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MANAGING MANAGED CARE:

The Changing Role of The FDA In Light of A Changing Market

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I. Introduction:

Change creates the necessity for more change. Advances in medical technology, and the incentives of a fee-for-service insurance system, drove up the costs of care. In response, insurers and purchasers of care began to seek ways to control these increases in health care costs. Eventually, managed care organizations sprouted which combined both the delivery and financing of care to provide cost-effective care. This combination not only changed many doctors' incentives to provide care, but more broadly transformed the overall structure of the American health care market.

This paper examines how the role of the Food and Drug Administration (FDA) has changed and how it should change due to the profound shift to managed care in our health care system. In particular, this paper focuses on the role of the FDA as a regulator of the flow of information between pharmaceutical companies and managed care companies. In short, this paper argues that FDA's restrictions on information are unduly restrictive and should be loosened.

II. Background on Managed Care:

Though many people feel as if managed care organizations are a recent invention, in reality the market has slowly moved toward managed care over the last 50 years.¹ The first managed care plans were merely prepaid group-practice plans, in which doctors provided all the necessary health care services to all members for a fixed up-front fee.² The need to reduce costs, however,

¹John K. Iglehart, *The American Health Care System: Managed Care*, 327 NEw ENG. J. MED. 742, 743 (1992).

²*Id.* at 743 (discussing the evolution of managed care plans and listing as examples the Kaiser-Permanente Medical Care Program, Health Insurance plan of New York and the Group Health of Puget Sound).

overwhelmed most opposition to managed care and the market moved forward.³ With the passage of the HMO act of 1973, the first major barrier to managed care fell. The use of these programs more or less expanded dramatically during the 1980's and continues to do so.⁵ For example though only half of US Workers received health care through managed care plans in 1993, this grew to 73% in 1995.⁶ Thus while Fee-for-service (traditional indemnity insurance) may have dominated medical history, managed care rules the present.

While the term Managed Care can refer to a variety of programs,⁷ managed care programs systematically use the theories of management to control the costs of health care. Furthermore, these programs on average give less deference and access to the judgment of a health professional than the traditional Fee-for-Service model. For example, many plans do not allow a patient to simply decide to see the world's leading heart surgeon. Instead the plans insist that a doctor chosen or approved by that plan refer the patient first. Even for the patient who sees the plan doctor, the decision of the doctor may be hampered by the knowledge that only certain kinds

³ See Alain Enthoven and Sarah J. Singer, *Market-Based Reform: What to Regulate and By Whom* HEALTH AFFAIRS, 105, 114, (Spring 1995) (the private market has been moving away quite rapidly from traditional free-choice, fee-for-service health care...the traditional model usually has not survived in competition on a level playing field because it prices itself out of business.).

⁴ 42 U.S.C. § 300 (1997).

⁵ Ross Waijen, *GeIR yfornvreofof. ot sanie; Eug indusby and twinaged care*, 31 vkbc

Marketing & Media, 28 (January 1996) (reporting that after the 1973 Act, within 10 years 12.5 million enrolled in HMO's, which expanded to 45.2 million by 1993, and surpassed 51 million in 1994).

⁶ *Study finds increase in managed health care*, BOSTON GLOBE, January 19, 1997 at A3 (discussing a study reported in the Winter 1996 edition of *Health Affairs*).

⁷ Iglehart *supra* note 1, at 744 (stating that managed care programs are endlessly varied.); *see also* Carl H. Hitchner, et al., *Integrated Delivery Systems: A Survey of Organizational Models*, 29 WAKE FOREST LAW REVIEW 273 (1994).

of care will be reimbursed for certain conditions.⁸ The threat of lost patients will force many doctors to adhere to the norms of the plan. Additionally, many of these plans use standardization and consolidation of resources to save money. Thus, these plans function with more coordination and arguably more efficiency than the traditional model of an isolated doctor billing random insurance companies for services.

Structurally, these programs can be accomplished in a range of ways, from contracts between insurance companies and individual doctors or through explicit organizational integration between insurance companies and groups of doctors. Differences in state laws and the actual competition present in markets, ~ to the differences in forms for managed care organizations. Despite the variation, one can still loosely group the most common types into either Integrated Delivery Systems (IDSs),¹⁰ Preferred-provider organizations (PPOs), or Health Maintenance

Organizations (HMO's).¹¹ Regardless of the form or name chosen, the net result is a system that

⁸ *Misuse of Prescription Drugs, Hearings before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Reform and Oversight, U.S House of Representatives, 104 th Cong.* (statement of Sarah F. Jagger, Director of Health Services Quality and Public Health Issues in the Health, Education, and Human Services Division)(Discussing a survey of doctors collected by the department which revealed that many doctors modified their optimal therapies because of reimbursement denials).

