UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

K-V PHARMACEUTICAL COMPANY, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 12-1105 (ABJ)

MEMORANDUM OPINION

Plaintiff K-V Pharmaceutical Company ("KV") and its wholly owned subsidiary, plaintiff Ther-RX Corporation ("Ther-RX"), own and market a drug called Makena, which is a hydroxyprogestoerone caproate injection. Makena was approved in 2011 for use by pregnant women with a history of preterm birth to reduce the risk that they would experience another preterm birth. Plaintiffs have sued the United States Food and Drug Administration ("FDA"), its Commissioner Margaret A. Hamburg, the United States Department of Health & Human Services ("HHS"), and HHS Secretary Kathleen Sebelius, alleging that defendants are violating the Administrative Procedure Act ("APA") and several provisions of the Food, Drug, and Cosmetic Act ("FDCA") by failing to take action against pharmacies that compound the drug and thereby creating a cheaper alternative for doctors to prescribe. The compounded form of the drug is referred to as "17P" in this action.

In particular, plaintiffs challenge a March 30, 2011 press release in which FDA announced its intention not to take enforcement action against the compounders except under certain circumstances. They also challenge FDA's failure to block foreign shipments of the

active pharmaceutical ingredient ("API") used in 17P from entering the United States. According to plaintiffs, FDA's actions have given rise to unlawful competition with Makena and caused them irreparable economic harm.

Defendants have moved to dismiss the action under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). [Dkt. # 7]. They argue that plaintiffs lack standing, and that the actions they challenge are the types of discretionary enforcement decisions that the Supreme Court found to be unreviewable in *Heckler v. Chaney*, 470 U.S. 821 (1985). Alternatively, they argue that the complaint fails to state a claim upon which relief can be granted. The Court concludes that Counts I through III of the complaint challenge FDA's discretionary enforcement activities and therefore assert unreviewable claims, and that Count IV fails to state a claim under Rule 12(b)(6).

BACKGROUND

Plaintiff KV is the owner of the drug Makena, which has been approved by the FDA. Compl. ¶ 24. Plaintiff Ther-RX is a "wholly-owned subsidiary of KV [that] markets, sells, and distributes Makena on behalf of KV." *Id.* ¶ 25. On January 25, 2007, FDA designated Makena as an "orphan drug" to be used for the prevention of preterm birth in women who have a singleton pregnancy and a history of prior preterm delivery.[1] *Id.* ¶¶ 50–51.

Under the Orphan Drug Act, 21 U.S.C. §§ 360aa–ee ("ODA"), an "orphan drug" is a drug used to treat a disease or condition that affects fewer than 200,000 people in the United States. Compl. ¶ 36. Congress passed the ODA in 1983, as an amendment to the Federal Food,

1 Although now named "Makena," the drug was named "Gestiva" when its application was submitted to FDA for approval. Compl. ¶ 50. In addition, although now owned by KV, the drug was owned by the company Adeza Biomedical at that time. *Id.* For the sake of convenience, however, the Court will refer to the drug as "Makena" and the owner as "KV" throughout this opinion.

Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq* ("FDCA").[2] The congressional findings reflect that Congress sought to create incentives for the development of drugs for rare conditions. Pub. L. No. 97-414, § 1(b)(4), 96 Stat. 2049, 2049 (1983). Accordingly, when a drug receives the FDA's orphan drug designation, section 360cc(a) of the OCA prevents the Secretary of Health from "approving another application under section 355 of this title . . . for such drug for [the same] disease or condition" within seven years after the approval date of the orphan drug. 21 U.S.C. § 360cc(a).

Makena, a hydroxyprogesterone caproate injection is the first drug approved by FDA to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Compl. ¶ 1. Because it has been designated as an "orphan drug," its seven year exclusivity period began running on the day it was approved, February 3, 2011. Compl. ¶ 14.

However, for a number of years before FDA approved Makena, women were treated for risk of preterm birth with versions of hydroxyprogesterone caproate that were compounded by entities known as "compounding pharmacies" or "compounders." *Id*. ¶ 9. According to the complaint:

> Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication customized to the needs of an individual patient. Compounded drugs generally are not reviewed or approved by FDA. Compounded versions of 17P were not and are not reviewed or approved by FDA; and, in general, their individual formulations, manufacturing processes, labeling, and adverse-event and treatment-failure histories were and are unknown to FDA. The facilities in which the compounding occurred and continues to occur generally were not and are not registered with or routinely inspected by FDA.

2 Since this action was filed, the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012), took effect, amending the FDCA. The provisions of the FDCA at issue here were not changed by the amendments.

Compl. ¶ 9.

When Makena was released, the media began reporting on its high list price of $1,500 per injection, or up to $30,000 for a course of treatment. *Id.* ¶ 68. Plaintiffs allege that these reports were misguided, *see id.* ¶¶ 69–73, but that the press accounts prompted members of Congress to pressure FDA to make the 17P injection available at a lower price than the initial list price for Makena. *Id.* ¶ 74.

On March 30, 2011, FDA issued a statement for immediate release titled, *FDA Statement on Makena*.[3] FDA Statement (Mar. 20, 2011), *available at* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm ("March Statement"). The statement explained that FDA had approved Makena on February 3, 2011, and that as a result, Makena obtained seven years of exclusivity under the Orphan Drug Act. *Id.* It further explained that for many years, a version of the active ingredient of Makena had been available to patients whose physicians requested the drug from a pharmacist who compounded the drug, and that FDA had generally exercised enforcement discretion with respect to those drugs. *Id.* The March Statement went on:

> Because Makena is a sterile injectable, where there is a risk of contamination, greater assurance of safety is provided by an approved product. However, under certain conditions, a licensed pharmacist may compound a drug product using ingredients that are components of FDA approved drugs if the compounding is for an identified individual patient based on a valid prescription for a compound product that is necessary for that patient. FDA prioritizes enforcement actions related to compounded drugs using a risk-based approach, giving the highest enforcement priority to pharmacies that compound products that are causing harm or that amount to health fraud.

3 Although the complete press release is not attached to plaintiff's complaint, it is incorporated by reference in paragraphs 75–94. Compl. ¶¶ 75–94; *see Gustave-Schmidt v. Chao*, 226 F. Supp. 2d 191, 196 (D.D.C. 2002) (finding that a court may consider documents incorporated by reference in the complaint for a motion to dismiss under Rule 12(b)(6)).

> FDA understands that the manufacturer of Makena, KV Pharmaceuticals has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct.
>
> In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion.

Id.

In their complaint, plaintiffs do not mention the language in the press release that suggests that the March Statement may have been prompted by their own actions. Instead, they allege that the March Statement was issued in response to public pressure about the price of Makena. Compl. ¶ 75. They further allege that some Medicaid programs have interpreted the March Statement as "authorizing the total displacement of Makena by compounded 17P." *Id*. ¶ 86.[4] Plaintiffs assert that "numerous compounded versions of 17P (not customized for individual patients) have entered, re-entered, or remained on the U.S. market, some manufactured on a commercial scale"; and that FDA is permitting unapproved 17P API to be imported into the United States. *Id.* ¶ 15. According to the complaint, many or all of the compounders of 17P use active ingredients manufactured in China by establishments that have not been identified in an approved new drug application and are not inspected by FDA. *Id.* ¶ 89.

4 The complaint also alleges that on the same day that FDA issued the March Statement, the Centers for Medicare and Medicaid Services ("CMS"), a unit of HHS, issued a coordinated statement that allegedly "authorized and encouraged state Medicaid agencies to pay for compounded 17P in substitution for Makena." Compl. ¶¶ 17, 83.

