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NEW DEVELOPMENTS AND PRODUCT LIABILITY IMPLICATIONS OF FDA PRESCRIPTION DRUG LABELING RULE

The January 2006 Food and Drug Administration (FDA) final rule on prescription drug labeling, with its significant product liability implications, opens the door to judicial interpretations of FDA's pronouncements. A recent district court case sheds some light on how this area of law is beginning to evolve. This article briefly revisits the provisions of the January rule, discusses reactions to the rule in recent litigation, analyzes the recent district court decision, and provides practical suggestions for drug manufacturers in the context of defending product liability actions related to product labeling and the FDA approval process.

I. Background: The New Rule and Preamble

FDA's final rule revises the content and formatting requirements for prescription drug package inserts. The primary purpose of the new rule is to replace prescription drug labeling for healthcare providers with more streamlined and meaningful prescribing information, thereby increasing the extent to which those providers will rely on labeling.¹ Significantly, FDA stated in the preamble to the regulations that FDA decisions on labeling matters preempt any conflicting state regulations, legislation, or product liability law.

A. Key Features of the New Labeling

New drug labels must include the following key features:

- **Highlights** – The *Highlights* section is designed to provide, in summary form, immediate access to what is considered by most healthcare professionals to be the most important information in the label. The highlighted section includes: (1) the original date of approval; (2) a list of substantive changes in the last year to the *Boxed Warning, Indications and Usage, Dosage and Administration, Contraindications, and Warning and Precautions sections*; and (3) adverse

drug reaction reporting contact information.

- **Table of Contents** – This section requires a table of contents to prescribing information consisting of a list of each heading and subheading along with its identifying number to facilitate healthcare practitioners' use of labeling information.²
- **Warnings and Precautions** – The *Adverse Reactions* section will follow the *Warnings and Precautions* section to consolidate risk information in one place.

B. FDA Statement on Preemption

FDA maintains that it is "the expert Federal Agency charged by Congress with ensuring that drugs are safe and effective and that product labeling is truthful and not misleading."³ Because FDA's very role is to review relevant scientific information about drugs and ensure that manufacturers communicate appropriate information to healthcare practitioners, FDA asserts that permitting a lay judge or jury to impose higher standards on a manufacturer for product labeling than were required by FDA, despite FDA's review process, familiarity with the products, and expertise in the area, would frustrate both FDA's charge to ensure safe and effective drugs, and its ability to "carefully control[]" the content of prescription drug labeling."⁴

Consistent with existing regulations, FDA notes that "[a] manufacturer may, under FDA regulations, strengthen a labeling warning" without prior agency approval.⁵ Concerned that state laws treat FDA labeling requirements as a floor, FDA states that labeling creates both a "floor" and a "ceiling," and that more warnings are not always better: "Additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use."⁶

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FDA stated that six “failure to warn” areas are preempted, including: (1) failure to emphasize information in the *Highlights* section; (2) failure to warn in an advertisement of information in the labeling, where the *Highlights* section is used properly in direct-to-consumer advertising; (3) failure to include contraindications or warnings not supported by evidence satisfying FDA standards; (4) failure to include a statement in labeling or advertising that had been proposed to, but not required by FDA; (5) failure to include a statement if the substance of the statement was prohibited by FDA; and (6) making statements approved by FDA for inclusion in the label.⁷

II. Plaintiffs’ Bar Believes it Can Still Defeat Preemption

The plaintiffs’ tort bar has praised the new, streamlined labeling regulations, yet heavily criticizes FDA’s statement of preemption. Nonetheless, the plaintiffs’ tort bar seems confident it will prevail in product liability lawsuits.

The plaintiffs’ bar argues that FDA will not be able to preempt state tort actions because section 314.70(c)(6)(iii)(A) of the regulations “still explicitly permits a drug manufacturer to change the labeling of a drug in order to ‘add or strengthen a contraindication, warning, precaution, or adverse reaction,’”⁸ thus signaling that plaintiffs will still bring claims for failure to change/strengthen a warning. Moreover, plaintiffs will argue that “the rules still place upon drug manufacturers the affirmative responsibility to revise a drug’s label ‘to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.’”⁹ Plaintiffs’ attorneys will argue that, notwithstanding the explicit contradiction with FDA’s statement that approved labeling is both a floor and a ceiling, this language creates only a “floor” for the minimum labeling required. Plaintiffs’ attorneys, therefore, will argue that state law continues to have the ability to require stricter warnings and labeling without risking preemption.¹⁰

