

# Pharmaceutical Industry Restructuring and New Marketing Approaches: Enforcement Responses

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## I. INTRODUCTION

The pharmaceutical industry has undergone an unprecedented restructuring in the past several years. New approaches to pharmaceutical marketing and distribution have been one of the major consequences of this restructuring. These new approaches principally are responses to exogenous changes in the structure of the U.S. health care system, principally the development of large, managed-care buyers of health care products and services, such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs).<sup>1</sup>

An enormous amount of attention and enforcement has accompanied this restructuring. The Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Office of Inspector General (OIG) of the Department of Health and Human Services, and state attorneys general have raised numerous challenges to and concerns about the restructuring and the related changes in industry promotional and distribution activity.

Legitimate questions can be raised, however, as to whether this enforcement activity is economically or analytically well-founded. Such regulation may not enhance market competition, produce consumer benefits, or contribute to the safe and effective use of pharmaceutical products. Rather, many of the states' and federal agencies' activities appear to be premature responses to a rapidly changing pharmaceutical industry. Such activity may hinder the efficient and cost-effective functioning of the pharmaceutical industry to the detriment of consumers, the government, and private purchasers of health care products and services. The bases for and the propriety of the states recent enforcement activities,<sup>2</sup> federal antitrust enforcement activity in the health

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<sup>1</sup> For a general overview of the current restructuring in the pharmaceutical industry, see Anita M. McGahan, *Industry Structure and Competitive Advantage*, 72 HARV. BUS. REV. 115 (1994), Fredric M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97 (1993). For a review of the major recent consolidations and strategic alliances in the pharmaceutical industry, see Jill B. Deal, *U.S. Health Care Reform*, 6 REG. AFFAIRS J. 113 (1995) (part I), 6 REG. AFFAIRS J. 191 (1995) (part II), 6 REG. AFFAIRS J. 300 (1995) (part III). See also Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 FOOD & DRUG L.J. 1 (1995); Stephen Paul Mahinka, *Strategic Responses by Drug Companies to the Changing U.S. Health Care System*, Remarks at Pharmaceutical Update '93 Conference, Food and Drug Law Institute, Washington, D.C. (May 1993).

<sup>2</sup> For a general overview and critique of the states' recent enforcement activities, see Stephen Paul Mahinka & Kathleen M. Sanzo, *Multistate Antitrust and Consumer Protection Investigations: Practical Concerns*, 63 ANTITRUST L.J. 213 (1994).

care industry,<sup>3</sup> and FDA and related regulatory agency enforcement responses<sup>4</sup> thus are subject to challenge.

It is important for pharmaceutical industry members to know that all of these enforcement initiatives have been resolved by either consent or other voluntary agreements. There has been no judicial review of the economic or regulatory rationales asserted in support of agencies' recent challenges to vertical integration or to new promotional activities in the pharmaceutical industry.

Because of the high volume and multiple sources (both states and federal) of recent enforcement activities, it has been difficult for industry members to appreciate the scope and breadth of the emerging enforcement responses. This article reviews and analyzes these enforcement responses, to assist industry members in evaluating their regulatory and economic bases and in assessing possible new marketing approaches in a rapidly changing competitive and regulatory environment.

## II. FEDERAL TRADE COMMISSION ENFORCEMENT ACTIVITY

The FTC has been particularly concerned with the effects that vertical integration in the pharmaceutical industry will have on competition in distribution and on non-integrated competitors. The FTC's principal concerns include foreclosure of non-integrated competitors from access to markets (for example, foreclosure from the practical ability to make sales to managed care entities), facilitation of collusion among the resulting smaller number of vertically-integrated competitors, and creation of barriers to new entry, if pharmaceutical companies are required to be active in both manufacturing and distribution in order to compete effectively.<sup>5</sup> The FTC also is the principal antitrust enforcement agency active regarding horizontal consolidations in the pharmaceutical industry.

### A. FTC Challenges to Vertical Consolidations and Restraints

Only during the past few years has the FTC again become interested in vertical mergers and acquisitions.<sup>6</sup> Vertical integration also has become of interest in recent

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<sup>3</sup> For an overview and critique of federal antitrust enforcement activity in the health care industry, see Kathryn M. Fenton & Barry C. Harris, *Vertical Integration and Antitrust in Health Care Markets*, 39 ANTI-TRUST BULL. 333 (1994).

<sup>4</sup> For a general critique of FDA's approach to regulation of promotional activities, see Paul H. Rubin, *Are Pharmaceutical Ads Deceptive?*, 49 FOOD & DRUG L.J. 7 (1994). For a discussion of FDA's regulatory authority and policies, see David Adams, *FDA Regulation of Communications on Pharmaceutical Products*, 24 SETON HALL L. REV. 1399 (1994).

<sup>5</sup> For general descriptions of the FTC's enforcement activities and concerns in the pharmaceutical industry, see Mary L. Steptoe, Acting Dir., Bureau of Competition, FTC, *FTC Vertical Enforcement: What's New in RPM and Vertical Mergers*, Remarks at ABA Section of Antitrust Law Program on Distribution Issues, American Bar Ass'n (Nov. 4, 1994); Mark D. Whitener, *Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace*, 50 FOOD & DRUG L.J. 301 (1995) [hereinafter *Competition*]; Mark D. Whitener, Acting Dep'y Dir., Bureau of Competition, FTC, *FTC Antitrust Enforcement in Pharmaceutical Markets*, Remarks at National Ass'n of Pharmaceutical Mfrs. (June 16, 1994) [hereinafter *FTC Antitrust*]. See also Christine A. Varney, Comm'r, FTC, *New Directions at the FTC — Efficiency Justifications in Hospital Mergers and Vertical Integration Concerns*, at Health Care Antitrust Forum (May 2, 1995).

<sup>6</sup> See Mark D. Whitener, Acting Dep. Dir., Bureau of Competition, FTC, & Susan J. DeSanti, Ass't Dir., Office of Policy & Evaluation, FTC, *Vertical Restraints and Vertical Mergers: Recent Developments in FTC Enforcement*, at Practising Law Inst. (Feb. 1995).

years to the U.S. Department of Justice Antitrust Division.<sup>7</sup> While the Department of Justice has been active in certain health care industry matters, such as antitrust review of hospital mergers,<sup>8</sup> the FTC has been concerned primarily with consolidations in the pharmaceutical industry.