Since issuing the March Statement, FDA has issued three additional press releases regarding Makena, Compl. ¶ 94, two of which are relevant to this action.[5] On June 15, 2012, FDA addressed safety concerns plaintiffs had raised about the 17P compounds, and it described the enforcement approach it was following with respect to compounded 17P. It announced that it had tested API from sixteen samples of 17P, and thirteen samples of compounded 17P prepared by eight different pharmacies, and that it had not identified any major safety problems. Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (the active ingredient in Makena) (June 15, 2012), *available at* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm ("June Statement"). However, it also stated that "approved drug products, such as Makena, provide a greater assurance of safety and effectiveness than do compounded products." *Id.*

The June Statement further explained:

> The drugs that pharmacists compound (including compounded hydroxyprogesterone caproate) are not FDA approved, which means they do not undergo premarket review nor do they have an FDA finding of safety and efficacy. Compounding large volumes of drugs that are copies of FDA-approved drugs circumvents important public health requirements, including the Federal Food, Drug, and Cosmetic Act's drug approval provisions. Consumers and health professionals rely on the Act's evidence-based drug approval process to ensure that drugs are safe and effective. For that reason, one factor that the agency considers in determining whether a drug may be compounded is whether the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.
>
> FDA emphasizes that it is applying its normal enforcement policies for compounded drugs to compounded hydroxyprogesterone caproate. The compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding. As the

5 Although these documents are not attached to the Complaint, they are incorporated into the complaint by reference in paragraph 94. *See Gustave-Schmidt*, 226 F. Supp. 2d at 196.

> Agency has previously explained, FDA generally prioritizes enforcement actions related to compounded drugs using a risk-based approach, giving the highest enforcement priority to pharmacies that compound products that are causing harm or that amount to health fraud.

Id.

Then, in a press release titled, *Questions and Answers on Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (the active ingredient in Makena)*, FDA provided further clarification. (June 29, 2012), *available at* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310215.htm ("Questions and Answers"). It posed and answered the following questions:

> **Will the agency take any enforcement action against pharmacies compounding versions of hydroxyprogesterone caproate products?**
>
> The FDA may take enforcement action against compounding pharmacies if warranted. The FDA makes its enforcement decisions about compounded products on a case-by-case basis after considering the particular facts at issue. As we explained in the June 15, 2012, statement, the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding.
>
> **Are pharmacies free to compound large volumes of hydroxyprogesterone caproate as long as none of their drugs are tested and found to be unsafe?**
>
> No. The FDA does not consider compounding large volumes of copies, or what are essentially copies, of any approved commercially-available drug to fall within the scope of traditional pharmacy practice. One factor that the agency considers in determining whether a drug may be compounded is whether the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product. . . .
>
> **The FDA stated it is using a risk-based approach to enforcement action against compounding pharmacies. The FDA also stated that its investigation did not identify a major safety issue, so does that mean that the FDA does not intend to take enforcement action against the compounders of hydroxyprogesterone caproate?**

> No. A risk-based approach to enforcement relates to how the FDA generally prioritizes its enforcement efforts. The FDA's June 15, 2012 statement should not be interpreted to mean that the FDA will take enforcement action only if the agency identifies a particular safety problem. We reiterate that the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding.

Id.

Plaintiffs complain that none of these statements evince an agency plan to take enforcement action against those compounding and marketing 17P on a large scale basis as opposed to individually customizing it for patients for whom Makena is medically inappropriate. Compl. ¶ 94. They allege that notwithstanding FDA's public statements, compounded versions of 17P are still actively being sold on the U.S. market. *Id.* ¶ 95. *See also* Plaintiffs' Opposition to Def's Motion to Dismiss and Reply Mem. in Support of Mot. for Temporary, Prelim., and Permanent Relief [Dkt. # 12] at 4–5 ("Pls.' Opp.") ("FDA has failed to date to take any action against the compounding of 17P. . . . In practical effect . . . FDA's lack of enforcement against unlawful compounding of 17P has not changed; and because FDA has done nothing to change the perception in the marketplace that it will not act against unlawful compounding of 17P, the unlawful compounding of 17P continues."). In essence, what plaintiffs challenge is defendants' failure to take enforcement action:

> The bottom line is that Defendants have done and, unless ordered by the Court, will do, nothing – nothing – to enforce the law against unlawful uncustomized compounding of 17P, unless and until FDA learns that patients have actually been harmed or defrauded by compounded 17P.

Pls.' Opp. at 6.

Plaintiffs assert that FDA's statements and inaction have undermined the exclusivity conferred with the orphan drug designation and devalued their substantial investment in the drug.

Compl. ¶¶ 95–99. The complaint alleges that KV is almost entirely reliant on the success of Makena to generate the cash it needs to finance its operations and to make obligatory debt payments, *id.* ¶ 95, and that the illegal production of 17P has displaced Makena in the market and substantially undercut plaintiffs' sales, *id.* ¶ 96. Since the time the complaint was filed, plaintiffs KV and Ther-Rx have filed voluntary Chapter 11 petitions in the United States Bankruptcy Court for the Southern District of New York.[6] *See* Notice of Filing for Bankruptcy Protection by K-V Pharma. Co., Ther-Rx Corp. [Dkt. # 18] (Aug. 6, 2012).

Plaintiffs filed a four-count complaint in this Court on July 5, 2012, [Dkt. # 1], along with a motion for temporary restraining order and preliminary injunction, [Dkt. # 2].

- Count I alleges that FDA's March Statement and the policy it sets forth violate section 360cc(a) of the FDCA by effectively nullifying Makena's statutory seven-year period of market exclusivity. It further alleges that by issuing the March Statement for the purpose of "support[ing] access to" HPC injection, FDA failed to comply with the procedural requirements of section 360cc(a), in violation of the APA, 5 U.S.C. § 558(c); section 360cc(a) of the FDCA, 21 U.S.C. § 360cc; and the Due Process Clause of the Fifth Amendment of the United States Constitution, and acted arbitrarily, capriciously, in an abuse of discretion, and in excess of its authority, in violation of the APA, 5 U.S.C. § 706(2)(A)–(D). Compl. ¶¶ 103–09.

- Count II alleges that the March Statement and the policy it sets forth are contrary to section 353a of the FDCA and are arbitrary, capricious, an abuse of discretion, and exceed FDA's authority, in violation of the APA, 5 U.S.C. § 706(2)(A), (C). Compl. ¶¶ 110–13.

- Count III alleges that the March Statement and the policy it sets forth "approve, authorize, invite, encourage, and permit the introduction, and delivery for introduction, into interstate commerce of unapproved new drugs" in violation of FDCA sections 355(a) and 301(d), 21 U.S.C. §§ 355(a), 331(d), and the APA, 5 U.S.C. § 706(2)(A), (C). Compl. ¶¶ 114–16.

- Count IV alleges that by allowing the import of API for compounded 17P, FDA is engaging in an ongoing violation of section 381(a) of the FDCA. Furthermore, the March Statement "announcing implicitly that [FDA] would allow such imports" is

6 The notice indicates plaintiffs' view that the automatic stay provision in the Bankruptcy Code, 11 U.S.C. § 362(a)(1), does not stay this case. [Dkt. # 18]. The Court agrees.

> arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, in violation of the APA, 5 U.S.C. § 706(2)(A), (C)–(D). Compl. ¶¶ 117–25.

