertising have been made on at least two occasions since the passage of the 1962 Amendments.[101] On both occasions, however, Congress

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96 21 C.F.R. § 202.1(*l*)(1) (1993). There is some debate over whether this list delimits the full extent of the FDA's regulatory authority over advertising, or whether it is merely a list of examples. Noah, *supra* note 3, at 324; Draft Concept Paper, *supra* note 9, at 3.

97 Adams & Nelson, *supra* note 74, at 1124 ("Any literature, other than labeling, which promotes a drug is advertising."); *see also* 21 U.S.C. § 352(n); Levine, *supra* note 10, at 23-24, 26; Noah, *supra* note 3, at 323-25.

98 21 C.F.R. § 202.1 (1993); *see also* Noah, *supra* note 3, at 323. Likewise, the FDA's definition of labeling explicitly concerns itself with written, printed, or graphic material. *See id.* at 318-26; Comment, *The Ubiquitous Detailman: An Inquiry Into His Functions and Activities and the Laws Relating to Them*, 1 HOFSTRA L. REV. 207, 211 (1973) [hereinafter Comment, *Ubiquitous Detailman*].

99 The Senate version of the bill defined advertisements as "all forms of advertising, whether transmitted directly to physicians, published in medical journals or other media, and whether in printed or oral form." S. 1552, 87th Cong., 1st Sess. § 4(a)(7) (1961).

100 Noah, *supra* note 3, at 313; Ruge, *supra* note 1, at 653. In fact, the provisions on the regulation of advertising were at one point deleted from the draft amendments. These provisions, however, were restored based on recommendations from the President. 108 CONG. REC. 16,073 (1962); Noah, *supra* note 3, at 325.

101 In 1968, the Senate conducted hearings on the specific problem of regulating promotional abuses by pharmaceutical detail men. *Competitive Problems in the Drug Industry: Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business*, 90th Cong., 2d Sess. 3506 (1968) [hereinafter *Competitive Problems*]. Likewise, in 1974, Senator Edward Kennedy chaired hearings on the pharmaceutical industry with an emphasis on the practice of detailing. *Examination of the Pharmaceutical Industry, 1973-74: Hearings on S. 3441 and S. 966 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st & 2d Sess. 141 (1973-74).

declined to amend the FDCA to include oral statements.[102] In view of these failed efforts it is reasonable to conclude that the FDA presently lacks statutory authority to regulate oral communications about drug products as advertising.[103]

2. Required Disclosures

The initial FDA regulations regarding prescription drug advertising were promulgated in 1963.[104] These regulations required that advertisements contain a complete presentation of all adverse information about a prescription drug product, including any side effects or contraindications.[105] This presentation was required to be fairly balanced, with the negative information presented in close association with any positive claims.[106] In addition, these regula-

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102 Noah, *supra* note 3, at 315. In 1968, the Legislative Reference Service of the Library of Congress, dealing with the problem of whether the FDA could regulate pharmaceutical detail men, concluded that "there is no clearly defined authority for the exercise of control by [the FDA] over oral statements of manufacturer's representatives to physicians in all situations." *Competitive Problems*, *supra* note 101, at 3517, *quoted in* Noah, *supra* note 3, at 318. In 1974, although Senator Kennedy specifically proposed a bill to add oral promotions to the definition of advertising, S. 3441, 93d Cong., 2d Sess. § 206(c) (1974), this bill was never acted upon by the Committee. Noah, *supra* note 3, at 315.

103 *See* Comment, *Ubiquitous Detailman*, *supra* note 98 (arguing that oral statements of detail men are not within FDA's jurisdiction). *See also* Ruge, *supra* note 1, at 653; Boland, *supra* note 23, at 209.

It should be noted, however, that congressional inaction does not necessarily mean that the agency lacks implicit authority to regulate under existing legislation. *See, e.g*, Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973); Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 381 n.11 (1969). The FDA may have authority to control oral statements indirectly, through the labeling provisions. Although oral statements cannot themselves be labeling, because the FDCA clearly defines labeling as including only written, printed, or graphic material, oral statements have been considered examples of the intended uses of the product, for which adequate directions must be included on the label. *Competitive Problems*, *supra* note 101, at 3242 (statement of William Goodrich, Chief Counsel to the FDA) ("any time an oral advertising claim is made which exceeds the permissible bounds of the approved labeling, this results in the product being misbranded for failure to bear adequate directions for use"). *See also* Boland, *supra* note 23, at 209; Noah, *supra* note 3, at 320-22.

The few litigated cases which involve oral statements generally deal with the question of whether or not a product is intended for use as a drug. Where there is a question as to the intended use of a product, courts will take oral statements by the company or its representatives into account. United States v. Articles of Drug, etc., 239 F. Supp. 465, 473 (D.N.J. 1965); United States v. 3 Cartons, 132 F. Supp. 569, 574 (S.D. Cal. 1952) (noting that a court may look at any source which discloses the intended use of a product).

104 The FDA published advertising regulations in the form of a final order in the Federal Register on June 20, 1963. Chadduck, *supra* note 56, at 15.

105 *Id.*

106 *Id.*

tions prohibited manufacturers from advertising new drugs for any uses that had not been approved by the FDA.[107]

The pharmaceutical industry clashed with the FDA over the scope of the information the administration could compel companies to place in advertising. These disputes ultimately led the FDA to revise its advertising regulations over time until they essentially reached their present state in the mid-1970s.[108]

In their present form, the FDA advertising regulations require all advertisements for prescription drugs to include: (1) a true statement of the established name for the drug and its formula; and (2) a brief summary of information about the drug relating to its side effects, contraindications for its use, and its effectiveness, in accordance with the appropriate regulations.[109] Advertisements must be fairly balanced; any negative or cautionary information must be presented in comparable depth and detail as any claims about the effectiveness and safety of the drug.[110]

The FDA regulations list over thirty specific instances in which advertisements would be or might be considered false or misleading.[111] Most relevant here, pharmaceutical manufacturers are specifically prohibited from promoting any use for drug products which has not been approved by the FDA.[112]

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107 *Id.* Older drugs which had not been subjected to the FDA approval process could be advertised only for those uses for which they were generally recognized as safe and effective. *Id.*

108 *Id.*; Adams & Nelson, *supra* note 74, at 1127. Questions were raised by the Pharmaceutical Manufacturers Association and various industry representatives about the proper extent of the FDA's statutory authority to regulate advertising, including its authority to require disclosure of adverse product information and its authority to limit advertising to only approved or generally accepted uses of a product. Chadduck, *supra* note 56, at 15. Other issues of contention included whether the FDA could compel the inclusion of a drug's generic name in advertisements, and what sort of information was required to make an advertisement fairly balanced. *Id.* at 15-16; Johnstone, *supra* note 59, at 7-10; *see also* Vincent A. Kleinfeld, *The Prescription Drug Advertising and Labeling Regulations*, 23 FOOD DRUG COSM. L.J. 12 (1968).

109 21 U.S.C. § 352(n) (1988). By permitting these disclosures to be made in "brief summary," the FDA made a concession to the pharmaceutical industry's arguments that full disclosure in advertisements was impractical. Johnstone, *supra* note 59, at 5-6. The question of what constituted a "brief summary," however, was a point of contention between the FDA and the industry for some time. Chadduck, *supra* note 56, at 15-16; Johnstone, *supra* note 59, at 7-10.

110 21 C.F.R. § 202.1(e)(5)(ii) (1993).

111 *Id.* § 202.1(e)(6)-(7).

112 *Id.* § 202.1(e)(4)(i)(a), (ii) & (iii); *id.* § 202.1(e)(6)(i).

III. THE FDA'S PROPOSED REGULATION OF INDUSTRY-SPONSORED SCIENTIFIC AND EDUCATIONAL ACTIVITIES

During the 1960s and 1970s, while the FDA was implementing its regulations on prescription drug advertising, the pharmaceutical industry relied primarily on printed advertising mediums or on their sales representatives (detailers) to sell their products.[113] During the past decade, however, changes in the pharmaceutical marketplace have made the industry increasingly competitive.[114] To compete in this changing marketplace, pharmaceutical companies began exploring new and more effective methods of communicating product information.[115]

Educational symposia are among the most effective ways of conveying product information to a large number of physicians.[116] Such programs, if properly executed, serve the medical community's need to acquire up-to-date information about new products and therapies,[117] as well as the pharmaceutical companies' need to

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113 Kessler & Pines, *supra* note 4, at 2409; *Advertising, Marketing and Promotional Practices, supra* note 1, at 206.

