Industry Tries Again For Clarity Concerning Off-Label Promotion

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With the ink barely dry on the Supreme Court's recent decision that pharmaceutical detailing is First Amendment protected commercial speech, see Sorrell v. IMS Health Inc., ___ U.S. ___, 2011 WL 2472796, at *8 (U.S. June 23, 2011), the industry is trying again for clarity in the morass that is the FDA's current regulation (if it can be called that) of off-label promotion.

Earlier this week, seven large drug/device manufacturers (Allergan, Eli Lilly, J&J, Novartis, Novo Nordisk, and Sanofi-Aventis) filed a Citizen Petition with the FDA demanding that the Agency replace its current mish-mash of non-binding guidance documents, letters, press releases, criminal plea agreements, and just plain tea leaves with real, live regulations concerning several aspects of off-label promotion. These aspects are:

(1) Manufacturer responses to unsolicited requests from health care providers (Petition at 5-7);

(2) Scientific exchange with the medical community (Petition at 7-10);

(3) Communications about off-label uses with formulary committees, third-party payers, and the like, necessary for reimbursement purposes (Petition at 10-11), and

(4) Manufacturer dissemination of clinical practice guidelines prepared by third parties (Petition at 11-12).

Since we also write on off label issues, we'd also like to point out that the Citizen Petition contains an excellent synopsis of the regulatory and medical background against which off-label use takes place (Petition at 3-4). There are a lot of useful cites here - and we're not above a little plagiarism.

All the legal uncertainty concerning off-label promotion has generated hordes of litigation, both civil and criminal. First the government shakes down industry under threat of criminal conviction and debarments. Then the False Claims Act trolls pile on, demanding that industry pay all over again, with a huge chunk for them. Finally, the third-party payers do the same – seeking recovery of drug costs, regardless of whether the off-label uses were safe, effective,

and/or medically indicated.

This Citizen Petition is a signal that industry is sufficiently fed up with the three-ring litigation circus to take formal action that does something about it. Hooray for that; it's been a long time coming.

That said, don't expect quick results. Rather the Petition marks the beginning of a long administrative process. But as long as it is pursued, at long last the FDA is going to have its superintendence – or more properly, lack of same – of this area subjected to outside review. That's because, if the petition is denied, that denial is judicially reviewable. See 5 U.S.C. §706; 21 C.F.R. §10.30. Alternatively, if the petition is granted and rulemaking follows, those regulatory proceedings will also be subject to review. E.g., 21 C.F.R. §10.40.

While the Citizen Petition itself, at this early stage, does not mention the First Amendment, we fully expect that free speech issues will be addressed as this process continues. Eventually, the FDA is going to have to come up with rational, and constitutional, regulations to govern off-label promotion.