UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WELLNESS PHARMACY, INC., *et al.*, Plaintiffs, v. **XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES,**[1] ***et al.***, Defendants.	Case No. 20-cv-3082 (CRC)

MEMORANDUM OPINION

Evoking Victorian apothecary scales and porcelain mortars and pestles, compounded drugs are formulated by pharmacists to create medicines tailored for individual patients. Federal law generally exempts these extemporaneous mixtures from the vast regulatory framework that governs the development and introduction of new drugs, leaving most regulation to the States. Congress has, however, authorized the Food and Drug Administration to exercise its enforcement powers over pharmacies that engage in the interstate distribution of compounded drugs under circumstances that might indicate large-scale drug manufacturing under the guise of compounding. For over twenty years, pharmacies that specialize in compounding and their industry representatives have jousted with FDA over where and how to draw the line between legitimate compounding and disguised new-drug distribution. This case presents the latest skirmish in this decades-old fight.

[1] Secretary Becerra is automatically substituted for former Secretary Alex Azar. See Fed. R. Civ. P. 25(d).

The plaintiffs here are seven compounding pharmacies located throughout the country. They challenge the recent finalization of a standard Memorandum of Understanding that Congress required FDA to develop in 1997 when it passed Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Final Standard MOU establishes an agreement between individual state pharmacy boards and FDA. The agreement requires States to identify and report information on pharmacies within the State that distribute "inordinate amounts" of compounded drugs interstate, as defined by the MOU. Pharmacies within signatory States may compound drugs exempt from the FDCA's otherwise applicable new-drug laws. Meanwhile, pharmacies located in States that do *not* sign the MOU must comply with a provision of Section 503A known as the five-percent limit, which removes the new-drug exemption for pharmacies that distribute compounded drugs interstate in quantities that exceed five percent of their total prescription orders.

The Final Standard MOU has been years in the making. FDA did not finalize the present MOU until October 2020. In the meantime, the agency exercised its discretion not to enforce the five-percent limit, the violation of which could otherwise subject compounding pharmacies to civil and criminal penalties. FDA recently announced that it intends to extend its forbearance until October 2022. Thus, States have another year to decide whether to sign the Final Standard MOU before their pharmacies will be subject to the five-percent limit and its attendant sanctions.

On the same day that FDA noticed the Final Standard MOU, plaintiffs initiated this lawsuit and moved for partial summary judgment. The complaint advances three counts—two allege procedural violations in FDA's development of the MOU and the third alleges that FDA exceeded its statutory authority under Section 503A in defining several key statutory terms. In the procedural counts, plaintiffs allege that FDA violated Section 503A by not developing the

Final Standard MOU through regulations and that it violated the Regulatory Flexibility Act by failing to conduct an analysis of the MOU's impact on small pharmacies. In the remaining count, plaintiffs contend that FDA exceeded its statutory authority by defining "distribution" in the MOU to include instances of compounding drugs pursuant to a prescription. Defendants cross-moved for summary judgment, arguing that plaintiffs lack standing to bring this lawsuit and that their claims otherwise fail on the merits.

The Court concludes that plaintiffs have standing and that the Final Standard MOU is a legislative rule and thus subject to the Regulatory Flexibility Act's procedural requirements. It will, accordingly, grant plaintiffs' motion for summary judgment and remand the MOU to the agency to either certify that it will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis. See 5 U.S.C. §§ 603, 604, 605.

I. Background

A. Regulatory Background

1. Statutory framework

FDA strictly regulates the development and introduction of new drugs through an extensive series of laws contained in the FDCA. For instance, each new drug's manufacturer or sponsor must seek FDA approval for the drug via an application that describes how the drug was manufactured, lists all of the drug's ingredients, and contains "full reports of investigations" into the drug's safety and effectiveness for each intended use. 21 U.S.C. § 355(a), (b). Once approved, a new drug is subject to a comprehensive set of current good manufacturing practices—known as "cGMPs"—that govern everything from the drug's ingredients to the quality of its manufacturing facility. See id. §§ 351(a)(2)(B), 355(e). Additionally, all approved

drugs are subject to FDA labeling requirements, which mandate (among other things) that they be labeled with adequate instructions for safe use. See id. § 352(f)(1).

This case involves the application (or lack thereof) of these laws to compounded drugs. "Drug compounding" refers to "the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." Thompson v. W. States Med. Ctr., 535 U.S. 357, 360–61 (2002). For example, a pharmacist may compound a drug for a patient who would otherwise be allergic to an ingredient in his or her medication. Though a compounded drug qualifies as a "new drug" under the FDCA, see 21 U.S.C. § 321(p), FDA has historically left regulation of compounded drugs to the States, Thompson, 535 U.S. at 362. Over time, however, FDA grew concerned that some pharmacies were compounding drugs at levels that rendered the pharmacies akin to drug manufacturers. Id.

Acting on this concern, in 1992, FDA issued a Compliance Policy Guide ("CPG") clarifying that "FDA may, in the exercise of its enforcement discretion, initiate enforcement actions against" compounding pharmacies "when the scope and nature of a pharmacy's activity raises the kinds of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the Act." Def. Cross-Mot. for Summ. J., ECF No. 36 (hereinafter, "Def. MSJ"), Ex. A (1992 CPG), at 195. The CPG set forth various factors that the agency would consider when evaluating whether to initiate such an enforcement action. Id. The relevant factors included the frequency with which the pharmacy was compounding copies of FDA-approved drugs, the pharmacy's use of commercial-scale manufacturing equipment, and the pharmacy's interstate distribution of an inordinate level of compounded drugs. Id. At the same time, FDA "recogniz[ed] that pharmacists traditionally have extemporaneously compounded . . . reasonable quantities of drugs upon receipt of a valid

prescription" and noted that "[t]his traditional activity [was] not the subject of th[e] CPG." Id. at 193.

Five years later, the 1992 CPG was effectively codified within the FDCA via the Food and Drug Administration Modernization Act. See Pub. L. No. 105-115, 111 Stat. 2296 (1997) ("FDAMA"). Most importantly for present purposes, the FDAMA added Section 503A to the FDCA. See 21 U.S.C. § 353a ("Section 503A"). Section 503A sets forth certain conditions that must be satisfied for compounded drugs to be exempt from the vast regulatory framework that would otherwise govern new drugs. The section begins by providing a general exemption for drugs that are "compounded for an identified individual patient based on the receipt of a valid prescription or a notation[.]" Id. § 353a(a). The statute then imposes *additional* requirements for such compounded drugs that are distributed interstate. Specifically, a drug may be compounded pursuant to Section 503A's general exemption *only if* it falls into one of two categories:

> (B) such drug product is compounded in a State—
>
> (i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

Id. § 353a(b)(3)(B). The Court will follow the parties' lead in referring to § 353a(b)(3)(B)(ii) as "the five-percent limit."

After setting out these two categories, subsection (b)(3) provides that "[t]he Secretary shall, in consultation with the National Association of Boards of Pharmacy ["NABP"], develop a

memorandum of understanding for use by the States in complying with subparagraph 353a(b)(3)(B)(i)." Id. Immediately thereafter, § 353a(c)(1), which is entitled "regulations" and subtitled "in general," instructs the Secretary to "issue regulations to implement this section." Id.

2. Development of a standard MOU

Section 503A was to take effect in November 1998. See FDAMA, 111 Stat. 2296. That month, FDA announced that it was developing proposed rules to implement the section. See Unified Agenda of Federal Regulatory and Deregulatory Actions, 63 Fed. Reg. 61,680, 61,707, 61,709–10 (Nov. 9, 1998) ("Fall 1998 Regulatory Agenda"). In particular, FDA said that it was developing proposed regulations "for the interpretation and enforcement of section 503A," which would "delineate the conditions under which compounding is exempt from the manufacturing, misbranding, and new drug provisions of the [FDCA]" and "set forth other definitions and conditions for distinguishing legitimate pharmacy compounding from pharmaceutical drug manufacturing performed under the guise of compounding." Id. at 61,709.