Unlike competition analysis of horizontal mergers and acquisitions, however, analysis of vertical consolidations is novel and unsettled, from both the legal and economic perspectives. While significant dispute may attend the evaluation of a particular horizontal consolidation, the general mode of antitrust analysis is not ordinarily disputed.<sup>9</sup> By contrast, challenges to vertical consolidations are highly controversial because the economic bases of support for vertical-derived competition concerns are tentative.<sup>10</sup> In any event, the antitrust enforcement agencies' challenges to vertical consolidations in recent years have not been subject to judicial review, and thus there is no precedent as to the acceptability or legal and economic coherence of any of the theories supporting the concern with vertical consolidations.<sup>11</sup>

Notwithstanding these substantial theoretical deficiencies, the FTC recently challenged the acquisition by Eli Lilly & Co. of PCS Health Systems, a pharmacy benefits management (PBM) company.<sup>12</sup> The FTC's challenge to the proposed acquisition was brought despite the Commission's prior failure to challenge the larger acquisitions of Medco Containment Services by Merck and Diversified Pharmaceutical Services by SmithKline Beecham.

The FTC's concerns with such acquisitions are based on the possibility that the

<sup>7</sup> See, e.g., *United States v. MCI Communications Corp.*, 59 Fed. Reg. 33,009 (June 27, 1994) (consent settlement regarding consolidation with British Telecom). For the Department's general position, see Steven C. Sunshine, Dep. Ass't Attorney General, Antitrust Div., Department of Justice, Vertical Merger Enforcement Policy, at American Bar Ass'n Antitrust Section Meeting (Apr. 5, 1995). See generally Scott A. Stempel, *Government Shows Increasing Concern with Vertical Mergers*, 8 ANTITRUST 17 (1994).

<sup>8</sup> See, e.g., *United States v. Morton Plant Health Systems, Inc.*, Civ. No. 94-748-CN-T-23E (M.D. Fla., June 17, 1994) (consent judgment). For the Department's areas of interest in health care, see, e.g., Anne K. Bingaman, Assistant Att'y Gen., Antitrust Div., Dept. of Justice, The Importance of Antitrust in Health Care, Remark at University of Utah, College of Law (Oct. 5, 1994). The Department of Justice and the FTC have issued joint antitrust guidelines regarding certain types of health care industry matters (not including pharmaceutical industry consolidations or marketing activities). See U.S. DEP'T OF JUSTICE & FTC, STATEMENTS OF ENFORCEMENT POLICY AND ANALYTICAL PRINCIPLES RELATING TO HEALTH CARE AND ANTITRUST (1994).

<sup>9</sup> The federal antitrust enforcement agencies' approach to horizontal mergers is set out in U.S. DEP'T OF JUSTICE ANTITRUST DIV. & FTC, HORIZONTAL MERGER GUIDELINES, reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,104 (Apr. 2, 1992). Generally similar, although not identical, guidelines have been issued by states. See NAT'L ASS'N OF ATT'YS GEN., HORIZONTAL MERGER GUIDELINES, reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,406 (Mar. 30, 1993).

<sup>10</sup> For a discussion in the health care industry context, see Fenton & Harris, *supra* note 3, at 335, 347, 352-53. On the economic rationales supporting the legality of vertical mergers under the antitrust laws, see generally IV P. AREEDA & D. TURNER, ANTITRUST LAW ¶ 1000-15 (1980); H. HOVENKAMP, FEDERAL ANTITRUST POLICY 331-46 (1994); ABA ANTITRUST SECTION, NON-HORIZONTAL MERGERS: LAW AND POLICY (1988) (monograph no. 14). For a recent discussion of the circumstances in which vertical consolidations might have adverse effects on competition, see Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 ANTITRUST L.J. 513 (1995). Compare David Reiffen & Michael Vita, *Is There New Thinking on Vertical Mergers? A Comment*, 63 ANTITRUST L.J. 917 (1995) with Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: Reply to Reiffen and Vita Comment*, 63 ANTITRUST L.J. 943 (1995).

<sup>11</sup> These weaknesses are apparent to certain enforcement officials as well. See, e.g., Roscoe B. Starek, III, Comm'r, FTC, *Reinventing Antitrust Enforcement? Antitrust at the FTC in 1995 and Beyond*, at Marina del Rey Conference (Feb. 24, 1995). Commissioner Starek noted that "[m]any of the theories for attacking vertical transactions have a relatively weak theoretical foundation and do not provide a sufficient basis for distinguishing anticompetitive transactions from other transactions based on any observable criteria. This is in marked contrast to current federal horizontal merger policy." *Id.* at 24.

<sup>12</sup> In re Eli Lilly & Co., FTC File No. C-3594 (July 31, 1995) (consent settlement).

consolidated entity might improperly influence the selection of therapeutic products by purchasers, make access to purchasers more difficult for competing nonvertically-integrated pharmaceutical manufacturers, create "spillover" effects by obtaining competitors' drug pricing information, or have other foreclosure effects.<sup>13</sup> While some or all of these fears may have motivated the FTC's challenge of the Lilly/PCS consolidation, none of them was specified by the FTC. The Commission has not presented a statement of the analytical process or factual elements relevant to assessing the effect on competition of such vertical consolidations. As a consequence, it remains unclear to the pharmaceutical industry whether, and on what basis, a proposed vertical consolidation will be challenged, and how to assess the Commission's competition concerns.

