



Interesting First Amendment Law Review Note

Thursday, July 21, 2011

A recent law review note, Kristie 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), copy here, puts an interesting twist on the First Amendment arguments against the FDA's ban against truthful promotion of off-label use. It analogizes between the FDA's vague and discretionarily enforced prohibition and the corporate campaign contribution limitations struck down in <u>Citizens United v. F.E.C.</u>, 130 S. Ct. 876 (2010). While the article was written before the Supreme Court's decision in <u>Sorrell v. IMS Health, Inc.</u>, 131 S.Ct. 2653, <u>slip op.</u> (2011), that <u>Sorrell</u> undertook review in a pharmaceutical detailing case that was more rigorous than your usual <u>Central Hudson</u> commercial speech case (something we noted <u>here</u>) provides additional basis for the author's analogy to <u>Citizens United</u> - a non-commercial speech case.

The note also discusses the <u>U.S. v. Caronia</u> case pending in the Second Circuit. That's the criminal case against a doctor - who happened to be working for a manufacturer - convicted of talking to another doctor (a government informant, as it turns out) truthfully about an off-label use. We've been following <u>Caronia</u>, most recently <u>here</u>, so we thought we'd see what's up. Turns out that, after oral argument, the Second Circuit ordered supplemental briefing on the Supreme Court decision in <u>Sorrell</u> (in which the Second Circuit was affirmed). That order was entered on 7/14/11, and the briefing has yet to be filed.

We mentioned in our <u>own post</u> on <u>Sorrell</u> how that decision implicated the FDA's off-label speech ban. Evidently the Second Circuit also thinks that it might.

Eventually, the Supreme Court will have to decide the First Amendment issues discussed in the note (and here). Conceivably <u>Caronia</u> could be that vehicle.

If and when it does, we think that the FDA will lose.