The complaint seeks a comprehensive regime of temporary, preliminary, and permanent declaratory and injunctive relief. It asks the Court to order defendants to withdraw the March and June statements in a formal announcement, and to discontinue the policy of non-enforcement that was set forth in the March Statement. Compl. 42 ¶ 5(a). It requests that the Court order defendants: to "take sufficient enforcement actions to stop the unlawful competition with Makena" by non-customized compounded 17P, *id.* ¶ 5(b); to report to the Court quarterly for one year and semi-annually for the following two years the actions they have taken to terminate shipments of non-customized compounded 17P, *id.* ¶ 5(c); and to bar entry into the United States, and release into domestic commerce, of any future shipments of foreign-manufactured API for use in compounding non-customized 17P except in certain specified instances. *Id.* ¶ 5(d).

After a telephone conference held on July 5, 2012, the Court consolidated the motion for temporary restraining order and preliminary injunction with the merits and issued an accelerated briefing schedule for a partial dispositive motion to be filed by defendants. Minute Order (July 5, 2012). In accordance with that schedule, defendants filed the instant motion to dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). In addition, this Court granted Alere Women's and Children's Health, L.L.C. and several interested physicians leave to file an amicus brief in support of defendants. [Dkt. # 11].

STANDARD OF REVIEW

In evaluating a motion to dismiss under either Rule 12(b)(1) or 12(b)(6), the Court must "treat the complaint's factual allegations as true . . . and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" *Sparrow v. United Air Lines, Inc.*, 216

F.3d 1111, 1113 (D.C. Cir. 2000), quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979). Nevertheless, the Court need not accept inferences drawn by the plaintiff if those inferences are unsupported by facts alleged in the complaint, nor must the Court accept plaintiff's legal conclusions. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002).

I. Subject Matter Jurisdiction

Under Rule 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Shekoyan v. Sibly Int'l Corp.*, 217 F. Supp. 2d 59, 63 (D.D.C. 2002). Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *see also Gen. Motors Corp. v. Envtl. Prot. Agency*, 363 F.3d 442, 448 (D.C. Cir. 2004) ("As a court of limited jurisdiction, we begin, and end, with examination of our jurisdiction."). Because "subject-matter jurisdiction is an 'Art[icle] III as well as a statutory requirement, . . . no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003), quoting *Ins. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982).

When considering a motion to dismiss for lack of jurisdiction, unlike when deciding a motion to dismiss under Rule 12(b)(6), the court "is not limited to the allegations of the complaint." *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Rather, a court "may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000), citing *Herbert v. Nat'l Acad. of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1993); *see also Jerome Stevens Pharms.*,

Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (finding that a district court can "consider materials outside the pleadings" to assess jurisdiction) (citations omitted).

II. Failure to State a Claim

"To survive a [Rule 12(b)(6)] motion to dismiss a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the pleaded factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal citation omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' 'that the pleader is entitled to relief.'" *Id.* at 679, quoting Fed. R. Civ. P. 8(a)(2). A pleading must offer more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action," *id.* at 678, quoting *Twombly*, 550 U.S. at 555, and "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* In ruling upon a motion to dismiss, a court may ordinarily consider only "the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint, and matters about which the Court may take judicial notice." *Gustave-Schmidt*, 226 F. Supp. 2d at 196 (citations omitted).

ANALYSIS

I. Plaintiffs have standing to bring this action as their alleged injuries are redressable.

A lack of standing is a defect in subject-matter jurisdiction. *Haase v. Session*, 835 F.2d 902, 906 (D.C. Cir. 1987). In order to establish constitutional standing, a plaintiff must demonstrate that a case or controversy exists by showing that (1) he has suffered an "injury in fact"; (2) that the injury is "fairly traceable" to the conduct of the defendant; and (3) that it is likely that the injury will be redressed by a favorable decision. *George v. Napolitano*, 693 F. Supp. 2d. 125, 129–30 (D.D.C. 2010), citing *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180–81 (2000). Defendants challenge plaintiffs' standing under the third prong: redressability.

To satisfy the redressability requirement of jurisdictional standing, a court must find that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision" on the merits. *Lujan*, 504 U.S. at 561, quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 38, 43 (1976) (quotation marks omitted). An injury is not redressable where the "only apparent avenue of redress for plaintiffs' claimed injuries . . . is unavailable." *Newdow v. Roberts*, 603 F.3d 1002, 1013 (D.C. Cir. 2010).

Plaintiffs' claimed injury is the loss of their market exclusivity, and the attendant profits, due to unlawful competition from non-customized compounded 17P. Pls.' Opp. at 9. To remedy this injury, plaintiffs ask the Court to order FDA to take enforcement actions against the unlawful compounders. *Id.* This, plaintiffs argue, would greatly diminish, or eliminate, the supply of unlawful 17P on the market. *Id.* at 16. As a result, Makena sales would rise, increasing revenue for KV and Ther-Rx. *Id*. Medicaid agencies, in particular, would have to change their policies as to Makena if the supply of compounded 17P were to diminish. *Id*.

Plaintiffs point to several enforcement mechanisms that FDA is authorized to, and indeed does, use against unlawful compounders, such as issuing warning letters; imposing import alerts; referring violators to the Department of Justice for a proposed civil action for seizure of the unlawful compound, for an injunction, or for criminal prosecution. Pls.' Opp. at 9–14. While nothing ensures that these enforcement actions will induce all 17P compounders to stop their unlawful production, the Court is satisfied that the complaint alleges sufficient facts to support the inference that enforcement tools at FDA's disposal would be "likely" to at least reduce the presence of compounded 17P on the market, which would compel more health care professionals to use Makena, or prompt insurers that have adopted policies favoring use of compounded 17P over Makena to ease those policies. *See* Compl. ¶ 19 (explaining that "some state Medicaid agencies have adopted policies" that make it challenging for pregnant women to gain access to Makena and favoring 17P compounds); *see also Lujan*, 504 U.S. at 561 ("At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim.") (internal quotation marks and citations omitted).

Defendants argue that plaintiffs' injuries are not redressable because FDA's decision whether to take enforcement action is committed to the agency's discretion. Defs.' Mem. in Support of Defs.' Mot to Dismiss and in Opp. to Pls.' Mot. for Injunctive Relief [Dkt. # 7] at 15 ("Defs.' Mem."). But this argument imports the examination of the reviewability of the agency's decision into the redressability inquiry. For that reason, the cases defendants cite in support of the argument are distinguishable from this case. *Chaney*, 470 U.S. at 821, *Block v. SEC*, 50 F.3d

1078 (D.C. Cir. 1995), and *Coker v. Sullivan*, 902 F.2d 84 (D.C. Cir. 1990) all concern the reviewability of an agency's enforcement decision and make no mention of redressability.[7]

In the final case that plaintiffs cite, *Judicial Watch, Inc. v. National Archives and Records Administration*, 845 F. Supp. 2d 288 (D.D.C. 2012), the plaintiffs asked the Court to order the National Archives and Records Administration to take custody and control of audiotapes created by former President Clinton and still in the President's control. *Id.* at 289–90. The Court found the plaintiff's injury not redressable because the Archives had no authority or means to obtain the records from the President at all. *Id.* at 304 ("Ultimately, plaintiff conceded that even an order deeming the materials to be Presidential records and directing the defendant to make an effort to retrieve them would not bind the former President to produce them. . . . This is the problem at the heart of the lawsuit that requires its dismissal."). Here, the FDA has the means and the authority to bring enforcement actions that would likely decrease the incidence of unlawfully compounded 17P, so *Judicial Watch* is inapplicable.[8]

Furthermore, plaintiffs have standing to challenge FDA's alleged permission of the active ingredient in 17P compounds to be unlawfully imported into the United States. Defendants do not challenge FDA's authority to reject shipments of drugs meant for import. And since plaintiffs allege that "many (possibly, all)" compounders of 17P use active ingredient manufactured abroad, Compl. ¶ 89, it is certainly likely that if FDA were to reject the imports of active ingredient meant for unlawfully compounded 17P, the amount of the compound that

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7 Plaintiff also cites *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004), but that case involved the reviewability of agency inaction under the APA and did not address redressability.

