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IN THIS ISSUE

Richard Dean, Mollie Benedict, and Avril Love recommend employing the doctrine of primary jurisdiction in pharmaceutical products liability litigation to defeat plaintiffs challenging federal regulators' authority to supervise product recalls.

Out of Your Jurisdiction: Why FDA Recalls and Courts Do Not Mix

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INTRODUCTION

A lesser known but equally helpful cousin of federal preemption, the doctrine of primary jurisdiction allows courts to avoid consideration of complex legal issues involving a regulatory agency's particular expertise.[1] Courts can defer the case until the agency with "primary jurisdiction" over an issue has had an opportunity to consider the dispute.[2] In recent years, courts have put this established doctrine to a new use in cases involving the recall of medical devices and pharmaceutical medications by manufacturers regulated by the U.S. Food and Drug Administration.

Though the FDA has federal regulatory authority over the conduct of product recalls, plaintiffs commencing litigation immediately after such recalls have, in recent cases, attempted to influence the course of the recalls themselves. Fortunately for consumers and manufacturers, courts are declining to interfere with an FDA-approved recall strategy. In addition to other arguments on preemption and judicial abstention, defendants should employ the primary jurisdiction doctrine to convince courts not to interrupt an FDA-approved recall when aggressive plaintiffs (and their law firms) seek to secure a litigation advantage by impeding or altering product recalls under the banner of consumer safety or evidence spoliation.

The History and Policy of the Primary Jurisdiction Doctrine

First recognized in the 1940s, the primary jurisdiction doctrine generally allows courts to defer to a federal agency's specialized knowledge, expertise, and central position within a regulatory regime in resolving issues arising under the applicable federal law.[3] Primary jurisdiction applies where a plaintiff seeks to enforce a legal claim that requires the resolution of issues within the "special competence" of a regulatory agency; "in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views."[4]

Pharmaceutical and Medical Device Recalls Are within the FDA's Authority and Expertise

Congress empowered the FDA to oversee recalls of prescription medications and medical devices under the Food, Drug & Cosmetic Act (FDCA).[5] The FDA has long

[1] Judicial abstention is another cousin to primary jurisdiction that practitioners should consider.

[2] *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) (courts defer to FDA's regulatory process because "the heart of new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created."); *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 767-68 (1947) (primary jurisdiction doctrine applicable where Congress has delegated initial or exclusive responsibilities to an administrative agency to resolve certain issues in complex matters in which the agency has special competence).

[3] *Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 672 (2003) (Breyer, J., concurring) (issue is whether "preliminary reference of issues to the agency will promote that proper working relationship between court and agency that the primary jurisdiction doctrine seeks to facilitate.").

[4] *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956); *accord Reiter v. Cooper*, 507 U.S. 258, 268 (1993) (doctrine is "applicable to claims properly cognizable in court that contain some issue within the special competence of an administrative agency.").

[5] *See United States. v. C.E.B. Prod., Inc.*, 380 F. Supp. 664, 668 (N.D. Ill. 1974) ("recalls have played an increasingly significant role in the FDA's enforcement of the [FDCA]."); *see also* 21 U.S.C. § 331(a) (prohibiting "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."); 21 U.S.C. § 393(b)(1) ("The [FDA] shall ... promote the

exercised extensive and predominant regulatory authority to monitor product recalls and assesses the adequacy of a firm's recall efforts through a comprehensive set of regulations that establish specific recall procedures. 21 C.F.R. § 7.40 *et seq.*

Under these regulations, the FDA exercises authority over the details of the recall based on its expertise. For example, the FDA evaluates the extent of the health hazard to at-risk populations presented by the recalled product, and its conclusion must be "supported as completely as possible by scientific documentation." 21 C.F.R. §§ 7.41, 7.41(a)(2). The regulations specify the factors that firms must consider when developing their recall strategies, including the "depth" of the recall, meaning the "level in the distribution chain to which the recall is to extend," depending on "the product's degree of hazard and extent of distribution." *Id.*; *see* 21 C.F.R. § 7.46(b) (in a firm-initiated recall, the FDA will advise the firm of the assigned recall classification based on the information submitted). The FDA reviews the adequacy of a firm's proposed recall strategy and communications and recommends changes as appropriate. 21 C.F.R. § 7.42. If the FDA is not satisfied with a pharmaceutical or device manufacturer's compliance with recall laws and regulations, it can — and does — seek enforcement of the FDCA in the courts.[6]

Courts Are Wielding the Doctrine of Primary Jurisdiction to Deny Plaintiff Requests for Injunctive Relief Regarding Recalls of FDA-Regulated Products

