IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, et al.,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:20-cv-03402-TJK

BRIEF OF THE FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Statutes

Administrative Materials

Other Authorities

INTRODUCTION AND INTEREST OF AMICUS[1]

For over twenty years, Section 804 of the Federal Food, Drug, and Cosmetic Act—Congress's authorization for the importation of drugs from Canada—has laid dormant, languishing as an untapped tool to help American consumers reduce the cost of medicine.[2] Now the Department of Health and Human Services ("HHS"), after a fulsome review process, has promulgated a Final Rule to make Congress's Section 804 vision a reality. *See* Importation of Prescription Drugs, 85 Fed. Reg. 62094 (effective Nov. 30, 2020); 21 C.F.R. § 251 *et seq.* This Court should uphold the Final Rule and dismiss Plaintiffs' Complaint.

Congress first authorized the importation of Canadian drugs to "empower pharmacists and wholesalers to purchase" medicines "in Canada and pass the discounts along to American patients" in 2000 (with the current framework enacted in 2003). *See* Importation of Prescription Drugs, 84 Fed. Reg. 70796, 70799 (proposed Dec. 23, 2019). This made for good policy because what was true in the year 2000 is even more true now: prescription drug costs in the United States have been too high for too long. And those costs continue to rise. Yet Section 804 gave HHS a tool to reverse this trend. With the Final Rule implementing Section 804, States and tribes have the ability to take lawful steps to lower drug costs. At the same time, the Final Rule takes great care to make sure adequate safeguards are in place to make certain those imported drugs are safe, as required by Section 804. By ensuring both safety and savings, the Final Rule is fully consistent with HHS's

[1] Florida Agency for Health Care Administration files this amicus brief pursuant to Local Civil Rule 7(o)(1), which provides, in relevant part, that "a state may file an amicus curiae brief without the consent of the parties or leave of Court."

[2] Section 804 is the section of the Federal Food, Drug, and Cosmetic Act that governs the importation of Canadian drugs. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1121, 117 Stat. 2066, 2464 (2003). Section 804 has been codified at 21 U.S.C. § 384. This brief will refer to Section 804, as the parties do, when discussing the general scope of Canadian drug imports, but to the codified section number, Section 384, when analyzing the text of particular provisions.

obligations under Section 804.

The Final Rule also fulfills a long-sought priority of the American people themselves. Lowering drug costs is a "top concern for the public." Meredith Freed, et al., *10 FAQs on Prescription Drug Importation*, KAISER FAMILY FOUNDATION (Oct. 8, 2020), available at https://bit.ly/390sjIY. It thus should come as no surprise that an overwhelming and bipartisan majority of Americans support a plan like the Final Rule: 78 percent of Americans overall favor allowing the purchase of drugs from our neighbor to the north, including 75 percent of Democrats, 75 percent of Republicans, and 82 percent of independents. *Id.* This policy is so popular, in part, because it is also vital. "[A]lmost one-third (29 percent) of U.S. adults have reported not taking their medicines as prescribed due to the expense, and almost 1 in 10 (8 percent) said this led to a decline in their condition." 84 Fed. Reg. at 70799 (internal quotation marks omitted). It is thus no hyperbole to say that securing Americans access to lower cost drugs can be a matter of life and death. The Final Rule will help give Americans the safe access to lower cost drugs that they need.

Amicus is the Florida Agency for Health Care Administration, the state agency tasked with administering Florida's Medicaid Program, licensing and regulating Florida's health facilities, and providing information to Floridians about the quality of their health care. Consistent with its purpose to ensure better health care for all Floridians, Amicus submitted a Section 804 Importation Proposal ("SIP") to FDA to implement Florida's Canadian Prescription Drug Importation Program under the Final Rule. Florida's SIP is initially targeted at providing safe and lower cost drugs for those Floridians who need maintenance medications for chronic health conditions such as asthma, COPD, diabetes, and HIV/AIDS. In particular, these drugs will assist Florida in meeting the needs of vulnerable populations who rely on the State for access to their drugs. Amicus thus has a compelling interest in HHS providing a lawful pathway, like the Final Rule, for the safe and cost-

effective importation of Canadian drugs.

Amicus respectfully submits that this Court should dismiss Plaintiffs' claims because their alleged injuries are too speculative to support standing. In the alternative, at the very least, this Court should dismiss Plaintiffs' claims that the Certification and Final Rule are "contrary to law" because both are fully consistent with Congress's commands.

