UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DONALD EDWARD BEATY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Case No. 11-289 (RJL)**
	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
and	)	
	)	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
	)	
and	)	
	)	
KATHLEEN SEBELIUS, in her official capacity as Secretary of the U.S. Department of Health and Human Services,	)	
	)	
and	)	
	)	
MARGARET A. HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION
(March 27, 2012) [#12 and #13]

Plaintiffs, a group of death row inmates currently incarcerated in Arizona, California, and Tennessee, bring this action against the Food and Drug Administration ("FDA"), the United States Department of Health and Human Services ("HHS"), Kathleen Sebelius in her official capacity as Secretary of HHS "(Secretary"), and

Margaret A. Hamburg, M.D. in her official capacity as Commissioner of Food and Drugs ("Commissioner") (collectively, "defendants"), alleging violations of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701, *et seq.* Specifically, plaintiffs allege that defendants violated provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. §§ 301, *et seq.*, by improperly allowing shipments of a misbranded and unapproved new drug to enter the United States for use in state lethal injection protocols, which will be used during plaintiffs' executions. Before the Court are plaintiffs' Motion for Summary Judgment and Declaratory Relief on Counts I and III [Dkt. # 12] and defendants' Motion to Dismiss and/or for Summary Judgment [Dkt. #13]. After careful consideration of the relevant law, the pleadings, and the entire record herein, plaintiffs' motion is GRANTED and defendants' motion is DENIED.

BACKGROUND

I. The Federal Food, Drug, and Cosmetic Act

The FDA has the authority to regulate the production and distribution of drugs in the United States to promote public health and safety. *See* Pls.' Statement of Undisputed Material Facts in Supp. of Mot. for Summ. J. ("Pls.' SUMF"), Mar. 21. 2011, ¶ 76 [Dkt. #12]. Under the FDCA, it is unlawful to introduce "misbranded" drugs into interstate commerce. 21 U.S.C. § 331(a). A drug is deemed misbranded if: (1) it was "manufactured, prepared, propagated, compounded, or processed in an establishment" not registered with the FDA, *id.* §§ 352(o), 360(i); (2) it is not properly listed with the FDA, *id.* §§ 352(o), 360(j); or (3) its packaging does not display the symbol "Rx only," *id.* § 353(b)(4)(A). It is also unlawful to introduce a "new drug"—a drug that has not

been previously reviewed and approved by the FDA, *id.* § 321(p)—into interstate commerce. *Id.* § 355(a). A "new drug" must have an effective application that has been approved by the FDA. *Id.* An application for a new drug must provide the FDA with, *inter alia*, information sufficient to determine whether (1) when used for its proposed uses, the drug is safe and effective, (2) the benefits of the drug outweigh any risks, and (3) the production and regulation methods in place can "ensure the [drug's] identity, strength, quality, and purity." *See* 21 C.F.R. § 314.50 (2008); Mem. in Supp. of Pls.' Mot. for Summ. J. ("Pls.' Mot. Mem."), Mar. 21, 2011, at 5 [Dkt. # 12].

The FDCA has separate provisions concerning the distribution of domestic and foreign drugs. *See* 21 U.S.C. §§ 381(a), (e). With respect to imports, as originally enacted, the FDCA gave the FDA the authority to inspect samples of imported drugs, but it did not impose an affirmative obligation on the FDA to do so. *See* Pub. L. No. 75-717, § 801, 52 Stat. 1040, 1058 (1938) ("The Secretary of the Treasury shall deliver to the Secretary of Agriculture, *upon his request*, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States.") (emphasis added). In 1962, however, Congress amended the FDCA in response to calls for increased domestic and foreign drug regulation. Pls.' Mot. Mem. at 6. Pursuant to the 1962 Amendments, Congress required any foreign establishment that manufactures, prepares, propagates, compounds, or processes a drug to be imported into the United States to both "immediately register" with the Secretary of HHS, *see* 21 U.S.C. §§ 321(a)(2)(d), 360(i)(1)(A), and provide the Secretary with a list of all its imported drugs and devices, *id.* §§ 360(i)(2), 360(j). Also under the amended Act, the Secretary of HHS

"shall furnish to the Secretary of the Treasury" a list of registered foreign establishments and "shall request that if any drugs, devices, or tobacco products 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, devices, or tobacco products be delivered to the Secretary of Health and Human Services." *Id.* § 381(a). "If it appears" the imported product "is forbidden or restricted in sale in the country in which it was produced or from which it was exported" or "is adulterated, misbranded, or in violation of 21 U.S.C. section 355, . . . then such article shall be refused admission."[1] *Id.* Finally, if an imported article is refused admission, the Secretary of the Treasury "shall cause the destruction of any such article" unless it "is exported . . . within ninety days." *Id.*

