

**THE NEW PHARMACEUTICAL LITIGATION:
WHAT IS IT AND WHERE IS IT GOING?**

AMERICAN ENTERPRISE INSTITUTE PRESS
BRIEFING

featuring

JOHN E. CALFEE, AEI
MICHAEL S. GREVE, AEI

JUNE 18, 2002

PROCEEDINGS

MR. JOHN CALFEE: I'm Jack Calfee and my colleague is Michael Greve, and we welcome you all here to the American Enterprise Institute. I will speak first, and I will talk about what seems to be a relatively new wave of litigation involving pharmaceuticals, and then my colleague, Michael, will move on to more profound and more troubling issues which relate to, roughly speaking, the distribution of power between the federal government and the states.

So, to begin with, I think it's fair to say that pharmaceuticals always have been and always will be the subject of litigation, but usually the litigation has involved personal injury. This, I think, is inevitable, because pharmaceuticals are designed to deal with issues of personal harm, health and safety. Since pharmaceuticals are almost never perfect, that means there's usually some residual risk of devastating harms or death, and pharmaceuticals are a ripe target for losses over that residual risk. That kind of litigation can generate large damages payments, and in some cases has actually driven useful drugs from the marketplace.

What's going on now I think is quite different. It's mostly litigation that does not have to do with personal injury. It rather strongly resembles the wave of tobacco litigation that came in the mid 1990's, and culminated, although it has not yet ceased, but culminated in 1998, in a mass settlement that is yielding payments of more than \$200 billion.

I'm certainly not a lawyer, but it seems to me there are at least three different kinds of litigation that are proving to be quite important and are still in their early stages. Type one pertains to the Medicare system. Medicare, although it does not generally cover pharmaceuticals, does cover outpatient drugs for certain purposes. The most prominent purpose is for the administration of cancer drugs in the doctor's office.

Reimbursement for these drugs is typically based upon what's called the "average wholesale price," or AWP. Currently, reimbursement tends to be on the order of 95 percent of AWP. A lot of people have noted over the years that the AWP actually bears little relationship to the real transaction prices. The way it works out is that physicians issue a bill to Medicare; they get reimbursed at 95 percent of the AWP, but pay substantially less than that to the manufacturers. The doctors keep the difference.

In 2000 litigation started between the federal government and TAP Pharmaceuticals, which is a joint venture of an American firm and a Japanese firm. This litigation concerned marketing in the context of Medicare reimbursement based upon AWP. Essentially what the federal government charged was that the marketing in connection with a single drug, called Lupron, was, in some sense, fraudulent. That is, it involved payoffs to doctors and related activities. This litigation led to a settlement in October of 2001 for \$875 million, which is a lot of money for one lawsuit over one drug, involving nothing but the financial terms surrounding that drug - again, nothing resembling personal injury.

In the wake of that settlement for almost a billion dollars, came an avalanche of litigation relating to Medicare and the uses of AWP. These lawsuits have been brought by the Teamsters Union, other unions, state attorneys general, private class action firms, and U.S. attorneys in Boston and I presume elsewhere. The remedies have included financial compensation, and punitive damages, and they use the RICO Act and other rather sophisticated tools for litigation.

Essentially what they're arguing is that the Medicare system was paying these bills without being aware that the bills did not reflect the actual amounts being paid to the doctors. This is a striking accusation to make, since the process has been well established, well known, and much debated for more than 30 years. Congress conducted investigations, GAO issued reports, and President Clinton even devoted part of a speech to the well-known and much documented fact that AWP--which most people refer to as signifying "ain't what paid" rather than "average wholesale price"--has generally exceeded the prices that are actually paid for drugs, especially drugs used by oncologists.

Congress has debated this more than once, most notably in 1997. At that time, Congress passed legislation that explicitly incorporated the use of AWP for compensating oncologists in the Medicare system. Essentially, what is going on right now is what Congress dictated would happen.

That's one kind of litigation. A second kind concerns the Medicaid system. This litigation derives primarily from a law Congress passed a number of years ago saying that

the Medicaid system would pay a price for drugs equal to or less than the lowest price that the manufacturers negotiated in the private market.

This provision has been much criticized by economists and others, including the Government Accounting Office, because it tends to inhibit competition in the private market. It does that by making pricing strategies more open and by giving firms an incentive to avoid price cuts if they possibly can, because they know when they cut their prices in private markets, they may have to cut their Medicaid prices.

But that's not the only problem with this provision. Another is that we usually think of price controls as being very complicated and certainly that is true in the Medicaid system. What people tend to forget is that competitive prices in an open market are also very complicated, and that applies specifically to pricing of pharmaceuticals. Typically, what happens is not a simple matter of a manufacturer and a pharmaceutical benefit manager, or a managed care system, negotiating on a price, reaching one number, and agreeing on that price for the next year. You may sometimes get that, but often the prices will be essentially tied prices, either for different versions of a single drug, for more than one drug, or for services provided by the manufacturer--services such as disease management--which makes it difficult to specify exactly what the price of the drug is, all by itself, unpackaged, or unbundled from other services.

The arbitrary assignment of a specific price to a drug obviously makes for difficulties in adhering to the Medicaid provision that seeks to link Medicaid prices to prices in private markets. This situation has given rise to a substantial amount of litigation.

