Caronia, The Latest

Wednesday, August 31, 2011

The moment we saw the Supreme Court's First Amendment decision in Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011), we knew it had implications for the FDA's suppression of truthful commercial speech concerning off-label uses, and we said so. Not only that, the dissent in Sorrell caught the FDA angle, too. Id. at 2678. Only the dissenters didn't like it – we did.

It appears that the first place that the Sorrell rubber is likely to meet the off-label promotion road is in our old friend, the Caronia case, which has been on appeal in the Second Circuit for what seems like forever. As readers may recall, Caronia was an FDA "sting" where a doctor, wearing a wire, affirmatively sought out off-label promotion, and (through the manufacturer's representative (Caronia)) drew another doctor (Dr. Gleason) who worked for a drug company, into a discussion of an off-label use. Both the other doctor, and the rep, who facilitated the conversation, were prosecuted. Nothing false was said, but the government went ahead anyway, and obtained a conviction.

Caronia had already been argued after Sorrell was decided. The court (we think) on its own motion asked for additional briefing on Sorrell. Those briefs were filed this past week. The government's brief – arguing in favor of criminal suppression of truthful promotion of off-label use – predictably takes the position that Sorrell doesn't change anything. Since we like to gripe, we'll spend most of our time on that one.

According to the government, the speech, even if truthful, wasn't itself banned, but was merely used as "evidence of intent." U.S. br. at 1. Sorell was just more of the same, the government argued, simply another application of the Central Hudson test, and the court should ignore the Supreme Court's references to "heightened" judicial scrutiny:

> "Read in this context, the Supreme Court's references to "heightened judicial scrutiny" do not reflect a decision to abandon intermediate scrutiny in favor of a still more demanding level of judicial review. Instead, the term simply means a more rigorous form of judicial review than the rational-basis review employed by the First Circuit and urged by Vermont. The Court's opinion makes clear that "heightened scrutiny" encompasses not only strict scrutiny, but intermediate scrutiny as well."

U.S. br. at 5. The Court's "heightened" scrutiny reference "singles out," the government claims, Cincinnati v. Discovery Network, Inc., 507 U.S. 410 (1993), which was a Central Hudson intermediate scrutiny case. U.S. br. at 5-6.

The only trouble with that last statement is that it's far less truthful than anything the defendants were prosecuted for in Caronia. We took a look at Sorrell, and Cincinnati was one of five, count 'em, five cases cited to support the Court's "heightened scrutiny" statement. See Sorrell, 131 S. Ct. at 2664. The other four, Turner Broadcasting System, Inc. v. FCC, 512 U.S. 622, (1994); United States v. Playboy Entertainment Group, Inc., 529 U.S. 803 (2000); Simon & Schuster, Inc. v. Members of New York State Crime Victims Board, 502 U.S. 105 (1991); and Minneapolis Star & Tribune Co. v. Minnesota Commissioner of Revenue, 460 U.S. 575 (1983), all suffer from the same problem, from the government's perspective – they don't even mention Central Hudson. So, by a Phillies-like 4-1 score, in the actual opinion, strict scrutiny prevailed over intermediate scrutiny.

Next, the government argued that, even if more scrutiny than Central Hudson was required, it still doesn't matter.

Remember that. What that means is that, from now on, we're getting the government's position on so-called "strict scrutiny" - which is how restrictions on things such as political/religious speech are evaluated.

The government's positions are positively retro - as in 1984.

Under strict scrutiny, the would-be speech suppressors distinguish between a conviction for "conspiring to promote off-label uses" (supposedly not what happened) and a conviction for "conspiring to distribute [the drug] without adequate directions for use." U.S. br. at 6. That's a distinction without a difference. An ancient FDA regulation (substantively unchanged since the 1950s), 21 C.F.R. §201.128, equates one with the other. Promoting (truthfully or otherwise) off-label automatically changes the "intended use," and the new "intended use," since it's off-label, by definition doesn't have "adequate directions for use." The government's position seems uncomfortably close to an argument that "conspiring" to advocate, say, medicinal marijuana, could be equated, through regulatory hocus-pocus, to selling pot.

