The Effect of Managed Care on the Pharmaceutical Industry

The Effect of Managed Care on the Pharmaceutical Industry

Cheryl B. Carson
ID#: 1 04-36-8260
For Peter Barton Hutt,
Food & Drug Law/3rd Yr. Paper
Spring 1997

The Effect of Managed Care on the Pharmaceutical Industry

I. INTRODUCTION

The pharmaceutical industry has transformed itself in response to the growth of managed care, which developed as a method to contain the costs of health care.' Under the traditional fee-for-service system of practicing medicine, doctors practiced medicine without incentives to reduce the costs imposed on patients, their insurers, and the health care system. Most doctors practiced independently and were reimbursed for each service rendered by passive insurance companies. Shielded from the oversight of third-party intermediaries, doctors had financial incentives to provide more services, regardless of whether those services were therapeutically necessary. In this context, pharmaceutical companies directed their marketing efforts toward individual physicians, who had complete discretion as to what drugs to prescribe. Under the fee-for-service system, doctors and the drug industry prospered, but the cost of health care skyrocketed, leading to calls for change.

1 For a concise description of managed care, *see* Jonathan P. Weiner & Gregory de Lissovoy, *Razing a Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans,* 18 J. HEALTH POL. PoL'Y AND L. 75, 97 (1993). The authors define managed care as follows:

A term often used generically for all types of integrated delivery systems, such as HMOs [Health Maintenance Organizations] and PPOs liPreferred Provider Organizations], implying that they manage the care received by consumers (in contrast to traditional fee-for-service care, which is unmanaged). More recently, this term is often used to denote the entire range of utilization control tools that are applied to manage the practices of physicians and others, regardless of the setting in which they practice. In addition to being used in all HMOs, PPOs, and EPOs [Exclusive Provider Organizations], these controls are increasingly being applied to conventional fee-for-service indemnity plans. The types of methods used to manage the patient's care may include preadniission certification, mandatory second opinion before surgery, certification of treatment plans for discretional nonemergency services (such as mental health care), primary care physician gatekeepers and nonphysician case managers to monitor the care of particular patients.

In the mid- 1970s, managed care arose as one solution to control the rising costs of health care.[2] Since then, managed care organizations have come to replace individual physicians, fee-for-service reimbursement, and independent hospitals. In a managed care system, individual physicians do not have complete discretion to prescribe whatever medication they deem appropriate. Physicians are constrained, to various degrees, to prescribe only medications listed on a formulary, a list of preferred drugs. By getting their products listed on a formulary, drug companies can reach large patient populations and realize substantial profits.

The pharmaceutical industry has restructured itself to keep pace with the revolutionary changes in the health care system. Drug manufacturers have formed alliances with pharmacy benefits managers (PBMs), which exert considerable influence over what drugs physicians prescribe. The legal implications of these alliances are still unclear. The Federal Trade Commission (FTC) has raised concerns about the anticompetitive effects of industry consolidation. The Food and Drug Administration (FDA) has reconsidered its traditional analysis of pharmaceutical communications in light of these changes. The Office of the Inspector General (OIG) at the Department of Health and Human Services has investigated practices that may violate the federal antikickback statute. How its mission will be affected by the Health Insurance Portability and Accountability Act of 1996 has yet to be determined. As the pharmaceutical industry continues to adapt to the new world of managed care, the government agencies that

[2] *See generally,* Thomas R Mayer & Gloria Gilbert Mayer, *HMOs: Origins and*

Development, 312 NEw ENG. J. MiD., 590-94 (1985), Alain C. Enthoven, *The History and*

Principles of Managed Competition, HEALTH AFFAIRS, 24-48 (1993), Troyen A. Brennan &

D.M. Berwick, NEW RULEs: REGULATION, MARKETS AND THE QUALITY OF AMERICAN HEALTH

CARE, 149-174 *(1995).* The managed care revolution is largely attributable to the HMO Act of
1973, which was passed by the Nixon administration as a part of health care reform.

regulate the industry are adapting as well.

II. THE MANAGED CARE REVOLUTION

A. A Sh{ft in the Balance of Power: From Physicians to PBMs

Under the traditional fee-for-service system, drug companies marketed their products directly to individual physicians. Companies would send out salespeople (known as detailers) who provided drug samples and information to physicians in an effort to encourage their use of the company's products.[3] Doctors made prescribing decisions based on their knowledge of the therapeutic value of a drug, not cost considerations.[4]

Today, the majority of privately insured people in this country are enrolled in managed care plans.[5] Seventy five percent of all doctors practice under managed care controls, such as oversight and capitated fees, for at least some of their patients.[6] Under a managed care system, decisions about which drugs to prescribe are often made by a committee or a Pharmacy Benefits Manager (PBM), rather than an individual doctor.[7] Committees and PBMs are meant to supplant

[3] *See generally,* Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?,* 47 FOOD & DRUG L.J. 309 (1992); Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry,* 50 FOOD & DRUG L.J. 1 (1995) [hereinafter *Health Care Reform].*

[4] In some cases, prescription decisions are influenced by gifts such as meals, trips, and cash payments provided by drug companies. *See infra* Part lV.

[5] Thomas A. Hayes, *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy, 51* FooD & DRUG L.J. 57 [hereinafter *Drug Labeling].*

[6] *1d*

Ron Winslow, *Buyer's Market: Prescribing Decisions Increasingly Are Made By the Cost-Conscious; Doctors Are Pressured to Bow to Votes of Committees and Their Formularies,*

drug company detailers and provide doctors with advice on which medications are the most cost-effective.[8]

PBMs are companies that provide a variety of pharmaceutical services to employer group health plans and managed care entities such as HMOs and PPOs.[9] As part of an overall effort to control costs, managed care organizations purchase pharmaceuticals through PBMs, which have the expertise and the market power to obtain discounts from pharmaceutical companies.[10] PBMs negotiate discounts from drug companies by agreeing to list the company's products on the PBIvVs formulary, which ensures that the products will be prescribed in volume.

PBMs and managed care organizations exert varying degrees of control to encourage doctors to prescribe drugs listed on a formulary. Under some plans, doctors are merely given incentives to prescribe the preferred drugs; under other plans, they are required to prescribe from the formulary. PBMs may encourage use of their preferred drugs by paying pharmacists a fee when they convince doctors to switch to formulary drugs, or by requiring higher co-payments for drugs that are not on the formulary. The incentives that managed care organizations use may include providing the formulary to physicians, tracking prescribing behavior, and notifying and

WALL ST. J., Sept. 25, 1992 at Al [hereinafter *Buyer's Market].*

[8] *k1*

˜ Bruce N. Kuhuik, *The FDA '˜s˜ Regulation of Pharmaceutical Communications in the Context of Managed Care: A Suggested Approach,* 50 FOOD & DRUG L.J. 23, 31-32 (1995) [hereinafter *Pharmaceutical Communications].* PBMs are not the only organizations that manage pharmaceuticals; HMOs and insurers operating PPOs may perform this function on in-house basis. *Id*

10 *See Health Care Reform, supra* note 3, at 2.

˜ *Id*

counterdetailing non-complying physicians.'[2] Although formularies narrow the range of doctors' choices, ˜aged care strategists argue that differences between drugs in the same class are negligible.'[3]

PBMs operate in different ways and can serve a variety of functions.'[4] Some dispense prescription drugs through mail orders or their own facilities. PBMs may also perform drug utilization review (DUR), which involves monitoring prescribing patterns to promote appropriate and cost-effective use of drugs. DUE. may include the electronic review of prescription records and review of patient medical records. A related service is outcomes research, which assesses the outcomes of particular drug treatments. PBMs may then sell this information to drug companies. Another function PBMs serve is conducting disease management programs (DMIPs), which involve the development of protocols for treating certain diseases. The programs target diseases that can be treated with long-term drug therapy, which may reduce the need for surgery and other medical treatments. Finally, PBMs and pharmaceutical companies are increasingly assuming financial risk under capitation or risk-sharing arrangements. The PBM or drug company agrees to provide an unlimited amount of certain prescription drugs in exchange for a fixed fee, which puts them at risk of losing money if plan participants require more medication than anticipated.

12 *Pharmaceutical Communications, supra* note 9, at 30.

'˜ *Buyer's Market, supra* note 7.

For a general description of PBMs, see Kevin J. Dunne & Ciara R Ryan, *How Management of Medical Costs Is Revolutionizing the Drug Industry,* 62 DEF. CouNs. J. 177, 178-79 (1995).

