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EXPERT ANALYSIS

The Problem of the 'Intended Use' Regulations Continues to Fester

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In 2015, FDA proposed revising the so-called intended use regulation (21 CFR 201.128; ***id***. § 801.4) to remove the famous "knowledge" sentence: "But if a manufacturer knows, or has knowledge of facts that would give him notice, that a [drug or device] introduced into interstate commerce ... is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug/device which accords with such other uses to which the article is to be put."

In the proposed rule, FDA indicated that removing the sentence was nothing more than a clarification "to better reflect FDA's interpretation and application of these regulations." At the time, we blogged very favorably on this change, describing it as long overdue.

On January 9, 2017, FDA issued the final rule. Shockingly, it does it not delete the "knowledge" sentence as expected.

On the contrary, it "amends" the sentence to create an entirely new sentence that FDA had not mentioned in original proposal. Now the sentence incorporates a brand new "totality of the evidence" standard:

> And if the totality of the evidence establishes that a manufacturer objectively intends that a device [or drug] introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (if any), he is required, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly promulgated regulations exempting the device from the requirements of section 502(f)(1), to provide for such device [or drug] adequate labeling that accords with such other intended uses.

It appears that FDA has now written itself a blank check to find whatever intent it wishes to find, using an unconstrained calculus as to what the "totality of the evidence" shows.

Worse, the manufacturer's knowledge can be part of this evidentiary mix, thus negating the long overdue proposal to eliminate "knowledge" as an element of intended use.

On February 8 a trio of pharmaceutical industry groups filed a petition to stay and for reconsideration (petition), asking FDA not to move forward with this final rule. The petition points out that when FDA veered off in an entirely new direction in the final rule, as compared to the original proposal, it violated the requirements of the Administrative Procedure Act (APA).

The APA requires "fair notice" and an opportunity to comment on a regulatory proposal. In this case, no one has had a fair opportunity to comment on the new regulatory language.

As the petition puts it (quoting a court case), a federal agency may not use a rulemaking "to pull a surprise switcheroo" (p. 12, internal quotation marks and citation omitted). If anything qualifies as a "surprise switcheroo" it is this final rule.

The petition has an extended discussion of the history and language of the intended use regulation, and shows convincingly that the new language is a departure from existing law.

It also explains why the new proposal is a bad idea that would negatively impact the public health by chilling valuable scientific speech, raising a First Amendment concern.

The petition argues that the totality of the evidence standard is so vague that it may even raise due process concerns under the Fifth Amendment per recent Supreme Court cases such as *FCC v. Fox Television Stations, Inc.*, 132 S.Ct. 2307 (2012).

What is likely to happen? It is a safe bet that FDA will not grant this petition. If FDA persists, it may find itself in court defending the new final rule.

The outcome of litigation is never a sure thing, but this new rule is definitely vulnerable, on APA grounds if nothing else.

One wildcard is the new Trump administration. It is not clear how new management will view the new rule or what they might do to stop it, especially if it goes into effect while the Obama holdovers continue to run FDA. (The final rule was supposed to become effective on February 8, but it was caught up in the regulatory freeze imposed by the Trump administration. The new implementation date is March 21.)

In our view, the intended use regulation is a root cause of FDA's First Amendment problems. In the next few weeks, we will post additional commentary analyzing the adverse effects of this regulation. We will suggest how this regulation can be revised to comport with the First Amendment without impeding FDA's public health mission.

Our proposed fix will go beyond just eliminating the knowledge sentence, but that would have been a good start. It is too bad that FDA's final rule did not follow through fair and square on the proposed rule.

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