~ Hitchner, *supra* note 7~ at 274.

¹⁰IDSs refers to a capitation plan in which participants pay a fixed fee to receive a stated range of benefits from hospitals and doctors affiliated with the plan. The insurance plan in turn pays these doctors and hospitals a set amount to provide all the necessary care. Thus every patient reduces the amount of money the hospital or doctor has to care for the other covered patients—and indeed, to care for their own profit margin. *See Generally* Keith M. Korenchuk, *Overview: who are the players and what are their needs?*, 11 HEALTH SPAN 3 (1994).

¹¹ The LIMO offers lower fixed fees to doctors but in return give increased patient volume. Furthermore and the physicians face peer rather than external review of their medical decisions. While the physicians maintains autonomy with respect to individual medical decisions, the 1-IMO severely limits the physicians access to patients. For example, all specialists get patients only after a gatekeeper doctor refers the patient. Indeed, if a doctor makes too many expensive medical decisions, the doctor may be pushed out of the plan! IIMOs come in two basic varieties: the staff model IIMO or the independent practice association (IPA). The former makes the physicians employees of the plan, while the latter merely contracts with individual physicians or groups of physicians for care. *See Generally*, Iglehart, *supra* note I, at 744-745.

unites (although to different degrees) the financing and delivery of medical care to provide the most cost-effective care.

Today the principles of managed care control pharmaceutical companies as well as doctors and hospitals.¹² One estimate found that 50 percent of the drug market volume was influenced by managed care, and projections suggest that this figure will climb to 90 percent by the year 2000.¹³ Consequently, managed care plans have considerable leverage to negotiate prices. Furthermore, managed care's creation of financial strain may have induced pharmaceutical companies to reduce their research and development of new drugs.¹⁵ Furthermore, pharmaceutical manufacturers are seeking alliances with treatment centers through contracts or through buying managed care

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organizations. Others are cooperating to create complete disease management centers in order to adapt to managed care.¹⁷ For example, pharmaceutical manufacturer Glaxo Wellcome created a

¹² Bruce N. Kuhlik, *FDA's regulation of Pharmaceutical Communications in the Context of Managed Care: a suggested approach*, 50 *FOOD & DRUG LAW JOURNAL* 23 (noting that pharmaceutical manufacturers are transforming research and development, selling techniques in response to challenges of managed care).

¹³ Michael J. Malinowski, *Capitation, Advances In Medical Technology And The Advent of a New Era in Medical Ethics*, 22 *AM. J. L AND MED.* 331 (1996) (quoting a study by the Boston Consulting Group. The Changing Environment for U.S. Pharmaceuticals 18 (Apr. 1993); see also Jim Montague and Hilarie Pitman *Who's Paving for Prescriptions* 70(2) *HOSPITALS* 21(1996) (describing a finding in Retail Method of Payment Report showing that 50 cents of every dollar spent on prescription drugs is paid by MCO plans).

¹⁴ Peter J. Neumann, et. al. *How Should the FDA Regulate Drug Company Claims that their Products are Cost-Effective?*, 15(3) *HEALTH AFFAIRS* 54 (Fall 1996); Kuhlik, *supra* note 12, at 28.

¹⁵ Kate Nagy, *The Side Effects of Managed Care on the Drug Industry* 87 *J. NATL. CANCER INST.* 1279 (1995).

¹⁶ See Kate Nagy, *The Pharmaceutical Industry buys into Managed Care*, 87 *J. NATL. CANCER INST.* 1278 (1995).

¹⁷ *Id.*; See also Barbara Hesselgrave, *Pharmaceuticals; Drug Lovers* 70(2) *Hospitals* 1996 46-48, 50 (discussing disease management programs).

Care Management Division 18 while ZenecaGroup purchased 50% of Salick Health Care, Inc., a company which specializes in managing cancer and other chronic condition. 19 pharmaceutical companies have changed in response to managed care.