Two months later, FDA noticed its first draft MOU. See Administrative Record ("A.R.") 000001–2 (Federal Register Notice); id. at 000003–19 ("1999 draft MOU").[2] As part of the 1999 draft, the State agency agreed to "take action" regarding "any pharmacy or physician that "distribute[d] inordinate amounts of compounded drugs interstate." Id. at 000014. The draft defined inordinate amount of distribution as occurring when "[t]he number of compounded prescriptions dispensed or distributed interstate" constituted twenty percent or more of the "total number of prescriptions dispensed or distributed (including both intrastate and interstate) by such pharmacy or physician[.]" Id. The 1999 draft MOU excluded from this twenty-percent

[2] Although the draft MOU is dated December 23, 1998, the FDA noticed availability of the draft in January 1999. The Court will therefore refer to this draft as the "1999 draft MOU."

threshold instances of "local" interstate distribution, which FDA defined as sending a compounded drug to an out-of-state patient within fifty miles of the pharmacy. Id. at 000015. FDA announced that it would give States "at least 90 days after the standard MOU is finalized and made available to the States for their consideration and signature" before enforcing the five-percent limit against pharmacies. Id. at 000002. FDA noticed the draft in the Federal Register, and it received over 6,000 comments. Id. at 000030-028485.

Meanwhile, lawsuits across the country began calling Section 503A's validity into doubt. See, e.g., W. States Med. Ctr. v. Shalala, 238 F.3d 1090, 1092-93 (9th Cir. 2001), aff'd sub nom. Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002). In May 2002, the Supreme Court declared that Section 503A's advertising restrictions were unconstitutional but declined to decide whether those provisions were severable from the remainder of the statute. See Thompson, 535 U.S. at 366. Shortly thereafter, FDA announced that it was no longer developing proposed regulations to implement Section 503A, see 67 Fed. Reg. 33,040, 33,045 (May 13, 2002), and that the agency viewed the Supreme Court's decision in Thompson as invalidating Section 503A in its entirety, see Pharmacy Compounding Compliance Policy Guide; Availability, 67 Fed. Reg. 39,409, 39,410 (June 7, 2002).

Ten years later, a nationwide outbreak in fungal meningitis was traced to a contaminated compounded drug produced by a facility in Massachusetts. See Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013). The following year, Congress enacted the Drug Quality and Security Act, which, among other things, severed the unconstitutional advertising provisions from Section 503A but left the statute otherwise intact. See id.

With its statutory mandate thus revived, FDA turned back to drafting Section 503A's standard MOU. In 2015, the agency released a second draft, see A.R. 028760–67 ("2015 draft

MOU"); id. at 028752–759 (Federal Register Notice), which differed from the 1999 version in several respects. For starters, it raised the level of distribution that qualified a pharmacy as an inordinate distributor of compounded drugs from twenty to thirty percent of the pharmacy's total prescriptions. Id. at 028763. And in place of a carveout for local interstate distribution, the 2015 draft excluded from this threshold any instances in which a patient picked up a compounded drug in person and then took the drug out of state. Id. Like its predecessor, the 2015 draft MOU was noticed in the Federal Register, and FDA announced that it would not enforce the five-percent limit until States had time to evaluate and sign a finalized MOU. Id. at 028753. The agency also noted that it was "considering whether to propose regulations or issue guidance documents to further its implementation of [S]ection 503A(b)(3)(B)[.]" Id. at 028754 n.2. The 2015 draft MOU received over 3,000 comments. Id. at 028768–30838.

In September 2018, FDA noticed another substantially revised draft MOU. Id. at 030849–857 ("2018 draft MOU"); id. at 030839–848 (Federal Register Notice). The 2018 draft MOU required State agencies only to collect and report information on pharmacies that they identified as distributing inordinate amounts of compounded drugs interstate, id. at 030851–53, whereas prior drafts had required the State to take action against those pharmacies, id. at 000014 (1999 draft MOU); id. at 028762–63 (2015 draft MOU). Through this revision, FDA effectively changed the "inordinate amount" percentage from a *limit* on pharmacies' interstate compounding to a *threshold* that triggered information-gathering and reporting obligations on behalf of the States. Additionally, the 2018 draft increased the threshold for inordinate distribution from thirty percent to fifty percent of a pharmacy's total *compounding* orders (rather than total prescription

orders, compounded or otherwise). Id. at 030851–52.[3] In other words, a pharmacy met the 2018 MOU's threshold when over half of its compounded drugs were shipped out of state. Like its predecessors, the 2018 draft MOU was noticed in the Federal Register and accompanied by an extension of FDA's enforcement discretion of the five-percent limit. Id. at 030839–48. It received approximately forty comments. Id. at 031061–031226.

The following year, FDA sought applications for a three-year pilot project aimed at establishing an information management system for use by State pharmacy regulators, compounders, and FDA. See id. at 031631–50. FDA awarded the grant to NABP in October 2019. See id. at 031651. The pilot project remains ongoing.

3. Final Standard MOU

On October 27, 2020, FDA noticed the Final Standard MOU in the Federal Register. See id. at 031438–446 (Federal Register Notice); id. at 031447–459 (Final Standard MOU). As the Final Standard MOU is at the center of this litigation, the Court will describe it in some detail.

The MOU begins by declaring its purpose:

> This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the [insert State Board of Pharmacy or the appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a)[.]

[3] FDA explained that this change responded to comments to the 2015 draft, which noted that the prior calculation disfavored "specialty compounding pharmacies that engage in interstate distribution and only distribute compounded drug products[.]" Id. at 030843.

Id. at 031447 (internal footnotes omitted). It continues with a "background" section, which summarizes the statutory provisions governing compounded drugs. See id. at 031447–48. In particular, the MOU notes that Section 503A(b)(3) of the FDCA "directs FDA to develop a standard MOU in consultation with the National Association of Boards of Pharmacy" and declares that "[t]his MOU is the standard MOU developed by FDA for this purpose." Id. at 031448.

The MOU then details the substance of agreement. See id. at 031448–55. Relevant here, it declares that a pharmacy has distributed an inordinate amount of compounded drugs interstate when:

> the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:
>
> (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus
>
> (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

Id. at 031450–51; see also id. at 031452 (Figure 1). In other words, a pharmacy meets the "inordinate amounts" threshold when over half of its annual compounded drug orders are distributed interstate. On an annual basis, States that sign the MOU are required to identify pharmacies that meet this threshold through "surveys, reviews of records during inspections, data

submitted to an Information Sharing Network, or other mechanisms available to the [State]." Id. at 031452.[4]

For each pharmacy that exceeds the 50-percent threshold, States are further required to gather and report four categories of information: (1) "the total number of prescription orders for sterile compounded human drugs distributed interstate;" (2) "the names of States in which the pharmacy is licensed;" (3) "the names of States into which the pharmacy distributed compounded human drug products;" and (4) "whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients." Id. at 031452. The MOU instructs States to gather this information "using data submitted to an Information Sharing Network or other available mechanisms." Id.

B. Procedural Background

Plaintiffs are seven compounding pharmacies located in Alabama, Wisconsin, Colorado, Pennsylvania, California, Utah, and New York. Compl. ¶¶ 8–14. On the same day that FDA noticed its Final Standard MOU, plaintiffs commenced this action and moved for partial summary judgment. The complaint names as defendants the Secretary of Health and Human Services, the Commissioner of Food and Drugs, and FDA. Id. ¶¶ 15–17. In Count I, plaintiffs allege that FDA's issuance of the Final Standard MOU violates Section 503A's "shall issue regulations" command and should therefore be set aside as agency action undertaken "without observance of procedure required by law" under 5 U.S.C. § 706(2)(D). Compl. ¶¶ 87–92. In

[4] As described above, the MOU is an agreement with the "State Board of Pharmacy or other appropriate State agency." A.R. 031447. For ease of reference, the Court refers to this entity as the State.

