

## Medmarc Loss Control Podcast Transcript:

### Off-label Promotion - Allergan's Preemptive Strike Against the FDA

**Erlisa King:** This podcast features attorneys Lauren Tulli and Terry Henry. Terry leads Cozen O'Connor's Live Sciences Team. He is co-chair of Cozen O'Connor Industry Team, and chair of Cozen O'Connor's Live Sciences Practice Group. The focus of Terry's practice is on medical device and pharmaceutical clients. He has handled a variety of product-related claims in state and federal court throughout the country. Terry is National Coordinating Council for an orthopedic device manufacturer involving a series of cases arising out of design-defect allegations related to one of its knee replacement products. He is also National Coordinating Council for a medical device manufacturer in cases involving its pain pump. Lauren is also a member of Cozen O'Connor's Life Sciences Team. Lauren focuses her practice in the area of complex commercial litigation including dissent of pharmaceutical and medical device companies, products, liability, and aviation. Lauren is also developing a specialty in FDA regulation that is directly applicable to medical device cases, and will assist clients in their strategic planning for product development and in their dealings with the FDA. Today, Lauren and Terry will be discussing the Allergan versus United States of America case, which Allergan filed in an attempt to lift FDA restriction against promoting drugs for off-label uses. Most importantly today, we're going to be talking about the impact this case might have on the industry concerning off-label promotion. Terry, Lauren, thanks for speaking with my today.

**Terry Henry:** Erlisa, it's our pleasure.

**Erlisa King:** Great. Okay, so let's start with the basics. Can you explain to our listeners, what is off-label promotion?

**Lauren Tulli:** Erlisa, I can start off with that. We noticed that you had a webinar a few months ago on off-label promotion, so we can just generally carry over from that. The off-label use of a drug is one that is prescribed for a purpose that has not been approved by the FDA. The purpose here – the drug here – sorry – Botox, has been approved by the FDA for several indications, but it is also widely used for various other indications that have not been approved.

Once a drug is approved by the FDA, the physicians that prescribe these drugs are legally permitted to prescribe it for any use, whether it's approved use or a non-approved use. This occurs rather frequently. By the last estimation, which I believe was a report in 2006, nearly a quarter of prescriptions were written for off-label indications, and that percentage is even higher in some specialties. Oncology and Pediatrics are two, where the off-label indication is the only treatment available, or may be the only treatment available, and thus, it becomes the medically recognized standard of care for that illness or diagnosis, Terry?

Terry Henry: I was going to say I would agree with that, but I'd also like to add that the issue of off-label promotion also affects medical device manufacturers, too. So, the issues that the Allergan case raises are important across the spectrum for pharmaceutical manufacturers, manufacturers of biologics, and medical device manufacturers.

Erlisa King: Okay, great. Thank you for that clarification. Can you explain the controversy in Allergan versus the United States of America?

Terry Henry: Sure. The controversy in the Allergan case really involves the manner in which the government, and specifically here, the FDA, has identified the term, or defined the term "promotion" through its various regulation and enforcement action. More precisely, Allergan asserts that the FDA has expanded the definition of label or labeling far beyond what Congress ever intended to such an extent that it is an unconstitutional restriction on Allergan's right of free speech and as Allergan defines it, truthful, scientific speech. Would you agree with that, Lauren?

Lauren Tulli: I do agree with that, but I think it's also worth mentioning that under the current regulations, the physicians are free to prescribe any drug as we said, but it's important to note that the manufacturers of those drugs are not permitted to communicate to the medical community, the information that relates to those non-label drugs – off-label drugs. So, there are certain safety – pieces of safety information involving risks and benefits that these physicians don't have as part of their decision-making process when determining that this is an appropriate drug for their patients. That is something that they're prohibited from learning from the manufacturer according to the present regulations.

Erlisa King: Okay, that's interesting. Well, what prompted Allergan to file this complaint in the first place?

Lauren Tulli: Well, I think that it's fair to say that the suit was initially – which by the way, seeks declaratory relief. So, Allergan filed this suit, and I think it's fair to say that it was prompted by a requirement, or a mandate issued by the FDA called a REMS. That's something – REMS – that's a Risk Evaluation and Mitigation Strategy, and it's something that the government instructed Allergan to implement, which would be a program that Allergan used to specifically discuss some aspects of off-label prescriptions with the doctors, or the medical community. Of course, in responding to this REMS, Allergan is put in a difficult position, because it is their feeling that by complying with the REMS, or the FDA's mandate, that they will be subjecting themselves, or exposing themselves to fines, and criminal penalties, because they will be found to have violated this prohibition against promoting off-label uses. Terry, is that your impression?

