

# The New Drug Marketing: A Consumer Protection Perspective

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## I. INTRODUCTION

This article is based on comments submitted on behalf of Minnesota, a state with a long history of and commitment to public protection and health care reforms, pursuant to the Food and Drug Administration's (FDA's) request for public comments on issues of paramount public importance affecting consumers nationwide, a subject the FDA describes as "pharmaceutical marketing and information exchange in managed care environments." The nation's health care bill now exceeds one trillion dollars. Of that staggering amount, an estimated seven to ten percent, or \$70 to \$100 billion, is spent by American consumers on prescription drugs. How prescription drugs are advertised and marketed is one of the most important public protection concerns of this decade, and will remain at the forefront of consumer protection issues in the coming century.

The FDA is to be commended for seeking public comment on one of the most significant fronts of the prescription drug promotion revolution that is sweeping through the health care marketplace. Recent acquisitions by pharmaceutical companies of prescription benefit management (PBM) businesses affect over 160,000,000 American consumers, raise significant public protection issues, and offer a unique opportunity for the FDA to exercise its broad jurisdiction in a challenging new health care environment. To develop a fair and firm regulatory approach in this important area, the FDA should focus on its historic role of promoting public health and safety, as well as the integrity of the health care delivery system, by ensuring that prescription drug promotional activities and communications remain truthful and nondeceptive.

The public interest in promoting informed decisions by physicians and consumers in prescribing and using prescription drugs — decisions premised on complete, accurate, fairly balanced, truthful, and nonmisleading information — is fully compatible with the core managed care objectives of providing quality health care and containing health care costs. There is no inherent inconsistency between the policy and enforcement goals of furthering informed health care choices through truthful, nonmisleading advertising and marketing practices, and delivering high quality health care products and services at the lowest possible costs to consumers. Those objectives are mutually reinforcing; they represent common ground shared by the health care industry, regulators, and consumers, and they offer basic principles that should inform FDA regulation in this area.

This article consists of three parts. The first section provides background information on recent acquisitions and affiliations between drug manufacturers and PBM companies, and highlights the nationwide dimensions of these fundamental market transformations. The second section invokes the FDA's broad jurisdiction over prescription drug labeling, advertising, and promotional activities, and suggests that application of

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this established jurisdiction in the managed care context is fully consistent with the FDA's demonstrated experience in applying long-held principles to new forms of promotional activities. The third section suggests starting points for applying the FDA's jurisdiction in this area, by considering as a minimum threshold: (1) the uniform application of the standards and requirements from a recent multistate settlement between seventeen states and a large pharmaceutical company and its recently acquired PBM; (2) improving and safeguarding the information flow between PBM pharmacists and physicians; and (3) furthering the interests of the public and the health care industry in the provision of truthful, nonmisleading information to consumers and in the protection of consumers' privacy interests.

## II. BACKGROUND: FUNDAMENTAL CHANGES

The health care market, especially those forces driving the pharmaceutical industry, has undergone remarkable changes. The traditional marketplace, in which physicians occupied central roles as key decisionmakers and pharmaceutical manufacturers targeted their marketing activity on individual sales calls to physicians, has given way to an emerging health care environment characterized by rapid change. The physician's role as prescriber, and therefore is an important gatekeeper of public health, has remained key. Other realities must factor into an understanding of the current marketplace: cost containment has become a driving force in the new market; the role of third-party payors is becoming increasingly important; competitive pressures continue to mount in a pharmaceutical industry in which no major player exercises dominance across multiple therapeutic categories; and pharmaceutical industry promotional activities are becoming more aggressive as they reach beyond traditional detailing to include expanded direct-to-consumer advertising, promotional practices involving payments to health care providers, and a high level of merger activity (among pharmaceutical manufacturers and between pharmaceutical companies and PBMs).

If 1995 proved to be the year of the merger within several major industries,<sup>1</sup> it certainly was presaged within the health care industry by Merck & Co., Inc.'s acquisition of Medco Containment Services, Inc., in November 1993. Merck, the largest pharmaceutical company when measured by U.S. pharmaceutical sales and having net revenues of \$10.5 billion in 1993, purchased Medco for approximately \$6.6 billion.<sup>2</sup> At the time of the acquisition, Medco, the second largest PBM company, provided PBM services to health plan sponsors covering over 33,000,000 consumers and managed approximately 95,000,000 prescriptions, or \$4 billion in annual drug expenditures.<sup>3</sup> Medco's growth since its acquisition by Merck has been significant. At a December 1995 meeting with analysts, Medco reported that it provides services to health plan sponsors covering 47,000,000 Americans and handled 170,000,000 prescriptions in 1995, representing an annual increase of thirty-one percent.<sup>4</sup>

Merck's acquisition of Medco represented the first vertical penetration by a large pharmaceutical manufacturer into the market for PBM services. In May 1994, SmithKline

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<sup>1</sup> See, e.g., Jana Jiwolop, *Stalking The Next Big Takeovers*, N.Y. TIMES, Nov. 5, 1995, at F5, § 3; *The Year Of The Do-It-Yourself Megadeal*, N.Y. TIMES, Dec. 26, 1995, at A17.

<sup>2</sup> GENERAL ACCOUNTING OFFICE, PHARMACY BENEFIT MANAGERS: EARLY RESULTS ON VENTURES WITH DRUG MANUFACTURERS 10, app. II at 25 (1995) [hereinafter GAO PHARMACY BENEFIT MANAGERS REP.].