Plaintiffs’ reaction to the new regulations is directly at issue with FDA’s statement that although label changes to add or strengthen a contraindication, warning, precaution, or adverse reaction may be made without prior approval, FDA reviews all such information and may later deny approval. “Thus, in practice, manufacturers typically consult with FDA before doing so to avoid implementing

labeling changes with which the agency ultimately might disagree.”¹¹

Moreover, in most instances, a manufacturer will *not be able* to make any edits to the Highlights section without prior FDA approval:

[B]ecause Highlights is a summary of the most important information for prescribing decisions and some comments expressed concerns about the difficulty involved in summarizing the complex and often lengthy information in the FPI (see e.g., comments 16, 23 and 27), the agency believes that it is essential for FDA to review and approve most proposed changes to the information in Highlights.¹²

III. FDA Maintains Its Position in Court; Court Agrees

FDA has maintained its position on preemption in a recent amicus curiae filing in *Colacicco v. Apotex, Inc.* (E.D. Pa.), a products liability case alleging that the plaintiff’s wife committed suicide while taking generic Paxil® (paroxetine hydrochloride) at a time when FDA’s judgment was that there was no reasonable evidence associating adult use of paroxetine hydrochloride with suicide or suicidality, and thus no basis for such a warning in the product label. The court had asked FDA for its views on preemption.

Rejecting the idea that its preemption position is new, FDA’s amicus brief said that the principles requiring dismissal of the failure-to-warn claims “are well-established” and date back “long before the events” giving rise to the litigation. Addressing the seeming contradiction between FDA being the only arbiter of warning language on drug labels, and a manufacturer being able to act *sua sponte* to change its labeling to add or strengthen a warning statement, FDA again emphasized that while a manufacturer can do so without prior agency approval, “FDA may choose to reject the proposed labeling change ...and may also order the drug manufacturer to cease distributing the drug with the new labeling.”¹³

In this case, FDA noted that during the relevant time period, it had “specifically and repeatedly rejected claims that adult use of SSRIs was associated with an increased risk of suicide or suicidality.”¹⁴ Indeed, including such a warning would have been deemed misleading and a violation of federal law.

In urging the court to consider its views on preemption, FDA noted that its position is based on the principles of preemption generally, not on the January 2006 preamble

to FDA’s rule specifically.¹⁵ Further, the Agency noted that since 1979, FDA rules reflect its view that the ultimate decision on whether a warning is required rests with FDA, and that federal law prohibits including statements in a drug label that FDA did not determine were supported by substantial evidence.¹⁶

In a decision dated May 25, 2006, the court in *Colacicco* largely agreed with FDA and dismissed the case on the ground that a claim based on common law tort principles alleging inadequate labeling was preempted. The court agreed with FDA that, contrary to plaintiffs’ arguments and to the reasoning of courts that have rejected preemption, the generic drug manufacturer in this case was *not* permitted to add a warning or caution to the label without prior approval from the FDA. This conclusion may be very limited in that *Colacicco* involved a generic drug manufacturer, and the court recognized that FDA can withdraw approval of a generic drug if its label ceases to be the same as that of the name-brand drug. Thus, *Colacicco* does not specifically address whether a manufacturer of a name-brand drug can be liable for failing to unilaterally strengthen its warnings. However, the court noted several times that FDA’s position is entitled to deference; thus, FDA’s observation that “manufacturers typically consult with FDA... to avoid implementing labeling changes with which the agency ultimately might disagree” should carry some weight in future cases.

Nonetheless, this decision, one of the earliest following the new rule and addressing the preamble, strengthens manufacturers’ preemption defense. In agreeing with FDA that the plaintiff’s claim of failure-to-warn was preempted, the court based its analysis on FDA amicus briefs in this and other cases and on FDA’s preamble to the new rule. As interpretations of the new rule are issued, it remains important for manufacturers to plan carefully in the FDA approval process to minimize potential product liability challenges that may arise following approval.

IV. Practical Applications of New Rule in Drug Development and Approval

A. Defeating a Claim That Information was Buried or Withheld From FDA

A common theme in recent product liability litigation is that a drug sponsor has not been forthright with FDA because it did not highlight negative information in the New Drug Application (NDA). Plaintiffs often argue that because an NDA comprises “rooms full of

paper,” if a sponsor fails to highlight information during the review process that is later at issue in the lawsuit, the sponsor is portrayed as having “buried” the information. Because FDA does closely review all of the information submitted in an NDA, a drug sponsor can attempt to insulate itself from this type of argument by specifically summarizing for, and discussing with FDA during labeling negotiations, any test results or data that may show possible adverse events, even if such occurrences do not rise to the level of being required in the label. Such discussions should be memorialized to show that the data were considered, and either determined by FDA to be necessary to include in the labeling, or not.