ARGUMENT

I. Plaintiffs Do Not Have Standing.[3]

In their Complaint, Plaintiffs point to a number of alleged future harms that they argue *could* come to pass because of the Certification and the Final Rule. *See* Compl. ¶¶ 90–98, Doc.1 (Nov. 23, 2020). While Amicus vigorously contests the merits of Plaintiffs' claimed harms—*e.g.*, States like Florida are well-equipped to keep patients safe—these harms are far too speculative to meet the "the irreducible constitutional minimum" of Article III standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Accordingly, Plaintiffs' claims should be dismissed.

The doctrine of standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." *Id.* And the "[f]irst and foremost" requirement for Article III standing is that the plaintiff must establish an "injury in fact," *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 103 (1998)—that is, that they have suffered harm that is "concrete, particularized, and actual or imminent," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Where, as here, a plaintiff alleges only future harms, since those harms are not yet "actual," it thus falls to the plaintiff to demonstrate that they are "imminent." *Id.* at 411–12.

[3] Since Plaintiffs assert the prospect of as-yet indeterminate future harms, the Article III inquiries of standing and ripeness "boil down to the same question." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 n. 5 (2014). Consistent with the Supreme Court's practice, this amicus brief refers to this inquiry as "standing." *Id.*

That is not a low bar. The Supreme Court "has repeatedly reiterated that threatened injury must be certainly impending to constitute injury in fact, and that allegations of possible future injury are not sufficient." *Id.* at 409 (cleaned up). And although "imminence is concededly a somewhat elastic concept," the Court has conclusively established that an alleged injury that "relies on a highly attenuated chain of possibilities, does not satisfy the requirement that threatened injury must be certainly impending." *Id.* at 409–10 (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (rejecting a standing theory premised on a speculative chain of possibilities). For instance, in *Clapper* the Supreme Court held that the plaintiffs lacked standing to challenge recently enacted amendments to the FISA statute because any threat of surveilled communications was not certainly impending. Instead, the plaintiffs' allegations of harm depended on a "chain of contingencies" too speculative to establish an imminent injury-in-fact. *Id.*

As in *Clapper,* Plaintiffs in this case have not adequately alleged a "certainly impending" injury sufficient to establish standing to bring their claims. Plaintiffs allege that they are injured by the Final Rule in the following ways: Plaintiffs allege an increased risk to patient safety from imported drugs; Plaintiffs allege financial injury, reputational harm and litigation risks from the increased risk of counterfeit, substandard, or otherwise adulterated drugs being imported from Canada; Plaintiffs allege that the Canadian imports will require them to make substantial investments to address increased adverse events, medication errors, and consumer confusion stemming from Section 804 imports; Plaintiffs allege various intellectual property harms from the testing and labeling requirements of authorized Section 804 imports; Plaintiffs also allege that they will be deprived of their free speech rights because of the Final Rule's labeling requirements; and Plaintiffs allege that the increased competition from imported Canadian drugs will allegedly erode the earning potential of undefined patent exclusivity windows. *See* Compl. ¶¶ 91–98. But

critically, *none* of these alleged future injuries could possibly occur, if at all, *unless and until* a SIP is approved; and nearly all of the alleged harms cannot occur, if at all, until imports begin under the SIP's authority.

While Florida is committed to making lower cost Canadian drugs safely available to Floridians in as expeditious a manner as possible, the Final Rule establishes a number of required steps before Florida's or any other State's SIP will lead to the importation of lower cost drugs from Canada. Plaintiffs' alleged harms thus all rely on a chain of events that is simply too speculative.

First, FDA must conduct an in-depth review of any SIP sponsored by a State or tribe. *See* 21 C.F.R. § 251.4. Depending on whether the SIP proposal initially included a Foreign Seller, this may be "a phased review process." *Id.* During the review process, FDA may seek "additional information" from a SIP Sponsor if "FDA believes additional information would help FDA's review of a SIP proposal." *Id.* at § 251.4(c)(1). Only after this review is complete may FDA authorize a SIP. *Id.* at § 251.4. But FDA may also "deny a request for authorization" of a SIP when it "does not meet the requirements" set forth in the Final Rule. *Id.* at § 251.4(a). What is more, even "[w]hen a SIP Proposal or supplemental proposal meets the requirements of this part," the regulations provide that "FDA may nonetheless decide not to authorize the SIP Proposal." *Id.* The regulations provide a number of exemplar reasons for why FDA would deny authorization:

> FDA may decide not to authorize a SIP Proposal or supplemental proposal because of potential safety concerns with the SIP; because a Foreign Seller is not identified within 6 months of the initial submission of the SIP Proposal; because of the degree of uncertainty that the SIP Proposal or supplemental proposal would adequately ensure the protection of public health; because of . . . the relative likelihood that the SIP Proposal or supplemental proposal would not result in significant cost savings to the American consumer; because of the potential for conflicts of interest; or in order to limit the number of authorized SIPs so FDA can effectively and efficiently carry out its responsibilities . . . .