Terry Henry: I think it's also important to note that Allergan does have important commercial interests at stake here. Products, or I guess better said, uses for Botox that are in the pipeline, but not yet approved by the FDA. So, to the extent that it can provide truthful, scientific evidence or information to physicians, those physicians would have better information available for them. It would be more comfortable prescribing Botox for the unapproved uses, and that obviously would have additional benefits to Allergan.

Erlisa King: Okay. Well, what's the government's position in this case?

Terry Henry: Well, the government has had any number of responses to the specific allegations raised by Allergan. The first one though, is that the issues simply are not ripe yet – that Allergan has not uttered, or hasn't made the speech that Allergan fears they would be prosecuted. So, there's no immediate, justiciable issue for the court to decide. That's the initial prestige goal approach the government has taken, but more substantively, the government's response is that the FDA has carefully constructed its current regulatory and enforcement scheme in order to protect the public from unsafe and ineffective drugs, biologics, or medical devices, and that the system works; the public shouldn't fear the government overstepping into unconstitutional areas, and that if Allergan is successful in any aspect of that regulatory scheme is



eroded, that it would quite literally turn the clock back 100 years to the day that the snake oil salesman on the street corner. So, that's the position that the government takes that you pull out one card, and the whole house of cards falls down, essentially exposing the public to the evil pharmaceutical company promoting their drugs, and biologics, and medical devices for essential any reason.

Erlisa King: Okay, well further to that point, if Allergan prevails, how would this outcome affect the pharmaceutical and medical device industries directly?

Lauren Tulli: Well, I think the effect, at least from Allergan's perspective, would be that patients in the medical community – the public at large – would finally have full access to the information that it needs, that the physicians need, to make appropriate treatment decisions for their patients. That would be risk and benefit information; dosages information; in the context of Botox, injection information so that certain specificities can be appropriately treated by way of injection. These are pieces of information that presently, Allergan, who holds the best information obviously, because it's a drug that they manufacture, and have tested, Allergan is presently unable to provide this information to the medical community, and to the physicians who are prescribing Botox for these indications. So, if Allergan prevails, with respect to Allergan's drugs, this is a major win for any patient who would be benefiting from the various treatment options that Botox can make available, including some new options in the pipeline, such as treatment for migraine headaches. But it's also worth saying, in response to Terry's rendition of the government's position in this case, that this idea that the case is not ripe at this point is something that is nonsensical, because the – it doesn't make sense that Allergan would have to first expose itself to criminal prosecution before a court could consider its case. We know that's not realistic, because recently, several pharmaceutical companies have been hit, or have paid – I should say – extremely large, multi-billion dollar verdicts for enforcement actions for these types of alleged offenses. So, we know that this is an issue that the government is taking very seriously, and has actively begun to address, and Allergan is just preemptively asking for direction before it becomes – it faces the same fate.



Terry Henry: You know, I think it's really difficult at this stage to predict what will happen if Allergan wins, because there are any number of ways that Allergan could win; yet, the government may be left with some enforcement tools. If in fact Allergan gets a flat out win, and the FDA enforcement ability is essentially rolled back to only enforcing the printed material that a company, a drug, a biologic, or medical device, then really, it does open up the floodgates for what medical device and pharmaceutical companies – what information they can present to the public, and then it's going to impact other doctrines that's out there such as the learned intermediary doctrine, and whether that will continue to be a viable doctrine. We've already seen it erode somewhat, because of direct-to-consumer advertising, and so there's any number of, I guess, results that could occur, depending if Allergan wins or not. It's just a little, I think, premature to figure that all out.

Lauren Tulli: I agree. It's premature.

Erlisa King: Okay, Lauren and Terry, thank you so much for your time today, and most importantly, thank you for your willingness to share your insight on this very interesting, and timely topic.

Lauren Tulli: Our pleasure.

Erlisa King: If our listeners would like to learn more about this topic, please visit [medmarcprotect.com](http://medmarcprotect.com). On the website, you will be directed to a landing page that will feature a companion webinar presented by Terry and Lauren, as well as other related materials. Again, thank you for joining us, and be sure to check back for additional podcasts.

[