<sup>3</sup> *Id.* app. II at 25.

<sup>4</sup> Elyse Tanouye, *Merck's Medco Unit Moves "On Track," Chairman Gilmartin Assures Analysts*, WALL ST. J., Dec. 13, 1995, at B6.

Beecham Corporation (at that time the seventh largest pharmaceutical manufacturer in terms of 1993 domestic pharmaceutical sales) announced that it would acquire Diversified Pharmaceutical Services, Inc. (DPS) from United HealthCare Corporation for \$2.3 billion. In 1993 DPS was the third largest PBM firm. During 1993, DPS provided prescription drug benefit management services to approximately 14,000,000 consumers and accounted for approximately \$2 billion in drug spending.<sup>5</sup> In November 1994, Eli Lilly & Co., Inc. (at that time ranked fifth among pharmaceutical manufacturers in terms of U.S. pharmaceutical sales) purchased for \$4 billion PCS Health Systems, Inc. from McKesson Corporation. PCS has been ranked as the largest PBM company. At the time of its acquisition by Eli Lilly, PCS provided PBM services to approximately 1300 plan sponsors, covering over 50,000,000 consumers and accounting for about \$9 billion in drug expenditures.<sup>6</sup>

In addition to these acquisitions of PBMs by pharmaceutical manufacturers, the health care industry recently witnessed various affiliations between drug manufacturers and companies providing PBM services. In May 1994, Pfizer Inc., which had \$7.5 billion in net sales in 1993 and ranked eighth among U.S. pharmaceutical manufacturers in terms of domestic sales, announced a "strategic relationship" with Value Health, Inc., the parent company of Value Rx (a major PBM that ranked as the sixth largest PBM at the time of the announcement and provided services covering approximately 1,000,000 consumers). During May 1995, Value Health acquired Diagnostik, Inc., whose PBM unit covered about 16,000,000 consumers. This resulted in Value Rx ultimately covering about 32,000,000 consumers and placed it among the largest PBM companies. In 1994 Pfizer formed another "strategic alliance" with Caremark International, Inc., whose PBM and mail service pharmacy unit ranked fourth among PBMs in 1994 and provided benefit management services for approximately 1100 plan sponsors covering approximately 13,000,000 consumers.<sup>7</sup>

The impact of these fundamental realignments within the health care market is striking. In its November 1995 report, the U.S. General Accounting Office (GAO) noted that in 1989 PBMs managed prescription drug benefits for approximately 60,000,000 people. By 1993, that number had grown to approximately 100,000,000 (or almost forty percent of the entire national population). Projecting that rate of growth on a continuum, the GAO estimated that by the end of 1995 PBMs would provide services for health plans covering approximately fifty percent of the population. Of the more than forty PBMs in the United States, estimates suggest that the five largest PBMs (PCS Health Systems, Medco, Value Rx, DPS, and Caremark International, Inc.'s Prescription Services Division) provide PBM services for over eighty percent of consumers covered by health plans managed by PBMs.<sup>8</sup>

In the broader context of the managed care environment, of which PBMs represent a major part, managed care health plans account for over half of the total dollars spent for outpatient prescription drugs.<sup>9</sup> By the year 2000, that number may well increase to seventy-five percent or more.

In the midst of these sweeping changes, the interests of consumers in receiving

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<sup>5</sup> GAO PHARMACY BENEFIT MANAGERS REP., *supra* note 2, at 10, app. II at 25-26.

<sup>6</sup> *Id.* app. II at 26.

<sup>7</sup> *Id.* app. II at 27-28.

<sup>8</sup> *Id.* at 3-4.

<sup>9</sup> Jeannie Mandelker, *The Expanding Role of PBMs*, 13 BUS. & HEALTH 56 (1995); Bruce Kuhlik, *The FDA's Regulation of Pharmaceutical Communications in the Context of Managed Care: A Suggested Approach*, 50 FOOD & DRUG L.J. 23, 35 (1995).

high quality drugs at the lowest possible cost, and the public's interest in a prescription drug delivery system focused on public health, informed decisionmaking, and truthful, nonmisleading information, should remain paramount. The FDA has well established tools with which to safeguard these public interests.

### III. FDA JURISDICTION OVER PRESCRIPTION DRUG PROMOTIONAL ACTIVITIES

Anchored in its statutory and regulatory authority over prescription drug labeling and advertising, the FDA has broad jurisdiction over a wide range of prescription drug promotional and marketing practices engaged in by, or on behalf of, pharmaceutical manufacturers. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a prescription drug is misbranded, and its sale therefore prohibited, if its labeling is false or misleading.<sup>10</sup> The FDCA defines labeling to include any written, printed, or graphic matter on or accompanying a drug.<sup>11</sup> Courts have construed this definition liberally, so as to embrace written materials that do not physically accompany but are related to the drug.<sup>12</sup> By regulation, the FDA has identified a wide range of materials as falling within the definition of drug labeling.<sup>13</sup>

Although advertising is not defined in the FDCA, it includes under FDA regulations not only advertisements appearing in journals, magazines, and newspapers, but also advertisements broadcast through media such as radio, television, and telephone communication systems.<sup>14</sup>