Id. In other words, FDA must exercise independent judgment in determining whether or not to

approve any particular SIP.

The Supreme Court has long "been reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment." *Clapper*, 568 U.S. at 413. But guesswork is all Plaintiffs have. It is simply too soon to tell which, if any SIPs, will be approved or in what manner they may be approved. And critically, just as in *Clapper*, FDA's SIP review is a multifaceted one, and the result of the process is far from pre-ordained. *See id.* at 414 (noting that the FISA court needed to consider multiple factors before approving surveillance). "It is just not possible for a litigant to prove in advance that" FDA will approve a SIP "[in] any particular" way. *Whitmore v. Arkansas*, 495 U.S. 149, 159–60 (1990).

The contingency of SIP approval is alone enough to defeat Plaintiffs' standing. But there are still more contingencies before most of Plaintiffs' alleged harms may arise.[4] In addition to requiring approval of the SIP as a whole, SIP Sponsors must identify and ensure the registration of Foreign Sellers. *See* 21 C.F.R. § 251.9. In fact, before any SIP can be approved "[a]ny Foreign Seller(s) designated in a SIP Proposal must be registered with FDA." *Id.* at § 251.9(a). A Foreign Seller, of course, cannot merely be any entity, but must meet a variety of specific requirements. *Id.* at § 251.2. FDA anticipates that identifying a qualified Foreign Seller may prove burdensome for SIPs. Indeed, the phased review process described above includes a built-in delay of up to six-months for the identification of a Foreign Seller. *See* 21 C.F.R. § 251.4; 85 Fed. Reg. 62099 (providing for a phased review, in particular because of concerns about finding a Foreign Seller). Thus (1) the identification of an (2) eligible Foreign Seller, who (3) adequately registers with FDA

[4] The harms allegedly stemming from the Final Rule's testing and labelling requirements could begin to occur earlier in the chain of contingencies because testing and labeling are implicated as part of the Pre-Import Request described below. The remainder of Plaintiffs' injuries could not begin to eventuate until *all* of the contingent events described in this Section occur—if ever.

is yet another set of contingencies that must occur before any of Plaintiffs' alleged harms occur.

Finally, if a SIP plan—complete with a designated, qualifying Foreign Seller—is approved, *yet another* approval process must be completed before any individual prescription drug can actually be imported under its auspices. The Final Rule provides that the importer working on behalf of a SIP Sponsor must "file[] a Pre-Import Request" for each particular "eligible prescription drug" that they seek to import. 21 C.F.R. § 251.5(a). This "Pre-Import Request" must be complete and submitted to FDA "at least 30 calendar days prior to the scheduled date of arrival or entry for consumption, whichever occurs first, of an eligible prescription drug covered under an authorized SIP." *Id.* at § 251.5(b). Crucially, the drug "may not be imported or offered for import" unless "FDA has *granted* the Pre-Import Request." *Id.* at § 251.5(a) (emphasis added).

Here too is another future contingency. And this additional approval process does not simply add another link to the "highly attenuated chain of possibilities" akin to the ones discussed above. *Clapper*, 568 U.S. at 410. Because an importer has to submit this Pre-Import Request for a *particular* eligible prescription drug, at the end of the SIP approval process and before the import approval process, the importer must decide *which* eligible prescription drugs to *actually import*. And that means that even if Plaintiffs could plausibly allege that any given Pre-Import Request would be granted, they "can only speculate as to whether *their own*" prescription drugs will *ever be the subject* of such a Request. *Id.* at 414 (emphasis in original). Mere speculation has never sufficed for Article III standing. *Summers*, 555 U.S. at 499.

The difficulties with Plaintiffs' standing allegations do not end there. Even after this "chain of contingencies," *Clapper*, 568 U.S. at 410, many of Plaintiffs' alleged injuries are only allegations about an "increased risk" of harm. *See, e.g.,* Compl. ¶ 91 ("will pose *additional risk* to the public's health and safety"); ¶ 92 ("*increased likelihood*" that imported drugs bearing

Plaintiffs' members trademarks "will be counterfeit, of substandard quality, or otherwise adulterated."); ¶ 93 ("*increases the likelihood* that Plaintiffs' members will be forced to defend themselves in products-liability litigation"); ¶¶ 97(a), (c), 98(a)–(d) (alleging "increased risk" to U.S. consumers and to U.S. drug supply chain) (emphases added).

