### Managed Care and the Pharmaceutical Industry

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MANAGED CARE AND
THE PHARMACEUTICAL INDUSTRY

Jaqueline J. Wickersham

The 1992 presidential campaign turned the nation’s attention to a number of issues, but none was more controversial than the need for health care reform. As a result of the 1994 election, it appears that President Clinton’s proposed health care plan will not gather the support necessary to become law. This does not mean that reforms will fail; it merely means that change will continue as it has for the past ten years, fueled by the people footing the majority of the nation’s health costs: employers.\(^1\) As of 1993, employers were paying more than one-third of all medical bills in the United States.\(^2\) This is not to say that government has no role in this metamorphosis. Since state and federal governments employ large numbers of people, they, too, have a significant interest in cost controls. In addition, state and federal governments share the costs of Medicaid, and the federal government is responsible for Medicare.\(^3\)

The twin focus of health care reform is to control costs while maintaining quality care.\(^4\) There is little doubt that a country forced to choose between the two goals will prioritize the former.\(^5\) In order to maximize savings, those involved with various aspects of health care are integrating, so that the

\(^5\)Id. at 743.
actual providers are merging with hospitals and management systems.\textsuperscript{6} The form ultimately assumed depends on the particular plan, but the basic patterns are health maintenance organizations (HMO), preferred provider organizations (PPO\textsuperscript{D}), and preferred service organizations (P50).\textsuperscript{7}

Traditionally doctors, patients, and insurance companies were at odds. Normally doctors worked without the supervision of employers, the parties actually funding treatment of patients. By 1987, insured patients paid less than 26 cents for every dollar spent on their health care, and this figure has only fallen.\textsuperscript{8} This came about for a multitude of reasons, one of which is the structure of the income tax system.\textsuperscript{9}

Pharmaceuticals account for only seven percent of all medical expenses.\textsuperscript{10} Managed care is designed to align doctors’ interests with those of payors by rewarding them for cost-effective treatments.\textsuperscript{11} Under this system doctors join forces either as employees or partners in a managed care program (generically referred to as an HMO throughout this paper).\textsuperscript{12} Treatments prescribed by the doctors are monitored so as to reward those doctors who work in the most efficient manner.\textsuperscript{13} One simple cost saving step is to reduce the number of drugs prescribed, or to limit those which are covered or even available.

\textsuperscript{6}Id. at 745.
\textsuperscript{7}Id. at 745.
\textsuperscript{9}Blumstern, at 21.
\textsuperscript{11}Iglehart, Managed Care at 742.
\textsuperscript{12}Id. at 744-45.
\textsuperscript{13}Id. at 746.
This could have a profound effect on the pharmaceutical industry.

Economists and experts are already apprehensive about the that effects this will have on the industry. Pharmaceutical companies have begun to expand their repertoires of marketing techniques for existing drugs while limiting plans for future research and development. 14Like other branches of the medical community they are cutting back on expensive services to focus on the more basic. 15 However, drug manufacturers are not like the rest of the medical community. While other branches of medicine similarly provide innovative techniques for treatment of disease, none are as potentially cost effective as drugs. 16

The primary expense of drugs lies in their development. Out of an average of 5000 potentially marketable combinations, only one will actually be safe and effective enough to be marketed. 17 Manufacturers are required to incur significant expense by carrying out extensive testing prior to release of a new pharmaceutical. 18 This is the primary reason that drugs are often prohibitively expensive. If the market for drugs were to change, so that HMOs restricted drug availability on the basis of price, manufacturers would not have the capability to provide the $359,000,000 (in 1990 dollars) required to get a drug to consumers.

15Weber, at 1293.
16There are many costs inherent in medical procedures. They include everything from time lost from work to the labor resources consumed when a patient sees a doctor to the costs of the materials used in the actual procedure. Once a drug treatment is prescribed, on the other hand, a patient can be easily monitored by a nurse. Tracking the patient requires minimal resources.
17Weber at 1300.
18Grabowski, at 1236
This may not seem to be of critical importance to HMOs. After all, the existing market seems to be saturated with pharmaceuticals, and the purpose of an HMO is to prevent the need for medical treatment by encouraging subscribers to adopt healthier lifestyles and take a more active role in maintaining their own health.\textsuperscript{20} This would not, however, eliminate all need for medical care, and drugs are often a far cheaper method of treatment than surgery. In a system involving limited access to costly and complicated treatments such as surgery, drugs are an attractive alternative.

