OFF-LABEL USE FROM INJURED CONSUMERS' PERSPECTIVE

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I appreciate the introduction. Just listening to that introduction I think to myself, "Gosh, a number of students probably think I couldn't figure out what I wanted to do in life," since I've done so many different things. But the one thing I would just say generally to the audience, and I know there are a lot of students here: in looking at your career, for some reason we all come out of law school and we think we want to get a job at the biggest and best firm, in a city where we want to live, and that's precisely what I did and that's why I went to Reed Smith right after law school. But over time I started doing different things, experiencing different cases, the death penalty case I did, for example, had a big impact on me personally in terms of what type of litigation I wanted to do. And so, the piece about me in the brochure says I'm a former Assistant US Attorney, which is typically how I'm introduced, but I'm really a plaintiff's lawyer.

That's pretty much what I am, a plaintiff's lawyer and a trial lawyer. I usually don't get nervous in front of crowds, but I am a little nervous because I don't lecture really before audiences like yourselves, I'm used to being in front of a jury. I'm used to speaking to people that I typically grew up with in West Virginia, common people who, for the most part, go to work every day and do blue-collar jobs. Talking to everyday people is really what I enjoy in life, it's what I really like to do. It's a pleasure to be here to talk to you a little bit about what it is that I do. What I want to talk to you about is: what are the torts when consumers are injured by off-label use?

From a personal standpoint, I lost my father about three years ago to lung cancer, and I was very aggressive in working with doctors to get him off-label treatments and I see a lot of potentially good off-label uses for drugs. Personally speaking, I've never done any mass torts for any cancer patients that did not survive any type of off-label use. I frankly just don't believe

in it because I think, on a personal level, there's a lot of good there.

There are really four different areas that I think about when I see someone come through my door that have a potential off-label use case and I'm trying to decide whether there's a cause of action for them. Certainly the non-covered conditions and dosages are frequently seen, but in particular the one I'm going to talk to you about today is the non-covered method or application of the particular drug or device. I'm going to focus, I think unlike a lot of speakers today, somewhat on medical devices. I'll talk about preemption in that field here in a couple of minutes, but I want to focus mostly on medical devices, because I personally think that's some of the most egregious cases I've seen, and I'm going to go through a hypothetical situation with you today.

Some of the potential private litigants we see are whistleblowers who are insiders with companies. I've had people, you saw a website up on the screen, www.ConsumerInjury Lawyers.com is my website, through that website and others I frequently have people that work inside the companies that see an off-label promotion or some safety information that contraindicates, or contradicts I should say, the safety information that a company is putting out about an off-label use, and it's not being presented to the medical community, and they'll come to someone like myself and ask what to do with that information. Often, those people are ending up with the government. We're seeing significant cases, some of which were mentioned earlier today.

The other population of private litigants in the area of off-label that we're seeing is really the third-party payers, which has been mentioned some today. I do a lot of work in that area. It's not something I'm going to talk about, but there's big dollars at stake because the off-label use has gotten so large that it's really a reimbursement issue, which people have touched upon.

In terms of individual consumers, there are really two umbrellas you see, and I've done both types of cases. One is just a class action, and those are typically economic damages, because when you get into Rule 23 certification issues, those are the type of damages that might be recoverable from a class action perspective. But when it comes to actual personal injuries of the individuals, they're going to be individual cases—they're not going to be class cases. And that's really what I want to talk to

you about today is, the mass tort personal injury type case. Some of the cases I have seen recently, and I'll mention a company name once, but it doesn't necessarily relate to that particular company, Medtronic, there's been a lot of reports about a bone infuse implant that has hit the press, and there's a government investigation into it allegedly. I think that it's actually now reported by the company as to the off-label use of this bone infuse implant.