Courts carefully scrutinize such increased risk allegations. These allegations often implicate the imminence requirement because "[w]ere all purely speculative increased risks deemed injurious, the entire requirement of actual or imminent injury would be rendered moot [as] all hypothesized, nonimminent injuries could be dressed up as increased risk of future injury." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 914 (D.C. Cir. 2015) (internal quotation marks omitted). Accordingly, finding standing based on such speculative future injuries is inconsistent with the judiciary's role under Article III. As the D.C. Circuit has explained, "disputes about future events where the possibility of harm to any given individual is remote and speculative are properly left to the policymaking Branches, not the Article III courts." *Id.* To satisfy Article III, Plaintiffs thus must allege "both (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Id.* (emphasis in original).

Plaintiffs' Complaint fails to allege the requisite "*substantial risk*" that many of these alleged "harm[s] will occur." *Clapper*, 568 U.S. at 414 n.5 (emphasis added). For example, Plaintiffs allege an "increased likelihood that drugs imported under the Final Rule" will be "counterfeit" or "adulterated." *See* Compl. ¶ 92; *see also* ¶¶ 93, 98(d), 69 (arguing that, *inter alia*, the lack of transaction history requirements "increases the risk that unscrupulous actors will smuggle counterfeit or other illegitimate drugs into the United States"). But Plaintiffs cannot establish standing by "rely[ing] on speculation about 'the unfettered choices made by independent actors not before the court' "—such as smugglers and counterfeiters. *Clapper*, 568 U.S. at 414 n.5

(quoting *Lujan*, 504 U.S. at 562). Nor for that matter can Plaintiffs point to speculative products-liability lawsuits by yet unknown plaintiffs for yet unknown injuries. *See* Compl. ¶ 93. Instead, Plaintiffs "bear the burden of pleading and proving concrete facts showing that the defendant's *actual action* has caused the substantial risk of harm." *Clapper*, 568 U.S. at 414 n.5 (emphasis added). Plaintiffs' speculative assertions do not suffice.

Even if this Court were to find that some of Plaintiffs' injuries are not unduly speculative (they are), "standing is not dispensed in gross." *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996). After all, "[i]f the right to complain of one administrative deficiency automatically conferred the right to complain of all administrative deficiencies, any citizen aggrieved in one respect could bring the whole structure" of an administrative regime "before the courts for review." *Id.* Instead, Plaintiffs must adequately allege "all the elements of standing for each provision they seek to challenge." *In re Gee*, 941 F.3d 153, 162 n.4 (5th Cir. 2019) (per curiam); *accord DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Thus, the Court can only review Plaintiffs' claims challenging specific administrative actions allegedly causing specific non-speculative injuries.

When alleged harms are "contingent in nature," the proper course of action for the judiciary is to "let[ ] the Executive Branch's decisionmaking process run its course." *Trump v. New York*, 141 S. Ct. 530, 536 (2020). In this case that means after the completion of FDA's careful and fulsome review of SIPs submitted by States like Florida. Waiting until Plaintiffs' alleged harms actually eventuate (if they ever do) "brings 'more manageable proportions' to the scope of the parties' dispute" and also ensures that courts "'do not engage in policymaking properly left to elected representatives.'" *Id.* (quoting *Lujan*, 497 U.S. at 891; *Hollingsworth v. Perry*, 570 U.S. 693, 700 (2013)).

II. HHS's Section 804 Certification Is Not "Contrary to Law."

In addition to lacking standing, Plaintiffs' claims fail on the merits. In this amicus brief, we focus on the claims (pleaded in Counts I and IV of the Complaint) that the challenged certification and Final Rule are contrary to law, under the APA, because they purportedly conflict with various aspects of the governing statutes.

Under the framework established in *Chevron, USA, Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984), the Court must assess these claims under the familiar "two-step framework": (1) asking "whether Congress has 'directly spoken to the precise question at issue,' " and (2) if the answer is no because " 'the statute is silent or ambiguous with respect to the specific issue,' . . . defer[ring] to [HHS's] interpretation of the Act as long as it is 'based on a permissible construction of the statute.' " *Sierra Club v. EPA*, 985 F.3d 1055, 1058 (D.C. Cir. 2021) (quoting *Chevron*, 467 U.S. at 842–43). Plaintiffs' claims fail at Step One of *Chevron* because they are all unambiguously foreclosed by the plain text and structure of Section 804. And they certainly cannot survive Step Two. We begin with the claim related to HHS's certification under 21 U.S.C. § 384(*l*).