In order for innovation to continue, however, managed care systems must be willing to either pay the prices currently charged by drug manufacturers or there must be changes in the structure of research funding. It is to the possible changes that attention will be directed.

I. MERGER OF PHARMACEUTICAL COMPANIES INTO HMOS

One possibility would entail a merger of large pharmaceutical companies into individual HMOs.\textsuperscript{21} This is an attractive proposition in practical terms for a number of reasons. For such a transaction to be beneficial, however, the pharmaceutical company would have to be large enough to supply the HMO with essentially all of its drug needs. In addition, with the expense involved in a pharmaceutical company, only large HMOs could support this sort of drug habit.

This is an interesting proposition for a number of reasons. As tort
liability now stands drug companies are liable for many of the injuries caused by
their products, even when the products are properly tested and have obtained
FDA approval.\textsuperscript{22} The federal government has taken some steps to limit liability
in the form of the National Childhood Vaccine Injury Act, but this is minimal
protection in relation to the number of claims with which drug manufacturers
are threatened with on a regular basis.\textsuperscript{23}

Proponents of managed care have recognized the necessity of control-
trolling liability. There are several different means of by which plans may address
this issue. Some plans may simply limit the amount that their subscribers can
receive for an injury. Others advocate moving to a system of enterprise liability
in which individuals are not personally liable to the injured party; instead, the
corporation handles the claim.\textsuperscript{24} Within such a scheme a corporation would
have the right, and the responsibility, to review employee performance and dis-
cipline or dismiss workers as necessary. This sort of insurance shield could be
very attractive to pharmaceutical companies.

There would be some drawbacks, however. In order to be a part of
a managed care system the companies would lose some of their independence by
becoming part of a larger system. More importantly, since the focus of managed
care is on the allocation of resources, there is the potential that research budgets
will be slashed. In the alternative, a company would have a guaranteed market.

\textsuperscript{22}William M. Sage, Drug Product Liability and Health Care Delivery Systems, 40 STAN.
\textsuperscript{23}Huu and Merrill, Food and Drug Law, 718-719 (1991).
\textsuperscript{24}Darling v. Charleston Coin, numiri Memorial Hospital, 383 U.S. 946; 86 S.Ct. 1204 (1966).
their new concoctions. This would reduce some of the administrative costs of final rounds of drug testing.\textsuperscript{25} With consumers provided, firms could spend far less on marketing. This means that they could discontinue the advertisements that are now a regular part of magazines, which would entail substantial cost savings, as evidenced by figures indicating that pharmaceutical corporations currently spend almost as much on drug promotion as medical schools spend on all educational activities.\textsuperscript{26} In addition, it would no longer be necessary to entice doctors into finding out about a new drug by sponsoring symposia and other perks. Doctor education on the use of new pharmaceuticals could become a regular part of a doctor’s job, as, for instance, training could be done during regular staff meetings. However, if the individual health care system chose to handle it, this could become a contractual rather than optional requirement.

One of the main difficulties in developing new drugs is that the process is extremely expensive, and even with the 1964 Drug Price Competition and Patent Term Restoration Act, which extends the length of a patent term by allowing the developer to add to the 17 year patent term the time necessary for testing, patent turnover is relatively high in relation to the amount spent in bringing a drug to the market.\textsuperscript{27} Further, the current system is rife with freeriders and copycat drugs. As the system is presently organized, a manufacturer is faced with the risk of investing in a new drug, only to be undercut by a competitor or a generic drug long before the manufacturer has recaptured its costs. Because a competitor need only follow an abbreviated process to get FDA

\textsuperscript{25} C.f., Sage
\textsuperscript{26} at 1016.
\textsuperscript{27} at 1023.
approval, they may capture a large share of the market simply because they can sell a drug for less.\textsuperscript{28} It has been projected that by the year 2000 generic drugs could account for sixty-five percent of all new prescription drugs.\textsuperscript{29} If a drug company was part of an HMO it would be protected from these changes. Because manufacturers could be guaranteed a percentage of the market they would be willing to invest in developing a drug and settle for charging less. This results in a period of recovery which may be longer, but eventual recovery is virtually certain.

