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Catherine T. Struve

University of Pennsylvania Carey Law School

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GREATER AND LESSER POWERS OF TORT REFORM: THE PRIMARY JURISDICTION DOCTRINE AND STATE-LAW CLAIMS CONCERNING FDA-APPROVED PRODUCTS

Catherine T. Struve†

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INTRODUCTION

As the federal agency tasked with ensuring drug safety,¹ the Food and Drug Administration (FDA) is the single most important regulator in the pharmaceutical field. Currently, a vigorous debate exists over whether it should be the only regulator. Critics of the tort system see products liability suits as an additional, pernicious source of regulation. They argue that juries should not be allowed to second-guess

† Professor, University of Pennsylvania Law School. I thank James O’Reilly and Catherine Sharkey for thoughtful comments on a prior draft. I am grateful to Christopher Robbins for research assistance, Ronald Day and the staff of the Biddle Law Library for assistance in obtaining sources, and Jeffrey Baldwin, Brendan Mahan, Kenneth Meyer, and the editors of the *Cornell Law Review* for their editorial work. Errors, of course, are mine.

¹ See Federal Food, Drug, and Cosmetic Act § 903, 21 U.S.C. § 393 (2000).

the FDA's drug-safety determinations, and they contend that the risk of tort liability deters useful pharmaceutical innovations.² The current FDA agrees. Although the FDA, under past administrations, saw itself as setting only a floor for drug safety—such that, for example, state tort law could permissibly impose additional requirements on a drug manufacturer³—the current FDA views itself as setting both a floor and a ceiling.⁴ Defenders of the tort system, however, point out that many risks become apparent only after a drug has been widely used for some time; in contrast to the rigorous scrutiny of pre-marketing review, the FDA's "post-marketing surveillance" program—the means by which the FDA monitors a drug's safety after its approval—is woefully inadequate.⁵ The tort system, they contend, gives plaintiffs' lawyers an incentive to collect and analyze drug safety data in their search for valid tort claims, and the tort discovery process can bring to light new evidence concerning a drug's risks.⁶

This debate has focused a great deal of attention on the issue of preemption. Tort critics contend that FDA approval of a drug or medical device should preempt state-law tort claims concerning the approved product.⁷ Under the current preemption doctrine, the success of their argument depends on the type of claim and on the level of FDA scrutiny that the product received. For example, if a plaintiff asserts that the defendant violated FDA requirements, FDA approval does not preempt the plaintiff's state-law tort claim.⁸ If, instead, the plaintiff asserts that the defendant secured product approval by perpetrating a fraud on the FDA, FDA approval will generally preempt the plaintiff's state-law tort claim.⁹ In the latter context, however, FDA

² See, e.g., Amicus Brief at 25–26, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597) (arguing that “[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices” and that the threat of such actions “can harm the public health by retarding research and development”).

³ See Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 *FOOD & DRUG L.J.* 7, 11 (1997) (article by FDA's former-Chief Counsel stating that “FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection”).

⁴ See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* 3922, 3935 (Jan. 24, 2006).

⁵ See, e.g., Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 *YALE J. HEALTH POL'Y L. & ETHICS* 587, 600–06 (2005).

⁶ See, e.g., Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 *WASHBURN L.J.* 549, 571 (2002) (“Private attorneys are adept at uncovering evidence of fraud and misrepresentation in the discovery that precedes common law trials, and they are willing to spend the resources necessary to copy and organize documents, take depositions, and fight the company's efforts to resist discovery.”).

⁷ See, e.g., Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* at 3934.

⁸ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

⁹ See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

approval might not preempt the plaintiff's state-law tort claim if the plaintiff makes the fraud-on-the-FDA assertion not as an element of the plaintiff's claim but only as a way to avoid a state-law regulatory-compliance defense.¹⁰ The Supreme Court granted certiorari in 2007 to resolve a circuit split concerning this question as applied to Michigan law, but divided 4–4 (and thus created no precedent).¹¹ Furthermore, although claims challenging the safety of a medical device that the FDA has approved through its relatively streamlined “substantial equivalence” process are not preempted,¹² claims concerning devices that the FDA has approved through its more rigorous “premarket approval” process are preempted to the extent that they assert that the defendant violated duties imposed by state law that “are ‘different

¹⁰ A regulatory-compliance defense provides that a defendant's compliance with the relevant agency's regulatory requirements provides a defense to tort liability. For example, a Michigan statute provides that, subject to certain exceptions,

[i]n a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). One exception to Michigan's regulatory-compliance defense arises if the defendant

[i]ntentionally with[held] from or misrepresent[ed] to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

Id. § 600.2946(5)(a) (citation omitted).

¹¹ See *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168, 1168 (2008) (per curiam). The Second Circuit had held that

because Michigan law does not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*, and because Appellants' lawsuits depend primarily on traditional and preexisting tort sources, not at all on a “fraud-on-the-FDA” cause of action created by state law, and only incidentally on evidence of such fraud, . . . the Michigan immunity exception is not prohibited through preemption.

Desiano v. Warner-Lambert & Co., 467 F.3d 85, 98 (2d Cir. 2006), as amended Jan. 18, 2007, *aff'd sub nom. Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam). In reaching a different holding, the Sixth Circuit previously asserted that

Buckman prohibits a plaintiff from invoking the [Michigan statutory] exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*. But the same concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process.

Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004).

For an insightful discussion of the issues presented by such fraud exceptions in state immunity statutes, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. Rev. (forthcoming June 2008).

¹² See *Medtronic*, 518 U.S. at 493–94.

from, or in addition to' the [duties] imposed by federal law."¹³ Meanwhile, in the context of prescription drugs, the lower courts have reached varying views concerning whether FDA approval preempts claims that a manufacturer failed to provide appropriate warnings of a drug's risks.¹⁴ The United States Supreme Court recently granted certiorari to review the Vermont Supreme Court's determination that FDA approval did not preempt a failure-to-warn claim because the defendant could have added the warning without prior FDA approval.¹⁵

The current FDA has made clear its support for the preemption defense. The FDA has submitted amicus briefs on behalf of the drug industry in various products liability suits.¹⁶ And when amending its regulations concerning prescription drug labeling, the FDA added a "preamble," which states that "FDA approval of labeling under the act . . . preempts conflicting or contrary State law."¹⁷ However, it is currently unclear how much weight courts will accord the preamble.¹⁸ It is also unclear whether Congress will act in this area; in 2007, Democrats in the House introduced a bill that would override the FDA's current position on preemption.¹⁹

While it is hard to predict the ultimate scope of the preemption defense, it is quite possible that some types of claims will escape it. Consequently, defendants, continuing their search for ways to privilege FDA determinations over those of lay juries, have turned to the

¹³ Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1011 (2008).

¹⁴ Compare Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 537-38 (E.D. Pa. 2006) (finding that federal law preempted the plaintiff's failure-to-warn claims) with *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788-89 (E.D. La. 2007) (finding that federal law did not preempt the plaintiff's failure-to-warn claim).

¹⁵ See *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008) (No. 06-1249).

¹⁶ See, e.g., Brief for Amicus Curiae The United States of America, *Colacicco* (Civ. No. 05-CV-05500-MMB), 2006 WL 1724170.

¹⁷ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

¹⁸ The Supreme Court recently avoided reaching the question of how much deference courts should give to an agency regulation asserting preemption in *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 (2007). The three dissenting Justices, who reached the question of the regulation's effect, asserted that "generic authorizations of rulemaking authority . . . provide no textual foundation for [the agency's] assertion of preemption authority," *id.* at 1583 n.23 (Stevens, J., dissenting), and argued that "when an agency purports to decide the scope of federal preemption, a healthy respect for state sovereignty calls for something less than *Chevron* deference," *id.* at 1584.

Meanwhile, lower courts have begun to split on the question of the preamble's effect. Compare *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 (JBS), 2006 WL 2819046, at *5 (D.N.J. Sept. 29, 2006) (holding that the preamble, by itself, does not preempt) with *Colacicco*, 432 F. Supp. 2d at 532 (relying in part on the preamble in holding a failure-to-warn claim was preempted).

¹⁹ See Food and Drug Administration Improvement Act of 2007, H.R. 2273, 110th Cong. § 6 (2007).

primary jurisdiction doctrine as an alternative.²⁰ For example, Judge William A. Dreier, who now practices products liability defense,²¹ proposes that if a court fails to find a failure-to-warn claim preempted, the court should apply the primary jurisdiction doctrine to stay the case “until the FDA has been requested to pass upon the alleged [labeling] misstatements and responds to the request.”²²

The primary jurisdiction doctrine, if applied in this context, would require a court hearing a products liability claim concerning an FDA-approved product to stay the case and refer the parties to the FDA for a determination of certain issues, including whether the product is defective and whether a defect caused the plaintiff’s injuries. This Article considers the extent to which courts can constitutionally use the primary jurisdiction doctrine to refer to the FDA issues arising in tort suits concerning FDA-approved drugs. Part I describes the doctrine and considers its possible use in drug products liability suits. Parts II and III analyze the constitutionality of applying the primary jurisdiction doctrine in such suits. Specifically, Part II addresses federal-court litigation, where the key constraints are those imposed by Article III and the Seventh Amendment. And Part III addresses state-court litigation, where the key constraints are those imposed by the scope of the commerce power and federalism concerns embodied in the Tenth Amendment.

I

THE PRIMARY JURISDICTION DOCTRINE

The primary jurisdiction doctrine may apply if a court faces an issue that an administrative agency should decide in the first instance.²³ The doctrine comes into play if a decision by an agency

²⁰ See, e.g., *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1053 (W.D. Wis. 2006) (“Defendants’ first motion raises questions whether Food and Drug Administration regulations preempt plaintiff’s state common law claims and whether the court should abstain from hearing this case in deference to the FDA’s primary jurisdiction and expertise.”).

²¹ Profile of William A. Dreier, http://www.nmmlaw.com/index.php?option=com_content&task=view&id=62&Itemid=29 (last visited Apr. 7, 2008).

²² William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 *RUTGERS L. REV.* 615, 644 (2006).

²³ The primary jurisdiction doctrine is different from the related doctrine of administrative exhaustion. As the Supreme Court has explained:

“Exhaustion” applies where a claim is cognizable in the first instance by an administrative agency alone; judicial interference is withheld until the administrative process has run its course. “Primary jurisdiction,” on the other hand, applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.

United States v. W. Pac. R.R. Co., 352 U.S. 59, 63–64 (1956).

would serve one or more of the goals of uniformity, expert technical or policy decision making, and judicial efficiency.²⁴ If the doctrine is in play, the court may require the parties to seek an agency's determination of certain issues before proceeding with the litigation.²⁵ Courts have sometimes applied the doctrine to require litigants to seek a determination from the FDA.²⁶ Some case law indicates, however, that courts are less likely to apply the doctrine to tort suits for personal injury damages.²⁷

Courts consider various factors in deciding whether to stay an action under the primary jurisdiction doctrine. Such factors include whether the relevant issue is within judges' normal competence²⁸ or whether it requires the agency's expertise;²⁹ whether the litigation may subject the defendant to obligations that conflict with those imposed by the agency;³⁰ whether the agency is already in the process of considering the relevant issue;³¹ the risk of undue delay if the court stays the suit to await the agency's determination;³² and the type of remedies available to the plaintiff in court and before the agency.³³

The arguments typically made in support of the primary jurisdiction doctrine could be made in the context of actions concerning FDA-regulated drugs or devices. For example, in upholding a district court's application of the doctrine to an action by drug makers seeking a declaratory judgment that their drugs were generally recognized as safe and effective, and thus were not "new drugs" requiring new drug applications,³⁴ the Supreme Court explained:

[T]he District Court's referral of the "new drug" and the "grandfather" issues to FDA was appropriate, as these are the kinds of issues peculiarly suited to initial determination by the FDA. . . . The deter-

²⁴ See *Far E. Conference v. United States*, 342 U.S. 570, 574-75 (1952).