A fundamental safeguard contained in the FDCA and implementing regulations is the prohibition against false or misleading labeling or advertising. These proscriptions include both affirmative misrepresentations and the failure to disclose material facts.<sup>15</sup> The FDA's advertising regulations identify twenty ways in which prescription drug advertisements will be deemed false or misleading, as well as thirteen ways in which advertisements may be deemed false or misleading.<sup>16</sup>

The FDCA further provides that a drug is considered misbranded if its advertisements do not include "such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations . . ."<sup>17</sup> The requirement of a "brief summary" is integral. FDA regulations require that the brief summary be a true statement of information relating to side effects, warnings, precautions, and contraindications.<sup>18</sup> Another core public protection safeguard contained in existing law is the requirement that prescription drug labeling and advertising must demonstrate "fair balance."<sup>19</sup> Drug advertisements must present a fair balance of benefit and risk information. Advertising claims relating to the benefits of a drug, such as safety or efficacy, must be balanced with disclosures concerning the risks and limitations of efficacy. Additionally, risk information is to be presented with comparable prominence and readability as claims about the drug's benefits.<sup>20</sup> Similarly, FDA regu-

<sup>10</sup> Pub. L. No. 75-717, § 502(a), 52 Stat. 1040, 1050 (1938), as amended 21 U.S.C. § 352(a) (1994).

<sup>11</sup> *Id.* § 201(m), 21 U.S.C. § 321(m).

<sup>12</sup> *See Kordel v. United States*, 335 U.S. 345 (1948).

<sup>13</sup> 21 C.F.R. § 202.1(l)(2) (1996).

<sup>14</sup> *Id.* § 201.1(l)(1).

<sup>15</sup> FDCA § 201(n), 21 U.S.C. § 321(n).

<sup>16</sup> 21 C.F.R. § 202.1(e)(6), (7).

<sup>17</sup> FDCA § 502(n), 21 U.S.C. § 352(n).

<sup>18</sup> 21 C.F.R. § 202.1(e)(1), (4).

<sup>19</sup> *Id.* § 201.1(e)(5)(ii), (6), (7). *See also* FDCA §§ 502(a), 201(m), 21 U.S.C. §§ 352(a), 321(n).

<sup>20</sup> 21 C.F.R. § 202.1(e)(7)(viii).

lations direct that labeling and advertising generally be accompanied by the drug's prescribing information.<sup>21</sup>

Broadcast advertisements (including those disseminated via radio, television, or telephone) must contain a brief summary unless "adequate provision" is made for disseminating the drug's approved labeling. Broadcast advertisements also must present information relating to major risks (side effects, warnings, precautions, and contraindications) of the drug. This required "major statement" must be an integral part of the broadcast advertisement and be communicated in understandable language.<sup>22</sup>

A cornerstone prerequisite for application of FDA jurisdiction over prescription drug promotional activity is that the activity, materials, or statements at issue must be those of, or be made by or on behalf of, the drug manufacturer or distributor.<sup>23</sup> Representatives of PBMs or pharmaceutical companies can be expected to argue that the FDA has no jurisdiction over drug-related communications disseminated by PBMs because such statements purportedly are made on behalf of the same customers to which the PBM provides benefit management services, health plan sponsors (including, for example, major corporations, large insurance carriers, and public employee health and retirement benefit plans, Blue Cross and Blue Shield organizations, and local governmental entities providing health plan coverage to employees and their dependents). According to this view, since PBM drug-related information purportedly is disseminated on behalf of plan sponsors and not any particular pharmaceutical manufacturer or distributor, such communications do not fall within the established definitions of labeling or advertising and the FDA therefore lacks jurisdiction over them. The FDA should reject this argument, however, as it is both unpersuasive and insupportable.

A prime motive for pharmaceutical manufacturers to invest huge sums in purchasing PBMs is to increase market share for the manufacturer's drugs by ensuring access to formularies operated by the acquired PBMs and to realize preferential treatment within PBM-managed formularies and formulary compliance programs.<sup>24</sup> Merck's acquisition of Medco provides an illustrative case study. At the time of the landmark Merck-Medco acquisition, Merck's then-Chief Executive Officer, P. Roy Vagelos, in a published interview was quite candid about the purposes of the merger. Mr. Vagelos identified numerous changes in health care reforms, noted that "[i]n the future, Merck will have to grow through increased volumes without considerable price increases," and stated, "[w]e see a tremendous opportunity to create a new model for the pharmaceutical industry that would simultaneously improve the quality of health care, help contain costs, and increase Merck's market share."<sup>25</sup> Merck recognized that "having salespeople visit doctors offices does not allow us to reach PBMs, HMOs or plan sponsors — the major players in the emerging market; . . . [w]e realized that we needed an entirely new method to deal with the changes we saw coming in the market."<sup>26</sup> Mr. Vagelos clearly articulated a major purpose behind the purchase of Medco:

Our acquisition of Medco — and, in fact, our competitors' new alliances with

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<sup>21</sup> See *id.* §§ 201.100(d) (labeling), 202.1(e) (advertising).

<sup>22</sup> See *id.* § 202.1(e)(1); 60 Fed. Reg. 42,583 (Aug. 16, 1995).

<sup>23</sup> FDCA § 502(n), 21 U.S.C. § 352(n) (advertising); 21 C.F.R. § 202.1(I)(2) (labeling).

