First Amendment Toolkit

Thursday, September 01, 2011

Thursday is normally the day for our longer and meatier posts. However, the crush of business at the moment really is a crush. So we're putting up something today that, frankly, doesn't require as much work. Yesterday we provided our opinions about the latest First Amendment briefing in the Caronia off-label promotion case. We remarked that we were gratified that the industry itself – instead of just interest groups (kudos to the Washington Legal Foundation for engaging in a fairly lonely battle on this issue for years), criminal defendants, and miscellaneous bloggers like us – appeared to be getting into the game.

Our desire to see more First Amendment challenges to the FDA's suppression of truthful commercial speech in this area is tempered by a countervailing concern not to see any newcomers screw up the law. Large companies with correspondingly large cases and large legal budgets, we don't worry about much, but many FDA regulated entities whose free speech rights are being chilled by the threat of FDA enforcement aren't so big.

So we've decided to do our bit to help by collecting the best First Amendment/off-label use litigation references that we know about and offering the here. That's our toolkit.

First, some cases. For anyone even thinking about an FDA-related First Amendment challenge, the Supreme Court's decisions in Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011), and Thompson v. Western States Medical Center, 535 U.S. 357 (2002), are absolutely required reading. The relevant test, at least up until Sorrell, was stated in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557, 566 (1980).

There are too many lower court opinions to cite them all, but a good place to start is with WLF v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998), partially mooted, 202 F.3d 331 (D.C. Cir. 2000), and WLF v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999), which are really part of the same case. Not as closely on point, but from an appellate court is, Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). In the same category as Pearson we'd put Alliance for Natural Health U.S. v. Sebelius, 714 F. Supp.2d 48 (D.D.C. 2010). The District of Columbia federal courts are a frequent forum for litigating FDA issues, and they've been pretty friendly to the First Amendment so far.

There's also a helpful discussion of the issue in United States v. Caputo, 517 F.3d 935 (7th Cir. 2008), but it's *dictum*.

It's not all sweetness and light though, as the district court decision being appealed in Caronia demonstrates, United States v. Caronia, 576 F. Supp.2d 385 (E.D.N.Y. 2008).

And finally, it has nothing to do with the First Amendment, but Richardson v. Miller, 44 S.W.3d 1 (Tenn. App. 2000), has what we'd describe as the most thorough discussion of off-label use by a court in a non-regulatory context.

Second, some briefs. Here are some briefs that not only make the right legal arguments, but collect a lot of the relevant factual material needed to support a serious First Amendment challenge. Perhaps the best of the bunch – at least those we know of – is the preliminary injunction brief filed by Allergan in its regrettably settled litigation against the FDA. It's what one would expect from an actual party to litigation backed by the resources of an AmLaw top 50 firm. With the industry coming on board, we're hoping to see more.

Then there are sophisticated amicus briefs. Most recent, of course, is the Medical Information Working Group amicus brief in Caronia that we discussed yesterday. The WLF's amicuss brief at an earlier stage in Caronia is also quite comprehensive and useful. A bunch of groups signed on to support Allergan in its litigation; their brief compiles lots of useful regulatory and medical sources about off-label use. The *amicus* brief that Bexis filed in Caputo on behalf of WLF ain't too shabby either.

Third, some law review articles. The newest thing we know of is, LaSalle, "A Prescription For Change: *Citizens United*'s Implications For Regulation Of Off-Label Promotion Of Prescription Pharmaceuticals," 19 J. L. & Pol'y 867 (2011), although we caution that the legal approach it recommends pushes the envelope somewhat. We were consulted by the author, so we have a pre-publication copy online here.

A couple of fairly recent treatments, heavy on the regulatory side, are Gentry, "Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion Prosecutions," 64 Food & Drug L.J. 441 (2009) (the author sent us a link, here), and

Leghorn, et al., "The First Amendment & FDA Restrictions on Off-Label Uses: The Call for a New Approach," 63 Food & Drug L.J. 391 (2008).

We're also partial to Hall & Sobotka, "Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review under *Greater New Orleans*," 62 Food & Drug L.J. 263 (2007) (available here), especially since Professor Hall loaned it to Bexis in pre-publication form for use in his in his Caputo brief.

For more about policy and less about law, check out: Osborn, "Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific & Medical Information," 10 Yale J. Health & Pol. L. & Ethics 299 (2010), Dresser & Frader, "Off-Label Prescribing: A Call For Heightened Professional & Government Oversight," 37 J.L. Med. & Ethics 476 (Fall 2009), and Fritch, "Speak No Evil, Hear No Evil, Harm the Patient?: Why the FDA Needs to Seek More, Rather Than Less, Speech From Drug Manufacturers On Off-Label Drug Treatments," 9 Mich. St. U. J. Med & L. 315 (2005).

Another good, if old, place to look is Smith, "Avoiding Awkward Alchemy in the Off Label Drug Context and Beyond: Fully-Protected Independent Research Should Not Transmogrify into Mere Commercial Speech Just Because Product Manufacturers Distribute It," 34 Wake Forest L.R. 963 (1999).

Finally, they're a little long in the tooth right now, but back before he started blogging, Bexis wrote law review articles. Blackwell & Beck, "Drug Manufacturers' First Amendment Right to Advertise & Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory," 58 Food & Drug L.J. 439 (2003), has a good discussion of the issues, especially alternatives to the FDA's speech ban, and also some things to watch out for in bringing these sorts of actions. His even older article (the first law review article ever that really discussed off-label use in depth), Beck & Azari, "FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 Food & Drug L.J. 71 (1998) (available here), isn't First Amendment-centric, but is still a decent source for general information on off-label use and the regulatory scheme. *Debunking* has also been cited a lot, so it can be a fruitful springboard for finding more recent stuff.

Fourth, to give the other side its due, for the FDA's official view of off-label promotion, the best place to look is probably the Guidance on Reprint Practices. Other regulatory materials can be

located via the briefs or law review articles already discussed.

Fifth, and finally, if anyone's interested in our First Amendment musings, they are compiled here.

So you have are the resources, as best as we can supply them. So go forth and litigate. Maybe your case will be the one the Supreme Court ultimately takes.