²⁵ Ordinarily, there is no statutory authority for the court itself to refer the issue to the agency. Therefore, the court stays its proceedings and waits for a party to obtain the agency's ruling on the relevant issues. See, e.g., *Reiter v. Cooper*, 507 U.S. 258, 268 n.3 (1993). Because the plaintiff may be able to continue to litigate after the agency decides the relevant issues, the court should stay, rather than dismiss, the action to avoid any statute-of-limitations problems. See, e.g., *Ryan v. ChemLawn Corp.*, 935 F.2d 129, 132 n.2 (7th Cir. 1991).

²⁶ See, e.g., *Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042 LMM, 2000 WL 1738645, at *2 (S.D.N.Y. Nov. 22, 2000).

²⁷ See, e.g., *Ryan*, 935 F.2d at 131.

²⁸ See *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 305-06 (1976).

²⁹ See *Nat'l Commc'ns Ass'n, Inc. v. Am. Tel. & Tel. Co.*, 46 F.3d 220, 223 (2d Cir. 1995).

³⁰ See *Friends of Santa Fe County v. LAC Minerals, Inc.*, 892 F. Supp. 1333, 1350 (D.N.M. 1995).

³¹ See *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 532 F.2d 412, 420 (5th Cir. 1976).

³² See *Am. Tel. & Tel.*, 46 F.3d at 225.

³³ See *infra* notes 40-54 and accompanying text.

³⁴ See *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 647-49 (1973).

mination whether a drug is generally recognized as safe and effective within the meaning of § 201(p)(1) necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.³⁵

The argument for primary jurisdiction seems strongest when a plaintiff asks the court to order the defendant to do something that the FDA itself might require—such as an order to notify doctors and patients of particular information. Thus, for example, in *Bernhardt v. Pfizer, Inc.*, the district court applied the doctrine to a products liability plaintiff's request for an injunction requiring Pfizer to notify doctors and patients of study findings regarding Cardura, a Pfizer drug.³⁶ The court reasoned that the FDA's expertise was required in order to interpret the study's findings.³⁷ The court noted that Congress has empowered the FDA to notify doctors and patients about a drug's risks and to ask drug companies to alter a drug's labeling.³⁸ Likewise, another district court, citing *Bernhardt*, recently applied the primary jurisdiction doctrine in refusing to order the defendant to further notify class members of their need to obtain a blood test.³⁹

The nature of the relief sought can be key when a court decides whether to apply the primary jurisdiction doctrine. If the FDA could provide the plaintiff with the relief sought, then a court may be more likely to apply the primary jurisdiction doctrine. For example, in *Bernhardt*, the court observed that the plaintiffs could bring a citizen petition asking the FDA to notify patients and doctors,⁴⁰ which assured that plaintiffs had an avenue of relief even if the court held that the issue fell within the FDA's primary jurisdiction. Moreover, the fact that a requested action could be taken by the FDA may provide courts with additional reasons to apply the primary jurisdiction doctrine. If statutes and regulations explicitly authorize the FDA to take a particular action, a court may take that authorization as an indication that the issues involved in that action are committed to the agency's expertise and judgment.⁴¹ And if both the FDA and the court may take a particular action—such as ordering notice to class members of the need for a medical test—applying the doctrine avoids the risk that a

³⁵ *Id.* at 653–54.

³⁶ *Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042 LMM, 2000 WL 1738645, at *1 (S.D.N.Y. Nov. 22, 2000).

³⁷ *Id.* at *2.

³⁸ *Id.* at *3.

³⁹ See *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 433 (D.N.J. 2007) (citing *Bernhardt*, 2000 WL 1738645, at *3).

⁴⁰ See *Bernhardt*, 2000 WL 1738645, at *3 (citing 21 C.F.R. § 10.30).

⁴¹ See, e.g., *In re Human Tissue Prods.*, 488 F. Supp. 2d at 433.

court would subject a defendant to inconsistent notice obligations (and the concomitant risk that doctors and patients would receive multiple and possibly inconsistent notices).⁴² Finally, requests for injunctive relief, which invoke the court's discretionary powers, may be more likely than requests for monetary relief to lead to the application of the primary jurisdiction doctrine.

Even in cases involving damages claims, courts have in some circumstances applied the primary jurisdiction doctrine to require parties to submit certain issues to the FDA. In *Israel v. Baxter Laboratories, Inc.*, for example, a drug maker sued several of its competitors for damages, alleging that they conspired to induce the FDA to deny approval to the plaintiffs' drug.⁴³ The court of appeals viewed the lawsuit as presenting two issues: whether the plaintiffs' drug was safe and effective, and whether the defendants conspired to induce the FDA to deny approval.⁴⁴ The court held that the first of these issues fell squarely within the areas committed by Congress to the FDA's expertise. Thus, the court held, the primary jurisdiction doctrine required the district court to stay its proceedings to permit the plaintiffs to seek a determination from the FDA.⁴⁵ But, recognizing that the plaintiffs' conspiracy allegation fell outside the FDA's sphere of authority and noting that the FDA could not award the plaintiffs the damages they sought, the court ruled that the plaintiffs could reactivate their litigation after obtaining a determination from the FDA on their new drug application and that "[i]f . . . plaintiffs do not . . . obtain full and fair consideration by the FDA as to the safety and efficacy of their drug . . . , they may obtain a full hearing in the District Court on all their allegations."⁴⁶ Therefore, the *Israel* court required referral to the FDA on

⁴² See *id.*

⁴³ 466 F.2d 272, 274 (D.C. Cir. 1972).

⁴⁴ *Id.* at 280.

⁴⁵ See *id.* at 280–82. Similarly, in *Rutherford v. American Medical Ass'n*, the Seventh Circuit applied the primary jurisdiction doctrine to cancer patients' claims that defendants—including the American Medical Association and the FDA—conspired to prevent the distribution approval of Krebiozen, a cancer drug. 379 F.2d 641, 642–43 (7th Cir. 1967). Reasoning that “an essential element of the . . . case is a showing that under the appropriate standards, Krebiozen would be approved or exempted” and that “initial approval or exemption of a drug is within the primary jurisdiction of the FDA,” the Seventh Circuit affirmed the lower court's dismissal of plaintiffs' claims, stating that “[w]ithout an attempted good faith application for approval or exemption, we have no jurisdiction to determine whether the FDA has illegally placed impossible or unreasonable conditions on approval or exemption, or has made requests for information impossible to fulfill, or whether the FDA has been dilatory, biased, or discriminatory.” *Id.* at 643, 645. The application of the primary jurisdiction doctrine in *Rutherford* was perhaps more predictable than in *Israel* because the sole relief that the plaintiffs sought in *Rutherford* was an order enjoining interference with the drug's distribution—an order that would fall within the core of the FDA's own sphere of discretion. See *id.* at 642.

⁴⁶ See *Israel*, 466 F.2d at 282.

the issues of safety and efficacy, but also contemplated a searching district court review of the FDA's determinations on those issues.

Yet, other cases suggest that damages claims merit a different approach because the FDA is not empowered to award damages to a tort claimant injured by a defective drug or device. Some courts have relied on a plaintiff's request for damages as a reason not to apply the primary jurisdiction doctrine.⁴⁷ Likewise, some courts have indicated that even when the elements of a tort claim implicate technical judgments—such as a drug's safety, the adequacy of warnings, or injury causation—those judgments are no different from the judgments required in other products liability cases, and thus do not require application of the primary jurisdiction doctrine.⁴⁸

In *Ryan v. ChemLawn Corp.*, the Seventh Circuit took this view when it reversed the district court's application of the primary jurisdiction doctrine in state-law products liability litigation arising from the defendant's use of pesticides that had been registered with the Environmental Protection Agency (EPA) as required by federal law.⁴⁹ Reasoning that the case required an assessment of "arcane technical data, uniquely within the EPA's competence," the district court had refused "to substitute its judgment for that of the EPA and to decide whether the active and inert chemical ingredients in ChemLawn's products [were] safe for commercial use."⁵⁰ The Seventh Circuit, however, held the primary jurisdiction doctrine inapplicable,⁵¹ and explained that it "fail[ed] to understand what role the EPA [could] play in [the] suit," given that the EPA could not award the damages sought by the plaintiff.⁵² The court also stressed that the case involved "state common law causes of action and remedies that [were] not dependent on any EPA provisions," and that it viewed the case as posing no unusual challenges to judicial competence in light of "the tens of

⁴⁷ See, e.g., *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1058 (W.D. Wis. 2006) ("The FDA does not have authority to grant the compensatory or punitive damages sought by plaintiff in this case."); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001) ("[C]ourts generally do not defer jurisdiction where plaintiffs seek damages for injuries to their property or person."). The Seventh Circuit has used similar logic in refusing to apply the primary jurisdiction doctrine in a case involving the EPA:

[T]he plaintiff has dropped her claim for injunctive relief against the defendant. Therefore, hers is a claim that seeks only monetary damages, and as both parties agree that the EPA cannot provide the plaintiff with any form of compensatory or punitive damages, we fail to understand what role the EPA can play in this suit nor has the district court given this court any reason to rule otherwise.

Ryan v. ChemLawn Corp., 935 F.2d 129, 131 (7th Cir. 1991).

⁴⁸ See, e.g., *Peters*, 417 F. Supp. 2d at 1057–58.

⁴⁹ See *Ryan*, 935 F.2d at 130 & n.1.

⁵⁰ *Id.* at 131 (quoting the district court opinion).

⁵¹ *Id.*

⁵² *Id.*

thousands of personal injury suits alleging defective design or an inherent defect that are decided each year in state and federal courts.”⁵³ Finally, the court noted an alternative way to obtain input from the EPA: instead of applying the primary jurisdiction doctrine, “[i]f the district court believed that it needed specific information from the EPA to decide this case, it could have asked the EPA to file an *amicus* brief.”⁵⁴

There is, accordingly, some reason to doubt that a court would apply the primary jurisdiction doctrine to require referral to the FDA in a suit seeking damages for injuries allegedly caused by an FDA-approved drug. But even if courts refuse to apply the doctrine in this context, proponents might still ask Congress to mandate its application by statute. It is thus worthwhile to consider whether the Constitution would limit such a use of the doctrine.

II CONSTITUTIONAL CONSTRAINTS IN FEDERAL-COURT LITIGATION

This Part examines whether a court’s referral to the FDA of issues such as product safety and causation—under the primary jurisdiction doctrine—would be constitutional.⁵⁵ Two basic questions present themselves:⁵⁶ first, would referral comport with the limits imposed by Article III, and second, would referral comport with the limits imposed by the Seventh Amendment. Part III.A answers the first question and concludes that some uses of primary jurisdiction would probably comply with Article III. But, even assuming that the demands of Article III are met, the Seventh Amendment would pose an independent hurdle to the use of the primary jurisdiction doctrine.

⁵³ *Id.* at 132.