Before HHS could issue the Final Rule or any other regulation to implement Section 804, Congress required that the Secretary certify:

> that the implementation of this section will—
>
> > (A) pose no additional risk to the public's health and safety; and
> >
> > (B) result in a significant reduction in the cost of covered products to the American consumer.

21 U.S.C. § 384(*l*). On September 23, 2020, then-Secretary Alex M. Azar II provided the requisite certification for "implementation of section 804(b)–(h) through the final rule Importation of Prescription Drugs." Compl. ¶ 81. Plaintiffs offer several arguments for why HHS's certification was "contrary to law." *Id.* ¶¶ 99–107. None is persuasive. We confine our discussion to two.

A. Certification of the Commercial Pathway Was Not "Contrary to Law."

First, Plaintiffs contend that it was contrary to law for HHS to certify only Section 384(b)–(h) and not also Section 384(j). Congress has provided two pathways for HHS to allow the importation of drugs from Canada: a commercial pathway and an individual pathway. These pathways are wholly distinct in the statute. In 21 U.S.C. Section 384(b)–(h), Congress set out the parameters for the *commercial* pathway for imports from Canada. This includes HHS's authority to promulgate regulations, § 384(b), certain limits on that authority, § 384(c), and a variety of statutory requirements for any commercial importation program that HHS develops, such as recordkeeping, § 384(d), testing, § 384(e), registering foreign sellers, § 384(f), suspending importers, § 384(g), and labeling the imported drugs, § 384(h).

In Section 384(j), Congress established a completely separate, *individual* import pathway. This provision "declares" Congress's enforcement priorities on violations of individual import restrictions, § 384(j)(1), and provides that HHS can allow individual importation via case-by-case waivers or via regulation, § 384(j)(1)–(3).

Despite Congress's careful separation of the commercial and individual importation pathways, Plaintiffs argue that Section 384(*l*)'s certification requirement jumbles those distinct pathways back together—forcing HHS to certify, and implement, *both* pathways at the same time *or neither of them*. Plaintiffs' argument hinges entirely on a mistaken reading of Section 384(*l*)(1)'s opening language. That clause provides, as noted above, that "[t]his section shall become effective only if the Secretary certifies to the Congress that the implementation of this section" is consistent with health and safety and would result in cost savings. Plaintiffs assert that the clause's reference to "*this section*" required HHS to certify that *every part* of Section 384—both the commercial and individual pathways—meet the requirements of Section 384(*l*), rather than only the specific

provisions governing the commercial importation pathway. The argument attempts to squeeze far too much meaning into those two statutory words.

All Section 384(*l*)(1)'s reference to "this section" means is that if HHS elects to allow importation under *either pathway* set forth in Section 384, it must make the required certifications *regarding that pathway*. The certification requirement, in other words, applies to the "section" as a whole—both subsections (b)–(h) (the commercial pathway) and subsection (j) (the individual pathway). But *nothing* in the plain text of Section 384(*l*) *further* requires HHS to certify *both* separate pathways *simultaneously*. Instead, "Congress authorized, but did not require, the agency" to certify none, one, or both pathways in its discretion. *Gonzalez v. Cuccinelli*, 985 F.3d 357, 371 (4th Cir. 2021) ("Just as Congress does not have to exercise the powers delegated to it by the people, neither does the agency have to exercise its delegated powers where the text and structure of the relevant statute provide it with complete discretion."). Viewed in isolation, the text of Section 384(*l*)(1) is thus, at most, "silent . . . with respect to the specific issue" of simultaneous certification. *Chevron*, 467 U.S. at 843.

Moreover, at Step One of *Chevron* the Court must also consult "the language and design of the statute as a whole," *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988), asking whether the statute's "structure [or] purpose" commands one particular interpretation, *Eagle Pharm., Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020). Here, the broader statutory context and design conclusively show that Section 384(*l*)(1)'s reference to "this section" *cannot* bear the meaning Plaintiffs would attribute to it.