One difficulty lies in convincing HMOs that it is advantageous for them to make this sort of investment. That will depend, in part, on the behavior of the pharmaceutical industry. If drug manufacturers cooperate to keep prices high, HMOs may well find it in their best interests to acquire a drug manufacturer and institute some sort of supply system. However, if the drug companies merely compete with one another, as is now occurring, drug prices will most likely be driven down.\textsuperscript{30} It then becomes a question of whether drug prices will sink far enough for HMOs to decide that it is more cost effective to contract with the companies than to actually bring them inside the system.

If an HMO is interested in utilizing drugs, and desires continued innovation, it may opt for a halfway point such as subsidizing research. This is currently the position taken by the federal government.\textsuperscript{31} If the HMO chooses merely to subsidize, it will have far less control over the company’s actions. This

\begin{itemize}
  \item \textsuperscript{28}Id. at 1242.
  \item \textsuperscript{29}Id.
  \item \textsuperscript{30}Id. at 124t.
  \item \textsuperscript{31}Weber, at 1303.
\end{itemize}
is very important. Part of the cost saving that should occur under managed care will occur because corporations will simply choose not to treat some conditions, or to limit the treatments available. Rare conditions will likely receive lower priority throughout the HMO than common ones, whereas drug research by independent drug companies currently focuses on discovery of pharmaceutical solutions for basically anything that insurance will pay for. In addition, by investing in an actual manufacturer, HMOs, in the advent of a new drug, would be able to market the substance to other HMOs at an inflated price, bringing additional profits to the original HMO. This advantage could tip the scale in favor of acquiring a pharmaceutical corporation of its own.

Belonging to an HMO could potentially reduce the costs of the latter stages of drug research for pharmaceutical companies. One characteristic of managed care is extremely good record keeping. This is necessary in order for administrators to monitor doctors' work. It would not be unusual to require extensive recordkeeping for each patient, as is necessary when running drug trials. Even more to the point, this could be made a contractual duty. An HMO would likely have access to many kinds of specialists, and would have much information available about the practices of specific physicians so that any biases they might have that could prejudice an experiment could be more easily identified.

Access to specialists would, however, be more limited in HMOs. This is a fundamental aspect of controlling costs. Because it would be more

\(^{32}\)Sage.
difficult to see a specialist, it is entirely possible that patients would be willing to participate in drug trials in exchange for access to more specialized care than might have otherwise been available for their condition. For example, a person having chest pains might normally only have access to a general physician; but if she were willing to try a new drug she might see a cardiologist. In such a case the patient, HMO, and pharmaceutical company would benefit, at least so long as there were no adverse reactions.  

A managed care system is a risky proposition because, in part, of federal regulation of trade and competition. This arrangement is unlikely, however, to be a problem because it a vertical integration rather than horizontal. The savings resulting from this arrangement stem not from a lack of competition but from the nature of a monopsony, which uses its size to drive prices down. The focus of both the Sherman and Clayton Acts is on preventing the restraint of competition between parties who are supposed to be in competition with one another. In this case pharmaceutical companies are not supposed to compete with doctors or insurance companies. The government will also take action when a corporation has a monopoly on a good or service and refuses to make it available on reasonable terms to anyone else.

The McCarran-Ferguson Act may provide additional protection from federal antitrust laws. It protects the business of insurance from an-

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33. Id. at 1059.
34. Id. at 1069.
35. Id. at 1075-76.
36. Id. at 1069.
37. Id. at 1075-76.
titrust laws so long as the corporation does not engage in boycotts, coercion or intimidation.\textsuperscript{38} This law could potentially shelter HMOs from federal regulation, though there may be complications if the HMO has subscribers in more than one state, which will probably be the case if the HMO is big enough to support a pharmaceutical manufacturer.