⁵⁴ *Id.*

⁵⁵ I touched upon this question in a prior article. *See* Struve, *supra* note 5, at 630–43 (2005). Arguments that I first made in that article are reproduced below in Part III.A and Part III.B.

⁵⁶ Another question might be: do principles of due process pose additional constraints? But the answer to this question depends on the details of the proposed system (for example, the nature of the litigants’ opportunity to be heard in FDA proceedings on the referred issues). For brevity’s sake, I omit further discussion of the due process constraints on the assumption that it is possible to design the primary jurisdiction process so that due process principles impose no additional barriers beyond those set by Article III and the Seventh Amendment. I make a similar assumption in Part III when I discuss the constitutional framework that applies to state-court litigation.

Given that the claims at issue in this Article are state-law tort claims, one might also argue that the referral discussed here implicates questions of federalism. But as to claims asserted in federal court, the Court has previously rejected the argument that “the fact that a federal agency rather than a federal Article III court initially hears the state law claim gives rise to a cognizably greater impairment of principles of federalism.” *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 858 (1986).

Thus, Part II.B addresses the second question. Part II.B begins by discussing the Court's primary jurisdiction precedents, which are silent on the Seventh Amendment question, and then reviews some basic outlines of Seventh Amendment doctrine. Based on this analysis, Part II.B. concludes that the Seventh Amendment would permit the use of the primary jurisdiction doctrine only if courts treat the FDA's findings as, at most, *prima facie* evidence.

A. Article III Constraints

Article III assures life tenure and salary protection for federal judges appointed under its authority.⁵⁷ These assurances protect separation-of-powers values by insulating the federal judiciary from undue control and influence by the political branches, and they also protect individual litigants' interest in fair decision making.⁵⁸ Litigants can waive the latter protection,⁵⁹ but the former protection is structural and not subject to waiver.⁶⁰ In this subpart, I first frame the question by situating it within modern doctrines concerning non-Article-III decision makers, and I argue that applying the primary jurisdiction doctrine to state-law tort suits brought in federal court complies with Article III only if we can view the FDA as an "adjunct" to the Article III federal courts. I then briefly review the Court's primary jurisdiction precedents, concluding that they provide no reason to depart from my initial assessment.

The Court has stressed that suits between private parties involving state common-law claims fall within the "core" of what the Court terms "private rights" suits.⁶¹ This appears to mean that non-Article-III federal tribunals can adjudicate such claims only if those tribunals function as "adjuncts" to an Article III court.⁶² True, in *Thomas v. Union Carbide Agricultural Products Co.*, the Court allowed Congress to relegate what might seem like a "private rights" claim to a non-Article-III decision maker, with minimal Article III court review, partly on the ground that the claim was "closely integrated into a public regulatory scheme."⁶³ And some might be tempted to argue that tort claims regarding FDA-approved products are, likewise, closely integrated into the FDA's regulatory scheme. However, such a comparison is tenuous because *Thomas* involved congressionally mandated arbitration of disputes between pesticide registrants concerning compensation (by a

⁵⁷ See U.S. CONST. art. III, § 1.

⁵⁸ See *Schor*, 478 U.S. at 848.

⁵⁹ *Id.* at 848–49.

⁶⁰ *Id.* at 850–51.

⁶¹ See, e.g., *id.* at 853; *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 584 (1985).

⁶² See *infra* notes 70–84 and accompanying text.

⁶³ *Thomas*, 473 U.S. at 593–94.

follow-on registrant) for use of a prior registrant's health and safety data.⁶⁴ Moreover, the claims in *Thomas* did "not depend on or replace a right to . . . compensation under state law,"⁶⁵ so *Thomas* is of limited relevance to the sort of state-law tort claims at issue here.

Likewise, the Court's decision in *Commodity Futures Trading Commission v. Schor* has limited relevance here. *Schor*, in upholding the Commodity Futures Trading Commission (CFTC)'s authority to hear brokers' state-law counterclaims in reparation proceedings brought by customers, relied in part on the notion that the customer in question had consented to have the claims heard by the non-Article-III decision maker.⁶⁶ (The Court also noted that the CFTC was a relatively independent body⁶⁷—a claim that is harder to make about the FDA.⁶⁸) Litigant consent is likely absent in the scenario considered in this Article because plaintiffs are likely to prefer a jury determination to a binding determination by the FDA on issues such as product safety and causation.⁶⁹

Accordingly, if the use of the primary jurisdiction doctrine by federal courts in tort cases involving FDA-approved products complies with Article III, it will be because it adheres to the "adjunct" model approved in *Crowell v. Benson*.⁷⁰ *Crowell* involved a workers' compensation scheme designed to replace traditional negligence claims that would have been brought in admiralty.⁷¹ Under the workers' compensation scheme, officials of the United States Employees' Compen-

⁶⁴ See *id.* at 571–75.

⁶⁵ *Id.* at 584.

⁶⁶ See *Schor*, 478 U.S. at 849.

⁶⁷ See *id.* at 855.

⁶⁸ See John W. Lundquist & Sandra L. Conroy, *Defending Against Food and Drug Prosecutions*, CHAMPION, July 1997, at 20, 20 (explaining that, although the FDA Commissioner must be confirmed by the Senate, the Commissioner "serves at the pleasure of the [Health and Human Services] Secretary and, therefore, the President").

⁶⁹ One can imagine a scenario in which a court could infer a plaintiff's consent—for example, if federal courts are known to apply the primary jurisdiction doctrine but the state courts do not, and if the plaintiff nonetheless chooses to sue in federal court. Such a scenario, however, is unlikely.

One reason why plaintiffs and their lawyers would likely prefer jury determinations to binding FDA determinations is that the plaintiff's bar may question the FDA's willingness to admit that an FDA-approved product is, in fact, unreasonably dangerous. See James T. O'Reilly, *Drug Review "Behind the Curtain": A Response to Professor Struwe*, 93 CORNELL L. REV. 1075, 1078 (2008) ("The likelihood that a highly politicized FDA management would support plaintiffs in product liability actions by plaintiffs during a conservative administration is minimal. And even under a more liberal administration, bureaucratic self-esteem is so great that the FDA would still probably decline to support plaintiffs, because supporting plaintiffs would be supporting claims contrary to the prior approval of bureaucratic peers.").

⁷⁰ 285 U.S. 22, 50–52 (1932); see *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 78 (1982) (plurality opinion) ("The use of administrative agencies as adjuncts was first upheld in *Crowell v. Benson*."). (citation omitted).

⁷¹ See *Crowell*, 285 U.S. at 38–41.

sation Commission would determine damages claims, and federal courts would enforce the Commission's compensation orders.⁷² In so doing, the federal court would review legal issues *de novo*, but would defer to the Commission's findings of fact.⁷³ (The Court, however, interpreted the statutory scheme as not requiring federal courts to defer to the Commission's findings of fact relevant to the Commission's jurisdiction⁷⁴ or to constitutional rights.⁷⁵)

The Court clearly did not think the *Crowell* case fell within the "public rights" doctrine—a doctrine that, if it had applied, would have allowed a non-Article-III decision maker to determine the claims.⁷⁶ But, despite viewing the dispute in *Crowell* as a "private rights" case,⁷⁷ the Court upheld the scheme's directive that the courts defer to the Commission's findings of fact, explaining that "there is no requirement that, in order to maintain the essential attributes of the judicial power, all determinations of fact in constitutional courts shall be made by judges."⁷⁸

A federal court's referral to the FDA of product safety or causation issues arising in a tort suit could thus comport with *Crowell's* view of Article III requirements. Such referrals would occur only in cases involving FDA-regulated drugs,⁷⁹ and they would "furnish a prompt, continuous, expert, and inexpensive method for dealing with a class of questions of fact which are peculiarly suited to examination and

⁷² See *id.* at 42–44.

⁷³ *Id.* at 45–46.

⁷⁴ *Id.* at 63.

⁷⁵ *Id.* at 60.

⁷⁶ See *id.* at 50–51. The Court in *Crowell* explained that "public rights" matters are cases that "arise between the government and person subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." *Id.* at 50. "Private rights" matters, on the other hand, concern "the liability of one individual to another." *Id.* at 51. It is well established that "public rights" disputes can be assigned to a non-Article-III decision maker. See, e.g., *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 69–70 (1982) (plurality opinion).

⁷⁷ *Crowell*, 285 U.S. at 51 ("The present case . . . is one of private right . . .").

⁷⁸ *Id.* It was, however, key that the courts could provide independent review, under the statutory scheme, with respect to jurisdictional and constitutional facts. See *id.* at 62.

⁷⁹ If a federal statutory scheme vests a non-Article-III decision maker with authority over only a narrow subject matter, the restriction may help to establish, under *Crowell*, that the non-Article-III decision maker is serving merely as an adjunct to the Article III courts. For example, in *Crowell*, the Court noted that the statute in question had "a limited application, being confined to the relation of master and servant." *Id.* at 54. This was one of the points on which the *Northern Pipeline* plurality relied in distinguishing *Crowell* and concluding that bankruptcy judges (under the system created by the Bankruptcy Act of 1978) could not be viewed as mere "adjuncts" to the Article III district judges:

[T]he agency in *Crowell* made only specialized, narrowly confined factual determinations regarding a particularized area of law. In contrast, the subject-matter jurisdiction of the bankruptcy courts encompasses not only traditional matters of bankruptcy, but also "all civil proceedings arising under title 11 or arising in or *related* to cases under title 11."

N. Pipeline, 458 U.S. at 85 (quoting 28 U.S.C. § 1471(b) (repealed 1984)).

determination by an administrative agency specially assigned to that task.”⁸⁰

Admittedly, one might distinguish the present context from that in *Crowell* by observing that the claim at issue in *Crowell* was a creature of federal statute, whereas the claim at issue in a tort suit involving an FDA-approved product would be a creature of state law.⁸¹ The Court has acknowledged that separation-of-powers concerns are stronger when Congress seeks to assign to a non-Article-III tribunal the adjudication of a claim that Congress has not created.⁸² Thus, the Court will very closely scrutinize any congressional attempt to assign to a non-Article-III “adjunct” the determination of a private rights claim arising under state law.⁸³ However, even though the workers’ compensation scheme in *Crowell* was a creature of federal statute, it resembled a state-law tort claim more closely than it may seem because it supplanted an older field of judge-made doctrine recognizing claims in admiralty.⁸⁴

The speculative tone of this discussion arises from the fact that none of the Court’s primary jurisdiction decisions address these questions in any depth. And few of those decisions involve the configuration implicated here (i.e., a state-law claim between private parties in federal court). One rare—and early—example of the configuration implicated here is *General American Tank Car Corp. v. El Dorado Terminal Co.*, which involved a breach of contract action concerning a railroad car lease.⁸⁵ After the Interstate Commerce Commission (ICC) held in 1934 that certain arrangements concerning mileage allowances constituted rebates, General American refused to continue paying the full amount due under the lease on the ground that a portion of that amount would constitute an unlawful rebate.⁸⁶ El Dorado sued General American in federal district court in assumpsit, seeking the sums due under the lease.⁸⁷ After the district court and court of appeals reached differing conclusions on the merits, General Ameri-

⁸⁰ *Crowell*, 285 U.S. at 46.

⁸¹ A violation of the Federal Food, Drug, and Cosmetics Act does not give rise to a private right of action under federal law. *E.g.*, *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002).