As an initial matter, reading Section 384(*l*)(1) Plaintiffs' way would completely upend Congress's careful separation of the commercial and individual pathways. As noted above, Section 384 establishes these routes as separate and distinct. That makes considerable sense, since the two

pathways are designed to further Congress's cost-savings and safety objectives in very different ways. The individual pathway is streamlined and succinct: Section 384(j)(2)(3) simply allows the Secretary to authorize individual importation of prescription drugs, by waiver, if six simple requirements are met, including that the importation be "for personal use," pursuant to "a valid prescription" and from "a seller registered with the Secretary." The commercial pathway, by contrast, is much more detailed and complex. For that route, Section 384 sets forth, over the span of seven separate subsections, comprehensive and granular documentation, recordkeeping, testing, and labelling requirements. *See, e.g.*, 21 U.S.C. §§ 384(d)(1), (e), (h). Requiring HHS to implement *both* of these pathways *or neither of them* nullifies Congress's decision to establish them as separate and distinct routes for importation. "A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *King v. Burwell*, 576 U.S. 473, 492 (2015) (cleaned up). Here, Plaintiffs' interpretation is contrary to Section 384's design as a whole in just this way. Accordingly, it fails at Step One of *Chevron*.

Worse still, Plaintiffs' argument effectively blocks a central purpose of the two-path structure of Section 384. The commercial importation pathway—which allows for importation on a much larger scale, but subject to all of the detailed restrictions and safeguards that commercial importers must satisfy—expresses Congress's conclusion that the commercial pathway may allow for safe, cost-saving importation even if the individual pathway ends up not doing so. Else, Congress would have created *only the individual pathway*.

The implausibility of Plaintiffs' reading of the "this section" language in subsection (*l*)(1) can also be seen from the individual-importation side of the coin. Subsection (j) authorizes HHS to allow individual importation on either a blanket basis, "by regulation," or "on a case-by-case

basis." 21 U.S.C. § 384(j)(2)(A). Of course, under Section 384(*l*), HHS can only authorize case-by-case importation, say, if it certifies that such importation yields cost savings and does not pose a health and safety risk. But under Plaintiffs' "all or nothing" interpretation of 384(*l*), HHS would *also* have to certify—before granting any case-by-case waiver—that those cost-savings and health-and-safety criteria are *also* satisfied *both* for blanket individual importation "by regulation" *id.* § 384(j)(2)(A), *and for commercial importation*, *id.* §§384(b)–(h). Again, that renders Congress's decision to allow importation on an individual "case-by-case basis," *id.* § 384(j)(2)(A)—not just a blanket, nationwide basis—completely nugatory.

Plaintiffs' interpretation is also inconsistent with the rest of Section 384(*l*) *itself*. In Section 384(*l*)(2), Congress provided discrete steps for the de-certification of a Section 804 program. Under that provision, HHS can de-certify such a program "[i]f, 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date," HHS provides a new certification "based on substantial evidence obtained after the effective date" that "the benefits of implementation of this section do not outweigh any detriment of implementation of this section." 21 U.S.C. § 384(*l*)(2)(A). This de-certification authority is triggered by the "effective date of the regulations under *subsection (b)*," which, as discussed above, is the subsection granting HHS regulatory authority for the *commercial pathway*. *See id.* at § 384(b) ("The Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations *permitting pharmacists and wholesalers* to import prescription drugs from Canada into the United States."). The regulatory authority for the individual pathway is in a wholly different subsection with wholly different requirements. *See id.* at § 384(j)(3) (not requiring, for example, consultation with any other agency prior to promulgating individual pathway rules). If Congress did not envision that

HHS would be able to implement the commercial pathway, separate and apart from the individual pathway, then it would make little sense to tie the de-certification authority to the effective date of only that commercial pathway. *See* A. SCALIA & B. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 167 (2012) ("If any section [of a law] be intricate, obscure or doubtful, the proper mode of discovering its true meaning is by comparing it with the other sections, and finding out the sense of one clause by the words or obvious intent of the other." (internal quotation marks omitted)).

Of course, Congress *could have* written Section 384(*l*)(1) to require that all parts of the statute be certified together:

> This section shall become effective only if the Secretary certifies to the Congress that ~~the implementation of~~ **any and all means of importation authorized by** this section will—
>
> (A) pose no additional risk to the public's health and safety; and
>
> (B) result in a significant reduction in the cost of covered products to the American consumer.