In doing this, a sponsor can invoke one of two claims that FDA says are preempted.¹⁷ First, when the questionable or negative data run contrary to the greater weight of the evidence, thus not requiring labeling, a plaintiff cannot later claim that the drug sponsor “failed to warn by failing to include contraindications or warnings” if such warnings were not supported by evidence satisfying FDA standards, because such a claim would be preempted. Second, in light of FDA’s stated goal of streamlining warnings so as to prevent overly broad warnings from “erod[ing] and destr[oying] the careful and truthful representation of risks and benefits,”¹⁸ it may benefit a drug sponsor to have a discussion with FDA representatives about adverse events that will likely not rise to the level of requiring a place in the *Warnings and Precautions* section. By doing so, a drug sponsor can thereafter argue that it did not fail to warn a plaintiff about such information in labeling or advertising, if that statement was discussed with FDA and determined by FDA not to be required at the time plaintiff

claims the sponsor had an obligation to warn. Indeed, FDA’s amicus brief in *Colacicco* detailed the considerations FDA had given to the Paxil® label and to subsequent citizen petitions and scientific studies when determining at the time of plaintiff’s use of the drug that adult suicide warnings were *not* required. Thus, frank and informed science-based discussion with FDA before and during launch of a new drug, as well as in the post-marketing phase, can help to establish the basis for a strong preemption claim in later litigation claiming a failure to warn.

B. Requiring Plaintiff to Define a Claim

If a plaintiff asserts vague negligence claims, such as “negligently warning, marketing and promoting,” a manufacturer should consider moving for a more definite statement to force plaintiff to articulate what plaintiff claims was the negligent conduct, omission, or misrepresentation. In doing so, plaintiff will be forced to state a claim that may fall within the FDA enunciated categories of preemption. As a result of forcing a plaintiff to state a concrete claim, a manufacturer can either exclude discovery and evidence not on that specific point, or discern and argue that plaintiff is seeking to bring a preempted claim.

C. Implications of FDA Approval of Highlights Revisions

As noted previously, plaintiffs will continue to argue that the preamble does not override the ability of a manufacturer to strengthen a warning on its own without prior FDA approval. As discussed, under FDA regulations, manufacturers can still strengthen warnings, prior to FDA review, but edits to the *Highlights* section are not permissible without prior FDA approval. Accordingly, the argument that the *Highlights* section could have been stronger,

or made without FDA approval, is clearly preempted. Moreover, given that the *Highlights* section must provide a list of substantive changes in the last year to the *Boxed Warning, Indications and Usage, Dosage and Administration, Contraindications, and Warning and Precautions* sections of the label, there is an inherent tension between strengthening the *Warnings and Precautions* or *Contraindications* sections prior to FDA approval, and updating the *Highlights* section, which requires prior approval. FDA has not yet provided guidance about resolving this tension.

If faced with a need to strengthen a warning unilaterally in advance of FDA approval of the change, manufacturers should be mindful of this tension and seek FDA input or review as soon as is practicable in order to successfully navigate between potential plaintiffs’ claims of “failed to strengthen warning” and FDA’s position that changes to the *Highlights* section should be approved in advance by the agency.

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Endnotes:

1 “FDA Announces Final Rule on the Requirements for Prescribing Information for Drug and Biological Products,” 1/18/06. (<http://www.fda.gov/cder/regulatory/physLa bel/summary.pdf>)

2 71 Fed. Reg. 3922, 3965 (January 24, 2006)

3 As part of this charge, FDA carefully controls the content of prescription drug labeling “because such labeling is FDA’s principal tool for educating health care practitioners about the risks and benefits of the approved product to help ensure safe and effective use.” *Id.* at 3934 and 3967.

4 71 Fed. Reg. 3934 and 3968.

5 *Id.* See also 21 C.F.R. § 314.70(c)(6)(iii)(A).

6 *Id.* at 3935.

7 *Id.* at 3935-3936.

8 *Breathing Life Into Federal Preemption After FDA’s Final Rule On Prescription Drug Labeling*, Mealey’s Litigation Report, Vol. 9, Issue #4, Feb. 2006,

9 *Id.* quoting 21 C.F.R. § 201.80(e) (formerly 21 C.F.R. § 201.57(e)).