The FDA is responsible for the obligations imposed by Section 381 of the FDCA. *See* Pls.' Mot. for Summ. J. ("Pls.' Mot."), Mar. 21, 201, ¶ 15 [Dkt. #12]. As a result, the FDA promulgated several regulations regarding the importation of drugs into the United States that mirror the FDCA. First, new drugs may be imported after a new drug

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[1] Entities importing products into the U.S. must first file an entry notice with U.S. Customs and Border Patrol ("CBP") identifying, *inter alia*, the product, manufacturer, shipper, and country of origin. *See* Defs.' Mem. in Supp. of Mot. to Dismiss and/or for Summ. J. ("Defs.' Mot."), Apr. 20, 2011, at 4 [Dkt. #13-1]. Most importers file these notices electronically, allowing CPB to review the notices via its automated system before forwarding the information to the FDA. *Id.* The FDA reviewer can then decide to admit the product, detain the product, or gather more information by physically examining the product or requesting a sample. *Id.* at 4-5.

In 2004, there were 355 "points of entry" for access into the United States. *Id.* at 4. In 2010, over 21 million products were offered for importation into the United States. *See id.* at 5. Of those products, the FDA physically examined approximately 1% and refused admission to approximately 0.13%. *Id.* When a product is refused admission, it must be destroyed unless it is exported within 90 days. *See* 21 U.S.C. § 381(a).

application has been submitted and approved by the FDA, or if the drugs comply with the regulations regarding investigational new drugs. 21 C.F.R. § 314.410(a)(1) (2008). Second, *no* drug may be legally imported unless it is both properly listed with the FDA and comes from a properly registered foreign drug establishment. *Id.* § 207.40(b) (2001).

II. Thiopental

Sodium thiopental ("thiopental") is an intravenously-administered, short-acting barbiturate used to induce general anesthesia. Am. Compl. ("Compl."), July 1, 2011, ¶ 37 [Dkt. #20]. Substances used to induce general anesthesia, even as a part of an euthanasia process, are considered "drugs" under the FDCA as they are "intended to affect the structure or any function of the body of man." *See* 21 U.S.C. § 321(g)(1); Compl. ¶ 48. Multiple states have used thiopental as the first step in their lethal injection protocols to render prisoners unconscious before administering pancuronium bromide—a paralytic—and potassium chloride—which causes cardiac arrest and death. *See Baze v. Rees*, 553 U.S. 35, 44 (2008); Pls.' Mot. Mem. at 12. Although once widely used by anesthesiologists, the FDA neither approved nor reviewed thiopental for safety and effectiveness. Compl. ¶ 54. Beginning in the 1980s, thiopental use decreased dramatically as anesthesiologists began using propofol—a drug approved by the FDA in 1989—to achieve the same results. *Id.* ¶¶ 40-42, 44. In 2009, the U.S. manufacturer of thiopental stopped producing the drug, *id.* ¶ 45, prompting certain state departments of correction ("DOC") to look abroad for suppliers, *see* Exs. 30-32 to Declaration of Sean C. Griffin ("Griffin Decl."), Pls.' Mot., Mar. 21, 2011 [Dkt. #12-4].

Dream Pharma, Ltd. ("Dream"), a London wholesaler that purchases thiopental manufactured in Austria for distribution, shipped to the United States the thiopental at issue here. Compl. ¶¶ 88-89. Dream has neither registered with the FDA nor listed its thiopental product with the FDA. *Id.* ¶¶ 90-91. In total, the FDA released at least seven shipments of Dream's thiopental—a "misbranded" and unapproved "new drug"[2]—to various states.[3] Pls.' Mot. Mem. at 14-15. In June 2010, Dream sent a shipment of thiopental to the Georgia DOC, which the FDCA detained in July on the ground that the thiopental was misbranded. *See* Pls.' SUMF ¶¶ 35-37. In August, however, the FDA released the shipment to Georgia. *Id.* ¶ 39. In September 2010, Dream sent a shipment of thiopental to the Arkansas DOC, which the FDA detained on the ground that thiopental was an unapproved new drug. *Id.* ¶¶ 40-42. After receiving correspondence from the Arkansas DOC indicating the drug was necessary for use in lethal injections, the FDA released the shipment in late September 2010. *Id.* ¶¶ 43-44. Dream also sent a shipment of thiopental to Arizona in September 2010, which the FDA released to Arizona

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[2] It is undisputed that thiopental is both "misbranded" and an unapproved "new drug" under the FDCA. Thiopental is clearly a new drug because the FDA has never reviewed or approved the drug. *See* Pls.' SUMF ¶ 15. Further, foreign thiopental is a misbranded drug because it is not listed with the FDA, *see id.* ¶¶ 16-19, and it fails to display the symbol "RX Only," *id.* ¶ 20.

