United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 25, 2013 Decided July 23, 2013

No. 12-5176

DANIEL WAYNE COOK, ET AL.,
APPELLEES

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLANTS

Consolidated with 12-5266

Appeals from the United States District Court
for the District of Columbia
(No. 1:11-cv-00289)

Daniel Tenny, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were *Stuart F. Delery*, Principal Deputy Assistant Attorney General, *Ronald C. Machen Jr.*, U.S. Attorney, *Scott R. McIntosh*, Attorney, *William B. Schultz*, Acting General Counsel, U.S. Health and Human Services, and *Eric M. Blumberg*, Deputy Chief Counsel.

Kent S. Scheidegger was on the brief for *amicus curiae* Criminal Justice Legal Foundation in support of appellant.

Eric A. Shumsky argued the cause for appellees. With him on the brief were *Coleen Klasmeier* and *Dale A. Baich*, Assistant Federal Public Defender, Office of the Federal Public Defender for the District of Arizona.

Before: ROGERS, *Circuit Judge*, and GINSBURG and SENTELLE, *Senior Circuit Judges*.

Opinion for the Court filed by *Senior Circuit Judge* GINSBURG.

GINSBURG, *Senior Circuit Judge*: A group of prisoners on death row in Arizona, California, and Tennessee sued the Food and Drug Administration, the Department of Health and Human Services, and the official in charge of each agency (collectively, the FDA) for allowing state correctional departments to import sodium thiopental (thiopental), a misbranded and unapproved new drug used in lethal injection protocols, in violation of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 381(a), and the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A). The district court entered summary judgment for the plaintiffs, permanently enjoined the FDA from allowing the importation of apparently misbranded or unapproved thiopental, and ordered the FDA to notify state correctional departments that the use of imported thiopental is unlawful and that existing stocks must be sent to the FDA. For the reasons that follow, we affirm the judgment of the district court but vacate the portion of its remedial order pertaining to thiopental already in the possession of the states.

I. Background

The Food, Drug, and Cosmetic Act (FDCA), makes it unlawful to introduce into interstate commerce a misbranded drug, 21 U.S.C. § 331(a), or an unapproved new drug, § 355(a).* A drug is misbranded if, among other things, it was "manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" with the FDA. § 352(o). An unapproved new drug is one that is neither "generally recognized, among experts ... as safe and effective" for its labeled use, § 321(p)(1), nor approved by the FDA as safe and effective for its proposed use, § 355(d).

The FDCA also regulates the importation of drugs. 21 U.S.C. § 381(a) provides:

> The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services [HHS], upon his request, samples of ... drugs ... being imported or offered for import into the United States .... The Secretary of [HHS] shall furnish to the Secretary of the Treasury a list of establishments registered [with the FDA] ... and shall request that if any drugs ... manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs ... be delivered to the Secretary of [HHS] .... If it appears from the examination of such samples or otherwise that ... such article is adulterated, misbranded, or [an unapproved new drug] ..., then such article shall be refused admission.

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* The FDCA is codified at 21 U.S.C. § 301 *et seq*. For convenience, we refer to sections of 21 U.S.C. as though they were sections of the Act.

The duties of the Secretary of the Treasury under § 381(a) are administered by Customs and Border Protection, a unit of the Department of Homeland Security, *see Del Monte Fresh Produce N.A., Inc. v. United States*, 706 F. Supp. 2d 116, 117 n.1 (D.D.C. 2010); those of the Secretary of HHS are administered by the FDA, *see* FDA, 2 STAFF MANUAL GUIDES 1410.10, at 1 (2012), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf. In addition to physically examining samples, as required by § 381(a), the FDA "receives notification from [Customs] of all formal and informal entries of articles under FDA jurisdiction at ports of entry" and "electronically screen[s]" those entry data "against criteria developed by FDA." FDA, REGULATORY PROCEDURES MANUAL 9-2 to 9–3 (2013), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf.