The basic effect of all these changes in structures is to change a doctor from a patient's advocate to one who must allocate scarce health resources in a utilitarian way.²⁰ Whether this lowers the quality of care actually provided remains an open question. Some argue that while fee-for-service plans gave physicians incentives to overservice patients,²¹ physicians now have an

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incentive to underservice in managed care plans. - Whether underservice causes more harm than overservice, or the extent of underservice still needs to be calculated.

Former Surgeon General C. Everett Koop has commented that HMOs cannot assure us that physicians will, in every instance, put their patients interests first. 23 Alarmists argue that plan administrators and not doctors will be limiting the services provided and making judgments about what kind of care the patient needs. Consequently the average patient could find this means less

¹⁸ See *supra* text accompanying note 17.

19 Nag)', *supra* note 16

²⁰ Malinowski, *supra* note 15 at 337-338 (noting that modern medicine is entering a third era in medical ethics of socioethics, in which the rights of each patient to care are balanced against the needs of society as a whole).

²¹ Malinowski, *supra* note at 336.

²² Steve Schade, *Can you trust your doctor?* EVENTION, August 1996 at 88 (discussing the pressures on doctors to think about the costs of care rather than the patient); Korenchuk, *supra* note 10 at 4.

²³ Quotes of the year: the year in review as they said it, HEALTH LINE, Dec 24, 1996 available in Lexis, Health Library, Medical and Health News File (quoting a statement made by Dr. Koop in regard to the direction of HMO's on 9/11).

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time in the doctor's office and less time for explanations.²⁴ One study found that HMO enrollees

tended to complain of unmet health care needs, and were more likely to have difficulty in getting

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appointments. Furthermore, others question whether competition belongs in health care at all.²⁶ Simply put, most health care consumers cannot compare or even chose their plans.²⁷ Thus market

forces would not operate as a check on HMO's which force doctors to get people out quicker and sicker than under fee-for-service.

Proponents of managed care respond to these points by saying that these fears are mostly unfounded. Studies so far show no discernible decrease in the health of plan participants.²⁸ A recent study indicates that those in HMO's are generally just as satisfied with their overall care as those in FFS plans.²⁹ Furthermore continual shopping by employers creates pressure on the

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industry to provide good care. Furthermore, supporters argue that threat of malpractice liability will prevent care from reaching substandard levels. Even if malpractice liability and common law

²⁴ See Schwade, *supra* note -- at 89.

²⁵ *Developments in Brief: SHMO enrollees*, Medical Utilization Management, November 14, 1996 *available in* Lexis, Health Library, HCARE file, (quoting a study reported in the Winter 1996 addition of Health Affairs).

²⁶ See Lester Thurrow, *Sounding Board: Learning to Say No*, 311 NEW ENG. J. OF MED. 1569, 1571 (1984)(competition would lead to less egalitarian medical care).

²⁷ Enthoven, *supra* note -- at 110. (Discussing the nature of the demand for health insurance).

²⁸ See *Generally* Frances C. Cunningham & John Williamson, How does the Quality of Health Care in

1-IMO's Compare to that in Other settings? An analytic literature review: 1958 to 1979, 1 Group Health J. 4 (1980).

²⁹ Benchmarking Guide: Consumer Satisfaction, Hospitals, January 5, 1997, *available in* Lexis, Health Library, HCARE file (Overall, the study did note that those in 1-IMO's were not as happy with their emergency care as those in other plans.

³⁰ See Warren, *supra* note ---at 29.

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3i21 U.S.C. 331 (a), (d), (k)

court action would be too slow to establish minimum standards, Congress can act to prohibit egregious mistreatment policies.

III. The Effect of these Changes on the role of the FDA:

Despite these changes the FDA does not need to so radically change direction that Congress should revise its statute to give FDA more powers. Keeping within the scope of its existing regulatory powers regarding labeling, the FDA would be able to fulfill its mandate of protecting the health and safety of the country. FDA does, however, need to change its strategy now that the FDA faces a market that essentially has two tiers: The sophisticated prescribers (isolated doctors and managed care companies) and the patients. The FDA should, with certain exceptions, refrain from stifling exchanges of information between managed care organizations and pharmaceutical companies. The main areas where FDA should think about loosening its positions are cost-effectiveness claims and off-label usage claims. Furthermore, the FDA needs to establish a standard for how to treat the statements of partially owned subsidiaries.