[3] Although the U.S. Drug Enforcement Administration ("DEA") seized at least one of these seven shipments as violative of the Controlled Substances Act, Arizona, California, and Tennessee still possess the thiopental they purchased from Dream. Pls.' Mot. Mem. at 15. Thiopental is a schedule III non-narcotic controlled substance under the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970). *See* 21 U.S.C. §§ 812(b)(3), 812(c) Schedule III(b)(1); 21 C.F.R. § 1308.13(b) (2012); *see also* Defs.' Mot. at 6. Any establishment that imports a schedule III non-narcotic controlled substance without submitting the required import declaration to the DEA may be prosecuted and the controlled substance may be seized. *See* 21 U.S.C. §§ 853, 881, 960, 970; *see also* Defs. Mot. at 6.

the day after the shipment arrived. *Id.* ¶¶ 54-55. In October 2010, Dream sent and the FDA released a shipment of thiopental to the Tennessee DOC. *Id.* ¶ 64-65. In November 2010, Dream sent shipments of thiopental to the California and South Carolina DOCs, which the FDA released in January 2011. *Id.* ¶¶ 66, 69, 71, 74. In September 2010, the FDA identified another shipment similar to the foreign thiopental shipped to Arizona. *Id.* ¶ 75.

In January 2011, the FDA released a statement explaining its position on the importation of thiopental. Compl. ¶ 103. Defending the release of the drug as an act of "enforcement discretion," the FDA indicated it "deferred to law enforcement in the use of substances for lethal injection." *Id.* ¶ 104. It explained "[r]eviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role."[4] *Id.*

On July 1, 2011, plaintiffs filed an amended complaint, seeking, *inter alia*, a declaratory judgment that the defendants acted contrary to law, in an arbitrary and capricious manner, and in abuse of their discretion when they allowed shipments of the misbranded and unapproved new drug thiopental to be imported into the U.S., and a permanent injunction prohibiting the FDA from releasing any future shipments of unapproved foreign drugs into interstate commerce. *See* Compl. On March 21, 2011, plaintiffs filed a Motion for Summary Judgment and Declaratory Relief on Counts I and

[4] Since the commencement of this litigation, several states—including Arizona—have announced they will no longer use thiopental in their lethal injection protocols. *See* Defs.' Mot. at 9-10. Additionally, news reports indicate that the Tennessee DOC has relinquished its entire inventory of thiopental to the DEA. *Id.* at 10.

III. *See* Dkt. #12. On April 20, 2011, defendants filed a Motion to Dismiss and/or for Summary Judgment. *See* Dkt. #13. For the reasons stated below, plaintiffs' motion is GRANTED and defendants' motion is DENIED.

STANDARD OF REVIEW

Under the APA, the Court must set aside an agency action that is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law." *Jicarilla Apache Nation v. U.S. Dep't of the Interior*, 613 F.3d 1112, 1118 (D.C. Cir. 2010) (quoting 5 U.S.C. § 706(2)(A)). Summary judgment is appropriate when the movant demonstrates that there is no genuine issue of material fact in dispute and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the burden, and the court will draw "all justifiable inferences" in the favor of the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255-56 (1986). Nevertheless, the non-moving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Id.* at 248 (internal quotation marks and citation omitted). Factual assertions in the moving party's affidavits may be accepted as true unless the opposing party submits its own affidavits, declarations, or documentary evidence to the contrary. *Neal v. Kelly*, 963 F.2d 453, 456 (D.C. Cir. 1992).

LEGAL ANALYSIS

I. Standing

Defendants contend that plaintiffs lack Article III standing to bring their claims. *See* Defs.' Mot. at 27-35. To have standing, a plaintiff must have suffered an injury that

is "(a) concrete and particularized and (b) actual or imminent." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks and citations omitted). A plaintiff must further show "a causal connection between the injury and the conduct complained of," making the injury "fairly traceable" to the defendant's action. *Id.* (citation omitted). Defendants contend that plaintiffs have not adequately shown injury or causation. *See* Defs.' Mot. at 27-35. I disagree.