Among the recent actions is one by Montana, which is suing the manufacturers in connection with both Medicaid and Medicare pricing. Now one of the things that's making the Medicaid system as prone to litigation as it is, is that a number of states have been expanding Medicaid by trying to apply Medicaid prices to the purchase of drugs for state citizens who are not actually served by the Medicaid system. This leads to the next category of litigation, in which the pharmaceutical industry itself litigates against state-level attempts to control prices.

If any industry is inherently susceptible to price controls, it is the pharmaceutical industry. That is because most of their costs are born up front. The bulk of their R&D costs, which are very high, are usually incurred before a drug even reaches the market. By the time a drug is ready for market, the manufacturer is providing the drug at a price that's far above the marginal cost of manufacturing that drug.

That gives government purchasing authorities an incentive to free ride by getting low prices closer to marginal cost in their own jurisdictions and letting other jurisdictions pay market prices and provide the bulk of support for research and development. This situation has led every advanced economy in the world, save the United States, to institute pharmaceutical price controls of various degrees. Individual states have

essentially the same incentives to free ride on the other states. The smaller states have especially strong incentives to erect price controls within their boundaries because they know that the effect of what they do within a state, such as Maine or Vermont, will have relatively little impact on the overall research and development enterprise which will be supported by the rest of the nation.

Consequently, there have been quite a few rather original and creative attempts to adjust or outrightly restrict pharmaceutical prices within the various states. The industry has resisted this by litigating against these laws. Often they've litigated on matters that relate to federalism, and this litigation has been fairly intense. In fact, there is one case right now in which at least one side has petitioned for review by the Supreme Court and we're waiting to see whether the Court will take that case.¹ AARP and other consumer groups have joined, with great enthusiasm, in helping the states defend themselves in this litigation.

Finally, a third category of litigation concerns patent expirations. The Hatch-Waxman Act comes into play when the patent on a drug expires. That law was passed in 1984 to ease the path for the introduction of generic drug brands into the market to compete with branded drugs. The problem here is that the Hatch-Waxman Act is written in such a way that it strongly encourages litigation when patents expire.

¹ The Supreme Court will decide *Pharmaceutical Research v. Concannon* in its 2002 Term.

One reason is that the generic manufacturer that challenges a patent as it is about to expire can, in return, get a six-month period of exclusivity. In many cases, most of the profits that a generic firm makes for a particular drug are made in that six months period of exclusivity. If litigation ensues, however, the FDA is more or less instructed by the law to list the drug in a special category which delays for as long as 30 months, the process of approving a generic competitor to a branded drug, while the litigation takes place.

I think it's easy to miss the fact that the nature of this litigation is ripe for settlements, settlements that involve cash transactions between the parties. The prime reason is that most of the litigation involves a very small generic firm versus a large branded manufacturer. Then the issue is, will the generic drug be admitted into the marketplace while the litigation takes place?

The problem is that if a generic drug is manufactured and distributed while the litigation takes place, and if the generic manufacturer eventually loses, it could be liable for damages on the order of hundreds of millions or even billions of dollars. Those damages could vastly exceed the resources of the generic firm itself. In this category of litigation, in which one of the parties tends to be judgment-proof or close to judgment-proof, there are strong incentives for the two parties to get together and reach some kind of financial accommodation. This is common, and sometimes the settlement will involve the manufacturer making payments to the generic litigant who stays out of the market while the litigation proceeds.

These kinds of arrangements are not inherently inefficient, speaking from an economist's standpoint. That is, these arrangements may be the best way to handle these situations. Fortunately, we have a Federal Trade Commission that has jurisdiction over these arrangements. It is supported by a very competent Bureau of Economics, and as far as I can tell, they're doing a reasonably good job of figuring out when these settlements make sense, and when they should be attacked. The FTC sometimes does attack these settlements, sometimes it lets them go, sometimes it intervenes in litigation that's taking place. That strikes me as a reasonable way to take care of this litigation.

But what's happening is that private parties are getting into the litigation. The states are intervening on one side or another, as is the AARP and others. Most of those intervening, if not all of them, are on the side of the generic manufacturers, with a goal of getting generic drugs to the market more quickly.

That's three basic kinds of non-personal injury litigation taking place these days. A lot of it is new. Much of it has arrived in the past six or eight months since the massive TAP Pharmaceuticals settlement of October 2001, then the almost one billion dollar settlement. I want to mention a few of the larger issues that this kind of litigation raises, before Michael deals with the really big issues.

This litigation and this market illustrate, once again, that lawsuits, not over personal injury, but over purely monetary matters, can generate very large amounts of money in the form of damages payments, settlements, et cetera. An example from a very different

market was an Illinois verdict in a 1999 class action suit against State Farm Insurance. At issue was the repair of automobiles using spare parts that had been provided by so-called generic manufacturers rather than by the original manufacturer. In that case, the jury awarded more than one billion dollars for what amounted to an accusation by a large class of litigants that their insurance policy wasn't worth as much as they thought it had been worth.²

A far more dramatic example of damages being paid in connection with non-personal injury litigation is the 1998 mass settlement of the tobacco litigation, that is, the Master Settlement Agreement (MSA) between 46 states and four tobacco companies. It involves more than \$200 billion paid over time for purely financial harms, or alleged financial harms.