⁸² *See N. Pipeline*, 458 U.S. at 83–84; *see also* *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 854 (1986) (“[T]he state law character of a claim is significant for purposes of determining the effect that an initial adjudication of those claims by a non-Article-III tribunal will have on the separation of powers for the simple reason that private, common law rights were historically the types of matters subject to resolution by Article III courts.”).

⁸³ *See N. Pipeline*, 458 U.S. at 84 (plurality opinion).

⁸⁴ *See Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 587 (1985) (discussing *Crowell*).

⁸⁵ 308 U.S. 422, 423–25 (1940).

⁸⁶ *Id.* at 426.

⁸⁷ *Id.* at 423.

can (the loser in the court of appeals) sought Supreme Court review.⁸⁸ The ICC filed an amicus brief arguing that the courts lacked jurisdiction to hear the suit because it was within the Commission's purview.⁸⁹ The Court rejected the ICC's jurisdictional argument, noting that "[t]he action was an ordinary one in assumpsit on a written contract";⁹⁰ but the Court nonetheless reversed, holding that "[w]hen it appeared in the course of the litigation that an administrative problem, committed to the Commission, was involved, the court should have stayed its hand pending the Commission's determination of the lawfulness and reasonableness of the practices under the terms of the Act."⁹¹

The *General American Tank Car* decision mentioned neither the Seventh Amendment nor Article III. Although El Dorado's brief did not raise constitutional objections in response to the ICC's arguments,⁹² Article III separation-of-powers concerns are not subject to waiver.⁹³ But at the time, the Court's case law concerning non-Article-III decision makers was less developed than it is today. And to the extent that private suits arising under state law pose particularly strong Article III concerns under modern case law, those concerns might have been somewhat more muted in 1940 because the very notion that an assumpsit action arose under state law (as opposed to general common law) was itself of recent vintage.⁹⁴ In any event, the *General American Tank Car* decision does provide a precedent for applying the primary jurisdiction doctrine to a state-law claim between private parties in federal court.

Among modern cases, one can find another analogue to the present context in *Coit Independence Joint Venture v. Federal Savings and Loan Insurance Corp.*⁹⁵ *Coit* presented "the question whether Congress granted the Federal Savings and Loan Insurance Corporation (FSLIC), as receiver, the exclusive authority to adjudicate the state law

⁸⁸ See *id.* at 427–28.

⁸⁹ *Id.* at 428.

⁹⁰ *Id.* at 432.

⁹¹ *Id.* at 433.

⁹² See Brief for Respondent in Answer to Brief of Interstate Commerce Commission as Amicus Curiae, *Gen. Am. Tank Car Corp. v. El Dorado Terminal Co.*, 308 U.S. 422 (1940) (No. 129), 1939 WL 48376.

⁹³ See *supra* note 60 and accompanying text.

⁹⁴ See *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) ("There is no federal general common law.").

⁹⁵ 489 U.S. 561 (1989). As noted above, the configuration that interests us is one in which state-law claims between private parties are litigated in federal court. In *Coit*, the plaintiff sued in state court, seeking damages on a state-law usury claim. *Id.* at 565. FSLIC, newly appointed by the Federal Home Loan Bank Board as receiver for the defendant savings and loan, substituted itself as defendant, removed the case to federal court, and secured a dismissal for lack of subject matter jurisdiction; the court of appeals affirmed. See *id.* at 565–67.

claims asserted against a failed savings and loan association.”⁹⁶ The Court interpreted the statutory scheme so as not to grant such authority; instead, the Court held, “the creditors of a failed savings and loan association are entitled to de novo consideration of their claims in court.”⁹⁷ The Court noted that its interpretation of the statutory scheme avoided what otherwise would be grave constitutional questions:

[W]e need not reach Coit’s claim that adjudication by FSLIC subject only to judicial review under the Administrative Procedure Act would violate Article III of the Constitution under *Northern Pipeline* Similarly, we need not reach Coit’s due process and Seventh Amendment challenges to adjudication by FSLIC of its state law claims. We note, however, that the usury and breach of fiduciary duty claims raised by Coit . . . involve “private rights” which are at the “core” of “matters normally reserved to Article III courts.” The court below adopted an interpretation of the statutes governing FSLIC and the [Federal Home Loan] Bank Board that raises serious constitutional difficulties. In our view, those statutes can and should be read to avoid these difficulties.⁹⁸

Thus, although *General American Tank Car* provides precedent for applying the primary jurisdiction doctrine to state-law claims between private parties litigated in federal court, *Coit* suggests that courts should carefully cabin such an application in order to avoid constitutional problems. One important factor is the nature and extent of the review (in the federal court action) of the FDA’s findings on the referred questions; the more searching the review, the more likely the referral will fit within the “adjunct” model. In *Crowell*, the commissioner’s factual findings (other than those relating to jurisdictional or constitutional questions) were final unless they were “arbitrary” or “contrary to the indisputable character of the evidence.”⁹⁹ A primary jurisdiction mechanism that permits more searching review of the FDA’s findings—for example, by permitting either party to present rebuttal evidence and providing that the FDA’s findings were, at most, prima facie evidence—would be more likely to constitute a permissible example of the “adjunct” model under *Crowell*.

⁹⁶ *Id.* at 564.

⁹⁷ *Id.*

⁹⁸ *Id.* at 578–79 (citations omitted) (quoting *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 853 (1986)).

⁹⁹ *Crowell v. Benson*, 285 U.S. 22, 49–50 (1932) (“There is thus no attempt to interfere with . . . the exercise by the court of its jurisdiction to deny effect to any administrative finding which is without evidence, or ‘contrary to the indisputable character of the evidence,’ or where the hearing is ‘inadequate,’ or ‘unfair,’ or arbitrary in any respect.”) (quoting *Interstate Commerce Comm’n v. Louisville & Nashville R.R. Co.*, 227 U.S. 88, 91–92 (1913)).

B. Seventh Amendment Constraints

1. Primary Jurisdiction Decisions and the Seventh Amendment

As I detailed in a prior article, the Court's primary jurisdiction decisions shed little more light on the Seventh Amendment question than they do on the Article III question.¹⁰⁰ Most of these decisions arose in cases where the litigants either lacked¹⁰¹ or failed to properly raise¹⁰² a Seventh Amendment right. Two cases—*Keogh v. Chicago & Northwest Railway Co.*¹⁰³ and *Carnation Co. v. Pacific Westbound Conference*¹⁰⁴—did implicate the Seventh Amendment but, as I will explain, they do not settle the question at hand.

In *Keogh*, the plaintiff claimed the right to have a jury decide his claims for antitrust damages.¹⁰⁵ But by the time of trial, the ICC had approved the rates that the plaintiff sought to challenge, and the lower court accordingly dismissed the plaintiff's claims.¹⁰⁶ Seen in this context, the Supreme Court's affirmance of the dismissal¹⁰⁷ can be viewed as merely presaging the Court's later holding that issue preclusion can apply (in a case where there would be a Seventh Amendment jury right) even if the preclusive judgment arose from a nonjury proceeding.¹⁰⁸

¹⁰⁰ See Struve, *supra* note 5, at 640–42.

¹⁰¹ There is no Seventh Amendment right to a jury if the suit is litigated in state court or if the suit seeks solely injunctive relief. See, e.g., *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 719 (1999). Some of the Court's primary jurisdiction decisions involved suits litigated in state court. See, e.g., *S.D. Bldg. Trades Council v. Garmon*, 359 U.S. 236, 239 (1959); *Texas & Pac. Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 426 (1907). Other decisions involved suits in which the plaintiffs sought injunctive relief. See, e.g., *Far E. Conference v. United States*, 342 U.S. 570, 573 (1952) (involving a suit by the United States to enjoin alleged antitrust violations); *U.S. Navigation Co. v. Cunard S.S. Co.*, 284 U.S. 474, 478 (1932) (involving a suit to enjoin alleged antitrust violation); *Bd. of R.R. Comm'rs v. Great N. Ry. Co.*, 281 U.S. 412, 416 (1930) (involving a suit to enjoin enforcement of a state agency's rate-setting order).

¹⁰² See, e.g., *Andrews v. Louisville & Nashville R.R. Co.*, 406 U.S. 320, 324–25 (1972) (refusing to answer the Seventh Amendment question because the Court “do[es] not reach for constitutional questions not raised by the parties”); Brief for the Petitioner, *Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289 (1973) (No. 71-858) (failing to assert right to jury trial as basis for reversal); Petitioner's Reply Brief, *Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289 (1973) (No. 71-858) (same); Brief for Respondent, *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62 (1970) (No. 99) (making no mention of right to jury trial); Respondent's Brief in Opposition to the Petition for a Writ of Certiorari, *Chi. Mercantile Exch. v. Deaktor*, 414 U.S. 113 (1973) (No. 73-241) (same).

¹⁰³ 260 U.S. 156 (1922).

¹⁰⁴ 383 U.S. 213 (1966).

¹⁰⁵ See Brief and Argument for Plaintiff in Error at 13, 15, *Keogh*, 260 U.S. 156 (No. 823).

¹⁰⁶ See Transcript of Record from the District Court of the United States for Northern District of Illinois at 41–42, *Keogh* (No. 823).

¹⁰⁷ See *Keogh*, 260 U.S. at 165.

¹⁰⁸ See *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 337 (1979).

Carnation involved a claim for antitrust damages arising from rate agreements implemented by shipping company associations.¹⁰⁹ The parties' Supreme Court briefs focused on whether the Federal Maritime Commission (FMC)'s statutory authority over rate agreements barred the plaintiff from bringing an antitrust claim against the associations. The plaintiff asserted, in its petition for certiorari, that precluding the antitrust remedy would "improperly . . . deprive [it] of a right of trial by jury."¹¹⁰ The FMC, for its part, argued for a stay of the antitrust action in order to give the FMC an opportunity to decide whether the rate agreements violated the Shipping Act.¹¹¹ But before the briefing in the Supreme Court was concluded, the FMC reached its determination on that issue, ruling that the rate agreements challenged by the plaintiff did indeed violate the Shipping Act.¹¹² Because this finding favored the plaintiff, it is understandable that the plaintiff's reply brief did not argue that the application of those FMC findings in its antitrust suit would violate the Seventh Amendment.¹¹³ And because Seventh Amendment rights are waivable, the plaintiff's failure to press a Seventh Amendment argument in its reply brief explains the Supreme Court's failure to mention the Seventh Amendment when, ultimately, the Court remanded the antitrust suit with instructions to stay it "pending the final outcome of the Shipping Act proceedings" (because the FMC's decision had been appealed).¹¹⁴

The Court's primary jurisdiction cases, thus, do not settle the question at hand. The few commentators to discuss the question have noted doubt as to whether an agency determination on a referred issue can be binding in a case where a Seventh Amendment jury right applies.¹¹⁵ We must therefore turn to more general Seventh Amendment principles in order to analyze the question.

2. Reasoning from General Principles of the Seventh Amendment

The Seventh Amendment, when it applies to a claim, protects a litigant's right to have a jury rather than a judge determine material

¹⁰⁹ See *Carnation Co. v. Pac. Westbound Conference*, 383 U.S. 213, 215 (1966).

¹¹⁰ Petition for a Writ of Certiorari at 4, *Carnation*, 383 U.S. 213 (No. 20) (listing questions presented).

¹¹¹ See Memorandum for the Federal Maritime Commission at 5–6, *Carnation*, 383 U.S. 213 (No. 20); see also Brief for the United States and the Federal Maritime Commission at 13, *Carnation*, 383 U.S. 213 (No. 20).