For standing purposes, an increased risk of future harm is a category of the injury-in-fact prong. *NRDC v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006). An increased risk of harm constitutes an injury-in-fact where there is a substantially increased risk of harm and a substantial probability of sustaining the threatened injury. *See Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2007). While there are no "hard-and-fast numerical rules," *id.* at 1295-96, for what constitutes a substantially increased risk, our Circuit has held that where the threatened injury is "severe," "relatively modest increments in risk should qualify for standing." *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1235 (D.C. Cir. 1996); *see Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003) ("Because the evaluation of risk is qualitative, the probability of harm which a plaintiff must demonstrate in order to allege a cognizable injury-in-fact logically varies with the severity of the probable harm.").

Here, the threatened injury—that unapproved foreign thiopental will fail to anesthetize plaintiffs properly during execution, causing conscious suffocation, pain, and cardiac arrest, *see* Compl. ¶¶ 17, 33, 127-29—is, to say the least, severe. Indeed, few in our society are more vulnerable than a death row inmate facing lethal injection. *Compare*

Mountain States, 92 F.3d at 1234 ("Plaintiffs' aesthetic and environmental interests in having [forests] free of devastating forest fire are clearly sufficient for Article III standing."). Thus, because the threatened injury is severe, plaintiffs are required to show only a "relatively modest" increment of risk. *Id.* at 1235; *see NRDC*, 464 F.3d at 6-7, 11 (holding that a one in 200,000 lifetime risk of developing nonfatal skin cancer was sufficient injury for standing).

It is undisputed that the FDA has *never* approved or even reviewed foreign thiopental (let alone thiopental previously manufactured in the United States) for safety and effectiveness. *See* Pls.' SUMF ¶ 15. The FDCA protects consumers from drugs that are "not generally recognized, among experts qualified by scientific training and experience . . . as safe and effective." 21 U.S.C. § 321(p); *see id.* § 381(a). This protection exists because there is no guarantee that an unapproved or misbranded drug will serve the purpose for which it was intended or that the drug itself will be safe for use. According to the FDA, "FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources" because the foreign sources may, *inter alia*, "dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use." *Safety of Prescription Drugs From Foreign Sources, Before the Subcomm. on Human Rights and Wellness, House Comm. on Government Reform* (June 12, 2003) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning) ("Hubbard Statement"); *see* FDA, *Unapproved*

Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm ("The Agency has serious concerns that drugs marketed without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling."). Because unapproved thiopental exposes plaintiffs to the risk that the drug will not function as intended, plaintiffs have shown at least a "modest" increment of risk that the use of foreign thiopental in their executions would result in conscious suffocation, pain, and cardiac arrest.

Defendants also contend that there is no causal connection between the FDA's failure to reject unapproved foreign thiopental and plaintiffs' threatened injury. Defs.' Mot. at 29-31. The threatened injury, however, arises directly from defendants' actions. Defendants' admission of foreign thiopental shipments allows state DOCs to use thiopental in their lethal injection protocols. In so doing, plaintiffs' risk of conscious suffocation, pain, and cardiac arrest increases. Thus, plaintiffs have standing to pursue their claims.

II. Plaintiffs are Entitled to Summary Judgment on Count I Because Defendants Acted Contrary to Law.

A. The Word "Shall" Imposes a Mandatory Obligation.

Plaintiffs allege that defendants have violated the APA by taking agency action that is not in accordance with the FDCA—specifically, by improperly allowing shipments of a misbranded and unapproved new drug to enter the United States. The FDCA

requires that if an examined shipment even *appears* to violate the FDCA's misbranding or new drug approval requirements, then the drug "shall be refused admission." 21 U.S.C. § 381(a). According to plaintiffs, the plain language of the statute thus clearly required defendants to refuse to admit the shipments of thiopental—a drug that actually is misbranded and unapproved—into the United States. *See* Pls.' Mot. Mem. at 21. By not refusing the shipments, plaintiffs contend that defendants acted contrary to law. I agree.

Defendants contend that the statute does not impose a mandatory duty to refuse admission. *See* Defs.' Mot. at 11. But, it is difficult to construe Section 381 as anything but mandatory. Indeed, the plain language of the statute states that an article that appears to be misbranded or unapproved "*shall* be refused admission." 21 U.S.C. § 381(a) (emphasis added). "'Shall' has long been understood as 'the language of command.'" *Zivotofsky v. Sec'y of State*, 571 F.3d 1227, 1243 (D.C. Cir. 2009) (citing *Escoe v. Zerbst*, 295 U.S. 490, 493 (1935)). "The word 'shall' generally indicates a command that admits of *no* discretion on the part of the person instructed to carry out the directive." *Ass'n of Civilian Technicians, Mont. Air Chapter No. 29 v. Fed. Labor Relations Auth.*, 22 F.3d 1150, 1153 (D.C. Cir. 1994) (emphasis added).