Given this expertise and federal authority to supervise recalls, courts may defer to the primary jurisdiction of the FDA in matters where its specialized expertise in science and medicine justifies deferral to its judgment in enforcing its regulatory authority.[7] Generally, in deciding whether to refer a particular issue to an appropriate administrative agency, courts consider: 1) whether judges have experience with the issue; 2) whether resolving the issue is within the agency's discretion or requires agency expertise; 3) whether there is a risk that inconsistent rulings may disrupt the statutory scheme; and 4) whether an application to the agency has previously been made.[8]

public health by ... taking appropriate action on the marketing of regulated products in a timely manner").

[6] *See, e.g., United States v. Lit Drug Co.*, 333 F. Supp. 990, 999 (D.N.J. 1971) (granting preliminary injunction preventing future production where manufacturers stipulated to having marketed adulterated drugs).

[7] *See, e.g., Weinberger v. Bentex Pharm., Inc.*, 412 U.S 645, 654 (1973) ("The determination whether a drug is generally recognized as safe and effective . . . 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."); *Israel v. Baxter Laboratories, Inc.*, 466 F.2d 272, 282 (D.C. Cir. 1972) (deferring consideration of lawsuit because no injunctive relief possible without "FDA evaluation, in view of its primary jurisdiction, of the safety and efficacy of [drug] for interstate sale"); *Physicians Comm. for Responsible Med. v. Gen. Mills, Inc.*, No. 1:05cv958, 2006 WL 3487651, at *6 (E.D.Va. Nov. 30, 2006) (dismissing complaint under primary jurisdiction doctrine where plaintiff also filed petition with FDA to order recall of dairy products promoting weight loss benefits); *Heller v. Coca-Cola Co.*, 646 N.Y.S.2d 524, 526 (N.Y. App. Div. 1996) (affirming application of primary jurisdiction of FDA to stay putative class action suit seeking injunctive relief that would require labeling changes to food additive because stay "would ensure that there will be national uniformity in the labeling of Aspartame and will utilize the special expertise of the FDA in evaluating the relevant factors for approving food additives.").

[8] *IPCO Safety Corp. v. WorldCom, Inc.*, 944 F. Supp. 352, 356 (D.N.J. 1996) (citation omitted); *accord*

Recently, plaintiffs and their law firms have attempted to convince a court that it should change the recall notices that pharmaceutical and device manufacturers send out to the public after FDA-approval of a recall strategy. In each case, the court has invoked the primary jurisdiction doctrine to deny these requests.[9]

In *In re Human Tissue Products Liability Litigation*, 488 F.Supp.2d 430 (D.N.J. 2007) ("*Human Tissue*"), plaintiffs alleged that they received unscreened human tissue harvested from corpses without proper consent. After the initiation of an FDA-regulated recall, plaintiffs filed an emergency motion for "prompt and urgent notice to unnamed class members of the need to have a blood test." *Id.* at 431. The court held that the content of a recall notice to unnamed class members was best left to the FDA and denied the motion on the grounds of primary jurisdiction, noting that, under the doctrine of primary jurisdiction, "courts must defer to the exclusive competence of [an] agency" when an activity is subject to its expertise. *Id.* at 432-33. Based on the FDA's guidelines for the "'format, content and extent' of the recall communications…," *id.* at 433 (quoting 21 C.F.R. § 7.49(a)) and the FDA's exercise of oversight regarding the tissue recall at issue, the court ruled that deference was in order:

> As these regulations show, Congress clearly vested the FDA with the regulatory authority to assess and manage the communications regarding product recalls. Implicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is required, what the notice should contain, and who the notice should be sent to. By requesting the Court to issue a similar notice here, Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA. The Court, though, does not have the expertise to undertake such a task. Therefore, as the court found in *Bernhardt [v. Pfizer]*, this matter is best left to the FDA's considered competence in these matters.

Id. In addition, the court noted that compelling defendants to issue the requested notice could "create a potentially dangerous situation" if the notice was inconsistent with a later FDA-required notice. *Id.* The court concluded that if plaintiffs wanted the FDA to issue a specific order regarding the recall, they could file a "citizens' petition" under 21 C.F.R. § 10.30. *Id.*

In *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y.), upon which the *Human Tissue* court relied, plaintiffs filed product liability actions regarding a hypertension drug after a clinical study concluded that it was less effective than a similar drug. *Id.* at *1. Pfizer moved to dismiss the claims for injunctive relief where plaintiffs sought to require label changes and warning letters regarding the findings of the clinical study to all of the drug's users and their physicians. *Id.*

Nat'l Comms. Ass'n, Inc. v. AT&T, 46 F.3d 220, 222-23 (2d Cir. 1995) (enumerating same four factors).

