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Preemption: A Physician's Friend or Foe?

WHY DOCTORS SHOULD WORRY ABOUT PREEMPTION

Our presidential election is only days away. Forty eight million people in America are uninsured and healthcare costs are rising two to three times faster than our nation's GDP. Where will America's healthcare system be in 5 years?

Welcome to ReachMD's monthly series focussed on public health policy. This month, we explored many questions facing healthcare today.

According to a recent article published by the New England Journal of Medicine, drug companies and medical device manufacturers can be effectively immunized against Tort Litigation if the Food and Drug Administration have approved their products. This protection is granted under legal doctrine known as preemption.

You are listening to ReachMD XM 157, the channel for medical professionals. Welcome to the Business of Medicine. I am your host Dr. Larry Kaskel and joining me today is Mr. Mark Herman, partner of the law firm, Jones Day and he defends drug and device companies in product liability cases. He also co-hosts a blog called the Drug and Device law blog.

Dr. KASKEL:

Mr. Herman, welcome to the show.

Mr. HERMAN:

I am glad to be here. Thanks for inviting me.

Dr. KASKEL:

I am looking for a new rumination to keep me up at night, but before adding one, I kind of like to know exactly what it is? So, what is preemption?

Mr. HERMAN:

At its simplest, preemption is really easy concept. It says if federal law requires you to do one thing, state law cannot require you to do the opposite. So, let's see as, you know, often it is in the constitution. The constitution says that if federal and state law conflict, then federal law is the supreme law of the land. What that means in the context of drugs and medical devices is that if the FDA requires a drug company to put a certain warning on a package insert, then may be state law that says that warning is inadequate, should be displaced. The FDA requires you to do something so that state can't tell you to do something different. That is preemption.

Dr. KASKEL:

Why, all of the sudden are we hearing all about preemption? Why is it such a hot topic right now?

Mr. HERMAN:

There are probably two answers to that question. One that is more abstract, one it is more specific. Sort of the abstract answer is that law over time, state law over time has begun to regulate drug companies more aggressively than it did in the past. That is 50 years ago, there were relatively few claims that people who said they were hurt by drugs, could make against drug companies; and now there are more legal claims that they can make. So, state law has become more regulatory over drug companies.

Dr. KASKEL:

Well, I am confused a little, because you said earlier that federal takes precedence over state law that if it is approved by the FDA, then the states can't do anything?

Mr. HERMAN:

Right and what we are seeing increasingly over time, the reason why preemption is becoming a hot topic is because in the past, federal law and state law did not collide because state law did not put too many obligations on drug companies and because the FDA did not historically, you know, in 1906, the FDA was not putting too many obligations on drug companies. Today, state law is putting more and more obligations on drug companies and the FDA is increasingly putting obligations on drug companies. So, today they start running into each other. Today, you are seeing the clash between state and federal law that is what triggers preemption.

Dr. KASKEL:

So, are the manufacturers and big pharma in court pretty much every day now as compared to before?

Mr. HERMAN:

Sure. I mean 20 years ago, you were not hearing about the sorts of cases you are hearing, I mean just, just speak the word, for example Vioxx and everybody know which the drug companies are in court every day that simply was not true 20 years ago. Those sorts of mass tort cases against drug companies didn't exist; and in fact, now it's reached the point where these cases have gotten to

the US Supreme Court and that really is why preemption is such a hugely hot topic today, which is the Supreme Court decided a preemption case for medical device companies in February 2008 and the supreme court will be hearing argument in a preemption case involving a drug company in November 2008. So, all of a sudden, this really is a hot topic because you are finding out from the Supreme Court, what the law is going to be.

Dr. KASKEL:

Are you allowed to talk about Vioxx cases?

Mr. HERMAN:

In the abstract, sure.

Dr. KASKEL:

Okay, so, did they get to qualify under preemption that they had whatever listed what they did with the FDA and so the states could not go after them?