The rule that the word "shall" is a mandatory command is subject to "rare exceptions," which "apply only where it would make little sense to interpret 'shall' as 'must.'" *Zivotofsky*, 571 F.3d at 1243. Here, however, it makes little sense to interpret Congress' use of the word "shall" as anything but "must." In the very same section of the statute at issue here, Congress used both the language in question (shall) and permissive language (may). For example, Congress directed that imported drugs that are misbranded

or unapproved "shall be refused admission," 21 U.S.C. § 381(a), whereas an imported drug that does not have a registration statement "*may* be refused admission," *id.* § 381(o) (emphasis added).[5] Given the structure of the statute, it is clear that Congress intended for the word "shall" to have a different meaning than "may"—specifically, to be mandatory rather than permissive.[6] *See Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005) (juxtaposing the permissive "may" with the mandatory "shall").

Indeed, Congress' intent is further revealed by the fact that it created an exception to the command that misbranded and unapproved drugs "shall be refused admission." 21

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[5] Congress' use of the word "may" in Section 381 is not limited to this example. For example, the statute allows for extensions of time for the re-exportation of offending goods "as may be permitted pursuant to . . . regulations." 21 U.S.C. § 381(a). Additionally, the statute states that the Secretary of the Treasury "may authorize" the delivery of an article pending FDA examination upon the posting of a bond. *Id.* § 381(b). As another example, the FDA "may authorize" the re-importation of certain articles "if the drug is required for emergency medical care." *Id.* § 381(d)(2).

[6] Defendants contend that interpreting "shall" as imposing a mandatory obligation will produce "absurd results." *See* Defs.' Mot. at 46-47; Defs.' Reply in Supp. of Mot. to Dismiss and/or for Summ. J. ("Defs.' Reply"), July 8, 2011, at 30-33 [Dkt. #21]. I disagree. First, the FDA is not obligated to examine *all* imported goods; it is only required to examine "drugs, devices, or tobacco products" that were "manufactured, prepared, propagated, compounded, or processed" in an unregistered foreign establishment. *See* 21 U.S.C. § 381(a). The FDA has a computerized system already in place where foreign imports are "electronically screened against criteria developed by FDA" and alerts can "identify problem commodities and/or shippers and/or importers." FDA Regulatory Procedure Manual, Import Operations and Actions 9-3, 9-50 (2011). Thus, any burden on defendants with respect to examining imported goods is, to say the least, minimal. Indeed, this "burden" was one intended by Congress. The purpose of the FDCA is to promote public health and safety, which, in the context of imported drugs, requires the FDA to ensure that only drugs approved as safe and effective enter into the country. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 69 (D.D.C. 1998) (vacated on other grounds) (finding that the purpose of the FDCA is to "ensur[e] that when a citizen takes a prescription drug, that individual has absolute assurance that the product is safe and effective"). And although protecting the health of an inmate being put to death may seem like an oxymoron to some, those vulnerable few have a right to die with the dignity that an effective pain killer was intended, in part, to afford them.

U.S.C. § 381(a). Section 381(a) states that these drugs "shall be refused admission, *except as provided in* [21 U.S.C. § 381(b)]." *Id* (emphasis added). Accordingly, if the owner of the offending drugs posts a "sufficient bond," and the FDA determines that the drugs "can, by relabeling or other action, be brought into compliance" with the FDCA, then the drugs may be admitted after the owner brings them into compliance. *Id.* § 381(b). The cannon of avoiding surplusage makes clear that if Congress intended "shall" to be permissive, it would not have included any exceptions to the provision. *Beverly Health & Rehab. Servs. v. NLRB*, 317 F.3d 316, 321 (D.C. Cir. 2003).