[9] *See, e.g., Clark v. Actavis Group hf*, 567 F.Supp.2d 711, 716-17 (D.N.J. 2008); *In re Human Tissue Prod. Liab. Litig.*, 488 F.Supp.2d 430, 431-32 (D.N.J. 2007); *Bernhardt v. Pfizer, Inc.*, Nos. 00 Civ. 4042 LMM, 00 Civ. 4379 LMM, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000).

The FDA — at the request of the court — submitted a brief and urged the court to deny injunctive relief on the grounds of primary jurisdiction. *See* Statement of Interest of the United States, *Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042 (LLM) (S.D.N.Y., Nov. 13, 2000). The FDA argued that a court order granting the requested labeling changes and warning letters would interfere with the FDA's responsibility to protect the public with respect to prescription drugs. The FDA also asserted that "any decision with respect to plaintiffs' proposed warnings involves complex scientific analysis with respect to the [clinical] study as well as policy considerations pertaining to whether, to what extent, and in what form, warnings should be issued." *Id.* at 14. The FDA objected to dissemination of "information that lacked the benefit of FDA's scientific expertise…" *Id.* at 2, 8-9. The agency also noted that if it later determined the court-ordered notices were "not supported by the evidence, and thus misleading, [Pfizer's drug] would be deemed misbranded." *Id.* In addition, if FDA later required a different warning notice than the court's, then "competing warnings [would issue] from different branches of government" — a problem the doctrine of primary jurisdiction was "designed to prevent." *Id.* at 14-15.

The court agreed with the FDA, concluding that the "FDA, not th[e] Court, has the relevant expertise…to determine, on the basis of presumably scientific and medical principles…, that the [clinical study's] findings warranted a notice to all [the drug's] users and their physicians." *Bernhardt*, 2000 WL 1738645, at *2. The court emphasized that the content of the warning notice was "within the FDA's informed expert discretion." *Id.* at *3. The court opted to avoid the "substantial danger" that conflicting notices might give "inconsistent directions concerning a serious medical ailment and how it is best treated." *Id.* As a result, the court deferred to the primary jurisdiction of the FDA and denied the request for injunctive relief.

Finally, in *Clark v. Actavis Group hf*, 567 F.Supp.2d 711 (D.N.J. 2008)[10], plaintiff alleged he received an excessive dose of a heart medication after it was recalled due to the possibility that double-thick tablets had been commercially released. Plaintiff's counsel requested that the court modify the terms of an FDA-approved recall to require the recalling manufacturer and distributors to disseminate what plaintiff believed was better information about the drug. Plaintiff sought to tell consumers that they should preserve their tablets, instead of returning them as the FDA-approved recall notice had advised. Plaintiff requested, in essence, that the court stop the recall of the product, on the grounds that the court has the power to require any potential evidence to be preserved.[11]

Based on the primary jurisdiction doctrine, the court declined to interfere with the recall. The court held that the issue before it posed the question: "what is the appropriate dissemination of medical information to the consuming public?" *Id.* at 716. The court noted that answering this question would require "understanding, deciphering, and decision-making regarding the FDA's prior determination of the content of the recall notice." Thus, the court concluded that the FDA, not it, had "the expertise to conduct such an intense medical analysis." *Id.* at 717-18.

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[10] Richard Dean and Tucker Ellis & West LLP were attorneys of record in the *Clark* litigation and national counsel for Actavis entities involving the recall of the heart medication Digitek®.

[11] *Clark*, 567 F.Supp.2d at 714.

The *Clark* court declined to interfere with the FDA's supervision of the recall process. Id. at 718 n.11. The court relied on an *amicus* brief filed by the FDA, in which the agency stated that it did "not have any information that would indicate that another notice at this time would add any benefit to the public health, and is concerned that it might confuse patients and potentially lead to adverse consequences." *Id.* The court noted that plaintiffs who took issue with a product recall could "file a Citizen's Petition with the FDA regarding the appropriateness of the notice and recall procedures." *Id.* at 719.

CONCLUSION

Courts have recently applied the doctrine of primary jurisdiction to protect the FDA's right to regulate the drug and device recall process in the United States. As a result, defense counsel faced with a plaintiff seeking court action to alter the recall of a product should determine whether the doctrine of primary jurisdiction can provide effective protection from unwarranted interference.

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