Each of the plaintiffs in this action has been sentenced to death under the laws of Arizona, California, or Tennessee. At the time of the complaint those states and many others executed prisoners by injecting them with a sequence of three drugs: (1) sodium thiopental, which induces anesthesia; (2) pancuronium bromide, which causes paralysis; and (3) potassium chloride, which stops the heart. *Baze v. Rees*, 553 U.S. 35, 44 (2008) (plurality opinion). The administration of thiopental is critical because absent "a proper dose ... render[ing] the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Id*. at 53. Although thiopental has been used as an anesthetic since the 1930s, it is presently an unapproved new drug.

In 2009 the last domestic manufacturer of thiopental stopped making it. Several state departments of correction then began ordering thiopental from Dream Pharma Ltd., a wholesaler located in the United Kingdom. The thiopental sold by Dream was prepared and marketed by Archimedes Pharma UK, Ltd., which obtained unfinished thiopental from a facility in Austria; neither Dream nor Archimedes was registered with the FDA. The FDA therefore detained the first two shipments from Dream because, per § 381(a), the thiopental appeared to be a misbranded and unapproved new drug. After state officials explained the purpose of the imported thiopental, however, the FDA released the shipments. Several states, including Arizona, California, and Tennessee, thereafter imported thiopental from Dream without interference from the FDA.

In 2011 the FDA issued a policy statement concerning the importation of thiopental for the execution of state prisoners. The FDA stated that it "neither approves nor reviews [thiopental] for use in lethal injections." Rather, in "defer[ence] to law enforcement" agencies, henceforth it would exercise its "enforcement discretion not to review these shipments and allow processing through [Customs'] automated system for importation."

The plaintiffs then brought this suit alleging the FDA's policy statement and its failure to "refuse[] admission," § 381(a), to certain specific shipments of thiopental coming from Dream violated the APA. The FDA argued first that its "decision not to take enforcement action with respect to thiopental is not subject to judicial review because 'agency refusals to institute investigative or enforcement proceedings' are 'committed to agency discretion.'" *Beaty v. FDA*, 853 F. Supp. 2d 30, 39 (D.D.C. 2012) (quoting Defendants' Memorandum in Support of Motion to Dismiss and/or for

Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment at 1, 14–15). The district court, however, reasoned the FDA's conduct was reviewable because it "did not involve a decision whether to initiate enforcement proceedings ... [but rather its] duty to obey the law and deny admission to a drug according to unambiguous statutory provisions." *Id*. at 40. On the merits of the dispute, the district court held the FDA acted contrary to law because § 381(a) "impose[s] a mandatory obligation on [the FDA] to refuse to admit the misbranded and unapproved drug, thiopental, into the United States." *Id*. at 39. The district court also held the FDA had been arbitrary and capricious, in violation of the APA, because it had "acted inconsistently with FDA regulations, acted inconsistently with its longstanding practices, and acted in a manner contrary to the purpose of the FDCA, thereby threatening the public health." *Id*. at 41. The district court therefore granted summary judgment for the plaintiffs.

In a separate order, the district court granted the plaintiffs declaratory and injunctive relief. It declared the thiopental that had been imported already was a misbranded and unapproved new drug that "cannot lawfully be ... imported into the United States." The district court permanently enjoined the FDA from "permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental that appears to be misbranded or [an unapproved new drug]." Finally, the district court ordered the FDA to "immediately notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned [sic] immediately to the FDA."

II. Analysis

The FDA's principal contention on appeal is that its "determination whether to invoke [§ 381(a)] and refuse admission to any particular drug offered for import is ... not subject to judicial review." On the merits, the FDA briefly argues its actions were neither arbitrary and capricious nor otherwise contrary to law. Underlying both arguments is the claim that § 381(a) gives the FDA unreviewable enforcement discretion and that, pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court should defer to the FDA's interpretation of the statute.