A. Cost-Effectiveness Claims

Perhaps one of the most powerful changes caused by managed care is the development of Pharmacoeconomics—the study of the relative cost-effectiveness of treatments. Manufacturers of drugs use these pharamcoeconomic studies to try and convince purchasers that a particular product will save money. Managed care organizations (MCOs) use these studies to create their list of formularies. The primary benefit of these studies is an economic one, as an aid to decision making, allowing MCO's to lower their costs. The FDA, however, could use its authority under the 1962 drug amendments³¹ to regulate these cost-effectiveness claims with the same rigorous validation procedures for claims of safety and effectiveness. MCOs will be educated enough to

adequately assess the validity of any such cost-effectiveness claims without too much assistance from the FDA.

The FDA created draft guidelines in March of 1995 to respond to this issue of cost-

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effectiveness claims. The director of FDA's Center for Drug Evaluation and Research (CDER), Janet L. Woodcock, commented at a conference on this issue that the market cried out for FDA

intervention, but that the FDA cannot afford to be the referee in a game that has no rules.³³ The draft rules primarily focus on developing methodological standards in order to protect the patients. For example, these guidelines declare, among other things, that pharmacoeconomic claims (including quality of life claims) need to be supported by two adequate and well-controlled studies. Furthermore, these claims need to be consistent with the approved label.

Claims of effects which are not included could be considered off-label promotion. ³⁶ Additionally, the CDER Director of Drug Evaluation, Robert Temple, commented in the conference that the audience of a manufacturer would make no difference as to how a claim should be evaluated.

After much criticism of the guidelines, in October of 1995, the agency took its first formal step to changing the pharmaceutical marketing policies and held a public hearing to assess

³² *See* 60 Fed Reg. 156, 41891 (1995); *see also* Neumann, *supra* note 14; *see also* . James G. Dickinson FDA speaks on cost-effectiveness, 30 MEDICAL MARKETING & MEDIA 48, May 1995 (noting that the director of FDA's Center for Drug Evaluation and Research (CDER) told participants at a conference on this issue that the market seemed to demand FDA interference).

³³ Dickinson, *supra* note 32, (quoting Woodcock's statements at the conference).

³⁴ *See* note 32.

³⁵ *See* note 32.

³⁶ *See* note 32.

Pharmaceutical Marketing and Information Exchange in Managed Care Environments.³⁷ The FDA primarily wanted to investigate the changing business relationships, audiences, marketing claims and channels of communication used in the industry.³⁸ Woodcock commented that the FDA did not intend to regulate internal MCO's pharmaeconomic studies but that the dissemination of any studies conducted by a manufacturer would be considered promotional.³⁹ At these hearings some industry leaders complained that FDA interaction would be premature, and unlikely

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to improve protection to consumers. The agency still has not formulated a final guideline or position, though one should be forthcoming.⁴¹

The basic spirit of health care reform resides in a renewed belief that competition can work to improve health care. The FDA needs to encourage this competition without being overly protectionist or alarmist. Unfortunately, FDA's first stab at playing umpire created rules (draft guidelines) that were too restrictive, and that should be replaced. Instead of trying to clamp down on questionable promotional claims, the FDA should focus on acting as a screen by making sure the methods used for claims were ok, but not necessarily as strictly as claims of safety and effectiveness. Indeed, a recent study shows that **59%** of large MCO's would favor such a system

³⁷ 60 Fed. Reg. 156,41891 (A notice of public hearing to discuss pharmaceutical marketing and information exchange in managed care environments).

³⁸ *Id.*

393 Health Care Policy Report 42 d 17 (*BNA*)(1995) (quoting Mitchell Daniels of Eli Lilly as saying that It would be counterproductive for FDA to move from its traditional position).

⁴⁰ *Id.*

41 FDA Cost-Effectiveness Regs could be tailored to the Sophistication of the Audience, The Pink Sheet (May 13, 1996) (F-D-C Reports (DDMAC Deputy director said FDA still considering comments, and hopes to have something soon.)

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for pharmaeconomic claims. Furthermore, the study found that 69% would support a change from the 1995 draft guideline standards of 2 well controlled studies. Simply put, MCO's would prefer to have data faster even if that data is less than perfectly accurate. After all, there is a cost to gaining absolute certainty. These figures indicate that MCO's recognize that though there could be problems of groundless claims, these MCO's feel capable of distinguishing between useful and useless claims themselves.