So today suppose that we have a hypothetical. Let's say a thirty-five year old client that comes in the door and he has some cervical spine problems and went in for ultimately what the doctor suggested doing: a fusion of the C6 and C7 vertebrae. Instead of using what I understand to be a traditional method, which is taking bone from another place in the patient, the doctor decided to use a bone infuse cage. It's a small device usually, and I think these ones are titanium. There's a sponge that has a growth protein that's in it. It's then put in the cage and the cage is surgically implanted in the vertebrae to cause a fusion of the vertebrae. I won't use highly technical sort of medical terms. It's probably a good thing for you, but it's also good for me because you don't want to hear me butcher the terms.

In terms of what the FDA has approved the device for, basically it's only supposed to be used in the lumbar area, which is the lower portion of the spine, and it's supposed to be inserted frontally through the abdomen. The person that comes to us, of course, as already mentioned, has a C6-C7 spinal fusion and it's inserted through the back of the neck instead of through the front. Shortly after surgery the client experiences difficulty breathing. Typically I think this population of reported cases is about three to five days after surgery there's swelling and inflammation of the neck, the airway is blocked and a tracheotomy is typically necessary. There's been at least, I believe, one reported death from this, and obviously the clients are fairly injured even if they don't die. The device itself typically is, having to be ex-planted if it can be, depending on how the growth is. So what do you do? This is the type of situation I'm faced with quite commonly, whether it's in this case or others.

You sit down, you talk to the client first. In these particular cases I have to say I was kind of surprised to hear the lack of informed consent that was talked about earlier this morning. So oftentimes, for example, I've got a situation right now where a

client had the surgery two years ago, which is a statute of limitations issue, two years ago as of March, and he was not told anything about this particular bone infuse implant being off-label by the doctor. What do the medical records show? Typically the client will come in, they say they had some sort of implant. Unless we know that there's some issue with those implants through public reports, we have to get the medical records and try to figure out what device was used, was it on or off-label, was there malpractice by the doctor, for example.

We typically—I know the medical device reporting through the FDA is something that was spoken of earlier—that's something we as plaintiff's lawyers often go and look at, because one of the things we want to see of course is, you know, what is being reported to the FDA in terms of adverse events about the particular product? I've seen numbers that suggest for a device like this that perhaps as high as two-thirds of the adverse events that have been reported are actually off-label reported events, which would be something significant we can talk about in a minute—we typically have a nurse or somebody review the records with us who has a working knowledge of the medicine. Additionally, we typically get to an expert pretty quickly, have them look at the case and then have them help us evaluate what the negligence potentially is, but something I'll talk about in a few minutes is really the duty of care and whether this is an accepted to some degree off-label use of the particular product. Potential defendants, no secret here, obviously the doctors are potential defendants depending on what they had disclosed to the patient. Of course, depending on the foreseeability of the particular off-label use, the manufacturer may also be on the hook from a liability standpoint from our prospective.

What state law applies? Most of the claims, actually all of the claims pretty much in a tort case, are state court claims unless you're doing a federal RICO action on the class action side. It's pretty much all state-law claims, and unfortunately from a manufacturer's standpoint they would say. But also from a plaintiff perspective, you have to look, especially if you have a national practice like mine, you really have to consider where the particular client is a resident as well as where the surgery was done. I've got clients, for example, in Michigan where there's a really terrible statute for plaintiffs, frankly, that really gives almost complete immunity to the drug manufacturers and device manufacturers. It's a real problem. So the state law is

important.

Was the off-label use related to the injury? This becomes an issue, as a practical matter, because a lot of times when someone comes in they have a device or a drug that's being used, and there's a problem, the question becomes, "Well, did the off-label use actually cause a particular injury or was it something else unrelated to the device or the drug that actually created the injury?" For example, was it malpractice? That will impact the statute of limitations in a case, because if it turns out that the off-label use really wasn't the reason for it and it's really medical malpractice—there's a discovery rule in this state, which is something you always look for, there's not going to be necessarily a discovery rule that allows you to toll the statute of limitations until they found out about the off-label use—related to something else about the surgery for example.