114 Several factors contributed to this increased level of competition. Whereas demand for prescription drugs had once been believed to be relatively static, during the late 1970s drug companies began to realize that demand could be increased substantially through media publicity and more effective advertising. *Advertising, Marketing and Promotional Practices, supra* note 1, at 19 (statement of David Jones, former Vice President of Abbott Laboratories).

In the 1980s, more sophisticated new drugs, requiring more complex instructions for effective use, were approved by the FDA. *Id.* at 206 (statement of Hoffman-La Roche, Inc.). As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, generic drugs assumed an increased role in the market. *See id.* at 164 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 193 (statement of Douglas G. Watson, President, Ciba-Geigy Pharmaceuticals Division); *id.* at 214 (statement of Hoffman-La Roche, Inc.). In addition, the costs of research and development rose, necessitating increased sales of a drug in order make a profit. *Id.* at 161, 163 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 193 (statement of Douglas G. Watson, President, Ciba-Geigy Pharmaceuticals Division).

115 *Advertising, Marketing and Promotional Practices, supra* note 1, at 77 (statement of Dr. Sidney Wolfe, Director, Public Citizen Health Research Group); *id.* at 157 (statement of Dr. Daniel H. Johnson, Vice Speaker, House of Delegates, American Medical Association) ("Pharmaceutical marketing is a fierce and competitive business. The stakes are extremely high, especially with the costs involved in bringing a new drug to market.").

116 *Id.* at 163 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 209 (statement of Hoffman-La Roche, Inc.).

117 *Id.* at 166 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 192 (statement of Douglas G. Watson, President, Pharmaceuticals Division of Ciba-Geigy). Even critics of drug company involvement in educational programs have recognized that these programs represent important opportunities for the medical community to receive information. *See, e.g.*, Bero, *supra*

disseminate product information quickly, efficiently, and memorably.[118] Further, given that continuing medical education (CME) programs are chronically under-funded and under-supported by government and academic sources,[119] industry sponsorship has proved a source of valuable opportunities.[120]

By the late 1980s, however, members of the medical community began to express concern about the influence of pharmaceutical company promotional practices on physician behavior.[121] In the context of industry-sponsored scientific and educational programs, many worried that the seemingly objective format of these programs could be used to present misleading or biased information about the sponsoring company's products.[122] While some

note 6, at 1138; Carl C. Peck & Peter H. Rheinstein, Editorial, *FDA Regulation of Prescription Drug Advertising*, 264 JAMA 2424, 2424 (1990).

118 *Advertising, Marketing and Promotional Practices*, *supra* note 1, at 187-88 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 192 (statement of Douglas G. Watson, President, Pharmaceuticals Division of Ciba-Geigy).

119 Skolnick, *supra* note 6, at 2948; Richard S. Wilbur, Editorial, *Continuing Medical Education: Past, Present, and Future*, 258 JAMA 3555, 3555-56 (1987).

120 One writer observed that "[s]upport from pharmaceutical companies has allowed for a fivefold increase in physician learning opportunities in the last decade, and the quality of today's CME programs surpass anything else in the world, despite lean financial times." Randall, *supra* note 7, at 1080; *see also* Nicole Lurie et al., *Pharmaceutical Representatives in Academic Medical Centers: Interaction with Faculty and Housestaff*, 5 J. GEN. INTERNAL MED. 240, 240 (1990), *reprinted in Advertising, Marketing, and Promotional Practices*, *supra* note 1, at 230 ("Drug companies have become a reliable and important source of support at a time when government funding for research has become scarce.").

121 Among the practices which caused concern was the acceptance of gifts from the pharmaceutical industry, including honoraria for speaking at or attending symposia. *See, e.g.*, Mary-Margaret Chren et al., *Doctors, Drug Companies, and Gifts*, 262 JAMA 3448 (1989); Stephen E. Goldfinger, *A Matter of Influence*, 316 NEW ENG. J. MED. 1408 (1987); Douglas R. Waud, *Pharmaceutical Promotions—A Free Lunch?*, 327 NEW ENG. J. MED. 351 (1992). Others worried about the ultimate effects of promotional spending by pharmaceutical companies on drug prices. Roger A. Rosenblatt, *Letter to the Editor*, 318 NEW ENG. J. MED. 52 (1988); *see also* Charles G. Moertel, Editorial, *Off-Label Drug Use for Cancer Therapy and National Health Care Priorities*, 266 JAMA 3031 (1991).

122 Kessler, *supra* note 8, at 201 ("To the extent that these activities are represented as independent educational efforts when they are in fact promotional, they can undermine the unbiased exchange of information, raise questions of professional ethics, and violate the standards set by the Food and Drug Administration."); J. Frederick Brodsky, *Letter to the Editor*, 327 NEW ENG. J. MED. 1687 (1992) ("[C]orporate-sponsored educational events must be closely monitored to ensure they are not simply veiled marketing ploys."); American College of Physicians, *Position Paper: Physicians and the Pharmaceutical Industry*, 112 ANNALS OF INTERNAL MED. 624, 626 (1990) ("This practice of underwriting CME offerings . . . creates the opportunity for the often subtle introduction of commercially oriented content."); *see also* Kessler & Pines, *supra* note 4, at 2412; Peck & Rheinstein, *supra* note 117.

In its position paper on the relationship between physicians and the pharmaceu-

commentators called for more exacting self-regulation by physicians and the industry, a few called for a regulatory response from the FDA.

Until the early 1990s, the FDA had paid little attention to industry-sponsored educational programs.[123] In December 1990, however, Senator Edward Kennedy conducted a series of congressional hearings on the advertising and promotional practices in the pharmaceutical industry; the hearings highlighted the medical community's concerns about undue influence and hidden promotional agendas.[124] Within a year of these hearings, in an effort to respond to the concerns raised by some in the medical community, the FDA published the Draft Concept Paper.[125]

A. *Effects of Proposed Regulations*

The Draft Concept Paper and its successor, the Draft Policy Statement, propose that statements made at industry-sponsored symposia should be treated as advertisements. As such, they would be required to conform with both the "true statement" and "brief summary" requirements of the FDCA.[126] In addition, such programs would be compelled to include fairly balanced presentations of negative or cautionary information, as well as claims about the

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tical industry, the American College of Physicians identified several situations which created a heightened potential for bias, including the selection of a program topic or speaker by the industry sponsor and the participation of industry employees in the preparation of a program. American College of Physicians, *supra*, at 626; *see also* Kessler, *supra* note 8, at 202-03 (recommending what physicians should do to ensure unbiased presentations); Kessler & Pines, *supra* note 4, at 2411 (discussing criteria for distinguishing promotional from educational activities).

123 Kessler & Pines, *supra* note 4, at 2412. One commentator expressed the view that industry-sponsored activities previously enjoyed a "safe harbor" from FDA regulation. David G. Adams, *FDA Policy on Industry-Supported Scientific and Educational Activities: Current Developments*, 47 FOOD & DRUG L.J. 629 (1992).

124 *Advertising, Marketing and Promotional Practices*, *supra* note 1, at 37 (statement of David Jones, former Vice President, Abbott Laboratories); *id.* at 87 (statement of Dr. Sidney Wolfe, Director, Public Citizen Health Research Group); *id.* at 98-99 (statement of John C. Nelson, M.D.); *id.* at 150-52 (statement of Sen. David Pryor, Chairman, Sen. Special Comm. on Aging).

125 The agency's present position represents an abrupt departure from its previous laissez-faire attitude towards drug company involvement in scientific and educational activities. *See, e.g.*, Ann M. Witt, Acting Director of FDA Division of Drug Marketing, Advertising, and Communications, Speech at the Second Conference on Industry-CME Provider Collaboration, Chicago, IL (1991), *quoted in* Skolnick, *supra* note 6, at 2947 ("One thing I'm afraid you're going to have to live with . . . is that the FDA is in the business of regulating prescription drug promotion. We have no choice about that. That's a statutory mandate. As long as promotion continues in CME, we will continue to regulate in that area. Right now, there is a lot of it in CME.").

