

# Product Liability Update

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## Bi-Annual Update Regarding Pharmaceutical Drug and Prescription Device Federal Preemption: Breaking Developments from the Supreme Court and More

*By Michael K. Brown, Lisa M. Baird and Michelle H. Lyu*

Since our last comprehensive preemption update in March 2007, drug and medical device preemption has taken on an even higher profile, with a lot of activity in the Supreme Court—including some breaking developments from earlier today. Below, we review this latest news and the cases pending before the Supreme Court, as well as the other state and federal drug and medical device preemption cases decided since March. At the end of this article, we also discuss recent federal legislative activity that has received little notice, but which may have a significant—and unwelcome—impact on preemption, particularly in cases involving prescription drugs.

### Drug and Device Preemption Matters Before the U.S. Supreme Court

***Riegel v. Medtronic, Inc.*** For the past six years, the United States Supreme Court has been silent on the express and implied preemption doctrines in medical device and pharmaceutical cases, routinely denying petitions for review presenting those questions. This term is shaping up to be quite different.

As we noted in our March update, the Supreme Court invited the Solicitor General to weigh in on whether certiorari should be granted in a case in which the Second Circuit had joined the majority view and upheld preemption for a medical device approved through the rigorous premarket approval (PMA) process, *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006). Reed Smith's Michael K. Brown and Lisa M. Baird briefed *Riegel* in the Second Circuit, and Michael argued the case.

The Solicitor General's amicus brief was supportive of the majority view; explained the rigors of the premarket approval process; and counseled against granting review. Brief for the United States as Amicus Curiae in *Riegel v. Medtronic, Inc.*, 2007 WL 1511526 (S. Ct. May 23, 2007) (No. 06-179).

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The Supreme Court nevertheless granted cert at the end of last term. *Riegel v. Medtronic, Inc.*, 127 S. Ct. 3000 (June 25, 2007) (granting cert.). The plaintiffs' merits brief was filed August 27, 2007 [2007 WL 2456946], along with briefs from supporting amici Senator Edward M. Kennedy and Congressman Henry A. Waxman [2007 WL 2456945], AARP and other organizations [2007 WL 2456947], Consumers Union [2007 WL 2456948], the State of New York, et al. [2007 WL 2456949], Public Health Advocacy Institute and other organizations [2007 WL 2456950], and American Association for Justice and Public Justice [2007 WL 2576842]. Medtronic's brief is due October 19, 2007.

*Earlier today, October 1, the Supreme Court granted the substitution, allowing Riegel to proceed.*

As merits briefing was underway, an unusual wrinkle developed when plaintiffs' counsel filed a motion on August 1, 2007 seeking to substitute an estate in place of plaintiff Charles Riegel, who had died several years earlier. Medtronic opposed. Earlier today, October 1, the Supreme Court granted the substitution, allowing *Riegel* to proceed. Two versions of the Supreme Court's order were available on its website—an odd occurrence—one indicating Chief Justice Roberts and Justice Scalia would have denied the motion, and another indicating Justice Kennedy also dissented.

***Baker v. St. Jude Medical.*** Also earlier today, the Supreme Court left pending a petition for review filed in *Baker v. St. Jude Medical, S.C., Inc. et al.*, 178 S.W.3d 127 (Tex. App. 2005), *rev. den.* (Tex. Dec. 15, 2006) (No. 06-0223). Reed Smith's James C. Martin and Lisa M. Baird briefed *Baker* and *In re Heart Valve Litigation*, 2005 WL 1541059 (Tex. App. June 30, 2005), a companion case involving the claims of an additional 69 Texas plaintiffs in

a coordinated proceeding from Harris County. They also represent St. Jude Medical before the Supreme Court.

*Baker* also involves questions regarding whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the FDA.