There is a prospect that as the pharmaceutical litigation proceeds, damages might be very large, on the order of a substantial number of billions of dollars, possibly billions of dollars against a single firm. It is by no means beyond the realm of possibility.

A second notable aspect of this litigation is the high-profile role for the so-called "good guys." Not long ago, AARP announced that it was going to actively support at least two branches of litigation: Hatch-Waxman patent expiration litigation, and AWP litigation.

² *Avery v. State Farm*, Circuit Court for the First Judicial Circuit, Williamson County, Illinois. In April 2001, an appellate court left standing nearly all of the trial court's findings and affirmed the judgment. State Farm has appealed the judgment to the state's supreme court.

This is a striking development. It was done under the leadership of William Novelli, who is the Executive Director of AARP. Not long ago, however, he was the head of the Campaign For Tobacco-Free Kids, an anti-smoking group, which was among the leaders in supporting and advocating litigation as a way to deal with the tobacco market. An AARP executive was recently 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," which is a reasonable summary of how some groups are looking at pharmaceutical litigation these days.

Added to AARP are the state attorneys general. Recently, a consortium of, I think, more than 30 state AGs announced their intention of pursuing some of this litigation. Many labor unions are also getting involved. An astonishingly large number of consumer groups, many of which are unfamiliar to most of us, have announced that they are supporting litigation in this market.

Another notable aspect is what one might think of as the demonization of an industry. Surveys show that the pharmaceutical industry is not very popular these days. A recent article from the *National Law Journal* reported the results of a survey asking consumers what they would do if they were on a jury involving a lawsuit against members of various industries. To the astonishment of the authors and a lot of other people, the tobacco industry did better than the pharmaceutical industry. The number of people who said they would be inclined to vote for the plaintiffs in personal injury cases was a much larger proportion for the pharmaceutical industry than it was for the tobacco industry. Now, that

survey was about personal injury litigation. But when you look at the polls about what people think of the pharmaceutical industry these days, it's pretty clear that those kinds of sentiments probably carry over to litigation against the industry generally.

With AARP and the state AGs, et cetera, supporting litigation as strongly and as visibly as they do, I think it's clear that a fair amount of progress has been made toward demonizing this industry. That's the kind of situation that greatly eases the path for litigation, especially mass litigation and class actions.

Another notable aspect of this litigation is the danger that, at some point, there could be a possibility produce very large settlements involving one or more defendants.

By large settlements, I mean settlements involving the transfers of large amounts of money, billions of dollars, along with detailed provisions for how those companies would proceed in their pricing and in their marketing, and in possibly other aspects of their business. Here again, the TAP Pharmaceutical case of less than a year ago is a model, because it involved not only almost a billion dollars for a single cancer drug, but it also involved detailed supervision of how that firm goes about its business, including its marketing and pricing activities.

If firms are coming to face the prospect of literally billions of dollars of damages--and bear in mind that's entirely possible given the availability of punitive damages and treble damages, et cetera, in some of this litigation--those firms would know that if they got an

adverse jury verdict, their only course would be a very onerous appeal process. An appeal requires paying a bond equal to the damages award plus the anticipated interest during the appeals process, which can take several years. That could provide a serious impediment to a firm continuing their normal course of business, and could even threaten bankruptcy.

This brings me to the last point that I think is worth noting in connection with this litigation: the strong possibility that this litigation is intended to be used as much as a public policy tool as it is for anything else. Again the TAP settlement is a model, because it involves not only the detailed management of certain aspects of the firm's marketing and pricing, but it also incorporates the specific notion that AWP prices are inappropriate for Medicare drug reimbursement. This is despite the fact that the incorporation of AWP prices into Medicare drug payments is the explicit instruction of Congress.

This litigation is therefore a tool for reversing policy decisions at the national level. If you look at the other litigation--the Hatch-Waxman patent expirations, state price controls, et cetera--it all gives the impression of using litigation as a way of reversing or expanding upon policies that have been adopted either by the federal government or, in some cases, by state governments.

I think with that, I will turn the microphone over to Michael Greve, and then, when he's done, we will take questions.

MR. MICHAEL GREVE: Thanks. I'm Mike Greve, and I direct the Federalism Project at AEI (www.federalismproject.org). I'm not going to talk about pharmaceutical cases themselves, but about their larger context. Within that context, there are comparable campaigns by trial lawyers and state AGs against other industries.

Jack mentioned the tobacco settlement that imposes a quarter of a trillion dollars in taxes over several years. Another campaign that's eerily similar to the law suits that are now being filed against pharmaceutical companies are the law suits filed against investment houses who allegedly hyped stocks that they knew to be worthless.

There's one settlement already, a \$100 million settlement between Eliot Spitzer, the New York AG, and Merrill Lynch. After that settlement was made, the states carved up the market so that other states get to go up against other investment house and become the sort of the lead underwriter for further settlements against other investment houses. The proceeds of all these settlements are shared among the states, with the bulk of the money going to the lead underwriter state. All of these settlements already contain or will contain de facto regulatory impositions that no investment bank can avoid to ignore.

The analysis of the larger context leads to two conclusions, both of which will demoralize you. First, you haven't seen anything yet. This is only the beginning of what will be a flood of lawsuits by other states and by other organizations against the pharmaceutical industry. For that matter, the pharmaceutical industry will not be the last victim of a regulation through litigation campaign.