Count II, plaintiffs maintain that FDA failed to conduct an analysis of the Final Standard MOU's impact on small entities as required by the Regulatory Flexibility Act. Compl. ¶¶ 93–97 (citing 5 U.S.C. § 604(a)).[5] And in Count III, they contend that FDA exceeded its statutory authority by defining "distribution of compounded human drug products interstate" and "inordinate amounts" to include interstate "dispensing," which plaintiffs understand to mean compounding drugs pursuant to a prescription.[6] Id. ¶¶ 98–101.

Plaintiffs moved for summary judgment on all three counts in their Complaint on February 10, 2021. See Mot. for Summ. J., ECF No. 26 (hereinafter, "Pl. MSJ"). A compounding industry group and a collection of other compounding pharmacies followed with amicus briefs in support of plaintiffs. See Amicus Br. by Alliance for Pharm. Compounding, *et al.*, ECF No. 39; Amicus Br. by Infuserve America, Inc., *et al*., ECF No. 41. Defendants then cross-moved for summary judgment on March 3, 2021. See Def. MSJ. Not to be outdone, a coalition of manufacturers of FDA-approved drugs filed an amicus brief in support of defendants. See Amicus Br. of the Campaign for Responsible Compounding, ECF No. 43. After

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[5] In addition to an allegation under the RFA, Count II alleges that "[t]he Final Standard MOU is a substantive rule for which prior notice-and-comment rulemaking was required by 5 U.S.C. § 553." Compl. ¶ 95. However, plaintiffs declined to brief this argument and abandoned it at oral argument. Oral Arg. Tr. 19:11–15 (explaining that plaintiffs' "position is that FDA did consider 30,000 comments, and that if [they] brought a notice and comment challenge, it could have been subject to a harmless error [analysis]. And, therefore, [plaintiffs] brought the procedural claims that have actually injured us[.]").

[6] This case involves several semantic disputes, one of which is worth noting at the outset. The term "dispensing," in plaintiffs' view, refers to the provision of compounded drugs pursuant to a prescription. Compl. ¶ 2; see also, e.g., Oral Arg. Tr. 09:22–10:01. Defendants, meanwhile, understand "dispensing" to encompass providing a compounded drug to a patient *in person*, regardless of whether that drug was compounded pursuant to a prescription. See, e.g., A.R. 031443–44; id. at 031450; Oral Arg. Tr. 58:24–59:19. The intended meaning of the term thus varies in the record depending on which party is using it.

briefing on the cross-motions had concluded, Colorado, in which plaintiff Belmar Pharmacy is located, executed a Final Standard MOU with FDA.

The Court heard oral argument on the cross-motions on July 14, 2021. Following the hearing, plaintiffs moved to file a supplemental declaration in support of their theory of standing. See Mot. for Leave to File Supp. Decl., ECF No. 54. Defendants' opposed the motion. See Mem. in Opp. to Mot. for Leave to File Supp. Decl., ECF No. 57. All the motions are ripe for the Court's resolution.

II. Standard of Review

When evaluating cross-motions for summary judgment under the Administrative Procedure Act ("APA"), "the Rule 56 standard does not apply." Alfa Int'l Seafood v. Ross, 264 F. Supp. 3d 23, 36 (D.D.C. 2017). The court instead "sits as an appellate tribunal" and "[t]he entire case on review is a question of law." Id. (quoting Am. Biosci., Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). The APA provides that a court must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), in excess of statutory authority, id. § 706(2)(C), or "without observance of procedure required by law," id. § 706(2)(D). Within this "narrow" standard of review, "a court is not to substitute its judgment for that of the agency," Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983), and "will defer to the [agency's] interpretation of what [a statute] requires so long as it is rational and supported by the record," Oceana, Inc., v. Locke, 670 F.3d 1238, 1240 (D.C. Cir. 2011) (cleaned up).

III. Analysis

FDA first argues that the Court lacks subject matter jurisdiction over this case because plaintiffs failed to establish standing and their claims are not ripe. It next contends that plaintiffs fail on the merits because FDA complied with Section 503A and was not subject to the Regulatory Flexibility Act when developing the MOU. Finally, FDA maintains that the final standard MOU constitutes a reasonable interpretation of Section 503A that should be upheld under Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

The Court first assures itself of its jurisdiction and then turns to the merits.

A. Jurisdiction

FDA argues that the Court should dismiss this action because plaintiffs lack standing and their claims are not ripe. The Court takes these arguments in turn.

1. Standing

Article III extends federal jurisdiction to cases and controversies. U.S. Const. art. III, § 2. "For a legal dispute to qualify as a genuine case or controversy, at least one plaintiff must have standing to sue." Dep't of Com. v. New York, 139 S. Ct. 2551, 2565 (2019). Standing is a claim-specific inquiry. Competitive Enter. Inst. v. F.C.C., 970 F.3d 372, 382 (D.C. Cir. 2020). At the same time, the Court need not conclude that each individual plaintiff has standing where, as is the case here, all plaintiffs "raise the same issues." Grocery Mfrs. Ass'n v. E.P.A., 693 F.3d 169, 175 (D.C. Cir. 2012). If one plaintiff has standing, then the Court has "established [its] jurisdiction to consider the merits" of plaintiffs' claims. Id.; see also R. Labor Execs. Ass'n v. United States, 987 F.2d 806, 810 (D.C. Cir. 1993) ("[I]f one party has standing in an action, a court need not reach the issue of standing of other parties when it makes no difference to the merits of the case.").

To have Article III standing, a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 578 U.S. 330, 136 S. Ct. 1540, 1547 (2016). The first two elements—injury in fact and traceability—are at issue here. As plaintiffs have alleged the same theories of injury for all three claims, the Court first evaluates whether these injuries satisfy the injury-in-fact element of Article III and then turns to whether they are fairly traceable to each claim.

a. Injury in fact

"To establish injury in fact, a plaintiff must show that he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." Id. at 1548 (cleaned up). While the imminence and redressability elements of standing are relaxed for procedural-rights plaintiffs, the injury-in-fact and causation requirements are not. Ctr. for L. & Educ. v. Dep't of Educ., 396 F.3d 1152, 1157 (D.C. Cir. 2005).

A plaintiff can establish standing based on future injures if they "satisfy either the certainly impending' test or the 'substantial risk' test." New Jersey v. Env't Prot. Agency, 989 F.3d 1038, 1047 (D.C. Cir. 2021) (quoting Attias v. Carefirst, Inc., 865 F.3d 620, 626–27 (D.C. Cir. 2017)). Plaintiffs advance two theories of injury here: (1) should their States sign the Final Standard MOU, plaintiffs claim that they will incur compliance costs as a result of the MOU's information-gathering and reporting requirements; and (2) should their States *not* sign the MOU, plaintiffs maintain that compliance with Section 503A's five-percent limit will force them to curtail business or close their pharmacies.

Starting with compliance costs for pharmacies in MOU states, plaintiffs argue that they will have to expend time and money gathering and reporting information because of two sets of conditions imposed by the Final Standard MOU. *First*, on an annual basis, the State must "identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available . . . pharmacies that distribute inordinate amounts" of compounded drugs interstate. A.R. 031452. This requirement extends to all pharmacies located in MOU States—not only those that are otherwise flagged as inordinate distributors of compounded drugs. *Second*, for those pharmacies that the State identifies as "distributing inordinate amounts" of compounded drugs interstate, the State must "identify, using data submitted to an Information Sharing Network or other available mechanisms during that same calendar year[,]" additional information and then report that information to FDA. Id. Specifically, the State must collect and report: (1) "the total number of prescription orders for sterile compounded human drugs distributed interstate;" (2) "the names of States in which the pharmacy is licensed;" (3) "the names of States into which the pharmacy distributed compounded human drug products;" and (4) "whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients." Id.

Defendants rejoin that that compliance costs associated with these requirements are too speculative to count as injuries-in-fact. See Def. MSJ at 18–19; Def. Reply Mem., ECF No. 48, at 6–8. They argue that it is not yet known which States will sign the MOU and that pharmacies in MOU States might not incur any costs given that the MOU obligates the *States* (rather than the *pharmacies*) to collect and report the relevant information. Def. MSJ at 18. The Court is not persuaded. As explained below, plaintiffs have established a substantial risk that some of their

States will choose to sign the MOU and pass on its information-gathering burdens to them. Plaintiffs' compliance-cost theory of injury therefore qualifies as an Article III injury in fact.