Further, Congress used the word "shall" several times in Section 381(a). For example, Section 381(a) states that the Secretary of HHS "shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to [21 U.S.C. § 360(i)]"; the Secretary of HHS "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]"; the Secretary of the Treasury "shall deliver to the Secretary of [HHS] upon his request, samples of . . . drugs . . . which are being imported or offered for import into the United States"; and if a drug is refused admission, the Secretary of the Treasury "shall cause the destruction of any such article." 21 U.S.C. § 381(a). Similarly, Section 381(c) provides that expenses related to the destruction of an illegal import "shall be paid by the owner or consignee." *Id.* § 381(c). The "normal rule of statutory construction" provides that "identical words used in different parts of the same act are intended to have the same meaning." *Dep't of Revenue of Or. v. ACF Indus., Inc.*, 510

U.S. 332, 342 (1994) (internal quotation marks and citation omitted). Under defendants' theory, the phrases "shall furnish," "shall request," "shall deliver," "shall cause," and "shall be paid" must be interpreted as permissive. The more reasonable interpretation, however, is that "shall" in all of these phrases is mandatory, especially when it is used in conjunction with specified exceptions.[7]

Thus, it is clear that in Section 381(a), Congress' intent was for "shall" to impose a mandatory obligation on defendants to refuse to admit the misbranded and unapproved drug, thiopental, into the United States.

B. Heckler v. Chaney Does Not Control.

According to defendants, this case is controlled by *Heckler v. Chaney*, 470 U.S. 821 (1985). Specifically, defendants contend that under *Heckler*, the FDA's 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.'" Defs.' Mot. at 1, 14-15 (quoting 5 U.S.C. § 701(a)(2)). Plaintiffs, however, contend that the FDA did not make a decision about whether to take enforcement action within the meaning of *Heckler*, and therefore,

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[7] Indeed, the FDA previously has agreed with such an interpretation. *See United States v. Eight Unlabled Cases, More or Less, of an Article of Food*, 909 F. Supp. 129, 131 (E.D.N.Y. 1995) ("The parties agree that when the government acts under § 381 . . . it . . . 'shall' destroy the goods unless they are exported."); *Carl Borchsenius Co. v. Gardner*, 282 F. Supp. 396, 403 (E.D. La. 1968) (FDA must give owners the opportunity to export a refused article to avoid destruction); Dep't of HHS, Report on Prescription Drug Importation (Dec. 2004), at 27 (Section 381(a) "requires FDA to refuse to admit into the U.S. any drug that appears to be misbranded.").

Heckler does not control. Pls.' Reply in Supp. of Pls.' Mot. ("Pls.' Reply"), June 3, 2011, at 27 [Dkt. #15]. Unfortunately for the defendants, I agree.

In *Heckler*, a group of death row inmates petitioned the FDA to take enforcement actions relating to lethal injection drugs to prevent what they believed to be violations of the FDCA's misbranding provisions. *Heckler*, 470 U.S. at 823-24. Specifically, the inmates 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 who knowingly distribute or purchase the drugs with intent to use them for human execution.

Id. at 824. Relying on its discretion to decline to pursue enforcement actions, the FDA refused to take the requested actions. *Id.* at 824-25. The Supreme Court, comparing agency enforcement discretion to the Executive Branch's prosecutorial discretion, agreed and upheld the FDA's decision, holding that the FDA's refusal to commence an enforcement action through the civil or criminal process was presumptively immune from judicial review. *Id.* at 831-33.

Plaintiffs contend, however, and I agree, that a decision to admit or exclude an imported product is not the type of discretion—like prosecutorial discretion—that the Supreme Court considered in its decision in *Heckler*. *Id.* at 832. Unlike in *Heckler*, here, the FDA's decision did not involve a decision whether to initiate enforcement proceedings against a violator of the Act; rather, it involved a decision to ignore an administrative directive. Here, the FDA was not required to prove that a violation of the

FDCA has occurred. Instead, the FDA was being called on to follow an administrative procedure established by Congress. Having taken the steps to detain and determine that the foreign shipments contained a misbranded and unapproved new drug, the FDA was *required* under the FDCA to reject the shipments in the interest of public safety. Clearly, the FDA's duty to obey the law and deny admission to a drug according to unambiguous statutory provisions is not analogous to its decision in *Heckler* to prosecute statutory violators.

Further, under *Heckler*, the FDA's decisions not to take enforcement actions are only *presumptively* unreviewable decisions. *See Heckler*, 470 U.S. at 837. Even if *Heckler* was controlling and a presumption against review applied, it has been rebutted here and judicial review is available. The presumption against review is "rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.* at 832-33. When a statute provides a "meaningful standard against which to judge" the agency's actions, those actions are not committed to agency discretion within the meaning of the APA. *Id.* at 830. Such a standard exists, for example, where the law establishes that the government's authority "should be used universally" or provides a "basis for distinguishing between the instances in which [those powers] should and should not be [exercised]." *See Hinck v. United States*, 550 U.S. 501, 504 (2007) (internal quotation marks and citation omitted).