The FTC's proposed consent settlement with Lilly requires offering an open formulary for drug products, as well as any closed formularies that the company might choose to offer; prohibits entry by Lilly/PCS into exclusive contracts with purchasers; and requires an information exchange "firewall" to preclude competitors' drug pricing information from being provided by PCS to Lilly.<sup>14</sup> Such information exchange "firewalls" are a common feature of recent consent settlements by the antitrust enforcement agencies. While most of them have been imposed in the more conventional setting of horizontal consolidations, a few recently have been imposed in vertical situations.<sup>15</sup>

The provisions of the proposed Lilly/PCS consent settlement demonstrate the uncertainty in analyzing the potential adverse effects of vertical consolidations on competition, and the most appropriate and effective ways to respond to such concerns. The formulary provisions of the proposed settlement are particularly illustrative. In summarizing the provisions, one FTC official noted that "[t]he order permits Lilly to offer closed formularies in order to preserve the potential for cost containment . . . . The order is carefully designed to avoid inhibiting Lilly/PCS from offering greater rebates in exchange for placement on a closed, rather than open, formulary."<sup>16</sup> As these remarks suggest, the proposed Lilly/PCS settlement illustrates the central and conflicting concerns in resolution of such challenges to vertical consolidations in the pharmaceutical industry. On one hand, the Commission and others are concerned with the possibility that a vertically-integrated entity would reduce the variety of therapeutic products available to purchasers and/or foreclose effective access to purchasers for competing, nonvertically integrated manufacturers. On the other hand, the Commission does not wish to prevent or reduce the ability of the combined entity to offer price reductions to purchasers (in this instance, through offering closed formularies at discounted prices). Presumably, such price reductions reflect, in part, the economic efficiencies that can be expected from some types of vertical combinations. By focusing solely on concerns about foreclosure and unspecified "distortions" of the process of sales and distribution of drug products, however, the states have protested that the FTC's proposed Lilly/PCS consent settlement is inadequate.<sup>17</sup>

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<sup>13</sup> See *supra* note 5.

<sup>14</sup> See *supra* note 12.

<sup>15</sup> See *In re Lockheed Corp.*, FTC File No. C-3576 (June 20, 1995) (consent settlement); *In re Martin Marietta Corp.*, FTC File No. C-3500 (June 28, 1994) (consent settlement); *In re Alliant Techsystems, Inc.*, FTC File No. C-3567 (Apr. 7, 1995) (consent settlement); *United States v. AT&T Corp. (McCaw Cellular)*, 59 Fed. Reg. 44,158 (Aug. 26, 1994); *United States v. MCI Communications Corp. (British Telecom)*, 59 Fed. Reg. 33,009 (June 27, 1994); *United States v. Int'l Ass'n of Machinists*, 1994-2 Trade Cas. (CCH) ¶ 70,813 (D.D.C. 1994) (consent settlement).

<sup>16</sup> See *Competition*, *supra* note 5, at 8-9.

<sup>17</sup> See Letter of Hubert H. Humphrey III, Att'y Gen., Minnesota, to FTC Comm'rs (Nov. 2, 1994).

Subsequent to its announcement of the Lilly/PCS proposed consent settlement, the FTC began re-investigating the prior Merck/Medco Containment Services and SmithKline/Diversified Pharmaceutical Services acquisitions.<sup>18</sup> In addition, the FTC opened an investigation of contractual alliances between Caremark, another PBM company, and pharmaceutical manufacturers, focusing on discount activity.<sup>19</sup> The consequence of the FTC's challenges to PBM acquisitions by pharmaceutical manufacturers has been the effective elimination of practical interest in such acquisitions.<sup>20</sup>

The FTC also is active in examining other vertical relationships within the pharmaceutical industry, including the competitive consequences of the formation and operation of generic drug manufacturing and distribution subsidiaries by research pharmaceutical manufacturers.<sup>21</sup> The Commission has not made it clear yet how distribution through dual sales channels raises competition concerns. Manufacturers in other industries, such as consumer electronics and household appliances, have used multiple distribution channels for their products for a long time, often differentiating them by brands and/or types of sales outlets. The FTC reportedly has undertaken investigations, in coordination with the FDA, of prescription drug advertising and promotional activities. One recent example is the investigation of Genentech's promotional activities concerning certain foundations and testing programs relating to its human growth hormone product.<sup>22</sup> The Commission also has taken enforcement action regarding certain other types of vertical restrictions in the pharmaceutical industry. In 1992, for example, the FTC announced a consent settlement with Sandoz Pharmaceuticals, resolving the Commission's allegations of an unlawful tying arrangement between the company's prescription drug product Clozaril (clozapine) and related blood monitoring services.<sup>23</sup>

### B. *FTC Challenges to Horizontal Consolidations and Restraints*

The FTC has scrutinized the horizontal aspects of acquisitions by research pharmaceutical manufacturers, generic drug manufacturers, and medical device companies, often requiring selective divestitures in certain areas of competitive or research overlap. This type of enforcement interest is a traditional area of antitrust enforcement agency activity, and the general analysis applied to such proposed transactions is relatively noncontroversial. Almost all of these FTC horizontal merger actions have been resolved by consent settlements, as is typical for such merger challenges. For example, in *In re American Home Products Corp.*, the FTC obtained a consent settlement requiring divestiture of the tetanus and diphtheria vaccines business, the licensing of rotovirus research, and the removal of reporting requirements in cytokine drug licenses that could provide competitively-sensitive information to the company, in the

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<sup>18</sup> See SCRIP, Nov. 1, 1994, at 19. Merck settled a private challenge by a pharmacy group to its acquisition of Medco Containment Services by agreeing to terms similar to those demanded by the FTC in its Lilly/PCS proposed consent settlement, including provision of an open formulary as well as any closed formularies and an information "firewall" prohibiting the exchange of nonpublic information between Merck and Medco. See *Bacon-Normandi Corp. v. Merck & Co.*, Civ. No. C93-2937-DLJ (N.D. Cal. filed Feb. 22, 1995) (consent injunction).

<sup>19</sup> See FTC: WATCH (Nov. 21, 1994) at 3.

<sup>20</sup> See, e.g., statements by Value Health regarding its decision not to sell its PBM affiliate, F-D-C REP. ("The Pink Sheet"), Dec. 5, 1994, at 11. See also F-D-C REP. ("The Pink Sheet"), Apr. 10, 1995, at 19.

<sup>21</sup> See *FTC Antitrust*, supra note 5, at 14-15.

<sup>22</sup> See FTC: WATCH, Sept. 12, 1994, at 6.