FDA has indicated that it expects all but five States to sign the MOU. See Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, 85 Fed. Reg. 28,961, 28,962 (May 14, 2020). Indeed, Colorado executed an MOU on June 29, 2021, effective immediately. See Notice of Subsequent Event, ECF No. 51. The president and CEO of plaintiff Belmar Pharmacy, which is located in Colorado, has submitted a declaration attesting that "[t]he data-sharing requirements that would likely be imposed upon us by the Colorado State Board of Pharmacy as a result of the Final Standard MOU would result in greater compliance costs." Hill Decl. ¶ 7. Mr. Hill further avers that "the assessment, compilation, reporting, and error-correction obligations would absolutely require the hiring of an additional full-time pharmacist." Id. ¶ 8. In fact, *every* pharmacy in this case submitted a declaration attesting to its expectation that the individual pharmacies (rather than the States) would be responsible for complying with the reporting requirements of the MOU. See Besteman Decl. ¶¶ 7–9 (attesting that pharmacy will have to hire a new employee to undertake the data-gathering and reporting processes required by the MOU if plaintiff's State chooses to sign); Bray Decl. ¶¶ 7–9 (same); Harbin Decl. ¶¶ 7–10 (same); Stuart Decl. ¶¶ 6–8 (same); Patel Decl. ¶¶ 7–11; Mansour-Awad Decl. ¶¶ 7–10 (same).

These statements are not mere speculation. Multiple declarants indicate that they were informed by officials within their respective State Boards of Pharmacy that pharmacies will be shouldering the compliance costs. See, e.g., Stuart Decl. ¶ 7 (averring that the Executive Director of the California State Board of Pharmacy indicated at a committee meeting in January 2021 "that the Board does not have the resources to collect this data itself and will pass the

burden of aggregating and reporting this burden to the pharmacies"); Harbin Decl. ¶ 7 (averring that Wellness Pharmacy's "assigned compliance officer from the Alabama Board of Pharmacy" informed Mr. Harbin that "he would require Wellness Pharmacy to provide these categories of data upon inspection" should Alabama sign the MOU); Bray Decl. ¶ 7 (averring that MedQuest Pharmacy has "been informed that responsibility for [the information-gathering and reporting] process will be imposed on us by the Utah Board of Pharmacy and [the pharmacy's] licensing agency"). These statements are corroborated by comments made by regulators in a California State Board of Pharmacy meeting. See Cal. State Bd. of Pharmacy, Recording of Enforcement Committee Meeting Webcast (Part 2) at 27:55–28:26 (Jan. 20, 2021), available at https://www.youtube.com/watch?v=oQoo6bZckug (California State Board Executive Officer stating that "we will probably be recommending at the staff level that some of these reporting obligations actually get pushed to the licensees that are actually performing the compounding" and that "the NABP as part of their deployment of the [information-sharing] system was envisioning actually the compounding pharmacies doing a lot of the reporting").

Defendants do not contest the pharmacies' averments. They merely point out that States may rely on the NABP information-sharing network, which might "further minimize any potential information collection burden on States and pharmacies." Def. MSJ at 15. But the NABP information-sharing network is currently in a three-year pilot and, in defendants' own telling, "requires ongoing research to evaluate the system as well as a final report and assessment of the project." Id. at 9. And defendants nowhere explain *how* the NABP information-sharing network might reduce pharmacies' information-gathering and reporting obligations. Meanwhile, a "Frequently Asked Questions" of the NABP's webpage indicates that the system relies on information input by the *pharmacies* rather than the State agency. See Frequently Asked

Questions, NABP (including answers to questions such as, "Can the state solely rely on pharmacies entering information into the Information Sharing Network to identify pharmacies that distribute inordinate amounts of compounded human drug products interstate under the MOU?" and "How do compounding pharmacies submit the requested data?") available at https://nabp.pharmacy/members/compounding-pharmacy-information-sharing-project/faqs/ (last visited Sept. 20, 2021). The existence of the NABP information-sharing pilot project does not render plaintiffs' theory of injury speculative.

Moreover, plaintiffs have submitted declarations indicating that neither the pharmacies nor their regulators currently maintain information required by the Final Standard MOU in *any* format. See Mansour-Awad Decl. ¶ 8; Bray Decl. ¶ 7 ("discern[ing] and report[ing] the categories of information that are currently not required by our regulators but are required by the Final Standard MOU . . . will undoubtedly come at a sizable cost"); Besteman Decl. ¶ 7 ("we do not currently report that type of data to our regulators in the ordinary course of business"); Harbin Decl. ¶ 9 ("Adding the never-before-requested layer of information to our compliance practices would increase my reporting-compliance employee's workload by approximately four to six hours each workday."). Regardless of whether the State relies on an information-sharing network, pharmacies in MOU States will *at least* be required to start maintaining the information called for by the MOU for purposes of accurate collection and reporting. In sum, plaintiffs in States that sign the MOU have demonstrated a substantial risk that the MOU will cause them financial injuries stemming from its information collection and reporting obligations.

The Court next considers whether plaintiffs have established injury in fact based on Section 503A's five-percent limit. Again, any pharmacy located in a State that declines to sign the Final Standard MOU with FDA must abide by Section 503A's five-percent limit. See 21

U.S.C. § 353a(b)(3)(B)(ii). All plaintiffs have filed affidavits attesting that compliance with this limit would spell doom for their pharmacies. See Besteman Decl. ¶¶ 4–6 (compliance with the five-percent limit will drastically curtail if not ruin plaintiff's business); Bray Decl. ¶¶ 4–6 (same); Harbin Decl. ¶¶ 4–6 (same); Stuart Decl. ¶¶ 4–5 (same); Patel Decl. ¶¶ 4–6; Mansour-Awad Decl. ¶¶ 4–6 (same). Defendants argue that this injury, too, is overly speculative because it is unknown which States will sign the MOU. They also point out that FDA has announced its intent to extend its enforcement discretion of the five-percent limit until October 2022. See Notice of Subsequent Event, ECF No. 56. Thus, States have another year to decide whether to sign the MOU without subjecting their pharmacies to penalties associated with the five-percent limit.

For plaintiff Wellness Pharmacy in Alabama, the injuries associated with the five-percent restriction are clearly not speculative. That is because Alabama has *already* indicated that it will not sign the MOU. Wellness's president, Mr. Harbin, has attested to his understanding that "both the Alabama Board of Pharmacy . . . and [the] State's Attorney General are unconvinced that the Board has the requisite the authority to sign the Final Standard MOU." Harbin Decl. ¶ 3. The FDA's website confirms that Alabama is not participating in the MOU due to "[l]egal or [t]echnical reasons." See FDA Compounding MOU Project, NABP, available at https://nabp.pharmacy/members/compounding-pharmacy-information-sharing-project/#mou-map (last visited September 20, 2021).

Like his co-plaintiffs, Mr. Harbin anticipates that the five-percent restriction "would have a devastating effect on both the financial condition of [his] business and the wellbeing of [his] patients" because "the majority of prescriptions dispensed by Wellness Pharmacy are dispensed outside of Alabama[.]" Id. ¶ 4. Consequently, Mr. Harbin predicts that he would have to

"downsize [his] staff" or "close [his] business entirely." Id. Wellness Pharmacy has thus established an Article III injury based on Section 503A's five-percent limit.

In sum, plaintiffs fall into one of two groups. Either they will operate in a non-MOU State and face the five-percent limit and its corresponding economic injuries, or they will operate in an MOU-State and face the various compliance costs associated with its terms. Either injury suffices for Article III's injury-in-fact requirement.

b. Traceability

Defendants also maintain that the plaintiffs' injuries are not fairly traceable to the alleged legal violations. The Court first addresses this dispute as it relates to plaintiffs' procedural claims before turning to their statutory-authority claim.