Whether *Chevron* applies to an agency's interpretation that a statute commits a matter to its discretion and thereby precludes judicial review is not entirely clear. Our recent opinions on agency claims to unreviewable discretion make no reference to *Chevron*. *See, e.g.*, *Sierra Club v. Jackson*, 648 F.3d 848, 855–57 (D.C. Cir. 2011); *Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1031–33 (D.C. Cir. 2007); *Drake v. FAA*, 291 F.3d 59, 70–72 (D.C. Cir. 2002); *but see Nat'l Wildlife Fed'n v. EPA*, 980 F.2d 765, 770–71 (D.C. Cir. 1992) (citing *Chevron* but refusing to defer to agency's "attempt to carve out ... discretion" because it could not "be squared with the language of the statute"); *see also Cornejo-Barreto v. Seifert*, 218 F.3d 1004, 1014 (9th Cir. 2000) (citing *Chevron* but refusing to defer to agency's claim of statutory discretion because it was "contrary to Congressional intent"), *overruled by Trinidad y Garcia v. Thomas*, 683 F.3d 952 (2012); *Dubois v. Thomas*, 820 F.2d 943, 951 (8th Cir. 1987) (deferring to agency's interpretation "impos[ing] only discretionary duties" upon the agency). Whether *Chevron* applies in this case, however, is of no moment because *Chevron* itself instructs that if the agency has "violated Congress's precise instructions ... 'that is the end of the

matter.'" *Village of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 660 (D.C. Cir. 2011) (quoting *Chevron*, 467 U.S. at 842). Here, we proceed "without showing the agency any special deference," *id.*, because, as we explain below, § 381(a) unambiguously imposes mandatory duties upon the FDA.

In addition to the arguments raised by the FDA, we consider the argument of the amicus curiae that the case must be dismissed because the states affected by the litigation were required parties under Federal Rule of Civil Procedure 19. Although ordinarily "we would not entertain an amicus' argument if not presented by a party," *Michel v. Anderson*, 14 F.3d 623, 625 (D.C. Cir. 1994) (emphasis deleted), in this case the argument of the amicus is in aid of our "independent duty to raise [a Rule 19(a) issue] *sua sponte*," *Wichita & Affiliated Tribes v. Hodel*, 788 F.2d 765, 772 n.6 (D.C. Cir. 1986); *see also Republic of Philippines v. Pimentel*, 553 U.S. 851, 861 (2008) ("A court with proper jurisdiction may ... consider *sua sponte* the absence of a required person"). Accordingly, we welcome the presentation of the amicus with our thanks for its contribution to this case.

A. Justiciability

Judicial review under the APA is unavailable insofar as "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This "very narrow exception" to the general rule applies only "in those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'" *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (quoting S. REP. NO. 79-752, at 26 (1945)). "In such circumstances, the courts have no legal norms pursuant to which to evaluate the challenged action, and thus no concrete limitations to impose

on the agency's exercise of discretion." *Drake*, 291 F.3d at 70.

1. The relevance of *Heckler v. Chaney*

The leading Supreme Court case applying § 701(a)(2), *Heckler v. Chaney*, is factually quite similar to the present case. 470 U.S. 821 (1985). There, too, a group of death row inmates claimed the drugs used for lethal injection were misbranded and unapproved new drugs. They had asked the FDA

> to affix warnings to the labels of all the drugs stating that they were unapproved and unsafe for human execution, to send statements to the drug manufacturers and prison administrators stating that the drugs should not be so used, and to adopt procedures for seizing the drugs from state prisons and to recommend the prosecution of all those in the chain of distribution.

Id. at 824. When the FDA refused to take the requested actions the inmates sought judicial review under the APA. The Supreme Court held "an agency's decision not to take enforcement action should be presumed immune from judicial review under § 701(a)(2)." *Id*. at 832. Although "the presumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers," *id*. at 832–33, the Court found no such guidance in the relevant provisions of the FDCA; for example, "the Act's general provision for enforcement, [21 U.S.C.] § 372, provides only that '[t]he Secretary is *authorized* to conduct examinations and investigations,'" *id*.

at 835.[*] Similarly, the Court refused to read the section "stat[ing] baldly that any person who violates the Act's substantive prohibitions 'shall be imprisoned ... or fined,'" as requiring "criminal prosecution of every violator of the Act." *Id*. (quoting 21 U.S.C. § 333).

Here the FDA argues *Chaney* applies straightforwardly to § 381(a), which provides that "[i]f it appears" an article offered for import violates a substantive prohibition of the FDCA, then "such article shall be refused admission." According to the agency, it has unreviewable discretion under both the antecedent and the consequent phrases: The antecedent "if it appears" implies the FDA may choose whether to "make a formal determination that a statutory obligation has been violated," and the consequent "shall be refused admission" provides a permissive sanction, as did the criminal provision in *Chaney* itself.