¹¹² See *Carnation*, 383 U.S. at 223 n.6.

¹¹³ See Petitioner's Reply Brief, *Carnation*, 383 U.S. 213 (No. 20) (making no mention of the Seventh Amendment).

¹¹⁴ *Carnation*, 383 U.S. at 223–24.

¹¹⁵ See, e.g., 5 JACOB A. STEIN ET AL., ADMINISTRATIVE LAW § 47.03[2] (2007); Robert B. von Mehren, *The Antitrust Laws and Regulated Industries: The Doctrine of Primary Jurisdiction*, 67 HARV. L. REV. 929, 963 (1954).

disputes of fact.¹¹⁶ (It is unnecessary, for purposes of this Article, to explore the boundaries of the Amendment's application, because tort claims for damages fall squarely within its ambit.) By requiring courts to submit some types of issues to a jury, the Amendment brings the general public's values into the adjudication process and ensures popular participation in governance.¹¹⁷ Although the Amendment does "not bind the federal courts to the exact procedural incidents or details of jury trial according to the common law" as of the Amendment's adoption in 1791,¹¹⁸ it does constrain a court's ability to refer to non-jury decision makers those issues to which a right to trial by jury attaches.¹¹⁹

To explore this constraint, it is instructive to examine the line of cases concerning court-appointed auditors and special masters.¹²⁰ *In re Peterson*, a 1920 decision concerning the use of an auditor in an action at law,¹²¹ provides one of the Court's most extended discussions of the constraints imposed by the Seventh Amendment. Faced with a dispute over payments for a series of coal purchases, the trial judge appointed an auditor to take testimony, examine the relevant accounts, and make a report that would "simplify[] the issues for the jury, but not . . . finally determine any of the issues in the action."¹²² The Court, rejecting the plaintiff's Seventh Amendment challenge to the appointment, held that the auditor could permissibly "define and simplify the issues" for the jury, and that the submission of the auditor's findings to the jury, as prima facie evidence, would not "unduly interfer[e] with the jury's determination of issues of fact."¹²³ Noting that the parties were free to submit evidence to controvert the auditor's findings, the Court found no constitutional bar to "endow[ing]

¹¹⁶ See U.S. CONST. amend. VII.

¹¹⁷ See, e.g., Stephan Landsman, *The Civil Jury in America: Scenes from an Unappreciated History*, 44 HASTINGS L.J. 579, 599–600 (1993) (discussing the events leading to the adoption of the Seventh Amendment and noting that "[i]t was critical to the Antifederalists that the jury serve the interests of democracy by injecting the values of the 'many' into judicial proceedings").

¹¹⁸ *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336–37 (1979) (quoting *Galloway v. United States*, 319 U.S. 372, 390 (1943)).

¹¹⁹ The Seventh Amendment requires courts to undertake an issue-by-issue analysis of the jury right. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996); *Ross v. Bernhard*, 396 U.S. 531, 538 & n.10 (1970). For the purposes of this Article, I assume that, in a tort suit for damages, questions of product safety and causation would be for the jury.

¹²⁰ See David Elbaum, Note, *Judicial Review of Natural Resource Damage Assessments Under CERCLA: Implications of the Right to Trial by Jury*, 70 N.Y.U. L. REV. 352, 392 (1995) (suggesting that, when assessing possible Seventh Amendment constraints on federal-court deference to administrative agency fact-finding, "useful analogies may be drawn to other areas of law where courts have permitted pretrial factual determinations by judicial adjuncts to be used in jury trials"—such as "the use of special masters' reports").

¹²¹ 253 U.S. 300, 304 (1920).

¹²² *Id.* (quoting *Peterson v. Davison*, 254 F. 625, 629 (S.D.N.Y. 1918)).

¹²³ *Id.* at 310–11.

an official act or finding with a presumption of regularity or of verity.”¹²⁴

Of particular note in the current context, the *Peterson* Court relied¹²⁵ on its then-recent decision in *Meeker v. Lehigh Valley Railroad*.¹²⁶ *Meeker* upheld a statute providing that the ICC’s findings would be prima facie evidence in reparation suits concerning violations of the Interstate Commerce Act.¹²⁷ In upholding the trial court’s award of damages to the plaintiff shipper, the Court rejected the defendant railroad’s contention that treating the ICC’s report as prima facie evidence violated the Seventh Amendment:

The provision only establishes a rebuttable presumption. It cuts off no defense, interposes no obstacle to a full contestation of all the issues, and takes no question of fact from either court or jury. At most, therefore, it is merely a rule of evidence. It does not abridge the right of trial by jury, or take away any of its incidents.¹²⁸

The referral to an auditor approved by the Court in *Peterson* may not perfectly equate to a similar use of an agency for initial fact-finding purposes. The *Peterson* Court observed that the case for constitutionality was “in one respect, stronger” in *Peterson* than in *Meeker* because the auditor in *Peterson* was court-appointed and court-supervised, and his report could “be used only if, and so far as, acceptable to the court.”¹²⁹ An agency fact-finding process, by contrast, would not be court-supervised, and opponents might argue that this distinction weakens the case for constitutionality. But reliance on this distinction seems unpersuasive. Although the degree of court control over the fact-finding process might well affect the Article III analysis, it is less clear whether this factor should strongly affect the Seventh Amendment analysis.

At any rate, one concept emerges plainly from the *Peterson* Court’s discussion: there is a vital distinction between using third-party factual findings as evidence (even as prima facie evidence) and using third-party factual findings to bind the jury. The Court explained that “[a] compulsory reference with power to determine issues is impossible in the federal courts because of the Seventh

¹²⁴ *Id.* at 311.

¹²⁵ *See id.* at 311 (citing *Meeker v. Lehigh Valley R.R. Co.*, 236 U.S. 412, 430 (1915)).

¹²⁶ 236 U.S. 412 (1915).

¹²⁷ *Id.* at 430. The Interstate Commerce Act, as amended in 1906, provided that if a carrier failed to pay damages awarded by the ICC for a violation of the Act, the complainant could sue in federal court and the suit would “proceed in all respects like other civil suits for damages, except that on the trial of such suit the findings and order of the Commission shall be prima facie evidence of the facts therein stated” Interstate Commerce Act § 16, 34 Stat. 590 (1906) (repealed 1978).

¹²⁸ *Meeker*, 236 U.S. at 430.

¹²⁹ *In re Peterson*, 253 U.S. at 311–12.

Amendment but no reason exists why a compulsory reference to an auditor to simplify and clarify the issues and to make tentative findings may not be made . . . when occasion arises.”¹³⁰ As the Court stated earlier in the opinion, “The limitation imposed by the amendment is merely that enjoyment of the right of trial by jury be not obstructed, and that the ultimate determination of issues of fact by the jury be not interfered with.”¹³¹

Peterson, which predated the adoption of the Federal Rules of Civil Procedure, influenced the subsequent use of court-appointed masters under Rule 53. Prior to 2003, Rule 53 permitted courts to appoint a master in jury cases involving complex issues,¹³² and provided that the master’s findings constituted admissible evidence that could be read to the jury.¹³³ The goal was to help the jury navigate an issue’s complexity, not to constrain the jury’s ultimate decision.¹³⁴ In 1962, the Supreme Court noted that the then-applicable version of Rule 53(b) authorized courts to appoint masters “to assist the jury in those exceptional cases where the legal issues are too complicated for the jury adequately to handle alone,” but stressed that the need for such appointments should be rare.¹³⁵ A number of court of appeals decisions, citing *Peterson*, stated that a court’s use of the Rule 53 procedure did not violate the Seventh Amendment.¹³⁶

Under the principles that emerge from the line of cases dealing with court-appointed auditors and special masters, we can see that the Seventh Amendment would permit the use of the primary jurisdiction doctrine in federal court only if the issues determined by the FDA can be reexamined by the jury once the parties return to court. If a federal court applies the primary jurisdiction doctrine to refer factual issues (such as product safety or injury causation) to the FDA, the FDA’s findings could permissibly be submitted to the jury as *prima facie* evi-

¹³⁰ *Id.* at 314 (citation omitted).

¹³¹ *Id.* at 310.

¹³² The pre-2003 version of Rule 53 provided that “[a] reference to a master shall be the exception and not the rule. In actions to be tried by a jury, a reference shall be made only when the issues are complicated” Civil Rules Amendments Transmitted to Congress, March 2003, at 109, available at <http://www.uscourts.gov/rules/congress0303/CV-Redline.pdf>. The current version of Rule 53 bars the court from using a special master to recommend findings of fact in a jury case unless the parties consent. See FED. R. CIV. P. 53(a)(1).

¹³³ The pre-2003 version of Rule 53 provided that “[t]he master’s findings upon the issues submitted to the master are admissible as evidence of the matters found and may be read to the jury, subject to the ruling of the court upon any objections in point of law which may be made to the report.” Civil Rules Amendments Transmitted to Congress, *supra* note 132, at 115.

¹³⁴ See, e.g., Irving R. Kaufman, *Masters in the Federal Courts: Rule 53*, 58 COLUM. L. REV. 452, 459 (1958).

¹³⁵ *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 478 & n.18 (1962).

¹³⁶ See, e.g., *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1566 (Fed. Cir. 1988); *Crateo, Inc. v. Intermark, Inc.*, 536 F.2d 862, 868 (9th Cir. 1976).

dence. But, in actions to which it applies, the Seventh Amendment requires that the parties be free to put in evidence to controvert the FDA findings, and that the jury be free to reach a different conclusion than the FDA if warranted by the evidence. It would not be permissible to require the jury to defer to the FDA's findings.¹³⁷

III

CONSTITUTIONAL CONSTRAINTS IN STATE-COURT LITIGATION

Thus far, I have discussed the constitutional constraints on the application of the primary jurisdiction doctrine in federal-court litigation. But much of the litigation (involving FDA-approved products) that implicates the primary jurisdiction doctrine will take place in state, rather than federal, courts.¹³⁸ In state courts, the constitutional questions are even murkier than in federal court. This Part explores those questions and concludes that the primary jurisdiction doctrine is most likely to avoid constitutional problems if Congress creates a substantive federal-law defense, provides for referral to the FDA of issues relating to that defense, and provides that FDA determinations are, at most, *prima facie* evidence.¹³⁹ After reviewing cases in which the Court applied the primary jurisdiction doctrine in state-court litigation, I turn to the Court's modern federalism decisions and consider factors that would affect a constitutional analysis of the primary jurisdiction doctrine's application to state-court litigation.

The Seventh Amendment, of course, does not apply to state-court litigation.¹⁴⁰ However, forty-eight states have constitutional provisions

¹³⁷ David Elbaum made this point with respect to natural resource damage claims under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). See Elbaum, *supra* note 120, at 391.

¹³⁸ For example, the proposed Vioxx settlement agreement, announced in November 2007 by Merck and certain plaintiffs' counsel, states that "[m]ore than 95% of the active plaintiffs are presently coordinated in one of . . . four 'Coordinated Proceedings.'" Settlement Agreement at 1 (2007), http://www.merck.com/newsroom/vioxx/pdf/Settlement_Agreement.pdf. Among those four proceedings, three were coordinated in state court. See *id.* at 1-2.