"To establish traceability in a procedural-injury case, an adequate causal chain must contain at least two links: (1) a connection between the omitted procedure and a government decision and (2) a connection between the government decision and the plaintiff's particularized injury." Hawkins v. Haaland, 991 F.3d 216, 224 (D.C. Cir. 2021) (cleaned up). "The first link does not require the plaintiff to show that but for the alleged procedural deficiency the agency would have reached a different substantive result." WildEarth Guardians v. Jewell, 738 F.3d 298, 306 (D.C. Cir. 2013). All that is necessary is "some sort of connection between the procedural requirement at issue and the substantive action of the agency[.]" City of Waukesha v. E.P.A., 320 F.3d 228, 234–35 (D.C. Cir. 2003) (citing Fla. Audubon Soc. v. Bentsen, 94 F.3d 658, 668 (D.C. Cir. 1996)).

Count One of the complaint alleges that the Final Standard MOU imposes costly information-gathering and reporting obligations on the individual pharmacies. The substantive action (the Final Standard MOU) is thereby directly connected to the procedural requirement that

plaintiffs claim was omitted (the development of that MOU through regulations). Count Two alleges that FDA was required to conduct an analysis of the Final Standard MOU under the Regulatory Flexibility Act. Among other things, a Regulatory Flexibility Act analysis "must include an explanation for the rejection of alternatives designed to minimize significant economic impact on small entities[.]" U.S. Telecom Ass'n v. F.C.C., 400 F.3d 29, 42 (D.C. Cir. 2005). Plaintiffs aver that compliance with the terms of the Final Standard MOU will require hiring a new employee, which they say is a sizable burden for their pharmacies, considering that some are comprised of only twenty to thirty employees. See Mansour-Awad Decl. ¶ 2; Stuart Decl. ¶ 2. Plaintiffs' allegation under the Regulatory Flexibility Act is thus connected to the financial injuries stemming from compliance with the Final Standard MOU.

Defendants contend that the causal chain is broken by the independent decision-making of the States, given that FDA "ultimately has no control over any given State's decision to sign (and if so, how that State intends to carry out its agreed upon information and collection sharing)." Def. MSJ at 20. Not so. When a plaintiff's theory of standing depends on third-party decisions, it is her burden "to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury." Lujan v. Defs. of Wildlife, 504 U.S. 555, 562 (1992). "[M]ere 'unadorned speculation'" does not suffice. Am. Freedom L. Ctr. v. Obama, 821 F.3d 44, 49 (D.C. Cir. 2016) (quoting Nat'l Wrestling Coaches Ass'n v. Dep't of Educ., 366 F.3d 930, 938 (D.C. Cir. 2004)). Instead, the plaintiff must establish the third-party's conduct by a "substantial likelihood[.]" Competitive Enter. Inst., 970 F.3d at 384 (cleaned up). Courts may "consider a variety of evidence" when evaluating whether plaintiffs have carried this burden, "including the agency's own factfinding, affidavits submitted

by the parties, evidence in the administrative record," and "arguments firmly rooted in the basic laws of economics[.]" Id. at 382 (cleaned up).

As described above in the context of injury in fact, plaintiffs have submitted extensive evidence that States will sign the MOU and then pass along its information-gathering and reporting obligations to the pharmacies. Indeed, Colorado, in which plaintiff Belmar Pharmacy is located, has already signed the MOU. Additionally, all plaintiffs have submitted declarations attesting to their conviction that they will be required to undertake information-gathering and reporting obligations. See Bestman Decl. ¶¶ 7–9; Bray Decl. ¶¶ 7–9; Harbin Decl. ¶¶ 7–10; Stuart Decl. ¶¶ 6–8; Patel Decl. ¶¶ 7–11; Hill Decl. ¶¶ 7–11; Mansour-Awad Decl. ¶¶ 7–10. Certain declarants claim to have been told as much by their State Boards of Pharmacy, see Stuart Decl. ¶ 7; Harbin Decl. ¶ 7; Bray Decl. ¶ 7, and others have averred that they will shoulder a cost *regardless* of the State's implementation procedure because they simply lack the requisite information in their current practice, see Mansour-Awad Decl. ¶ 8; Bray Decl. ¶ 7; Stuart Decl. ¶ 7; Besteman Decl. ¶ 7; Harbin Decl. ¶¶ 7, 9. Taken together, this evidence carries plaintiffs' burden to prove that the States are substantially likely to pass along compliance costs imposed by the Final Standard MOU.

As to Count III, plaintiffs argue that FDA exceeded its statutory authority "by defining 'distribution of compounded human drug products interstate' and 'inordinate amounts' to include interstate dispensing of compounded human drug products." Compl. ¶ 100. (Again, plaintiffs construe "dispensing" to mean sending compound drugs to a customer pursuant to a prescription.) FDA's definitional choice, plaintiffs contend, will subject them to the five-percent limit and its attendant economic harms. By contrast, plaintiffs' preferred reading of the statute—that the FDA may regulate only the distribution of compound drugs without a prescription—

would not trigger the five-percent limit. The Court takes no position on the merits of plaintiffs' argument. But, assuming *arguendo* that they are correct, their alleged theory of injury stemming from the five-percent limit is directly traceable to the allegation lodged in Count III.

Defendants counter that the five-percent limit is statutory, so any injury caused by that restriction is attributable to Congress rather than FDA. Def. MSJ at 2, 19–20; see 21 U.S.C. § 353a(b)(3)(B)(ii) (five-percent limit). The Court disagrees. In developing the MOU, FDA defined "[d]istribution of compounded human drug products interstate'' to encompass any instance in which the "pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded." A.R. 031443. Again, plaintiffs contend that *dispensing*—in the sense of sending out compounded drugs pursuant to a prescription—should be excluded from the meaning of *distribution*. FDA explicitly rejected that interpretation in the notice accompanying the Final Standard MOU. It explained:

> We received a number of comments on the 2015 draft standard MOU and the 2018 revised draft standard MOU stating that distributing and dispensing are mutually exclusive activities, such that if a drug product is distributed, it is not also dispensed, and vice versa. Some comments asserted, in particular, that a compounded drug product should not be considered to be "distributed" when it is provided pursuant to a prescription . . . . After considering these comments and the public health objectives of section 503A(b)(3)(B) of the FD&C Act, FDA considers that when a drug is picked up at the facility in which it was compounded, dispensing, but not distribution, occurs *for purposes of 503A(b)(3)(B).*

A.R. 031443–44 (emphasis added). Later on, FDA again rejected plaintiffs' distinction between dispensing and distribution by reference to how Congress identified those terms in Section 503A(b)(3)(B):

> Section 503A(b)(3)(B) of the FD&C Act does not define "distribution" to exclude dispensing . . . . Indeed, with respect to comments suggesting that drugs dispensed pursuant to prescriptions could not also be "distributed," we note that, in section 503A(b)(3)(B), Congress specifically contemplated that prescription orders could

> be 'distributed' when it directed the Agency to count the number of prescription orders that pharmacists and prescribers distributed.

Id. at 031444. At oral argument, defendants represented that they were unsure how FDA might interpret distribution for purposes of the five-percent restriction. See Oral Arg. Tr. at 42:23–43:02. But FDA has specifically declared that "Section 503A(b)(3)(B) of the FD&C Act," which contains the five-percent limit, "*does not define 'distribution' to exclude dispensing*." A.R. 031444. Meanwhile, the agency has nowhere indicated that it may interpret the terms otherwise.