Mr. HERMAN:

Vioxx made the argument in a trial court, was unsuccessful in the argument in the trial court and then settled all of its cases, and now the Supreme Court will be hearing argument this November and probably speaking sometime in the first half of 2009, as to whether or not there is preemption and at that point, if they are any remaining Vioxx cases depending on what the Supreme Court says, Mark may or may not be back in court arguing preemption again.

If you have just tuned in, you are listening to the Business of Medicine on ReachMD XM 157. I am Dr. Larry Kaskel. My guest today is Mark Herman, a partner at Jones Day and he defends drug and device companies in product liability cases and we are talking about why doctors should worry about preemption.

Dr. KASKEL:

Why do I need to worry about it. How does it affect me in my daily practice, Mark?

Mr. HERMAN:

Theoretically, it should not, that is this is all about the relationship between drug and device companies and plaintiffs who are suing drug and device companies and it shouldn't affect the physician at all because the claims against the physician if there are any would be entirely distinct, but I have certainly heard some physicians speculate that if you can't sue the drug company, then the only pocket book left standing is the doctor and so that there would be a chance that if there is preemption, there would be more cases against doctors. On the other hand, I have heard other people speculate that if you couldn't sue the drug company, the whole field of practice might be a

little less attractive for plaintiff's lawyer and there might be fewer cases against doctors. So, I don't know which way it will go or if there will be a change, but people are paying attention to it because they think there might be sort of tangential implications of what the Supreme Court does in terms of preemption.

Dr. KASKEL:

But, as of today, are there any cases against the physician yet that you are aware of?

Mr. HERMAN:

Cases against physician?

Dr. KASKEL:

The physician being sued when they were not able to go after a bigger pocket.

Mr. HERMAN:

You would never exactly know why they chose to go after the physician, right. Sometimes in cases the plaintiff's lawyer names both the physician and the drug companies. Sometimes the plaintiff's lawyer names just the physician; sometimes the plaintiff's lawyer names just the drug company. So, you can't get into the mind of the people who are making the decisions. I would guess that since the law is still unsettled at this point, people are probably filing law suits against everybody and seeing how it checks out.

Dr. KASKEL:

Mark, I want you to look into the future just a few months down the road. Do you think that it will matter, who is the President whether it is a republican or democrat in terms of what the FDA or the courts will do in terms of how view preemption?

Mr. HERMAN:

Well, the elections can change a couple of different things. They can change the presidency and you would guess that if you have replaced a republican President with the democratic President, then the President would be less receptive to preemption, but there are limits to how quickly that can make a difference that is the Supreme Court is going to hear the case on preemption in November, the administration is not going to change if it does at all until January 20, after November and at that point, all the President can do is appoint new people to the FDA, which wouldn't affect an already pending case or if somebody leaves the Supreme Court, appoint the new person to the Supreme Court, but that is unlikely to happen before this case is decided. So, the presidency won't matter. Congress people are paying lot of attention too because if congress is unhappy with the result in the Supreme Court case, it can pass a law to try to change what the Supreme Court did and obviously both the makeup of congress and whether or not it's still a <_____> whether or not it can override a veto could affect, whether or not congress could pass the law that would change the result of the Supreme Court case.

Dr. KASKEL:

Now, how active are the lobbyists in terms of affecting congressman from medical manufacturers and big Pharma?

Mr. HERMAN:

I don't have the numbers but I would guess that this is area of huge interest to people both on the side of the plaintiff's trial bar and for the drug and device industry and after the Supreme Court decided in February that for some categories of medical devices, the device companies would get preemption, those were introduced on both sides of congress, both in the house and in the senate to try to overturn that Supreme Court decision. So, there is no question that congress is looking closely, and I assume the lobby is just scurrying around.

Dr. KASKEL:

Mark, how exactly will those bills change the law?

