

Remarks on the 'New' Pharmaceutical Litigation

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Pharmaceuticals will always be a target for litigation precisely because they are used to prevent or cure the most serious harms imaginable. To the extent that pharmaceuticals are not perfect, the liability system will focus on the remaining harms, and large jury verdicts are then inevitable. Tort liability litigation for personal injury has occasionally driven useful products from the market (Bendectin, for example), and it nearly destroyed the child vaccine market in the 1980s before child vaccines were essentially removed from the liability system.

But now we see something rather different. The pharmaceutical industry is the target of several types of mass litigation that have little or nothing to do with personal injury litigation. In this, and in other respects, the new drug litigation resembles the tobacco litigation of the mid-1990s. This new wave of litigation could fundamentally alter the industry itself, and could substantially retard the research and development necessary to bring new cures to market.

Varieties of Litigation

The new wave of pharmaceutical litigation comes mainly in four distinct varieties:

Medicare Part B Drug Reimbursement Based on “awp” Prices

Medicare does not generally cover out-patient drugs, but it does pay for drugs used in certain procedures usually performed in physicians' offices. The most important category is cancer drugs administered by oncologists or other specialists. Medicare reimbursement for in-office oncology drugs has long been based on a certain percentage (often, 95%) of the “average wholesale price” or “awp,” which is listed in trade publications such as the “Orange Book.” Manufacturers typically charge physicians substantially less than the awp, so that physicians make a profit on oncology drugs. This circumstance has sometimes led manufacturers to encourage physicians to choose brands partly because of the size of the margin generated by awp-based payments. A lawsuit brought by the Department of Justice, which alleged fraudulent marketing such as payoffs to physicians but did not attack the use of awp *per se*, was settled in October 2001 for \$875 million. This litigation involved marketing for a single drug, Lupron, by TAP Pharmaceuticals, a joint venture of Abbott Laboratories and Takeda Chemical Industries (a Japanese firm). The sheer size of the settlement motivated a very rapid expansion in similar litigation by other parties, including state Attorneys General.

Although the TAP lawsuit did not allege that the use of awp was inherently fraudulent, the settlement essentially set forth the notion that awp usage in Medicare reimbursement *is* fraudulent. Most Medicare awp litigation has accordingly focused not on fraudulent marketing or payoffs, but on the allegation that charging prices based on awp is *per se* fraudulent behavior. This avalanche of lawsuits has been brought by, among others, the Teamsters and other labor unions, U.S. Attorneys, private class action law firms, and the states of Montana and Nevada in actions that represent all citizens of those states. The lawsuits have sought a variety of remedies including punitive damages, and employed multiple legal tools including the RICO act. These actions rely strongly

on the assertion that the payers in question did not realize that awp was a fictitious price that bears little relationship to actual transaction prices.

All this is remarkable because the awp “problem” is old (dating at least from the 1960s), much studied, and enshrined in legislation.¹ Not only have Congress, HHS, and other parties been aware of how awp works, Congress and HHS have made awp a part of pricing arrangements through legislation or regulation. The controversial results of this policy have been debated in Congress through hearings and other means. Largely due to resistance from the physician community (especially oncologists), Congress has refused to alter the way in which awp is used for physician reimbursement.

Medicaid “Best Price” Linkage to Prices in Other Markets

A second type of new-wave pharmaceutical litigation focuses on the legislative requirement that Medicaid drug prices be set at or slightly below the “best price” granted by the manufacturer to buyers in the private sector. This much-criticized provision tends to undermine competition by making discounting less secret and more costly to manufacturers (as documented by the Government Accounting Office and others).