<sup>24</sup> See, e.g., Milt Freudenheim, *A Shift of Power in Pharmaceuticals*, N.Y. TIMES, May 9, 1994, at D1; Elyse Tanouye, *Changing Minds — Owning Medco, Merck Takes Drug Marketing The Next Logical Step*, WALL ST. J., May 31, 1994, at A1; Nancy A. Nichols, *Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos*, HARV. BUS. REV., Nov.-Dec. 1994, at 105.

<sup>25</sup> Nichols, *supra* note 24, at 105, 106.

<sup>26</sup> *Id.* at 110.

other PBMs — represents an attempt to gain additional market access and to focus our selling efforts. Let's look at the numbers. Merck's market share is currently about 9.5 percent overall in the United States, but because some of the Medco formularies include Merck drugs, our products represent 11 percent of the drugs that Medco sells. Our goal is to increase that figure.<sup>27</sup>

When asked "How will owning the distribution system, Medco, allow Merck to shift market share to its own product?" Mr. Vagelos was equally candid: "Medco pharmacists make about 2 million calls a year to doctors . . . . When it's appropriate medically, we can use these calls to ask doctors to choose our products."<sup>28</sup> Later in the interview, Mr. Vagelos noted that "Merck products are Medco's house brand" and explained the consequences: "Consider what happens if instead of having 20 products on the formulary we have 40. The more Merck products on the formulary, the greater our power on the market and the more plan sponsors will save."<sup>29</sup>

In its recent report, *Pharmacy Benefit Managers: Early Results on Ventures With Drug Manufacturers*, the GAO noted the following:

Of the eight products that represent almost all Merck sales of brand name products to Medco enrollees, only one was on Medco's formulary in January 1993. In May 1993, 2 months before reaching their decision to merge and 6 months before closing their merger, Merck and Medco established an agreement to add the remaining 7 products to Medco's formulary.<sup>30</sup>

The GAO report further documented that shortly before its merger agreement with Merck, "Medco increased its preference for Merck drugs by adding a number of Merck's large-dollar volume products to its formulary and dropping several drugs that competed with Merck's drugs."<sup>31</sup>

After Merck's acquisition of Medco and beginning in approximately the middle of 1994, Medco included certain widely prescribed Merck drugs as preferred drugs in Medco's program of having Medco pharmacists telephone physicians to discuss changes from competitors' drugs to Merck drugs in prescriptions that had been received by Medco at its mail order pharmacies. After Merck's acquisition of Medco, prescriptions for Merck products dispensed to consumers participating in health plans managed by Medco increased significantly, as did dispensing of Merck products that gained status as formulary-preferred drugs for which Medco pharmacists telephoned physicians to discuss changes of prescriptions to the Merck drugs.<sup>32</sup> In a December 1995 report to

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<sup>27</sup> *Id.* at 111.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 113.

<sup>30</sup> GAO PHARMACY BENEFIT MANAGERS REP., *supra* note 2, at 3.

<sup>31</sup> *Id.* at 14.

<sup>32</sup> In the Matter of Merck & Co., Inc. and Medco Containment Servs., Inc., No. C6-95-10614 (Ramsey Co. D.C. Oct. 25, 1995) (agreement (assurance of discontinuance) and order approving assurance of discontinuance). The Merck/Medco agreement is the sixth of seven multistate settlements coordinated by Minnesota's Office of the Attorney General's Consumer Enforcement Division that involves the application of state consumer laws to various pharmaceutical industry practices in the advertising and promotion of prescription or over-the-counter drugs. *See* In the Matter of McNeil-PPC, Inc., McNeil Consumer Products Co., and the Arthritis Foundation, Inc., No. C4-96-10427 (Ramsey Co. D.C. Oct. 22, 1996) (assurance of discontinuance/assurance of voluntary compliance and order approving assurance of discontinuance); In the Matter of the Upjohn Co., No. C7-94-7856 (Ramsey Co. D.C. Aug. 1, 1994) (assurance of discontinuance/assurance of voluntary compliance and order approving assurance of discontinuance); In the Matter of

security analysts, Merck's Chairman reported that Medco was selling more Merck drugs, so that thirteen percent of prescription drugs dispensed through Medco are Merck products; this represents an increase from the ten percent figure applicable in 1993 when Medco was purchased.<sup>33</sup> As noted earlier, Merck's President further reported that the number of prescriptions handled by Medco has grown to 170,000,000, up thirty-one percent from the last year.<sup>34</sup>

The Merck/Medco experience is illustrative but probably not unique. Where drug related communications are disseminated by PBMs to encourage utilization of a manufacturer's drug product — particularly, but not exclusively, when the manufacturer is aligned with the PBM through ownership or affiliation — application of the FDA's established authority to regulate drug promotional practices, based on its jurisdiction over drug labeling and advertising, is fully warranted. There can be no serious question that in the context of an aligned PBM, such communications are made by or on behalf of the parent drug manufacturer. The FDA is to be commended for its efforts in this regulatory area: requesting information from pharmaceutical companies that have acquired or aligned themselves with PBMs, confirming before Congress that the agency is studying these marketplace changes, holding a public hearing, and inviting public comments. As observed recently by an agency representative, if a PBM's functions "were associated with or . . . part of a pharmaceutical firm's marketing efforts," the FDA would look at any "materials that they might disseminate to either physicians or patients as either labeling and/or advertising."<sup>35</sup> The challenge before the FDA lies not in the question of whether it has jurisdiction but in the exercise of its established jurisdiction.