8 While it is the Department of Justice that has the ultimate authority to decide whether to bring enforcement proceedings in Court, *see* Pls.' Opp. at 13–14, plaintiffs identify several other enforcement mechanisms within the FDA's control. *Id.* at 9–13.

pharmacies could create would drop, at least temporarily. This, in turn, would likely drive health care professionals to use Makena, or at least drive insurers like Medicaid to reverse its policies regarding Makena. *See* Compl. ¶ 19.

Since plaintiffs have alleged sufficient facts to support standing, the Court proceeds to defendants' next argument: reviewability.

II. The actions challenged in Counts I–III are not reviewable.

All four of plaintiffs' claims ask the Court to review agency conduct under section 706(2) of the Administrative Procedure Act.[9] But section 701 of the APA precludes judicial review of final agency action, including refusals to act, when review is precluded by statute or "committed to agency discretion by law." 21 U.S.C. § 701; *see Chaney*, 470 U.S. at 826.

Defendants contend that the Supreme Court's decision in *Heckler v. Chaney* is controlling here, and that the challenged agency action is not subject to judicial review because it is committed to agency discretion. Defs.' Mem. at 18–40, citing *Chaney*, 470 U.S. at 821. The Court agrees. In *Chaney*, the Supreme Court held that an agency's decision not to take enforcement action is presumed to be immune from judicial review unless Congress has expressed the intent to circumscribe agency enforcement discretion in the statute and provided meaningful standards in the statute for defining the limits of that discretion. 470 U.S. at 834–35. In this case, Congress has done neither.

In *Chaney*, a group of prison inmates sought to compel FDA to initiate an enforcement action with respect to the drugs used for capital punishment. *Chaney*, 470 U.S. at 823. Plaintiffs

9 The Court notes that Count I of the complaint also alleges that FDA violated the Due Process Clause of the Fifth Amendment to the United States Constitution. However, plaintiffs do not raise this claim in their motion for temporary restraining order and preliminary injunction and do not defend it in opposition to plaintiffs' motion to dismiss the action, so the Court will treat it as conceded.

initially petitioned the agency directly, arguing that the use of those drugs violated prohibitions in the FDCA against misbranding and constituted the unapproved use of an approved drug. *Id.* at 824. They also argued that the FDCA's requirements for approval of "new drugs" under section 355 applied, but were not being followed. *Id.* Accordingly, the plaintiffs asked FDA to take various investigatory and enforcement actions to prevent the perceived violations, such as:

> [A]ffix 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.

The FDA Commissioner responded by letter, refusing to take the requested actions. *Id.* The letter explained, in part:

> Generally enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions . . . .

Id. at 824–25. The plaintiffs then challenged this response in court under the judicial review provisions of the APA, claiming the same violations of the FDCA and asking the Court to require FDA to take the enforcement actions they had requested in the petition. *Id.* at 825.

The Supreme Court held that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion" and is therefore presumed to be unreviewable under the APA. *Id.* at 831. The Court explained that the availability of judicial review is determined by the legislature in the first

instance, and that if Congress has not provided courts with "law to apply," agency action will be considered to be committed to the agency's discretion. *Id.* at 834.

> If [Congress] has indicated an intent to circumscribe agency enforcement discretion, and has provided meaningful standards for defining the limits of that discretion, there is law to apply under § 701(a)(2), and courts may require that the agency follow that law; if it has not, then an agency refusal to institute proceedings is a decision committed to agency discretion by law within the meaning of that section.

Id. (internal quotation marks omitted). The Court determined that the action at issue in *Chaney* was committed to the agency's discretion because the statute was "drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Id*. at 830. The Court reasoned:

> [A]n agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. . . . The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.

Id. at 831–32. A plaintiff may overcome the presumption that agency enforcement decisions are unreviewable only by showing that "the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id*. at 833.

Here plaintiffs' claims in Counts I through III fall squarely within the *Chaney* presumption of unreviewability. Just as in *Chaney*, plaintiffs allege ongoing violations of substantive provisions of the FDCA, and they request that the Court order FDA to take investigatory and enforcement action to stop them. Compl. ¶¶ 103–116; pp. 40–43. A review of the extensive prayer for relief demonstrates that this case is fundamentally an effort to get the Court to direct and oversee the FDA's enforcement activities, and that it cannot do.

A. Congress did not express an intent in the FDCA to circumscribe agency enforcement discretion and it did not provide any law for the court to apply.

Under *Chaney*, the presumption of unreviewability can be overcome only if Congress "has indicated an intent to circumscribe agency enforcement discretion, and has provided meaningful standards for defining the limits of that discretion." 470 U.S. at 834. And *Chaney* is directly on point here because the Supreme Court was analyzing the very statute at issue in this case.

In *Chaney*, the Court examined each of the enforcement mechanisms available to FDA under the FDCA and found that "[t]he Act's enforcement provisions . . . commit complete discretion to the Secretary to decide how and when they should be exercised." *Id.* at 835. That finding continues to be controlling today. So the only remaining question is whether there is some other provision in the FDCA that would authorize the review that plaintiffs are seeking.

The *Chaney* plaintiffs pointed to substantive prohibitions in the FDCA, including the rules against misbranding in section 355, but the Court flatly rejected the notion that those sections supplied the necessary law to apply, saying: "These provisions are simply irrelevant to the agency's discretion to refuse to initiate proceedings." *Id.* at 836. The Court finds that the substantive provisions cited in this case are similarly irrelevant.

Count I points to 21 U.S.C. § 360cc, which is the grant of exclusivity under the Orphan Drug Act. It provides that the Secretary "may not approve another application under section 355 of this title" within seven years of approving an orphan drug, and identifies some exceptions to

the rule. 21 U.S.C. § 360cc(a)(2).[10] Count II is premised upon section 353a, which exempts compounded drugs from various provisions of the FDCA (including section 355 – the prohibition against the introduction of a drug into interstate commerce without FDA approval) under particular conditions, such as when the drug has been compounded for an individual patient based on a valid prescription. 21 U.S.C. §353a. But neither of those provisions requires FDA to proceed against unlawful compounders – they don't say a word about it. And Count III is based in part on section 355, which was the section considered and rejected by the Court in *Chaney*. Section 355(a) states that "no person shall introduce or deliver for introduction into interstate commerce any new drug," without approval by FDA. 21 U.S.C. § 355(a). It is also based on section 331(d), which states that "the introduction or delivery for introduction into interstate commerce of any article in violation of" various sections of the FDCA, including section 355, is prohibited. 21 U.S.C. § 331(d). So none of the cited provisions deal with the scope of the agency's enforcement discretion at all.