The second conclusion is that there's not much you can do about it. In particular, in contrary to widely-held and cherished beliefs, federal preemption is not going to solve or arrest these problems. What you're dealing with here is a systemic federalism problem that'll require a systemic solution. That'll take a whole lot of time, and probably will take steps and interventions that we haven't even begun to think about. I'll get to those at the end.

I'll start with the historical perspective. The New Deal model, as you may call it, of state-federal regulatory regulations was one of concurrent and cooperative regulation. Under this scheme, the feds provide a generalized, uniform regulatory framework for pharmaceuticals, for securities, for tobacco, etc., with the help of different, centralized, administrative agencies. In the interstices of the federal framework the states would continue to regulate. They would continue to play a role because federal statutes--and this will prove very important--typically do not preempt, but instead, explicitly preserve state fraud and other common law-like actions.

Now despite occasional conflicts that you have between the federal regulators and the state regulators, the New Deal arrangements proved by and large workable, although not exactly tidy.

But in the 1980's, these arrangements between the states and the feds collapsed in industry after industry. Two factors explain that collapse. The first of these factors was

that the federal government, under the influence of scholars and nefarious think tanks such as AEI, became much more skeptical of the role of federal regulation and of regulatory intervention in general.

But the interest group demand for regulation didn't simply disappear. It just migrated downward to the state level. The very first deregulatory showpiece that we had in America, airline deregulation, immediately produced an attempt by the National Association of Attorneys General to re-regulate the industry under so-called cooperative NAAG enforcement guidelines.

Similarly, when the Reagan administration encouraged the federal courts to shift to an efficiency-oriented, noninterventionist, antitrust policy, the NAAG immediately issued its own antitrust guidelines which looked like sort of Europe on America's soil. It began to enforce those anti-efficiency, antitrust laws on American corporations under state law that was allegedly not preempted by the Sherman Act nor the Clayton Act. That pattern has since become a familiar one.

Uniformly, state-based anti-industry campaigns have come in the wake of a perceived federal failure to regulate and quite often on the heels of a deliberate federal decision to deregulate or not to regulate.

The second factor that led to the collapse of the New Deal arrangements was the organizational integration of the litigation industry. That development, which has yet to

run its course, is characterized by the emergence of a very highly organized, very sophisticated trial bar, a dramatic increase in the size, portfolios, and professionalism of attorney generals' offices, a close cooperation among the AGs through the NAAG, and, finally, a symbiotic relationship between the NAAG and the trial bars.

Trial lawyers are a tremendous campaign fund source for attorneys general and AGs have, of course, found ways to return favor. That cooperation may take the form of direct trial lawyer participation in state-sponsored law suits, as was the case in the tobacco campaign and is now the case in some of the pharmaceutical cases.

But the exchange of course need not be that formal. Eliot Spitzer investigated Merrill Lynch and he unearthed mountains of evidence that can now be used by class action lawyers in subsequent private law suits. In other words, what Eliot Spitzer has done here is to reduce the trial bar's discovery costs. Those benefits can and will be monetized. Merrill Lynch's exposure, alone, is estimated at upwards of \$5 billion, and that's net losses only, without punitive damages and multipliers, and the like.

Now, naturally, corporate lawyers and leaders, especially in the targeted or at-risk industries, have thought about ways of curbing these practices or of cracking the coalition between trial lawyers and the AGs. In my judgment, that'll prove extremely difficult. If trying to establish a united front, that can protect political gains, it's corporate America, not the litigation industry, and not the AGs that face very demanding coordination problems. I'll mention two of those.

One is sectoral and the other one is jurisdictional. The sectoral problem is this: the litigation industry, the trial lawyers and the AGs, operate across economic sectors. They go from tobacco first, and then the securities houses, and then the pharmaceutical companies. They fundamentally don't care, within some constraints that I'll mention, what industry they're going after. The campaign against the drug industry is in fact brought to you by the same characters who litigated against the tobacco companies. And it's litigated with the same money.

In other words, the litigation outfits are repeat players. They learn, they build up capital, and they build up knowledge as they go along. Corporate America, by way of contrast, is compartmentalized.

When the tobacco deal was underway, there was a lot of talk in the papers and in the law journals, "Good God, what industry is next? Fast food? Gun makers? Liquor, beer, wine?" All of these industries could have been sued. Everything that's true of tobacco is also true of fast food. It's addictive. It's selectively marketed to children and the corporations lie about the products. You could have filed those same complaints by just substituting McDonald's for RJR and fast food for tobacco and you could have made substantial headway.

So from that vantage point, the at-risk industries had every reason to proclaim solidarity with the tobacco companies but they had a better reason to run away. They all hoped that they would not be sued immediately, but further down the line, and so they distanced themselves.

By the same token, if the pharmaceuticals companies now went to umbrella organizations and suggested that they ought to have a united corporate front because other industries could be next, they'd find no friends. Everybody will run away and say, "Those crooks--we're totally different, a completely different industry."

There's also a jurisdictional coordination problem. There are two related asymmetries between corporate America and the trial bar. First, if you're a trial lawyer, you know whom you have to buy. It's your own home state judges and your own home state attorney general, because that's where you're going to be playing. Whereas corporations can be sued in any of the 50 states. That, by definition, reduces their incentives to become active everywhere and to counter the litigation industry's efforts.