Here, Section 381(a) of the FDCA gives substantial guidance as to when and how imported drugs must be reviewed. The statute provides that the FDA shall request samples of imported drugs when they are "manufactured, prepared, propagated,

compounded, or processed" in an unregistered establishment. 21 U.S.C. § 381(a). Under the statute, the FDA must provide procedural protections in the form of notice to the owner and an opportunity to testify. *Id.* Additionally, the statute provides the FDA with a standard to apply during its examination of the imported drugs—specifically, to determine whether the drug "appears" to be misbranded, adulterated, or unapproved. *Id.* If an examination results in the imported drug appearing to be misbranded, adulterated, or unapproved, the statute then informs the FDA that it "shall" refuse the admission of the drug. *Id.* The statute then provides that the government must destroy or export the drug within ninety days. *Id.* Accordingly, the statute both mandates the universal exclusion of foreign drugs from unregistered establishments that appear misbranded, adulterated, or unauthorized, and also provides a clear basis for distinguishing when government power should or should not be exercised.

Thus, judicial review is available because there is a meaningful standard against which to judge the agency's action. Because defendants failed to reject the misbranded and unapproved drug, thiopental, into the United States, they have violated the APA by taking agency action that is not in accordance with the FDCA.

III. Plaintiffs are Entitled to Summary Judgment on Count III Because Defendants Acted Arbitrarily and Capriciously and Abused Their Discretion.

Plaintiffs allege that defendants have acted arbitrarily and capriciously and have abused their discretion by departing from longstanding FDA policies and undermining the purpose of the FDCA. *See* Pls. Mot. Mem. at 3-4. I agree. An agency action is arbitrary, capricious, or an abuse of discretion when it "depart[s] from a prior policy *sub*

silentio or simply disregard[s] rules that are still on the books," *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009); irrationally departs from an agency's governing policy, *Venetian Casino Resort, LLC v. EEOC*, 530 F.3d 925, 935 (D.C. Cir. 2008); or "frustrate[s] the policy that Congress sought to implement," *FEC v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981). Here, the FDA has 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.

First, FDA regulations state that (1) "[n]o drug may be imported or offered for import into the United States unless it is listed [with the FDA]," 21 C.F.R. § 207.40(b); and (2) new drugs may be imported into the United States if the drug is covered by an approved application or complies with regulations pertaining to investigational new drugs ("INDs"), *see* 21 C.F.R. § 314.410(a)(1). Although thiopental is neither listed with the FDA, covered by an approved application, nor in compliance with regulations pertaining to INDs, defendants allowed at least seven shipments of foreign thiopental to enter the United States, and they intend to continue to allow future shipments as well. *See* Pls.' SUMF ¶¶ 35-76. The FDA's actions are clearly inconsistent with its own regulations.

Second, the defendants have departed from a longstanding policy of not allowing the importation of unapproved prescription drugs. FDA policy reflects a cautionary approach to importing foreign drugs. The FDA has expressed concern about "the safety risks associated with the importation of prescription drugs from foreign countries," *see* FDA Letter to the State of California Department of Justice ("FDA Letter") (Aug. 25,

2003), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm179893.htm, as foreign drugs are more likely to be counterfeit or contaminated than FDA-approved products, *see* FDA, Imported Drugs Raise Safety Concerns (Aug. 24, 2011), *available at*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm. Indeed, from 2003 to 2008, FDA officials blocked multiple efforts by state and local governments to import cheaper versions of FDA-approved prescription drugs from foreign entities. *See* Importing Prescription Drugs, FDA Letters to State and Local Officials (2003-2008), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm. For example, in 2003, the FDA rejected a proposal by the State of California to import lower-cost prescription drugs from Canada and stated that if "any state, county, or city program" in California "were to import prescription drugs into the State of California from Canada," such importation would violate the FDCA "in virtually every instance." FDA Letter. When denying another such effort, the FDA made clear that it was unable to stray from the clear language of the statute when it stated: "[T]he petition [for this program] requests that FDA ignore the will of Congress and sanction the complete and systematic violation of the statutory provisions that FDA was created to enforce. FDA cannot simply substitute its (or your) judgment over the judgment of Congress as expressed in the Act." *See* Ex. 1 to Griffin Decl. at 4. By denying these programs, the FDA has reiterated its commitment to the FDCA. Here, however, defendants have created an exception for thiopental, resulting in a policy by which *FDA-approved* drugs cannot enter the United States, but thiopental—a drug that has *never been approved* by the FDA—can. This departure from longstanding policy makes little sense in light of the fact that alternative

barbiturates for use in lethal injection protocols exist. For example, in response to the end of U.S. thiopental production in 2009, several states, including Oklahoma, Texas, and Ohio, successfully changed their protocols to employ a different barbiturate—pentobarbital. *See* Declaration of Jennifer Moreno, Ex. 11 to Pls.' Mot., Mar. 18, 2011, ¶¶ 3-5 [Dkt. #12-15]. Put simply, this appears to be nothing more than the FDA, once again, stubbornly clinging to every last ounce of its discretionary authority!