126 *See* Draft Policy Statement, *supra* note 11, at 56,412 n.1.

effectiveness and safety of the drug product under discussion.[127]

The most significant effect of treating statements in industry-sponsored programs as advertising involves the discussion of new drug research. Participants in industry-sponsored educational activities would be prohibited from discussing any uses for a drug that had not already been approved by the FDA or for which the label did not already contain adequate directions.[128] The draft policy statement declared that "[i]n particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion."[129] If the FDA's proposals are implemented, any discussion of new, non-label uses during an industry-sponsored activity would render the product in question misbranded.

B. "Independent" and "Promotional" Programs

Both the Draft Concept Paper and the Draft Policy Statement distinguished between programs that are linked to the "promotional influence" of the company that funds or supports them, and those activities that are independent and non-promotional.[130] Those programs that meet the FDA's criteria for "independence" would not have to comply with the advertising regulations.[131] Discussion of unapproved or non-label uses would be permitted during "independent" programs, so long as the provider discloses that the product is not approved in the United States for the use being discussed.[132] If, however, a sponsoring pharmaceutical company is overly involved in, or has influenced the contents of, a scientific or educational activity, then that activity will be required to conform with the labeling and advertising provisions of the FDCA.[133]

The FDA has suggested that it will look to four criteria to de-

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127 21 C.F.R. § 202.1(e)(5)(ii) (1993).

128 Draft Policy Statement, *supra* note 11, at 56,412. Discussion of unapproved uses during independent activities is permissible, so long as the provider discloses that the product is not approved in the United States for the use being discussed. *Id.* at 56,414.

129 *Id.* at 56,412 (footnote omitted).

130 *Id.* at 56,412-13; Draft Concept Paper, *supra* note 9, at 6 *quoted in* Levine, *supra* note 10, at 28-29.

131 Draft Policy Statement, *supra* note 11, at 56,412-13; Draft Concept Paper, *supra* note 9, at 6, *quoted in* Levine, *supra* note 10, at 28-29.

132 Draft Policy Statement, *supra* note 11, at 56,414.

133 *Id.* at 56,412.

termine whether an educational or scientific activity is sufficiently independent to avoid regulation: independence, objectivity, fair balance, and scientific rigor.[134] "Independence" refers to the existence of a legal, business, or other relationship between the entity providing the activity and the sponsoring company,[135] or significant participation by the sponsor or its employees in the preparation and presentation of the activity.[136] It is presumed that too frequent contact between the sponsor and the provider carries the potential for undue influence over the contents of the activity.[137]

In addition to direct involvement with the provider, pharmaceutical companies are strongly discouraged from involving themselves in the selection of topics or speakers, for fear that they will improperly influence the contents of the presentation.[138] Presentations that focus on a single product, especially a product marketed by the sponsor, are suspect.[139] The FDA will also consider the selection of the audience for the program. An audience of experts or scientific specialists is considered an indication of an educational, rather than a promotional activity.[140] Multiple presentations of the same program are also discouraged as promotional in character.[141]

To ensure that an activity is treated as "independent," the Draft Policy Statement all but mandates a written agreement between a corporate sponsor and the entity actually presenting or providing the activity which clearly sets out the nature of their relationship.[142] Such written agreements should reflect the under-

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134 The precise language in which these criteria have been presented has varied over the course regarding discussions of the FDA's regulation of industry-sponsored scientific and educational activities. However, the basic criteria remain consistent throughout each version of the proposal. *See, e.g.*, Kessler & Pines, *supra* note 4, at 2411-12; Kessler, *supra* note 8, at 202; Levine, *supra* note 10, at 29; Draft Policy Statement, *supra* note 11, at 56,413-14.

135 Draft Policy Statement, *supra* note 11, at 56,414.

136 *Id.*

137 It has been suggested that "[l]ong-term or ongoing financial relationships between the speakers and the company will tilt the FDA's judgment toward the category of promotional activities." Kessler & Pines, *supra* note 4, at 2411.

138 Draft Policy Statement, *supra* note 11, at 56,414.

139 *Id.*; Kessler, *supra* note 8, at 202.

140 Kessler & Pines, *supra* note 4, at 2411; Kessler, *supra* note 8, at 203. In addition, although the presence of the scientific and medical press is acceptable, inviting the general media to an educational symposium will cause some concern. Kessler & Pines, *supra* note 4, at 2411-12.

141 Draft Policy Statement, *supra* note 11, at 56,414; Levine, *supra* note 10, at 30 (citing Draft Concept Paper, *supra* note 9, at 8); Kessler & Pines, *supra* note 4, at 2412.

142 Although the existence of a written agreement providing for the independence of the presenter is not determinative, the FDA regards it "as an important element in

standing that the sponsoring company is to have no involvement in the planned educational activity such that the content might be biased.[143] The provider is to maintain full control over the substantive content of the activity, with only minimal corporate involvement permitted.[144] It is expected that, if a company enters into such an agreement and abides by both the spirit and the letter of its terms, the FDA will not regulate the activity as advertising.[145]

IV. CRITIQUE OF THE FDA'S PROPOSED REGULATIONS

A. *The Proposed Regulations Contradict Established Policy*

Traditionally, the FDA has confined its regulatory efforts to promotional activities undertaken by or on behalf of a manufacturer. Where scientific research and discussion are concerned, the FDA has a longstanding policy of non-interference.

This policy is best illustrated in the context of investigational new drugs. While an investigational new drug is undergoing clinical study, neither the sponsor of the study nor the entity actually conducting the study is permitted to promote the drug for the purpose for which it is being studied.[146] However, the same regulation also indicates that "[t]his provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media."[147] While the commercial promotion of unapproved drugs is strictly prohibited, the discussion of these drugs in a scientific context by independent researchers plainly is not.

There are sound reasons for permitting discussion of unapproved uses for prescription drugs in a scientific context. Because

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establishing an activity as independent." Draft Policy Statement, *supra* note 11, at 56,413.

143 *Id.*

144 The Draft Policy Statement contains several specific statements about the degree of involvement permitted a sponsor before the activity will be subject to regulation. The sponsoring company must agree that the program is not intended for the promoting of its products, and that any incidental mention of its products will be "objective, balanced and scientifically rigorous." *Id.* The company must agree not to "direct or influence" the selection of topics or speakers, except to provide suggestions if approached. *Id.* The company is prohibited from advertising or promoting its products in the vicinity of the educational activity. *Id.* Further, the provider of the activity is required to disclose to the audience both the identity of the sponsor and any significant legal or business relationship between itself and the sponsor. *Id.*

145 *Id.*

146 21 C.F.R. § 312.7(a) (1993).

147 *Id.*; *see also* Kessler & Pines, *supra* note 4, at 2411 ("[T]he agency recognizes that educational exchanges among scientists regarding pre-approved drugs or non-approved uses must be permitted.").

of the lengthy approval process that any new drug application must go through, FDA approval often lags years behind the latest scientific developments.[148] Restricting discussion of new research until after the FDA has approved a drug could significantly slow the pace of research and development.[149] In an industry where information about a product is as valuable as the product itself,[150] restricting the flow of information until after FDA approval has been obtained can also have adverse effects on public health. If physicians are not at least minimally familiar with new therapies using a drug, they will be less prepared to use it appropriately.[151]

Further, physicians are not obligated to prescribe drugs only for the uses approved by the FDA—frequently, they will prescribe drugs for "off-label" uses.[152] Off-label prescribing generally is believed to be widespread, particularly in the treatment of cancer and AIDS.[153] A survey of the prescribing practices of oncologists revealed that nearly one-third of their prescriptions for cancer pa-

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148 In 1990, it was estimated that the drug approval process for a new prescription pharmaceutical took nearly twelve years and cost drug companies approximately $230 million. *Advertising, Marketing and Promotional Practices*, *supra* note 1, at 163 (statement of Gerald F. Mossinghoff, President, Pharmaceutical Manufacturers Association).

149 *See* Calfee, *supra* note 22, at 69; Rubin, *supra* note 14, at 91-92.

150 Calfee, *supra* note 22, at 67-68; Cooper, *supra* note 5, at 156.

151 *See* Rubin, *supra* note 14, at 91-92; *see also Advertising, Marketing and Promotional Practices*, *supra* note 1, at 161 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association) ("If physicians are not adequately informed about the availability of an important new therapy and kept current about its uses, patients are poorly served."); *id.* at 192 (statement of Douglas G. Watson, President, Pharmaceutical Division of Ciba-Geigy).