***Warner-Lambert Co. v. Kent.*** Last week, in the implied preemption context, the Supreme Court granted the petition for review in *Warner-Lambert Co. v. Kent*, : -- S. Ct. --, 2007 WL 1420397 (U.S. Sept. 25, 2007) (No. 06-1498). *Warner-Lambert* involves an appeal from the Second Circuit's *Desiano v. Warner-Lambert Co.*, 467 F.3d 85 (2d. Cir. 2006). At issue is the effect of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), on a Michigan statute that exempts pharmaceutical manufacturers from liability unless the plaintiff establishes that the manufacturer intentionally withheld from, or misrepresented information to, the FDA. Since *Buckman* barred “fraud on the FDA” claims under the doctrine of implied preemption, manufacturers contend the statutory exception is foreclosed, meaning there can be no liability for manufacturers who fit within the statute. The Second Circuit's decision was in conflict with the Sixth and Ninth Circuits on the issue.

It is possible that *Warner-Lambert* will provide further guidance on the reach of the *Buckman* holding, which could assist courts grappling with similar questions about how broadly it should apply. *Ledbetter v. Merck & Co., Inc.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Tex. Dist. April 19, 2007), for example, examined Texas

Civil Practice and Remedies Code Section 82.007, which provides that in failure-to-warn products liability cases, manufacturers have a rebuttable presumption of no liability if their product label had FDA approval. Similar to the Michigan statute, Section 82.007(b)(2) provided that the presumption could be rebutted with evidence the manufacturer withheld or misrepresented information to the FDA. The court reached a conclusion opposite the Second Circuit's in *Desiano*. It held that because of the extensive federal regulation and "the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue." *Id.* at \*9. Therefore, implied preemption barred the plaintiffs from rebutting the Section 82.007(b)(1) presumption, and led the court to enter judgment against the Texas Vioxx plaintiffs. The plaintiffs have now appealed.

Conversely, the court in *In re Baycol Products Liab.*, 495 F. Supp. 2d 977 (D. Minn. 2007), grappled with a similar question in interpreting *Buckman*. There, the District of Minnesota examined the propriety of admitting a plaintiffs' expert's opinion that the manufacturer misled the FDA to obtain approval for a drug, Baycol. That court concluded that the expert's testimony was inadmissible to show that the FDA was misled or that the information was unintentionally concealed from the FDA. At the same time, however, the court concluded that state law tort claims for failure to warn were not preempted, and the evidence not excluded, to the extent the expert's testimony instead went to alleged misrepresentations to the public rather than the FDA.

**Wyeth v. Levine.** Over the past year-and-a-half, questions about preemption in prescription drug cases have garnered a lot of attention, following the FDA's release of its Final Rule, "Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products," 71 Fed. Reg. 3922-01, 2006 WL 160271 (Jan. 24, 2006). One cert petition now pending may give the Supreme Court an opportunity to weigh in on these issues soon.

In *Levine v. Wyeth*, the Vermont Supreme Court majority rejected an implied preemption defense in a prescription drug case, concluding that the manufacturer could have implemented label changes without FDA approval, and warned against a method of drug administration when the FDA-approved label did not. In

reaching its decision, the majority refused to give any weight to FDA's Final Rule, stating that the FDA's analysis was "neither an authoritative interpretation of an ambiguous statutory provision entitled to deference, nor a persuasive policy statement entitled to respect."

Wyeth then petitioned for certiorari, seeking review of the following question: "Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ("FDA") pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make

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*As for state courts, in a case of first impression in Wisconsin, the Wisconsin Court of Appeals upheld express preemption in a PMA medical device case as well. See Blunt v. Medtronic, Inc., 738 N.W.2d 143 (Wis. Ct. App. 2007)*

drugs reasonably safe for use.” *Wyeth v. Levine*, No. 06-1249, 2007 WL 776723 (S. Ct. March 12, 2007) (cert petition).

In May, the Supreme Court invited the Solicitor General to file an amicus brief on whether certiorari should be granted. While there is no deadline for this filing, the Solicitor General’s amicus brief should be filed sometime this fall, perhaps soon. Once it does, the Court will decide whether to grant review a short time later. PhRMA and PLAC already have filed amicus briefs supporting certiorari as well.

### Express Preemption Cases

#### Medical Devices Amendment

Notwithstanding the activity in the Supreme Court, the lower courts continue to address and decide preemption questions based on existing law.