#### IV. INITIAL STEPS TOWARD PUBLIC PROTECTION

There are several initial steps the FDA might consider as it exercises its jurisdiction in this area of nationwide consumer importance.

##### A. *Uniform Application of Multistate Settlement Standards*

On October 25, 1995, the Minnesota Attorney General's Office announced a multistate consumer protection settlement between seventeen states and Merck & Co., Inc. and Medco Containment Services, Inc.<sup>36</sup> This settlement agreement, based on state consumer protection laws, focused on three important components of the pharmaceutical manufacturer-PBM equation: the flow of information from the PBM's pharmacists to prescribing physicians, the information flow from the PBM to consumers (through

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Miles Inc., No. C7-94-3189 (Ramsey Co. D.C. Apr. 4, 1994) (assurance of discontinuance and order approving assurance of discontinuance); In the Matter of Marion Merrell Dow, Inc., No. C5-93-6503 (Ramsey Co. D.C. June 9, 1993) (assurance of voluntary compliance and order approving assurance of voluntary compliance); In the Matter of Ciba-Geigy Corp., No. C1-93-2576 (Ramsey Co. D.C. Mar. 15, 1993) (assurance of voluntary compliance and order approving assurance of voluntary compliance); In the Matter of American Cyanamid Co., No. C2-93-10007 (Ramsey Co. D.C. Sept. 8, 1993) (assurance of discontinuance/assurance of voluntary compliance and order approving assurance of discontinuance/assurance of voluntary compliance).

<sup>33</sup> *Merck's Medco Unit Moves "On Track," supra* note 4, at B6.

<sup>34</sup> *Id.*

<sup>35</sup> *Mail Rx Firms May Lose "Pharmacy" Status at FDA*, DICKINSON'S PHARMACY, Oct. 1994, at 4.

<sup>36</sup> In the Matter of Merck & Co., Inc. and Medco Containment Servs., Inc. No. C6-95-10614 (Ramsey Co. D.C. Oct. 25, 1995) (agreement (assurance of discontinuance) and order approving assurance of discontinuance).

the health plan sponsors the PBM serves), and the protection of consumers' privacy interests. Under the settlement, Merck and Medco, without admitting any wrongdoing or law violation, agreed to reform their practices nationwide by adopting a number of consumer safeguards, including the following:

- In telephone calls made by Medco's pharmacists to doctors (after the company receives a prescription at one of its mail order pharmacies), Medco is required to disclose to the prescribing physician: (a) the name of the calling Medco pharmacist; (b) that (s)he is calling on behalf of Medco or its subsidiary; (c) that the pharmacy is owned by Merck; and (d) if the telephone call concerns a prescription change from a branded drug to another branded drug in the same therapeutic category<sup>37</sup> or is a drug utilization review telephone call that results in a prescription change to a branded drug in the same therapeutic category where the calling pharmacist suggests the change, the caller also shall disclose the name of the manufacturer of the suggested drug.
- In confirming letters sent by Medco to physicians and consumers after any substitution in the original prescription that results from a Medco pharmacist's call to physicians, Medco is required to disclose: the name of the Medco pharmacy, that the pharmacy is owned by Merck, and, for calls causing a change from a brand name drug to another brand name drug in the same therapeutic category, the manufacturer of the switched-to drug.
- If a Medco pharmacist represents in a telephone call to a prescribing physician that a consumer participating in a health plan to which Medco provides services will not incur any additional expenses from the change in prescription, Medco is required to honor each such representation. Specifically, Merck and Medco shall have in place a system for complying with any such authorized representation by a Medco pharmacist at the time it is made.
- In any telephone call from a Medco pharmacist or in any other medium, Medco shall not make any claim, express or implied, that the change of a prescription will or may save money for consumers participating in health plans managed by Medco, unless the company possesses adequate substantiation to support the claim at the time such claim is made.
- Medco will recommend to plan sponsors that they clearly and conspicuously disclose to current and future consumers who participate in such plans certain information about Medco's practices, including informing consumers (a) about Medco's program of having Medco pharmacists call consumers' physicians to discuss changes of prescriptions to other drugs (including Merck's); (b) that they should contact their doctor with any questions or if they want to receive the original prescription and not have it changed; (c) that Medco is owned by Merck; (d) about all uses that will be made of confidential consumer information, including consumers' medical histories and prescription drug usage that are maintained in Medco's computer files; and (e) that the employer or other health plan sponsor often retains the right under the health plan to access such confidential consumer data.

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<sup>37</sup> Although the particular circumstances did not warrant its application at the time of the Merck/Medco settlement, in the broader context of the FDA's development of a regulatory approach in this area, the same disclosure should be made with respect to communications involving changes in prescriptions from a branded to a generic drug (where the generic is made or sold by the pharmaceutical company owning or aligned with the PBM).

- Medco has distributed approximately 4,000,000 copies of a consumer information booklet and, under the settlement agreement, committed to continuing to provide the consumer booklet for a period of two years to consumers using its mail order pharmacy services. Merck and Medco are required to provide the above information and disclosures to consumers through this booklet. The settlement further provided for the filing by Merck and Medco of compliance reports with the states and payments to the states for costs of investigation, attorney fees, or consumer education purposes.