152 Although it does attempt to influence physicians' prescribing practices, the FDA is not empowered to regulate the practice of medicine. Christopher, *supra* note 5, at 250; Richard S. Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1110 (1992); David A. Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281, 285 (1989). In the past, attempts by the FDA to assert greater control over off-label uses of drugs have been unsuccessful, due to opposition from the medical community. David A. Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act*, 15 HARV. J. ON LEGIS. 694 (1978); Sidney A. Shapiro, *Limiting Physician Freedom to Prescribe a Drug for Any Purpose: The Need for FDA Regulation*, 73 NW. U. L. REV. 801, 802 (1978).

153 Christopher, *supra* note 5, at 248; Saver, *supra* note 152, at 1110; Shapiro, *supra* note 152, at 810-11. Off-label uses can take many forms. Some off-label uses are simply holdovers—physicians continuing to use drugs for uses which have since been withdrawn. Shapiro, *supra* note 152, at 808. More common, however, is the use of a drug for a use which has been discovered through research or experiments but has not yet been approved by the FDA. Christopher, *supra* note 5, at 248; Shapiro, *supra* note 152, at 809-10. A drug may be used for a disease which is closely related to those indicated on the label, or entirely unrelated. Christopher, *supra* note 5, at 248. A physician who varies the dosage or regimen of a drug, or applies it to someone other than the recommended population, would also be engaging in an off-label use. *Id.*

tients were for off-label uses.[154] Likewise, fifty-six percent of cancer patients were found to have received at least one drug for an off-label purpose.[155] Off-label use is most prevalent in cases where a cancer has reached an advanced stage, and where there are no standardized chemotherapy regimens or generally accepted courses of treatment.[156]

Physicians argue that off-label uses are essential to the effective practice of medicine, because of the unavoidable delay between the discovery of a new drug therapy and approval by the FDA.[157] Indeed, the FDA has recognized that, in certain circumstances, off-label prescriptions can be not only medically appropriate, but also reflective of the current state-of-the-art.[158] The FDA's recent efforts to expedite the availability of potentially lifesaving drugs prior to agency approval further emphasize the role of off-label drugs in medical practice.[159] Given the extensive, and often necessary, practice of prescribing off-label uses for drugs, there is a clear need for the open exchange of scientific and medical information about unapproved uses for drugs.

The FDA's proposed rules for industry-sponsored scientific and educational seminars contradict the established policy of permitting free scientific discussion of off-label treatments. If a pro-

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154 Thomas Laetz & George Silberman, *Reimbursement Policies Constrain the Practice of Oncology*, 266 JAMA 2996, 2997 (1991) (citing UNITED STATES GENERAL ACCOUNTING OFFICE, OFF-LABEL DRUGS: REIMBURSEMENT POLICIES CONSTRAIN PHYSICIANS IN THEIR CHOICE OF CANCER THERAPIES (1991)). This study involved questionnaires sent to a random sample of 1470 oncologists in the 11 states with the highest incidences of cancer. The results analyzed responses from 681 oncologists relating to their treatment of 2018 patients. *Id.*

155 Laetz & Silberman, *supra* note 154, at 2997.

156 *Id.* In addition, certain cancers were more likely to be treated with off-label uses than others. *Id.* at 2998.

157 Christopher, *supra* note 5, at 250; Shapiro, *supra* note 152, at 811. However, others have noted that the delay between discovery of a new use and approval by the FDA is aggravated by a lack of incentives for manufacturers to submit applications for approval. Christopher, *supra* note 5, at 250; Laetz & Silberman, *supra* note 154, at 2996; Marlin, *supra* note 43, at 193-95; Shapiro, *supra* note 152, at 811-12.

158 Laetz & Silberman, *supra* note 154, at 2996. Michael R. Taylor, FDA Deputy Commissioner for policy, in a speech before the Food and Drug Law Institute, acknowledged that off-label uses of drugs are often essential to good medical practice in certain fields, and that the flow of scientific information about off-label uses therefore should not be unduly inhibited. Michael R. Taylor, Speech to Food and Drug Law Institute (Feb. 26, 1992), *quoted in* Richard T. Kaplar, *Conclusion: Valuing Freedom of Speech*, *in* BAD PRESCRIPTION, *supra* note 2, at 111.

159 The changes to the investigational new drug study process are reflected in 21 C.F.R. § 312.7 (1993); *see also* Marlin, *supra* note 43; Kessler, *supra* note 152. These changes to the approval process were fueled in large part by reaction to the AIDS epidemic. Kathleen M. O'Connor, *OMB Involvement in FDA Drug Regulations: Regulating the Regulators*, 38 CATH. U. L. REV. 175 (1988).

gram does not meet the FDA's strict criteria for independence, researchers and scientists attending that program are prohibited from speaking about unapproved drugs or off-label uses whether or not their actual purpose is promotional. The FDA has recognized that "the constraints on advertising and labeling, when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views."[160] The proposed regulations fail to strike the necessary balance between the need to protect public safety by limiting commercial promotion of potentially unsafe drugs and the need to expand scientific and medical knowledge.[161]

B. The Proposed Regulations Exceed the FDA's Regulatory Authority

1. Independent Speakers Are Outside the FDA's Jurisdiction

Despite the FDA's extensive control over labeling and advertising, its jurisdiction does not extend to statements which may be construed as promotional, but which are not made by or on behalf of a drug company. Statements by independent third parties are not regulable as labeling or advertising.[162]

The proposed rules for regulating statements in industry-sponsored educational symposia overextend the FDA's authority by constraining independent speakers' statements. The criteria used by the FDA for determining whether an industry-sponsored program will be regulated as advertising erode the distinction between the drug companies and the third parties invited to participate in industry-sponsored programs. Speakers involved in programs sponsored or supported by a drug company are automatically presumed

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160 Draft Policy Statement, *supra* note 11, at 56,412 (footnote omitted).

161 During the hearings before the Senate Committee on Labor and Human Resources in 1990, David Jones, a former Vice President of Abbott Laboratories, recognized the difficulty of striking this balance.

> We need to stop the deceptive practices that are the foundation of too much pharmaceutical promotion today. It will not be easy. We should not interfere with the free exchange of useful scientific and medical information. We should not interfere with the right of corporations to tell investors and the public about promising new research. We should not discourage legitimate advocacy for a needed drug by doctors or consumer [sic] or companies. And we should not have a federal agency take over the discovery, development or distribution of prescription drugs.

Advertising, Marketing and Promotional Practices, *supra* note 1, at 34 (statement of David Jones, former Vice President, Abbott Laboratories).

162 Kessler & Pines, *supra* note 4, at 2410 ("A person with no ties to a drug company can say anything he or she wants about a drug—it is neither labeling nor advertising.").

to be speaking on behalf of that company, unless certain specific conditions are met.[163]

It is a well-settled principle that a person or entity is responsible for the actions and statements of another only if that person or entity exercises, or has the right to exercise, some degree of control over the other person.[164] In an employer-employee or agency situation, the existence of control is determined by several factors, including the extent to which the details of the employee's work are dictated by the employer, the extent to which the employer provides the necessary instrumentalities for the work, and the length of the work relationship.[165] Rather than presuming the requisite control from any degree of involvement with an employer, some actual connection must be demonstrated.

In the past, when the FDA and the courts have dealt with the problem of attributing third party statements to drug companies, their decisions have reflected this basic principle. In *United States v. Hohensee*,[166] for example, promotional lectures by the manufacturer's president which suggested various medicinal uses for peppermint tea were held attributable to the company for the purposes of determining the intended use of the product.[167] So too in *United States v. Article of Drug*,[168] a radio commentator who was hired by a drug distributor to promote its products was found to be speaking on behalf of the distributor. The court held that, on the basis of the contract and the close working association between the commentator and the distributor, the company had adopted the commentator's statements about its product, and that the intended uses of the product could be interpreted from the commentator's claims.[169]

In instances where the third party speaker has possessed some degree of independence, however, statements have not been attributed to the company. For example, where a private citizen without any ties to a drug company published a book about the benefits of a specific drug product, the FDA noted that the book did not fall

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163 Cooper, *supra* note 5, at 160 ("The agency views all of its detailed rules for such discussions as the conditions for the grant of its discretionary grace.").

164 *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 70, at 508 (5th ed. 1984) (discussing vicarious liability of a master for the actions of a servant); RESTATEMENT (SECOND) OF AGENCY § 220 (1957) (setting out the factors for determining "control" over an agent).

165 RESTATEMENT (SECOND) OF AGENCY § 220 (1957).

166 243 F.2d 367 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957).

167 *Id.* at 370-71; *see also* Kessler & Pines, *supra* note 4, at 2410.