Since our last update in March 2007, federal district courts in West Virginia, Missouri, Indiana, and Kentucky all have considered whether the express preemption clause for medical devices resulted in the preemption of tort lawsuits. Each held that the premarket approval granted for a Class III medical device created device-specific federal requirements that preempted different or additional state requirements generated through state tort lawsuits. *Cottengim v. Mentor Corp.*, No. 05-161-DLB, 2007 WL 2782885 (E.D. Ky. Sept. 24, 2007); *Rattay v. Medtronic*, 482 F. Supp. 2d 746 (N.D.W. Va. 2007); *Madsen v. Am. Home Products Corp.*, 477 F. Supp. 2d 1025 (E.D. Mo. 2007); *Thornburg v. Stryker Corp.*, No. 05-CV-1378, 2007 WL 1742172 (Mag. S.D. Ind. June 12, 2007), *adopted*, 2007 WL 1959117 (S.D. Ind. July 3, 2007); *Alfred v. Mentor Corp.*, No. 05-483-C, 2007 WL 708631 (W. D. Ky. March 5, 2007).

In a similar vein, the Utah District Court in *Tuttle v. CIBA Vision Corp.*, No. 05-CV-340, 2007 WL 677134 (D. Utah March 1, 2007), held that an FDA Guidance Document gave rise to preemption. The Guidance Document governed hydrogen-peroxide-based solutions like the defendant’s product, and the court concluded it constituted a federal labeling requirement. *Id.* at \*2. As a result, the plaintiff’s state tort claims that asserted liability based on the alleged defectiveness of the Guidance Document-specified warnings were preempted. *Id.*

As for state courts, in a case of first impression in Wisconsin, the Wisconsin Court of Appeals upheld express preemption in a PMA medical device case as well. *See Blunt v. Medtronic, Inc.*, 738 N.W.2d 143 (Wis. Ct. App. 2007) (holding that the PMA approval process created federal requirements that preempted state law tort claims), *petition for review filed*, No. 2006AP001506 (Wis. Aug. 30, 2007). Reed Smith’s Michael Brown and Lisa Baird represent Medtronic in *Blunt*.

Even though the overwhelming majority of cases favor preemption in Class III, PMA-approved medical devices, several notable adverse cases have been handed down in the past six months as well. Frequently in such adverse cases, the court believes the manufacturer’s compliance with the applicable federal requirements is in question. *See, e.g., Brown v. DePuy Spine Inc.*, 22 Mass. L. Rptr. 425, 2007 WL 1089337 (Mass. Super. Apr. 9, 2007).

Thus, in *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation (Duron)*, No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007), the court accepted for purposes of a summary judgment motion

on preemption that the PMA approval imposed device-specific federal requirements. However, it concluded that there was ambiguity in what these specific requirements were, and then concluded that material issues of triable fact existed as to whether Guidant complied with the federal requirements governing the device's design or manufacturing requirements. As to the product's label, the court concluded there was no evidence that the FDA actually considered evidence regarding the warning plaintiff wanted, and thus it likewise concluded that preemption was inapplicable.

Another adverse medical device express preemption decision was handed down in the Northern District of California, in a case in which the judge elected to follow Ninth Circuit precedent that predated the Supreme Court's *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). See *Notmeyer v. Stryker Corp.*, -- F. Supp. 2d --, 2007 WL 2257113 (N.D. Cal. Aug. 6, 2007). The court's reasoning turned on the question of whether the PMA approval process resulted in a specific federal requirement. *Notmeyer* recognized that *Lohr* had overruled *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), on whether state law tort claims can amount to state requirements, but it interpreted *Kennedy's* holding that premarket approval does not constitute a specific federal requirement to be still good law. *Id.*

### Over-The-Counter Drugs

Under the express preemption clause found in the National Uniformity for Nonprescription Drugs Amendment to the FDCA, homeopathic drugs are entitled to the preemption defense. In *Tesauro v. The Quigley Corp.*, No.

