Can We Still Be Friends? FDA and Pacira to Settle Lawsuit Relating to Off-Label Promotion?

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Taking a page (or lyric) from Todd Rundgren's 1978 song, "Can We Still Be Friends," it looks like the government, namely, the Food and Drug Administration and Department of Justice, and Pacira Pharmaceuticals, are looking to settle a pending lawsuit, whereby Pacira is challenging FDA's restrictions on the company's promotional efforts. According to the U.S District Court hearing the case, the parties have extended the deadline by which the government must respond to Pacira's lawsuit, indicating that they are looking to settle the case completely or narrow the dispute, which focuses, primarily, on promotion of off-label promotion. We discussed the *Pacira* lawsuit[1] in our last Newsletter, and we have written about the *Amarin* lawsuit[2], which was the precursor to this one.

Recently, in a rare move, FDA removed the Warning Letter issued to Pacira from the agency's website, suggesting settlement might be near, or at least is in discussions.

We won't re-review the facts of the *Pacira* case, as we have written about it previously. Furthermore, it's too early to predict exactly how this will be resolved. FDA is still smarting over the *Amarin* decision, and the *Pacira* case, being heard in the same court that decided the *Amarin* matter, would seemingly favor the drug company. However, FDA doesn't want to abdicate its ability to regulate drug promotion and wants to preserve the integrity of the new drug approval process. It doesn't want companies merely skipping the agency to market new uses by promoting off-label information and gaining market acceptance. It seems that FDA is looking for an out and to live for another day.

We have had many clients calling us post-*Amarin* and pending-*Pacira* to revisit promotional campaigns once thought a no-go as now a possibility. Several calls, from General Counsels or Compliance Officers, start, "Our CEO read about these cases [or your Bulletins]," "Our Board wants us to revisit," or "We are looking at a past idea," to assess the viability of a potential program where off-label information, frequently clinical data, will be proactively distributed. The discussions are now geared to "why can't we hand this to doctors" or "what do we have to do to make this material truthful and not misleading" (to paraphrase the *Amarin*'s court holding) and evaluating the risks in light of the recent litigation.

We remind them, as we remind you, that the cases settled and pending are fact-specific and are focused in one jurisdiction. We are not quite in Wild West territory, and we caution clients to consider FDA and non-FDA-related issues (*e.g.*, product liability, competitors, DOJ, states). We described these more in the aforementioned Newsletters, and we believe they still apply. While it might be possible to create material that will pass legal scrutiny, as we have tried with clients, it is important to remember that the "truthful and not misleading" standard seems to be the norm, however that might be interpreted, and merely distributing an off-label piece, without review, is not a good idea.

We will continue to follow these developments and update as needed.

1 http://www.agg.com/its-deja-vu-all-over-again--fda-sued-again-in-off-label-promotion-case-09-21-2015/
2 http://www.agg.com/Another-One-Bites-the-Dust-FDA-Doesnt-Like-the-Fishy-Smell-of-the-Latest-Court-Decision-on-Off-Label-Dissemation-08-19-2015/

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