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FDA Issues Final Ruling Allowing Medical Device Manufacturers to Use Stand-Alone Symbols on Labels

This week, on June 14, 2016, the FDA issued a final ruling revising its medical device and certain biological product labeling regulations to allow, for the first time, manufacturers to use graphical representations of information on its labeling without adjacent explanatory text (known as "stand-alone symbols"). The new ruling goes into effect on September 13, 2016.

The ruling brings the labeling regulations in line with the current use of symbols on labels in European and other foreign markets. Thus, in the view of the FDA, this ruling seeks to "harmonize" the U.S. device labeling requirements for symbols with international regulatory requirements. In addition to increasing consistency between U.S. device labeling requirements and international requirements, the FDA touts that, by allowing the use of stand-alone symbols, medical device manufacturers will experience a positive net benefit over time in the form of a reduction in costs for the design and redesign of labeling for medical devices currently marketed.

Specifically, the FDA estimated the total benefits annualized over 20 years to be between $7.7 and $25.5 million. Of course, the switch to stand-alone symbols will require some up front and recurring costs to redesign the labeling and to create an accompanying glossary (more on this below), which the FDA estimates at total annualized amount of $1.1 to $3.2 million over 20 years. Thus, the total annualized net benefit to medical device manufacturers stands to be in the range of $6.6 to $22.3 million.

Now for the fine print. The new ruling states that symbols established in a standard developed by a standards development organization ("SDO") may be used in medical device labeling without adjacent explanatory text, if: (1) The standard is recognized by the FDA under section 514(c) of the FD&C Act (21 U.S.C. § 360d(c)) and the symbol is used according to the specifications for use set forth in section 514(c), or, alternatively, (2) if the symbol is not recognized by the FDA or the symbol is recognized by the FDA but is not used according to the specification for use set out in section 514(c), the device manufacturer determines that the symbol is likely to be read and understood by "the ordinary individual under customary conditions of purchase and use" pursuant to section 502(c) of the FD&C Act (21 U.S.C. 352(c)) and uses the symbol according to the specifications of use as set forth in the SDO-developed standard.

According to the FDA, allowing the manufacturer to use symbols that have been sanctioned by an SDO, even though they have not been officially recognized by the FDA, will result in "more timely availability of stand-alone symbols for use in device labeling, more convenience for industry, and conserves limited Agency resources." Beyond making sure that the symbols are either already recognized by the FDA or are likely to be understood by customers, and that the symbols are being used according to their specifications, the ruling has another major component: the manufacturer must provide a symbols glossary contemporaneously accompanying the device that explains all of the symbols used. The labeling on or in the packaging must also bear a "prominent and conspicuous" statement identifying the location of the glossary.

Notably, the ruling explicitly allows for the glossary to be printed on paper or displayed electronically. This is an important distinction because device manufacturers stand to save significant printing costs by keeping the glossary online and referring to it in the device labeling. Indeed, the FDA specifically green lights the use of an online glossary and provides the following language as an example of how the manufacturer can identify the location of an online glossary: "The symbols glossary is provided [specify, e.g., in Section X of the package insert, as a separate insert within the package, on the side panel of the package, electronically at (insert URL address to symbols glossary on manufacturer's Web site)]."

The ruling requires the glossary to be included with all device replacement parts and on each item in a multi-pack of a product, so the ability to provide the glossary electronically is highly encouraged.
The ruling addresses numerous comments from manufacturers to provide further guidance. For instance, the ruling clarifies that no proprietary symbols may be used. Additionally, product graphics or pictograms, such as those showing the steps for using the device, fall outside of this ruling (and thus do not need to be part of a standard developed by an SDO or included in the glossary). Drugs and combination products also fall outside of the ruling.
To put manufacturers at ease, the FDA emphasizes that as long as the symbol is validated by an SDO standard, the manufacturer does not need to "revalidate" that the symbol meets the requirements under section 502(c) for its use on a particular device. However, manufacturers need to understand they are not fully off the hook because the FDA expressly stated it will consider post-market surveillance data where appropriate indicating that the symbol is not understood by consumers for a particular device or that it causes the labeling to be false or misleading.
Accordingly, although manufacturers are not required to do so, they may wish to undertake validation studies to ensure that consumers fully understand the symbols they intend to use on their medical devices. Furthermore, the FDA encourages manufacturers to monitor complaints and adverse events regarding any inadequate understanding of the labeling containing stand-alone symbols.

The FDA, of course, reserves its authority to make the definitive determination regarding compliance with section 502(c) of the FD&C Act, and can take enforcement action against violations. Furthermore, failure to use symbols not explicitly sanctioned by the FDA, or using symbols in a way that is confusing to consumers, could result in liability for the manufacturer. Thus, it is imperative that device manufacturers carefully consider these risks and consult seasoned counsel when deciding whether to incorporate stand-alone symbols in their labeling.
Nevertheless, this new ruling presents an opportunity for medical device manufacturers to benefit their bottom line and reduce production costs by redesigning their labels to include stand-alone symbols. As such, we suggest manufacturers learn more about the new regulation and determine whether to incorporate the symbols into their labeling.