1011, 2007 Phila. Ct. Com. Pl. LEXIS 64 (Phila. Ct. Com. February 28, 2007), the court examined the plaintiffs' claim that an over-the-counter homeopathic drug, Cold-Eeze, was falsely advertised for the treatment and prevention of the common cold and allergies. *Id.* at \*5. The court held that the plaintiff's tort claims were preempted, stating:

If the Court were to permit Plaintiffs' claims to proceed and Plaintiffs were successful, Defendant would be required to include different information in its label than that reviewed, approved and required by the FDA.

*Id.*

### Implied Preemption Cases

As noted above, some of the most important preemption issues of late have involved application of the

doctrine of implied preemption in cases involving prescription pharmaceuticals and whether courts should defer to the FDA's views on preemption promulgated in its Final Rule on drug labeling. In the preamble to the Final Rule, the FDA emphasized its view that its regulation of drug labels should have preemptive effect over product liability lawsuits involving prescription drugs, and took issue with the proposition that its label requirements are "minimum standards" that manufacturers may unilaterally strengthen. See 71 Fed. Reg. at 3934-35.

The Third Circuit is the current hot spot, as it has scheduled oral argument for December 10, 2007 in two companion cases reaching opposite conclusions on these questions. The first is *Colacicco v. Apotex, Inc.*, 432

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### Express Preemption: Vaccines

The National Childhood Injury Compensation Act of 1986 ("Vaccine Act") was designed to compensate individuals injured by routine childhood vaccines through a streamlined adjudication process. See 42 U.S.C. § 300aa-13; H.R. Rep. No. 99-908 (1986), reprinted in U.S.C.C.A.N. 6344. In tandem with this compensation scheme, the Vaccine Act also contained an express preemption clause precluding civil actions for damages arising from unavoidable side effects of properly prepared and labeled vaccines. See *Bruesewitz v. Wyeth, Inc.*, -- F. Supp. 2d --, 2007 WL 2463378, at \*6 (E.D. Pa. August 24, 2007).

Recent vaccine preemption cases include *Sykes v. GlaxoSmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007), in which the court upheld preemption for strict liability and negligence claims based on Congress' intent to limit tort liability to cases in which the vaccine deviated from its FDA-approved design or label. *Id.* at 301-303.

The court in *Bruesewitz*, 2007 WL 2463378, at \*9-\*14, similarly found in favor of preemption. It declined to follow an adverse vaccine preemption case, *Ferrari v. Am. Home Prods. Corp.*, 2007 WL 1933129 (Ga. Ct. App. July 5, 2007), which found the Vaccine Act ambiguous regarding preemption.

*Even when a court expresses deference to the FDA and its views of preemption, however, a manufacturer will not necessarily prevail if the plaintiff's theory is different from those identified in the Final Rule as presenting a conflict between the federal and state requirements leading to preemption.*

F. Supp. 2d 514 (E.D. Pa. 2006), *rev. pending* No. 06-3107 (3d. Cir. Dec. 29, 2006), a case in which the plaintiff sought to impose liability for the manufacturer's failure to provide particular warnings the FDA had rejected as scientifically unsubstantiated. In upholding preemption, the Eastern District of Pennsylvania deferred to the FDA's views as espoused in the Final Rule, and in an amicus brief the FDA filed in response to a request from the court. The second case set for argument December 10 is *McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D.N.J. Dec. 29, 2005), *rev. pending* No. 06-5148 (3d. Cir. Dec. 15, 2006). In *McNellis*, the New Jersey District Court concluded that conflict preemption principles do not shield a manufacturer from common law liability, even where the FDA has rejected the very warnings the plaintiff seeks to impose through litigation. It also was unwilling to provide any deference to the FDA's views on preemption. Because the District Court certified the issue for immediate appeal, the Third Circuit availed itself of the opportunity to decide an important issue based on the record in two separate cases.