Drug companies have recognized and responded to the proliferation of managed care and PBMs. As a result of these systemic changes, drug companies market their drugs to individual physicians far less than they did in the past. Formularies represent a large market share, whereas individual physicians generally do not. The focus of marketing activities has thus shifted from the individual physician to PBMs and managed care organizations, including LIMOs, insurance companies, hospitals, large corporations, and others.[15] These institutional customers provide drug companies access to millions of patients, but their clout also enables them to wrest sizable discounts.

As the discretion of doctors has diminished under managed care, so has the role of the drug detailers. Detailers, once the driving sales force behind the pharmaceutical industry, no longer have unrestrained access to physicians. For example, at Kaiser Permanente, a powerful managed care network, drug detailers are subject to thirty two rules, all of which were designed to block overly aggressive marketing.'[6] Detailers are forbidden from promoting any medicine that isn't on the Kaiser formulary and they cannot visit a Kaiser facility without an appointment.'[7] In response to changes such as these, drug companies have scaled back their detail forces.

In spite of the growing prevalence of managed care controls, pharmaceutical companies still find ways to influence physicians. A recent study found that traditional marketing directed at physicians continues to be effective in the managed care market.'[8] The study found that

˜ *Health Care Reform, supra* note 3, at 1.

16 George Anders, *Rxfor Sales: Managed Health Care Jeopardizes Outlook For Drug 'Detailers'; Pharmaceutical Marketing Demands New Strategies; Costs Over Camaraderie,* WALL ST. J., Sept. 10, 1993, at Al [hereinafter *Rxfor Sales].*

[17] *1d*

physicians who requested hospital approval for drugs to be placed on a formulary were much more likely than other physicians to have accepted funds from pharmaceutical companies to pay for travel, speaking, or research expenses.[19]

Whether the physicians recommended certain drugs based on their merits or based on remuneration is unclear. Given that drug detailers are known to make inflated sales pitches rather than objective assessments,[20] the results of the study are troubling. It is true managed care has diminished the impact of detailers, but drug companies and, for better or worse, doctors, still rely on them. In light of this study, Kaiser's policy of minimizing physician relationships with pharmaceutical companies seems vindicated. Kaiser's remedy for curbing industry's influence on physicians is to restrain the detailers and to provide an independent assessment of drugs. Savvy drug manufacturers, however, have found innovative ways to meet the challenges presented by managed care.

B. Managed Care Leads to Profit for Drug Makers

The growth of managed care has resulted in strong growth for pharmaceutical companies, despite predictions to the contrary in the early days of managed care.[2'] Managed care

18 Mary-Margaret Chren and C. Seth Landefeld, *Physicians'Behavior and Their Interactions With Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary,* 271 Ji,aMA 684-89 (1994).

'9 1d

20 The accuracy of statements made by detailers is often brought into question. *See, e.g.,* Ron Winslow, *Drug-Industry Sales Pitches to Doctors Are Inaccurate 11% of Time, Study Says,* WALL ST. J., Apr. 26, 1995, at B6; *Rrfor Sales, supra* note 16.

organizations, which demanded large discounts in return for putting a drug company's product on a formulary, were initially viewed as a threat to the pharmaceutical industry. Drug companies, however, have learned how to work with managed care customers and have scaled back discounting for health plans that cannot secure their preferred status or for plans that are too small.[22] Growing drug profits are also attributed to the greater use of phamaceuticals by managed care organizations, which are increasingly using drug therapy to help patients avoid surgery and other more costly treatments.[23] LIMOs have also enrolled patients, including many Medicare patients, who previously did not have coverage for prescription drugs. In an LIMO, prescriptions are usually reimbursed, prompting more people to fill their prescriptions for larger amounts of pills. As managed care organizations, however, enroll greater numbers of Medicare patients and their drug bills rise, they will have a greater incentive to rein in their drug spending.

One way to penetrate the managed care market is to join it. Many pharmaceutical companies have purchased or formed alliances with PBMs so that they will have the ability to influence directly physicians' prescribing decisions, thus increasing their market share. Within the space of a year, three major drug companies purchased three of the leading PBMs. In July 1993, Merck & Co., the world's largest drug company, purchased Medco Containment Services Inc.,

21 Elyse Tanouye, *Five Drug Makers Post Healthy Profits, As Managed Care Spurs Prescriptions,* WALL ST. J., Oct. 23, 1996, at A2.

22 Elyse Tanouye, *Big Drug Makers Regaining Control Over Their Prices; Companies Reduce Discounting, Learn to Deal With Managed Care,* WALL ST. J., July 12, 1995, at B4.

23 Elyse Tanouye, *Managed Care Is Boosting Drug Sales; Surprising Trend Helps Push Profit Higher at Merck, J&J, and Schering-Plough,* WALL ST. J., Oct. 17, 1996, at BlO.

one of the nation's largest PBMs, for $6.6 billion.[24] In May 1994, SmithKline Beecham PLC bought United HealthCare Corp.'s Diversified Pharmaceutical Services Inc. for $2.3 billion.[25] In July 1994, Eli Lilly & Co. bought McKesson Corp.'s PCS health systems for $4 billion.[26] The new alliances within the drug industry have led to profits, but also to controversy.

Sales rose at Merck & Co., SmithKline Beecham PLC, and El Lilly & Co., the three companies that purchased PBMs in 1993 and 1994, but sales have also risen at drug companies that didn't buy PBMs.[27] Drug companies who bought PBMs did so hoping to gain a large share of the managed care market, which was then seen as a threat to drug sales. Managed care, however, proved to promote drug sales rather than hinder them, leading to increased profits for the drug industry as a whole.

C. New Alliances Cause Controversy

1. Therapeutic Substitutions

PBMs carry a full line of pharmaceuticals, including those made by competing drug companies, but after an acquisition by a manufacturer, a PBM is more likely to sell a greater share

24 Michael Waldholz & George Anders, *Merck To Purchase Medco in $6 Billion Transaction,* WALL ST. J., July 29, 1993, at A3.

25 Ron Winslow & Stephen D. Moore, *SmithKline Sets To Purchase Benefits Firm,* WALL ST. J., May 4, 1994, at A3.

26 Thomas M. Burton & Elyse Tanouye, *Eli Lilly to Buy McKesson Unit for $4 Billion,* WALL ST. J., July 12, 1994, at A3.

27 Elyse Tanouye, *Value of Some Drug Firms'Acquisitions Is Questioned; Owning a Pharmacy Benefit Manager May Not Make Much Difference,* WALL ST. J., Nov. 19, 1996 at B4.

of its parent's drugs.[28] Merck, for example, used controversial sales tactics involving Medco, its PBM.[29] After its acquisition of Medco, Merck still employed detailers to visit physicians and to leave samples, but it also used Medco's pharmacists to sell Merck's products. Although most states permit generic substitutions, pharmacists are generally prohibited form making therapeutic substitutions of chemically different drugs without the authorization of the prescribing physician.[30]

Pharmacists employed by Medco would call physicians to try to persuade them to switch prescriptions to different, Medco-preferred drugs.[3'] When Medco was independent, it used telemarketing tactics to encourage physicians to prescribe lower-cost brand name or generic drugs. After Medco was purchased by Merck, Medco pharmacists used those same techniques to sell Merck's drugs. Medco's telemarketing pharmacists were able to switch 75,000 prescriptions a month, or nearly 1 million a year.[32] Medco could not deny that the telephone switches improved its market share, but it defended the practice as a cost-containment measure.[33]

28 *See* David Woodward, *The New Drug Marketing: A Consumer Protection Perspective,*

51 FooD & DRUG L.J. 637, 64 1-43 [hereinafter *New Drug Marketing]*

[29]Elyse Tanouye, *Changing Minds: Owning Medco, Merck Takes Drug Marketing The Next Logical Step; Pharmacists Cajole Doctors To Switch Prescriptions,* WALL ST. J., May 31, 1994, at Al [hereinafter *Changing Minds]*

30 *See Pharmaceutical Communications, supra* note 9, at 29.

31 *Changing Minds, supra* note 29.