21 U.S.C. § 384(*l*)(1). But this Court is tasked with interpreting the statute that Congress *did* enact, not the statute Plaintiffs *wish* it enacted. *Cf. Dean v. United States*, 556 U.S. 568, 572 (2009) ("[W]e ordinarily resist reading words or elements into a statute that do not appear on its face." (internal quotation marks omitted)). Plaintiffs' arguments for a higher threshold or a different process for certification belong in the halls of Congress. This Court is tasked with enforcing the law as written, and HHS's certification fully complies.[5]

[5] *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005), and *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006) are not to the contrary. In both of those decisions, plaintiffs argued that certification was not necessary for individual importation. *See Vermont*, 405 F. Supp. 2d. at 474 ("Vermont argues that, as a matter of statutory construction, the certification provision only applies to the commercial importation provisions of section 384 and not to the personal importation provisions."); *Montgomery Cnty.*, 445 F. Supp. 2d at 510–11 (same). And both cases held that the certification requirement applies to both the commercial pathway and the individual

B. HHS Could Certify the Commercial Pathway Based on State and Tribal SIPs.

Second, Plaintiffs argue that certification is contrary to law because the Final Rule is "an 'all-or-nothing' proposition" meaning that HHS cannot "certify importation on a state-by-state or tribe-by-tribe basis." Compl. ¶ 105. It appears to be Plaintiffs' theory that since the Final Rule allows for individual States or tribes to submit individual SIPs, HHS has certified an allegedly unlawful piecemeal certification.

Plaintiffs' theory is once again based on an implausible overreading of Subsection (*l*)'s reference to "this section." Indeed, so myopic is Plaintiffs' focus on those two words that they miss the phrase that immediately precedes it. Section 384(*l*) *does not* require certification that drugs may be imported under "this Section" in a safe and cost-effective manner; rather, it requires HHS to certify that "*the implementation* of this section" will result in safe cost savings. 21 U.S.C. § 384(*l*)(1) (emphasis added). That is a critical qualifier. The ordinary meaning of "implementation" is "an act or instance of implementing something; the process of making something active or effective." *Implementation*, Merriam-Webster, *available at* https://bit.ly/39oLWur; *see also* Cambridge Dictionary Online ("the act of starting to use a plan or system"), *available at* https://bit.ly/3suK3nG. This accords with the use of "implementation" in myriad other statutes. *See, e.g.,* 2 U.S.C. § 1313(c)(2) ("[T]he Board may determine, for good cause shown and stated together with the regulation, that a modification of such regulations would be more effective for the implementation of the rights and protections under this section."); 6 U.S.C. § 123 ("[T]he Secretary of Homeland Security . . . shall establish a program to oversee the implementation of the Secretary's responsibilities.). Thus, what HHS needed to certify was that its

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pathway. *See Vermont*, 405 F. Supp. 2d. at 475; *Montgomery Cnty.*, 445 F. Supp. 2d at 511. But neither case addressed the question of whether HHS is required to certify both at the same time. *See Vermont*, 405 F. Supp. 2d at 479 (declining to reach question of "partial certification").

chosen "process of making" Section 804 "effective" comported with the requirements of Section 384(*l*). That is precisely what it certified.

Plaintiffs also contend that HHS's certification is inconsistent with Section 384(*l*)(1)'s language requiring "no additional risk to the *public*'s health and safety" and "a significant reduction in the cost of covered drugs *to the American consumer*." Compl. 2, ¶ 105 (emphasis added). The theory is apparently that allowing the establishment of SIPs on a state-by-state basis can only ensure the absence of additional risk to the health *of that State*'s residents (not the public at large) and will only result in a reduction in cost to *that State*'s consumers (not American consumers generally). But the Final Rule makes clear that "*any* State or Territory of the United States, the District of Columbia, . . . the Commonwealth of Puerto Rico" or "Indian Tribe that regulates wholesale drug distribution and the practice of pharmacy" can be a SIP Sponsor. 21 U.S.C. § 321(a) (emphasis added) (defining "State" and "Territory"); 21 C.F.R. § 251.2 (defining "SIP Sponsor"). Accordingly, all Americans enjoy the opportunity to benefit from the Final Rule. Whether or not individual States take the opportunity to develop programs that comply with the safety and saving requirements of the Final Rule is not a defect of the certification of the Final Rule but a reflection of the priorities of those individual governments. HHS has certified a Final Rule that will benefit American consumers nationwide by opening a pathway to safe and lower cost drugs—just as Congress authorized.

Moreover, Plaintiffs' line of reasoning is once more flatly contrary to the rest of the statutory scheme. Again, in the provision governing the *individual* importation pathway, Congress authorized HHS to allow individual importation either on a blanket basis "by regulation or on a case-by-case basis." 21 U.S.C. § 384(j)(2). So again, if Plaintiffs were right that before allowing "case-by-case" importations, HHS first must certify that importation can be done in a safe and

cost-saving way *for all American consumers*, the case-by-case method authorized by Congress would be a dead letter. That is not how courts interpret Congress's handiwork. *See Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (canon against surplusage); *New York v. E.P.A.*, 443 F.3d 880, 887 (D.C. Cir. 2006) (rejecting agency's statutory interpretation that would give statutory text "virtually no role . . . to play.").