Indeed, in their papers, plaintiffs did not point to any specific language in these statutory provisions that supposedly expressed the legislature's desire to limit the agency's enforcement discretion or that could serve as the guide for a court's review. Moreover, when asked directly at the motions hearing, counsel for plaintiff would not concede the point, but he repeatedly failed to direct the Court to any statutory provision that would satisfy the *Chaney* test and overcome the presumption. Tr. of Motions Hearing (Aug. 7, 2012) ("Tr.") at 31–33, 36–38, 46. Accordingly,

10 Plaintiffs cite section 360cc for the proposition that the FDA is prohibited from "approving (formally or in any other way), authorizing, inviting, encouraging, or generally permitting the introduction into interstate commerce of any compounded version of that same drug product for the same orphan indication as to which the approved drug has been designated as an orphan drug." *See e.g.*, Compl. ¶ 104. But that language does not appear anywhere in that section of the statute, so the citation is somewhat disingenuous. The only express direction to FDA in section 360cc is that the Secretary "may not approve another application under section 355 of this title." 21 U.S.C. § 360cc(a)(2).

this Court finds that Congress did not express an intent to circumscribe FDA's enforcement discretion in the FDCA. And since the FDCA does not provide any law for the Court to apply, the Court finds that FDA's March Statement is unreviewable.[11]

Plaintiffs emphasize the prospective nature of FDA's pronouncement and argue that since it addresses future conduct, it constitutes an "affirmative public invitation" to compound 17P that is different from a mere failure to bring an enforcement action. Pls.' Opp. at 39; Pls.' Mot. for Temporary Restraining Order and Preliminary Injunction ("Pls.' Mot. for TRO/PI") [Dkt. # 2] at 37. However, the letter that the plaintiffs challenged in *Chaney* contained language nearly identical to the operative language in the March Statement. The *Chaney* response letter stated that enforcement proceedings are generally initiated only when there is a serious danger to the public health or a blatant scheme to defraud, and that FDA could not conclude that those factors were present under State lethal injection laws. *Chaney*, 470 U.S. at 824–25. Similarly here, the March Statement relays the factors FDA considers when deciding whether to bring enforcement action, and recites its current determination that those factors do not warrant action against pharmacies that compound 17P for individual patients, except under certain conditions.

Plaintiffs also contend that they fall outside *Chaney* because they are only requesting that the Court require FDA to take *some* enforcement action, and they are not asking it to specify the *type* of enforcement action. Pls.' Opp. at 23–24. But this distinction does not save the case. Plaintiffs' requests that the Court order "sufficient" enforcement action to restore plaintiffs'

11 Perhaps because the statutory support is absent, plaintiffs argue vehemently that the Court should grant relief in this case because "where agency action (or inaction) has harmed plaintiffs, it is well within the equitable powers of a court to order the specific relief necessary to cure the transgressions." Pls.' Opp. at 26–28. However, in light of the plain language of section 701 of the APA and the clear direction provided by *Chaney,* the Court declines to find that FDA's announcement of an enforcement decision that is well within its discretion constitutes the type of harm that warrants equitable intervention.

competitive advantage and that it monitor FDA's activities by requiring regular reports demonstrate that they are asking the Court to get right smack in the middle of agency operations. Directing the FDA to bring a particular sort of enforcement action, and a particular quantity of those actions, is directing it how to allocate its finite enforcement resources – a decision that is "peculiarly within the agency's expertise and discretion."[12] *Crowley v Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994).

B. Plaintiffs cannot avoid the impact of *Chaney* by characterizing the March Statement as a statement of agency policy.

Plaintiffs maintain that the case survives on the grounds that it is not actually about an enforcement decision. They cite *Crowley v. Pena*, 37 F.3d 671 (D.C. Cir. 1994), and argue that

12 Plaintiffs' argument that the March Statement is reviewable because FDA considered price in deciding how to exercise its enforcement discretion – a factor that FDA may not consider to determine whether a compound is legal under the FDCA – is also misguided. Compl. ¶¶ 80–81. The March Statement does not express a view that 17P compounds are legal because Makena is too expensive. If that were the case, the statement might constitute a reviewable agency policy. Rather, the statement explains why FDA does not intend to bring enforcement actions against certain pharmacies, even if the pharmacies are engaging in unlawful conduct. It is exactly that exercise of discretion that *Chaney* and *Crowley* explained is presumptively unreviewable.

the case falls within an exception to *Chaney* for challenges to statements of agency policy.[13] Pls.' Opp. at 36–38. In *Crowley*, the D.C. Circuit confirmed that enforcement decisions are presumptively unreviewable. 37 F.3d at 676–77. However, it noted in dicta that "an agency's statement of a *general enforcement policy* may be reviewable for legal sufficiency where the agency has expressed the policy as a formal regulation after the full rulemaking process . . . or has otherwise articulated it in some form of universal policy statement." *Id.* at 676. Plaintiffs argue that FDA's statement is reviewable because it sets forth a general policy, not a decision in an individual case. Pls.' Opp. at 36–37. But the letter challenged in *Chaney* also involved a broad class of alleged law violators, so the fact that the March Statement did not involve an individual declination is not dispositive. More important, the March Statement is neither the formal result of a rulemaking process nor a universal policy statement, so the limited circumstances that the D.C. Circuit said *may* call for a different result are not present here.

In *Crowley,* the D.C. Circuit noted that a statement might be reviewable if it "actually lay[s] out a general policy delineating the boundary between enforcement and non-enforcement

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13 At the motion to dismiss stage, the Court takes all the factual allegations in plaintiffs' complaint as true and makes all inferences that can be alleged from those facts in plaintiffs' favor. *See Sparrow*, 216 F.3d at 1113. However, the Court need not accept the many legal conclusions asserted in the complaint or any inferences unsupported by factual allegation. *Browning*, 292 F.3d at 242. For example, the Court need not accept plaintiffs' conclusion that "FDA's [March] Statement is not the exercise of case-by-case enforcement discretion as to past conduct, but, rather, addresses future conduct and announces a general policy that is binding on FDA personnel as long as it has not been revoked, and that approves, authorizes, invites, encourages, and permits an unlimited and unknown number of 'compounders' to distribute nationwide during plaintiffs' exclusivity period and for an unlimited time and thereafter non-customized 17P intended to be used for the same orphan indication for which Makena is approved." Compl. ¶ 80. Whether or not the March Statement is an exercise of enforcement discretion or a policy is a legal conclusion. And plaintiffs' characterization does not quite square with the language in the statement that "FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate *based on a valid prescription for an individually identified patient* unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products." (emphasis added). March Statement.

and purport[s] to speak to a broad class of parties." *Crowley*, 37 F.3d at 677. But this is a narrow exception to the presumption. As the Court of Appeals explained: "This will not be true in the ordinary case, however, and the more reasonable inference when faced with a context-bound non-enforcement pronouncement is that the agency has addressed the issue in comparatively ad hoc terms inherently implicating its non-reviewable enforcement discretion." *Id.* As the court predicted, that is the appropriate inference to be drawn here, as there is no clear demarcation set out in the statement at issue.