Other mechanisms will stop manufacturers from making and circulating unfounded claims. First, competition itself forms the first line of defense. MCO's will not rely on just one study, but will be able to compare claims of several manufacturers.⁴³ Secondly, peer reviewed medical journals also exist which provide reasonably reliable information. Additionally, the pharmaceutical industry has begun to create its own standards in order to establish credibility with managed care organizations.⁴⁴ Furthermore, Pharmaceutical companies would not benefit from making unfounded claims. On the contrary, the industry is trying to work with managed care, and thus would not want to take an adversarial and abusive position. In general, the repeat contact nature would do more to keep the promotions from being misleading than Agency's scrutiny of claims. Unlike the fragmented physicians of yesteryear, today's doctor works in concert. Thus any manufacturer 'which makes a groundless claim risks creating bad relationships with not just one prescriber, but ~vith many'.

Even if the market fails to provide adequate protection, the harm falls outside the realm of things which FDA should be protecting. At the worst a MCO pays more for a drug than for

42 Id.

43 *See id.* (Discussing that health care economist Mark Pauly argues that when information is costly, and the intended audience will be critical of the information, that dissemination of that information should be pennitted).

~ *See* Neuman, *supra* note 14.

another effective drug. Thus the victim will be the bottom line of the MCO. The FDA already makes sure that drugs are safe and effective before they can be sold, and the medical doctor who prescribed the drug presents a second layer of protection for a patient.

As with any approach to a complex problem, some drawbacks exist. Obviously, not all physicians are part of managed care organizations. Those physicians that continue in isolated practices may need the stamp of the FDA to help them decide how to assess the relative cost-effectiveness of drugs. Secondly, there could be other victims besides the MCO's profit margin. In an era of rising medical costs, economic losses have real health consequences—every dollar spent incorrectly could mean another person not getting adequate care. One study even showed that MCO's will use the information of cost-effectiveness to make trade-offs in treatment decisions, not just for equally effective treatments, but across treatments that have differing efficiencies and

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cost. 10% of surveyed plans might fail to endorse effective but more expensive therapies. These responses are more alarmist than actual. First of all, we are not at such a crisis of

health care that misallocations due to incorrect information will cost too many lives in terms of

wasted resources. If we were, then as a society we might be inclined to cut spending on other areas to concentrate on ensuring there was less of a scarcity' in medical care. Secondly, doctors still make and are liable for the medical decisions about what treatments a patient receives. No matter how much MCOs change doctor incentives, most doctors will still feel a moral responsibility to actually care for patients. Finally, the study' mentioned above apparently implies that 90% of plans would cover the use of more effective, but more expensive treatments. Thus patient care would not be likely' to be hurt by erroneous claims of cost-effectiveness—if a physician still thinks a treatment is the better treatment most plans would cover that treatment.

⁴⁵See The Pink Sheet *supra* note 41 (Discussing a report by Anne Elizhauser, of MEDIAP International, co-authored with Bryan Luce of MEDIAP and Claudia Steiner of Agency for Health Care Policy and Research. The study showed that 10% of MCO's would discourage cost-increasing, outcome-enhancing technologies).

B. The Subsidiary Problem

Another area for restraint on the part of the FDA lies in the related issue of monitoring communications between pharmaceutical manufacturers and subsidiaries formed as pharmacy benefit management companies (PBM), or create disease management centers (DMCs). PBMs administer and process benefits claims, and are often electronically linked to the pharmacies participating in its programs. Furthermore, PBMs seek to lower the MCO's costs by shifting a patient's choice of drugs to a lower-cost generic equivalent.⁴⁷ Often this switch relies on formularies chosen by the HMO's doctors to reduce drug costs. Sometimes however, PBMs may actively try to encourage Physicians to switch prescription patterns from one drug to another within the same therapeutic class. DMCs may exacerbate these concerns for these entities as they provide information on dosage, and choices directly to a consumer.

FDA addressed the PBM issue in the same hearing mentioned above, and has not yet formulated an official position on how these communications should be regulated. Manufacturers without PBM's argue that in order to create a level playing field the FDA must treat any PBM with significant contractual relationships with manufacturers as merely a marketing division of the manufacturer. Those with PBM's argue that to treat manufacturer owned PBM's differently than

non-manufacturer owned PBM hardly creates an unfair rather than level playing field.⁴⁹ The FDA should not choose to treat subsidiary PBM promotions and their drug-switch

Drug Benefits Under Health Care Reform, Hearing before the Committee on Finance, U.S. Senate, 103rd Congress (Statement of Judith L Wagner, Senior Associate in the Health Program of the Office of Technology Assessment before the United States Senate Hearing on Long-Term Care and Drug Benefits).