Second, a litigation campaign by the trial bar and the AGs, in substantially all states, is effectively a foregone conclusion once the first state has made its move. What that means is that in order to preclude these attacks industry would have to stop the first mover. Since that could be any of the fifty, you'd have to basically purchase all 50 state AGs and make sure that the state courts in every state play your game.

The trial bar, on the other hand, needs only one state to win because of the extraterritorial reach of state jurisdiction. That's most easily explained by way of example. Suppose all the AGs persuaded themselves that the environmental standards for stationary sources of one sort or another are far too low and that Superfund is going unenforced, which is actually true. Could they start a campaign like we've seen against tobacco, the investment houses, and the pharma companies?

The answer is no. That's because all the regulatory costs would accrue principally within each state, and at the limit, if you get too tough, firms might leave the states and locate elsewhere. That is why no state will want to make the first move, and every state has an incentive not to join the coalition, in other words, to be a holdout.

The organized state litigation campaigns occur precisely in areas where the litigation industry and the AGs have found a way to solve that holdout problem, or, more precisely, to make it work in reverse. It's such that no state can afford not to join this coalition. That dynamic arises, which is, by the way, the litigation equivalent of the Maine Rx problem that Jack briefly mentioned, whenever the costs of regulation by litigation fall principally on outside parties.

That's how the tobacco settlement came about. Four states, Texas, Mississippi, Florida, and Minnesota, obtained settlements from the corporations. The costs of those settlements fell disproportionately on consumers from out of state and the proceeds of course go in state. It was therefore rational for each state to join the litigation campaign.

Moreover it became rational for the industry to lock all of the states into one arrangement.

So, in the end, the tobacco agreement was hammered out by then-Colorado AG Gale Norton, whom I know didn't believe the complaint she filed against the industry. The very last holdout was my good friend, Bill Pryor, the attorney general of Alabama. He argued vociferously against the settlement. But of course, in the end, even he had to sign it because over 40 other states, and some entities that aren't even states, had already joined it, and all that he could opt out of was the proceeds of the settlements. The costs would fall on Alabama citizens, tobacco-consuming citizens, no matter what. He had no choice at all and so he signed.

The same dynamic operates in the investment industry cases and now in the pharmaceutical industry. The first mover states will undoubtedly recoup settlements, the costs of which are then distributed over the rest of the country. Every rational AG, even ones that are favorably disposed towards the industry, will join the crowd.

What I want to impress upon you is that what you're up against here is not some crazed ideological crusade. What you're up against is the logic of interstate exploitation and interstate extraterritoriality and, in a sense, that creates its own demand. If I were to run for AG in any state in the nation, I would run on a two-pronged platform. I would first promise to be tough on crime and I would, second, propose to loot out-of-state companies.

Since every state has only, relatively speaking, a small share of companies, by definition, most of them are from out of state. I would not call that looting. I would call it consumer protection and law enforcement. Rational voters will of course embrace that agenda, which is why you now have even conservative states—like Arizona and Kansas, where very liberal AGs have managed to win office.

In the Bristol-Myers case about the patent extension, not all of the 28 states are socialists. They come from all political stripes. The first cases come from Nevada and Montana, which are not collectivist states.

The same is true of judges. If you're a sensible state judge, you will of course redistribute income from out-of-state corporations to your in-state plaintiffs and to your in-state attorneys general. If you don't, then some other state will move first, and what have you gained by that?

If that analysis is correct, which I think it is, what you have to explain is not why these campaigns occur. What you have to explain is why there aren't more of them on a much grander scale.

There are two reasons so far. One reason is a sort of regulatory capacity constraint. Because the litigation industry, which is still sort of an "infant industry," is still

experimenting with its product, it can pursue only so many projects at any given time. I think that problem will take care of itself as we go along.

The second constraint on these campaigns has to do with the regulatory ambitions that accompany the quest for monetary transfers. All of these settlements embody some regulatory component that sometimes even assumes prominence.

In the tobacco settlement we regulated the markets. Eliot Spitzer started his campaign against Merrill Lynch, not by saying, "I want to shake these guys down for money," but "I want to restructure the nation's financial markets." The AARP and its plaintiffs lawyers, and the AGs, are quite explicit about their regulatory ambitions in the AWP and comparable cases.

If those ambitions are to be satisfied, the states and the targeted industries have to be able to lock themselves into an agreement. That presupposes on the part of the states that you can reach an agreement about the distribution of the financial proceeds, which was surprisingly easy in the tobacco case and in the investment cases so far. And the industry has to be able to promise adherence to a regulatory standard.

The tobacco industry had absolutely no problem doing that. There were only four major players and so they carved up the markets and then turned themselves into a public utility, the only one in America that we have without any price controls.

At the other extreme, if you have to ask, “Why hasn't the fast-food industry been sued yet, on a gargantuan scale, in an organized fashion?” I suppose it's because the industry is very fragmented. There's nobody you can authoritatively deal with. At the other end, who are you talking to?

It remains to be seen whether the investment houses and the pharmaceutical companies are already sufficiently concentrated and cohesive to lock themselves into a state-sponsored regulatory cartel. The AGs of course suspect that the answer is yes and I suspect that they're right.