The plaintiffs respond that *Chaney* is inapposite because the discrete actions here under challenge, *viz*., adoption of a "general policy of automatically releasing all thiopental shipments destined for correctional facilities" and "a series of FDA determinations that [particular shipments of] foreign thiopental 'may proceed' into domestic commerce," are affirmative acts of approval rather than refusals to take enforcement action. We do not consider this jejune dispute for, even assuming the presumption against judicial review announced in *Chaney* does apply to the FDA's refusal to enforce § 381(a), that presumption is rebutted by the specific "legislative direction in the statutory scheme." *Chaney*, 470 U.S. at 833. Contrary to the FDA's interpretation, § 381(a)

[*] *Chaney* concerned the FDCA's enforcement provisions governing "the use of drugs in interstate commerce," 470 U.S. at 828, not the provision governing importation, § 381(a), at issue here.

sets forth precisely when the agency must determine whether a drug offered for import appears to violate the FDCA, and what the agency must do with such a drug.

2. Textual analysis

Section 381(a) provides the FDA "shall furnish" to Customs a list of registered establishments and "shall request" from Customs samples of drugs offered for import that are "manufactured, [etc.,] in an establishment not so registered." Customs, in turn, "shall deliver" to the FDA the requested samples. *Id*. "If it appears from the examination of such samples or otherwise" that a drug violates a substantive prohibition of the FDCA, then the drug "shall be refused admission." *Id*. The plaintiffs argue each of these directives is unambiguously binding: The FDA must request samples of all drugs offered for import that have been made in an unregistered establishment, must examine those samples for a violation of the FDCA, and must refuse admission to any drug that appears, through the sampling process or otherwise, to violate the FDCA. We agree.

The plaintiffs begin by arguing simply that "the ordinary meaning of 'shall' is 'must.'" The case law provides ample support. *See, e.g., Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("[T]he mandatory 'shall' ... normally creates an obligation impervious to judicial discretion"); *Ass'n of Civilian Technicians, Montana Air Chapter No. 29 v. Fed. Labor Relations Auth.*, 22 F.3d 1150, 1153 (D.C. Cir. 1994) ("The word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive"). Citing *Chaney*, the FDA objects that "in the enforcement context ... [the word 'shall'] may not be properly read to curtail the agency's discretion." In *Chaney*, however, the word "shall" appeared

in the consequent of a section providing for criminal sanctions: A violator "shall be imprisoned ... or fined." 470 U.S. at 835 (quoting 21 U.S.C. § 333). The criminal statute in *Chaney* did not use "shall" in connection with the antecedent condition of prosecution; in fact, the Court emphasized that "[t]he Act's general provision for enforcement, [21 U.S.C.] § 372, provides only that '[t]he Secretary is *authorized* to conduct examinations and investigations;'" thus, "the Act charges the Secretary only with recommending prosecution; any criminal prosecutions must be instituted by the Attorney General." *Id*. The "enforcement" discretion held unreviewable in *Chaney*, therefore, was whether to recommend prosecution. *Cf*. *Her Majesty the Queen in Right of Ontario v*. *EPA*, 912 F.2d 1525, 1533 (D.C. Cir. 1990) (analyzing statute with a similar dichotomy between a discretionary antecedent and a mandatory consequent). Here, by contrast, the word "shall" appears in both an antecedent ("shall request ... samples") and the consequent ("shall be refused admission").

The plaintiffs further argue, and again we agree, that reading "shall be refused admission" as mandatory gives meaning to the exception to that command, "except as provided in subsection (b)." That subsection provides "[i]f it appears to the [FDA] that ... an article ... can, by relabeling or other action, be brought into compliance," then "final determination as to admission of such article may be deferred" while the owner posts a bond and takes remedial action. A permissive construction of "shall be refused admission" would render "the express exception ... insignificant, if not wholly superfluous." *TRW Inc*. *v*. *Andrews*, 534 U.S. 19, 31 (2001) (internal quotation marks omitted). The FDA objects that the Senate Report recommending that the exception in § 381(b) be added to the Act said it merely codified "a continuing administrative

practice of the [FDA]," S. REP. NO. 81-890, at 1 (1949); therefore, the FDA argues, "the authority to take steps short of outright refusing admission ... was inherent in the statutory scheme from the very beginning." On the contrary: The Senate Report states § 381(b) was needed to "provide specific authority" for the FDA's procedure because "[u]nder ... the act as it now stands, imports which are found to be inadmissible into the United States by reason of mislabeling ... must be either reexported or destroyed." *Id*. In other words, § 381(b) was added precisely because "shall be refused admission" left the agency with no discretion to make an exception, no matter how sensible making a particular exception might be.

