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EXPERT ANALYSIS

A Phoenix Rising From The Ashes: FDA Proposes a Rule Requiring Submission Of Device Labels and Package Inserts

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In 1976, the FDA first began comprehensive regulation of medical devices. Among the new statutory provisions, there was one requiring persons registering with FDA to list all marketed devices. Each device on the list was to be accompanied by a copy of the label and package insert (see Section 510(j) of the Federal Food, Drug, and Cosmetic Act).

Within two years, the FDA had decided that requiring a copy of the label and package insert was not going to be practical or useful. The FDA said that it might not need the information when submitted and, unless consistently updated, it might be out of date when needed. Also, there was no practical way to compile, update or access the information, much less provide routine public access.

Typically, the device listings were submitted on paper and manually transcribed into data storage on reels of magnetic tape and floppy disks. Therefore, in lieu of requiring compliance with the actual statutory requirement, the FDA required device firms to maintain a historical file of labels and labeling available upon the FDA's request.

Fast forward almost 40 years. The Internet is now pervasive and electronic storage is robust and easily searchable. Taking advantage of the now-established technology, the FDA is proposing to give new life to the requirement in Section 510(j).

As it happens, Section 510(j) has remained on the books the entire time even though not enforced for all of these years.

The foregoing history is recounted in the preamble to the FDA's new proposed rule. What are the features of the proposed rule? Those who are interested will, of course, want to read the entire proposal. The most important features can be summarized as follows:

- The new rule would be limited to Class II and Class III devices intended for home use. It would not apply to devices intended for use in professional health care facilities, such as hospitals, nursing homes, clinical laboratories, or physician offices.

- The label and package insert would be electronically submitted each time device listing is electronically submitted or updated, which is required at least annually. The information could be in a PDF format, which may someday transition to the FDA's Structured Product Labeling (SPL) format.

- The statutory term "package insert" would be defined by regulation (for the first time ever) to cover the information that is delivered to the lay home user with the device. It would not include information for device installers, servicers, or health care professionals. This limitation arises from the chief aim of the rule, which is to help lay home users find device instructions.

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- The FDA would archive the information in an easily searchable database. One particular advantage would be keeping information on file for older devices even after a manufacturer discontinues marketing (and may have stopped posting the package insert on its web site).

The FDA gives two primary reasons for the limited reach of the new rule. The first is the agency's belief that Class II and Class III home use devices have a higher risk of misuse due to lost or misplaced labeling and operating instructions. The second is that the FDA would like to gain experience maintaining this type of database before applying it more broadly.

Presumably, the program could be expanded if it proves beneficial. (One quibble with the proposed definition of package insert is that the definition is appropriate for this rule but would have to be revised if the rule were expanded. It would be better to define it properly and then limit the type of package insert required under this rule.)

The preamble to the proposed rule supplies little hard data to back up the supposed benefits. It does indicate that in-home device cause a significant number of serious adverse events (based on 2014 data) and also the FDA has received reports of lost labeling for high risk in-home devices. But the preamble does not provide data to establish that lost or missing instructions actually cause or contribute to a significant percentage of serious adverse events.

Even so, the proposed rule still seems generally like a good idea. The FDA's core function is regulating labeling and so the notion that device manufacturers would submit current labeling to the FDA makes sense. Indeed, it was part of the original statutory design in 1976 for all manufacturers to do so, even though the FDA found it impractical for many decades.

In 1976, moreover, Congress probably was more concerned about giving the FDA access for regulatory purposes. Nonetheless, perhaps the best part of the proposed rule is enabling FDA to provide *the public* with reliable access to current labeling.

Intuitively, the availability of easy-to-find instructions for use is likely to contribute to safe and effective device usage, even if supporting data for this proposition are currently scarce.

The FDA also proposes over time to add links to relevant information for affected devices, such as recalls and manufacturer notifications. It is easy to imagine that the FDA might eventually be able to build out a very robust public database with full device life cycle information, one that is easily accessible to the agency and device users, whether in the home or in professional healthcare facilities.

The painful UDI adoption process now underway may help make this database even more granular. If that is the future, and one hopes that it is, then this proposed rule is a useful step in that direction.

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