Are there any government investigations? To me this is an important thing for a couple of reasons. From a fact-building standpoint, the government investigations, having been a federal prosecutor myself, I know they have grand jury subpoena power. They also can get the SEC involved, and of course companies comply pretty quickly, or the FDA involved, and companies comply with the request of the government. It may take us on the plaintiff's side months, if not years, to get discovery that the government can get in a matter of weeks. And so the government investigation is very important. The problem of course is that the government investigations may take a long period of time, in which case that information is sat on. But from a practical standpoint, as a plaintiff's attorney, what I do is go into the companies and say, "I know you're producing for the government, don't tell the court that you can't go back and search custodian hard drives for all the particular people we're interested in because it's too costly because I know you already did it for the government." So there are very practical implications in a government investigation. It's very helpful from my standpoint as a plaintiff's attorney.

The off-label promotion doctor payments, you've heard some about this. There's becoming more and more information that's publicly available about what payments doctors might receive from the device manufacturers for example, and I'm not going to get into it too much, but that's something that's becoming more public. The off-label marketing efforts, I know the regulations changed more recently, may allow you to get more information

about what's actually being done. On a state level, we'll talk about it a little bit later, the attorney generals and legislatures are being more active in trying to get in settlement contacts and otherwise the drug companies to disclose more of what their marketing efforts are, and that's being somewhat successful in states like West Virginia, for example.

The final thing I'm just going to touch on, I was involved in the *Wyeth* decision. I didn't write the brief actually, I say. I was given credit for that. Ann Lipton, who is a former Supreme Court Clerk with my office, she wrote the brief. I worked closely with her. But one of the things we wanted to do is, because this is obviously an important practice area to us, as well as in the third-party payer side, a very important practice area for our third-party payer health and welfare fund clients, is to make sure to have a voice in the *Wyeth v. Levine* decision. To our delight, of course, that came down very favorably for consumers I think as best as it possibly could. The one unfortunate thing is, I'm talking about a medical device today, this bone infuse implant, right now with *Regal v. Medtronic*, essentially, with some exceptions, there's preemption right now for medical devices, meaning that consumers really cannot go after a drug company if they have an FDA approved label for medical devices. But there is the Medical Device Safety Act that's been introduced in Congress. We're hopeful that that's going to progress through and give some relief to the consumers.

Breach of warranties. There's at least one decision regarding Paxil out of the District of New Jersey where the court walks through some of the warranty claims in New Jersey. If you guys had a commercial paper class, UCC, I don't know if—I see a bunch of blank stares—I had that in law school, I think it was the first and only time I ever dealt with it. I wasn't doing transactional work so it really didn't matter to me, but doing plaintiff's tort cases, you see UCC breach of warranty-type claims, and certainly one of the things I do is look for the states like New Jersey for example where the drug company's representations in literature and promotional materials can actually be construed as a warranty about the particular product.

Fraud or negligent misrepresentation claims. One of the things you see in the off-label context, it's a little bit different than a typical mass tort, is that, because of the restrictions on the drug companies about what they can and cannot say, a lot of the promotion materials are kind of diffuse. You can't always get

a direct representation by the sales representative about the safety of Paxil, for example, in a minor, which would set up a fraud claim or a negligent misrepresentation claim because they had safety information they weren't giving to the doctor. That's not as easy to do as, for example, on an on-label case where they're giving information out in the label, which is contradicted by what they actually know.

Consumer Fraud Act claims. There's consumer fraud statutes in most jurisdictions and, as you know, in most states. Typically it is economic damages you're seeking, but from a plaintiff's attorney's perspective as well as a consumer perspective, the advantage of the Consumer Fraud Acts is that if you lose the tort liability claims and you win that you may only recover economic damages. It also provides for double or treble damages potentially assuming you can get around some of the FDA preemption punitive damages issues. In addition to that, it allows you to recover the attorneys fees and costs, which if you're doing contingency work for your clients and you're taking a third of the recovery, that's very meaningful to them. So the one problem with that, of course, is we see states like New Jersey, which have recently ruled in the Vioxx litigation, for example, in the Appellate Court, that the product liability statute essentially preempts the claims in the Consumer Fraud Act in a tort case, you can't bring those claims. That's something that we're seeing more often.