The best-price provision also clashes with the complex nature of pharmaceutical competition. Manufacturers and buyers, such as managed care organizations or pharmaceutical benefit managers (PBMs) may find it mutually advantageous to tie together the sales of two or more drugs, different versions of the same drug, or drugs and services such as disease management. The effect is to make the price of a specific dosage of a particular drug somewhat arbitrary, despite the fact that these arrangements make markets more efficient and more competitive. Nonetheless, these circumstances provide an opportunity for states and private parties to argue that manufacturers are systematically violating the Medicaid best-price rule. Much litigation has ensued. Some

¹ See James M. Spears, and Jeff Pearlman (2002) “Using Litigation to Regulate Drug Prices: The Assault On ‘awp,’” Washington Legal Foundation, Critical Legal Issues, Working Paper Series No. 107, February 2002.

lawsuits, such as the March 2002 action by the state of Montana, combine this litigation with Medicare awp actions.

One reason why Medicaid drug pricing has become litigious is that states have been attempting, with some success, to expand Medicaid drug price rules to cover purchases that are not made for Medicaid patients at all. This is one reason for the next category of modern pharmaceutical litigation.

Pharmaceutical Firms as Litigants Against State Price Controls

Almost everyone recognizes that pervasive pharmaceutical price controls would substantially reduce R&D incentives, with deleterious effects on the development of new preventatives and cures. Nonetheless, the fact that R&D costs are borne upfront, leaving drugs to be priced at far above marginal manufacturing costs, leaves pharmaceutical firms susceptible to price controls after products have been developed. Individual political entities -- both states and nations -- have a strong incentive to free-ride on research in other political jurisdictions by implementing price controls at a local level while leaving prices elsewhere undisturbed. This has led every advanced nation except the United States to implement some form of pharmaceutical price controls.

Individual states in the U.S. face the same incentives. Hence even as Congress has failed to seriously consider drug price controls, several smaller states have taken the lead in using various tools to restrict drug prices within their boundaries. One method is to expand the population who can purchase drugs at Medicaid prices. This and other measures have prompted vigorous litigation from the pharmaceutical industry, claiming among other things that these laws violate basic Constitutional prohibitions on abridging interstate commerce. This litigation has not proceeded without outside assistance, however. AARP and other consumer groups have joined some of these lawsuits on the side of the state governments in their attempts to restrict prices.

Hatch-Waxman-related Litigation over Patent Expirations

The 1984 Hatch-Waxman law provides a quick route for generic drug manufacturers to enter the market after pharmaceutical patent expirations. Essentially, generic manufacturers no longer had to repeat clinical trials for safety and effectiveness, but could focus on proving that their drugs were bio-equivalent to branded versions. The law was written, however, to ensure that litigation would play a large role when patents expire. Generic manufacturers who challenged the brand manufacturer's patent in court could obtain a six-month period of exclusivity (i.e., with no competition from other generics), while manufacturers who fought these challenges could cause the FDA to place the contested generic drug in limbo for as long as thirty months while litigation played out. These conditions are ripe for settlements instead of protracted litigation. A prime reason is that most generic manufacturers who market a drug while the patent is still under litigation are more or less judgment-proof if they should eventually lose, because they could easily arrange not to have the funds necessary to pay hundreds of millions or even billions of dollars in damages for patent infringement. This invitation to reach a settlement, combined with incentives for the branded manufacturer to claim new patents when a crucial patent nears expiration, has led to complex settlements, sometimes with manufacturers paying substantial sums to a generic challenger while the branded version continues as the sole version on the market.

Determining whether these arrangements are economically efficient and satisfy the antitrust laws (which themselves have come to take economic efficiency as their touchstone) entails a complex economic inquiry. The Federal Trade Commission, whose Bureau of Economics is well equipped for such inquiries, has intervened in private litigation and challenged specific settlements (sometimes successfully), while letting other settlements pass. In the meantime, however, many state AGs, along with consumer groups and private parties, have brought their own suits against many Hatch-Waxman settlements, as well as directly against brand manufacturers whose behavior at patent expiration has been suspicious.

Some Larger Aspects of the New Pharmaceutical Litigation

The new pharmaceutical litigation raises some very troubling questions about its foundations, its nature and dynamics, and its possible course. One issue of paramount importance is analyzed in a separate paper by my colleague Michael Greve. That issue is federalism, i.e., the role of state vs federal legislation and regulation. Greve points out the magnitude of the federalism question, which touches directly on such fundamental matters as maintaining freedom of commerce and its consequent economic efficiencies. In this section, I mention some other matters worthy of attention.