<sup>23</sup> See *In re Sandoz Pharmaceuticals Corp.*, FTC File No. C-3385 (July 30, 1992) (consent settlement).

proposed acquisition of American Cyanamid.<sup>24</sup> Similarly, in *In re Roche Holdings, Ltd.*, the FTC required the divestiture of the drug abuse testing business acquired from Syntex Corp. by Roche Holdings through consent settlement.<sup>25</sup> Most recently, in a unique proposed consent settlement, Hoechst AG accepted an agreement to hold Marion Merrell-Dow separate and operate it independently pending completion of the FTC's investigation, in return for the ability to close the acquisition.<sup>26</sup> The "hold separate" agreement precludes Hoechst from protesting an FTC determination that the acquisition or certain aspects of it are anticompetitive, that the premerger notification period has expired, or the validity of the consent agreement.

The FTC also is concerned with the horizontal aspects of market extension acquisitions. For example in the acquisition of the generic drug manufacturer Rugby-Darby Group by Marion Merrell-Dow, the FTC required the divestiture of Rugby-Darby's non-exclusive dicyclomine licensing assets.<sup>27</sup> Similarly, the Commission challenged the horizontal acquisition of Zenith Laboratories by IVAX Corp., a generic drug manufacturer, and prohibited IVAX in the consent settlement from obtaining any rights to market or sell generic extended-release verapamil pursuant to an exclusive distribution agreement with G.D. Searle Co.<sup>28</sup>

The Commission also has challenged horizontal acquisitions in the medical device industry. Its consent settlement with Wright Medical Technology Corp. required the transfer of research assets and the licensing of technology regarding orthopedic implants in that company's acquisition of Orthomet.<sup>29</sup> Earlier, the FTC filed a complaint in federal district court seeking to block the acquisition of Cardiovascular Imaging Systems by Boston Scientific Corp. The Commission alleged that the acquisition could lessen competition substantially for intravascular ultrasound imaging catheters.<sup>30</sup> Through a consent settlement that covered the company's acquisition of SCIMED Medical Systems as well, Boston Scientific agreed to grant a nonexclusive license to manufacture and sell these products.<sup>31</sup>

While the Commission's analytical approach to horizontal mergers is generally noncontroversial and well understood, recent focus by the antitrust enforcement agencies on the potential effects of a proposed merger on competition in innovation, that is, of overlaps in research and development activities (referred to as "innovation" markets), is novel and undeveloped.<sup>32</sup> Research and development activity is of central importance to the pharmaceutical and medical device industries. To include such activity as part of merger analyses by attempting to construct "innovation" markets in which to determine future potential competitive effects,<sup>33</sup> however, is highly specula-

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<sup>24</sup> See *In re American Home Prods. Corp.*, FTC File No. C-3557 (Feb. 14, 1995) (consent settlement).

<sup>25</sup> See *In re Roche Holdings, Ltd.*, FTC File No. C-3542 (Dec. 16, 1994) (consent settlement).

<sup>26</sup> *In re Hoechst AG*, FTC File No. 951-0090 (June 27, 1995) (proposed consent settlement).

<sup>27</sup> See *In re Marion Merrell-Dow*, FTC File No. C-3533 (Sept. 23, 1994) (consent settlement).

<sup>28</sup> See *In re IVAX Corp.*, FTC File No. C-3565 (Mar. 27, 1995) (consent settlement).

<sup>29</sup> See *In re Wright Medical Technology Corp.*, FTC File No. C-3564 (Mar. 23, 1995) (consent settlement).

<sup>30</sup> See *FTC v. Boston Scientific Corp.*, Civ. No. 1:95 CIV00198 (D.D.C. complaint filed Jan. 27, 1995). See generally M-D-D-I REP. ("The Gray Sheet"), Jan. 23, 1995, at I&W-6.

<sup>31</sup> *In re Boston Scientific Corp.*, FTC File No. C-3573 (Apr. 28, 1995) (consent settlement).

<sup>32</sup> Settlement of two prior FTC challenges to horizontal acquisitions in the pharmaceutical industry, *In re Roche Holdings, Ltd.*, FTC File No. C-3315 (Dec. 17, 1990) (consent settlement) and *In re Institute Merieux S.A.*, FTC File No. C-3301 (Sept. 21, 1990) (consent settlement), required divestitures in biotechnology/pharmaceutical production and in research and development activities, suggesting a concern with the effect of the acquisitions on innovation.

<sup>33</sup> See, e.g., Christine A. Varney, FTC Comm'r, *The Role of Competition Policy in Innovative Markets*, Remarks at The Manufacturers Alliance (Dec. 1, 1994). For detailed reviews, see Richard J. Gilbert & Steven C.

tive and of questionable utility in determining the likely competitive effects of a proposed transaction.<sup>34</sup> As the FTC's recent consent settlement with Glaxo (concerning that company's acquisition of Wellcome) illustrates,<sup>35</sup> however, agreement to some form of licensing or divestiture of research and development assets nonetheless appears to be a threshold requirement for obtaining authorization to undertake pharmaceutical industry consolidations.

### III. FOOD AND DRUG ADMINISTRATION ENFORCEMENT ACTIVITY

The FDA's traditional, restrictive regulation of pharmaceutical promotional statements and programs has been reconsidered by the agency, but has not been adapted effectively to the restructured pharmaceutical industry and its related new marketing activities. This reconsideration raises questions as to the agency's proper regulatory policy and the scope of its jurisdiction. In its general policy statements the agency has reiterated strongly its traditional policy concerning pharmaceutical promotional activity.<sup>36</sup> In several areas of new marketing activities responsive to the changing health care system, however, the agency has had to re-evaluate the applicability of its traditional policies.<sup>37</sup>

For example, the agency has reiterated its adherence to the traditional standard of two adequate and well-controlled clinical trials in substantiating pharmacoeconomic cost-effectiveness claims.<sup>38</sup> It is, however, unclear whether the FDA will continue this policy. The agency has recognized the growing concerns regarding its enforcement policy in this area by expressly seeking information and views concerning the generation and use of cost-effectiveness data in pharmaceutical promotions.<sup>39</sup> Nonetheless,

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Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569 (1995); Dennis A. Yao & Susan S. DeSanti, *Innovation Issues Under the 1992 Merger Guidelines*, 61 ANTITRUST L.J. 505 (1993).