Other courts also are deciding prescription drug preemption questions. In *Tucker v. SmithKline Beecham Corp.*, No. 04-CV-1748, 2007 WL 2726259 (S.D. Ind. Sept. 19, 2007), the plaintiff contended that a manufacturer failed to warn of an increased suicide risk from an anti-depressant. Supported by a robust record reflecting extensive FDA attention to this issue, the manufacturer moved for summary judgment on the basis of federal preemption and the district court granted the motion. It noted that the FDA had opportunity to consider the plaintiff's warning and had in fact, “affirmatively reject[ed]”

the theory on which it was based—thus allowing the plaintiff's claim that to move forward would pose a direct conflict with the FDA's conclusion. *Id.* at \*9–\*10; *see also Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007) (claim basing liability on FDA-approved labeling is preempted, but claims basing liability on an unapproved label can go forward); *Sykes v. GlaxoSmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007) (because the FDA approved the products' label and had rejected the unsubstantiated risk information plaintiffs argued should have been included, failure-to-warn claims preempted); *Price v. Cook*, No. 99-C-12, 2007 WL 2154766 (W. Va. Cir. Ct. July 9, 2007) (where the FDA rejected the suicidality warning that plaintiffs advocated, failure-to-warn claims preempted).

Even when a court expresses deference to the FDA and its views of preemption, however, a manufacturer will not necessarily prevail if the plaintiff's theory is different from those identified in the Final Rule as presenting a conflict between the federal and state requirements leading to preemption. In *Sarli v. Mylan Bertek Pharm.*, No. 07-CV-43, 2007 WL 2111577 (M.D.N.C. July 19, 2007), for example, the court acknowledged that in the “current posture” of the case, it could not determine whether the FDA had reviewed and rejected the labeling proposed by the plaintiff, or whether the manufacturer had failed to include a statement that it had proposed to include. *Id.* at \*3–\*4. Given the ambiguous state of the regulatory record for the drug, the court concluded that it could not determine whether a conflict existed, and thus could not grant summary judgment on a preemption defense. *See also Kelly v. Wyeth*, 22 Mass. L.Rptr. 384, 2007 WL 1302589 at \*5

(Mass. Sup. April 12, 2007) (holding that there was no implied preemption because the manufacturer did not propose new language for the FDA as consideration; therefore there was no conflict between state and federal laws).

In addition, many courts remain skeptical of implied preemption in drug product liability cases, and many decline to defer to the FDA's view of preemption or its position that its decision on warnings constitute both "a floor and a ceiling." Instead, these courts often conclude that there is a strong presumption against preemption; deem the FDA's views on preemption as inconsistent over time; and view the FDA's Final Rule and amicus briefs on preemption as nothing more than advisory suggestions. Such cases include *Deutsch v. Wyeth*, No. MID-L-998-06-MT, 2007 WL 2060072 (N.J. Super. June 22, 2007) (rejecting implied preemption in a prescription drug case); *Giles v. Wyeth, Inc.*, -- F. Supp. 2d --, 2007 WL 1810646 (S.D. Ill. June 20, 2007) (same); *In re Zyprexa Prods Liab. Litig.*, -- F. Supp. 2d --, 2007 WL 1678078, at \*35-41 (E.D.N.Y. June 11, 2007) (same); *Barnhill v. Teva Pharm. USA Inc.*, 2007 U.S. Dist. LEXIS 44779 (S.D. Ala. April 24, 2007) (same).

One other recent, significant implied preemption decision also merits discussion. In *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, -- F.3d --, 2007 WL 2376312 (3d Cir. Aug. 17, 2007), the manufacturers were sued for allegedly engaging in deceptive drug advertising under the Delaware Consumer Fraud Act and the consumer protection statutes of the 50 states. On appeal, the question was whether federal law preempted these advertising-based state consumer protection claims.

The Third Circuit concluded that advertisements complying with FDA-approved labeling were not actionable under state consumer protection laws. *Id.* at \*6. Of importance, the panel found that the "degree of discretion inherent in the regulations [governing the advertising of prescription drugs] demonstrates that the FDA envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising." *Id.* at \*8. Furthermore, the court found an "even stronger case for preemption" where it found that the consumer fraud laws could be used to "question the veracity of statements approved by the FDA," especially since the FDA approved labeling of the drug formed the basis for the allegedly fraudulent advertising. *Id.* at \*9. Hopefully, this decision foreshadows a favorable outcome for the *Colaccico* and *McNellis* cases that the Third Circuit soon will address.