For this reason, plaintiffs' declarations are consistent in stating that they will be injured by the five-percent limit "*as calculated by the FDA*." Harbin Decl. ¶ 4 (emphasis added); see also Bestman Decl. ¶ 5 ("[t]he 5-percent limit . . . *as that limit is calculated by FDA*, would have a grave impact on our overall business") (emphasis added); Bray Decl. ¶ 4 ("the effect on my business and our patients would be catastrophic if subjected to the 5-percent limit . . . *as that limit is calculated by FDA*") (emphasis added); Stuart Decl. ¶ 4 ("[t]he impact of the 5-percent limit . . . *as that limit is calculated by FDA*, would have dire consequences for our business") (emphasis added); Patel Decl. ¶ 5 ("[i]f subjected to the 5-percent limit . . . *as calculated by FDA*," plaintiff's "pharmacy will experience what is certain to be a precipitous decrease in revenue") (emphasis added); Hill Decl. ¶ 4 ("there is not a shred of doubt" that "the 5-percent limit . . . *as that limit is calculated by FDA*" would require plaintiff's pharmacy "to close its doors"); Mansour-Awad Decl. ¶ 5 ("the 5-percent limit . . . *as that limit is calculated by FDA*" will require "shutter[ing] the business . . . or drastically downsiz[ing]") (emphasis added).

Mr. Harbin of Wellness Pharmacy in Alabama, which has indicated that it will not sign the Final Standard MOU, explains that Wellness Pharmacy "does not send compounded drug products to patients without first receiving a patient-specific prescription, which is the act of

dispensing." Supp. Harbin Decl. at ¶ 2, ECF No. 54-1.[7] Therefore, his pharmacy would be in compliance with the five-percent restriction should FDA adopt plaintiffs' view that "distribution" is the act of sending out compounded drugs *without* a prescription. Id. That is so because Wellness Pharmacy *never* sends out compounded drugs without a prescription, which, again, plaintiffs' view as the only activity governed by the five-percent restriction. Id. Injuries associated with the five-percent restriction thus result from FDA's *interpretation* of the five-percent restriction in the MOU rather than the statutory restriction itself. Consequently, those injuries are attributable to the agency rather than Congress.

2. Ripeness

FDA also contends that plaintiffs' claims are not prudentially ripe. When evaluating whether a case is prudentially ripe, courts consider two factors: (1) "the fitness of the issues for judicial decision," and (2) "the hardship to the parties of withholding court consideration."

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[7] At oral argument, the Court asked plaintiffs' counsel whether they would be compliant with the five-percent restriction notwithstanding the Final Standard MOU. Oral Arg. Tr. 13:5–8. Counsel answered in the affirmative, explaining that "it's in the complaint . . . that they dispense pursuant to a patient-specific prescription. So notwithstanding [the MOU] definitions, . . . which include dispensing in the definition of 'distribution,' they would be compliant[.]" Id. at 13:9–14. Three days later, plaintiffs moved to file Mr. Harbin's supplemental declaration, which reiterates the point. Defendants oppose the motion, arguing that it is untimely without good cause. See Def. Opp. to Pl. Mot. for Leave to File Supp. Decl., ECF No. 55, at 2. The Court will consider the declaration. Plaintiffs may submit evidence after filing their opening briefs where "the parties reasonably, but mistakenly, believed that the initial filings before the court had sufficiently demonstrated standing[.]" Twin Rivers Paper Co. LLC v. Sec. & Exch. Comm'n, 934 F.3d 607, 614 (D.C. Cir. 2019) (cleaned up). As described above, every plaintiff in this case submitted a declaration averring that its injuries stemming from the five-percent restriction are dependent on FDA's interpretation of that provision. Likewise, plaintiffs' declarations and complaint allege that each pharmacy *dispenses* compounded drugs out of state pursuant to a prescription. Compl. ¶¶ 8–14. It was reasonable for plaintiffs to believe that they had sufficiently demonstrated that injuries associated with the five-percent restriction are traceable to FDA's interpretation of that provision. The Supplemental Harbin Declaration merely clarifies this point in response to the Court's questioning at oral argument.

Conservation Force, Inc. v. Jewell, 733 F.3d 1200, 1206 (D.C. Cir. 2013) (quoting Abbott Labs. v. Gardner, 387 U.S. 136,149 (1967)). The "basic rationale" for the prudential ripeness doctrine is "is to prevent the courts . . . from entangling themselves in abstract disagreements over administrative policies, and also to protect agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs., 387 U.S. at 148–49. "[T]here is also a 'usually unspoken' underlying rationale relating to the doctrine of mootness: a claim may be unripe where 'if we do not decide [the claim] now, we may never need to.'" Alcoa Power Generating Inc. v. F.E.R.C., 643 F.3d 963, 967 (D.C. Cir. 2011) (quoting Devia v. Nuclear Regul. Comm'n, 492 F.3d 421, 424 (D.C. Cir. 2007)) (second alteration in original).

a. Fitness

An issue's "fitness" for judicial resolution "depends on whether it is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." Devia, 492 F.3d at 424 (internal quotation marks omitted).

Again, plaintiffs bring three claims—one count alleging that FDA was statutorily required to develop the MOU through regulations, see Compl. ¶¶ 87–92, one count alleging that FDA failed to conduct an RFA analysis under 5 U.S.C. § 604(a), Compl. ¶¶ 93–98, and one count that FDA exceeded its statutory authority under Section 503A, Compl. ¶¶ 98–101. The first two counts are purely procedural challenges that require no further factual development for resolution. Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs, 417 F.3d 1272, 1281, 1286 (D.C. Cir. 2005) ("Home Builders I") (claim that rule violated RFA's procedural requirements was ripe "at the time the alleged failure occurred, *i.e.*, when the [agency] issued the [rule] without complying with those procedures") see also Gen. Elec. Co. v. E.P.A., 290 F.3d

377, 380 (D.C. Cir. 2002) (claim that document was a legislative rule improperly issued without notice-and-comment was "largely a legal, not a factual, question, turning as it does in this case primarily upon the text of the [d]ocument"). Plaintiffs' claim that FDA exceeded its statutory authority in developing the MOU likewise satisfies the fitness prong. Home Builders I, 417 F.3d at 1281–82 (claim that agency "exceeded its statutory authority in drafting" permits under the Clean Water Act "easily satisfie[d]" the fitness prong of ripeness).

Defendants nonetheless contend that this case is not ripe because "[i]t is not yet known" which States "will sign the Final Standard MOU." Def. MSJ at 13. This argument is unpersuasive. As discussed in the injury-in-fact context, plaintiff Belmar Pharmacy is *already* subject to the terms of the MOU because it is located in Colorado, which has executed a Final Standard MOU. See Notice of Subsequent Event, ECF No. 51; see also MOU 225-21-014 (July 2, 2021, available at https://www.fda.gov/about-fda/compounding-mous/mou-225-21-014. On the other side of the coin, plaintiff Wellness Pharmacy is located in Alabama, which FDA has indicated will *not* sign the Final Standard MOU for "legal or technical" reasons. See NABP, MOU Participation, available at https://nabp.pharmacy/members/compounding-pharmacy-information-sharing-project/ (last visited Sept. 20, 2021). So, while the complete roster of MOU- and non-MOU states has yet to materialize, these developments have fixed the legal consequences of the MOU for at least some plaintiffs.

Regardless, the fitness prong is concerned with whether judicial "consideration of the issue would *benefit* from a more concrete setting[.]" Devia, 492 F.3d at 424 (emphasis added). Though defendants have pointed out some degree of factual uncertainty, they have not identified any reason to delay judicial review until that uncertainty disappears completely. The Circuit rejected a similar ripeness argument in Home Builders I, where the plaintiffs challenged the

conditions contained in general permits developed for certain development projects by the Army Corps of Engineers. 417 F.3d at 1281. The Corps argued that the claims were unripe because plaintiffs had not yet applied an individual permit, which, if approved, would render them unaffected by the conditions in the general permits. Id. at 1282. The Circuit disagreed because "[n]o further factual development [was] necessary to evaluate the [plaintiffs'] challenge." Id. So too here.

b. Hardship

Given the Court's conclusion that plaintiffs' challenges are fit for judicial review, it need not consider the hardship prong of the ripeness inquiry. See Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1310 (D.C. Cir. 2010); see also Nat'l Ass'n of Home Builders v. U.S. Army Corps of Engineers, 440 F.3d 459, 465 (D.C. Cir. 2006) (where "there are no significant agency or judicial interests militating in favor of delay, lack of hardship cannot tip the balance against judicial review") (cleaned up). The Court nonetheless concludes that plaintiffs have demonstrated that hardship would result from delayed judicial consideration. The focus of the hardship prong is "not whether the parties have suffered any direct hardship, but rather whether *postponing* judicial review would impose an undue burden on them or would benefit the court." Vill. of Bensenville v. F.A.A., 376 F.3d 1114, 1120 (D.C. Cir. 2004). Defendants contend that this case would not be ripe until after the deadline has passed for States to sign the MOU, or (later still) until some point *after* States have ironed out the implementation of the MOU's terms. The Court disagrees.