⁴⁷Id.

⁴⁸ See Michael Conlan, *Tell All; Full disclosure in managed care Drug-Switch programs* 140 DRUG Topics 87.

⁴⁹Id.

programs as merely part of the manufacturing arm of the associated manufacturer. First, this would require costly preapproval of the promotional materials (as part of the labeling). Secondly, the FDA would need to assess the degree of independence which may prove impossible.⁵⁰ Instead, FDA should follow the approach suggested in the comments filed by the Federal Trade Commission. These suggested that the FDA should merely require PBM's to disclose any

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affiliation with manufacturers of drugs. The FTC also suggested that it might consider as a deceptive practice any failure to disclose major differences in side effects, dosing, and

interactions.⁵² This approach would be a sensible one—far less burdensome than pre-approval of all promotional materials of PBM's or drug switch programs. This recognizes, as mentioned above, that MCO's will be able to be skeptical of information presented by a manufacturer in order to provide good care.

C. Promotion of Off-label uses:

While FDA faced the issue of Off-Label promotion by manufactures for a long time, the problem grows more intense in a market of managed care. Dr. Goodwin commented, in a hearing on FDA reform, ...there is a stealth threat which could cripple medical progress...today's health

⁵*OFDA Letter, deputy's speech, define a dile,n,na, FDA's failure to address pharmaceutical marketing issues involving managed care.*³¹ Medical Marketing and Media 12. (Discussing comments by FDA Deputy Commissioner Mary Pendergast).

51 See Conlan, *supra* note 48.

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⁵³While disclosure of identity and problems may be enough for a promotion to 1-IMO's or medical doctors, these would not suffice for patients. Thus the FDA would need to monitor more closely the promotions used in DMCs in which manufacturers more directly target the end consumer. A discussion of how FDA should regulate such promotions in this setting is beyond the scope of the present paper.

care environment in which managed care policies and WDA] regulations reinforce each other. Often MCOs refuse to reimburse customers for off-label uses of drugs.⁵⁵ Furthermore, stifling communication on off-label use could stifle medical innovation. Similarly, the creation of PBM/DMCs adds another wrinkle to off-label uses. Would a DMC's recommendation of an off-label use constitute a prohibited off-label promotion by a manufacturer? How would FDA know about such hidden problems, without getting so entangled in the internal communications of the organization? The FDA's past actions seem to indicate a position that roughly says If off-label use must occur, then limit it to the confines of individualized treatments certified by medical doctor. Yet this position ignores the fundamental change in the way medical practice occurs in MCO's. MCO's tend to standardize treatments in order to control costs. They need to have information about off-label uses to create their formularies and guidelines for reviewing the prescription habits of affiliated doctors.⁵⁷ Structural differences in the market require a revised approach.

The FDA cannot credibly enforce a no-off-label promotion position. First, off-label uses are becoming increasingly common, and thus FDA could not stop all promotion. A recent

⁵⁴ *Hearing on FDA Reform, House Committee on Commerce, Subcommittee on Health and Environment*, May 2, 1996 (Statement of Dr. Frederick Goodwin, director of the Center on Neuroscience, Medical Progress and Society at George Washington University Medical Center).

⁵⁵ See Jagger Testimony, *supra* note 8, (nothing that these instances are already more isolated than before after Medicare allowed payment for nonapproved drugs).

⁵⁶ FDA Commissioner for Policy, William B. Schultz, testified before the Senate that since the legislative history of the Food, Drug & Cosmetic Act indicates that the Congress did not intend to interfere with the practice of medicine that physician can use drugs not listed on the FDA approved labeling. See Jagger Testimony, *supra* note

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⁵⁷ See James G. Dickinson *Off-label indications, Something's got to give* 30 **MEDICAL MARKETING & MEDIA** 72 (discussing MCO's which requested information about a then unapproved drug in order to create formularies 12 to 24 months ahead of actual availability).

study by the AMA found that in nine major drug categories, 60% of uses were off-label.⁵⁸

Doctors may prescribe even more off-label uses in treating AIDS or Cancer patients, and the

American Academy of Pediatrics claims that 80 percent of children's drugs are off-label.⁵⁹