32 *Id.*

Id

activities.[34] Under the settlement, Medco pharmacists must disclose that they are calling on behalf of Medco, and that Medco is owned by Merck.[35] Medco may not make unsubstantiated claims that changing a prescription will save money for consumers participating in health plans managed by Medco.[36] Even before the settlement was reached, Medco had akeady taken steps to reform its practices, such as explaining its services to physicians and disclosing that they are owned by Merck. ˜'

The settlement may have led to modifications at Merck and Medco, but it did not end the practice of therapeutic substitution.[38] The FDA recently expressed concern about the potentially harmful consequences of the practice. On March 3, 1997, the agency's Division of Drug Marketing, Advertising & Communications (DDMAC) issued a statement requesting reports of any adverse consequences of therapeutic switches.[39] The FDA issued the statement after becoming aware that health care professionals and patients have expressed concern about health

˜' In the Matter of Merck & Co., Inc. and Medco Containment Services, Inc., No. C6-95-106 14 (Minn. Ramsey Co. Dist. Ct. Oct. 25, 1995) (assurance of discontinuance and order approving assurance of discontinuance). This agreement was the sixth of seven multistate settlements coordinated by the Minnesota Attorney General's Consumer Enforcement Division. The settlements involved the application of state consumer laws to various promotional activities in the pharmaceutical industry. *See New Drug Marketing, supra* note 28.

'˜ *New Drug Marketing, supra* note 28, at 644.

[36] *Id*

[37] *1d* at 645.

38 *See* Milt Freudenheim, *Not Quite What the Doctor Ordered; Drug Substitutions Add to Discord Over Managed Care,* N.Y. TiMEs, Oct. 8, 1996, at Dl.

˜ *Therapeutic Switches Resulting in Adverse Events: Reports Requested By FDA,* F-D-C REP. (THE GREEN SHEET), Mar. 10, 1997, at 2.

becoming aware that health care professionals and patients have expressed concern about health care programs that use limited formularies and manage pharmaceutical care by substituting a different member of a pharmacologic class, or a drug of a wholly different pharmacologic class, for the prescribed drug.[40] After the FDA receives more information regarding switching practices, it will decide whether they present a public health concern.

2. Promotional Activities

In light of the changes that have taken place under managed care, the FDA has also reconsidered its traditional analysis of pharmaceutical communications.[4,] The FDA has expressed particular concern with respect to cost-effectiveness claims and the consequences of alliances between manufacturers and PBMs.[42]

Under the Federal Food, Drug, and Cosmetic Act (FDCA),[43] the FDA has responsibility for regulating the labeling and advertising of prescription drugs. The agency reviews promotional materials disseminated by, or on behalf of? pharmaceutical manufacturers to ensure that such materials are accurate, contain proper disclosures, are in fair balance in terms of risk and benefit information, and are consistent with approved drug labeling.

[40] *1d*

[~] *See Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearing and Request for Comments,* 60 Fed. Reg. 41,891 (Aug. 14, 1995).

[42] *Id*

'Pub. L. No. 75-717, 52 Stat. 1040 (1938), codified as amended at 21 U.S.C. §§ 301 et seq. (1988).

The FDA recognizes that pharmaceutical marketing has changed to emphasize value in addition to safety and effectiveness claims. In the past, doctors were the main customers of drug manufacturers, but under a managed care system, the customer is often an institutional decisionmaker. To achieve their cost-containment objectives, managed care and institutional decisionmakers need information about comparative costs. Since data on cost-effectiveness usually involves comparisons of the uses and benefits of drugs, the FDA regards such data as labeling that accompanies the drug. Whether the FDA can, or should, subject cost-effectiveness claims to stringent labeling requirements has been a matter of wide debate.[45]

Another question the FDA must grapple with is how the alliances between PBMs and pharmaceutical manufacturers have changed promotional activities. Since PBMs disseminate information to formulary decisionniakers, physicians, and patients about the manufacturer's product, the issue is whether a PBMs' drug-related statements are made on behalf of the parent drug manufacturer. If so, the statements would fall under the FDA's authority to regulate labeling and advertising. A related question is whether a PBM that has an off-label use on its formulary violates the law or whether a manufacture who sells to the PBM also violates the law. [46]

'Drug Labeling, supra note 5, at 63..

'See, e.g., Stephen Paul Mahinka and Kathleen M. Sanzo, *Pharmaceutical Industry*

Restructuring and New Marketing Approaches: Enforcement Responses, 50 FOOD & DRUG L.J.

313, 319-22 (1995) [hereinafter *Enforcement Responses]; Drug Labeling, supra* note 5, at 62-65.

For suggestions as to how the FDA should modify its approach to the regulation of

pharmaceutical communications, see *Pharmaceutical Communications, supra* note 9.

[46] *See Health Care Reform, supra* note 3, at 19.

3. Other Concerns

The alliances within the pharmaceutical industry have also led to a multitude of controversies. Privacy concerns are raised when PBMs, which have access to information about individual prescriptions, share that information with drug manufacturers. Manufacturers can use this information to influence drug selection and use, and to make cost-effectiveness claims. As the alliances among PBMs, drug manufacturers, and managed care organizations continue to evolve, new controversies can be expected to arise. For example, PBMs and drug companies are involved in disease management programs, particularly those that require heavy use of prescription drugs. These programs can lead to legal conflicts involving antitrust claims, state restrictions on the corporate practice of medicine, and the federal antikickback statute.[47] Despite these legal hurdles, there are no signs that the pharmaceutical industry's interest managed care is waning.[48]

D. The Paradox of Managed Care: Patients v. Profits

As technological breakthroughs in drug therapies promise improved treatment of diseases such as heart disease and depression, drug makers, doctors, and the managed care industry are struggling to find acceptable cost-benefit tradeoffs. Expensive new drug therapies may provide hope for patients and profits for drug companies, but squeeze the resources of managed care

˜ *See* Mark Learn, *Applying Medicare and Medicaid Antikickback Laws to Disease Management Programs: RamWcations for the Pharmaceutical Industry and a Regulatory Proposal,* 69 TEMP. L. **REv.** 245, 246-48 (1996) [hereinafter *Disease Management Programs]*

'See Elyse Tanouye & Greg Steinmetz, *Managed-Care Feeding Frenzy Probably Hasn't Ended; Drug Firms' Targets May Shift From Benefits-Plan Managers to HMOs,* WALL ST. J., July 13, 1994, at B3.

organizations, such as LIMOs, which heavily promote cost-containment. This dilemma is illustrated by a class of cholesterol-lowering drugs called statins, which have proven to be among the most effective therapies to help prevent heart attacks and heart disease.[49] The drugs, however, cost patients and their health plans over $700 a year, leading to questions as to whether they should be prescribed to low-risk patients.

Managed care organizations attempt to save money by investing in relatively inexpensive prevention measures and avoiding expensive surgery and hospital stays. Statins appear to fiillill the goal of prevention, which could benefit the thirteen million people who have heart disease, the leading cause of death in the nation and its most expensive health problem.[50] Despite the proven benefits of statins, a survey found that only 25% of eligible people were on statins, whether they were in an LIMO or not.[5'] More HMO's are approving the use of statins, but not without reservations as to its cost. One LIMO estimated that the cost of statins will initially exceed the avoided expense of hospital procedures, but that the LIMO would recover its investment by the sixth year. [52]

Some critics believe that many LIMOs will develop their guidelines on the prescription of statins based on short-term economic pressures, not long-term benefits to patients. Since HMOs are under pressure to meet quarterly financial targets, and since annual member turnover rate is

Ron Winslow, *Pricey Prescription: Powerful Medications For Cholesterol Pose A Paradox for HMOs; Curbing the Future Expense of Heart Disease Raises Concerns on Present Costs,* WALL ST. J., Dec. 6, 1996, at Al.

[50] *1d*

[5'] *Id*

[52] *Id*

typically more than 15%, HMOs may decide not to invest in such an expensive treatment only to have patients leave before the economic benefits are realized.[53]

Drug companies that produce statins are devising ways to overcome the HMOs' reservations. Merck & Co. and Bristol-Myers, the two leading statin makers, have bypassed doctors and LIMOs and launched a successful marketing campaign to appeal directly to consumers.[54] HMO members who might benefit from statins, and even those who might not, may pressure their doctors to prescribe statins once they become aware of the new drug. lIMOs may resist consumer pressure to prescribe statins, especially when those consumers are not at high risk for heart disease. They cannot, however, ignore the growing problem of heart disease among an aging population.