168 239 F. Supp. 463 (D.N.J. 1965).

169 *Id.* at 473.

within its regulatory authority.[170] Likewise, an independent physician who promoted off-label drug therapies to patients was found not guilty of misbranding the drug.[171]

By contrast, the FDA's criteria for distinguishing between "independent" and "promotional" activities do not focus on whether the sponsoring company actually controls the statements of the program participants. Rather, the test for independence equates substantive involvement by the sponsoring company with control over the speakers. The degree of pharmaceutical company involvement, in fact, may be quite minimal. For example, even if a sponsoring company does no more than recommend some speakers or provide ideas for some topics within a program, all speakers in the program may be presumed to be under the control of the sponsor.

Such a presumption is not justified—even the existence of an employer-employee relationship does not give rise to an automatic presumption that a drug company controls a speaker. Although the question of whether and how to effectively regulate conversations between pharmaceutical detailers and physicians has been debated since the 1962 Amendments transferred advertising to the FDA,[172] the FDA presently has no authority over these communications.[173] One of the primary reasons for this regulatory gap is the

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170 Kessler & Pines, *supra* note 4, at 2410 (*citing* KENNETH R. FEATHER, PRESCRIPTION DRUG ADVERTISING (1987)).

171 United States v. Evers, 643 F.2d 1043 (5th Cir. 1981). The court specifically distinguished a private medical opinion advocating an off-label therapy from similar promotional statements made by a drug manufacturer. *Id.* at 1053 n.16; *see also* Christopher, *supra* note 5, at 252-53.

172 At the time of the congressional hearings on the 1962 Amendments, Senator Kefauver pointed to the lack of effective control by either the FDA or the FTC as one of the serious flaws in the then-existing drug law. *Senate Hearings*, *supra* note 76, at 181.

In fact, many of the same arguments for the regulation of industry-sponsored symposia have also been raised in support of regulating communications between detailers and physicians—in particular, that detailers present promotional information under the guise of education. *See, e.g., id.* at 370 (statement of Dr. Julius B. Richmond) ("I have not yet encountered a detail man who does not represent a proprietary point of view, and I do not think that education is purveyed by articulating a proprietary point of view."); SENATE REPORT, *supra* note 76, at 191 (statement of Dr. Harry F. Dowling) ("Detail men are valuable for the purpose of getting information to physicians and pharmacists regarding the availability and prices of products distributed by their companies, but being salesmen, they cannot be expected to give unprejudiced advice. Not being physicians, they cannot instruct physicians regarding the principles upon which the use of a new drug is based.").

173 Despite several bills proposing to extend the FDA's authority to include oral statements by detailers, these statements continue to fall outside the agency's jurisdiction. *See, e.g.*, S. 1552, 87th Cong., 1st Sess. § 4(a)(7) (1961); S. 3441, 93d Cong., 2d Sess. § 206(c) (1974); *see also* S. 966, 93d Cong., 1st Sess. § 604(a) (1973) (proposing

practical difficulty of monitoring statements by detailers, a difficulty which applies equally to both regulators and employers.[174] Because of the great variability in presentations made by detailers, companies may, in reality, have little actual control over their speech.[175]

United States v. Various Articles of Device[176] illustrates this point. In that case, a single detailer made claims for a product that were unsupported by any promotional literature or company statements.[177] His employer was not held responsible for his misrepresentations because the court found no evidence that his statements were based on any company program or promotional policy.[178] If detailers—whose primary purpose is the dissemination of promotional information—are not automatically presumed to be speaking on behalf of their employer, then a presumption of control cannot reasonably be applied to speakers who are not drug company employees.

Further, the FDA's presumption that virtually any degree of drug company involvement in a program confers control over the

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that detailers be required to present physicians with written pamphlets on each drug containing the labeling information required by the FDA).

174 The FDA has acknowledged that, absent reporting by doctors, it would have no effective means of detecting misrepresentations made by detailers. Former Chief Counsel of the FDA William Goodrich has noted that, "in terms of what the detail man says in the doctor's office, legally we could do something about that. But as a practical matter, we have no means of regulating that unless the doctor who is detailed tells us what happened and is willing to be a witness." Noah, *supra* note 3, at 317 (quoting *Competitive Problems*, *supra* note 101, at 3241-42 (statement of William Goodrich, Chief Counsel of the FDA)). Instead, Goodrich pointed to the FDA's ability to regulate the written materials used by detailers. *Id.*; *see also* SENATE REPORT, *supra* note 76, at 191 (statement of Dr. Harry F. Dowling).

175 The ability to engage a physician in a personal dialogue is the key to a detailer's effectiveness. One writer noted that "[a]s a personal source of information that comes directly to the physician and engages with him in an active dialogue, the detail man has several advantages over impersonal sources and colleagues . . . . The detail man is convenient. The physician does not have to do anything except listen." Miller, *Prescribing Habits of Physicians: A Review of Studies on the Prescribing of All Drugs (Part VII)*, 8 DRUG INTEL. & CLINICAL PHARMACOLOGY 81, 84 (1974), *quoted in* Noah, *supra* note 3, at 311.

176 256 F. Supp. 894 (S.D. Cal. 1966).

177 *Id.* at 896. The court found that there was:

> no showing that the capabilities attributed to the device by the salesman are in any manner supported by promotional literature published or distributed by Niagara, nor is there any contention by the Government that Niagara in any manner encouraged, approved, or even knew of the claims that the salesman made concerning the devices . . . .

Id.

178 *Id.* at 897. As a result, the company's medical device was found not to have been misbranded, and all of the articles seized by the FDA were ordered returned to the company. *Id.*

participants neglects the fact that the scientific and medical experts invited to participate in these programs are highly educated, sophisticated actors.[179] Rather than being easily manipulated, they are often in the best position to determine the content of the presentations.[180] Many physicians have taken issue with the arguments of their colleagues that participation in industry-sponsored seminars is the equivalent of intellectual bribery.[181] It is unrealistic to expect that established scientific and medical experts will be dissuaded from highly researched and well thought-out opinions merely because of a few contacts with a pharmaceutical company.

In those instances where real abuses may occur, the FDA does have the authority to act. Applying the established principles of agency and respondeat superior, the FDA can regulate statements by speakers actually controlled by drug companies. If a sponsoring company really dictates the content of a speaker's presentation,[182] that presentation may be regulated as advertising by or on behalf

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179 Not only are doctors generally better educated than the rest of the population, Calfee, *supra* note 22, at 67, but they are also accustomed to reviewing various sources of medical information and making clinical judgments on that basis. *Id.*; *see also* Rubin, *supra* note 14, at 95.

180 Commissioner Kessler, writing before he was appointed to head the FDA, recognized the unique ability of physicians to influence the contents of programs in which they agreed to participate.

> Physicians who are asked to participate in industry-sponsored events can exert considerable influence over their content. Most physicians set their own limits for involvement in activities sponsored by pharmaceutical firms. Such standards reflect not only the physicians' professional integrity but also their self-interest. After all, medical experts who earn the reputation of being paid evangelists damage their credibility in the eyes of their colleagues and thus may find less demand for their real expertise.

Kessler, *supra* note 8, at 202.

181 *See, e.g.*, Richard E. Blackwell, *Letter to the Editor*, 326 NEW ENG. J. MED. 133 (1992) ("Unlike the mass of technical junk that ends up in one's trash can, these educational experiences produce lasting benefits for the physicians and their patients."); Barry J. Sobel, *Letter to the Editor*, 327 NEW ENG. J. MED. 1686 (1992) ("If the pharmaceutical companies do not help us [with CME], then who will? I think that there is a middle ground, where intelligent and honest physicians can benefit from such help without being adversely affected in any way."); S. Verma, *Letter to the Editor*, 318 NEW ENG. J. MED. 52 (1988) ("I for one see little wrong, morally or academically, in being sponsored by a pharmaceutical firm to say in public the same things I would say in an academic setting.").

182 During the hearings before the Senate Committee on Labor and Human Resources, one of the speakers complained that marketing personnel from sponsoring companies would draft papers for busy physicians who were unable to prepare adequately. *Advertising, Marketing and Promotional Practices*, *supra* note 1, at 37 (statement of David Jones, former Vice President, Abbott Laboratories). Such blatant manipulation of content would certainly meet any test for control over the speaker.

of the company.[183] On the other hand, where a speaker receives input and suggestions from a sponsor, but retains control over the content of the presentation, that level of control would be insufficient to justify regulation. While considerations of control necessarily require specificity to a particular program or speaker, the proposed FDA criteria also require specific inquiries about the sponsoring company's involvement with the particular program. By altering its criteria to focus on control by the industry sponsor, rather than mere involvement, the FDA would anchor its proposed rules in established regulatory authority.