When this cooperative settlement was finalized, Medco already had taken steps to implement these consumer reforms: changing its telephone scripts to ensure that the required information is disclosed by Medco pharmacists in telephone calls to physicians; informing over 430,000 physicians that Medco and its mail order pharmacies are owned by Merck, and explaining Medco's services (one of which is Medco's practice of having its pharmacists call physicians to discuss changes to preferred drugs, including Merck products); establishing a system for honoring any authorized representations by Medco callers that a change in prescription will not mean increased expenses for the consumer; revising its follow-up letters to doctors and consumers; and distributing the consumer booklet to consumers using Medco's mail order services.

The FDA should consider the standards and disclosure requirements contained in this cooperative multistate settlement as a model for uniform application to drug related communications disseminated in the managed care context, including communications between PBMs owned by or aligned with pharmaceutical manufacturers and physicians and consumers. The disclosure requirements contained in this consumer protection settlement dovetail the FDA's traditional mission of ensuring that prescription drug promotional communications are truthful and do not mislead physicians or consumers, either through affirmative misrepresentations or omissions of material facts. The disclosure requirements contained in this multistate settlement center on information important to physicians and consumers concerning drug utilization decisions. Under the generally applied legal standards, this information is material because it would naturally affect the purchasing or utilization decision of the person to whom the communication is addressed. Information concerning the origin of a drug related communication, the purpose of the communication, and the ownership of the PBM by the pharmaceutical company whose products are being promoted constitute minimal information that is not only material but would assist physicians to make decisions about the appropriateness of changing originally-issued prescriptions.<sup>38</sup>

### *B. Information Conveyed to Physicians*

Adoption and uniform application of the standards reflected in the recent multistate

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<sup>38</sup> Similar disclosure requirements are contained in the FDA's policy governing drug related communications made during continuing medical education (CME) seminars sponsored by the health care industry. The provider of the CME is required to disclose to the audience the sponsoring company's funding of the activity and "any significant relationship between the provider and the company and between individual presenters or moderators and the company." Additionally, the provider is to undertake "steps to ensure that the data will be selected and presented objectively, that both favorable and unfavorable information about the product will be represented fairly, and that there is a balanced discussion of the prevailing body of scientific information on the product and of reasonable, alternative treatment options." The provider also is required to make "meaningful disclosure of any limitations on information that is presented." 57 Fed. Reg. 56,412, 56,413-14 (Nov. 27, 1992).

accord with Merck and Medco would represent a necessary and positive first step; however, it is hardly a sufficient one. The FDA should scrutinize carefully the communication flow between pharmaceutical industry-owned or industry-affiliated PBMs and physicians. Recent realignments within the health care industry have contributed to a metamorphosis of the cost containment functions traditionally performed by PBMs (seeking to provide low-cost PBM services to health plan sponsors) to include a marketing function (serving as a means of promoting, marketing, and distributing the products of the manufacturer owning or affiliated with the PBM). If the central or exclusive messages being communicated to physicians by PBMs in the performance of their prescription benefit services (including communications designed to prompt switches of prescriptions) is that the alternative drug is available and that the switch purportedly will save health plans' or their participants' money, the information flow is inadequate to ensure fully informed decisionmaking. This is significant because this information flow underpins millions of decisions by physicians concerning critically important prescribing judgments — each of which potentially affects the health and welfare of the individuals who will receive that prescription drug.

Key ingredients of the FDA's prescription drug labeling and advertising requirements are not only that drug related communications must be truthful and not misleading, but that they include accurate information about the drug, including its side effects, contraindications, and effectiveness, and that they are presented clearly and in a manner characterized by a fairly balanced discussion of the product's risks and benefits. The underlying purpose of these requirements is one of protecting public health — ensuring that health care professionals and consumers base decisions about which drugs to prescribe or use on sound, accurate, complete, and nonmisleading information.

The FDA should discount arguments that drug related communications by PBMs to physicians or consumers that take place, for example, by telephone, are ill suited because of the nature of the medium to comply with FDA's existing advertising requirements. Broadcast prescription drug advertisements are not exempt from the FDCA's implementing regulations. A drug manufacturer or distributor that issues or causes to be issued communications constituting advertising should not be able to escape compliance through choice of the medium selected to make the communication. There is no inherent time limitation built into telephone communications, independent of the practical time demands involved in communications between busy health care providers. Furthermore, drug related communications made by or on behalf of drug manufacturers that own or are affiliated with PBMs are not limited to telephone communications.

Application of existing regulatory requirements governing prescription drug labeling and advertising represents nothing more than a continuation of the FDA's decades old experience in furthering the public interest in truthful, balanced drug promotional communications. Indeed, the present discussion resonates with echoes from the past. Prompting the 1962 Amendments to the FDCA<sup>39</sup> were advertising practices brought before Senator Estes Kefauver's Subcommittee on Antitrust and Monopoly in 1960-1961.<sup>40</sup> At that time, Congress was concerned about a number of abusive practices,

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<sup>39</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

<sup>40</sup> See *Hearings on S.1552 Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary*, 87th Cong., 1st Sess. (1961); REPORT OF THE SUBCOMM. ON ANTITRUST AND MONOPOLY OF THE SENATE COMM. ON THE JUDICIARY, "ADMINISTERED PRICES: DRUGS," S. REP. NO. 448, 87th Cong., 1st Sess. (1961); S. REP. NO. 1744, 97th Cong. 2d Sess. (1962), reprinted in 2 U.S.C.C.A.N. 2884, 2903-05 ("views of Senators Estes Kefauver et al." discussing and summarizing information from the hearings warning of false or misleading drug advertisements).

including drug advertising that touted the benefits of the drug but omitted or downplayed information about side effects, contraindications, warnings, and other limitations on the drug's usefulness.<sup>41</sup> More than three decades have passed since the Kefauver hearings and the 1962 Amendments in which Congress passed the jurisdictional baton to the FDA to regulate the advertising of prescription drugs. The need for vigilance and stamina in running that public interest marathon remains undiminished.