¹³⁹ I focus this Part on a hypothetical federal statute authorizing the use of the primary jurisdiction doctrine because it presents the strongest case for the doctrine's valid application in state courts. Admittedly, courts have applied the primary jurisdiction doctrine in a number of contexts without any explicit statutory directive. See, e.g., *TCG New York, Inc. v. City of White Plains*, 305 F.3d 67, 74 (2d Cir. 2002) (characterizing the primary jurisdiction doctrine as "judge-made"). But, because applying the doctrine to state-court litigation would alter the balance of power between the states and the federal government, the Court should be wary of imposing the doctrine in state courts without clear direction from Congress. Direction from Congress would at least provide some assurance that the federalism implications had been weighed by a democratically accountable branch in which the interests of the states might be represented to some degree.

¹⁴⁰ See, e.g., *Osborn v. Haley*, 127 S. Ct. 881, 900 n.17 (2007).

guaranteeing the right to a jury in civil cases,¹⁴¹ and the two states that lack such provisions have provided a right to a jury by statute.¹⁴² Although a survey of state law on the right to a jury is beyond the scope of this Article, it is likely that, in many instances, state constitutional law protects a litigant's right to have issues of product safety and causation submitted to the jury in a products liability suit (assuming the litigant has submitted sufficient evidence to survive judgment as a matter of law).

The states' basic laws, therefore, entrust to juries issues that the primary jurisdiction doctrine would instead place before the FDA. This raises federalism concerns because the Court has recognized that state control over state-court structure and procedure is central to state sovereignty. Even when a state court adjudicates a federal claim, "[t]he general rule, 'bottomed deeply in belief in the importance of state control of state judicial procedure, is that federal law takes the state courts as it finds them.'" ¹⁴³ Therefore, the states "have great latitude to establish the structure and jurisdiction of their own courts."¹⁴⁴ And, considering that federalism concerns are heightened when the federal government requires a state court to alter its decision-making structure¹⁴⁵—as the application of the primary jurisdiction doctrine would require—one might question the constitutionality of applying the primary jurisdiction doctrine to state-court litigation. But a handful of early- to mid-twentieth-century Supreme Court decisions have sanctioned the doctrine's application, without giving any indication

¹⁴¹ See ALA. CONST. art. I, § 11; ALASKA CONST. art. I, § 16; ARIZ. CONST. art. II, § 23; ARK. CONST. art. II, § 7; CAL. CONST. art. I, § 16; CONN. CONST. art. I, § 19; DEL. CONST., art. I, § 4; FLA. CONST. art. I, § 22; GA. CONST. art. I, § 1, para. XI; HAW. CONST. art. I, § 13; IDAHO CONST. art. I, § 7; ILL. CONST. art. I, § 13; IND. CONST. art. I, § 20; IOWA CONST. art. I, § 9; KAN. CONST., B. OF RIGHTS, § 5; KY. CONST. § 7; ME. CONST. art. I, § 20; MD. CONST., DECL. OF RIGHTS, art. 5; MASS. CONST. pt. I, art. XV; MICH. CONST. art. I, § 14; MINN. CONST. art. I, § 4; MISS. CONST. art. III, § 31; MO. CONST. art. I, § 22(a); MONT. CONST. art. II, § 26; NEB. CONST. art. I, § 6; NEV. CONST. art. I, § 3; N.H. CONST. pt. I, art. XX; N.J. CONST. art. I, pt. 9; N.M. CONST. art. II, § 12; N.Y. CONST. art. I, § 2; N.C. CONST. art. I, § 25; N.D. CONST. art. I, § 13; OHIO CONST. art. I, § 5; OKLA. CONST. art. II, § 19; OR. CONST. art. I, § 17; PA. CONST. art. I, § 6; R.I. CONST. art. I, § 15; S.C. CONST. art. I, § 14; S.D. CONST. art. VI, § 6; TENN. CONST. art. I, § 6; TEX. CONST. art. I, § 15; UTAH CONST. art. I, § 10; VT. CONST. ch. I, art. 12; VA. CONST. art. I, § 11; WASH. CONST. art. I, § 21; W. VA. CONST. art. III, § 13; WIS. CONST. art. I, § 5; WYO. CONST. art. I, § 9.

¹⁴² Colorado Rule of Civil Procedure 38(a) provides that factual issues shall be tried to a jury "in actions wherein a trial by jury is provided by constitution or by statute, including actions . . . for injuries to person or property." COLO. R. CIV. P. 38(a). The Louisiana Code of Civil Procedure provides a right to trial by jury in tort suits, but provides an exception for suits "where the amount of no individual petitioner's cause of action exceeds fifty thousand dollars exclusive of interest and costs." LA. CODE CIV. PROC. ANN. art. 1731, 1732(1) (2003).

¹⁴³ *Howlett v. Rose*, 496 U.S. 356, 372 (1990) (quoting Henry M. Hart, Jr., *The Relations Between State and Federal Law*, 54 COLUM. L. REV. 489, 508 (1954)).

¹⁴⁴ *Id.*

¹⁴⁵ See, e.g., *Johnson v. Fankell*, 520 U.S. 911, 922 (1997).

that it was constitutionally problematic. Part III.A considers the impact of those decisions.

A. Primary Jurisdiction Cases Involving State Courts

Two statutory schemes—the Interstate Commerce Act and the National Labor Relations Act (NLRA)—have given rise to Supreme Court decisions applying the primary jurisdiction doctrine to state-court litigation.

In *Texas & Pacific Railway Co. v. Abilene Cotton Oil Co.*, a shipper sued a carrier in a state-court action at law, seeking damages and alleging that the carrier's rates were unreasonable and discriminatory.¹⁴⁶ The Supreme Court held that the state court lacked power to entertain the suit unless and until the ICC declared that the rates were unreasonable.¹⁴⁷ According to the Court, application of the primary jurisdiction doctrine was necessary to achieve Congress's goal of uniform rates:

For if, without previous action by the Commission, power might be exerted by courts and juries generally to determine the reasonableness of an established rate, it would follow that, unless all courts reached an identical conclusion, a uniform standard of rates in the future would be impossible, as the standard would fluctuate and vary, dependent upon the divergent conclusions reached as to reasonableness by the various courts called upon to consider the subject as an original question. Indeed, the recognition of such a right is wholly inconsistent with the administrative power conferred upon the [ICC], and with the duty, which the statute casts upon that body, of seeing to it that the statutory requirement as to uniformity and equality of rates is observed.¹⁴⁸

The *Abilene* litigation appears not to have involved a jury,¹⁴⁹ but the *Abilene* Court's reference to juries in the above passage indicates that the Court contemplated that its primary-jurisdiction ruling would apply with equal force in cases tried to a jury. Indeed, when the Court subsequently held in *Great Northern Railway Co. v. Merchants' Elevator Co.* that a state court need not await an ICC ruling before hearing a case involving the *construction* of a tariff (as contrasted with a case involving the *reasonableness* of a tariff), the Court's rationale was that tariff interpretation presented an issue of law that the Supreme Court could review, thus providing national uniformity.¹⁵⁰ Issues of fact that would ordinarily go to a jury, by contrast, were not subject to *de novo*

¹⁴⁶ 204 U.S. 426, 430–31 (1907).

¹⁴⁷ *Id.* at 448.

¹⁴⁸ *Id.* at 440–41.

¹⁴⁹ *See id.* at 431–32 (recounting trial court's findings of fact).

¹⁵⁰ 259 U.S. 285, 290–91 (1922).

Supreme Court review—hence the need for the primary jurisdiction doctrine to provide national uniformity.¹⁵¹

Although the Court's decision a few decades later in *San Diego Building Trades Council v. Garmon* did not discuss the role of juries, the Court similarly stressed uniformity as a reason for applying the primary jurisdiction doctrine.¹⁵² In *Garmon*, the Court held that activities protected under section 7 and activities designated as unfair labor practices under section 8 of the NLRA were within the core of matters to which Congress directed the NLRA and, thus, were outside state regulatory power.¹⁵³ It was unclear whether the union activities at issue in *Garmon* constituted unfair labor practices; if not, then the NLRA would not oust state jurisdiction.¹⁵⁴ But the Court held that the primary jurisdiction doctrine applied anyway and that the state court could not proceed unless and until the Nation Labor Relations Board reached a determination that the activities fell outside the purview of the NLRA.¹⁵⁵ The Court supported its application of the primary jurisdiction doctrine by asserting that if the doctrine applied to federal courts, it must also apply to state courts: "What is outside the scope of this Court's authority cannot remain within a State's power and state jurisdiction too must yield to the exclusive primary competence of the Board."¹⁵⁶

Abilene and *Garmon* apply a somewhat different model of the primary jurisdiction doctrine than the one on which this Article focuses. Rather than require referral to a federal agency during the course of an ongoing state lawsuit, those cases prohibit the state lawsuit from even commencing until the parties have obtained the necessary agency determination. But by approving that model of primary jurisdiction, the cases suggest that the doctrine, in general, can constitutionally apply to state-court litigation, even litigation in which there is a state-law jury trial right. Nonetheless, before we conclude that these cases—now roughly half a century old or more—prove the permissibility of such an application, we should consider whether such federal regulation of state-court procedure would conform to the Court's more modern federalism decisions.

B. The Court's Modern Federalism Decisions

As we have seen, the Court recognizes that control of state-court structure and procedure are basic aspects of state sovereignty.¹⁵⁷

¹⁵¹ See *id.* at 291.

¹⁵² See 359 U.S. 236, 242–43 (1959).

¹⁵³ *Id.* at 244.

¹⁵⁴ See *id.* at 244–45.

¹⁵⁵ See *id.* at 246.

¹⁵⁶ *Id.* at 245.

¹⁵⁷ See *supra* notes 143–45 and accompanying text.

Therefore, when a state court hears a federal claim—as indeed state courts must, absent a valid excuse¹⁵⁸—the state court is largely free to use its own procedure. On occasion, the Court has required state courts hearing federal claims to adopt certain aspects of federal procedure. For example, the right to a jury trial is so integral to the remedy provided by the Federal Employers' Liability Act that the right applies in state as well as federal court.¹⁵⁹ Federal procedure has likewise displaced state procedure concerning notice-of-claim requirements,¹⁶⁰ pleading,¹⁶¹ burdens of proof,¹⁶² and awards of prejudgment interest.¹⁶³ But though it is clear that the federal government can require state courts to adopt some federal procedures when hearing a federal-law claim, it is much less clear whether the federal government can require state courts to adopt federal procedures when hearing a state-law claim.

Congress might implement a primary-jurisdiction mechanism in state court in a variety of ways, and the details of the implementation would affect the constitutional analysis.¹⁶⁴ I will first consider the strongest case for such a mechanism's validity: a hypothetical federal statute, which creates a federal-law defense to state products liability suits and requires referral of that defense to the FDA for a non-binding advisory determination. I will then alter the variables so as to consider two different, more questionable examples of the hypothetical legislation.

1. *The Strongest Case for Constitutionality*

In the strongest-case example, the hypothetical legislation (creating a federal-law defense and requiring referral of that defense to the FDA for a non-binding determination) would be a valid use of Con-

¹⁵⁸ See, e.g., *Testa v. Katt*, 330 U.S. 386, 392–93 (1947).

¹⁵⁹ See *Dice v. Akron, Canton & Youngstown R.R. Co.*, 342 U.S. 359, 363 (1952).

¹⁶⁰ See *Felder v. Casey*, 487 U.S. 131, 152 (1988).

¹⁶¹ See *Brown v. W. Ry. of Ala.*, 338 U.S. 294, 295–96 (1949).