10 *Id.* Note that this refers to jury-made state “law,” not to regulations or laws passed by, e.g., a state health agency or other body with science and health expertise.

11 71 Fed. Reg. at 3934.

12 71 Fed. Reg. at 3932.

13 FDA amicus curiae Brief at 6.

14 *Id.*

15 *Id.* at 18.

16 *Id.* at 20.

17 71 Fed. Reg. at 3936.

18 *Id.* at 3935.

EU PHARMACEUTICAL REVIEW

2005 heralded a number of significant changes for the European pharmaceutical industry, thanks in large part to three new pieces of EU legislation that completely overhauled the existing pharmaceutical regulatory framework. As a result, 2006 promises to be an interesting, albeit challenging, year for many pharmaceutical companies as they come to terms with the changes and their impact on the industry.

The deadline for member states to implement the new legislation was October 30, 2005 for EU Directive 2004/27/EC¹ (the Directive), and November 20, 2005 for Regulation (EC) No 726/2004². As such, the end of 2005 prompted a flurry of activity both at the national level and the EU level, with member states introducing or amending legislation, and the European Commission (EC) and the European Medicines Agency (EMA) releasing a number of guidance documents.

Major Changes

Key changes introduced by the legislation include the following:

1. Harmonization of the period of data and marketing protection afforded to medicinal products across the EU to a period of between 8 and 11 years (the so-called 8+2+1 provision).
2. A third route to authorization – the new Decentralized Procedure.
3. Conditional and Exceptional Marketing Authorizations.
4. The introduction of a “Bolar” type provision that enables generic companies to conduct, without liability for infringement, certain studies and trials to support abridged marketing authorization applications before the expiry of any relevant patent or supplementary protection certificates (SPCs).
5. The introduction of a European reference product for abridged marketing authorizations for generic medicines.
6. The introduction of a “sunset clause” invalidating the marketing authorization of a product if it is not placed on the market within three years of grant of authorization, or for a continuous three-year period.
7. New and improved patient information on packaging.

1. The 8+2+1 Data Protection Period

The 8 + 2 Protection Period

Under the old legislation, medicinal products were afforded either a 6- or 10-year data exclusivity and marketing protection period, depending in which EU country the application was made. The Directive harmonizes the protection period and introduces a new marketing and data exclusivity period for medicinal products that are granted a marketing authorization in the EU after October 30, 2005. Under the new legislation, generic applicants can apply using the “abridged” application procedure for a generic version of a new medicinal product once the original product has been authorized for 8 years, and may rely on the dossier of clinical trials and pre-clinical tests submitted with the original application. In addition, for the purposes of generic applications, the original product will be deemed to be the very first marketing authorization of an active substance. Thus “line extension” products, where the active substance has been subsequently authorized in a form that differs from the original product, will not be afforded the same protection.

Regardless of when the abridged application is granted under the new procedure, a generic version of a medicinal product may not be placed on the market until 10 years after the reference product was first authorized.

The + 1 Protection Period

Additionally, holders of original marketing authorizations can extend the period of marketing protection for a further year if, during the first 8 years of authorization of the original product, the marketing authorization holder obtains an authorization for one or more new therapeutic indications that are deemed to be of “significant clinical benefit” when compared to existing therapies. “Significant clinical benefit” means that no product containing the same active substance has ever previously been authorized in the relevant indication and/or is extended to new categories of patients.

It is important to note that the 8+2+1 protection period will only apply to applicants using the abridged application procedure. It is still open to generic manufacturers to obtain an authorization using the full marketing

authorization procedure as has, until now, been required for generic versions of biological products. The Directive, supported by guidelines, now provides a mechanism for applications for so called “biosimilar” products.

2. The New Decentralized Procedure

In response to concerns that the mutual recognition procedure was often taking too long, due in large part to disputes between member states, the revised framework now also contains a third pathway to authorization. As opposed to the older mutual recognition procedure, which requires an applicant to obtain authorization in one member state and then to seek to have this authorization mutually recognised in other member states, the new decentralized procedure enables an applicant to submit a dossier in all member states where the marketing authorization is sought at the time the authorization is first sought. One member state will then be chosen as the reference member state who will be responsible for preparing the assessment documents and circulating them among the other chosen member states for consideration and approval. The decentralized procedure is, therefore, only open to applications for new products that do not presently have an authorization in any of the member states. For such products it aims to offer a speedier route to authorization by engaging all concerned member states at the beginning of the process in order for them to air their views and resolve issues as quickly as possible. However, it remains to be seen how popular the new procedure will be.