Quite often, an off-label use may be the most accepted and soundest treatment. Secondly, the agency cannot practically seize or otherwise hamper the sale of the products

of every offending manufacturer—thus some manufacturers will not back down. Indeed, an August 1996 Warning Letter to Pfizer Inc. about its promotion of Zoloft for depression therapy resulted from just this problem.⁶⁰ The company responded to the letter in a news release which essentially continued the promotion of using Zoloft for depression (an unapproved use). If a product saves lives or improves health, then FDA violates its mission by keeping that product off the market just because a promotional error ~ lead to misuse of the product. Furthermore, because many products have relatively short lives (invention creating superior versions relatively

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quickly), the FDA cannot respond fast enough. While this may jeopardize future relations with the FDA, intense competitive pressures make many companies bold enough to take that chance.

After all, for some drugs off-label uses may be as much as 60% **62** of the market, and many pharmaceutical manufacturers wish to become a partner to MCO's in disease management.

Third, changes in technology extend the arena in which off-label uses can be promoted. For example, a sa~'vy Pharmaceutical company could provide MCO's with links to its internet

⁵⁸ See Goodwin Testimony, *supra* note 54.

⁵⁹ *Id.*

⁶⁰ See note 50.

⁶¹ *Id.*

⁶² *Id.*

homepage. The interconnected nature of the web would allow the company to very quickly shuttle MCO's to information about its off-label uses. Thus if the FDA wanted to stop off-label promotions, the FDA would eventually need to stop off-label discussions that occur electronically.

Despite these difficulties, the FDA does have valid concerns with allowing wholesale off-label promotion. After all, to lower the incentives of manufacturers to get uses on-the label could lower the overall safety and effectiveness of the drug supply. Manufacturers may just get drugs tested for one use, and then promote their drugs for any conceivable use! Instead, the FDA could continue to stamp out off-label promotion but still make the process of amending the efficacy supplements easier.⁶³ This would lower the gap between on-label uses and off-label without undermining the value of the label. Finally, journals exist which would allow the dissemination of knowledge to encourage research on off-label uses. Thus allowing off-label promotion may cause harm of lowering the safety and efficacy of the drug supply, without offsetting benefits.

Yet the FDA does not need to allow wholesale off-label promotion, just some off-label promotions. Speeding the approval process will not solve the underlying problem that manufacturers would have little incentives to conduct controlled studies to get additional uses on-the-label. The FDA could allow submission by anyone or itself of independently performed research (such as in peer-reviewed journal articles) to solve the incentive problem. Yet this approach would create the danger of watering down the gold standard of FDA's approval.

Instead, a better approach would be to create a safety zone for off-label promotions, which would allow manufacturers to disseminate peer reviewed journal articles or other material to MCO's. Currently, the FDA allows manufacturers to disseminate unbiased reference texts and

⁶³ See Jagger Testimony, *supra* note 8.

articles which were used by the FDA to approve the drug. This policy should be changed to

allow disseminations of similarly scholarly materials focussing on unapproved uses as long as the

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manufacturer prominently indicates the use is off-label. The intense competition in the industry would soon give MCO's plenty of counter evidence as to any efficacy claims of particular

unapproved drugs. Since Fda would need to step in less frequently to catch abuses, threats of actions by the FDA would carry more weight. Thus this would create two kinds of promotional material—that based on approved uses, and that which MCO's would take with the proverbial grain of salt.

IV. Conclusion:

Managed Care is not an unsafe or ineffective cure for controlling increasing costs, and FDA should not react to MCO's as such. Instead, the FDA should take advantage of the sophistication of MCO's by letting the market assess the validity of promotions, whether they are about off-label uses or cost-effectiveness. MCO's do not need to be protected as did the country doctors of yesteryear. If this strategy causes indirect effects on patients, the FDA can then focus on strengthening its direct protection of the consumer through more heavily restricting promotions to the consumer. The FDA must do its share to reduce medical costs, which means reducing the burden of regulations. To do otherwise imposes needless costs on society in an era where cost-containment should be a governmental priority'.

~ 61 Federal Register 1%, 25728

65 The FDA should probably continue to prohibit any advertising of off-label uses which are directed at patients. The primary assumption in advocating loosened restrictions is that MCO's can view the information critically—but this does not hold true for patients. A discussion of how FDA should handle the issue of protecting the consumer is beyond the scope of the present paper.