2. The Marketplace Provides Incentives to Avoid Abuses

Even before the FDA promulgated the Draft Concept Paper, both the pharmaceutical industry and the medical profession had acknowledged the potential for bias and improper influence in industry sponsorship of educational activities, and were taking steps to deal with this potential.[184] The Accreditation Council for Continuing Medical Education adopted guidelines dealing with pharmaceutical industry involvement in CME in March 1991—guidelines which the FDA copied in its Draft Concept Paper and the Draft Policy Statement.[185] The Pharmaceutical Manufacturers Association endorsed similar position statements from the American College of Physicians in May 1990.[186] Although these efforts at self-policing were criticized as weak and vague,[187] voluntary compliance would in many ways be preferable to the regulations proposed by the FDA.[188]

The pharmaceutical marketplace also provides significant in-

183 Control over content could be considered control over the details and instrumentalities of a speaker's work. *See generally* KEETON, *supra* note 164, § 501; RESTATEMENT (SECOND) OF AGENCY § 220 (1957).

184 Opinion is widely split within the medical community, however, on whether pharmaceutical company influence actually results in biased behavior. *See, e.g., Letters to the Editor: Pharmaceutical Promotions*, 327 NEW ENG. J. MED. 1686 (1992); *Letters to the Editor: Drug Promotion and Scientific Exchange*, 326 NEW ENG. J. MED. 133 (1992); *Letters to the Editor: Gifts to Physicians From Industry*, 266 JAMA 61 (1991); *Letters to the Editor: "A Matter of Influence": Graduate Medical Education and Commercial Sponsorship*, 318 NEW ENG. J. MED. 52 (1988).

185 Randall, *supra* note 6, at 440; Skolnick, *supra* note 6, at 2947.

186 American College of Physicians, *supra* note 122; *see also* Randall, *supra* note 7, at 1080. The Pharmaceutical Manufacturers Association also has adopted the American Medical Association's opinion on gifts to physicians from industry. Council on Ethical and Judicial Affairs of the American Medical Association, Editorial, *Gifts to Physicians from Industry*, 265 JAMA 501 (1991); *see also* Randall, *supra* note 6, at 440.

187 *See* Randall, *supra* note 7, at 1080.

188 Commentators have raised concerns about the propriety of the FDA "regulating" medical education. Skolnick, *supra* note 6, at 2948.

centives for the pharmaceutical industry to use self-regulation when sponsoring educational symposia. Promotional abuses by one company can undermine the reputation of the entire industry. Drug companies have an interest in preventing such abuses in order to preserve consumer confidence in their own statements. Further, in an atmosphere of increased competitiveness, companies will work to curtail the unfair advantages that result from promotional abuses. Companies make it a general practice to monitor—or even attend—educational programs sponsored by their competitors.[189] It is in their interest to report any promotional violations to the FDA.

Moreover, even absent the threat of FDA regulatory action, other market forces will operate on manufacturers to minimize the provision of exaggerated or unbalanced product claims in educational symposia. Overpromotion of drugs can give rise to tort liability, even where the drugs in question are approved by the FDA. Where otherwise adequate warnings to physicians about side effects and contraindications have been diluted by excessive promotion of the beneficial aspects of the drugs, manufacturers have been held liable as if they failed to provide a proper warning.[190] In cases where a drug has not yet received FDA approval for a particular use, activities which might be recognized as promotional similarly could subject a pharmaceutical company to liability. The prospect of tort liability for injury from an overpromoted drug product is a powerful impetus to avoid inappropriate promotional practices.[191]

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189 *See* Cooper, *supra* note 5, at 157. Moreover, because educational programs are, by their very nature, public statements, there is always the chance of imbalanced or improper promotional claims being reported to the FDA by some hearer. *Id.*

190 The leading case on this theory of liability, *Incollingo v. Ewing*, held that "whether or not the printed words of warning were in effect canceled out and rendered meaningless in the light of the sales effort made by the detail men" was a question of liability for the jury. Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971). "Action designed to stimulate the use of a potentially dangerous product must be considered in testing the adequacy of a warning as to when and how the product should not be used . . . ." *Id.*; *see also* Stevens v. Parke, Davis & Co., 507 P.2d 653, 661 (Cal. 1973) ("[A]n adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.") (citations omitted); Love v. Wolf, 38 Cal. Rptr. 183, 197 (Cal. Dist. Ct. App. 1964) (holding the drug manufacturer liable for failure to warn where it "had watered down its regulations-required warnings and had caused its detail men to promote a wider use of the drug by physicians than proper medical practice justified").

191 Indeed, because the question of whether a particular practice constitutes overpromotion is left to the jury, pharmaceutical companies should be encouraged to be conservative. *See, e.g.*, Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1363 (4th Cir.

Market forces also act to deter physicians from prescribing off-label drugs or therapies in the absence of reliable scientific evidence in support of the treatment. The tort system encourages physicians to exercise their independent medical judgment about whether or not to use an unapproved drug or off-label therapy. The drug label or package insert listing the FDA-approved uses of a drug can be used as evidence of the standard of care in a medical malpractice case involving that drug—deviation from the approved uses therefore is evidence of negligence.[192] Where the use of an unapproved drug comports with the currently accepted medical practice in the community or reliable medical research, however, physicians will not be held liable.[193] Consequently, physicians are deterred from actually using any unapproved drugs they have heard discussed at industry-sponsored educational or scientific seminars unless they have access to accepted, reliable scientific information.[194]

Prevailing policies in the health insurance field also discourage the indiscriminate use of unapproved drugs by physicians. Unproven or experimental treatments are not reimbursed by most medical insurance policies.[195] Insurers only are likely to pay for

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1975) (noting that the jury reasonably could infer overpromotion from the absence of a warning on a reminder calendar featuring the name of the drug).

192 Paul v. Bochenstein, 482 N.Y.S.2d 870, 871 (N.Y. App. Div. 1984) (holding that prescribing dosages in excess of those recommended by the manufacturer was evidence of malpractice); Christopher, *supra* note 5, at 254; Shapiro, *supra* note 152, at 823-31. Compliance with the instructions for use provided in a label or package insert is prima facie proof that a physician acted properly. *See, e.g.*, Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 180 (Cal. 1957).

Deviation from the label or package insert does not create a prima facie case of negligence, however. Rather, the label and package insert are treated as one factor among many in establishing a standard of care. Ramon v. Farr, 770 P.2d 131, 135 (Utah 1989) ("Although package inserts may provide useful information, they are not designed to establish a standard of medical practice . . . ."); *Salgo*, 317 P.2d at 180 (holding that the manufacturer's brochure "may be considered by the jury along with the other evidence in the case to determine whether the particular physician met the standard of care required of him"). *See generally* James R. Bird, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits*, 44 U. CHI. L. REV. 398 (1977).

193 *Ramon*, 770 P.2d at 135-36; *see also* Christopher, *supra* note 5, at 254.

194 Several commentators have questioned the effectiveness of tort liability as a regulator of physician or manufacturer behavior, in part because of the deference given to independent medical judgment. *See* Christopher, *supra* note 5, at 255-56; Shapiro, *supra* note 152, at 837-39.

195 For example, Medicare does not cover treatments which are "not reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A) (1988). This clause has been interpreted by the Health Care Financing Administration (which also oversees Medicaid) to preclude reimbursement for experimental treatments, or treatments that are not safe and effective. Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302

treatments which, while not yet approved by the FDA, are supported by reliable medical evidence and accepted by the medical community.[196] Even in the treatment of cancer, where off-label uses are more common than approved uses, a large percentage of off-label treatments are not reimbursed by insurance carriers.[197] As a result, oncologists often are compelled to alter their preferred courses of treatments of certain cancers to ensure that the costs will be reimbursed.[198] Thus, although physicians may be encouraged by various forces to apply off-label therapies, this practice is discouraged by the likelihood that such therapies will not be covered by the patient's insurance unless reliable scientific evidence demonstrates that they are safe and effective.