### *C. Information to Consumers and Consumers' Privacy Interests*

As important as the information disseminated to physicians is, ensuring the accuracy and truthfulness of the information flow to consumers is vital. Important provisions of the multistate settlement with Merck and Medco were: the requirement that Medco urge plan sponsors with which it contracts to make clear and conspicuous disclosure to consumers participating in Medco-managed health plans of certain information, including the existence of Medco's program of having Medco pharmacists telephone physicians to discuss drug interchanges; the fact that if the consumer has questions concerning any change in prescription, or wishes to receive the originally issued prescription, then the consumer should communicate this to his or her physician; the fact of Merck's ownership of Medco; what uses will be made of confidential information about consumers collected by Medco; and the extent to which such personal consumer information will remain confidential including, where applicable, that the employer or other health plan sponsor often retains a right of access to such personally identifiable consumer data. Under the settlement, Medco also undertook to provide the required disclosures to consumers utilizing the company's mail pharmacy services. Medco included a consumer information booklet, which contains the required information, as part of each mail order prescription it dispensed, and provided the booklet to consumers participating in Medco managed health plans who contact Medco or any of its mail service pharmacies for information about Medco's managed pharmacy programs.

Consumers' interest in complete and accurate information about PBM programs and practices, however, transcends the particulars of any individual enforcement initiative. The central focus of the radical changes currently shaking the health care market must remain not on maximizing profits, market share, or on securing drug distribution mechanisms, but on the health and safety of each individual consumer. After all, prescription drugs are complex and never risk-free. The information imbalance is striking in the process by which prescription drugs are marketed and sold, including the most recent alignments between drug manufacturers and PBMs. The need for consumers to have accurate and complete information provided in a clear, understandable format is great. As noted earlier in this article, when drug related communications are issued on behalf of manufacturers through PBMs to promote drug utilization, including those directed to consumers, the FDA's labeling and advertising requirements must be satisfied as threshold safeguards.

Independent of FDA intervention, however, the pharmaceutical industry and PBMs should be encouraged to provide the public with clear, accurate information about their programs and practices. Few consumers understand the intricacies, or perhaps even the existence, of many PBM practices and services. Still fewer consumers are aware of drug utilization review procedures, formularies, generic substitution programs and thera-

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<sup>41</sup> See H.W. Chaddock, "In Brief Summary:" *Prescription Drug Advertising, 1962-71*, in FDA PAPERS 2 (1972).

peutic switch programs. It is incumbent upon pharmaceutical companies and PBMs, whether or not they are owned or affiliated with manufacturers, to inform not only their immediate customers, health plan sponsors, but their ultimate customers, consumers, of the full range of practices engaged in and services provided by PBMs.

A parallel public protection objective to safeguarding the flow of information to consumers is the need to protect both the confidentiality of information received from consumers and consumers' privacy rights. Information has become a centerpiece of the health care revolution. In many respects, managed care increasingly will lead to managed information. In the context of pharmaceutical industry acquisitions and affiliations with PBMs, information collected and maintained in the computer databases of PBMs can be a powerful asset. PBMs collect and maintain information of the most personal nature about millions of American consumers — for example, the consumer's name, address, social security number, date of birth, sex, medical history, allergy history, prescription drug utilization, and often the medical histories of the consumer's spouse and dependents. Acquisition of information databases has been a prime motivator behind recent pharmaceutical industry-PBM mergers.<sup>42</sup>

The manner in which such vast amounts of personal information about American consumers is collected and utilized is of fundamental importance. Neither PBMs nor pharmaceutical manufacturers should utilize such confidential information for marketing purposes. Representations made in the collection of such consumer data (for example, that such information will be used only for drug utilization review purposes) should be honored and should fully describe all uses that may be made of such information (including, for example, review of such information by a PBM in its communications with physicians to encourage changes to another prescription drug, including a product produced by the manufacturer who owns or is affiliated with that PBM). The confidentiality of consumer data must be strictly maintained and safeguarded.

The increasing importance consumers place on medical record privacy should be assigned high priority by pharmaceutical manufacturers and PBMs in the design and implementation of PBM programs and practices. For example, a privacy survey conducted for Equifax in 1993 by Louis Harris & Associates, in association with Columbia University's Dr. Alan Westin, revealed that forty-eight percent of the public, representing 89,000,000 Americans, are highly concerned about issues of medical privacy.<sup>43</sup> For example, the survey found that a majority of Americans (sixty percent) feel that it would be unacceptable for pharmacists to provide pharmaceutical companies with the names of customers using certain medications for use in direct mail; sixty-six percent felt that it would be unacceptable for hospitals to use the names of patients to solicit donations; and sixty-four percent stated that their permission should be required before their medical records could be used for research purposes, even if no personally identifiable information were published.<sup>44</sup> Public concern about issues centering on the privacy of medical records also is reflected in media attention<sup>45</sup> and congressional<sup>46</sup> efforts to pro-

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<sup>42</sup> See, e.g., Nichols, *supra* note 24, at 105, 106, 111; *A Shift of Power in Pharmaceuticals*, *supra* note 24, at D3; Mandelker, *supra* note 9, at 56; *Changing Minds — Owning Medco*, *supra* note 24, at A1. See generally Michael W. Miller, *Data-Tap — Patients' Records are Treasure Trove for Budding Industry*, WALL ST. J., Feb. 27, 1992, at A1.