Failure to warn, we're going to go through that in more detail. And of course one thing that I didn't know was an issue, and there's a least one reported case in Georgia we'll talk about, in an off-label context where the court said there's essentially a duty to test for the safety of the off-label use, which I hadn't heard of before, we'll talk about it briefly.

So generally what's not actionable, and some of this is touched on from a practical and sort of ethical standpoint earlier and people making general statements. There's no manufacturer duty to prevent off-label use. In fact, in some states like New Jersey, there's actually recorded decisions that say that doctors can use a drug or device for an off-label purpose as long as it's been approved by the FDA for something. That can become important in a third-party payer context, for example, talking about reimbursements and whether a doctor had submitted a fraudulent reimbursement for an off-label purpose when they knew it was an on-label purpose, that could become an issue.

No fraud on the FDA claims. This is really the *Buckman* decision for those of you who have read about preemption. That's something that there's a lot of discussion on in the case law in this area whether what plaintiffs are trying to do is show fraud on the FDA. The typical example we see in the off-label context is that the allegations that the drug manufacturer or the device company simply got the FDA approval for one purpose but intended to use it for a different purpose.

Just one example, there's some pain pump cases that are being litigated. Essentially you go through a shoulder surgery or a knee surgery, doctors may use a catheter with a pump that has pain medication in it, you push a button and it delivers pain medication. It's used for one to three days after surgery and then removed. There's some evidence in those cases that the manufacturers had actually sought an FDA label for approval to use it in the joint space in the knee. Well, it turns out that when you inject the pain medication directly into the joint, it destroys the cartilage and can actually leave you in a much worse position having to have a shoulder replacement or a knee replacement than what you were in originally. So the evidence in that case allegedly suggests that the manufacturers went and tried to get a label for the knee, it was rejected, so then they went and started promoting it for the shoulder, but then didn't tell the doctors about the rejection regarding the off-label purpose for the knee, as well as didn't really disclose some of the information they knew of course about the destruction of the cartilage. So no fraud on the FDA claims.

Failure to warn claims. Basic point, it's the duty to warn consumers of non-apparent risks. As there is more direct consumer advertising there are more allegations you see in cases about the duty to warn consumers directly. Most states do recognize a duty to warn for off-label use. I think Maryland actually doesn't, but for the most part the courts are recognizing it. Also—and I'm going to go into the learned intermediary in a couple of minutes—the focus on these cases in the off-label context is really on the evidence that the manufacturer knew of the particular off-label use. So, for example, I'll just run through these, did the particular off-label use present a serious risk? And if it's not something that presented a serious risk, it may not be on the radar screen.

Was the off-label use a gross misuse by the doctor? There's at least one reported case where a doctor was using it as sort of a

regimen to cause a patient to lose weight and had combined some prescriptions, but then the plaintiffs had gone after the manufacturer for the combination of prescriptions, and the judge said, "Look, there's nothing to tell us that they knew about this gross misuse of the particular product." Those cases aren't typically the ones you're seeing brought as tort actions. The cases that are more common are the ones like the bone infuse implant case I was mentioning earlier. I don't think there's that many of the gross misuse cases out there. I think most of the time the doctors are using it because they've read something that suggests this might be effective. We don't see the really just clear-cut, negligence malpractices by the doctor using the product grossly in a wrong fashion.