The language in the March Statement that animates the plaintiffs – that "FDA does not intend to take enforcement action against pharmacies" – does not constitute an announcement of policy that would differentiate this case from *Chaney*. March Statement. In *Chaney*, FDA's intention not to take enforcement action against states using the challenged drugs for lethal injections was implicit in its denial of the plaintiffs' petition. *Chaney*, 470 U.S. at 837–38. States could have viewed it, as plaintiffs suggest here, as a "green light" to continue their allegedly illegal behavior. Yet, the Supreme Court still found the decision enunciated in the letter to be unreviewable. *Id.*

Moreover, here, FDA did not disavow an intention to proceed against compounding pharmacies as a general matter. What it said was: "FDA does not intend to take enforcement action *against pharmacies that compound . . . based on a valid prescription for an individually identified patient* unless the compounded products are unsafe . . . ." March Statement (emphasis added). Inherent in that statement is a consideration of the individual circumstances of each case: was there a valid prescription for an individually identified patient? So, contrary to plaintiff's assertion, the March Statement is not a universal policy statement "setting forth FDA's decision not to regulate the class of noncustomized compounded products that contain 17P (or

what purports to be 17P) . . . ." Pls.' Opp. at 19. Furthermore, the March Statement was simply a statement of present intent and it included the caveat, "[a]s always, FDA may at any time revisit a decision to exercise enforcement discretion." March Statement (emphasis added). It does not bind FDA to any future action or inaction, and does not lay out any discrete boundary between enforcement and non-enforcement. It is the sort of ad hoc, context-bound non-enforcement pronouncement that the *Crowley* court suggested would inherently implicate an agency's unreviewable enforcement discretion. *Crowley*, 37 F.3d at 677.

This case is also distinguishable from those precedents where the courts were willing to adopt the *Crowley* approach. In *Crowley*, the Court of Appeals observed that expressions of broad enforcement policy are more likely to be direct interpretations of the commands of the substantive statue rather than the sort of mingled assessments of fact, policy, and law that drive an individual enforcement decision and are peculiarly within the agency's expertise and discretion. *Crowley*, 37 F.3d at 677. Thus, in the cases where courts have reviewed an enforcement policy, they have emphasized that their review was limited to the question of whether or not the agency's express statement of policy unlawfully construed a statute. *See, e.g.*, *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998) (considering the pure question of statutory interpretation of whether the agency's interpretation of section 506 of the Merchant Marine Act of 1936 – permitting certain vessels built with federal aid for service in foreign trade to be used for domestic trade after the expiration of its economic life – as a challenge to agency policy and not as a decision not to enforce the statute's ban on domestic trade by that type of vessel); *Edison Electric Institute v. EPA*, 996 F.2d 326, 333 (D.C. Cir. 1993) (explaining that petitioners are challenging EPA's interpretation of the statute and its implementing regulations, which "clearly . . . [have] to do with the substantive requirements of

the law; it is not the type of discretionary judgment concerning the allocation of enforcement resources that [*Chaney*] shields from judicial review"); *Roane v. Holder*, 607 F. Supp. 2d 216, 226–27 (D.D.C. 2009) (finding that "to the extent the plaintiffs are claiming that the defendants have made a general statement about their policy of enforcement of the CSA with respect to federal lethal injections divorced from any fact-specific enforcement decision, the plaintiffs have stated a claim outside the scope of the [*Chaney*] presumption against judicial review"); *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 171–72 (D.D.C. 2000), ("Although the Court may not review FDA's policy-laden individual enforcement decisions, the Court has jurisdiction to review whether or not FDA's Statement of Policy comports with Congressional directives.").

In this case, FDA's press release does not purport to interpret the commands of the substantive statute. To the extent that it does convey some legal principle, plaintiffs concede that FDA's interpretation of the FDCA is in line with theirs: uncustomized compounding of 17P is unlawful. Pls.' Mem. in Opp. to Amici Curiae Brief [Dkt. # 14] at 2. The March Statement simply assesses the considerations that have led it to anticipate that enforcement action against particular compounding pharmacies will not be warranted. This is the type of analysis that the *Crowley* court found to be peculiarly within the agency's expertise and discretion, and therefore presumptively unreviewable.

Along the same lines, the *Crowley* court also explained that agency policies – as opposed to enforcement decisions – might be amenable to review because agencies generally provide statements of reasons when they formally announce broadly applicable guidelines, while statements justifying individual decisions to forego enforcement tend to be cursory, ad hoc, or post hoc. *Crowley*, 37 F.3d at 677. "These latter cases confront courts . . . with the task of

teasing meaning out of agencies' side comments, form letters, litigation documents, and informal communications." *Id.*

This reasoning also suggests that the March Statement is not subject to review. It is a short summary of FDA's position, which appears to have been issued to quell confusion generated by plaintiffs' efforts to disseminate their own characterization of that position. March Statement ("FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct.").

At the hearing, plaintiffs argued that the press release qualifies as a *Crowley* policy statement, noting that even less formal documents have been found to be subject to review. Tr. at 38–39, citing *OGS Bulk Ships, Inc.*, 132 F.2d at 808 (agency letters); *Center for Auto Safety, Inc. v. National Highway Traffic Safety Administration*, 342 F. Supp. 2d at 1 (D.D.C. 2004) (same); *Chiang v. Kempthorne*, 503 F. Supp. 2d at 343 (D.D.C. 2007) (informal guidelines). But even though the documents were "informal" in the sense that they were not subject to notice and comment rulemaking procedures, they contained the elements the *Crowley* court described: express statements of generally applicable policy and explanations for the reasons behind the policies. *OGS Bulk Ships, Inc.*, 132 F.3d at 811; *Center for Auto Safety*, 342 F. Supp. 2d at 6–8, 13; *Chiang*, 503 F. Supp. 2d at 347, 351–52. Thus, the courts were able to determine in those cases whether the agencies' policies were in accordance with Congressional intent, and those cases are distinguishable from the situation here.

Finally, *Crowley* noted that it might be necessary to recognize an exception to the presumption of non-reviewability for statements of enforcement policy because an announcement of a broad policy against enforcement poses special risks that the agency has

consciously and expressly adopted a general policy that is "so extreme as to amount to an abdication of its statutory responsibilities." *Crowley*, 37 F.3d at 677, *citing Chaney*, 470 U.S. at 833 n.4. Plaintiffs argue that is exactly what happened in this case:

> FDA has abdicated its duty under 21 U.S.C. § 360cc(a) not to subvert the grant of orphan drug exclusivity that Congress intended parties in plaintiffs' position to have . . . and its duty under . . . 21 U.S.C. § 393(a) to "(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; (2) with respect to such products, protect the public health by ensuring that . . . (B) human . . . drugs are safe and effective . . . ."

Pls.' Opp. at 22 (internal quotation marks omitted).

But this argument has both legal and factual flaws that can be derived even from the factual allegations in the complaint. FDA's March Statement does not "consciously and expressly" indicate that it will *never* bring enforcement actions against unlawful compounders, or that it will never bring enforcement actions against unlawful compounders of 17P. Moreover, the cases where courts find agency policy to be so extreme as to amount to an abdication of governmental responsibility have been civil rights cases. *See, e.g.*, *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973); *Young v. Pierce*, 544 F. Supp. 1010 (E.D. Tex. 1982). And the fact that those opinions preceded *Chaney* suggests that they provide little precedential value here.[14]

In *Adams*, the D.C. Circuit held that by continuing to give federal funding to segregated public schools, appellants – the Secretary of Health, Education, and Welfare ("HEW"); and the Director of HEW's Office of Civil Rights – had abdicated their duty to enforce Title VI of the Civil Rights Act of 1964. 480 F.2d at 1161–63. At the time of the *Adams* decision, as still

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14 Citing *Adams*, Justice Rehnquist's opinion in *Chaney* noted that "[w]e do not have in this case . . . a situation where it could justifiably be found that the agency has 'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities," but stated, "we express no opinion on whether such decisions would be unreviewable under § 701(a)(2)." *Chaney*, 470 U.S. at 833 n.4.