¹⁶² See *Garrett v. Moore-McCormack Co.*, 317 U.S. 239, 249 (1942).

¹⁶³ See *Monessen Sw. Ry. Co. v. Morgan*, 486 U.S. 330, 335–36 (1988).

¹⁶⁴ In fact, the Biomaterials Access Assurance Act of 1998 might be read to impose a mechanism akin to the primary jurisdiction doctrine for a narrow subset of products liability cases involving medical implants. See 21 U.S.C. § 1601 (2000). The Act provides federal liability standards for claims against suppliers of medical implant components, including making such suppliers subject to liability if they should have registered with the FDA as the device's manufacturer but failed to do so. See *id.* § 1604(b)(2). The Act further provides a mechanism for the court to stay a tort action pending a determination on this issue by the FDA. See *id.* § 1604(b)(3)(D). The Act, however, is ambiguous on the question of whether the FDA determination is a prerequisite for this avenue of liability. See *id.* §§ 1604–1605. If the FDA determination is a prerequisite, then the Act imposes something similar to the primary jurisdiction doctrine. But because the Act applies only to a narrow subset of potential cases, is ambiguous, and has not yet been construed in any published court opinions, this Article does not explore it further.

gress's commerce power,¹⁶⁵ and it would likely not violate the federalism values embodied in the Tenth Amendment.¹⁶⁶ Clearly, drug safety has a substantial effect on interstate commerce,¹⁶⁷ and drugs have long been subject to comprehensive federal regulation.¹⁶⁸ Congress could exercise its commerce power to enact a statute providing defendants in drug products liability cases with a defense to liability if—under specified federal standards—the drug was safe or it did not cause the plaintiff's injury. Congress's ability to control state-court procedure might not be as great in this instance as in the case of a *claim* created by federal law, but the fact that a federal law *defense* is at issue should bolster Congress's authority to alter state procedure.¹⁶⁹ Arguably, Congress can require state courts to use certain procedures that it deems integral to the federal statutory scheme to ensure that the state courts properly apply the federal defense (as the Supremacy Clause¹⁷⁰ requires).¹⁷¹

¹⁶⁵ See U.S. CONST. art. I, § 8, cl. 3 ("The Congress shall have Power . . . To regulate Commerce . . . among the several States . . .").

¹⁶⁶ See U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."). The Court has suggested that the Commerce Clause and Tenth Amendment questions are simply mirror images of each other. See *New York v. United States*, 505 U.S. 144, 159 (1992). More recently, however, the Court has first asked the question of whether Congress has regulatory power under the Commerce Clause and then asked about the limits imposed by the Tenth Amendment. See *Reno v. Condon*, 528 U.S. 141, 148–51 (2000); see also Anthony J. Bellia, Jr., *Federal Regulation of State Court Procedures*, 110 YALE L.J. 947, 964 & n.92 (2001) (citing *New York*, 505 U.S. at 155–56 and *Condon*, 528 U.S. at 149).

¹⁶⁷ See *Gonzales v. Raich*, 545 U.S. 1, 17 (2005) ("Congress has the power to regulate activities that substantially affect interstate commerce.").

¹⁶⁸ See generally Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420 (1981) (giving a historical account of drug regulation from 1848 to 1976).

¹⁶⁹ See Wendy E. Parmet, *Stealth Preemption: The Proposed Federalization of State Court Procedures*, 44 VILL. L. REV. 1, 23 (1999) ("Congress can create a federal defense and by extension, when the necessity arises due to federal interest, Congress should have the authority to regulate the manner in which state courts hear and decide that defense.").

As discussed in the introductory portion of Part III.B., the classic cases concerning federal authority over state-court procedure arise in the context of federally created *claims*. But the rationale the Court applied in those cases (roughly speaking, to ensure the appropriate vindication of the federal right) should also apply to federally created *defenses*. To the extent that burdens of proof might be considered procedural, one example might be the requirement that a public figure prove "actual malice" in a defamation case by clear and convincing evidence. See *New York Times Co. v. Sullivan*, 376 U.S. 254, 279–80, 285–86 (1964). In such a case, the federal burden-of-proof requirement arises because of the federal-law (First Amendment) defense. See *id.*

¹⁷⁰ U.S. CONST. art. VI, cl. 2.

¹⁷¹ A congressional finding that the procedural requirements are integral to the statutory scheme would serve to rebut the argument that court procedures are not themselves activities that are subject to regulation under the commerce power. As the Court explained in *Hodel v. Indiana*:

A complex regulatory program . . . can survive a Commerce Clause challenge without a showing that every single facet of the program is independently and directly related to a valid congressional goal. It is enough that

In the strongest-case example, the federally-required procedure would be the non-binding referral of the safety and causation issues (relevant to the federal-law defense) to the FDA for a non-binding determination. This would disrupt state-court procedures in three ways: (1) it would delay the suit for the length of time necessary to obtain a finding from the FDA; (2) it would require the admission of the FDA's findings as prima facie evidence on drug safety and causation; and (3) it would require the dismissal of the claim as a matter of law if the plaintiff failed to present evidence to rebut an FDA finding in the defense's favor on safety or causation. But, assuming that the plaintiff presented rebuttal evidence, this procedure would not remove the jury's authority over the ultimate liability determination. And, although a survey of state law on jury rights is beyond the scope of this Article, it seems safe to say that the non-binding nature of the FDA determination would reduce the likelihood that the procedure would offend state jury trial rights.

2. *A Weaker Case: No Issues of Substantive Federal Law*

This weaker case contains the same procedural provisions as the strongest case, but it does not create a substantive federal-law defense. This version of the hypothetical statute, in other words, would create no substantive rules for products-liability lawsuits, but it would require state courts hearing such suits to refer certain issues of product safety and causation to the FDA for an advisory determination. Can Congress regulate state-court procedure in cases where the claims and defenses involve no issues of substantive federal law? As commentators have noted,¹⁷² it has already done so through a number of statutes.

Some of those statutes have already been upheld by the Court. For example, the Federal Arbitration Act (FAA) requires state (as well as federal) courts to enforce written arbitration clauses concerning disputes over contracts involving interstate commerce,¹⁷³ even if they otherwise would have proceeded to hear the claims. Although one

the challenged provisions are an integral part of the regulatory program and that the regulatory scheme when considered as a whole satisfies this test.

452 U.S. 314, 329 n.17 (1981).

¹⁷² See, e.g., Perry H. Apelbaum & Samara T. Ryder, *The Third Wave of Federal Tort Reform: Protecting the Public or Pushing the Constitutional Envelope?*, 8 CORNELL J.L. & PUB. POL'Y 591, 620-27 (1999) (discussing the Biomaterials Access Assurance Act of 1998 and the Y2K Act); Bellia, *supra* note 166, at 954, 967-68 (discussing the Y2K Act and the Federal Arbitration Act); Parmet, *supra* note 169, at 7-8 (discussing the National Childhood Vaccine Injury Act); A.C. Pritchard, *Constitutional Federalism, Individual Liberty, and the Securities Litigation Uniform Standards Act of 1998*, 78 WASH. U. L.Q. 435, 437 (2000) (discussing the Securities Litigation Uniform Standards Act of 1998).

¹⁷³ The FAA covers, inter alia, disputes arising from "a contract evidencing a transaction involving commerce." 9 U.S.C. § 2 (2000).

might distinguish the FAA on the grounds that the parties consented in advance to arbitration, presumably the parties could not, by their consent, cure a Tenth Amendment problem with the statute.¹⁷⁴ Thus, when the Court in *Southland Corp. v. Keating* interpreted the FAA to “withdr[a]w the power of the states to require a judicial forum for the resolution of claims which the contracting parties agreed to resolve by arbitration,”¹⁷⁵ it can be taken to have indicated that it perceived no Tenth Amendment problem with its interpretation.¹⁷⁶ For another example, the supplemental jurisdiction statute, 28 U.S.C. § 1367, includes a tolling provision relating to limitations periods for certain state-law claims dismissed from a federal lawsuit and later asserted in state court¹⁷⁷—a provision the Court upheld in *Jinks v. Richland County* as an exercise of Congress’s power “to establish the lower federal courts and provide for the fair and efficient exercise of their Article III powers.”¹⁷⁸ And in *Pierce County v. Guillen*,¹⁷⁹ the Court held that a federal statute, which created an evidentiary privilege for a variety of documents that local governments collected to comply with federal highway safety grant provisions,¹⁸⁰ constituted a valid exercise of the commerce power.¹⁸¹ The Court declined, however, to address a Tenth Amendment challenge because the court below had not resolved the issue.¹⁸²

Commentators have questioned the validity of these statutes, expressing doubt over whether Congress has the authority to regulate state-court procedure in state-law cases that present no issues of substantive federal law. For example, Professor Bellia has argued that “[u]nder traditional conflicts principles . . . Congress has no authority to prescribe procedural rules for state courts to follow in state law

¹⁷⁴ The Tenth Amendment serves structural goals concerning the allocation of power between the state and federal governments. See, e.g., *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (“Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.”). Thus, Tenth Amendment concerns presumably could not be wholly cured by an individual litigant consenting to a particular exercise of federal legislative power. (Analogously, as noted above, although an individual litigant may waive any individual-rights-based objections to the use of a non-Article-III federal decision maker, such a waiver would not cure structural Article III objections. See *supra* text accompanying notes 59–60.)

¹⁷⁵ 465 U.S. 1, 10 (1984).

¹⁷⁶ One might argue, though, that the FAA poses less of a threat to federalism values than the hypothetical statute because the FAA requires submission of disputes to an arbitrator, not to a federal agency—and thus raises less concern about federal aggrandizement.

¹⁷⁷ See 28 U.S.C. § 1367(d) (2000).

¹⁷⁸ 538 U.S. 456, 464 (2003).

¹⁷⁹ 537 U.S. 129 (2003).

¹⁸⁰ 23 U.S.C. § 409 (2000).

¹⁸¹ See *Guillen*, 537 U.S. at 147.

¹⁸² See *id.* at 148 n.10.

cases.”¹⁸³ The *Jinks* Court, noting Bellia’s argument, avoided the question by characterizing section 1367’s tolling provision as “substantive” rather than “procedural”:

Assuming for the sake of argument that a principled dichotomy can be drawn, for purposes of determining whether an Act of Congress is “proper,” between federal laws that regulate state-court “procedure” and laws that change the “substance” of state-law rights of action, we do not think that state-law limitations periods fall into the category of “procedure” immune from congressional regulation. . . . [I]f the substance-procedure dichotomy posited by respondent is valid the tolling of limitations periods falls on the “substantive” side of the line. To sustain § 1367(d) in this case, we need not (and do not) hold that Congress has unlimited power to regulate practice and procedure in state courts.¹⁸⁴

One can argue, as the Court did in *Jinks*, that a tolling provision is not truly “procedural,” and that, likewise, an arbitration requirement or an evidentiary privilege is not truly procedural. But they are all arguably procedural—certainly they are routinely covered in civil procedure courses—and the Court’s approval of federal control over state practices in these areas in *Southland*, *Jinks*, and *Guillen* suggests a willingness to submit the states to some (but not an unlimited) degree of federal procedural regulation, even in purely state-law cases.