Building on its distinction without a difference, the government tries to describe the "adequate directions for use" language as creating some sort of "disclosure statute." U.S. br. at 7. What would the government have these defendants disclose about off-label use? Somehow, we don't think there's any additional "disclosure" that either defendant could have made that would have kept them out of jail – the more they said, the more they would get into trouble. The only "disclosure" one can make about off-label use (if one works for an FDA-regulated company) is to say nothing. Disclosure = silence; love = hate.

In another sleight of hand, the government argues that the prohibition is not "content based" for purposes of strict scrutiny because there is no "official hostility to the manufacturer's message." U.S. br. at 8. That's contradicted, we suspect, by every Central Hudson brief the government has ever filed on the question of off-label promotion. Of course there's "official hostility" to off-label promotion. It's the "substantial government interest" that the government claims is advanced under the Central Hudson test. The FDA is institutionally opposed to off-label promotion because it believes that to allow such speech (truthful or otherwise) reduces the incentive for companies to get new uses approved by the FDA. The FDA's entire regime is based on "official hostility." Off-label promotion strikes at the FDA's bureaucratic *raison d'être*.

Then the government inserts the other foot, claiming that its speech suppression isn't even "speaker-based." U.S. br. at 8. They put the man in jail, didn't they? How more speaker-based can you get? Supposedly the FDA's regulations aren't "limited by their terms" to certain speakers, so they can constitutionally be used to convict particular speakers, even under strict scrutiny. Id. The government seems to believe that it can suppress speech all it wants if it does so vaguely enough. Oh, and if it's not "speaker based," how come everybody in the universe not affiliated with a regulated entity (even us, if we wanted) can put their uninformed two cents in on this or that off-label use, but only FDA regulated speakers (probably the most knowledgeable) can't? That seems pretty "speaker based" - and dumb - to us.

Next, the government offers the following "distinction" from Sorrell: "The Vermont law restricted the dissemination of information. In contrast [the federal act] requires it." U.S. br. at 9. When we picked our jaws off the floor, we had to laugh. These defendants were convicted because they opened their mouths, not because they didn't. Later (in a different section of its brief), the government even states, "the court did instruct the jury that '[t]he manufacturer, its agents, representatives and employees, are **not permitted** to promote uses for a drug that

have not been cleared by the United States Food and Drug and Administration.'" Id. at 12 (emphasis added). "Not permitted" sure sounds like a "restriction" on "dissemination" to us. Arguments like this - that the FDA's total prohibition (outside of certain narrow categories) of off-label promotion is not a "restriction" on "dissemination" - is the kind of stuff that gives lawyers a bad name.

The government next tries to scare the court by demonizing off-label uses. They are "unapproved," "unproven," and "potentially false." U.S. br. at 10. But not actually false, and doctors engage in off-label use every day. We don't know about this particular use, but the government – through Medicare/Medicaid – actually pays for a large number of off-label uses. The promotion of off-label use is no more unsafe or false (and probably less so) than the promotion of various "dietary supplements" we see us every time we turn on, say, the Weather Channel (which we did a lot recently).

Then, after discussing non-First Amendment issues, the government circles back and goes after off-label use again. We see more scare tactics – using DES (used off-label to prevent miscarriage) as an example of a harmful off-label use. U.S. br. at 14-15. But DES was FDA approved without the "breast cancer" risk ever being discovered (it was before the 1962 FDCA amendments, for one thing). And, as defense lawyers in prescription drug products liability litigation, we'd be remiss if we didn't point the number of on-label uses for drugs that the other side alleges cause breast cancer or other potentially fatal injuries.

Certainly, there's "no assurance" that an off-label use is safe or effective. U.S. br. at 16. But every drug on the market was originally an off-label use – before it was approved. That lack of "assurance" doesn't make any particular use less safe the day before the FDA approves it, than it was the day after.