Like heart disease, the treatment of depression and other mental illnesses also illustrates the tension between profits and patient welfare. Managed care organizations prefer to treat mental health problems with drugs, which is cheaper than psychotherapy.[55] Many managed care plans limit coverage for psychotherapy and pay psychiatrists more to supervise drug treatment than to provide counseling.[56] Drug therapy may offer benefits to patients, but many psychiatrists feel more effective results are achieved through a combination of drugs and traditional psychotherapy.[57] In some cases, drugs alone are offered, or with a limited number of therapy

˜ *Id*

[54] *1d*

˜ Ellen Joan Pollock, *The New Economics of Mental Health; Side Effects: Managed Care's Focus On Psychiatric Drugs Alarms Many Doctors; They Say Effort to Cut Costs Leads to Overuse, Misuse Of Pills for Mental Illness,* WALL ST. J., Dec. 1, 1995, at Al.

56 *Id*

sessions. In other cases, older drugs with unpleasant side effects are prescribed instead of the newer, but more expensive, drugs such as Prozac, Zoloft and Paxil.[58]

When doctors or their patients request a combination of psychotherapy with drugs, or the newer drugs, they are often overruled by the managed care organizations and LIMOs that determine whether the treatment will be covered by insurance.[59] Some managed care plans maintain a hierarchy of preferred treatments for mental illnesses, with older, less expensive drugs being the first choice, newer drugs the second choice, and psychotherapy, the most expensive option, the last choice.[60] Other plans put deterrents in place, such as requiring doctors to get prior authorization from a senior clinician before prescribing an expensive drug.[6']

Managed care organizations cut costs by using drugs to treat mental illnesses, but whether these cuts lead to long-term savings is an open question. One study found that total health care expenses are higher when depression is treated with the older tricycic drugs than when Prozac is used.[62] The study found that patients treated with older anti-depressants required more doctor˜s visits, lab tests and hospitalizations.[63]

˜ *Id* [58] *1d*

[59] *Id*

[60] *Id*

61 *Id*

[62] *Id*

63 *Id* Because the study was funded by Eli Lilly & Co., the maker of Prozac, some questioned the validity of the findings. *Id*

Calculating the costs of treatment for mental illness is not always easy, since symptoms may not appear in the form of physical ailments that can be treated. Moreover, evaluating the success of treatment for mental illness is not as easily accomplished as evaluating the success rate for physical Thesses and diseases. With drug therapy, patients may experience short-term success, only to find that drugs do not provide a lasting solution. Since patients frequently switch managed care plans, managed care organizations may not have a sufficient economic incentive to ensure that patients receive the best long-term therapy.

Managed care systems are faced with the dilemma of how to make a profit while ensuring the health ofpatients[6] Doctors are caught in the middle as they try to be responsive to the patients they serve as well as to the managed care organizations that employ them. Drug companies, meanwhile, promote expensive treatments that might save lives, but at a cost that may put such treatments out of the reach of those who do not have generous insurance coverage. These difficult issues will only become more complicated as drug companies develop new technologies and new alliances in a health care system increasingly dominated by managed care.

In. ANTITRUST IMPLICATIONS

A. FTC Challenges Vertical Integration in Pharmaceutical Markets

The mergers and alliances between pharmaceutical companies and PBMs have raised antitrust concerns. The Federal Trade Commission (FTC) has kept track of changing

64 A recent study of cost-containment practices at LIMOs has added more fuel to this debate. The study found that patients whose access to prescription drugs was most restricted incurred the highest overall health care costs, while patients in an LIMO with an open formulary had the lowest costs. Ron Winslow, *Limiting Drugs A Doctor Orders May Cost More,* WALL ST. J., Mar. 20, 1996, at Bl.

pharmaceutical markets and has challenged transactions that could lead to anticompetitive effects.[65] The agency traditionally investigates mergers of competitors, or horizontal mergers, but in recent years it has shown increased interest in vertical integration. Vertical integration in the supply and distribution of a product can be accomplished through a merger or through internal expansion. These types of transactions, which often result in the increased efficiency of an operation, ordinarily do not lead to antitrust problems.[66] The emergence of PBMs, however, has led the FTC to reexamine its analysis of vertical integration.[67] The agency's main concern is that some of the largest drug companies have purchased or formed alliances with the leading PBMs, effectively putting the majority of the nation's PBMs under the control of the drug companies.

In light of this concern, the FTC challenged Eli Lilly's purchase of McKesson Corp. and its PBM business, PCS LIealth Systems. Eli Lilly is ranked as one of the largest pharmaceutical manufacturers in the country, and PCS is the largest PBM.[69] In its complaint, the FTC alleged that Lilly could discriminate against other drug makers by foreclosing them from the PCS formulary.[70] The agency also alleged that the acquisition would facilitate collusion among Lilly

65 Mark D. Whitener, *Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace,* 50 FOOD & DRUG L.J. 301(1995) [hereinafter *Antitrust Enforcement].*

66 *Id*

[67] *Id* at 302.

68 *Id*

69

[70] *1d* at 303.

and other vertically integrated pharmaceutical companies.[7'] Other allegations were that the acquisition would lead to increased prices, diminished product quality, a reduction in the incentives of other pharmaceutical manufacturers to innovate, and increased barriers to entry in the pharmaceutical market.[72]

Lilly and the FTC ultimately entered into a consent agreement that addressed the agency's concerns.[73] The agreement requires Lilly to maintain an open formulary that does not give undue preference to Lilly's products.[74] All drugs on the formulary must be selected by an independent Pharmacy and Therapeutics Committee, which must use objective criteria to create and maintain the formulary.[75] The consent agreement also requires the placement of a firewall between Lilly and PCS, preventing the exchange of information concerning bids, proposals, prices, discounts, and other information related to competitors' products. [76]

The FTC's investigation has led to suggestions that the Commission has departed from its general view that vertical mergers often foster competition, and that the FTC can be expected to scrutinize future vertical mergers in the pharmaceutical industry.[77] The Commission has been criticized for its inconsistent analysis of vertical consolidations, which has led to uncertainty

[~'] *Id*

[72] *Id*

[73] *In re* Eli Lilly and Co., Inc., Proposed Consent Agreement, FTC File No. 941-0102 (Nov. 28, 1994) (59 Fed. Reg. 60,815 (1994)).

[~] *Antitrust Enforcement, supra* note 65, at 303.

[~] *Id*

at 304.

[~] *See Health Care Reform, supra* note 3, at 16-17.

within the industry and to diminished interest in acquisitions of PBMs.[78] Fewer acquisitions, however, may ease fears that the industry has become overly consolidated.[79]

B. Less Research and Development

A decline in research and development may be another possible effect of consolidation.

Since many drugs within a class are similar, the less expensive ones are typically selected to be on a formulary. With only a few drugs listed on a formulary, companies have little incentive to invest in research and development of new drugs that may offer only marginal improvements.[80] Unless a manufacturer can produce a breakthrough drug, it will difficult to get its product on a

formulary.[8'] Larger companies will be better able to bear the risk of research than smaller companies, which could be driven out of business. Small companies may be deterred from

entering the field altogether. The regulatory and technological requirements for entering the

pharmaceutical industry present additional barriers. Some analysts, however, predict that large drug makers may eventually rely on small biotechnology companies, rather than their own

research and development departments, to do most breakthrough research, and then market

78 *See Enforcement Responses, supra* note 45, at 316-17.

For the proposal that large consolidation in the pharmaceutical industry is economically undesirable, see Christine Dodd, *The Merck-Medco Merger: An Isolated Incident Or a Catalyst for the Transformation of an Industry?,* 63 U. Cmi. L. REv. 1767 (1995), and Ruth Barber Timm, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry:*

A Proposed Exception to the Copperweld Holding, 31 VAL. U. L. REv. 309 (1996).

80 *See Health Care Reform, supra* note 3, at 7-8.

81 *Id*

successful drugs under licensing agreements.