### Federal Legislative Activity

Given the life sciences industry's recent success raising the preemption defense in product liability litigation, it perhaps is not surprising that the defense is under increased scrutiny and that the plaintiffs' bar is pressing to have new limits imposed.

On Sept. 12, 2007, Senator Patrick Leahy (D-Vt.) called a Senate Judiciary Committee hearing entitled "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?" 110th Cong. 1-47 (Senate Judiciary Committee Sept. 12, 2007). The witnesses testifying for and against preemption echoed many of the public policy themes common in litigation briefs.

Perhaps more importantly, the plaintiffs' bar was active in negotiations

regarding the PDUFA reauthorization legislation, and the FDA Amendments Act of 2007 (H.R. 3580; Public Law Number 110-085), and succeeded in adding a provision that may have a deleterious impact on preemption in prescription drug cases. The bill was signed by the President Sept. 27, 2007, after Senator Henry A. Waxman (who filed an amicus brief opposing preemption in *Riegel*) reportedly insisted on a last-minute amendment to provide pharmaceutical plaintiffs with new ammunition when faced with a preemption defense.

Section 901 of the bill amends 21 U.S.C. section 355 regarding the new drug approval process. It provides new authority for the FDA to require postmarket studies and clinical trials and new provisions regarding labeling. More particularly, within a paragraph specifying a process by which the FDA can initiate a dialogue with a manufacturer about strengthening warnings, the bill contains a "Rule of Construction" (subparagraph (4)(I)) that plaintiffs' lawyers undoubtedly hope will limit use of the preemption defense in prescription drug failure-to-warn-cases—perhaps even in cases already in progress, like the *Colaccico* and *McNellis* cases pending before the Third Circuit.

H.R. 3580's section 901 follows, on the next pages.

**Postmarket Studies and Clinical Trials; Labeling—**

- (1) IN GENERAL—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.
- (2) DEFINITIONS—For purposes of this subsection:
  - (A) RESPONSIBLE PERSON—The term ‘responsible person’ means a person who—
    - (i) has submitted to the Secretary a covered application that is pending; or
    - (ii) is the holder of an approved covered application.
  - (B) COVERED APPLICATION—The term ‘covered application’ means—
    - (i) an application under subsection (b) for a drug that is subject to section 503(b); and
    - (ii) an application under section 351 of the Public Health Service Act.
  - (C) NEW SAFETY INFORMATION; SERIOUS RISK—The terms ‘new safety information,’ ‘serious risk,’ and ‘signal of a serious risk’ have the meanings given such terms in section 505-1(b).
- (3) STUDIES AND CLINICAL TRIALS—
  - (A) IN GENERAL—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.
  - (B) PURPOSES OF STUDY OR CLINICAL TRIAL—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:
    - (i) To assess a known serious risk related to the use of the drug involved.
    - (ii) To assess signals of serious risk related to the use of the drug.
    - (iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.
  - (C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.
  - (D) DETERMINATION BY SECRETARY—
    - (i) POSTAPPROVAL STUDIES—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).
    - (ii) POSTAPPROVAL CLINICAL TRIALS—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).
  - (E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS—
    - (i) NOTIFICATION—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.
    - (ii) TIMETABLE; PERIODIC REPORTS—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has

begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

- (F) DISPUTE RESOLUTION—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.
- (4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY—
- (A) NEW SAFETY INFORMATION—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).
- (B) RESPONSE TO NOTIFICATION—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—
- (i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or
  - (ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.
- (C) REVIEW—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.
- (D) DISCUSSIONS—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.
- (E) ORDER—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.
- (F) DISPUTE RESOLUTION—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.
- (G) VIOLATION—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.
- (H) PUBLIC HEALTH THREAT—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.
- (I) RULE OF CONSTRUCTION—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).
- (5) NON-DELEGATION—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

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