The FDA next objects that even if the agency lacks discretion under the consequent "shall be refused admission," it at least has discretion under the antecedent condition "if it appears." "[B]y authorizing refusal of admission when 'it appears' that the statutory requirements have not been met, [§ 381(a)] contemplates a role for FDA in making a formal judgment about the relevant facts. ... The provision does not speak to, much less eliminate, FDA's discretion whether to make such a determination." The FDA, however, omits the second half of the relevant clause: "If it appears from the examination of such samples or otherwise." § 381(a). The clear implication is the FDA must examine the samples that it must request and determine whether they appear to violate the FDCA. Indeed, it would make no sense for the Congress to mandate the collection, but not the examination, of samples of drugs made in an unregistered facility.

Of course, the clause "[i]f it appears from the examination of such samples or otherwise" may leave the FDA enforcement discretion in other respects. For example, the open-ended phrase "or otherwise" implies the FDA may

examine drugs it is not obligated to sample, such as those made in a registered establishment. Indeed, the FDA interprets § 381(a) as giving it general authority to examine "drugs ... offered for entry into the United States." FDA, INVESTIGATIONS OPERATIONS MANUAL ch. 6.1.1 (2012), http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123512.pdf. The same phrase also implies the FDA may detect a violation through a method other than "examination," such as electronic screening of entry data that importers submit to Customs. Moreover, the phrase "if it appears" implies discretion in making the substantive determination whether a drug appears to violate the FDCA; a drug may appear to violate the FDCA to one examining officer but not to another.

We identify these oases of possible agency discretion not to suggest they are beyond judicial review, a question not before us, but rather to delineate the bounds of our interpretation. We do not say the FDA must sample and examine every article under its jurisdiction that is offered for import but only that it must sample and examine drugs "manufactured, [etc.,]" in an unregistered establishment. *Id*. Nor do we say the FDA must find any type of drug "appears" to violate a substantive prohibition of the FDCA but only that, having found a drug apparently violates the Act, the FDA must "refuse[] [it] admission." *Id*.

3. Policy considerations

Ordinarily, if a statute is "plain and unambiguous," as is the FDCA in relevant respects here, "our analysis ends with the text." *Chao v*. *Day*, 436 F.3d 234, 235 (D.C. Cir. 2006). We may, however, in rare instances depart from the plain text when "adherence to the plain text leads to an 'absurd' result." *United States ex rel*. *Totten v*. *Bombardier Corp*., 380 F.3d

488, 494 (D.C. Cir. 2004). Although the FDA does not use the word "absurd," perhaps because the doctrine of avoiding absurd results is so rarely applied, *see Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 459 (2002) ("the Court rarely invokes [the absurdity] test to override unambiguous legislation"); *Territory of Hawaii v. Mankichi*, 190 U.S. 197, 223 (1903) (only in "rare cases" does "adherence to the letter lead[] to manifest absurdity"), the FDA does argue the practical consequences of reading § 381(a) as we do should give us pause.

The FDA argues the court should not read § 381(a) to require enforcement because the agency is better able to determine "how to most effectively allocate scarce resources." According to the FDA, § 381(a) "applies, by its terms, to the 21 million discrete 'lines' of FDA-regulated imports each year ... [and] the agency understandably declines to take enforcement action in every case in which it suspects that a single importation may violate the statute." Our reading of § 381(a), however, does not require the FDA to inspect 21 million articles offered for import; rather, it requires only the FDA examine the samples of articles that it is obligated to collect because they were "manufactured, [etc.,]" in an unregistered facility. Of course the FDA is free to go further, as it has chosen to do by electronically screening "formal and informal entries of articles under FDA jurisdiction at ports of entry." FDA, REGULATORY PROCEDURES MANUAL 9-2.