<sup>34</sup> See generally Joseph Kattan, *Antitrust Analysis of Technology Joint Ventures: Allocative Efficiency and the Rewards of Innovation*, 61 ANTITRUST L.J. 937 (1993); Thomas M. Jorde & David J. Teece, *Innovation and Competition: Implications for Competition and Antitrust*, 4 J. ECON. PERSP. 75 (1990); William F. Baxter, *The Definition and Measurement of Market Power in Industries Characterized by Rapidly Developing and Changing Technologies*, 53 ANTITRUST L.J. 717 (1985); Richard T. Rapp, Pres., Nat'l Economic Research Assoc., *Policing R & D in Merger Analysis: The Innovation Market Mistake*, at ABA Antitrust Section Meeting (Apr. 5, 1995).

<sup>35</sup> In re Glaxo plc, FTC File No. C-3586 (June 20, 1995) (consent settlement) (requiring divestiture of Wellcome's research program and assets for treatment of migraine headaches).

<sup>36</sup> See, e.g., remarks of Dr. Peter H. Rheinlein, Dir. of Medicine Staff, Office of Health Affairs, FDA, in SCRIP, Dec. 6, 1994, at 18 (indicating FDA adherence to its traditional standard of two adequate and well-controlled clinical studies to support all significant promotional claims, notwithstanding the agency's lack of expertise to review and comment on new classes of claims, for example, relating to cost-effectiveness); see also remarks by Dr. Robert Temple, Dir., Office of Drug Evaluation I, FDA, WASH. DRUG LETTER, June 26, 1995, at 1.

<sup>37</sup> See, e.g., FDA ENFORCEMENT MANUAL MONTHLY BULL., July 1995, at 1, 7-8 (discussing current views of FDA officials). For a recent critical analysis and review of the FDA's policies in this area, see Bruce N. Kuhlik, *The FDA's Regulation of Pharmaceutical Communication in the Context of Managed Care: A Suggested Approach*, 50 FOOD & DRUG L.J. 23 (1995).

<sup>38</sup> See FDA guidance letter concerning cost-effectiveness claims to all holders of applications for antibiotic/anti-infective products, from Janet L. Rose, Dir., Div. of Drug Marketing, Advertising, and Communications, and Dr. Lillian Gavrilovitch, Acting Dir., Div. of Anti-Infective Drugs, Center for Drug Evaluation and Research, FDA (Sept. 12, 1994), in F-D-C REP. ("The Pink Sheet"), Sept. 26, 1994, at 8.

<sup>39</sup> See, e.g., F-D-C REP. ("The Pink Sheet"), Apr. 10, 1995, at 14-15 (summarizing a March 1995 conference concerning use of cost-effectiveness data and other comparative claims in drug marketing). See also FDA ADVERTISING AND PROMOTION MANUAL, Feb. 1995, at 1-2 (summarizing recent meetings and correspondence between FDA Deputy Commissioner Mary Pendergast and officials of the FDA's Division of Drug Marketing,

the agency has reiterated its traditional standards in its draft *Principles for Review of Pharmacoeconomic Promotion*,<sup>40</sup> which would continue to make pharmacoeconomic claims difficult to develop and present lawfully and effectively. The Pharmaceutical Research and Manufacturers of America<sup>41</sup> and a joint industry-academic-government task force<sup>42</sup> recently have proposed guidelines for pharmacoeconomic studies that are, in varying degree, less restrictive than the agency's draft approach.

Serious questions can be raised regarding the FDA's current enforcement position concerning cost-effectiveness claims, in view of its lack of expertise in economic analyses and in evaluating cost-effectiveness claims. Concerns also can be raised regarding the agency's current refusal to accept cost-effectiveness studies (other than controlled clinical trials), such as retrospective database studies, case control studies, and economic decision analysis models. Finally, there is serious question as to whether there is a basis for assertion of FDA jurisdiction over cost-effectiveness or other cost-based claims, because cost-based claims relate neither to safety nor to efficacy of drug products.<sup>43</sup>

Another controversial area of FDA enforcement activity is the agency's regulation of the promotion of off-label uses of approved products.<sup>44</sup> For example, the FDA's warning letter to Eli Lilly & Co. regarding alleged improper promotion of off-label uses for Axid (nizatidine) focuses on cost-effectiveness claims and other comparative claims.<sup>45</sup> The agency's restrictive policies concerning promotion of unapproved uses of approved drugs and devices have been challenged in court by a public interest organization<sup>46</sup> that also has criticized the agency's draft policy statement regarding industry-supported educational and scientific activities.<sup>47</sup>

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Advertising, and Communications, with representatives of Eli Lilly, Merck, SmithKline Beecham, and Pfizer, regarding affiliated PBM marketing and promotional practices, prescription drug "switch" programs, and communications to formulary decision makers, providers, and users concerning drug products).

<sup>40</sup> DIV. OF DRUG MARKETING, ADVERTISING AND PROMOTION, FDA, PRINCIPLES FOR THE REVIEW OF PHARMACOECONOMIC PROMOTION (Mar. 20, 1995) (Draft). Obstacles to development of useful pharmacoeconomic research are summarized in Bryan R. Luce, *Cost-Effectiveness Analysis: Obstacles to Standardization and Its Use in Regulating Pharmaceuticals*, 3 PHARMACOECONOMICS 1 (1993).

<sup>41</sup> PhRMA, METHODOLOGICAL AND CONDUCT PRINCIPLES FOR PHARMACOECONOMIC RESEARCH (Jan. 1995). FDA officials have criticized the PhRMA recommendations and approaches. See F-D-C REP. ("The Pink Sheet"), July 3, 1995, at 17; F-D-C REP. ("The Pink Sheet"), Apr. 10, 1995, at 14-15.

<sup>42</sup> Task Force on Principles for Economic Analysis, *Economic Analysis of Health Care Technology: A Report on Principles*, 123 ANNALS OF INTERNAL MED. 61 (July 1, 1995). The report is briefly summarized in F-D-C REP. ("The Pink Sheet"), July 3, 1995, at 15-16.

<sup>43</sup> See 21 U.S.C. § 321(p)(1) (1988) (definition of "new drug"). It is useful, in this regard, to compare the significant difficulties that the National Institutes of Health (NIH) has had in attempting to negotiate and administer "reasonable pricing clauses" in Cooperative Research and Development Agreements (CRADAs) between it and private research entities. After considerable discussion and controversy, NIH officials recently have eliminated the reasonable pricing clause. See F-D-C REP. ("The Blue Sheet"), Apr. 12, 1995, at 2-3.