Massive Damages Payments for Non-Personal Injury Claims

A striking aspect of recent litigation in other markets has been the very large magnitude of verdicts and settlements based purely on compensation for monetary losses, plus punitive damages. An example was the \$1.2 billion verdict in a 1999 class action case against State Farm insurance for automobile repairs using “generic” rather than original manufacturer parts in the state of Ohio. Large class actions against managed care organizations have also sought very large compensatory and punitive damages for purely financial harms. A much larger example is the 1998 mass settlement of tobacco litigation, where so-called damages payments -- again for purely financial losses -- will amount to over \$200 billion.

One might think that with pharmaceuticals, large litigation verdicts would inevitably involve personal injury. But the litigation described above does not involve personal injury at all. Yet the Tap Pharmaceuticals settlement involving the price of a single drug amounted to nearly a billion dollars. This is an indication of larger possibilities. Taking into account the variety and force of litigation that has arrived in the wake of the Tap settlement, the new pharmaceutical litigation could yield very large amounts, easily many billions of dollars.

The secret to large verdicts and settlements is large numbers of plaintiffs, the use of damage multipliers (treble damages in antitrust and RICO suits, for example), and the

availability of punitive damages (which remain essentially unlimited in federal law and in many states). Thus the February 2002 state of Montana suit on awp prices was launched on behalf of every citizen of that state, requested double damages under state law, and asked for punitive damages of an unspecified magnitude.

A High-profile Role for “Good Guys”

AARP recently announced that it is supporting pharmaceutical litigation of at least two kinds: Hatch-Waxman-derived patent litigation, and the defense of state price control laws against attacks by pharmaceutical firms. This innovation in AARP policy was devised by its new director, William Novelli. A retired advertising executive, Novelli had previously headed the Campaign for Tobacco-Free Kids (CTFK), a well-funded anti-smoking organization. Litigation has become a favored tool for most anti-smoking organizations, not just for voluntary organizations such as CTFK but also for international quasi-government organizations such as the World Health Organization. CTFK was (and remains) a prominent advocate of pervasive tobacco litigation. It is no surprise, therefore, that an AARP executive was quoted as saying “We are looking at the full range of litigation concerning drug costs, with an intention to become involved in those cases that we think would be most appropriate for our members.”²

AARP is not alone, of course. Numerous other consumer groups are actively supporting or participating in pharmaceutical litigation, as are labor unions and their health plans.

State Attorneys General are playing a central role. Individual states have brought a variety of actions, while more than 30 AGs have formed a consortium to bring coordinated actions. In some cases (the Montana suit mentioned above, for example) the states are using outside law firms. Whether that will be done on contingency basis (as in tobacco litigation) remains to be seen.

² *New York Times*, April 23, 2002, “AARP Wants a Bigger Role in Prescription Drug Cases,” by Robert Pear.

Demonization of the Industry

A recent article in the *National Law Journal* described a survey in which potential jurors said they were more likely to vote for plaintiffs in a pharmaceutical personal injury suit than they were in a tobacco suit.³ This striking result does not bode well for the industry, even for litigation not involving personal injury. Surveys have shown the pharmaceuticals to be among the least popular industries. The fact that the state of Vermont passed a law explicitly designed to halt pharmaceutical firm “profiteering” is an indication of public attitudes about drug pricing.

Clearly, the demonization of an industry eases the path of mass litigation, especially in litigation brought by individual states under the leadership of elected politicians. The arousal of public feeling against the drug industry is facilitated by several factors. One is the rapid escalation of prescription drug expenditures at the rate of about 15% annually. Another is the sheer importance of these expenditures in terms of individuals’ health. One might think that the production of goods of such high value would induce favorable rather than unfavorable public sentiment, but then the peculiar economics of pharmaceuticals comes into play. The extremely low marginal costs of most drugs offers the opportunity to obtain drugs at much lower prices via legislation, and attempts by manufacturers to resist this through legal means transforms the debate into what appears to be a fight between sick patients and pharmaceutical firms bent on profits. Finally, aggressive marketing simultaneously reinforces the value of pharmaceuticals while drawing attention to their cost.

