



# **How FDA's New Labeling Rule Could Preempt State Law**

**John R. Fleder, Esq.**

**Kurt R. Karst, Esq.**

**Hyman, Phelps & McNamara, P.C.**

**[www.hpm.com](http://www.hpm.com)**

**202-737-5600**

**[jrf@hpm.com](mailto:jrf@hpm.com) • [krk@hpm.com](mailto:krk@hpm.com)**

**PART I: FDA's New  
Prescription Drug Labeling  
Rule – An Overview**

- On Jan. 24, 2006, FDA formally issued its prescription drug labeling regulations (proposed in Dec. 2000), and two draft and two final guidance documents further describing the implementation of those regulations. 71 Fed. Reg. 3922-4000. The regulations become effective on June 30, 2006.
- FDA has stated that the regulations and documents are part of the Agency's ongoing initiative to manage product risks and reduce adverse events by providing physicians with a simplified format to communicate risk information to patients.

## ● **Applicability:**

- The regulations apply to “prescribing information” (also known as “labeling,” “package inserts,” “professional labeling,” “direction circulars,” “package circulars,” or “detailed product information”) for prescription drugs approved under an NDA and biological products approved as drugs under an BLA.
- The new regulations are not intended to provide additional information to patients. The regulations do not apply, with minor formatting exceptions, to either FDA-approved patient labeling (e.g., Medication Guides), or to drug labels.

- **The new regulations apply to drugs approved since June 30, 2001 (referred to by FDA as “new and recently approved products”). FDA is not requiring sponsors to have the new labeling format on the effective date of the new regulations. Instead, FDA has established a phased-in timeframe. Also, FDA’s current labeling regulations (with minor clarifications) will remain applicable to drugs approved prior to June 30, 2001 (referred to by FDA as “older products”) without reference to the new labeling format and content.**

## ● **Overview:**

- **The new regulations substantially change the content and format of prescribing information for new and recently approved products, and divide drug labeling into three primary sections:**
  1. **Highlights of Prescribing Information (“Drug Highlights”);**
  2. **Full Prescribing Information: Contents (“FPI Contents”); and**
  3. **Full Prescribing Information (“FPI”).**
- **For any currently-marketed drug covered by the new regulations, FDA requires that the sponsor will submit for FDA prior approval a supplement to the earlier marketing application, which will set forth the information required by the new regulations.<sup>6</sup>**

## ● **Drug Highlights:**

- **According to FDA, the Drug Highlights labeling section serves to “increase the likelihood that practitioners will . . . retain critical information about a drug” by providing a summary of the most important information for prescribing decisions.**
- **It will be limited to a half page with summarized information presented in language that is succinct and imparts a complete piece of information.**
- **Once FDA approves new labeling with a Drug Highlights section, the Agency will require another prior approval supplement for any subsequent changes to the Drug Highlights section (except for minor changes).**

## ● **FPI Contents:**

- **It serves as a table of contents to the information in the FPI.**
- **“[Whereas Drug] Highlights presents a succinct summary of the information in the FPI that is most crucial for safe and effective use, with cross-references to direct prescribers to more details in the FPI. . . [FPI] Contents serves as a navigational tool that references all the sections and subsections in the FPI. . . .” 71 Fed. Reg. at 3941.**
- **Must contain 17 numbered sections and, where applicable, subheadings.**



## ● **FPI:**

- **Much of the information included in the new FPI section is currently found in existing labeling, but will need to be reordered in order to make more prominent the information considered to be most important to, and most often referenced by, practitioners.**
- **FDA anticipates that “in many cases, amending labeling to meet new § 201.57(c) will involve rearranging large segments . . . of information in existing labeling without substantially changing the content. In some cases, however, it will be necessary to parse information from several parts of the existing labeling into a new section.” 71 Fed. Reg. at 3943.**

- **Changes Applicable to “Older Products”  
(drugs approved prior to June 30, 2001)**

- **FDA’s current prescription drug labeling regulations concerning the content and format of prescribing information are at 21 C.F.R. § 201.57. Under FDA’s new regulations, § 201.57 will just cover new and recently-approved products as of June 30, 2006. At that time, the former § 201.57 regulations will be redesignated as § 201.80, and will apply to older products that are not subject to the new labeling requirements. [The labeling requirements for newer drugs will be set forth in “new” § 201.57].**
- **New § 201.80 is almost identical to current § 201.57, with minor exceptions (e.g., font size).** 10