today, Title VI provided that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." *Id.* at 1161 n.1. The statute "directed" all federal agencies with the authority to provide federal funding to effectuate that provision by either terminating or refusing to grant assistance to programs engaging in discriminatory conduct or by any other means authorized by law. *Id.* at 1162–63. HEW had continued to provide federal funds to schools without regard to whether they engaged in racial segregation. *Id.* at 1162. The Court emphasized that HEW was not simply neglecting certain schools while carrying out a "generally effective enforcement program," but rather, that it was funding all schools as matter of general policy. *Id.* at 1162. This, it found, constituted a complete abdication of its statutory duty. *Id.* The Supreme Court in *Adams* also found that the express language of Title VI not only required the agency to enforce the Act, but also set out two alternative means of enforcement that the agency was bound to use. *Id.* at 1162–63. By failing to adhere to one of these alternative means of enforcement, the Court found, HEW was derelict in its duty to enforce the Act. *Id.*

The defendants in *Adams* argued that the enforcement of Title VI was committed to agency discretion, and was therefore not reviewable by the courts. *Id.* at 1161. But here, plaintiffs challenge only FDA's decision with respect to compounded 17P; they do not allege that FDA is refusing to enforce the FDCA's compounding provisions across the board "as a matter of general policy. Moreover, *Adams* did not implicate the concerns that would be raised by telling an agency how to allocate its valuable enforcement resources; the case involved the government's continuing grant of federal funds to segregated institutions. *Id.* at 1161–62. Most importantly, the Court found that Title VI expressly required the agency to enforce its provisions

and set forth specific enforcement procedures. *Id.* at 1162. This aligns with the Supreme Court's later decision in *Chaney* and is distinguishable from instant situation because those provisions are absent from the FDCA. Therefore, this case involving one company's competitive advantage does not in any way resemble the extreme abdication of statutory responsibility to enforce fundamental rights that the Supreme Court confronted in *Adams*. *See also Young*, 544 F. Supp. at 1013–17 (finding, based in part on *Adams*, that the court could review a class action claim that HUD had abdicated its duty under several statutes to eliminate financial participation by the federal government in illegal racial discrimination by refusing to decline federal funding to local housing authorities that engage in racially discriminatory housing practices).

Accordingly, the Court finds that the March Statement is a presumptively unreviewable exercise of FDA's enforcement discretion, and not a reviewable statement of policy.

C. Even if the March Statement constitutes a reviewable enforcement policy, it has been superseded.

Even if the Court were to assume that the March Statement constitutes a universally applicable statement that FDA would, as a matter of policy, stay its hand and exercise enforcement discretion with respect to the entire class of non-customized compounded products that contain 17P, that policy has been superseded by FDA's June Statement, along with the Questions and Answers document. The June Statement states: "FDA emphasizes that it is applying its normal enforcement policies for compounded drugs to compounded hydroxyprogesterone caproate." June Statement. It goes on to explain that compounding should not exceed the scope of traditional pharmacy compounding and that the agency prioritizes enforcement actions using a risk-based approach. *Id.* And if there was any lingering confusion, the Questions and Answers document clears it up. It answers the question, "Does that mean that

the FDA does not intend to take enforcement action against the compounders of hydroxyprogesterone caproate?" with a definitive "no." Questions and Answers.

Plaintiffs argue that those two documents did not alter the agency's previously announced policy of non-enforcement because they did not expressly commit the agency to taking enforcement action. Compl. ¶ 94.[15] To prove that point, plaintiffs point to the fact that the FDA has not brought any enforcement actions against illegal compounders of 17P. *See* Pls' Opp. at 4-6; Tr. at 44 (Attorney for plaintiffs: "But they're not enforcing it. Words without actions don't do anything."). This argument simply serves to demonstrate the basic deficiency in the complaint: the fact that plaintiffs are challenging an FDA decision (or series of decisions) not to initiate enforcement action, rather than its stated policy on whether and how the statute should be enforced.[16]

III. Plaintiffs fail to state a claim under Count IV.

Count IV of the complaint alleges that FDA is permitting the foreign-manufactured active pharmaceutical ingredient for compounded 17P to be imported into the United States in violation of section 381(a) of the FDCA. Compl. ¶123.

The FDCA requires 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 Health and Human Services, 21 U.S.C. §§ 321(d), 360(i)(1)(A),

15 This represents something of a reversal for plaintiffs, who advanced the position in another lawsuit that FDA has become increasingly more direct in its public communications concerning its enforcement priorities, and that it left "no room for doubt" that it considered bulk compounding to be unlawful. Compl. and Appl. for Prelim. Inj., *K-V Pharma. Co. v. Cook,* Case 1:12-cv-2491, at ¶¶ 5, 47 (July 17, 2012 N.D. Ga).

16 The Court notes that plaintiffs' complaint contains no claim that FDA has failed to act in accordance with the "normal enforcement policies" FDA claims in its June Statement to be applying with regard to illegal compounders of 17P.

and provide the Secretary with a list of all its imported drugs and devices, *id.* §§ 360(i)(2), 360(j). Under Section 381(a), the Secretary of the Treasury "shall deliver to the Secretary of Health and Human Services, upon his request," samples of the product being imported or offered for import into the United States. *Id.* § 381(a). In addition, the Secretary of Health and Human Services "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.*[17] "If it appears from the examination of such samples or otherwise that . . . such article is adulterated, misbranded, or in violation of section 355 of this title . . . then such article shall be refused admission," with limited exceptions. *Id.*[18]

Count IV alleges that the foreign-manufactured API for compounded 17P "appears to be – and, indeed, is – an unapproved new drug and, when imported or offered for import into the United States, appears to be – and, indeed, is – in violation of Section 355." Compl. ¶ 121. It asserts that FDA is in violation of section 381(a) because "[s]ince March 30, 2011 and continuing to the present, Defendants have been, and are, allowing the import of such API for compounded 17P." *Id.* ¶ 123.

FDA submits that an alleged failure to enforce the rules against the importation of unlawful substances is presumptively unreviewable, and plaintiffs do not contest that

17 The complaint does not specify whether the API for 17P that FDA is allegedly permitting to enter into the United States is coming from registered or unregistered foreign facilities.

18 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." 21 U.S.C. § 381(a).

proposition. Pls.' Opp. at 33 n.34 ("[p]laintiffs do not dispute that . . . FDA's decision as to a particular article offered for import, like its decision as to enforcement against a particular company in a particular factual setting, is within FDA's enforcement discretion."). But the complaint does not allege the existence of a policy, and even if one concludes that section 381(a) imposes a mandatory, and not a discretionary, obligation, the complaint fails to state a claim upon which relief could be granted.

A. The complaint does not allege the existence of a reviewable policy.

At the outset, the Court notes that plaintiffs do not point to any reviewable FDA statement of policy that explicitly or implicitly permits unlawful imports, and the complaint contains no non-conclusory allegation that such a policy exists. To the extent plaintiffs are arguing that the language in the complaint asserting that "[s]ince March 30, 2011, and continuing to the present, Defendants have been, and are, allowing the import of [the] API for compounded 17P," reasonably leads to the inference that FDA has a policy, the Court finds that this vague statement is insufficient to support such an inference under *Twombly* and *Iqbal*. *Iqbal*, 556 U.S. at 678 (A pleading must offer more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action."), quoting *Twombly*, 550 U.S. at 555; *see* Compl. ¶¶ 121–23. Furthermore, although the complaint asserts that the March Statement "announc[es] implicitly that they would allow such imports," Compl. ¶ 124, the March Statement does not even mention the import of components of compounded 17P. The only subjects of the statement are the "pharmacies that compound" 17P. March Statement; *see O'Gilvie v. Corp. for Nat'l Cmty. Serv.*,

802 F. Supp. 2d 77, 82 (D.D.C. 2011) (conclusory allegations "need not be treated as true, and . . . are insufficient to defeat [a] motion to dismiss.").[19]

B. Even if the complaint contained sufficient factual allegations to support the existence of a reviewable policy, it does not allege that the policy violates section 381(a).