The FTC has also analyzed whether horizontal mergers and joint ventures lead to less innovation, higher prices and reduced output. A horizontal merger or acquisition involves the combination of firms at the same level of production or distribution. The FTC analyzes such transactions under Section 7 of the Clayton Act[83] and the 1992 LIorizontal Merger Guidelines.[84] In the context of the pharmaceutical industry, anticompetitive effects may occur when a transaction eliminates a direct competitor in a therapeutic category, especially when there are few alternatives and entry is difficult.[85] Anticompetitive effects may also occur when an acquisition eliminates competition between firms that were potential entrants in a market, such as a firm that is awaiting FDA approval or a firm that has undertaken significant research and development efforts.[86]

In recent years, the FTC has challenged acquisitions that raised concerns about innovation and competition. For example, in *In re* American LIome Products Corp., the FTC obtained a consent settlement in the proposed acquisition of American Cyanamid.[87] The FTC determined that the merger would eliminate direct competition between American Home Products and

82 Elyse Tanouye & George Anders, *Drug Industry Takeovers Mean More Cost-Cutting, Less Research Spending,* WALL ST. J., Feb. 1, 1995, at Bl.

~ 15 U.S.C. § 18 (1988).

844 TRADE REG. REP. (CCLI) ¶ 13,104 (1992).

85 *See Antitrust Enforcement, supra* note 65, at 305.

86 *Id*

87 FTC File No. C-3557 (consent settlement) (Feb. 14, 1995).

American Cyanamid and would increase the likelihood of coordinated interaction. The FTC was concerned about anticompetitive effects in five different product markets, including research and development of a rotavirus vaccine. There is no authorized vaccine for rotavirus, a disease that leads to the hospitalization or death of thousands of children each year. American Cyanamid and American LIome were two of three firms undertaking significant research and development of a vaccine. The consent agreement requires American LIome Products to license American Cyanamid's rotavirus vaccine research, which will ensure than an independent competitor will continue to work on the vaccine.[89]

C. Retailers Accuse Drug Companies of Price Discrimination

In a $351 million settlement reached last year, eleven major drug companies agreed to stop charging retail pharmacies higher prices for medicine than the companies charged managed care organizations.[90] Some forty thousand retail pharmacies had brought a lawsuit against virtually all of the leading manufacturers and wholesalers of brand name prescription drugs. One group of plaintiffs alleged a price-fixing conspiracy under the Sherman Act, [~] in which the defendants agreed to eliminate price competition and to keep prices of prescription brand name drugs artificially high to retail pharmacies. Another group of plaintiffs, which opted out of the

[~] *See Antitrust Enforcement, supra* note 65, at 305.

[89] *1d* at 306.

[90] *1n re* Brand Name Prescription Drugs Antitrust Litigation, (Apr. 4, 1996, N.D. Ill.),

1996 WL 167350.

91 Sherman Act, 15 U.S.C. § 1.

class, alleged Sherman Act conspiracy violations and price discrimination claims.[92] Both groups of plaintiffs claimed that the defendants collusively created and maintained a dual pricing system that raised or stabilized the prices that retail pharmacies paid for prescription drugs. The plaintiffs alleged that the defendants refused to make discounts and rebates available to the pharmacies, while making them available to institutional or managed care buyers.

The defendants denied collusive behavior and argued that economic considerations drove their denial of discounts to retail pharmacies. They argued that retail pharmacies do not possess the same market power, or the same power over the prescribing decision, compared to institutional and managed care buyers. Managed care groups can restrict their doctors' prescriptions to the drugs listed on a formulary, thereby ensuring that the drugs will be prescribed in volume. Because managed care and institutional buyers have the power to affect market share, they can negotiate discounts or rebates from pharmaceutical manufacturers. Manufacturers, enticed by gaining access to a large patient population, and threatened with the prospect of exclusion from a formulary, offer discounts and rebates in return for large-volume sales. The plaintiffs disputed the amount of market power that managed care groups exert, and contended that they, too, can affect market share.

Under the terms of the settlement, the drug companies must make the same discounts available to any institution, whether managed care or pharmacy, provided the buyer can show it can shift market share. The settlement remains controversial, however, since it is unclear whether

92 Robinson-Patman Act, 15 U.S.C. §§13(a), (d) and (f).

it will result in lower prices for consumers.[93] Drug companies, instead of giving discounts to everyone, may just give discounts to no one. Even if the drug companies do give pharmacies discounts, the stores may not pass the savings on to consumers.

IV. FRAUD AND ABUSE

A. Questionable Marketing Practices in the Pharmaceutical Industry

1. Gifts to Physicians

For many years, it was a common practice for phannaceutical companies, as well as device and medical equipment companies, to give gifts to physicians.[94] These gifts ranged from the extravagant, such as all-expense paid cruises to the Caribbean, to the mundane, such as pens and pads of paper embossed with a company's name. Other promotional activities included making cash payments to physicians for attending or speaking at conferences, or awarding physicians money or prizes on the basis of the prescriptions they generated. With no clearly drawn line to differentiate innocuous gifts from unethical or illegal kickbacks, such activities proliferated.

˜ *See, e.g.,* Laurie P. Cohen & Elyse Tanouye, *Bitter Pill: Drug Makers Set to Pay $600*

Million to Settle Lawsuit by Pharmacies; Retailers Object to Practice Of Granting Discounts to

HMOs But Not Them, WALL ST. J., Jan. 18, 1996 at Al; Elyse Tanouye & Ron Winslow,

Pharmaceuticals: Drug-Suit Settlement May Be Bitter Pill for Consumers, WALL ST. J., Jan. 19,
1996, at B 1; Roger Lowenstein, *Intrinsic Value; Drug Pact May Be Worse Than the Disease,*

WALL ST. J., Jan. 25, 1996, at Cl; Robert Langreth, *Settlement Cleared in Pharmacies' Suit Over*

Price Fixing, But Debate Lingers, WALL ST. J., June 24, 1996, at B5.

See Mary-Margaret Chren & C. Seth Landefeld, *Doctors, Drug Companies, and G{fts,* 262 JAMA 3448 (1989).

Giving and accepting gifts can have practical and ethical repercussions.[95] Accepting a gift establishes a relationship between the physician and the drug company that obliges a response from the physician.[96] Moreover, the cost of gifts is ultimately passed on to patients. Taxpayers bear the burden when the cost of prescription drugs is subsidized by government programs. Serious ethical issues arise when physicians alter their prescribing practices to the detriment of their patients.

Some types of gifts are an outright attempt to buy influence, while other gifts, such as the provision of funds for educational seminars and conferences, serve a socially beneficial purpose. Through funding conferences and research projects, drug companies have made significant contributions to medical knowledge. Such contributions, however, are motivated by financial considerations, which can lead companies and physicians to engage in self-interested practices that can ultimately harm patients.

2. Ethical Guidelines Reassessed

In response to widespread criticism of excessive gift-giving practices, American Medical Association's (AMA) Council on Ethical and Judicial Affairs ultimately revised its code of ethics for the medical profession. On December 3, 1990, before the beginning of a congressional

~ Social scientists have described the norm of reciprocity as a fundamental principle that guides human interactions. Pharmaceutical companies rely on this principle by giving gifts to physicians with the expectation that those physicians will prescribe their pharmaceutical products in return. *See* Teri Randall, *Ethics of Receiving G{fts Considered,* 265 JAMA 442 (1991).

96 *Id.*

hearing concerning promotional practices in the pharmaceutical industry,[97] the AMA Council issued guidelines addressing gifts to physicians from industry.[98] The Council subsequently published a report that provided the reasoning behind the guidelines and its interpretations of specific provisions.[99] Two days after the AMA issued its guidelines, the Pharmaceutical Manufacturers Association (PMA) adopted the guidelines as part of its code of pharmaceutical marketing practices.

The AMA's guidelines attempted to address three ethical concerns. The first concern is that physicians' practices are influenced by gift-giving.[100] The council acknowledged that promotional activities are intended to increase sales and that these activities affect physician's behavior.[10]' Under such influences, physicians may prescribe drugs based on considerations that go beyond scientific knowledge and patient needs.'[02] The second concern is with the appearance of impropriety, especially where gifts are of substantial value.'[03] The third concern is that the

[97] *Advertising, Marketing and Promotional Practices of the Pharmaceutical Industry:*

Hearing Before the Senate Committee on Labor and Human Resources, 101st Cong. (Dec. 1990). During the hearings, physicians and former pharmaceutical executives revealed extravagant marketing practices, such as sending physicians and their spouses on all-expense paid trips to exotic locations for educational conferences.

98 Council on Ethical and Judicial Affairs, American Medical Association, *G{fis to Physicians from Industry,* 265 JAMA 501 (1991).

˜ Council on Ethical and Judicial Affairs, American Medical Association, *Guidelines on Gals to Physicians from Industry: An Update,* 47 FOOD DRUG L.J. 445 (1992).

[00] *1d* at 447.