## ● Implementation Timeline

<b>Applications (NDAs, BLAs, and Efficacy Supplements) Required to Conform to New Labeling Requirements</b>	<b>Time by Which Conforming Labeling Must Be Submitted to FDA for Approval</b>
Applications submitted on or after June 30, 2006	Time of Submission
Applications Pending on June 30, 2006; Applications Approved 0 to 1 year before June 30, 2006	June 30, 2009
Applications approved 1 to 2 years before June 30, 2006	June 30, 2010
Applications approved 2 to 3 years before June 30, 2006	June 30, 2011
Applications approved 3 to 4 years before June 30, 2006	June 30, 2012
Applications approved 4 to 5 years before June 30, 2006	June 30, 2013
Applications approved more than 5 years before June 30, 2006	Voluntary at Any Time

# ● Abbreviated NDA Considerations

- The FDC Act and FDA’s generic drug regulations require that the labeling of a drug submitted for approval under an ANDA must be the same as the labeling of the Reference Listed Drug (“RLD”), except for certain differences (e.g., labeling protected by patents and/or exclusivity).
  - “For ANDA products (generic products), the implementation schedule for the affected reference listed drug applies.” 71 Fed. Reg. at 3977.
- FDA clarified that “the requirement to revise the labeling of a [RLD] in the new format does not have any impact on the duration of exclusivity for the drug and, therefore, does not prevent a manufacturer of a generic product from using the revised labeling of the [RLD].” Id. at 3961 (emphasis added).

# **PART II: State Law Preemption**

- **The “Supremacy Clause” (U.S. Constitution, Article VI, cl. 2)**
  - **“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”**
  - **Federal laws (and even regulations of a federal agency) can trump conflicting state laws and regulations, and thereby foreclose lawsuits that seek to enforce those state laws and regulations.**

# ● General Preemption Principles

- The courts have ruled that a federal law or regulation may preempt a state law in three different ways:
  - Express preemption
    - Congress enacts a law that expressly preempts state laws.
  - Implied preemption
    - In the absence of express preemptive language, Congress' intent to preempt state law is inferred from the statutory language enacted by Congress.
  - Conflict preemption
    - Even when Congress has not displaced state law or regulation, the courts will nullify a state law when the court finds it actually conflicts with federal law, such as when compliance with both federal and state laws and regulations are a physical impossibility, or state law stands as an obstacle “to the accomplishment and execution of the full purposes and objectives of Congress.”
  - See Hillsborough County, Florida v. Automated Medical Labs, Inc., 471 U.S. 707, 713-14 (1985).
  - State laws can be preempted by federal regulations as well as by federal statutes. Id.

# ● FDA's Recent Position Statements Regarding Prescription Drug Labeling

- “[U]nder existing preemption principles, FDA approval of labeling under the [FDC Act], whether it be in the old or new format, preempts conflicting or contrary State law.” 71 Fed. Reg. at 3934.
- FDA asserts that its recent statements “represent the government’s long standing views on preemption,” and is a position that the government has taken in a number of amicus briefs submitted on FDA’s behalf.
- “FDA has determined that the exercise of State authority conflicts with the exercise of Federal authority under the [FDC Act].” Id. at 3967.



- **Specific concerns with state laws that FDA believes compels its preemption position**

- A “State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product’s risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the [FDC Act].” 71 Fed. Reg. at 3935.
- “State law actions also threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.” Id.
- “State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.” Id.

- **FDA interprets the FDC Act to establish both a floor and a ceiling such that FDA believes that additional disclosures of risk information would expose a manufacturer to liability if the additional statement is unsubstantiated or otherwise false and misleading. FDA says that given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling, any additional requirements to be imposed by a court would not necessarily better protect patients.**

- **Six state law claims FDA believes are preempted by the new regulations (71 Fed. Reg. at 3936):**

1. **Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;**
2. **[C]laims 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, 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 . . . .;**
3. **[C]laims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule . . . .;**

4. [C]laims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn);
5. [C]laims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and
6. [C]laims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).