The reflexive industry response to all of this is to demand federal preemption or to insist that the states are already preempted. I think that'll prove unsuccessful. In essence, the industry demand for federal preemption is an effort to salvage the New Deal model. But that can't be done because that model always required a certain respect by the states of federal prerogatives in these areas, and the states have already shown that they don't have that respect anymore.

The historical pattern and the constitutional expectation in America is that states will be extremely ornery, that they'll constantly try to evade and eviscerate federal preemptions. The New Deal period and the post-New Deal era is a big historical exception to that pattern and we've now returned to the historical norm.

If preemption affords you no refuge, what can be done? I'll give you two suggestions without much hope that either of them will be pursued. One of them is to change how state attorneys general gain office. In all but four or five states attorneys general are independently elected and that's a very weird phenomenon. American states mimic the federal model even when they don't have to. Forty-nine states have bicameral legislatures, even though nothing says they have to. They have two-party systems, for the most part, and so on.

What we think about federal law enforcement is that (a), the executive has to be unitary, and (b), that law enforcement is the hard core of executive authority. You can't have an independent attorney general, it's ridiculous, but most states in fact do have one. What that means is that the attorney general has absolutely no incentive to look at the considerations that would motivate a governor, such as the general business climate.

If you went to the normal AG and pointed out that his actions were making for a very unpleasant business climate, the AG will say that that's the governor's problem. He'd say, "Talk to the governor, it's not my department." That I think would change if state attorneys general were appointed. They'd have to play to a larger audience than the trial lawyers.

The second sort of reform proposal that I think is worth looking at is jurisdiction. As I mentioned, the secret to the trial lawyers and the AG successes is interstate exploitation, or to put it legally, the extraterritorial reach of state law. Mississippi AG Mike Moore got

to apply his law to corporations all across the country. Eliot Spitzer can reach anybody, all across the country. Nevada can sue and home cook you in its home state under its own law, in its own courts.

Suppose, however, that corporations and their customers got to choose their venue and their law, by contract. Or suppose that the law of the seller state rather than the customer state governed the transaction. If that were true, then the state AGs or the trial lawyers' campaigns could never get off the ground. There would be no first mover, because the AGs or the trial lawyers would simply punish in-state industries and at the limit, make them move elsewhere. These coordinated state trial bar campaigns would never get underway for lack of a first mover.

I think that neither of these proposals is radical, but, on the other hand, I harbor no illusion that either of one of them will be pursued. Both bump against very demagogic passions that Jack mentioned. Both also would require a really concerted, serious corporate strategy, and I, for one, don't believe that corporate America is capable of executing such a strategy or even agreeing on it.

What you're going to get here is a series of regulatory cartels under the sponsorship of the NAAG and the trial bar. In other words, the trial bar and NAAG will increasingly perform the function that Congress and regulatory agencies are supposed to perform, which is to establish and administer regulatory cartels.

I wouldn't look to Congress to arrest that development. These litigation campaigns move faster than Congress for a number of reasons. The attorneys general all have the same incentive structure, they're a little more mobile than Congress. The process that was invented in the tobacco litigation, and is now being perfected, involves only a few constituencies, whereas in Congress you have to strike a compromise among all these messy interest groups.

Once you have reached an agreement at the state level, it can't be dislodged in Congress. Neither the trial lawyers nor the constituencies that are locked into the agreement have any incentive to upset it and that of course includes the industries.

The fiercest defender of the tobacco settlement is the tobacco industry itself. If you think it's tough negotiating with Citizens for what-have-you--or Tobacco Free Kids, or whatever--you should try negotiating with Skadden Arps and the other law firms that defend these arrangements with great ingenuity.

What we're building here is a parallel constitution, a constitution for the enactment of federal regulation that's parallel to the constitution that we actually have. That's not a good thing because inherent in the notion of a constitutional republic is that you're not supposed to have an alternative constitution on the side.

I've argued elsewhere, at great length, that the actual Constitution forbids the tobacco settlement and the arrangements that are now being established in other industries. That

argument of course is properly addressed to the Supreme Court. I wouldn't hold my breath for judicial intervention in this area either, but it may be the best chance that any of us have. Thank you.

Q & A

MR. CALFEE: Any questions?

MS. FRITZ: Hi. I'm Sarah Fritz. I'm a reporter for the *St. Petersburg Times* and I was absolutely fascinated, Mike, by your analysis. The one flaw I see in bringing the pharmaceutical industry into larger litigation patterns is that it has not experienced a deregulatory move in the federal government. In fact the federal government does regulate drugs fairly seriously, but it doesn't regulate it in ways that consumers are interested in.

Secondly, it seems to me that the reason that business does not come to the aid of these companies is because business is part of the victim class. They're paying the freight, along with the states, of high prices for pharmaceuticals. So I think this is a somewhat different case.