101 *Id*

[02] *Id*

103 *Id* at 449.

costs of gifts are ultimately passed on to the public.'[04]

The guidelines instruct physicians to avoid the acceptance of inappropriate gifts. Acceptable gifts should primarily entail a benefit to patients and should not be of substantial value.'[05] Cash payments should not be accepted, but textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Gifts of minimal value, such as pens and notepads, are permissible if they relate to the physician's work. A physician may not accept a gift if there are strings attached. An example of such a situation would be accepting a gift that is given in relation to a physician's prescribing practices.

Funds provided to subsidize the cost of continuing medical education conferences are permissible as long as the funds are given to the sponsor of the conference and not to the individual physician. Sponsors can use the subsidy to reduce the registration fee of the conference, thus providing a more indirect benefit to physicians. The rationale behind this provision is that such conferences contribute to the improvement of patient care and should thus be encouraged. Companies should not, however, give money directly to a physician, since that type of gift could improperly influence the use of the company's products. The guidelines advise physicians not to accept payment, whether direct or indirect, for the costs of travel, lodging, or other personal or compensatory expenses incurred for attending a conference or meeting.

Although it is unclear how effective the AMA's guidelines have been in curbing unethical behavior, they have caused some drug companies and physicians to reassess promotional activities that were once taken for granted. Shortly after the guidelines were published, the drug company

'[04] *Id* at 450.

[105] *Id* at 451.

Collagen cancelled a South Pacific cruise for principal physician users of the company's Zyderm and Zyplast injectable collagen products.'[06] Physicians were invited to attend the cruise based on the quantity of injectable collagen they had purchased during a promotional campaign and the percentage increase over the amount they had purchased the previous year.'[07]

Collagen, which is not a member of either the AMA or PMA, was concerned about perceived conflicts between the trip and the guidelines on industry gifts to physicians. In a letter to physicians, Collagen stated that although it believed that physicians participating in this program would in no way be violating any ethical guideline, they would be cancelling the trip because they did not want to put their physician customers in a politically awkward s1tuat1on.'˜'˜ Even though Collagen was not technically subject to the AMA or PMA guidelines, physicians who went on the trip would be violating their own guidelines. Specilically, they would violate the provision that physicians should not accept gifts based on their prescribing practices and the provision that physicians should not accept travel or lodging from industry. Furthermore, if the physicians received federal reimbursement for collagen, they might be violating the Medicare and Medicaid Antikickback Statute.

The possibility of violating the ethical guidelines as well as the antikickback statute made the Collagen promotion a risky venture. Whether the guidelines, alone, would have been a sufficient deterrent is debatable. By themselves, the guidelines seem to be weak deterrents to unethical conduct because violating them does not lead to serious consequences. Combined with

106 F-D-C REP. (THE GRAY SHEET), June 17, 1991, at 4.

'07 *Id*

a strong federal statute, however, the promotional schemes of the past are not as blatant as they once were. While drug companies still use traditional methods to market their products, vigilant enforcement efforts have caused the industry to modify or cease some longstanding practices. The emergence of managed care has also led the drug industry to develop new types of promotional activities. Some of these activities, however, test the bounds of the law.

B. The Federal Antikickback Statute

The federal antikickback statute, which is commonly called the Medicare and Medicaid Antikickback Statute, supplies federal prosecutors with a tool to combat health care fraud. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the statute has been expanded to cover federal health care programs other than just Medicare and Medicaid. The antikickback statute has curtailed unlawful practices in the health care industry, but it has also been criticized for its broad scope. The language of the statute arguably encompasses lawful, as well as unlawful activities, leaving the health care industry with little guidance on how to structure its affairs. The safe harbor regulations provide assurance that certain activities will be beyond the reach of the anti-kickback statute, but these regulations have been criticized for being overly narrow. New regulations will be adopted and old ones modified as industry practices continue to evolve in the context of managed care.

1. Development of the Antildckback Statute

The federal antikickback statute, which applies to health care programs funded by the federal government, is the primary enforcement weapon to combat fraud and abuse in the health

care industry. The statute makes the knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of goods or services payable by the federal government a felony punishable by up to five years in prison and a fine of up to $25,000.109 The relevant portions of the Act provide that:

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind–

(A) in retum for referring an individual to a person for the furnishing or arranging the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or

(B) in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal healthcare program,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly willfully offers or pays any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made, in whole or in part under a Federal healthcare program,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.[0]

109 Social Security Act § 1 128B(b); 42 U.S.C. § 1320a-7b(b) (as modified by the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, Tit. II § 204, 110 Stat. 1936, 1999 (1996)).

110 *Id*

Violators are subject to criminal penalties as well as exclusion from the federal health care programs. The Department of Health and Human Service (EllIS). through the Office of the Inspector General (OIG), has the authority to investigate potential violations of the statute and to bring enforcement actions. The OIG does not have the authority to impose civil money penalties, but it has entered into monetary settlements with those under investigation for violating the statute.

The development of the statute can be traced as follows. A provision proscribing kickbacks was first included in the Social Security Act in 1972.' Violations were then classified as misdemeanors, not felonies, as they are today, and there was no requirement of intent. In 1977, Congress enacted the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 to expand the scope of the statute and to provide greater specificity. The amendment prohibited any remuneration, not just kickbacks or bribes, raised the violations from misdemeanors to felonies, and listed two statutory exceptions for employees and certain discount arrangements.[112]

In 1987, Congress passed the Medicare and Medicaid Patient and Program Protection Act of 1987, which gave the OIG civil sanction authority for kickback violations.[3] The Act also mandated that the OIG promulgate safe harbor regulations specifying permissible practices under the antikickback law.

' Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972).

112 Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. 95-142, 91 Stat. 1175 (1977).

'Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93, 101 Stat. 682 (1987).

Most recently, Congress passed the Health Insurance Portability and Accountability Act of 1996 (LIIPAA), which made several changes to the antikickback statute.[4] H[PAA expanded the reach of the statute beyond Medicare and Medicaid and other state health care programs. As of January 1, 1997, the antikickback statute will apply to all federal health care programs, defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded in whole or in part, by the United States Government with the exception of the federal employee health benefits programs.[5] HIPAA also created a new statutory exception for certain risk-sharing agreements, and it requires HHS to provide advisory opinions determining whether a transaction will be subject to the antikickback statute.

2. Statutory Exceptions and Safe Harbor Regulations

Because the language of the anti-kickback statute is broad, it prohibits many commercial arrangements. The reach of the statute is limited, however, by statutory exceptions and safe harbor regulations. The antikickback statute currently includes the following exceptions, which describe acts that are immune from prosecution: (1) discounts that are properly disclosed and reflected in the costs claimed or charges made by the provider, (2) payments by an employer to an employee for bona fide employment in the provision of covered items and services, (3) amounts paid by providers to a group purchasing organization (GPO), in which there is a written

Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

˜ Social Security Act § 1 128B(b); 42 U.S.C. § 1320a-7b(f) (as modified by the Health Insurance Portability and Accountability Act of 1996, P.L. 104-19 1, Tit. II § 204, 110 Stat. 1936, 2000 (1996)).

agreement between the providers and the GPO specifying the fee and the GPO discloses the amount of the administrative fee to providers purchasing from the GPO, (4) waivers of comsurance amounts in connection with certain federally qualified health care centers, (5) activities protected by the safe harbor regulations, (6) certain risk sharing agreements.'[16]

The safe harbor regulations, which were promulgated pursuant to the Medicare and Medicaid Patient and Program Protection Act of 1987, further narrow the scope of the antikickback statute.[7] In July, 1991, the OIG promulgated the first set of safe harbor regulations, which explicitly describe permissible conduct.[8] The OIG developed safe harbor regulations to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.[9] Business practices that conform with the safe harbor regulations will not be treated as criminal offenses under the antikickback statute and will not serve as a basis for program exclusion. The preamble states, If a person participates in an arrangement that fully complies with a given provision, he or she will be assured of not being prosecuted criminally or civilly... •120 Compliance with the safe harbor provisions is voluntary. Activities that are not in compliance with the regulations are not per se illegal and will not necessarily result in prosecution.

116 Social Security Act § 1 128B(b)(3); 42 U.S.C. § 1320a-7b(3) (as modified by the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, Tit. II § 216, 110 Stat. 1936, 2007 (1996)).

˜ 42 C.F.R. 1001.952.