Finally, defendants have undermined the purpose of the FDCA and acted in a manner contrary to the public health. The purpose of the FDCA is to "ensur[e] that when a citizen takes a prescription drug, that individual has absolute assurance that the product is safe and effective." *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 69 (D.D.C. 1998) (vacated on other grounds). As the FDA has explained, by establishing a "'closed' drug distribution system," the import provisions of the FDCA protect the public from the risk that potentially unsafe drugs obtained from foreign sources will enter into the marketplace. *See* FDA Letter. By opening up the "closed" drug system by allowing an unapproved drug—thiopental—into the United States, defendants jeopardize their own system and threaten the public health by creating a risk that thiopental could incorrectly end up in the hands of the general public.[8] Even when in the correct hands, prisoners on death row have an unnecessary risk that they will not be anesthetized properly prior to

[8] Indeed, the District Court for the Northern District of California has documented instances in which thiopental went missing from the California DOC's facilities. *See Morales v. Tilton*, 465 F. Supp. 2d 972, 979, 979 n.9 (N.D. Cal. 2006) (noting that the person responsible for maintaining custody of thiopental was discovered to be an illicit drug smuggler and that "substantial quantities" of thiopental had been diverted from San Quentin prison). Further, at least one shipment of foreign thiopental was received by a pharmacy in Georgia. *See* Defs.' Statement of Facts, Apr. 20, 2011, ¶ 4 [Dkt. #13-2]

execution. Further, defendants' actions also create a slippery slope that other unapproved foreign drugs may be allowed to enter into the United States to the detriment of the general public.

Defendants have failed to provide a reasoned explanation for departing from the FDA's own regulations, longstanding practices, and the purpose of the FDCA. Instead, defendants provide two explanations for this departure: (1) that its resources would not be best served in an area that it considers to be "distant from its public health mission," and (2) that its actions are consistent with a policy of deferring to law enforcement with respect to drugs used for lethal injection. *See* Defs.' Mot. at 39-40. Simply stating that the FDA decided it would be best not to expend resources to ensure illegal foreign shipments of thiopental were not admitted into the United States is not a reasoned explanation for disregarding the FDA's regulations, its longstanding practices, or the purpose of the FDCA.[9] *See Bluewater Network v. Salazar*, 721 F. Supp. 2d 7, 15 (D.D.C. 2010) (a reasoned explanation must supply "a rational connection between the facts found and the choice made") (internal quotation marks and citation omitted). Similarly, asserting that the FDA is deferring to law enforcement does not provide a reasoned explanation. Just as it is not a court's role "to 'correct' the text so that it better serves the statute's purposes . . . [nor] may an agency avoid the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better

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[9] Further, the FDA's mission is to ensure that *all* drugs are safe and effective, regardless of why the drug is being administered. *See* 21 U.S.C. § 393(b)(2)(B); *Colacicco v. Apotex Inc.*, 521 F.3d 253, 257 (3d Cir. 2008) (vacated on other grounds). The law does not create an exception for drugs purchased for use by a state DOC.

policy." *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996); *see Nat'l Ass'n of Broadcasters v. FCC*, 569 F.3d 416, 422 (D.C. Cir. 2009) ("[C]ourts have no authority to enforce [a] princip[e] . . . that has no statutory reference point.") (internal quotation marks and citation omitted). In the final analysis, the FDA appears to be simply wrapping itself in the flag of law enforcement discretion to justify its authority and masquerade an otherwise seemingly callous indifference to the health consequences of those imminently facing the executioner's needle. How utterly disappointing!

Thus, defendants have acted arbitrarily and capriciously, and have abused their discretion both by departing from FDA's own regulations and longstanding policies and by undermining the purpose of the FDCA.

CONCLUSION

Thus, for all of the foregoing reasons, plaintiffs' Motion for Summary Judgment and Declaratory Relief on Counts I and III [Dkt. #12] is GRANTED and defendants' Motion to Dismiss and/or for Summary Judgment [Dkt. #13] is DENIED. An appropriate order will accompany this memorandum opinion.

RICHARD J. LEON
United States District Judge