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A Symbolic Victory? FDA's Final Rule On Stand-Alone Symbols In Medical Device Labeling Raises Important Litigation Risk Questions

Author:

Adam M. Masin
(860) 251-5154
amasin@goodwin.com

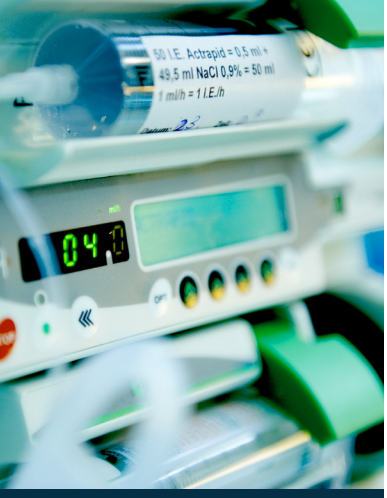
FDA this week released a final rule that will undoubtedly raise new litigation questions for medical device manufacturers in the context of product liability claims.[1] The final rule for the first time permits medical device manufacturers to include "graphical representations of information, or symbols" in product labeling without adjacent explanatory text if certain requirements are met. Previously, except for in vitro diagnostic devices, symbols could only be used with adjacent English-language explanatory text. Nothing in the final rule mandates that manufacturers utilize stand-alone symbols, but they are now an option under the circumstances described therein.

Any FDA final rule expanding the possibilities of product labeling for medical products of course implicates arguments about the adequacy of product labeling and causation under the learned intermediary doctrine. Under the proposed rule, FDA would have only permitted stand-alone symbols established in a FDA-recognized standard developed by a standards development organization (SRO) and used in accordance to the specifications for use of the symbol set out in FD&C Act section 514(c). That rule would have essentially allowed FDA to dictate the pool of useable symbols. Under those circumstances, a plaintiff seeking to challenge the adequacy of the labeling under state law by suggesting that the manufacturer should have used a non-FDA-recognized symbol would have run into an "impossibility" preemption challenge based on the reasoning in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).

Under the final rule, however, FDA eliminated the requirements of FDA recognition of the standard and use according to section 514(c) specification. The final rules states that manufacturers can "determine themselves whether an SDO-established symbol is likely to be read and understood by the ordinary individual under customary conditions of purchase and use in compliance with section 502(c) of the FD&C Act." FDA noted that "[t]his would be consistent with what industry currently does when it uses text in labeling." Although FDA repeatedly notes "the device manufacturer's responsibility" to comply with FDA requirements, FDA added that "manufacturers always have the option to request FDA recognition of certain standards if the manufacturer does not want to determine for itself the section 502(c) compliance of the use of the stand-alone symbol in device labeling." Taking this step may prove helpful to insulate against later litigation attacks, and manufacturers should take note that FDA does not require revalidation of FDA-recognized standards for future use.

Manufacturers wishing to use stand-alone symbols should take well-documented steps to establish the reasonableness of their conclusion that "an SDO-established symbol is likely to

1 https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-13989.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery,



be read and understood by the ordinary individual under customary conditions of purchase and use." That standard is likely to make its appearance in future expert reports. The standard itself suggests a number of issues that a manufacturer should pay attention to when considering the use of stand-alone symbols. As an initial matter, manufacturers should ensure that they are utilizing a SDO that is consistent with FDA's definition of an SDO, which requires the organization have "a process for standard development that is transparent (i.e., open to public scrutiny), where the participation is balanced, where an appeals process is included, where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope."

The FDA considers "proprietary symbols" subject to the owner's exclusive rights, product graphics, and pictograms to be outside the SDO context. The latter two exclusions are based on FDA's intent to permit symbols that are "broadly applicable or used across a wide range of devices" rather than those that are "unique to the individual product." This strongly suggests that stand-alone symbols intending to warn about a specific risk of a specific device would not be permitted under the final rule. Experts who opine that a manufacturer should include a product or risk-specific symbol in the labeling should be challenged to provide authority permitting that use in light of FDA's comments on the final rule.

Manufacturers also need to consider how the use of the desired stand-alone symbol might appear down the road in a litigation context, and particularly how physician-users under deposition questioning may respond to the symbol on its own and in the context of the full labeling. The symbol itself will not be the only consideration. The final rule also requires manufacturers to include a paper or electronic symbols glossary in the labeling for the device, and "labeling on or within the package containing the device must bear a prominent and conspicuous statement identifying the location of the symbols glossary…" Thus, the text definition of the symbol as well as the prominence and conspicuousness of the statement identifying its location are also potential avenues of attack during litigation. The FDA notes that there is some "flexibility" built into the final rule regarding the symbols glossary, and thus the manufacturer's decision-making in this area is open to scrutiny.

Case law involving the text of medical product warnings is plentiful, but there is a dearth of precedent discussing the use of symbols in medical product labeling. Claims involving non-textual concerns about medical product labeling are equally rare, and have tended to focus on the lack of a bold or black box warning for pharmaceuticals. There is a smattering of precedent involving the use of symbols on labeling outside of medical products, but those cases do not involve the learned intermediary doctrine. Although product liability law is not yet developed in this area, it is also true that plaintiffs' experts who would opine on the inadequacy of symbols in medical device labeling will not have many facts or much experience to draw upon. The *Daubert* barrier to admitting such testimony should be a high one.

Questions or Information:

If you have questions or for more information about the FDA's final rule on the Use of Symbols in Labeling, please contact Adam Masin at amasin@goodwin.com.

289 Greenwich Avenue
Greenwich, CT 06830-6595
203-869-5600

One Constitution Plaza
Hartford, CT 06103-1919
860-251-5000

265 Church Street - Suite 1207
New Haven, CT 06510-7013
203-836-2801

400 Park Avenue - Fifth Floor
New York, NY 10022-4406
212-376-3010

300 Atlantic Street
Stamford, CT 06901-3522
203-324-8100

1875 K St., NW - Suite 600
Washington, DC 20006-1251
202-469-7750

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