<sup>44</sup> For a recent discussion of the policy issues in this area, see Richard M. Cooper, *Unapproved Uses of Drugs: An Analysis and Some Proposals*, 49 FOOD & DRUG L.J. 533 (1994).

<sup>45</sup> See FDA Warning Letter to Eli Lilly & Co. (July 19, 1994) (regarding alleged improper promotion of off-label uses for Axid (nizatidine)).

<sup>46</sup> See *Washington Legal Foundation v. Kessler*, Food, Drug, Cosm. L. Rep. (CCH) ¶ 38,396 (D.D.C. 1995) (The FDA's draft policy statement on promotion of approved drugs for unapproved uses was appropriately subject of judicial review). The constitutional limitations on agency regulation of truthful labeling and advertising are discussed in the Supreme Court's recent decision in *Rubin v. Coors Brewing Co.*, 115 S. Ct. 1585 (1995), invalidating the Bureau of Alcohol, Tobacco and Firearms' ban on alcohol content labeling.

<sup>47</sup> See FDA Request for Comments on Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59,820 (Nov. 18, 1994) (in response to the Citizen Petition of the Washington Legal Foundation challenging the agency's draft policy statement concerning industry-supported educational and scientific activities).

The agency's enforcement policy regarding pre-approval promotion to managed-care organizations is the subject of debate. The FDA's recent warning letter to Burroughs-Wellcome, for example, challenged pre-approval contacts by the company with managed-care organizations, specifically the provision of information packages to managed care pharmacy directors to prepare them for the introduction of the company's new epilepsy drug, Lamictal (lamotrigine).<sup>48</sup> In the warning letter the agency acknowledged that health care providers desire information about forthcoming drugs "as early as possible" for formulary development and other purposes, but stated that this does not permit the dissemination of promotional materials prior to FDA approval for any indication, including uses for which a company has not sought approval. In view of the current, and increasing, predominance of managed-care organizations and state formulary committees in purchasing pharmaceutical products, continued controversy can be expected should the FDA's restrictive policy concerning pre-approval promotion remain unchanged.

The agency also is concerned with the effects of acquisition of PBMs by pharmaceutical manufacturers, particularly on product promotion and drug distribution.<sup>49</sup> The agency reportedly has investigated such acquisitions and alliances for their possible effects on drug promotion and for violations of the FDA's marketing practices regulations.<sup>50</sup> The FDA expressed its concerns in comments to the FTC regarding the Commission's proposed consent settlement for Eli Lilly's acquisition of PCS Health Systems.<sup>51</sup>

The effect of the recent development of disease management programs by pharmaceutical manufacturers on the FDA's traditional policies concerning promotional activities also is uncertain. In such programs, comprehensive management is undertaken of all therapies utilized in the treatment of a particular disease including cost-effectiveness analysis and outcomes research.<sup>52</sup> Questions can be raised, however, as to whether the FDA has jurisdiction to regulate a managed care entity (for example, an HMO) that is not a corporate affiliate of a pharmaceutical manufacturer, but that selects drug products for its formulary, makes comparative claims for drug products that are included in its formulary, or makes claims or recommendations for unapproved uses of the drug products. Questions also may be raised as to whether the FDA has jurisdiction to regulate such activities when undertaken by an incorporated subsidiary of a pharmaceutical manufacturer, in particular, one in which an information exchange "firewall" has been established either by company policy or through consent settlement with another governmental entity.

Finally, the effect of the agency's traditional enforcement policy for drug promotional activity on consolidation of pharmaceutical manufacturers with health care service providers is unclear. The acquisition announced earlier this year by Zeneca Group

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<sup>48</sup> See FDA Warning Letter to Burroughs-Wellcome Corp. (Dec. 2, 1994), in F-D-C REP. ("The Pink Sheet"), Dec. 12, 1994, at 7-8.

<sup>49</sup> See F-D-C REP. ("The Pink Sheet"), June 19, 1995, at T&G-10-11.

<sup>50</sup> See F-D-C REP. ("The Pink Sheet"), Nov. 21, 1994, at 10.

<sup>51</sup> See Letter from Mary K. Pendergast, Deputy Comm'r, FDA, to Donald Clark, Sec'y, FTC (Jan. 26, 1995). In that letter, Ms. Pendergast states that in recent years, FDA has become increasingly concerned that pharmaceutical companies are actively promoting their products for unlabeled uses and without sufficient disclosures regarding the risks and limitations of these products. With continued vertical integration and the use of 'innovative marketing interventions,' we are concerned that pharmaceutical companies may find new ways to circumvent these [FDA] legal requirements.

<sup>52</sup> See the summary discussion of FDA and others' views in SCRIP, Sept. 23, 1994, at 15. For a discussion of the potential applicability of disease management approaches in Europe, see Maria Hall, *Disease Management — What Role for the Industry in Europe?*, SCRIP, June 1995, at 29.

of a fifty percent interest in Salick Health Care, which operates cancer diagnostic and treatment centers and kidney dialysis centers,<sup>53</sup> is the first such consolidation. Other such vertical acquisitions, however, can be expected as pharmaceutical manufacturers seek to integrate with health care service providers that administer pharmaceutical products and medical devices.

FDA Commissioner Kessler and other senior FDA officials recently have questioned many of these new industry promotional activities, including comparative cost effectiveness claims, "seeding trials" of products that are not intended to be utilized for product approval purposes, and switch campaigns by manufacturers or mail-order PBMs based on price or other comparative claims that utilize incentives to pharmacists to encourage physicians to switch a patient to the sponsor's product.<sup>54</sup> While the FDA's concerns are understandable in part,<sup>55</sup> continuation of the agency's traditional policies without adjustment to these significant marketplace changes appears impracticable and inappropriate.