MR. GREVE: Good points. No, there's no deregulatory experience. What there is, however, is a perception of prolonged and protracted federal failure to regulate. Congress looked at the AWP issue and decided not to change it. It affirmatively said

that. It's the same in the investment companies. We have SEC regulation of corporate disclosure in investment banking practices in spades. All these Internet offerings that are allegedly fraudulent, all of these telecom offerings that were allegedly fraudulent, were issued in meticulous observance of SEC and state rules. What Eliot Spitzer is saying is, "You guys are sitting on your duffs while Rome is burning now I'm going to move." You've got the same phenomenon in the pharmaceutical industry. It's easy enough to imagine: "Congress is beholden to all these special interests. I'm the attorney general of the State of Nevada. I represent the people, and I'm coming after you."

The fact that other industries have an added incentive not to assist the pharmaceutical industry, I think is a point well taken and cuts in the same direction as the factors that I mentioned earlier.

MR. CALFEE: If I could add something. It seems to me that there are at least two factors accounting for the much greater role of litigation. One is that the industry itself is simply much bigger, much more prominent. Expenditures are far greater than they were even five years ago. The payoff from reducing expenditures is greater than it was before.

The other relates to your latter point about business paying so much of the bill. That's actually a fairly recent phenomenon. Right now, I think third parties pay for something on the order of 70-75 percent of all pharmaceutical purchases. You go back twenty years ago and it was more like 25 percent. Even ten years ago, it was much less than it is now.

Business is covering a big part of the tab, but that's a relatively recent phenomenon and, of course, the tab is much bigger now.

MR. MAJOR: Thanks. Neil Major [ph] with Pfizer. I sit here in depression over this presentation, which was excellent. I'm curious to know--Jack, you might have a sense of this, given how long you've been looking at the industry. The litigation issue has been a background issue for the last 18 months for us at Pfizer who look at policy issues. It's been picking up steam as you note in your report, and it's gotten to what I would consider to be a critical mass. Now, we consider it a major issue. At what point do you think, given your experience, Michael, with other industries, will it become the *biggest* issue for us? Further, what's the life cycle like for this litigation industry?

MR. CALFEE: The answer to the second question is, it'll last as long as the money lasts.

MR. MAJOR: So, in other words, it will last until I retire.

MR. CALFEE: Yeah, but you may not be able to take that early retirement that you're thinking about.

MR. MAJOR: Okay. But at what point does it become our biggest concern?

MR. CALFEE: My first reaction is it becomes an issue when the plaintiffs get some really big jury verdicts. The TAPS settlement was quite significant, it was \$900 million, but it was a settlement. It involved behavior that, at least on paper, looked pretty bad.

If you get a large jury verdict which forces the industry to pay a lot of money for practices that fit into the mold that we were describing before, that everyone knows is going on, that are probably efficient rather than being harmful, then I would think that that would make a big difference.

Michael, what do you think?

MR. GREVE: I have only the vaguest idea of money-wise how important this is to the industry compared to say, the Canada issue, the Europe issue, and so forth. I'll say this, and especially about the average wholesale price issue, I think it will crest and then disappear. Once you figure out a way to lock all of the states into a settlement that the drug companies can live with financially and one can be defended against subsequent collateral attacks, either by the trial bar or by some wildcard, that'll be the arrangement. I don't believe that the AWP cases will go to trial--ever. None of the tobacco cases ever went to trial.

MR. CALFEE: Except for Minnesota.

MR. GREVE: Minnesota; sorry. But even in Minnesota it didn't go to a verdict, right? I think that'll be the pattern in these types of cases, too. In the end, you'll be haggling over two things. One, how much money is going to change hands. That'll be somewhere short of something that spells ruin for the pharmaceutical industry or has demonstrable adverse consequences. By demonstrable, I mean something that would drive the general economic point home to the reader of the *New York Times*. I don't mean the generic economic argument.

The second thing that you'll be haggling over, if it's not the federal average wholesale price system, then what is the appropriate pricing structure? How do we administer it? What is the regulatory regime that we can all live with?

MR. ANTOS: Joe Antos, AEI. I think that this presentation was, if anything, a little too optimistic. We have to remember that there are congressmen who are also interested in getting a piece of the publicity pie, so to speak, and if you have the attorneys general grabbing at it, they've got to react. I really think that the patent protection issue is going to be a big one and it's not entirely clear to me how that's going to play out.

I could easily see that some grand settlement would appear to keep the industry running along with whatever money is to be extracted, and then, subsequently, Congress taking action on behalf of its own political interests. That could really upset the financial stability of the industry. So I think it's an even darker picture than you two have suggested.

MR. GREVE: It's a possibility. I was quite serious in suggesting that deals made at the state level can't be dislodged in Congress. I would suggest, second, that of course there are a lot of lawmakers who want a piece of the action on this stuff, but that was also true of tobacco. The tobacco settlement had a predecessor. The states believed, quite correctly, that they needed federal approval for this.

There were antitrust implications. This was Medicaid recoupment. Remember, half the money was, technically speaking, the federal government's. There were regulatory issues related to cigarette advertising and on and on and on.

MR. ANTOS: There were also FDA regulations.

MR. GREVE: Yes, there were FDA regulations. So they crammed this thing into Congress, John McCain runs with it, and the thing collapses under conflicting interest group demands. At that point the states said, "why, thank you very much, now we'll do it on our own and we're not even asking you."

Only two federal actions that happened afterwards. One was that the federal government filed its own recoupment suit. That was strictly copycatting. The second thing was that the Clinton administration vaguely mumbled that half of the Medicaid money was actually theirs and then the states went ballistic.

