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ADVERTISING AND PREEMPTION UNDER FDA'S NEW DRUG LABELING RULE

by
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The Food and Drug Administration (FDA) has issued a new regulation that significantly revises the content and format of prescription drug labeling. 71 Fed. Reg. 3921 (Jan. 24, 2006). The labeling, known as the full prescribing information or “FPI,” is a technical, FDA-approved document that guides medical professionals in the safe and effective prescribing of the drug. Under the new rule, FPIs will be easier for physicians to use. Addressed here is how the new FPIs may also improve direct-to-consumer (DTC) prescription drug print advertising by providing a more useful alternative to the typical, and inaptly named, “brief summary.”

Under FDA’s old regulations, FPIs have become very long, dense, and technical. An FPI began with the drug’s chemical properties and clinical trial results. Other information critically important for clinical health care professionals – such as which patients should not take the drug – was buried in the middle of the typical FPI.

The new rule re-organizes the FPI to make it easier for physicians to find important facts. FPIs will also begin with a concise one-half page “Highlights” of the drug’s significant risk information and usage. FDA “strongly believes that limiting the length of Highlights is critical to preserving its usefulness.” *Id.* at 3958.

The new Highlights section has important implications for DTC prescription drug advertising. Currently, a prescription drug print advertisement must contain, among other things, “information in *brief summary* relating to [the advertised drug’s] side effects, contraindications, and effectiveness.” 21 U.S.C. § 352(n) (emphasis added). This “brief summary” has blossomed into a long, dense, medically technical document that often repeats all or most of the FPI verbatim. As FDA has acknowledged, the typical brief summary is “less than optimal”¹ for DTC print advertising.

Two years ago, FDA issued a Draft Guidance encouraging drug manufacturers to adopt more concise brief summaries. 69 Fed. Reg. at 6308. Anticipating the FPI rule, which was then still under review, FDA stated it would not object to a DTC print advertisement that, in lieu of the traditional, lengthy brief summary, instead reproduces the Highlights section of the FPI in consumer-friendly language. Brief Summary Draft Guidance at 3, 6.

Despite the many benefits to consumers of a simpler brief summary, drug manufacturers have expressed concerns that a more concise format, such as a Highlights section, might make companies

¹Draft Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, 69 Fed. Reg. 6308 (February 10, 2004) (“Brief Summary Draft Guidance”) at 2.

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more vulnerable to product liability claims. *See e.g.*, 71 Fed. Reg. at 3933; Comment of PhRMA (May 10, 2004) (available for download at <http://www.fda.gov/ohrms/dockets/dailys/04/may04/051204/04d-0042-c00019-vol2.pdf>). By quoting all or most of the FDA-approved FPI in a DTC print advertisement, the drug manufacturer might avoid potential liability based on a failure-to-warn theory. Consequently, improvements to the brief summary have been slow.

The FPI rule resolves this tension between a brief summary that can be comprehended, and one that is exhaustively comprehensive. In the FPI rule, FDA references the Brief Summary Draft Guidance and provides security for drug advertisers that use the new Highlights section to satisfy the brief summary requirement.² FDA states its belief that ***“claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling,” would be preempted “in those cases where a drug’s sponsor has used Highlights consistently with FDA draft guidance regarding the ‘brief summary’ in direct-to-consumer advertising.”*** 71 Fed. Reg. at 3936 (emphasis supplied).

For consumers and for drug advertisers, FDA’s encouragement of the Highlights section in DTC advertising is enormously important. A one-half page Highlights of prescribing information, translated into consumer-friendly language, will be a vast improvement over the medically technical, lengthy FPI (or excerpts of it) that now accompanies most DTC advertising. Considering that the old FPI was said to have become too dense even for most medical professionals, it was certainly not useful for the typical consumer when reprinted in a DTC print advertisement.

For drug manufacturers, FDA provides crucial guidance and a modicum of protection if they adopt the Highlights approach in their DTC print campaigns. FDA states that when an advertiser provides a brief summary in the form of a Highlights section that is consistent with the Draft Brief Summary Guidance, the advertiser should not be subject to suit for failing to include in its advertisement warnings about other, more remote risks that FDA did not deem appropriate for inclusion in the Highlights section.³ Thus, the FPI rule provides a critical incentive to and protection for a drug advertiser who opts for a clear and useful, rather than exhaustive, recitation of risk information in the brief summary.⁴

The FPI rule acknowledges a critical truth that extensive, detailed risk information is “not necessarily more protective of patients” because “[e]xaggeration of risk could discourage appropriate use of a beneficial drug.” 71 Fed. Reg. at 3935. The FPI rule resolves the two-decades-old conflict between a useful brief summary and an exhaustive one, and achieves the elusive goal of a better brief summary for consumers.

²See 71 Fed. Reg. at 3960, 3961. Although FDA states that it does intend to address advertising in the FPI rule, 71 Fed. Reg. at 3953, the agency does link the new FPI to the brief summary.

³As the Washington Legal Foundation has observed, the FPI rule’s preemption does not insulate a manufacturer of an adulterated or otherwise defective drug. Nor does it protect a manufacturer who has defrauded the FDA or withheld material information from the agency. Press Release of the Washington Legal Foundation, <http://www.wlf.org/upload/012506RS.pdf>.

⁴Interested consumers, of course, can obtain the entire FPI from a variety of public sources.