Are they actively pushing the doctors to use the device? One of the things that we have seen, I have seen personally, from the bone infuse cases as well as in the defibrillator litigation I was involved in, is that many of the sales representatives, perhaps to some of your amazement, are actually in the operating room with the patients while they're getting a device implanted. For example, if they're defibrillators, and it's typically the case, the defense from the company is, "Look, we have to program these devices." And the doctors will say, "These guys know how to program the devices in terms of how many beats per-minute the heart should be and how it needs to be regulated, I tell them what to do or what I'm looking for the result." And just like I was making a joke earlier, you know, it's sort of like—I grew up in West Virginia so I'll use a lawnmower—it's like having the John Deere guy come out and work on your lawnmower making sure that the timing's right. That's the defense by the company: that the sales reps actually provide a valuable tool, a resource to the doctors in implanting these devices. So there's a legitimate purpose for some of this, but then the question becomes how much of that legitimate purpose versus how much they're talking the doctors into using it for an off-label purpose, and are they disclosing to the doctors what the safety risk is, and is that information getting down to the patients who are getting the off-label procedure?

The one thing I noted after *Wyeth*, in drug cases at least, not with medical devices, is that the manufacturers, I think, shouldn't now be able to claim that they can't strengthen the labels absent FDA action, which is something we have seen consistently is going before the Supreme Court and the Supreme

Court didn't buy: "Hey, we can't strengthen the label." It just seems like a ridiculous position. In my opinion, and the Supreme Court I think has said it, you can strengthen the label and therefore you can't have failure to warn claims.

The one exception, and I asked about this point earlier, that I think is a really interesting issue—if anyone's a second year looking for a notes issue to write on next year—is in the generic drug context there are cases against generic manufacturers. For example, Darvocet is a popular pain medication that's causing accidental overdoses, and one of the things about Darvocet is it's been on the market for a long time. There are a lot of cost-effectiveness studies that have been done more recently. I've got clients, for example, who their loved ones have died from Darvocet toxicity, the death certificate says Darvocet toxicity, we go and look and see who the manufacturer of the Darvocet was, and it's not the brand manufacturer, it's the generic manufacturer. We go and say, "okay, so do we have a failure to warn claim against the generic manufacturer?"

Depending on which jurisdiction you're in, oddly enough, you may actually have to sue the brand manufacturer who essentially controls the label. There's been at least one reported case, though it may strike you as economically irrational, that suggests that the brand manufacturer, because of the control over the label, actually can be sued for the injury caused by the generic. It's an area of law that I think there isn't much written about it. I think there should be more done, and certainly from a policy standpoint it's probably a big issue, especially because, and we've heard some about the patents, a lot of drug companies right now, they're facing a lot of drugs that are coming off patent, and some of these are ones where there's been a lot of litigation about them. We're going to continue to see that litigation I think, and the question is going to be, "Can we sue based upon those generic drugs on the market?"

The learned intermediary defense. It's really an exception to the general rule that the manufacturers have the duty to warn consumers of risk. Essentially, and I'm telling you guys stuff that you probably know already, but it really just says you've got to inform the doctor and then the doctor makes a decision as to what to inform the consumer about. Of course, I strongly advocate that the doctor has a duty to pass on the information, and that may or may not be successful in a given case. There are some cases where, in an off-label context, the label may actually

say that it's approved for a particular purpose only, suggesting that there are other off-label purposes that are excluded. So in the off-label context, the issue becomes, "Did the doctor know about the risk associated with the off-label use?" If they did, then can you sue the drug manufacturer or device manufacturer as a consumer? This case suggests for example that as long as the label says it's for x-use only, that may be sufficient, in which case the defense is invoked and you may never get to a jury on the case.

The one area that there is some litigation in is where there is some warning or some disclosures or safety information about the off-label use, and I think this is in the Paxil context, is whether there is so much over promotion of the drug that the promotion overshadows what the safety information is out there? And that's really the over promotion sort of claim that the warning label is adequate to disclose to the doctor that the off-label use shouldn't have been done.