C. *The Proposed Regulations Unduly Restrict Socially Valuable Speech*

It is often overlooked that, by regulating what a pharmaceutical company can say about its products, the FDA is, in fact, controlling speech. Pharmaceutical companies have a First Amendment right to speak about their products.[199] Equally, scientists and researchers have First Amendment rights both to speak about their

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(1989) (to be codified at 42 C.F.R. pts. 400 & 405) (proposed Jan. 30, 1989); *see also* Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989) (action challenging state Medicaid rule precluding reimbursement for experimental AIDS therapy); Christopher, *supra* note 5, at 256-58; Saver, *supra* note 152, at 1098-99.

Private insurance policies usually contain clauses precluding coverage for experimental treatments. *E.g.*, Adams v. Blue Cross/Blue Shield of Maryland, Inc., 757 F. Supp. 661, 663 (D. Md. 1991) (quoting insurer's clause precluding coverage for "any treatment . . . not generally acknowledged as accepted medical practice by the suitable medical specialty").

There is no generally applied definition of "experimental" therapies; what is considered experimental depends on the insurance carrier. Saver, *supra* note 152, at 1098-1104. It is clear, however, that a treatment is not automatically considered experimental because it has not been approved by the FDA. *Weaver*, 886 F.2d at 198; Saver, *supra* note 152, at 1109-11. The Health Care Financing Administration is attempting to clarify its definition of "experimental." 54 Fed. Reg. 4302 (1989) (to be codified at 42 C.F.R. pts. 400 & 405) (proposed Jan. 30, 1989).

196 *See, e.g.*, Pirozzi v. Blue Cross-Blue Shield of Virginia, 741 F. Supp. 586, 590 (E.D. Va. 1990) (holding that a breast cancer treatment which was "in accordance with generally accepted standards of medical practice" and "of scientifically proven value" was covered by a group health plan); *Adams*, 757 F. Supp. at 663 (same).

197 Of the 681 oncologists studied by the U.S. General Accounting Office, approximately one-half reported that an insurer had denied reimbursement for the cost of an off-label prescription. Laetz & Silberman, *supra* note 154, at 2997.

198 The U.S. General Accounting Office study found two ways in which oncologists deviated from their preferred course of treatments as a result of insurance company denials. First, they would change their prescribing practices to use drugs more likely to be reimbursed. Second, they would often admit patients to hospitals to avoid the greater scrutiny of off-label prescribing in an office setting. *Id.* at 2998-99.

199 That they are corporations, rather than natural persons, does not diminish the

own work and to receive important product information. The FDA's proposals for regulating industry-sponsored scientific and educational activities, if implemented, would have serious implications for the exercise of these rights.

The FDA considers every statement made in connection with a pharmaceutical company to be promotional, and seeks to regulate these statements accordingly. Even purely promotional speech, however, serves an important social purpose which should be taken into account when considering new FDA regulations. Preventing significant speech by the pharmaceutical industry about its products can hamper innovation.[200] Because the pharmaceutical industry is closely involved in primary research and development, it is most informed about newly-developed products or newly-discovered therapeutic uses.[201] Activities which help introduce innovations into the marketplace quickly and effectively, by presenting information in a format which will attract and keep physicians' attention, are very much in the public interest.[202] That such speech also has the effect of encouraging the purchase of a product does not diminish its informational value to the audience.[203]

The speech implicated by the FDA's proposed regulations is at the very least commercial speech, and therefore is entitled to at

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free speech rights of drug companies. *See, e.g.*, First Nat'l Bank of Boston v. Bellotti, 435 U.S. 765 (1978) (recognizing First Amendment rights of corporations).

200 One writer observed:

> Drug development and innovation require active collaboration between pharmacists, pharmacologists, and doctors in the industry and outside, and clinical studies can be undertaken only by doctors actively engaged in medical practice. When a new drug is marketed, the company concerned will inevitably be the main holder of information on its safe and effective use.

Rawlins, *supra* note 7, at 277.

201 Peck & Rheinstein, *supra* note 117, at 2424; Rawlins, *supra* note 7, at 277. The pharmaceutical industry spends approximately $8 billion a year on research and development. *See Advertising, Marketing, and Promotional Practices*, *supra* note 1, at 161 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association).

202 Leffler, *supra* note 1, at 58, 74. Studies of physicians' prescribing practices demonstrated that physicians are, in fact, influenced by advertising and promotional materials. Jerry Avorn et al., *supra* note 7, at 7-8. Indeed, one study has suggested that medical educators should learn from the promotional presentation techniques used by pharmaceutical companies because these presentations are so effective in conveying information to physicians. Stephen B. Soumerai & Jerry Avorn, *Principles of Educational Outreach ('Academic Detailing') to Improve Clinical Decision Making*, 263 JAMA 549 (1990). However, other studies have noted a variety of other factors which contribute to prescribing decisions. Rebecca K. Schwartz et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 SOC. SCI. & MED. 577 (1989).

203 *See supra* notes 27-32 and accompanying text.

least that degree of constitutional protection.[204] To sustain a government regulation of truthful commercial speech about lawful activity,[205] the government must show that: (1) it has a substantial interest in regulating the speech in question;[206] (2) the restriction directly advances this substantial interest;[207] and (3) the restriction in question is narrowly tailored to accomplish its regulatory goal.[208] Assuming that the speech involved in industry-sponsored scientific programs is neither misleading nor related to an unlawful activity, the regulatory dictates contained in the Draft Policy Statement and the Draft Concept Paper plainly fail the second and third parts of this test.[209]

First, the FDA's proposed rules lack a reasonable, direct, and immediate connection between the restriction on speech and the regulatory goal sought.[210] The FDA's general purpose in regulating all forms of drug labeling and advertising is to prevent the dis-

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204 There is no bright line that distinguishes commercial from non-commercial speech. *See, e.g.*, Kozinski & Banner, *supra* note 26, at 638-41. Strong arguments could be made, however, for treating industry-sponsored promotional activities as fully protected non-commercial speech. The presence of an underlying profit motive for speaking is not sufficient in itself to transform speech into "commercial speech." Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 66-67 (1983). Where a speaker's primary interest is conveying truthful information on public issues, rather than selling a particular product, courts have tended to find that the speech is fully protected. *Compare* Pacific Gas & Elec. Co. v. Public Util. Comm'n of Cal., 475 U.S. 1 (1986) (holding that a public utility company's newsletter was fully protected speech because its purpose and content extended significantly beyond simply proposing a commercial transaction), *with Bolger*, 463 U.S. at 67 (finding that contraceptive advertisements were commercial speech where the discussion of public issues was secondary to the commercial message).

205 Speech that is false or misleading, or concerns an illegal activity, is not protected from government regulation. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 563-64 (1980); *see also* Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico, 478 U.S. 328, 340 (1986).

206 *Central Hudson*, 447 U.S. at 566; *see also Posadas*, 478 U.S. at 340; *Bolger*, 463 U.S. at 68-69.

207 *Central Hudson*, 447 U.S. at 564-66; *see also Posadas*, 478 U.S. at 340; *Bolger*, 463 U.S. at 69.

208 Board of Trustees of the State Univ. of New York v. Fox, 492 U.S. 469, 476-79 (1989) (explaining that this requirement was not a "least restrictive means" test); *Central Hudson*, 447 U.S. at 565-66; *see also Posadas*, 478 U.S. at 340; *Bolger*, 463 U.S. at 69.

209 As the party seeking to uphold its regulations, the FDA would bear the burden of justifying them. *Bolger*, 463 U.S. at 71 n.20; *Central Hudson*, 447 U.S. at 570.

210 *E.g., Posadas*, 478 U.S. at 341-42 (finding that the ban on casino advertising directly advanced the state's goal of preventing excess casino gambling); *Central Hudson*, 447 U.S. at 569 ("There is an immediate connection between advertising and demand for electricity."). Where the connection between the restriction and the regulatory goal is indirect, or where a regulation provides "only ineffective or remote support" for the government's goals, the regulation violates the First Amendment. *Central Hudson*, 447 U.S. at 564.

semination of false, misleading, or deceptive statements about drug products.[211] The Draft Concept Paper and the Draft Policy Statement, however, do not seek to regulate industry-sponsored programs because the statements made are actually false or misleading. Rather, both documents rely on the presumption that too close an involvement of a pharmaceutical company in an educational program necessarily corrupts the information presented.