Delaying judicial consideration until either point would put plaintiffs in an untenable position. In non-signatory States, a delay would force plaintiffs to either shutter their businesses, see Harbin Decl. ¶ 5, or risk civil and criminal penalties by flouting applicable laws, see 21

U.S.C. § 331(a) (prohibiting the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded"); id. at § 333(a) ("Any person who violates a provision of section 301 [of the FDCA, 21 U.S.C. § 331] shall be imprisoned for not more than one year or fined not more than $1,000, or both."). "To use the Supreme Court's words, we 'normally do not require plaintiffs to bet the farm' by violating the law in order to challenge the constitutionality of the regulating agency." State Nat'l Bank of Big Spring v. Lew, 795 F.3d 48, 54 (D.C. Cir. 2015) (quoting Free Enter. Fund v. Public Co. Acct. Oversight Bd., 561 U.S. 477, 490 (2010)). Meanwhile, pharmacies located in signatory States (such as Belmar Pharmacy in Colorado) would be forced to continue expending resources on the MOU's information-gathering and reporting requirements until other States determine whether they will sign and, if so, the manner in which they will comply with the MOU's terms. Plaintiffs have thus satisfied the hardship prong of ripeness.

B. Merits

Having assured itself of its jurisdiction to hear this case, the Court turns to the merits of plaintiffs' allegations. In the first two counts, plaintiffs allege that FDA failed to promulgate the MOU by regulations as required by Section 503A and failed to conduct an analysis of the MOU's impact on small entities as required by the Regulatory Flexibility Act. Compl. ¶¶ 87–92 (Count I), ¶¶ 93–97 (Count II). And in Count III, plaintiffs contend that FDA exceeded its statutory authority by defining "distribution of compounded human drug products interstate" and "inordinate amounts" to include sending compounded drugs interstate pursuant to a prescription. Id. ¶¶ 98–101. Because the Court concludes that the MOU is subject to the Regulatory Flexibility Act, it will remand the rule to the agency without deciding the remaining counts.

The Regulatory Flexibility Act requires an agency issuing a final rule to either conduct "an analysis of the rule's impact on small businesses," Nat'l Tel. Co-op. Ass'n v. F.C.C., 563 F.3d 536, 538 (D.C. Cir. 2009), or to "certify" that there will be "no impact for those small businesses that are subject to the regulation," Cement Kiln Recycling Coal. v. E.P.A., 255 F.3d 855, 869 (D.C. Cir. 2001) (internal quotation marks omitted). See 5 U.S.C. § 605. Defendants do not dispute that plaintiffs qualify as small businesses under the Act and that they are "subject to" the MOU under § 605(b).

Nor do defendants contend that they conducted a regulatory flexibility analysis or certified an analysis to be unnecessary. Instead, defendants pin their hopes on the contention that the MOU is an interpretive rule and is therefore not subject to the requirements of the Act. See Nat'l Ass'n for Home Care v. Shalala, 135 F. Supp. 2d 161, 164 (D.D.C. 2001) ("[I]nterpretive rules, because they are exempted from the APA's notice and comment procedures, are exempted from the RFA's strictures as well."). Plaintiffs counter that the MOU falls within the Regulatory Flexibility Act's compass because it is a legislative rule. Plaintiffs have the better of this dispute.

"The line between interpretive and legislative rules is fuzzy and enshrouded in considerable smog." Nat. Res. Def. Council v. Wheeler, 955 F.3d 68, 83 (D.C. Cir. 2020) (internal quotation marks omitted). That said, "a basic taxonomy" emerges from the D.C. Circuit's decisions on the divide. Id. On one hand, "[a] legislative rule is one that has legal effect or, alternately, one that an agency promulgates with the intent to exercise its delegated legislative power by speaking with the force of law." Id. (cleaned up). On the other hand, "[a]n interpretive rule . . . derives a proposition from an existing document, such as a statute, regulation, or judicial decision, whose meaning compels or logically justifies the proposition." Id. (cleaned up). Whereas legislative rules "effect a substantive change in existing law or

policy," interpretive rules "clarify a statutory or regulatory term, remind parties of existing statutory or regulatory duties, or merely track preexisting requirements and explain something the statute or regulation already required." Mendoza v. Perez, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (cleaned up).

The Final Standard MOU falls on the legislative side of the line. By defining key statutory terms in Section 503A that have binding legal consequences, FDA has evinced its intent to speak with the force of law in the MOU. For starters, the MOU defines "distribution" to incorporate the act of sending compounded drug products interstate pursuant to a prescription. See A.R. 031450–51. This same term is used in § 353a(b)(3)(B)(ii), which, in non-MOU States, limits pharmacies' compounded drug "distribut[ion]" to five-percent of their "total prescription orders dispensed or distributed[.]" Determining what activity counts as "distribut[ion]" for purposes of calculating this five-percent threshold matters, because violation of that restriction carries civil and criminal penalties. See 21 U.S.C. §§ 303, 331(a), 333(a); see also A.R. 028750, (guidance document advising that any pharmacy that compounds in violation of Section 503A may be subject to criminal prosecution).

The declarations submitted in this case illustrate the legal consequences created by the MOU. Take plaintiff Wellness Pharmacy. It has been operating a compounding business for fifty-seven years in Alabama, which has indicated that it will not sign the Final Standard MOU. Harbin Decl. ¶¶ 2–3. Under plaintiffs' view of "distribution"—which *only* encompasses instances in which a compounded drug has been sent out *without* a prescription—Wellness Pharmacy would be compliant with Section 503A *regardless* of whether Alabama signs because it *exclusively* sends out drugs pursuant to prescriptions. See Supp. Harbin Decl. ¶ 2. Under FDA's interpretation, however, all compounding orders that Wellness Pharmacy ships out of

state will be counted towards the five-percent restriction under § 353a(b)(3)(B)(ii). Because out-of-state prescription orders constitute the majority Wellness Pharmacy's business, Harbin Decl. ¶ 4, the pharmacy would quickly find itself in violation of § 353a(b)(3)(B)(ii) and subject to its corresponding penalties.

Resisting the conclusion that the Final Standard MOU carries legal consequences, defendants urge the Court to instead treat the MOU as an interpretive rule. In doing so, they insist that the MOU "does not impose any penalties or define any violations of the law," Def. Reply at 16 n.7, that by its terms it "does not create or confer any rights," A.R. 031448, and that its defined terms are limited to the "purposes of th[e] MOU," id. at 031456.[8] This argument is unavailing. As discussed in the context of standing, FDA explained its interpretation of "distribution" versus "dispensing" as follows:

> FDA considers that when a drug is picked up at the facility in which it was compounded, dispensing, but not distribution, occurs *for purposes of 503A(b)(3)(B)* . . . . FDA is not persuaded by comments urging the Agency to interpret "distribution" and "dispensing" to be entirely separate activities *for purposes of section 503A(b)(3)(B) of the FD&C Act*. These comments . . . generally conclude that distribution does not include the transfer of a drug pursuant to a prescription.

A.R. 031443–44 (emphases added). In other words, FDA explicitly rejected plaintiffs' interpretation of distribution, *not only* for the MOU *but also* "*for purposes of [§] 503A(b)(3)(B)*."