The system as envisioned can easily sidestep these pitfalls. The only real problem arises if an I-IMO tries to use ownership of a drug as a selling point of a managed care package within its own companions while making the drug inaccessible for members of other HMOs. Such limitations would be unlikely, however, since an HMO would likely earn larger profits by pedaling a drug to outside HMOs, so economic motivations encourage making the drug available. Therefore, the antitrust law should pose few problems.

II. HORIZONTAL SYSTEMS

No HMOs have taken steps to acquire a pharmaceutical company as of yet. Drug manufacturers, suppliers, and pharmacies are beginning to form their own organizations modeled after managed care systems. The most recent of these is the merger of Merck and a distribution corporation, Medco.\textsuperscript{39} This is a smaller form of the merger proposed above. It involves fewer health care providers, which may make it less expensive because there will be fewer administrative costs to forming the alliance. Because this is a vertical system there should be few problems with antitrust laws for the reasons listed above.

These organizations typically contract with HMOs and other health

\textsuperscript{38}Id. at 1075.
\textsuperscript{39}Weber, at 1304.
care providers to supply pharmaceuticals. One advantage, of course, is that there are fewer overall service charges because a middleman has been cut out of the process. It is also less costly to administer, if done properly, because many of the functions typically required by both corporations, such as moving the pharmaceuticals, tracking the drugs, and general administration, can now be performed by just one. In addition, when the manufacturer and distributor work independently they both have an interest in advertising their products to the medical community and public. This leads to inefficiencies as each tries to reach the public in order to ensure a market. In a merged system this can be handled by one department so that there will not be the repetition that currently exists.

Another trend within the pharmaceutical industry is for independent pharmacies to join forces. This form of organization has less potential than that of a manufacturer and distributor for a number of reasons. The most important problem with this form is that it is horizontal, which leads to problems with antitrust regulations. This is exactly the sort of system that fosters price controls, even when that was not the original purpose, because businesses that would normally be competitors are allying. In addition, many of the administrative efficiencies that are present in a vertical alliance will not be present here. The independent pharmacies will still have to maintain most of their normal staff. The one important economy of scale would be that bulk purchases of medications would be possible, rather than each pharmacy acting


\[41\] Id.
as an independent buyer.

Drug manufacturers face more liability in arrangements of this sort. If a manufacturer is part of an HMO, it is in the HMO’s best interests to limit the liability of the pharmaceutical corporation. When they have not joined forces, however, the manufacturer is merely a target for plaintiffs whose claims against an HMO for negligent care may be limited or barred. Because drug treatments are often less expensive than surgery, there is economic motivation for an HMO to use new drugs, which may not be fully understood, to try to treat a patient, rather than conventional surgery. The patient may sue the drug manufacturer for any adverse reactions, especially if the tort climate is similar to that existing today, in which new forms of liability are invented every day.

The HMOs may self-regulate to some extent, simply because they must treat any patients who experience adverse drug reactions. This will temper any desire to conduct outlandish experimentation. However, doctors are permitted, by law, to prescribe any pharmaceutical, and they will be under much pressure to reduce costs. This combination of pressures will result in novel uses of drugs. It is difficult to predict the extent of the use, because much of it will probably be surreptitious, unless the drug is clearly effective.

III. PHARMACEUTICAL COMPANIES AS INDEPENDENT ENTITIES

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42 C.J. Sage at 989.
43 Id. at 1010.
44 Id. at 1005.
45 Id. at 1021.
If the nation continues its move to managed care without actively incorporating pharmaceutical companies into the system the availability of new drugs will be severely limited unless HMOs are willing to pay prices as they now stand. This is highly unlikely. Even now the pharmaceutical industry is making changes, trying to make itself more attractive to the cost-conscious consumer, the HMO. The marketing strategies used with ACE inhibitor cardiovascular medicines are a good example. Unfortunately, many of these changes must be announced, raising the costs of advertising. Even so, the short term effects will be very beneficial for consumers, who will save money. The long term effects are less clear.