- **FDA's preemption position is a modification of FDA's position under the Clinton Administration.**
  - **In 2000, FDA stated in the preamble to the proposed rule that: “this proposed rule does not preempt State law.” 65 Fed. Reg. at 81,103 (emphasis added).**
  - **In the 1990s, FDA filed several briefs in courts seeking to narrowly construe the preemptive effects of FDA statutes.**

- See FDA’s brief in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). However, in 2000, FDA submitted a brief in Buckman Co. v. Plaintiff’s Legal Comm., 531 U.S. 341 (2001) that asserted that a fraud on the FDA claim was preempted.
  - “Permitting state-law suits for fraud on a federal agency could also distort the behavior of regulated entities. Those entities base their behavior largely on their understanding of how federal law has been applied in the past and how it will likely be applied in the future. If a regulated entity knows that juries applying the tort law of any one of the 50 States will play a central role in interpreting the entity’s duties to the federal government, that concern could cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme. For example, if, in order to avoid a risk that a jury in one of 50 States might conclude that they have withheld relevant information, regulated entities began to flood FDA with information that FDA does not need, it could significantly complicate the clearance process.”

- **In 2004, FDA filed a brief in a medical device product liability case that argued for preemption. FDA acknowledged that its position represented a change of position for the U.S. as had been earlier articulated in 1997.**
- **After issuance of the 2006 labeling regulations, FDA has received objections from Public Citizen and the National Conference of State Legislators to FDA's position.**
- **Some members of the United States Senate and the House of Representatives have threatened to stymie implementation of the labeling rule by enacting legislation that would prevent FDA from preempting state law.**

- **What is not preempted under FDA's preemption position?**
  - **“State law requirements that parallel FDA requirements . . . .” 71 Fed. Reg. at 3936.**
  - **Manufacturing defects (the rule only applies to “failure-to-warn” actions).**
  - **State tort law when companies withhold valuable information from FDA.**



- **The expansion of FDA's preemption position?**
  - **FDA's Chief Counsel (Sheldon Bradshaw) recently stated: "Although the physician labeling rule in the preemption discussion here didn't talk about OTC drugs . . . The same sort of principles are true with respect to [OTC] drugs."**
  - **Mr. Bradshaw also recently stated that preemption could be used with regard to cosmetic labels.**

# ● FDA Cases Involving Preemption

- Hillsborough County, Florida v. Automated Medical Labs, Inc., 471 U.S. 707, 713-14 (1985) – blood collection facility;
- Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) – no preemptive effective from FDA clearance of a medical device 510(k) notice;
- Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001) – fraud on FDA claim preempted by FDC Act;
- Horn v. Thoratec Corp., 376 F.3d 163 (3rd Cir. 2004) – state common law claim preempted with regard to FDA approval of medical device PMA;
- Ellis v. C.R. Bard, Inc., 311 F.3d 1272 (11th Cir 2002) – state common law claim with regard to medical device labeling was not preempted by FDC Act labeling provisions and FDA regulations;
- Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Apr. 15, 2004) – Proposition 65 requirement for health warnings regarding nicotine preempted by FDC Act;

- Cosmetic, Toiletry & Fragrance Assoc. Inc. v. State of Minnesota, 440 F. Supp. 1216 (D. Minn. 1977) – state labeling regulation preempted by FDA regulation containing different requirements for warnings; and
- Witczak v. Pfizer Inc., 377 F. Supp. 2d 726 (D. Minn. 2005) – federal regulation of prescription drugs does not preempt state law claim that manufacturer failed to warn of side effects.

## ● Other Recent FDA Preemption Statements

- Brief filed in In Re Paxil Litigation (C.D. Cal. 2002);
- Brief filed in Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004);
- Brief filed in Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Apr. 15, 2004);
- Brief filed in Horn v. Thoratec Corp., 376 F.3d 163 (3rd Cir. 2004) (court ruled that FDA's preemption brief was "significant and should inform our interpretation of" the FDC Act);
- Letter to Oregon Gov. John A. Kitzhaber (Oct. 1, 2002) objecting to ballot initiative relating to proposed mandatory labeling of foods and food additives produced using genetic engineering; and
- Letter to Rhode Island Gov. Donald L. Carcieri (July 1, 2004) objecting to state legislation relating to the licensing of Canadian pharmacies.

# ● Issues

- Will FDA seek to bar Lanham Act or False Claims Act cases that assert a company has violated the FDC Act?
- Will FDA seek to preempt lawsuits brought by state and local governments alleging FDA-type violations of state law?
- In what new areas might FDA seek to expand its preemption position?
- How do you seek to get FDA involved in a possible preemption case?