The other thing that we see, and there's some reported decisions about is, many of the state statutes have changed. So in New Jersey, and in Michigan particularly it's problematic, you see that the state product liability statutes actually have a built-in presumption, a laudable presumption, that if the FDA approved the label then there really isn't a failure to warn claim. I'm stating it more strongly today as I've certainly argued that it's not that strong of a presumption, and oftentimes we get to juries on it. But there's the *Knight* case that was recently reported, as well as the *White* case out of Michigan, that essentially reached different conclusions on different statutes. The Court in New Jersey found there was sufficient evidence presented by the plaintiff to overcome the presumption, and therefore submitted to the jury. One of the things you of course ask yourself is, "If it's off-label, wouldn't it suggest that there isn't anything in the label to protect the manufacturer?" In Michigan, for example, the courts have said there's a pretty clear interpretation of the statute on its face that says if there's an FDA approved label, it's not false, and there's no fraud on the FDA, so you can't sue for failure to warn claim and that off-label use should be protected just the same. I think there's going to be litigation in this area and it's going to be continuing to develop in different states that have these types of statutes in an off-label context.

So you remember our bone infuse client? The company where

the drug was being used off-label? I think in most instances the answer is going to be yes in these cases. Did they know the increased risk of problems when used in the cervical spine? As I mentioned already, there's a lot of adverse event reports about this, so I think the knowledge of the swelling in the neck area for example is common knowledge for the company, certainly enough that they should be warning about it.

Was there a failure to provide adequate warning to the doctors of the risk? The one thing is that in New Jersey they say that there's a duty to warn as soon as a risk was reasonably foreseeable. One thing that I just scratch my head sometimes with what the companies do is when they have a drug representative in the operating room teaching the doctor how to do the off-label procedure, it creates liability problems for them. On top of that, most of the people that I speak to don't actually know that it's a sales representative that's in the operating room. And they have a strong visceral reaction to it, and oftentimes it creates a problem for the doctor and their relationship with the client because the client feels like the trust had been breached with them.

Did the manufacturer provide a safety message inconsistent with the warning label? This is really where the government investigations as well help a lot, and also the adverse event reports again are helpful in routing that out. I did a lot of securities fraud prosecutions as a federal prosecutor. Tort liability claims become essentially the same thing when you're talking about off-label because oftentimes you're looking for that private information that's inconsistent with the public statements, just like in a securities case. And the routine becomes pretty simple.

The one case, which I hadn't read before, before this, in looking at this issue, is this case out of Georgia that essentially is unique involving a drug company that was marketing a drug, but wasn't the manufacturer. But the court essentially said there was a duty to test and provide a product, to essentially show that a product is reasonably safe for a purpose for which it could be foreseeably used, as distinct from a duty to warn. I think there are a lot of problems with the decision itself, but it certainly shows, in a case where there's really bad facts and there's a really significantly injured plaintiff, courts go out of their way to find a way for the plaintiff to recover, and really in this case the court took some facts and came up with a theory that was kind of

presented by the plaintiff and ultimately was successful, but I haven't seen any other cases like this that have been recorded.

Just some thoughts in terms of the off-label debate. You know, what is the right balance? The people I talk to, the people that I represent, they just want to know that if there's an off-label use it's motivated by their interests, their medical interests, and not motivated by a profit motive. And that really is something that, in my opinion, Wall Street forgets sometimes, the drug companies can tend to forget, and certainly they may get a bad rep in some circumstances where they really are trying to do the right thing. But the reality is is that they are incentivized by the economics, unlike a doctor or medical facility that the common person thinks is looking out for their interest. So I often look for the breach of that trust when I'm presenting a case to a jury, because I know that's something that's going to resonate with a jury just like it does with my clients.

The doctor, again, and that segues into the next point, the doctor/client relationship has to remain sacred. Do we really need sales representatives in the operating room? With some of these really complicated medical devices there's potentially justification for it. It's an extreme example, but when is enough? And I think we've seen a lot of debate about that in the last few years and that's part of the reason why I think we're all here today.