118 56 Fed. Reg. 35,932 (July 29, 1991).

˜ *Id* at 35,952.

120 *Id.* at 35, 954.

The first set of safe harbor regulations covered the following areas: (1) investment interests, (2) space rental, (3) equipment rental, (4) personal services and management contracts. (5) sale of practice, (6) referral services, (7) warranties, (8) discounts, (9) employees, (10) group purchasing organizations, and (11) waiver of beneficiary coinsurance and deductible amounts for inpatient hospital services and certain federally qualified and federally funded health care facilities.

In November 1992, the OIG published, in interim final form, three safe harbors related to managed care activities. The safe harbors cover: (1) incentives offered to beneficiaries, such as the waiver or reduction of coinsurance and deductible amounts, (2) provider discounts to managed care plans, and (3) waivers of inpatient coinsurance and deductible amounts by Medicare SELECT PPOs.'[2]' After reviewing comments from the public, in January 1996, the OIG issued the managed care safe harbor regulations in final form.'[22]

The OIG is currently in the process of finalizing additional safe harbor provisions, which would expand protection for investment interests in rural areas, ambulatory surgical centers and group practices.'[23] Furthermore, in accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, the OIG has solicited proposals and recommendations for developing new and modifying existing safe harbor provisions.'[24]

121 ˜ Fed. Reg. 52,723 (Nov. 5, 1992).

122 61 Fed. Reg. 2,122 (Jan. 25, 1996).

123 58 Fed. Reg. 49,008 (Sep. 21, 1993).

124 61 Fed. Reg. 69,060 (Dec. 31, 1996). The OIG will consider the following factors for new or modified safe harbor provisions: access to health care services, the quality of health care services, patient freedom of choice among healthcare providers, competition among health care providers, the cost to the federal health care programs, the potential overutilization of the health care services, and the ability of health care facilities to provide services in medically underserved

3. Current Developments

After the Health Insurance Portability and Accountability Act of 1996 was passed, the Clinton Administration recommended that three of the fraud and abuse provisions be repealed.'[25] First, the Administration would like to repeal the managed care exception for risk-sharing agreements, since it believes that the exception provides too much protection for possibly fraudulent arrangements.'[26] Second, the definition ofknow or should know, which requires the government to prove that an act was committed with deliberate ignorance or reckiess disregard of the truth, may be repealed.'[27] Third, they are seeking to repeal the OIG's authority to issue advisory opinions.'[28] The OIG itself is opposed to issuing advisory opinions, as it believes that such opinions would impede law enforcement efforts.'[29] One concern is that approval of a particular transaction may be difficult, since liability often turns on the fact-specific question of intent. Another concern is that companies will obtain advisory opinions, misconstrue them, and

areas or to medically underserved populations. *Id*

'[25] *See* Came Valiant & David E. Matyas, LEGAL ISSUES IN HEALTHCARE FRAUD AND

ABUSE: NAVIGATING THE UNCERTAINTIES 387 (2d ed. 1997) [hereinafter NAVIGATING THE UNCERTAINTIES].

'[27]*d* In *Hanlester Network v. Shalala,* the Ninth Circuit developed a two-part test for determining whether a defendant has violated the scienter requirement of the antikickback statute, which provides that a defendant must have acted knowingly and willfully. In *Hanlester,* the court held that for a violation to be found, the defendant must know of the statutory prohibitions against offering or paying remuneration to induce prohibited behavior. The defendant must also have formed a specific intent to break the law. 51 F.3d 1390 (9th Cir. 1995).

128 NAVIGATING THE UNCERTAINTIES, *supra* note 125, at 387.

then use the opinion to shield their conduct from liability.'[30]

Companies would have to pay a fee to obtain an advisory opinion, but the cost may be worth the certainty the opinion would provide.'[3'] It is unclear, however, how much certainty or guidance the opinions will offer. The OIG, through these opinions, can only interpret the broad statutory language. An overly broad opinion, like the statute itseW will not provide useful guidance. The advisory opinions would only be truly useful to the health care industry **W** based on the OIG's review of the specific facts of each transaction, the opinion provides protection against enforcement actions.'[32]

C. Investigations and Enforcement Activities

1. The Office of the Inspector General

In 1976, Congress established the Office of Inspector General (OIG) to identify and eliminate fraud, abuse, and waste in HHS programs.'[33] The OIG investigates cases of fraud and abuse connected with LIHS programs, and refers cases to the Department of Justice for civil or

See Eric Weissenstein, *Update: White House After Fraud Reform Repeal,* MODERN HEALTHCARE, Feb. 17, 1997, at 80.

See HHS IG Advisory Opinion Interim Final Rule Lays Out Payment System, Information Requirements for Requestors Under HIPAA , 9 HEALTH NEWS DAiLY 1, Feb. 20,

1997.

132 *See* Carrie Valiant, *Revising Anti-Kickback Law May Provide Best Guidance,* MODERN HEALTHCARE, Oct. 24, 1994, at 50.

'~' The Department of Health and Human Services (hITS), through the Health Care Financing Administration (HCFA), is responsible for administering the Medicare and Medicaid programs. Medicare is a federal program, and Medicaid is a joint federal/state program. HCFA administers claims and payment for Medicare through private insurance companies.

cnminal prosection. The OIG also has the authority to exclude parties from the Medicare and Medicaid programs, but they do not have authority to impose civil money penalties for violations of the antikickback statute. Parties under investigation have, however, voluntarily entered into monetary settlements with the 01G.

As part of its ongoing investigation into prescription drug marketing practices, the OIG has found that pharmaceutical companies offer physicians money and other items of value. The OIG has described four major categories of offers used for promotional purposes: studies, speaking engagements, program attendance, and gifts:'[34]

- Studies. Pharmaceutical companies ask physicians to participate in studies of FDA-approved drugs. The companies may offer cash, medical equipment, large grants, and trips for participation in a study.
- Speaking Engagements. Pharmaceutical companies pay a physician honoraria and travel expenses in exchange for speaking on various topics, including the benefits of the company's products.
- Program Attendance. Pharmaceutical companies offer payments of cash, travel expenses, lodging, meals, entertainment, and recreational activities to physicians for attending promotional programs.
- Gifts. Pharmaceutical companies offer physicians gifts, such as items useful in medical practice, meals, promotional gadgets, trips, and prizes.

˜ *Prescription Drug Marketing: Questionable Practices Within the Pharmaceutical Industry: Hearing before the Subcomm. on Regulation, Business Opportunities, and Technology of the Comm. on Small Business,* 103rd Cong. 68 (Oct. 1994) [hereinafter *Hearings]* (testimony of June Gibbs Brown, Inspector General of the Department of Health and Human Services).

The OIG found that the prescribing practices of physicians are sometimes affected by the promotional efforts of pharmaceutical companies and that the companies are more likely to offer gifts and payments to physicians who are frequent prescribers than to those who are infrequent prescribers. '

The Caremark case is one notable example of an OIG investigation. The investigation, which involved a promotional scheme giving physicians financial incentives for prescribing growth hormone drugs, also led to Congressional involvement.'[36] Caremark, a national home health care company, had been promoting human growth hormone drugs to treat short children. Treatment with these synthetic hormones, which are harvested from cadavers, costs $20,000-$30,000 per year.'[37] Caremark was accused of giving kickbacks to physicians to prescribe the drugs to children who were not clinically hormone deficient, but just shorter than average. The antikickback statute was implicated because some of the drugs were reimbursed by Medicaid.

OIG's investigation revealed that Caremark and Genentech, the manufacturer of the growth hormone drug Protropin, paid Dr. David K Brown, a pediatric endocrinologist, kickbacks to induce him to prescribe the drugs to his juvenile patients. The kickbacks were paid in the guise of research grants, as revenue generated from patient referrals, as consulting agreements, and

'Id.

136 at 40. Although the hearings were sparked by the growth hormone controversy, the

focus of the hearing was broader. Rep. Ron Wyden, the chairman of the subcommittee, stated
that his concern about drug marketing and promotion goes far beyond allegations that a couple
of drug companies have mistreated short children. It seems to me that what you have described is

a pattern [of] organized state-of-the-art marketing abuses that are exploiting patients. *Id* at 12-

13.

'i *Id* at 2.