There is an established market for drugs such as penicillin and insulin. Production of those staples should continue unhindered. Prices on the drugs may fall as HMOs force drug manufacturers to charge a price closer to the actual production costs of the substance. There may be a slight fall in the amount consumed because of a tendency among HMOs to regulate prescription through drug utilization reviews and drug formularies. Depending on how much over medication now occurs this may or may not affect the industry. As prices drop for these staples because of the effects of competition, manufacturers must be resigned to smaller profits, and may have to reallocate funds in order to meet the general costs of doing business.

Pharmaceutical companies may also face a risk of higher amounts of litigation. One of the components of managed care is enterprise liability.

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46 Gm4'dlcj at 1242-43.  
47 Id.  
48 Id. at 1241. Formularies are lists of drugs which the HMO allows practioners to prescribe.
Most HMOs limit the amounts available to patients through contractual liability limitations. With large recoveries barred by contract, injured plaintiffs will be turning an eye towards pharmaceutical companies as the new deep pocket.\footnote{C.f. Sage.} Even if most of the suits brought are unsuccessful, the costs of litigation will be high. In addition, there is the risk that companies will settle merely to avoid the costs of litigation.\footnote{C.f., W. Kip Viscusi, et al, A Statistical Profile of Pharmaceutical Industry Uability, 1976-1989, 24 SETON HALL L. REV., 1418, 1436(1994).} This could lead to additional trouble in the form of strike suits. As discussed above, plaintiffs may also attack companies for doctors’ inappropriate use of medications.\footnote{1) at 1012.}

There is no doubt that drug manufacturers are a target of litigation today. One need only look the reasons for the National Childhood Vaccine Injury Act to see that the costs are currently devastating to corporations.\footnote{Viscusi, at 1425-28. In 1986 Merrell Dow lost 11 cases, and "id an average of $7.1 million to each plaintiff. In 1985 the median pharmaceutical award was $10.5 million.} As the system now stands, there are many different targets. A pharmaceutical company is not necessarily the most fruitful entity to sue. In the future, it may be the only one.

Faced with the possibility of even more liability, and coping with a shortage of consumers willing to pay the high prices necessary to make developing a new drug a reasonable proposition, the drug industry will severely reduce the amount of research undertaken in the future. The drugs most likely to be lost are the exotic drugs which are necessary for treating rare diseases such as multiple sclerosis. In addition, if 1-IMOs, to save costs, refuse to allow
speculative treatment of diseases such as AIDS which are currently recognized as incurable, and instead limit the patients to maintenance care, experimentation on to invent curatives will cease. It makes little economic sense to search for a cure for a condition which kills one’s consumer. A pure economic analysis would indicate that manufacturers will continue to search for substances which treat disorders which are serious enough to require continuous care and are not curable, but are also not fatal. A good example of such a condition is a seizure disorder.

Unless HMOs are willing to actively subsidize research, such activity will continue in a limited fashion. As was argued earlier, the development of new pharmaceuticals could be cost efficient in the long term. However, many HMOs may view this differently. If a drug does not exist, there will be far less patient demand for the substance. If a treatment is available and the HMO is simply denying its patients coverage, patient outcry is a likely response. Therefore, it is probable that if the industry continues to be comprised of separate units it is unlikely that HMOs will interfere with the status quo except in indirect manners such as refusing to pay the prices drug manufacturers are now asking.

IV. GOVERNMENT

It now appears that government mandated health care reform is not going to occur during this presidency. This does not mean that the government is unconcerned with the reforms occurring as a result of market influences. Federal and state governments have an interest in the pharmaceutical industry
for a number of different reasons. The federal government has more direct authority over drug manufacturers because regulation of the substances has been done primarily through federal law and the institution of the FDA. In addition, antitrust laws are also federal in origin. However, tort law is generated by the states. Examining the industry from this vantage point, though, the problem looks no more complicated than any issue arising from a national corporation.