#### IV. OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ENFORCEMENT ACTIVITIES

The Office of Inspector General of the Department of Health and Human Services also is involved with new pharmaceutical industry promotional programs.<sup>56</sup> The OIG has reviewed promotional payments for products in the new managed care context, to determine whether such payments are violative of the Medicare and Medicaid anti-kickback provisions.<sup>57</sup> Last year, the OIG brought indictments against Genentech and Caremark for allegedly paying out \$1,100,000 in "kick-back" in the marketing and distribution of Genentech's human growth hormone product,<sup>58</sup> which recently have been settled, with Caremark agreeing to pay \$161,000,000 in costs and penalties.<sup>59</sup> A civil action last year against Hoffmann-LaRoche, alleging implementation of an improper incentive prescription plan (including payments to physicians for prescribing an antibiotic, Rocephin) and for clinical studies that were allegedly of little or no value, was settled with agreement to pay \$450,000 to resolve the government's claims.<sup>60</sup> Also in 1994, the OIG issued a Special Fraud Alert concerning prescription drug marketing practices, which enumerated specific violative marketing activities, including certain research grant programs and product conversion programs.<sup>61</sup> The breadth and unclarity of the anti-kickback provisions, however, has led to reluctance by some in

<sup>53</sup> See F-D-C REP. ("The Pink Sheet"), Jan. 2, 1995, at 3-5. Glaxo also has made a minority investment in Circadian, a network of asthma clinics. See F-D-C REP. ("The Pink Sheet"), Nov. 14, 1994, at 8.

<sup>54</sup> See Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 NEW ENG. J. OF MED. 1350 (Nov. 17, 1994).

<sup>55</sup> See, e.g., OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING HEALTH TECHNOLOGIES THAT WORK: SEARCHING FOR EVIDENCE (1994) (a critical analysis of the present status of outcomes research).

<sup>56</sup> See generally Testimony of June Gibbs Brown, Inspector General, DHHS, Prescription Drug Marketing: Questionable Practices Within the Pharmaceutical Industry, Before the House Subcomm. on Regulation, Business Opportunities, and Technology (Oct. 12, 1994).

<sup>57</sup> See 42 U.S.C. § 1320a-7b(b) (1988). The OIG has promulgated "safe harbor" regulations setting out arrangements that would not constitute violations of the anti-kickback provisions. 42 C.F.R. §§ 1001.951 et seq. (1994).

<sup>58</sup> See F-D-C REP. ("The Pink Sheet"), Aug. 8, 1994, at 3-4; M-D-D-I REP. ("The Gray Sheet"), Oct. 3, 1994, at I&W-17.

<sup>59</sup> See F-D-C REP. ("The Pink Sheet"), June 19, 1995, at T&G-10-11.

<sup>60</sup> See FDA ENFORCEMENT MANUAL MONTHLY BULL., May 1995, at 7.

<sup>61</sup> See OIG, DHHS, SPECIAL FRAUD ALERT ON PRESCRIPTION DRUG MARKETING SCHEMES, (Aug. 1994) (OIG-94-18).

industry to fund product evaluations in association with managed-care organizations.<sup>62</sup>

While the OIG's statutory authority and actions occasionally are cited as support for challenges by other agencies to prescription drug promotion programs, such reliance raises difficulties. The OIG takes action in the particular area of Medicare and Medicaid reimbursement under very specific and comprehensive statutes, and these are not readily analogous or usable in other regulatory or enforcement contexts.

## V. MULTISTATE ENFORCEMENT ACTIVITIES

The most novel source of recent enforcement has been the states. They have been active in bringing group challenges under their individual consumer protection statutes to drug marketing and promotional activities in the new managed care environment. The states also have raised issues regarding pharmaceutical industry restructuring.<sup>63</sup>

One area of state enforcement activity has been direct-to-consumer prescription drug advertising. For example, eleven states recently entered into a consent settlement with Ciba-Geigy Corp., resolving allegations that the company used misleading direct-to-consumer advertising (which had previously been approved by the FDA), in marketing its prescription nicotine patch, Habitrol.<sup>64</sup> The settlement required that future advertising to consumers include information concerning the product's lack of efficacy and potential adverse health risks and that the company refrain from making certain other claims relating to its product. Ciba-Geigy also agreed to provide information to consumers through a toll-free number and direct mailings, and paid \$550,000 in administrative costs. Similarly, Marion Merrell-Dow agreed to a consent settlement resolving allegations by twelve states that the company had engaged in misleading advertising for its prescription antihistamine drug, Seldane, and its prescription nicotine patch, Nicoderm.<sup>65</sup> The company agreed to include certain information about the adverse health effects of both products in any future advertising to consumers, to refrain from certain other claims, and to provide information in a patient package insert or direct mailing. The company also consented to pay a total of \$600,000 in administrative costs.

In the area of advertising over-the-counter (OTC) drugs, the attorneys general of eleven states and one state district attorney entered into a consent settlement with Sandoz Pharmaceuticals Corp. resolving allegations that the company had engaged in false and misleading advertising regarding a reformulation of its Triaminic cough-and-cold products.<sup>66</sup> The states alleged that the new Triaminic product was identical to the previous version, except that one-half of the active ingredient was removed. As a consequence, the recommended dosage was doubled and consumers received one-half as many dosages per bottle. The company agreed to not represent on the packaging that the product was "new" and/or "improved" on the basis of this reformulation, and to refrain from making certain other claims. The company also agreed to pay a total

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<sup>62</sup> See F-D-C REP. ("The Pink Sheet"), Mar. 13, 1995, at T&G-11.

<sup>63</sup> For a detailed discussion of practical concerns in responding to such multistate investigations, see Mahinka & Sanzo, *supra* note 2, at 227-37.

<sup>64</sup> In the Matter of Ciba-Geigy Corp., (Minn. Dist. Ct. filed Mar. 15, 1993).

<sup>65</sup> The "kick-back" inducements for which OIG cited Genentech and Caremark included the reimbursement of physicians for patient recruitment in research studies. In the Matter of Marion Merrell-Dow, (Minn. Dist. Ct. filed June 9, 1993).

<sup>66</sup> In the Matter of Sandoz Pharmaceuticals Corp. (filed June 18, 1993).

of \$800,000 to the states in administrative costs and to provide a coupon redeemable for a comparable-size product to any consumer who complains about a Triaminic product.