Although some have argued that the commerce power does not permit Congress to regulate state courts (which are not themselves actors in interstate commerce),¹⁸⁵ this argument would not necessarily sway the Court if it were confronted with our hypothetical statute. In *FERC v. Mississippi*, the Court rejected a similar argument when it upheld, against a Commerce Clause challenge, the Public Utility Regulatory Policies Act of 1978 (PURPA)’s provisions directing state utility regulators and the utilities themselves to consider adopting certain regulatory standards.¹⁸⁶ As in *FERC*, where the Court focused on the fact that the underlying regulated activity (electrical power generation) clearly affected interstate commerce,¹⁸⁷ the underlying regulated activity here (drug manufacture and distribution) clearly affects interstate commerce. It is true that the Court later stated in *New York v. United States* that “[t]he allocation of power contained in the Commerce Clause . . . authorizes Congress to regulate interstate commerce

¹⁸³ Bellia, *supra* note 166, at 952.

¹⁸⁴ *Jinks v. Richland County*, 538 U.S. 456, 464–65 (2003).

¹⁸⁵ See, e.g., A. Benjamin Spencer, *Anti-Federalist Procedure*, 64 WASH. & LEE L. REV. 233, 267 (2007) (“[R]egulating non-economic activity (state court adjudication), in an area of traditional state regulation (punitive damages for state law claims), by regulating courts rather than economic actors themselves—all based on the idea that such adjudications substantially affect interstate commerce—is a few bridges too far.”).

¹⁸⁶ See *FERC v. Mississippi*, 456 U.S. 742, 746, 757 (1982).

¹⁸⁷ See *id.* at 757.

directly; it does not authorize Congress to regulate state governments' regulation of interstate commerce," but the Court nonetheless cited *FERC*'s analysis with approval.¹⁸⁸

In any event, if the Court were to apply its *New York* analysis, it would suggest that the Commerce Clause and federalism analyses are merely two ways of looking at the same problem. In that event, it cannot hurt to now turn to the Tenth Amendment analysis. That analysis, as noted above, starts with the recognition that state control over court procedure is central to state sovereignty.¹⁸⁹ The Court should therefore scrutinize the hypothetical statute to see whether it impermissibly alters the balance of state and federal authority.

In scrutinizing federal legislation that arguably intrudes upon state prerogatives, the Court might ask—as it did in *Printz v. United States*—whether the legislation blurs the constitutionally-mandated lines of governmental accountability.¹⁹⁰ Voters may be less likely to hold federal officials accountable for procedural regulation than for substantive regulation. As Professor Parmet suggests, such procedural regulation may prevent the effective enforcement of state laws without forcing Congress to “clearly accept[] the onus for that nonenforcement by more forthrightly preempting state laws.”¹⁹¹ In the context of our hypothetical legislation, state courts could become, in the public's mind, identified with outcomes that are more properly attributable to the decisions made by the FDA on referral.¹⁹² (Some states already have provisions that might similarly blur lines of accountability, such as provisions that bar punitive damages resulting from products approved by the FDA;¹⁹³ but, of course, in such instances an organ of state government has chosen to adopt the relevant provisions.)

A Tenth Amendment challenge to the sort of procedural regulation discussed here inevitably evokes the argument that the greater power includes the lesser. Here, the argument would be that because Congress could altogether preempt state tort claims concerning FDA-approved products, it can exercise the lesser power of controlling the state courts' procedures for adjudicating those claims. Invoking *Printz*, Professor Bellia has challenged this contention:

188 505 U.S. 144, 166 (1992).

189 See *supra* notes 143–45 and accompanying text.

190 See 521 U.S. 898, 922 (1997).

191 Parmet, *supra* note 169, at 50.

192 In striking down a statute that required state law enforcement officers to conduct background checks on gun purchasers, the Court noted that under that provision “it will likely be the [state officer], not some federal official, who will be blamed for any error (even one in the designated federal database) that causes a purchaser to be mistakenly rejected.” *Printz*, 521 U.S. at 930.

193 See, e.g., N.J. STAT. ANN. § 2A:58C-5(c) (West 2001).

Controlling the enforcement of state rights in state courts may well be a greater power than controlling their enforcement in federal courts because the latter would demand the use of federal resources. Indeed, under the Tenth Amendment, the “greater” power to preempt state law does not include the “lesser” power to commandeer state legislatures or executives.¹⁹⁴

It is possible, however, that the most relevant precedent here is not *Printz* but *FERC*. In upholding PURPA’s requirements that state regulators consider adopting certain federally-prescribed regulatory standards, follow certain procedures when considering those standards, and fulfill reporting duties, the *FERC* Court stressed that Congress could have chosen to supplant altogether state regulation of electric utilities:

Congress could have pre-empted the field, at least insofar as private rather than state activity is concerned; PURPA should not be invalid simply because, out of deference to state authority, Congress adopted a less intrusive scheme and allowed the States to continue regulating in the area on the condition that they *consider* the suggested federal standards.¹⁹⁵

In this respect, PURPA can be contrasted with the “take title” provision invalidated in *New York v. United States*.¹⁹⁶ The latter provision “offer[ed] state governments a ‘choice’ of either accepting ownership of [low level radioactive] waste or regulating according to the instructions of Congress.”¹⁹⁷ The problem was that neither option, by itself, would have been constitutional:

Because an instruction to state governments to take title to waste, standing alone, would be beyond the authority of Congress, and because a direct order to regulate, standing alone, would also be beyond the authority of Congress, it follows that Congress lacks the power to offer the States a choice between the two. . . . A choice between two unconstitutionally coercive regulatory techniques is no choice at all.¹⁹⁸

FERC accordingly seems to suggest that Congress’s power to preempt state tort liability for FDA-approved products could justify Congress’s choice not to preempt, but instead to regulate, the procedures by which state courts adjudicate such claims. The latter sort of measure would, like PURPA, offer states a choice: continue to hear such

¹⁹⁴ Bellia, *supra* note 166, at 990. Similarly, Professor Parmet has suggested that when Congress chooses to regulate state-court procedures for hearing state-law claims, “the particular type of federal intrusion envisioned, although more subtle than outright preemption, may be especially onerous for the states.” Parmet, *supra* note 169, at 10.

¹⁹⁵ *FERC v. Mississippi*, 456 U.S. 742, 765 (1982).

¹⁹⁶ 505 U.S. 144, 177 (1992).

¹⁹⁷ *Id.* at 175.

¹⁹⁸ *Id.* at 176.

tort claims and follow the federally-prescribed procedures, or cease to hear such claims altogether. Because Congress could validly impose the latter result, it arguably could force a state to choose between that result and some procedural regulation.

3. *A Weaker Case: Giving FDA Determinations Binding Effect*

Up to this point, the hypothetical legislation has required referral of certain issues (arising in state-court tort suits) to the FDA, but has provided that the FDA's determination of those issues is non-binding. If the legislation instead required state courts to refer such issues to the FDA and to give the resulting FDA determinations binding effect, the latter requirement would call the legislation's validity into serious question. *FERC* did not approve any and all types of federal regulation; instead, *FERC* stressed that PURPA merely required state commissions to *consider* the relevant federal standards.¹⁹⁹ Thus, even if the greater power to preempt includes some lesser power to regulate procedure without preempting substance, it is likely that the Court would set bounds on that principle.

We can discern one such bound by reference to the analysis in Part II, where we saw that the primary-jurisdiction mechanism would be valid in federal court only if the FDA's determinations were, at most, *prima facie* evidence; otherwise, the mechanism would violate the Seventh Amendment. Although the Seventh Amendment does not apply in state court, it is problematic to argue that Congress can accomplish a result in state-court litigation that the Seventh Amendment would ban in federal-court litigation. In another context, the Court has noted the incongruity of suggesting that the federal government might "wield greater power in the state courts than in its own judicial instrumentalities."²⁰⁰ Notably, in none of the cases where the Court approved a federal statute that dictated arguably procedural measures to the state courts did the statute in question assert a power over state-law claims in state-court proceedings that Congress could not also have asserted over federal-law claims in federal-court proceedings.²⁰¹ Removing key issues from the purview of state juries would dramatically restructure the states' chosen allocation of decision-making authority and should be impermissible in light of the fact that the

¹⁹⁹ See *FERC*, 456 U.S. at 764–65; see also *Printz*, 521 U.S. at 926 ("In *FERC*, we construed the most troubling provisions of the Public Utility Regulatory Policies Act of 1978 to contain only the 'command' that state agencies 'consider' federal standards, and again only as a precondition to continued state regulation of an otherwise pre-empted field.")

²⁰⁰ *Alden v. Maine*, 527 U.S. 706, 712, 752 (1999) (holding that Article I does not empower Congress to abrogate state immunity from private suits for damages in state court).

²⁰¹ See *Jinks v. Richland County*, 538 U.S. 456, 464–65 (2003); *Pierce County v. Guillen*, 537 U.S. 129, 146–47 (2003); *Southland Corp. v. Keating*, 465 U.S. 1, 15–16 (1984).

Seventh Amendment would bar a similar arrangement in federal court.

CONCLUSION

Accordingly, it seems likely that Congress can require courts to apply the primary jurisdiction doctrine to state-law products liability claims only if courts treat the FDA's determination of the referred factual issues as, at most, *prima facie* evidence. The fact that courts could not give the FDA's determinations binding effect does not rob the primary jurisdiction doctrine of all potential significance in this field. To the extent that the Supreme Court ultimately rejects arguments for outright preemption of state-law tort claims concerning FDA-approved products, advocates of preemption would likely prefer a primary-jurisdiction mechanism—even one that promises only non-binding FDA determinations—to the current tort system, in which FDA input comes largely through *ad hoc* submissions in the form of *amicus* briefs. Conversely, opponents of preemption, who view litigation as a necessary backstop to FDA oversight and who are skeptical of the FDA's decision making, would likely oppose application of such a primary-jurisdiction doctrine for the same reasons that they oppose outright preemption. Professor O'Reilly's Response to this Article gives a forceful summary of the latter skeptical position,²⁰² and—as I discussed in a prior article—I share many of his concerns.²⁰³

My goal in writing this Article, however, was not to weigh those questions of policy, but rather to address the doctrinal question of the constitutional constraints on the application of the primary jurisdiction doctrine. In filling that gap in the doctrinal literature, this Article has also considered an interesting example of the limits on the notion that greater powers include lesser ones. It may seem ironic that more serious constitutional difficulties would arise from use of the primary jurisdiction doctrine than from outright preemption of state-law products liability claims. If Congress has the power to preempt, why should it not also have the power to require binding determinations by the FDA on certain challenging factual issues such as product safety and causation?

As to federal-court litigation, though, the greater-powers argument rings hollow. Congress's power to preempt a state-law claim carries with it no power to override the dictates of Article III and the Seventh Amendment when a federal court hears the claim. And even

²⁰² See O'Reilly, *supra* note 69.

²⁰³ See Struve, *supra* note 5, at 594–606 (discussing flaws in the FDA's system for postmarketing surveillance); *id.* at 648–50 (noting the possibility of bias in FDA decision making); *id.* at 663–66 (emphasizing the importance of the litigation discovery process for bringing safety information to light).

as to state-court litigation, the greater-powers argument goes only so far. The Constitution does not permit Congress to impose on state courts hearing state-law claims strictures that it could not impose on federal courts hearing such claims.²⁰⁴ This is particularly true in the light of the respect that Congress owes to the state courts as loci of state sovereignty.²⁰⁵

²⁰⁴ See *supra* Part III.B.3.

²⁰⁵ See *supra* notes 143–45 and accompanying text.