The last thing, and I see this sort of as a continuum or a wheel of interest, and it's been presented today already I think, but you look at patient demands, the demand I made on the doctors from a consumer standpoint to get my father Draceve and other drugs to help him in his late stage cancer. The health care cost is something to keep in mind, because the drugs are a very expensive. He actually was a steel worker and lost his insurance right at the last stage of his life, so he was paying for a lot of it himself, but for the most part it's reimbursement dollars we're looking at.

The sales revenues from the company—I think Dr. Thompson did a wonderful job, in fact the good, bad, and the ugly, it was probably something I'll use in the punitive damages stage in front of a jury at some point because it was very effective I thought—is the sales revenue, that's really what the companies are about, and believe me, I know that because I do the securities fraud cases, and I'm representing the investors who are looking at the material misstatements from the company about what

they're doing in terms of revenue stream. So I can see both sides of it.

And then the other part of it of course is patient safety. This is critically important; can we possibly do clinical studies for everything? No. But the free flow and freedom of information, extremely important in my view, extremely important to clients, because they want to know if they go see a doctor in Missouri, he can get online, or he can go to *Physician's Desk Reference*, or whatever it might be, and if he's going to use something off-label he's learned about it. Now some of that may be from the sales representative, but they want to know that they're learning about it from a credible source.

In terms of going forward, are we going to see more or less litigation? This isn't just on off-label, and I'll be very quick because I see my time is up. In the off-label area we see the federal government definitely has an appetite for it. If you, and I don't have any statistics with me, but if you look at how much the federal government has collected from whistle blower cases for example in the last five years, it's gone up astronomically. A big portion of that is off-label settlements. Are we going to have a more active or protective FDA with the new administration? You know attorney generals, they're really getting out and becoming more of a marketing police to the extent they can. There is a really strong and I think a very good brief put together by the National Association of Attorney Generals to the Supreme Court in the *Wyeth* case, really looking out for the state's rights to police in this area.

The patents are expiring. I don't know much about this area, but from what I understand that as these patents come to expiration, the drug companies have to figure out how to keep their revenue. We will see litigation that in protecting patents, but in addition to that, how aggressive will these companies be in terms of creating some of these later generation drugs and how sloppy are they going to be in their safety studies?

The company combinations, you know, the Merck Schering-Plough merger for example, I'm sort of a cynic in my view in terms of how litigations get cleaned up sometimes. The Vioxx settlement happened and it was a very substantial settlement. I think it should have been settled much earlier. Merck changed its strategy at some point, and low and behold, look, we're at a year, year and half later, and they're now combined with Schering-Plough, and you've got to bet your bottom dollar if

you're one of the people working on that merger you're thankful that litigation's done. There's some other litigation regarding Vytorin, which is actually a drug co-manufactured by those two companies. And so, you know, in terms of company combinations, I mean it's a toss-up what's going to happen, but certainly the companies have incentive to do things.

Effectiveness issues. The benefit of the bargain theories, you're seeing a lot more of the third-party payers come in and make arguments about not getting the benefit of the bargain. In Trasylol for example, which is a drug there's a lot of personal injury cases about, there's also an issue because it's so much more expensive. An injection of Trasylol might be $2000 or $3000 per injection versus an alternative that might cost $100 to $200. There's a lot of off-label use surrounding that particular drug by doctors in open-heart surgery, and the off-label use has really just caused the costs related to Trasylol to skyrocket.

States and third-party payers are motivated to make up revenue shortfalls in a bad economy. I think that's a very real thing. A lot of my clients, not just individuals, I also represent attorney generals in litigation, and, you know, many of them are looking around with budget cuts, and they've got to figure out ways to make sure they're collecting all the potential revenue and protecting the state's dollars, some of which is protecting state health plans that are spending money on these drugs. And so that's what I'll leave you with. Thank you.