These factors have made it easier for politicians, health care payers, and the news media to portray pharmaceutical firms as being uniquely devoted to pursuits contrary to the public good. The crucial point is the distinction between current profits and long-run R&D costs, which helps to explain why it is manufacturers rather than oncologists who are the targets of litigation over awp-based reimbursement, even as physicians struggle mightily to maintain the awp system. With AARP joining state AGs and consumer

³ *National Law Journal*, March 22, 2002, “Poll Finds Smokers’ Suits Face Juror Doubt: Tobacco fares well in opinion poll,” by Bob Van Voris.

groups in litigation against pharmaceutical firms, the process of demonizing the industry has already progressed a considerable distance.

The Danger of Extorted Mass Settlements

One danger in the dynamics of the new pharmaceutical litigation is the possibility of extorting broad, very expensive settlements with one or more defendants. I use the expansive term “extorting” because defendants may be compelled to face juries who in effect will have to choose between their own elected representatives and the much criticized pharmaceutical firms, with the financial stakes being so large that firms must take seriously the possibility that their overall operations could be substantially affected by an adverse verdict. The availability of punitive damages and damages multipliers can transform hundreds of millions of dollars of claimed harms into potential verdicts of billions of dollars. Even the fact that some of the broader litigation is premised on implausible arguments, such as the assertion that Medicaid and Medicaid authorities did not realize how the awp system works, would be of little comfort to defendants faced with the prospect of a lengthy appeals process to overturn a verdict whose costs (plus interest) would have to be paid before the appeal could even be launched.

Litigation as a Public Policy Tool

The possibility of immense verdicts from a series of lawsuits, arising from a process in which state officials, consumer groups, and other policy-minded organizations play a lead role, suggests that pharmaceutical litigation, like other recent episodes in mass litigation, could end up being used partly to achieve changes in public policy. Certainly the Medicare awp litigation has turned in that direction. The TAP settlement spelled out awp-based prices as being essentially fraudulent, and then dictated detailed oversight of many marketing and pricing practices that had little or nothing to do with the subject of the litigation itself. Lawsuits brought by the states and other litigants are likely to follow suit, and these actions clearly aim to overturn Congress’ own policy of tolerating or encouraging the use of awp as a basis for Medicare reimbursement.

The other components of the new pharmaceutical litigation -- the expansion of Medicaid prices beyond Medicaid beneficiaries, Hatch-Waxman patent disputes, the battle over state price controls -- can also be expected to aim at reshaping public policy and regulation in defiance of what has actually been legislated by Congress. It should be borne in mind that this struggle is in no sense a zero-sum game fought between consumers and manufacturers.

What is lost in this kind litigation are the most important components of the consumer interest: the development of new drugs, and free competition among manufacturers. The establishment of "best-price" for pharmaceuticals in the Medicaid system is widely viewed as having suppressed competition in the rest of the market (although firms seek to compete as best they can, generating some of the new litigation as a byproduct). When deals are cut between large firms and state governments, with law firms serving as brokers, there is no guarantee the free competition will be the result. More likely are new arrangements that inhibit competition.

Far more harmful would be the expansion and institutionalization of price controls in their many possible forms. The pharmaceutical industry is uniquely susceptible to price controls because so much of their costs are borne before the pricing game even begins. As soon as the pharmaceutical research enterprise realizes that future pricing freedom has been lost, and that prices will be henceforth be determined by the highly unpredictable process of politically inspired litigation, the incentives to take on the toughest problems in pharmaceutical research will have been fatally undermined. The consequences would be difficult to measure -- how can one know whether cystic fibrosis or cervical cancer would have been cured in the absence of price controls? -- but costs would surely be immense.