The states also have undertaken several controversial challenges concerning prescription drug marketing and compensation programs. The attorneys general of five states challenged American Cyanamid's pharmacist reimbursement program for dispensing prescriptions of its nicotine transdermal system, Prostep.<sup>67</sup> The company's pharmaceutical division, Lederle Laboratories, had undertaken a nationwide pharmacy promotion program whereby pharmacists were compensated for counseling services provided to consumers in connection with dispensing prescriptions for the company's drug. The pharmacists were paid \$2 each time they obtained certain information from a consumer who presented them with a Prostep prescription. The pharmacists were not required to disclose to consumers the existence of the compensation program. The company agreed, in settlement of the states' challenge to the program as a deceptive marketing practice, to pay a total of \$50,000 in administrative costs. They also agreed not to offer or provide compensation to pharmacists participating in the counseling program without requiring that they disclose to the consumer the existence of the compensation program.

In a similar action against Miles, Inc., the attorneys general of eleven states entered into a consent settlement resolving allegations that the company's advertising practices in promoting its prescription hypertensive drug, Adalat CC, were deceptive and a violation of state consumer protection statutes.<sup>68</sup> The company had instituted a pharmacy information program that provided pharmacists \$35 for filling new prescriptions for Adalat CC and giving patients certain other information. Participating pharmacists were not required to disclose to consumers or physicians that the pharmacists would be paid for Adalat CC prescriptions. The consent settlement's scope is broad, preventing the company not only from resuming its program or any substantially similar program for that drug product, but also preventing implementation of any such program for any other drug made or sold by the company. The company also agreed to pay a total of \$605,000 in administrative costs.

In the most recent settlement of a multistate investigation of pharmaceutical company promotional practices, the attorneys general of eight states entered into a consent agreement with The Upjohn Company, to resolve allegations that the company's advertising and promotional practices for its diabetes drug, Glynase PresTab, were deceptive and misleading, in violation of the states' consumer protection statutes.<sup>69</sup> As in the investigations of Miles and American Cyanamid, the states based their false advertising allegations on those previously raised with the FDA and since resolved through corrective action by the company. In addition to the false advertising allegations, the states also objected to the company's cognitive services reimbursement program for pharmacists. Under this program, the company paid \$8 to a pharmacist who obtained the approval of a patient and their physician to use the company's drug product, and then either provided information about the relative benefits of the company's product or compared the product to another diabetes drug provided by the

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<sup>67</sup> In the Matter of American Cyanamid Corp. (filed Sept. 8, 1993).

<sup>68</sup> In the Matter of Miles, Inc. (filed Apr. 4, 1994). A private action seeking an injunction against comparative claims made in drug advertising also challenged Miles' pharmacy information program, under the FTC Act, the Medicaid anti-kickback statute, and state consumer protection law. See *Pfizer Inc. v. Miles, Inc.*, 1995-1 Trade Cas. (CCH) ¶ 70,863 (D. Conn. 1994). Because of the multistate consent settlement, the court denied preliminary injunctive relief. *Id.* at 73,767-68.

<sup>69</sup> In the Matter of The Upjohn Co. (Minn. Dist. Ct. filed Aug. 1, 1994).

company. The company did not require participating pharmacists to disclose the payment to the consumers or physicians. As part of the settlement, the company agreed not to engage in programs that would provide direct or indirect payments to pharmacists or pharmacy chains for encouraging the sale of a particular drug product. In addition, the company agreed to pay \$675,000 in administrative costs.<sup>70</sup>

The economic and evidentiary bases of support for the conclusion that such pharmaceutical promotional programs are misleading is questionable because it is legally necessary to obtain the authorization of a patient's physician to use a particular drug or to convert from current use of a different drug. Moreover, the general consumer protection statutes utilized by the states' attorneys general for these actions may not be intended to address prescription drug promotion in the manner asserted by the states. Most prescription drug distribution programs, whether through physicians, pharmacists, distributors, or other health care providers, entail some element of promotional payment, whether related to particular product conversions or provided as general inducements for successful shifts of market share. Such marketing practices are common in other industries, and the legal or economic basis for different treatment of the pharmaceutical industry has not been demonstrated clearly by the states or subjected to judicial review.

Notwithstanding such questions as to the propriety of the states' activities in this area, twenty states have urged that the FDA increase federal-state collaboration and take enforcement action similar to that of the states against promotional payment programs.<sup>71</sup> The FDA recently has proposed expansion of its information exchange program with the states, which would allow trade secret nonpublic safety, efficacy data, and nonpublic FDA predecisional documents to be provided to the states.<sup>72</sup> The states also have shown an interest in pharmaceutical industry restructuring. Comments were filed by the states urging the FTC to reject the acquisition of PCS Health Systems by Eli Lilly & Co., arguing that the FTC's proposed consent settlement is inadequate to deal with the alleged "unfair" competition from such vertically-integrated manufacturers.<sup>73</sup>

## VI. CONCLUSION

The current, unprecedented restructuring of the pharmaceutical industry, and the development of new approaches to marketing and distribution of pharmaceutical products, will continue as they are the consequence of systemic changes in the health care system. In view of the scope and number of enforcement activities by federal agencies and multistate groups, however, industry members must assess carefully the trends of enforcement when developing new marketing approaches and considering acquisitions or strategic alliances.

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<sup>70</sup> The states also have challenged the advertising of medical devices. A group of 36 states entered into a consent settlement with Dahlberg, Inc., resolving allegations that the company made false and misleading claims regarding the features and/or performance characteristics of its hearing aid products. The company also agreed to pay \$700,000 in administrative costs to fifteen of the investigating states. *See In the Matter of Dahlberg, Inc.* (filed Apr. 6, 1994).

<sup>71</sup> *See* letter from Hubert H. Humphrey III, Att'y Gen., Minn., to Dr. David A. Kessler, Comm'r of Food and Drugs, FDA (May 4, 1994).

<sup>72</sup> *See* 60 Fed. Reg. 5530 (Jan. 27, 1995). For a discussion of protection under the Freedom of Information Act for trade secrets and other confidential proprietary information submitted to FDA, *see* Stephen Paul Mahinka & Jill B. Deal, *Information Disclosure in the USA (Parts I and II)*, 6 REG. AFFS. J. 7 (1995) (part I), 6 REG. AFFS. J. 99 (1995) (part II).

<sup>73</sup> *See* Letter from Hubert H. Humphrey III, Att'y Gen., Minn., to FTC Comm'rs (Nov. 2, 1994).