[8] As FDA concedes, an MOU (at least in the abstract) cannot be "neatly categorized" within the APA's taxonomy of interpretive rules, legislative rules, and policy statements. See Oral Arg. Tr. at 41:06-07. The case law bears this out. Contrast W. Virginia Mining and Reclamation Ass'n v. Snyder, No. 91–0123–W(S), 1991 WL 331482 (N.D. W. Va. 1991) (MOU was a legislative rule) with Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Vilsack, 6 F.4th 983, 991 n.8 (9th Cir. 2021) (MOU was not a legislative rule); Reynolds Metals Co. v. Rumsfeld, 564 F.2d 663 (4th Cir. 1977) (same); and Defs. Of Wildlife v. Tuggle, 607 F. Supp. 2d 1096 (D. Ariz. 2018) (same). Accordingly, Courts must look to the substance of an MOU, rather than its label, when categorizing it as either an interpretive or legislative rule.

A.R. 031444 (emphasis added). Section 503A(b)(3)(B), importantly, contains the five-percent limit. See 21 U.S.C. § 353a(b)(3)(B)(ii).

Regardless, the MOU's definition of an inordinate amount of interstate distribution necessarily extends beyond the four corners of the agreement. That is so because that language is precisely what defines the scope of FDA's authority to develop a standard MOU in the first instance. Section 503A instructs the Secretary to develop an MOU that "addresses *the distribution of inordinate amounts of compounded drug products interstate*." 21 U.S.C. § 353a(b)(3)(B)(i) (emphasis added). In the MOU, FDA has thus simultaneously defined the phrase for the purposes of *both* the MOU *and* delineating its authority to develop that MOU under Section 503A. And by developing the MOU, FDA has implemented its authority under § 353a(b)(3)(B)(i) to entitle certain pharmacies to distribute compounded drugs exempt from the FDCA's new drug laws. Legislative rules "are those that grant rights, impose obligations, or produce other significant effects on private interests." Home Builders I, 417 F.3d at 1285. The Final Standard MOU does precisely that.

This point is underscored by defendants' position that the five-percent restriction is enforceable under § 353a(b)(3)(B)(ii) regardless of whether a Final Standard MOU exists under § 353a(b)(3)(B)(i). Oral Arg. Tr. 42:4–9. In defendants' telling, compounding drugs in excess of § 353a(b)(3)(B)(ii)'s five-percent limit was necessarily illegal for *all* pharmacies from 1997 through the issuance of the Final Standard MOU in October 2020. Through the Final Standard MOU, FDA has exercised its authority under Section 503A to entitle certain pharmacies to lawfully exceed this limit for the first time in over two decades. Far from having clarified a pre-existing rule or policy, the Final Standard MOU has thereby "effect[ed] a substantive change in

existing law or policy[.]" POET Biorefining, LLC v. Env't Prot. Agency, 970 F.3d 392, 407 (D.C. Cir. 2020).

To be sure, "even a consequential, conduct-altering rule remains interpretive so long as it can fairly be viewed as interpreting—even incorrectly—a statute or regulation." Id. at 408. An agency thus performs an interpretative function when it has "derive[d] a proposition from an existing document whose meaning compels or logically justifies the proposition." Mendoza, 754 F.3d at 1021 (cleaned up). By contrast, "[a]n agency performs a legislative function when it makes reasonable but arbitrary (not in the 'arbitrary or capricious' sense) rules that are consistent with the statute or regulation under which the rules are promulgated but not derived from it, because they represent an arbitrary choice among methods of implementation." Cath. Health Initiatives v. Sebelius, 617 F.3d 490, 495 (D.C. Cir. 2010). The Final Standard MOU rests in the latter camp.

Tellingly, defendants have not argued that Section 503A compels or logically justifies the MOU and its interpretation of "distribute" and "inordinate amounts." Any such argument would fail. Most importantly, the MOU reduces the phrase "inordinate amounts" to a numeric 50-percent threshold. "When agencies base rules on arbitrary choices they are legislating," and "[a] rule that turns on a number is likely to be arbitrary in this sense." Cath. Health Initiatives, 617 F.3d at 495 (quoting Hoctor v. U.S. Dep't of Agric., 82 F.3d 165, 171 (7th Cir. 1996)). Section 503A nowhere suggests that inordinate amounts of interstate distribution means anything greater than 50 percent. While this figure may well be *consistent* with the statutory language, it is nonetheless an arbitrary choice. Nor does Section 503A compel FDA's present interpretation of what instances of compounding should be counted towards that 50-percent figure.

The realm of potential options available to FDA is perhaps best illustrated by the various MOUs that the agency has proposed over the years. In 1999, the initial draft of the MOU concluded that a pharmacy distributed an inordinate amount of compounded drugs interstate when the number of compounded drugs dispensed or distributed interstate constituted 20 percent of the pharmacy's dispensed or distributed drugs. A.R. 000014. However, "local" interstate distribution, in which a compounded drug was given to an out-of-state patient located within fifty miles of the pharmacy, was excluded from that 20-percent figure. Id. at 000015.

Sixteen years later, FDA raised this threshold to 30 percent and removed the carve-out for "local" distribution, having determined that "special calculations to address interstate distribution between contiguous States or over short distances [were] not needed." Id. at 028755. Instead, the 2015 draft MOU excluded instances in which patients picked up compounded drugs in person and subsequently carried them interstate. Id. Three years later, FDA changed course again, increasing the threshold from 30 percent to 50 percent of the pharmacy's total compounded (but not non-compounded) drug orders. Id. at 030851.

Finally, in the present draft, FDA settled on the following definition: a pharmacy has distributed an inordinate amount of compounded drugs interstate when the number of compounded drugs distributed interstate is greater than 50 percent of the total number of compounded drug orders sent out of the pharmacy *plus* the total number of compounded drugs "dispensed (e.g., picked up by a patient) at the facility[.]" Id. at 031450-51. In other words, FDA has concluded that a pharmacy is an inordinate interstate distributor of compounded drugs if over half of the pharmacy's total compounding business is interstate. Additionally, FDA determined that—unlike prior draft MOUs—the threshold for inordinate distribution should be

based on the pharmacy's annual rather than monthly business in order to account for any "significant monthly fluctuations[.]" Id. at 031443.

The Final Standard MOU constitutes one choice among many available to FDA when implementing Section 503A. Its ultimate decision has significant binding legal consequences for plaintiffs and pharmacies across the country, and it signals a substantive change in the current legal regime governing interstate compounding.[9] The Final Standard MOU is therefore a legislative rule. As a result, FDA was required to comply with the Regulatory Flexibility Act before issuing it. It did not. The Court, accordingly, will remand the MOU to FDA to either prepare a regulatory flexibility analysis, 5 U.S.C. §§ 603–604, or to certify that the MOU "will not . . . have a significant economic impact on a substantial number of small entities," id. § 605(b). See id. § 611(A). The Court will request a progress report from the agency within sixty days.

[9] To be clear, this ruling says nothing on the merits of Count One, which claims that Section 503A required the Secretary to develop the Final Standard MOU by issuing regulations. That claim would require the Court to accept plaintiffs' argument that Section 503A's general admonition that "[t]he Secretary shall issue regulations to implement this section," 21 U.S.C. § 353a(c)(1), overrides—and is exclusive of—the statute's more specific instruction that "[t]he Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States," id. § 353a(b)(3)(B)(ii). Nor does the Court express an opinion on the statutory-authority claim presented in Count Three. Additionally, the Court's conclusion that the Final Standard MOU constitutes a legislative rule does not require FDA to now conduct notice-and-comment rulemaking. As stated previously, plaintiffs have abandoned their notice-and-comment claim in recognition of the fact that FDA *did* in fact develop the Final Standard MOU through several rounds of notice and comment. See Oral Arg. Tr. 19:11–17 ("Our position is that FDA did consider 30,000 comments, and that if we brought a notice and comment challenge, it could have been subject to a harmless error [test]. And, therefore, we brought the procedural claims that have actually injured us[.]").

IV. Conclusion

For the foregoing reasons, the Court will grant Plaintiffs' Motion for Summary Judgment in part. A separate Order will follow.

CHRISTOPHER R. COOPER
United States District Judge

Date: September 21, 2021