138

through the payment of overhead support such as office expenses and the salary of a nurse. In return for these payments, the physician, who was one of the largest prescriber of Protropin in the country, generated over $4 million in patient referral revenue for Caremark. ˜

On August 4, 1994, a federal grand jury in Minneapolis returned a 51-count indictment against Dr. Brown for receiving kickbacks from Caremark.'[40] Dr. Brown was ultimately found guilty of receiving kickbacks in exchange for prescribing Protropin, but changes against the individual executives of Genentech and Caremark were dismissed.'[4']

As a result of the OIG's investigation, Caremark and Genentech agreed to withdraw direct support for height screening programs. They also agreed to stop providing direct research grants, nurses, and office equipment to clinicians. In June 1995, Caremark, Inc. pleaded guilty and paid $161 million in criminal fines, civil restitution and damages for committing fraud in its human growth hormone business. 142

2. Special Fraud Alerts

The OIG periodically issues Special Fraud Alerts that describe impermissible conduct in the healthcare industry. The Special Fraud Alerts, which are widely distributed throughout the

138 *Id* at 6.

"Id

Doctor Is Found Guilty Of Receiving Kickbacks, WALL ST. J., Oct. 20, 1995.

142 United States v. Caremark, CCLI Medicare and Medicaid Guide, ¶ 43,406, No. Cr. 4-

97-95 (D. Minn., June 16, 1995).

healthcare industry, provide notice that the OIG is aware of and plans to take action against, specified abusive practices.'[43] The alerts also serve as a tool to encourage industry compliance by giving affected entities an opportunity to examine their practices.' The Health Insurance Portability and Accountability Act of 1996 requires the OIG to solicit proposals for new Special Fraud Alerts that would provide additional guidance regarding unlawful practices.'[45]

In August, 1994, the OIG issued a Special Fraud Alert which described prescription drug marketing schemes that would violate the anti-kickback statute.'[46] The alert was released in response to questionable marketing practices that go beyond traditional advertising and educational contacts. The alert notes that physicians and other suppliers are increasingly being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands.'[47] The alert describes the danger of these marketing schemes:

Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.... A marketing program that is illegal under the anti-kickback statue may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining

61 Fed. Reg. 69,061 (Dec. 31, 1996).

"Health Insurance Portability and Accountability Act of 1996, Pub. L. No 104-191, Tit. ll§210, 110 Stat. 1936, 2000(1996).

146 HHS, OFFICE OF INSPECTOR GENERAL, *Special Fraud Alert: Prescription Drug Marketing Schemes* (1994) [hereinafter *Special Fraud Alert].*

the most appropriate treatment for a patient.'[48]

Since the prescription drugs supplied under one of these aggressive marketing programs are often reimbursed by Medicaid, those participating in such programs may be prosecuted for violating the antikickback statute.

The OIG identified three types of cases that violate the antikickback statute. '~ One type of case involved a product conversion program, whereby a drug company offered cash to a pharmacy each time a drug prescription was changed to that drug company's product. The OIG had investigated Bayer AG's Miles Inc. for a program that paid pharmacists to counsel patients about its heart drug, Adalat CC.

Another case concerned a frequent flier program in which a drug company gave airline frequent flier mileage to physicians each time they completed a questionnaire for a new patient placed on the drug company's product. In 1993, Ayerst Laboratories, Inc. had a promotion scheme called the Patient Profile Program, under which it provided participating physicians with a pharmaceutical product it manufactured, preprinted prescription pads, and a questionnaire. Ayerst then awarded physicians frequent flyer points each time the physician completed a brief questionnaire for new patients prescribed the company's product. Ayerst denied wrongdoing, but agreed to pay the federal government $830,000 to settle civil and administrative claims.'[50]

"¡ The OIG did not name specific companies in the Special Fraud Alert, in part because the activities are typical in the industry. Elyse Tanouye, *Drug Marketers May Use Illegal Tactics to Sell,* WALL ST. J., Aug. 23, 1994, at Bl.

150Id

The final case identified by the Special Fraud Alert involved a research program in which physicians received remuneration for a drug manufacturer under the guise of payments for conducting research. Hoffmann-LaRoche's grant-in-aid program offered money to physicians who prescribed their products and performed minimal record keeping tasks, which the company characterized as studies. Many physicians were selected based on their ability to recommend the company's products or because they were in a position to include the company's drugs on a hospital formulary. The participating physicians were paid substantial amounts for making brief notes, sometimes one word, about the treatment outcome of a patient taking the company's product. In a number of cases, the physicians never completed the research and still received the full grant payment. Hoffman-LaRoche eventually agreed to pay $450,000 to settle civil and administrative claims.'[5]'

The Special Fraud Alert noted that even if these schemes involve a legitimate purpose, if one purpose of a scheme is to induce the provision of a drug reimbursable by Medicaid, the antikickback statute is implicated.'[52] The Special Fraud Alert warns that OIG investigation may be warranted when a prize, gift, or cash payment is offered to drug suppliers[153] in exchange for

' *Hoffinann-LaRoche To Pay HHS $450, 000 Settlement,* WASH. POST, Sept. 3, 1994, at Cl.

152 *Special Fraud Alert, supra* note 146. The one purpose test was articulated in *United States v. Greber,* 760 F.2d 68 (3rd Cir. 1985), *cert. denied,* 474 U.S. 988 (1985). In *Greber,* the owner of a cardlo-monitor company characterized payments made to physicians as interpretation fees. The Third Circuit held that the antikickback statute is violated if one intended purpose of payment is to induce physicians to use defendant's services, even if the payments were also made for professional services. Thus, violations of the statute may be found when at least one purpose is to induce prohibited behavior.

A supplier includes physicians, pharmacies, mail order prescription drug companies, and managed care organizations.

prescribing or providing pharmaceutical products. The scheme is particularly suspect when the payments are based on the volume of business generated for the drug company. Payments made to pharmacists for marketing tasks are also suspect, as are payments made to physicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. 's

3. The Managed Care Context

Members of the heath care industry have expressed concern that some managed care practices may be construed as violations of the antikickback statute. For example, formulary rebates to PBMs, HMOs, pharmacies, and other managed care entities could give rise to an OIG investigation and enforcement action. Specifically, payments made to PBMs to influence prescribing practices through formularies could constitute remuneration in return for recommending or arranging the purchase of a product.' In a sense, PBMs are analogous to group purchasing organizations (GPOs) since they both operate as middle men who get rebates but are not the ultimate product purchasers.'[56] Payments to a GPO, however, can be protected under the GPO safe harbor regulation. There are currently no safe harbors to protect PBMs.

Disease Management Programs (DMIPs) could become another target of an antikickback

Special Fraud Alert, supra note 146.

'[55] HH5 IG Auditing Pharmaceutical Pricing, Impact of PBMs on Patient Quality of Care, F-D-C REP. (THE PINK SHEET), June 3, 1996, at 7-8.

investigation.'[57] Pharmaceutical companies and managed care organization have formed DMP arrangements, which are programs to manage the health care of patients through medication regimens. For a fixed price, drug companies provide their products to managed care organizations, which then list the drugs on a DMP formulary. Antikickback concerns arise since payments are, in effect, being made to encourage the increased use of drugs.

Some commentators have argued that the antikickback statute is becoming increasingly irrelevant under managed care.'[58] The antikickback statute was passed under the fee-for-service system, which provided incentives to physicians to increase the volume of services provided. The statute was designed to deter such behavior so that costs to the Medicare and Medicaid programs would be reduced. Now, managed care systems have put in place their own incentives, such as capitation, to limit services. Patients pay a flat fee regardless of services provided, so additional services do not generate additional revenue. With these self-imposed incentives to keep costs down, the need for government-imposed incentives has decreased.

V. CONCLUSION

Managed care has revolutionized the pharmaceutical industry, as well as the entire health care system. Managed care organizations achieve cost-containment objectives by controlling, to various degrees, how physicians practice medicine. This has led the drug companies to redesign their marketing programs with an eye toward the institutional or managed care customer. As the

'~ *See Disease Management Programs, supra* note 47. The author suggests that DMPs are beneficial arrangements that should be given safe harbor protection.

158 *See, e.g.,* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Lfe in the Health Care Speakeasy,* 22 Am. J.L. & Med. 205 (1996).

pharmaceutical industry explores different types of managed care alliances, it must be prepared to face various legal challenges. Drug companies have successfully taken advantage of profitable arrangements in the new health care market. As they aggressively pursue profits, however, they must be careful not to let their zeal lead to illegal or unethical practices.