<sup>43</sup> HARRIS-EQUIFAX, HEALTH INFORMATION PRIVACY SURVEY (1993) (study no. 934009; available from Louis Harris and Assocs., 630 Fifth Ave., New York, NY 10111).

<sup>44</sup> *Id.* at 3, 18.

<sup>45</sup> See, e.g., Gina Kolata, *When Patients' Records Are Commodities for Sale*, N.Y. TIMES, Nov. 15, 1995, at B1; Deborah L. Jacobs, *Can a Visit to the Company Doc Help a Cold but Hurt a Career*, N.Y. TIMES, May 21, 1995, at F10; *Computers and Your Health Care Records*, CONSUMERS' RES., Apr. 1993, at 33; *Washington Ponders Health Privacy Reform*, 1 PRIVACY & AM. BUS., Jan./Feb. 1994, at A1; Larry Tye,

tect the privacy of medical information.

Courts also have recognized consumers' interests in the privacy of medical records. In holding that patient-physician records are protected under California's constitutional right of privacy, the California Court of Appeals has explained that "[a] person's medical profile is an area of privacy infinitely more intimate, more personal in quality and nature than many areas already judicially recognized and protected."<sup>47</sup> Underscoring the private nature of a consumer's medical records, the Court of Appeals observed:

The individual's right to privacy encompasses not only the state of his mind, but also his viscera, detailed complaints of physical ills, and their emotional overtones. The state of a person's gastro-intestinal tract is as much entitled to privacy from unauthorized public or bureaucratic snooping as is that person's bank account, the content of his library or his membership in the NAACP.<sup>48</sup>

Clear, accurate disclosure of the purposes of collecting confidential information from consumers, and of the uses to which such information will be put, are important consumer safeguards, as are measures to safeguard the confidentiality of such consumer data. A central aspect of privacy is the right to control personal information about oneself, including medical information. There can be no control, nor informed consent, without knowledge. Consumer databases are much more than informational treasure troves to be sought after and acquired; they carry clear obligations to safeguard the underlying privacy interests of the consumer owners of that data.

## V. CONCLUSION

The common thread running through the FDA's history of preserving the integrity of drug promotional activities, including its more than three decades of experience in protecting the public against untruthful or misleading prescription drug advertising practices, is the need to implement statutory and regulatory safeguards that keep pace with changes in the marketplace. As Dr. Kessler wrote, prior to his joining the agency as Commissioner, the federal role in regulating prescription drug advertising and promotion must be responsive to change. "As the field of pharmaceutical advertising and promotion grows, as new communication technologies evolve, and as innovations in marketing appear, the FDA's regulatory framework must be able to meet the challenges of a changing environment."<sup>49</sup>

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*In a computer world, privacy is mythical*, ST. PAUL PIONEER PRESS, Oct. 17, 1995, at 1A; Gary A. Seidman, *This is Your Life, Mr. Smith* . . . , N.Y. TIMES, Aug. 1, 1993, at F7.

<sup>46</sup> See, e.g., Medical Records Confidentiality Act of 1995, S. 1360, 104th Cong., 1st Sess. (Oct. 24, 1995); Fair Health Information Practices Act of 1994, H.R. 4077, 103d Cong. 2d Sess. (May 17, 1994).

<sup>47</sup> Board of Med. Quality Assurance v. Gherardini, 156 Cal. Rptr. 55, 60 (Cal. Ct. App. 1979).

<sup>48</sup> *Id.* at 61. One of the principal "mischief[s]" that the 1972 amendment to California's constitution, recognizing the right to privacy, was directed at was the improper use of information properly obtained for a specific purpose — for example, the use of such information for another purpose or its disclosure to a third party. *Id.* at 60. See also *White v. Davis*, 120 Cal. Rptr. 94, 106, 533 P.2d 222, 234 (1975) (noting that the right to privacy protected by the California constitution "prevents government and business interests from misusing information gathered for one purpose in order to serve other purposes," and recognizing that the protection was designed, in part, to address the improper use of information obtained for a specific purpose, for another purpose, or its disclosure to a third party). This constitutional privacy protection, which extends to consumers' medical histories, has been held to protect against invasions not only by the state, but also by private conduct. *Heda v. Superior Court*, 275 Cal. Rptr. 136 (Cal. Ct. App. 1990).

<sup>49</sup> David Kessler & Wayne Pines, *The Federal Regulation of Prescription Drug Advertising and Pro-*

If there is one constant in today's health care marketplace, it is change. This article has suggested that FDA should not only meet the challenges ahead, but should seize the positive opportunities presented by these changes as well. Public protection should remain the focal point of health care reforms and the key to prescription drug promotional and advertising practices in an ever-changing health care environment.

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*motion*, 264 JAMA 2414 (1990). See also Louis A. Morris & Joseph P. Griffin, *The Evolving Role of FDA in Prescription Drug Promotion*, 22 J. OF DRUG ISSUES, INC., 245-56 (1992); Chadduck, *supra* note 38.