The FDA is equating the pharmaceutical industry's fundamental economic interest in speaking about, and encouraging speech about, its products with a greater likelihood to deceive or present misinformation. Restricting pharmaceutical company speech merely on the basis of the underlying profit motive of the speaker is contrary to longstanding First Amendment principles. Many speakers, including political speakers, are motivated by some underlying self-interest.[212] Yet the existence of an economic motivation for speaking has never been an adequate basis for placing restrictions on speech.[213]

Moreover, the speaker with the greatest economic motivation to provide information is also usually the speaker with the best information.[214] Providing accurate and truthful product information can have incidental promotional value, which, in turn, benefits the economic interests of the speaker.[215] Indeed, advertising practices in other industries indicate that companies are, in fact, less likely to present misleading information because they appreciate the pro-

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211 Undoubtedly, the FDA's interest in preventing the dissemination of false and misleading information about prescription drugs is a substantial government interest. *Compare Bolger*, 463 U.S. at 70-74 (finding no substantial government interest in shielding the public from receipt of "offensive" mailings about contraceptives) *with Central Hudson*, 447 U.S. at 568 (finding that the state had a substantial interest in energy conservation) *and Posadas*, 478 U.S. at 341 (finding that the state had a substantial interest in preventing excessive casino gambling among its citizens).

212 Martin H. Redish, *Product Health Claims and the First Amendment: Scientific Expression and the Twilight Zone of Commercial Speech*, 43 VAND. L. REV. 1433, 1447-48 (1990). Although a political candidate has as much motive to distort information about his qualifications as a company does to distort information about its products, no one has seriously suggested limiting political speech on the grounds of self-interest. *See* Geyh, *supra* note 17, at 26-28.

213 Geyh, *supra* note 17, at 26-28.

214 This is particularly true in the drug industry, where individual companies invest an enormous amount of money in research and development of new information, much of which is then considered proprietary. *See generally Advertising, Marketing and Promotional Practices*, *supra* note 1, at 161 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association); *id.* at 190 (statement of Douglas G. Watson, President, Pharmaceuticals Division of Ciba-Geigy).

215 Cooper, *supra* note 5, at 161.

motional value of truthful advertising.[216]

As a practical matter, then, the existence of an economic motivation for speaking does not necessarily lead to distorted information. In the absence of a reasonable connection between the limitations imposed on statements in industry-sponsored symposia and the governmental interest in preventing false and misleading speech, the FDA's proposed rules cannot be said to directly advance a substantial governmental interest.

Second, in so far as they subject *all* speech funded or supported by pharmaceutical companies to the limitations of advertising, the FDA's proposals are not narrowly tailored to serve its regulatory interest. Where First Amendment rights are at issue, regulations should be "no more expansive than necessary" to accomplish the stated governmental interest.[217] Courts discourage the blunderbuss approach to regulation, contending that all speech should not be restricted in order to control harmful or misleading speech.[218] Instead, the Supreme Court has recognized that "the free flow of commercial information is valuable enough to justify imposing on the would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful."[219]

The regulatory approach outlined in the Draft Concept Paper and the Draft Policy Statement provide for no such distinctions. Rather, the FDA's proposals implicate speech that is not directly related to the agency's underlying regulatory goal. If a program does not meet the criteria for "independence," the results of the program are viewed as advertising. If unapproved uses for the drug product are discussed, the entire content of the program is subject to regulatory action. This is so even though the program may contain only accurate, reliable, and truthful scientific information about new uses for drug products.[220] Moreover, the FDA's re-

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216 *See* Rubin, *supra* note 14, at 88-90.

217 Board of Trustees of the State Univ. of New York v. Fox, 492 U.S. 469, 477 (1989); *In re* R.M.J., 455 U.S. 191, 207 (1982); *see also* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 644 (1985); Central Hudson Gas & Elec. Co. v. Public Serv. Comm'n, 447 U.S. 557, 565 (1980) ("The regulatory technique may extend only as far as the interest it serves.").

218 While the government is not limited to using only those methods of regulation that burden the least possible amount of speech, it is clear that restrictions on advertising should not "'burden substantially more speech than is necessary to further the government's legitimate interests.'" *Fox*, 492 U.S. at 478 (*quoting* Ward v. Rock Against Racism, 491 U.S. 781, 799 (1989)).

219 *Zauderer*, 471 U.S. at 646; *see also Fox*, 492 U.S. at 480.

220 In practice, regulations constraining useful, socially informative advertising are more likely to be struck down. Daniel H. Lowenstein, *"Too Much Puff": Persuasion,*

strictions on the discussion of unapproved uses apply not only to those speakers actually controlled by the drug companies, but to independent speakers participating in the same program as well. Where, as here, a restriction on advertising implicates otherwise fully protected speech, such a restriction violates the First Amendment.[221]

Finally, the FDA's proposals are contrary to the general economic and constitutional principle that breakdowns in the market for information are best remedied by more speech, rather than less.[222] If implemented and enforced, the FDA's proposals would result in the dissemination of less information in the marketplace.[223] Producing and providing information is costly. When low-cost methods of information dissemination are restricted, information costs are increased.[224] As noted, pharmaceutical companies and their investigators are often in the best position to provide accurate information about the developing uses of drug products. If the FDA, through its regulatory efforts, raises the risks and costs involved in drug company sponsorship of educational programs, there will be little incentive to continue to finance such events.[225]

Paternalism and Commercial Speech, 56 U. CIN. L. REV. 1205, 1228-30 (1988). *Compare* Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60 (1983) (striking down ban on unsolicited mailing of contraceptive advertisements) *with* Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico, 478 U.S. 328 (1986) (upholding ban on advertising of casino gambling).

221 *Central Hudson*, 447 U.S. at 569-70 (holding that a regulation on all promotional advertising by utilities, regardless of its impact on energy conservation, violates the First Amendment).

222 Beales et al., *supra* note 18, at 513, 521. Regulatory efforts to control misleading or deceptive statements usually have the secondary effect of reducing the amount of speech, and, as a result, should be carefully scrutinized. *Id.* at 516.

223 There is every reason to believe that, if implemented, the FDA would enforce these proposed rules broadly. *E.g.*, Kessler & Pines, *supra* note 4, at 2411 ("Until further judicial decisions or congressional action clarifies the FDA's specific authority in the area of promotion, the FDA will continue to assert broad jurisdiction.") (endnote omitted). Even without being implemented as official, binding rules, the Draft Policy Statement and the Draft Concept Paper have already affected industry behavior. Levine, *supra* note 10, at 37-38. Because of the exceptional degree of control it exercises over both drug products and drug information, the FDA effectively can jawbone the industry into compliance without having to take enforcement actions. *See* Kaplar, *supra* note 2, at 46-47.

224 Beales et al., *supra* note 18, at 515.

225 Cooper, *supra* note 5, at 161 ("If the FDA squeezes out all ancillary promotional benefit for the companies from activities in medical education and scientific exchange, the companies presumably will find other things to do with their marketing dollars.").

The prospect of drug companies withdrawing their support for CME programs and research has raised significant concerns within some sections of the medical community. *See, e.g.*, Barry J. Sobel, *supra* note 181, at 1686; Rawlins, *supra* note 7, at 277.

Instead, drug companies might well reallocate the funding for symposia into other activities. The net result of the FDA's action will be the provision of less useful, state-of-the-art information about the developing uses for pharmaceutical products.

By focusing on the potential for biased information, rather than on the actual occurrence of false and misleading presentations, the FDA has drawn its regulation too broadly. Restricting the scope of discussion available at industry-sponsored symposia on the basis of drug company involvement unduly constrains truthful and socially valuable speech. If implemented in its present form, the Draft Policy Statement would violate the First Amendment.

V. CONCLUSION

There are several serious flaws in the FDA's proposed regulations for industry-sponsored educational and scientific programs, flaws that are the result of faulty underlying assumptions. In order to correct these flaws, the FDA should re-focus its criteria for assessing whether an activity should be regulated as advertising to turn on the question of the industry sponsor's actual degree of control over the content. By concentrating on the presence of control, rather than mere involvement, the resulting regulations would send a clearer message both to drug companies and CME providers about what sort of behavior is objectionable. Under a control test, false or overly biased information coming from unscrupulous sponsors would be regulable by the FDA, without restricting the exchange of scientific information. Rewriting its enforcement policy in this fashion would also remedy the First Amendment problems by removing the most serious restrictions on drug company and third party speech. In short, although the Draft Concept Paper and the Draft Policy Statement represent a legitimate effort to remedy perceived abuses, they must be refocused to achieve the FDA's objective without interfering with socially valuable speech.