3. Conditional & Exceptional Marketing Authorizations

Regulation 726/2004 also introduces two new marketing authorizations to cover situations when an applicant may not have all the required data, or is unable to obtain all the required data, but nonetheless, the benefit of granting the authorization outweighs the risks.

The first of these—conditional marketing authorizations—will be considered for newly developed drugs for life-threatening, seriously debilitating, or rare diseases or medicines for use in emergency situations under strict conditions. The new rules will enable medicines to enter the EU market using a conditional marketing authorization, which will be valid for one year and which will legally

bind the authorization holder to complete studies to confirm the medicine's safety and effectiveness. Conditional marketing authorizations will only be granted if the benefits to public health of the immediate availability of the medicine outweigh the risk inherent in the fact that additional data are still required. The rules concerning conditional marketing authorizations are now set forth in Regulation 507/2006, which came into force on April 1, 2006.

Exceptional marketing authorizations, on the other hand, will be considered where the applicant can demonstrate in the application that he or she is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence; in the present state of scientific knowledge, comprehensive information cannot be provided; or it would be contrary to generally accepted principles of medical ethics to collect such information.

Exceptional marketing authorizations will be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken.

4. The "Bolar" Provision

Previously, except where specific legislative exception exists, as in the United States following *Roche Products, Inc. v Bolar Pharmaceutical Co.*, (1984), generic pharmaceutical companies were not allowed to conduct tests on a patented substance prior to patent expiry. This prevented generic pharmaceutical companies from making a generic application until after patent expiry. The Directive introduces a new provision that effectively mirrors the United States' position and allows generic applicants to conduct certain necessary studies and trials with a view to submitting an abridged application.

Although the Directive states that such tests and studies "shall not be regarded as contrary to patent rights of to supplementary protection certifications," implementing this change into national law will require many member states to also amend their patent laws. This presents a risk in that each member state may interpret and implement the provision differently, and it is likely that the

scope of the Bolar provision will be defined by rulings of the European Court of Justice in years to come.

The UK is currently proposing an amendment that refers expressly to the provision in the Directive, and it is hoped that this will avoid confusion by referring expressly to the requirements of the Directive.

5. A European Reference Product for Abridged Applications

One further amendment aimed at facilitating abridged applications is the introduction of the concept of a European-wide reference product for abridged applications. The Directive introduces a definition of a "reference medicinal product" that encompasses any product authorized in accordance with the Directive. As a result of this change, generic applications will now be able to rely on the dossiers of original or reference medicinal products that have been submitted in any member state and not just the member state which had granted the original authorization.

6. The "Sunset Clause"

The Directive and Regulation 726/2004 also introduce a so-called "sunset clause"—this means that marketing authorizations of products that have not been placed on the market within three years of grant or have not been marketed for three consecutive years following authorization will automatically expire. Previously, medicinal products were initially authorized for five years, with an additional five-year renewable period.

7. New and Improved Patient Information on Packaging

The Directive also introduces a number of measures aimed at protecting patients and providing them with better access to information about medicinal products. Changes include requiring the majority of products to be labeled with their name in Braille; large-print patient information leaflets (PILs); or PILs available on the Internet, on audio tapes, or on CD-rom. Additionally, patients are to be given direct input into the design and content of PILs by the introduction of user testing requirements.

In the UK, the MHRA has indicated that these requirements will apply to all products authorized after October 30, 2005.

Conclusion

The above-mentioned points highlight some, but by no means all, of the changes introduced by the legislation. However, as these changes illustrate, the new legislation is bound to have a far-reaching impact on the pharmaceutical industry, both from the perspective of pharmaceutical companies and patients.

It is still too early to gauge whether or not all the amendments will transition smoothly into easy-to-follow practices and procedures, but the issue of a growing volume of guidance by the EC and the EMEA will assist both the national regulatory agencies and pharmaceutical companies to come to grips with the changes.

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Endnotes:

- 1 EU Directive 2004/27/EC on the Community Code relating to medicinal products for human use, amending the Community Code on Medicines for Human Use, Directive 2001/83/EC.
- 2 EU Regulation (EC) No 726/2004 laying down community procedures for the authorization and supervision of medicinal products for human use and veterinary use and establishing a European Medicines Agency.

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Kathleen M. Sanzo

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Stephen Paul Mahinka and James D. Pagliaro

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