Mr. HERMAN:

The Smart Money says that those bills aren't going to change anything in the short term because it is too near the end of the session in Congress. So, those bills aren't going to pass in 2008. So, why then were they introduced? and all you can do is speculate but it might just be a shot across the bow to tell the Supreme Court and the world that congress is looking at this, so everybody should pay attention. Then, if the Supreme Court goes away, Congress doesn't like and if new legislation is proposed in 2009, depends what they write and how they approach it.

Dr. KASKEL:

Mark, have you personally used preemption as your defense when you defend a manufacturer.

Mr. HERMAN:

Yes.

Dr. KASKEL:

And were you successful?

Mr. HERMAN:

I have used it in a number of different cases and have been successful more often than unsuccessful.

Dr. KASKEL:

And, so I guess my last question really after talking with you it doesn't sound like I need to be worried about preemption as a physician and the general physician out there listening doesn't need to be worried, but they should at least be aware of what preemption is?

Mr. HERMAN:

You can never predict the unexpected side effects of things that will happen. If the law of preemption changes, perhaps it will somewhat change, how people view law suits against physicians, but that is just speculation. As a matter of theory, it really ought not to affect doctors at all because the FDA and drug companies they provide the medicine, but they otherwise don't affect the practice of medicine.

Dr. KASKEL:

Mark, can you talk a little bit about the case that is going in front of the Supreme Court; so we can kind of get an idea of what is playing out?

Mr. HERMAN:

Everybody has their eye on it. That is the 600-pound gorilla, the case is called Wyeth against Levine and it's going to be argued in November 2008. That case involved the anti-nausea drug, Phenergan and at the time the events underlying the law suit happened in 2000, the package insert for Phenergan warned in four separate places about the risk of gangrene if the drug was exposed to arterial blood. Diana Levine was a popular children's guitarist. I believe she might have actually been on some local television shows as a children's guitarist who went to a health center complaining about a migraine headache and nausea. The physician's assistant injected Demerol for the migraine and Phenergan for the nausea.

Dr. KASKEL:

All sounds appropriate, so far.

Mr. HERMAN:

Well, of course, since we are talking about it today, since there was a lawsuit.

Dr. KASKEL:

Something must have gone terribly.

Mr. HERMAN:

The Phenergan purportedly hit arterial blood, but in any event Levine developed gangrene and her right arm was amputated at the forearm for a children's guitarist.

Dr. KASKEL:

That is not good.

Mr. HERMAN:

Not good. She sued the physician. She sued the physician's assistant. She sued the healthcare center and she settled the malpractice case; and then she came back and she sued Wyeth saying that the warning was inadequate, even though the FDA had looked at the label and it had four separate warnings about the risk of exposing Phenergan to arterial blood. So, the question is can Wyeth be liable for giving an inadequate warning when the FDA approved the warning.

Dr. KASKEL:

It sounds like the warning was there for everyone to see. So, I don't see where there is a case there. If the warning is there, they should be able to hide behind preemption.

Mr. HERMAN:

They would argue that as a matter of public policy, preemption makes more sense that is as between having a jury that is sitting in the presence of an injured person decide whether or not a warning is right and having the FDA, which has physicians and Ph.D. and scientists sitting dispassionately looking at the risks and benefits of drugs that America is better served by having the FDA make that decision than having jurists make that decision, but that is a hot public policy controversy in addition to being a hot legal issue.

Dr. KASKEL:

Well Mark Herman I truly enjoyed talking to you today, thanks for coming on the show.

Mr. HERMAN:

Thank you very much for inviting me.

Our guest was Mark Herman, partner of the law firm, Jones Day and we were discussing preemption and whether or not doctor need to worry about it. I am Dr. Larry Kaskel and you have been listening to Business of Medicine on ReachMD XM 157. We would like to hear from you if you would like to give us your comments or suggestions please visit our websites www.reachmd.com, once there you can download any of our on demand podcasts and listen to them day or night. If you like to reach us by phone now, we are available at 188-MDX-M157 and thanks for listening.

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