November 14, 2016

FDA Holds Public Hearing on Manufacturer Communication of Scientific and Medical Information

Doug Hallward-Driemeier: I'm Doug Hallward-Driemeier, Chair of Ropes & Gray's appellate and Supreme Court practice. I'm here today with partner Kellie Combs and senior counsel Alan Bennett, from our FDA Life Sciences practice, to discuss this week's open FDA hearings regarding off-label communications. We've seen a growing concern among pharmaceutical and medical device manufacturers over the degree to which FDA regulates off-label communication. And, Kellie, you testified at the FDA open hearings on November 9, on behalf of the Medical Information Working Group, a coalition of more than a dozen drug and device manufacturers seeking changes to FDA's regulatory scheme. So, tell us about the hearings, about your testimony, and whether you think it was a significant step toward meaningful reform.

Kellie Combs: Sure, Doug, I'd be happy to. The MIWG has been urging the FDA for nearly ten years now to clarify its regulatory framework governing manufacturer speech, and in 2014 the agency actually promised to issue guidance later that year, in four critical areas: scientific exchange, payer communications, responses to unsolicited requests and dissemination of clinical practice guidelines. So, the agency also promised, at that time, to engage in a comprehensive review of its policies to determine whether any revisions were necessary in view of First and Fifth Amendment limitations. Unfortunately, more than two years have now passed, and we haven't had any meaningful action from FDA. So, at the hearing, we emphasized that because off-label use is common that it's absolutely essential there be clear pathways for manufacturers to actually provide scientific and medical information about those off label uses to healthcare professionals and to payers. And, then we also described the First and Fifth Amendment principles that the agency needs to be mindful of in this space. In particular, that FDA can't restrict manufacturers from providing truthful and non-misleading information, even if it is off-label, unless those restrictions are clear, precise and narrowly drawn to advance a compelling interest. And, then finally, we urged the agency to issue those four overdue guidance documents immediately so that industry could finally have clarity on how to communicate in those areas and so that valuable information could be shared to inform treatment decisions.

DHD: And I know that you had prepared remarks, as did the other speakers, but I also know that, somewhat unexpectedly, it was a fairly live active panel from the FDA, and so they were asking questions. So, did their questions give you any hint of where you think FDA is going with this?

KC: You know, I think I and many of us were pleasantly surprised at how engaged the agency actually was. The panelists asked really thoughtful, substantive questions of almost all the speakers, and it was really clear from the questions that the panel, number one, recognizes that there is value in off-label communications, and that additional clarity and flexibility is needed. But, number two, the panelists really appeared to be grappling with how to implement the clarity and flexibility that everyone knows is needed.

Alan Bennett: Kellie, I would add something to that. As you said, the panel was quite involved, and I think they were probing the outer boundaries of our arguments. Questions like do we view the rules for consumer audiences and professional audiences as the same, who judges what's true, and what's the appropriate standard for evaluating data are all designed to see how far free speech advocates are willing to push the arguments.

KC: Yeah, Alan, I think that's a really good point, and you know, Doug, I would be interested in your view on this. So one of the questions we heard repeatedly over the course of the two days, is that, you know the panel has expressed some concern that off-label communications could ultimately lead to patient harm, and that as a result there should be greater restrictions on the extent to which manufacturers could share off-label information. How would you respond to that concern?

DHD: Because I look at this from a constitutional perspective, I think that the FDA is looking at this sort of from the wrong angle. They're trying to ask what are the justifications for allowing the speech, when what the constitution requires is that you look at what are the justifications the government has to limit this speech. And, they're limiting speech that is actually quite valuable, and, as a consequence, doctors are less informed as they make decisions about their patient care than they should be. But the fact that the speech is First Amendment protected doesn't mean that the government doesn't have any role to play, or that all speech, necessarily, is going to get out, even really unfounded claims. The government has a role, but it has to justify restrictions. And right now what the government is doing is imposing limitations on manufacturers' ability to speak, such as requiring they have two well-controlled randomized trials for anything they want to say, that the government itself does not apply to its own speech. FDA, CDC, ACIP, all rely on much different evidence and much lesser forms of evidence than it demands of the manufacturers, and that is what the First Amendment really doesn't allow, is that the government assigns itself the role of arbiter of truth, and setting up a rule that manufacturers can't speak unless the government allows it to. So I think that the meeting is going to be very important, to the extent that it sort of really compels FDA to grapple with that. I wanted to turn it back, though, to Alan, because you've been at this for 25 years. You have seen a long history of development here. I want to get your sense of where we have we come from, and where do you see this going.

AB: Well, it has been a long while, Doug, and it's interesting to look back. I think you have to look at that question in a couple of different ways. As a strictly regulatory matter, change, in fact, has been minimal over the last 25 years. FDA's policies haven't budged, and the agency strongly resists efforts to modify those policies and guidance, regulation or law. I would say, at a more practical level, the agency's interest in forcing some of those policies has been curtailed in recent years, in certain circumstances. For example, if a company has strong, adequate and well-controlled studies about an endpoint that's consistent with the label, it might consider options in a way that it might not have 5 or 10 years ago. While the regulatory scheme has not budged much, on a policy level I've never seen the agency under such immense pressure to make changes. Some of this comes from the way information is disseminated today, and the increasing need for information from physicians, from doctors, from payers. But we also can't forget the outside pressure that the courts are bringing by applying First Amendment principles to the regulatory system. I don't think the current set of rules and policies can survive. A new system is being born, based on truthful, non-misleading speech accompanied by adequate disclosures, but we don't know yet exactly what the contours of that system will be. That will make the next several years quite interesting for those who practice in this area.

DHD: Interesting, indeed, and we will keep you informed of future developments. Thank you, Alan and Kellie, for sharing your insights, and thank you for listening. Please visit Ropes & Gray's FDA regulatory page at www.ropesgray.com for additional insights and developments.