The FDA next argues it must have discretion not to enforce § 381(a) in order to combat domestic shortages of medically necessary drugs. According to a report cited by both parties, the FDA has allowed "controlled importation of similar products approved abroad but not approved in the United States in 5% of" the drug shortages it studied. FDA, A REVIEW OF FDA'S APPROACH TO MEDICAL PRODUCT

SHORTAGES 4 (2011), www.fda.gov/DrugShortageReport. By its own account, however, the FDA has ways short of allowing importation of inadmissible drugs to counteract a drug shortage, including: "Asking other firms to increase production (31%)," "Working with manufacturers" to mitigate quality problems (28%), and "Expediting review of regulatory submissions (26%)." *Id*. The FDA may exercise enforcement discretion to allow the domestic distribution of a misbranded or unapproved new drug, as the Supreme Court recognized in *Chaney*, 470 U.S. at 837, and in some cases may invoke its express statutory authority to permit the importation of an unapproved new drug. For example, the FDA may designate an unapproved foreign manufactured drug as an investigational new drug (IND), thereby allowing its lawful importation. 21 U.S.C. § 355(i); 21 C.F.R. § 314.410(a)(1)(ii); *see also* 21 C.F.R. 312.315(a)(3)(ii) (FDA may expand access to an IND "contain[ing] the same active moiety as an approved drug product that is unavailable through ... a drug shortage"). In any event, even if reading § 381(a) by its terms, as we do, deprives the FDA of one possible response to five percent of all drug shortages, that is hardly an absurd result.

In an effort to bolster its drug shortage argument, the FDA points to two provisions in a 2012 statute that it says reveal the Congress's "understanding that FDA already has authority to exercise enforcement discretion." 21 U.S.C. § 356d(c) instructs the Secretary of HHS to "evaluate the risks associated with the impact" of a drug shortage before taking an enforcement action that "could reasonably cause or exacerbate a shortage," and § 356c-1(a)(5) directs the Secretary to issue an annual report listing, among other things, "instances in which the [FDA] exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage." The Congress enacting these directives may have

implicitly — and correctly — assumed the FDA already had some discretion in combating a drug shortage, but the agency gives us no reason to think the Congress was referring to the discretion to ignore § 381(a) and not to the discretion to allow the domestic distribution of a violative drug or to admit an unapproved foreign manufactured drug as an IND.

Finally, the FDA argues it must have discretion to ignore § 381(a) in order to allow the "importation of drugs that are clearly for personal use." As evidence that the Congress is aware of and agrees with this view, the FDA points to a 2003 statute, not yet in effect, directing the Secretary of HHS to "exercise discretion to permit individuals to make ... importations" of prescription drugs for personal use. 21 U.S.C. § 384(j)(1)(B). The FDA, however, conveniently overlooks the very next subsection, which effectuates the statute by authorizing the Secretary to grant individual waivers to import prescription drugs. § 384(j)(2). The Congress would have had no reason to grant the FDA explicit waiver authority if, as the FDA argues, the agency was already authorized not to enforce § 381(a).

* * *

In sum, we hold 21 U.S.C. § 381(a) requires the FDA to (1) sample "any drugs" that have been "manufactured, prepared, propagated, compounded, or processed" in an unregistered establishment and (2) examine the samples and determine whether any "appears" to violate the prohibitions listed in § 381(a)(1)–(4). If, "from the examination of such samples or otherwise," the FDA finds an apparent violation of the Act, then it must (3) "refuse[] admission" to the prohibited drug. Because these are clear statutory "guidelines for the agency to follow in exercising its enforcement powers,"

Chaney, 470 U.S. at 833, the FDA's compliance with § 381(a) is subject to judicial review under the standards of the APA.

B. The APA on the Merits

From the foregoing analysis it follows apodictically that the FDA's policy of admitting foreign manufactured thiopental destined for state correctional facilities, as well as the several individual admissions of such shipments challenged by the plaintiffs, were "not in accordance with law." 5 U.S.C. § 706(2)(A). The FDA's policy was not in accordance with law because § 381(a) requires the agency to sample and examine for violations any drug offered for import that has been prepared in an unregistered facility; as the FDA acknowledges, the preparer of the finished thiopental identified in this case, Archimedes Pharma UK, Ltd., is not registered with the FDA. The FDA's individual admissions of thiopental shipments were not in accordance with law because § 381(a) requires the FDA to refuse admission to any drug that appears to violate the substantive prohibitions of the FDCA, and the FDA conceded before the district court that the thiopental in these shipments "clearly 'appears' to be an unapproved new drug."