State and federal governments actively take responsibility for the welfare of American citizens. This takes the form of regulations promulgated by Congress requiring that foods and drugs meet certain standards. It is also evidenced by vaccine laws and public health programs. If no one else is available to provide health care for the needy, the government is supposed to do so. To meet these needs it established Medicaid. The government is also responsible for the healthcare of the elderly through Medicare. As if that were not enough, state and federal governments employ huge numbers of people, many of whom they now insure.

People over the age of 65 are responsible for three times the consumption of pharmaceuticals of that of people under 65 in the country today. They far outstrip any other age group in drug use. Drug treatment is preferable to the options now available in many cases. For instance, it costs approximately two dollars per day to treat a patient for a heart condition using drugs. Surgery costs approximately $6000. Unless a person is expected to live for

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54Weber, at 1308.
55ID.
many years, it is far more cost effective to treat them with drugs, especially when the risks of surgery are factored into the equation. While Medicare currently covers only a small amount of the actual drugs prescribed, this may soon change.  

Even if Medicare does not directly cover the costs of medications, there are indirect costs to the program. These come in the form of patients opting for surgical treatments instead of drugs, because Medicare will cover the costs of the procedure. In addition, Medicare is responsible for any hospitalization that is a result of an adverse drug reaction or a condition stemming from the failure to take medications. Many elderly people cannot afford treatments. In addition, all medications prescribed to people receiving Medicaid are publicly funded.

As noted earlier, the private sector pays for approximately one-third of all medical care. State and federal governments pay for a majority of the rest. Medicare and Medicaid make state and federal governments especially interested in pharmaceuticals because of the high amount of drug usage by these patients, who tend to have more health problems and be more vulnerable in general. Even if health care reform is privatized, the government must take an active role in shaping the future of drug research. As the single largest consumer of health care, it has the ability to do so.

V. CONCLUSION

The forms proposed above are sketches of what is possible. The

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system that actually results, no matter which pattern it follows, will almost undoubtedly vary in the details. The only open question is how this will affect the consumer. It seems clear that patient choice will be more limited. This will occur not only because HMOs will limit the availability of drugs, but because it is too costly to do research. More importantly, much of the truly innovative work is being done by small bioengineering companies which lack the capacity to produce more than a few products. It is not worthwhile for HMOs to acquire these small companies. They may be able to function in a system organized as distributors and manufacturers, but that reduces the economies of scale which makes the structure worthwhile in the first place. If pharmaceutical companies remain independent in the face of managed care, these small corporations will be at risk because of difficulties in finding a market for their drugs. In addition, there may be increased risks of liability.

Pharmaceutical corporations may be saved by the existence of a world market. Marketing new drugs in other countries with fewer regulations might allow cheaper development, at least in the later stages, of new drugs so long as the manufacturers are willing to collect data regarding the outcomes of such usage. The FDA would also have to be willing to accept those tests without requiring them to be replicated as clinical studies in the United States. At this point in time this is not a viable option. If changes in the medical community continue, though, consumers, producers, and government regulators may be willing to make the compromises necessary to allow this to work.

If continued research is desirable, it must be subsidized. First, how-
ever, society must decide whether it wants research to continue at the breakneck speed at which it has occurred over the last fifteen years.\textsuperscript{57} Some might argue that this is in fact a waste of resources and that the money might be better spent on education or another social cause. Further, there is a problem recognized by the medical community. It has been named Maxwell’s Paradox. It is an acknowledgment that the more that is spent on medical care now, the more money will be necessary in the future.

If people desire continued innovations, they must make a clear statement of their wishes. The government has the ability, outside of its legislative functions, as a consumer, to stimulate continual development. In addition, research could be stimulated through grants to hospitals and even by tax reform. Before any of this occurs, however, people must make some hard decisions about priorities.

\textsuperscript{57}Bendavid, at S33. During the 1980s pharmaceutical corporations raised their prices by more than twice the rate of inflation. This has not gone unnoticed, so that now reformers turn their attention to the industry.