You're entirely right about the patent issues. If anything is federal law at all, if anything ought to be preempted, if there's anything the states shouldn't be screwing around with its patents. But again, that's also true of bankruptcy and the tobacco settlement purports to simply abrogate the federal bankruptcy statute. So then why not purport to abrogate the federal patent statutes? What's wrong with that?

We have one precedent already. Could we make that stick? I don't know. But you have to find, ex post, a federal agency that has the guts to say, "Damn it, this was none of your business," and I doubt that you'll find them.

MR. CALFEE: One could spend all day talking about the implications of tobacco, but, to me, most striking is that you had a situation with four groups with very strong interests. Namely: the states, the litigation community who were litigating, the manufacturers, and smokers. But only two of the parties were parties in the litigation, that is, the states and the manufacturers. The results are exactly what you would predict.

You had an agreement that was mutually beneficial for the litigants, and the smokers were absolutely the losers. So an anti-smoking movement that began as a way to help smokers ended up as something that penalized smokers.

Turning back to litigation involving the states and the pharmaceutical manufacturers, there's always a possibility that when everything is said and done, you're going to have an arrangement that looks good to the plaintiffs because they do something about this

supposedly outrageous AWP, et cetera. It will look good to the other side because it will do something about all the competition that they would prefer not to engage in, and the losers could be the people who are actually using the drugs.

The patients could lose access, and they could lose lower prices, et cetera. I think that's always a danger. It sounds like kind of a theoretical danger, an obscure game theoretical analysis, but the tobacco litigation tells us it is not at all theoretical. It can easily happen.

MR. GREVE: One subtle difference between the pharmaceutical cases and the tobacco settlement is that advocacy groups have learned from the tobacco settlement.

They opposed the ultimate tobacco settlement because it wasn't tough enough on tobacco companies. They rightly saw that this was just a way to lock in monopoly profits and give the states a share of the deal, and that the smoke-curbing measures were just for show. They've learned from that, so they're more involved in the pharmaceutical cases than they were in the tobacco litigation. They don't want to be frozen out again.

The second point is that the most astonishing thing about the tobacco settlement is that nobody who was actually harmed by tobacco got a nickel of the settlement. Those people just keep paying. That is also true of the investment house cases against Merrill Lynch.

There's not a nickel of restitution for the investors and there won't be. The AWP cases that I've seen, specifically I mean the case from Nevada, at least have a claim for

restitution for people who allegedly overpaid on their Medicaid co-payment. Will that actually materialize? I very much doubt it.

MS. MEANS: Good morning. I'm Kathy Means with Patton Boggs. Recently, I've had some experience at the Senate Finance Committee where we were working quite a bit on Medicare and Medicaid drug pricing issues as part of the prescription drug debate. I wanted to comment that I was very struck by Michael's comment that a big part of what could emerge from this litigation in pharmaceuticals is a regulatory scheme that, whether the federal government acts or not, could involve a very broad-based drug pricing scheme.

One of the things I see going on from a dynamic standpoint is a very strong interest in getting closer to what the states see as actual acquisition cost. This is true not only in pharmaceuticals but it's also true in durable medical equipment, and medical devices. So you're seeing these themes emerge both at the state level and some discussion of it at the federal level. I think that's one of the more significant things, other than the money, which could be very significant, that would emerge from this over the next few years.

MR. GREVE: Yes, there's a distinct possibility that, at some point, there'll be such pressure emerging from the litigation and negotiation process, that federal agencies and Congress will, in anticipation, take the steps just to maintain the facade that they actually did it *sua sponte*.

The investment banking cases are perfect foil for this. What happened after Eliot Spitzer got going was that the financial industry went to the SEC and it went to Congress, squealing, and said, “What are you doing, sitting on your duffs? He's nailing us. You ought to preempt this.”

The only way Harvey Pitt knew how to do it was to say, “I'm going to get tough, and I congratulate my dear friend, Eliot Spitzer, for taking the initiative. I've seen the light! Now we're all going after them and we're now all going to impose the regulatory requirements that Eliot Spitzer wants on the industry, and that way we're saving federal preemption.”

In that sense, it is really true that what Spitzer has done has turned loose sort of a whole lot of stuff at the federal level and I think that's a very good observation. That may very well happen - it may already have happened in the pharmaceutical context. I don't think that makes the state initiatives here any less troublesome and any less disturbing, but it's a distinct possibility and if that were to happen, the states will just negotiate over the money.

MS. MEANS : I would just point out one particular aspect of this that's interesting. Both Medicare and Medicaid regulate payments that they make to providers, and with few exceptions, they're not directly reimbursing pharmaceutical companies or medical technology companies. They are suppliers to providers, and so they're trying to get at the

provider acquisition cost. A lot of people have looked at the Bayer settlement, looking at the average sales price methodology, by having manufacturers report actual sales.

I mean, these are very proprietary data, so I just see a lot of movement in that direction.

MR. CALFEE: Yes. I think it could be a two-step process. The first step is to make competitive pricing more open to scrutiny, which would tend to severely inhibit competition. The next step would be to look at the appalling results of doing that, and then decide that the market isn't working very well and the prices need to be controlled directly, with all the adverse consequences that would follow.

Thank you very much for being here. We hope it's been of some value.