Because our holding the FDA acted contrary to law requires that we affirm the judgment of the district court, we need not decide whether the FDA's actions were also arbitrary and capricious. *See Duke Power Co. v. FERC*, 864 F.2d 823, 831 (D.C. Cir. 1989).

C. Rule 19

Federal Rule of Civil Procedure 19(a)(1)(B)(i) provides:

> A person who is subject to service of process and whose joinder will not deprive the court of subject-matter jurisdiction must be joined as a party if ... that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may ... as a practical matter impair or impede the person's ability to protect the interest.

The rule reflects the bedrock principle "that one is not bound by a judgment *in personam* in a litigation in which he is not ... a party," *Hansberry v. Lee*, 311 U.S. 32, 40 (1940), or to put it more simply, that "everyone should have his own day in court." 18A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & EDWARD H. COOPER, FEDERAL PRACTICE AND PROCEDURE § 4449 (2d ed. 2002). For this reason, the parties before a district court, who "presumably know better than anyone else the nature and scope of relief sought in the action, and at whose expense such relief might be granted ..., [bear] a burden of bringing in additional parties where such a step is indicated." *Martin v. Wilks*, 490 U.S. 755, 765 (1989). The district court, too, "has an independent responsibility" to seek the joinder of a required party, sua sponte if need be. *Weisberg v. Dep't of Justice*, 631 F.2d 824, 830 & n.40 (D.C. Cir. 1980).

The amicus argues, and we agree, the district court erred by failing, when the complaint was filed, to seek the joinder of the "state governments whose possession and use of [foreign manufactured] thiopental [the court] declared illegal." In their complaint, the plaintiffs sought "[a]n order compelling FDA to immediately take reasonable steps to recover and remove from interstate commerce all shipments of foreign thiopental that have been released by FDA into interstate commerce during the preceding twelve months." The states that had received those shipments – Arizona,

Arkansas, California, Georgia, South Carolina, and Tennessee — had an obvious interest in keeping them and therefore had "an interest relating to the subject of the action" within the scope of Rule 19. Although the plaintiffs did not renew their request for injunctive relief in their motion for summary judgment, the district court nevertheless ordered the FDA to notify the states that "the use of [foreign manufactured thiopental] is prohibited by law and that, that thiopental must be returned [sic] immediately to the FDA." That order, "as a practical matter" did "impair or impede" the named states' "ability to protect the[ir] interest" in those shipments. FED. R. CIV. P. 19(a)(1)(B)(i).

Although we agree with the amicus that the affected states were required parties, we do not agree their absence means the case should have been dismissed. Under Rule 19 a district court is to join a required party if feasible; if joinder is not feasible, however, then the court is to consider, among other things, whether "any prejudice could be lessened or avoided by ... shaping the relief." FED. R. CIV. P. 19(b)(2)(B). Here, the district court neither assessed the feasibility of joining the states as parties nor considered whether the prejudice to their interests might be reduced by shaping the relief.

To remedy a departure from the strictures of Rule 19, "a court of appeals may ... require suitable modification [of the judgment] as a condition of affirmance." *Provident Tradesmens Bank & Trust Co. v. Patterson*, 390 U.S. 102, 112 (1968). Accordingly, we shall vacate the remedial order insofar as it directs the FDA to "notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned immediately to the FDA."

III. Conclusion

The FDCA imposes mandatory duties upon the agency charged with its enforcement. The FDA acted in derogation of those duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug, and by declaring that it would not in the future sample and examine foreign shipments of the drug despite knowing they may have been prepared in an unregistered establishment. The district court could not remedy the FDA's unlawful actions, however, by imposing upon the interests of nonparties to this suit. The order of the district court pertaining to the thiopental already in the possession of the states, quoted in the paragraph above, is therefore vacated, but the underlying judgment of the district court is

Affirmed.