Moreover, even if the Court were to accept the conclusory assertions in the complaint as supporting the existence of a reviewable policy, Count IV fails to state a claim under section 381(a) because the complaint does not allege that the policy is illegal.

Plaintiffs maintain that the section 381(a) "mandates the universal exclusion of foreign drugs that are in violation of Section 355, whether the factories that manufactured them are registered or not," and they cite *Beaty v. FDA*, -- F. Supp. 2d --, Civ. Case No. 11-289(RJL), 2012 WL 1021048 (D.D.C. Mar. 27, 2012), in support of that contention. Pls.' Opp. at 31. In *Beaty*, another court in this district examined the language of section 381(a) to determine whether it satisfied the *Chaney* requirements. *Id.* at *1. In that case, a foreign wholesaler of a drug began exporting the drug to state departments of corrections within the United States for use in lethal injections. *Id.* at *2. The company had neither registered with the FDA nor listed its drug product with the FDA. *Id*. FDA detained one shipment of the drug on the ground that it was misbranded, yet proceeded to release the shipment into the United States anyway. *Id.* It

19 The Court also struggles to find any "final agency action" to review here. Only "final agency actions" are reviewable under the APA. *See Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1278 (D.C. Cir. 2005). For an action to be "final," it must "mark the consummation of the agency's decisionmaking process," and "be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). In the D.C. Circuit, the second requirement is met if an action "imposes an obligation, denies a right or fixes some legal relationship." *Home Builders*, 417 F.3d at 1278 (internal citation and quotation marks omitted). Plaintiffs have not identified any action that imposes any obligation, denies any right, or fixes any legal relationship. They do not allege that FDA engaged in some decisionmaking process which led to the decision to allow imports of the API for 17P. And they have not pointed to any particular shipment or shipments of the API that FDA permitted into the United States.

detained another shipment shortly after on the basis that the drug was an "unapproved new drug," yet after receiving correspondence from a state department of corrections indicating that the drug was necessary for use in lethal injections, it released the shipments into the United States. *Id.* In total, FDA released seven shipments into the United States. *Id.* The amended complaint in that case alleged that FDA had acted contrary to law, in an arbitrary and capricious manner, and in abuse of its discretion when it allowed shipments of the misbranded and unapproved new drug to be imported into the United States, and sought a permanent injunction prohibiting the FDA from releasing future shipments into interstate commerce. *Id.* at *3. FDA argued that the release of the drug was an act of "enforcement discretion." *Id.*

In analyzing section 381(a) under the *Chaney* test, the court first focused on the word "shall": "if it appears from the examination of such samples," or otherwise, that the article is misbranded, "then such article *shall* be refused admission," *id.* at *1, citing 21 U.S.C. § 381(a) (emphasis added). The court found that Congress's use of the word "shall" revealed sufficient intent to circumscribe agency enforcement discretion. *Id.* at *5–6. Furthermore, it found that "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.* at *8. Accordingly, the court found that "[h]aving 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." *Id.* at *7.

Here, "plaintiffs are not seeking review of any particular FDA decision as to an article offered for import." Pls.' Opp. at 33 n.34. Indeed, they concede – apparently in direct conflict with *Beaty* – that "FDA's decision as to a particular article offered for import, like its decision as

to enforcement against a particular company in a particular factual setting is within FDA's enforcement discretion." *Id.* Rather, they argue that in accordance with *Beaty*, section 381(a) requires FDA to deny admission to a drug offered for import that appears to be in violation of section 355. *See* Pls.' Mot. for TRO/PI at 35–36. And they assert that FDA has neglected that duty by failing to reject shipments of "unapproved 17P API not shown to be destined for lawful use." Pls.' Opp. at 31–32.

But the problem is that the complaint simply assumes that *every* shipment of the ingredient for 17P appears to violate section 355. Yet the complaint itself establishes that 17P can be compounded lawfully under certain circumstances, Compl. ¶ 46, and plaintiffs concede that the API can therefore be lawfully imported in certain circumstances, Tr. at 34:18–22 (Counsel for plaintiffs: "if it appears from the description of the shipment that what it is is active pharmaceutical ingredient from an unapproved source *and it's not for personal importation*, then it appears to be in violation of Section 355") (emphasis added); *id.* 53:6–20 (conceding that there are a group of patients using compounded 17P legally and that these 17P compounds are lawful). In cases where the substance is being imported for lawful customized compounding, it would be exempt from section 355. Pls.' Opp. at 32.

According to FDA, "it is usually not possible to evaluate *at the border* whether the pharmacy that eventually receives the foreign-manufactured API will compound it [lawfully]," which would render the API exempt from section 355 and permissible for import.[20] Defs.' Mem. at 28. And plaintiffs agree that API that will be used for lawful compounding is exactly the same

20 Plaintiffs attempt to get around this ambiguity by arguing that there are methods FDA could use at the border to determine whether a particular sample of API is intended for use in lawful or unlawful compounds. Pls.' Opp. at 32. But this does not cure the problem that the complaint fails to sufficiently allege that any shipment of API for 17P "appeared" to violate section 355 at the time of import.

substance as API that will be used for unlawful compounding. Pls.' Opp. at 32. So, while the complaint alleges that shipments of the API for compounded 17P have entered and are continuing to enter the United States, and that FDA is permitting their entry, the complaint is devoid of the factual allegations needed to support the conclusory assertion in Count IV that the shipments contain a substance that "appears" to violate section 355. Thus, it fails to state a claim that FDA ever violated section 381(a).

C. This case is not controlled by *Adams*.

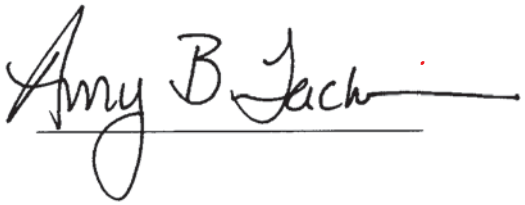
To the extent plaintiffs once again point the Court to the Supreme Court's pre-*Chaney* decision in *Adams* and argue that an agency's dereliction of duty is reviewable, the Court finds that *Adams* does not apply here.

First, as stated above, the Court finds that plaintiffs' complaint fails to assert that FDA has neglected any statutory duty, so *Adams* is inapplicable. Moreover, as with plaintiffs' allegations in Counts I through III, the allegations in Count IV that FDA has permitted illegal substances to enter the country concern only a small subset of violators in the course of a generally effective program. *Cf. Adams*, 480 F.2d at 1162. The complaint does not allege that FDA has failed to enforce a particular import restriction in the FDCA altogether. It merely alleges that FDA has permitted the import of one particular unlawful compound. This does not amount to the sort of abdication of a statutory duty that troubled the Supreme Court in *Adams.*

Accordingly, plaintiffs' allegations under Count IV are insufficient to state a claim under Federal Rule of Civil Procedure 12(b)(6).

CONCLUSION

Because the claims in Counts I through III of plaintiffs' complaint are unreviewable and Count IV fails to state a claim under Federal Rule of Civil Procedure 12(b)(6), defendants' motion to dismiss will be granted. A separate order will issue.



AMY BERMAN JACKSON
United States District Judge

DATE: September 6, 2012