Then the government states that the "new and qualitatively more reliable" information generated by FDA clinical trials "would never become available" if manufacturers could promote off-label uses. U.S. br. at 17. That's not true, either. The FDA could easily abandon its speech-based prohibitions and simply mandate that off-label uses attaining some specified threshold of frequency **must** be submitted to the FDA for approval. Not only would that be more effective, it would suffer from no constitutional deficiencies.

Finally, the government claims the FDA isn't criminalizing "speech qua speech" because under the law it has to prove something else as well. U.S. br. at 20. What's that something else that's supposedly sufficient to satisfy strict scrutiny? Introduction into interstate commerce. Id. Wow, if that's all it takes to make any speech ban constitutional, I would hate to be a network broadcaster.

Defendant Caronia also submitted a brief, pursuant to the court's direction. Guess what? We like it better than the government's brief. It emphasizes that the government's parade of horribles simply isn't implicated where the speech in question is true. "The "typical" neutral justification for "why commercial speech can be subject to greater governmental regulation than noncommercial speech" is the "concern for fraudulent or misleading statements in commercial transactions." Caronia br. at 5. Sorrell, of course, was all about "truthful" speech. Id. at 9 (quoting Sorrell, 131 S. Ct. at 2671).

Caronia then argues that the FDA's suppression of truthful off-label promotion was "content based" and "speaker based" just as was the governmental attempt to restrict on-label detailing in Sorrell. Any other medical doctor would have been perfectly free to discuss off-label use with a colleague if not affiliated with a drug company. Caronia br. at 9. Like the detailers in Sorrell, a company-affiliated physician was within "a narrow class of disfavored speakers." Id. And, like the restriction in Sorrell, it was also viewpoint based. If either of the defendants had said "don't do that," instead of "do that" (assuming that's what happened), neither would have been criminally prosecuted. Id. at 9-10. We'd have hoped that was so obvious it didn't have to be stated, but apparently it does. Nobody's ever been prosecuted either for warning against off-label use (although in the past the FDA has sometimes taken the position, albeit not in court, that warnings are "promotion") or for simply knowing about it without speaking.

Caronia then equates the banning-too-persuasive speech rationale of Sorrell with off-label promotion, Caronia br. at 10, calling the similarities "striking." Id. We probably wouldn't go that far, because the FDA bans all off-label promotion, whether it's persuasive or not, but we do agree fully that what was unconstitutional in Sorrell and the similar problem with the speech ban in Caronia stem from the same root – that pharmaceutical promotion is constitutionally protected speech. Nor is it just us being biased (which we freely admit to being) – as we mentioned at the beginning of this post, the Sorrell dissenters make the connection, too. Frankly, we think the off-label ban is worse (as does Caronia, br. at 11), because it's criminal

and because it's more overtly tied to the content of the information than were the restrictions on use of data in Sorrell.

And this just in - A group called the Medical Information Working Group also filed an amicus brief in Caronia. We want to get this post done, so as to the substance we'll just say "what they said." The MIWG brief is, in fact, closer to our First Amendment position than either of the parties' briefs, even Caronia's. What might be even more significant than the legal argumentsit makes, is the makeup of the MIWG - eleven major pharmaceutical companies. Finally, the big boys have had enough and are getting into the ring. Rather than let their rights be determined in appeals of criminal prosecutions selected by the government, we're hoping to see big pharma pick the First Amendment playing fields from here on out.

Anyway, let's not forget that the Supreme Court in Sorrell resolved a First Amendment circuit split – affirming a pro-First Amendment ruling by the Second Circuit. It's not lost on us that Caronia is also in the Second Circuit. We're hoping that the Second Circuit, having received the Supreme Court's good-jurisprudence seal of approval in Sorrell, sees fit to build on its First Amendment precedent in this area by reversing the conviction and holding unconstitutional the FDA's outright suppression of truthful promotion of off-label uses.

Finally, thanks to Rich Samp of WLF and attorneys at Ropes & Gray (representing MIWG) for providing us copies of the Caronia briefing - since PACER inexplicably doesn't include most appellate briefing.