III. HHS's Section 804 Rule Is Not "Contrary to Law."

Plaintiffs additionally argue that the Final Rule itself is contrary to law for a variety of reasons. None of them has any merit. Here too, we focus our attention on two of Plaintiffs' arguments. Both arguments depend on statutory interpretations so strained that they fail at *Chevron* Step One—and certainly cannot surmount the deference HHS is entitled to at Step Two.

A. The Final Rule Does Not Violate 21 U.S.C. Section 355.

First, Plaintiffs argue that the Final Rule violates the Federal Food, Drug, and Cosmetic Act ("FDCA") because it allows for the importation of "new drugs" contrary to FDCA's provisions in 21 U.S.C. Section 355. *See* Compl. ¶ 125. Section 355 bans the "introduction into interstate commerce" of "any new drug" that is not approved by the FDA pursuant to a new drug application (NDA) or abbreviated new drug application (ANDA). 21 U.S.C. § 355(a). These applications require FDA approval of, *inter alia*, the manufacture, processing, packaging, and labeling of prescription drugs. *See id.* at § 355(b)(1)(A)(iv), (vi); *id.* at § 355(d); *id.* at § 335(j)(2)(A)(v), (4)(A). But, Plaintiffs say, under the Final Rule, prescription drugs that are made in Canada will be "tested, relabeled, and transported in ways not described by existing NDAs or ANDAs." *See* Compl. ¶ 125. Moreover, the Final Rule does not require that imported drugs gain approval via an NDA or ANDA. Instead, the imported drugs have to "meet[] the conditions [of drugs]" already approved by the FDA, *i.e.*, those found to be safe and effective. 85 Fed. Reg. 62114; *see also* 21

C.F.R. § 251.5(xii) (providing that a Pre-Import request must include an "[a]ttestion and information statement from the manufacturer that establishes that the drug proposed for import," but for labeling, "meets the conditions in the FDA–approved NDA or ANDA."). Ergo, Plaintiffs conclude, the imported drugs allowed by the Final Rule are unlawful because they are not subject to Section 355's approval process.

Plaintiffs' interpretation of the interplay between Section 355 and Section 804 is untenable because it would effectively render the whole of Section 804 superfluous. "[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013). If Section 804 required all imported drugs to strictly comply with Section 355 and obtain approval via an NDA or ANDA, then Section 804 would serve no conceivable purpose. "If an Importer sought and obtained FDA approval of a drug that was previously only approved for sale in Canada, it would not need to import the drug under Section 804. Instead, it could simply import the drug" under existing statutory authority "without meeting any of the additional safeguards imposed under section 804." 85 Fed. Reg. 62114. In other words, should Plaintiffs' interpretation prevail, this Court would have to read the entirety of Section 804 to authorize essentially a null set of imported drugs from Canada. That is farcical. "We cannot interpret federal statutes to negate their own stated purposes." *King*, 576 U.S. at 493 (quoting *N. Y. State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405, 419–420, (1973)); *see also Allegheny Def. Project v. Fed. Energy Regul. Comm'n*, 964 F.3d 1, 15 (D.C. Cir. 2020) (en banc) ("Agencies, no less than courts, cannot render statutory language a nullity and leave entire operative clauses with no job to do." (internal quotation marks omitted)).

Plaintiffs' reading fails for an additional reason as well: it flies in the face of the canon of statutory interpretation that a specific statute governs over the general. *Morton v. Mancari*, 417

U.S. 535, 550–51 (1974). "The most common example of irreconcilable conflict—and the easiest to deal with—involves a general prohibition that is contradicted by a specific permission." SCALIA & GARNER, *supra*, 183. In these circumstances, the application of the general prohibition "is suspended" for those "cases covered by the specific provision." *Id.* at 184. Here, Section 804 is a specific provision that was enacted to allow for a specific subset of foreign prescription drugs to be imported under a specific (and separate) regulatory regime. Accordingly, it is not "controlled or nullified" by the general ban on unapproved new drugs. *Morton*, 417 U.S. at 550–51.

To be sure, 21 U.S.C. Section 384(c) also requires "safeguards . . . to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of the prescription drug)." But reading this phrase to mean "complies with *all* of section 355"—including that Section's application procedures—would render the Statute self-contradictory in the way just discussed. "It is implausible that Congress meant the Act to operate in this manner." *King*, 576 U.S. at 494; *see also J & G Sales Ltd. v. Truscott,* 473 F.3d 1043, 1050 (9th Cir. 2007 (upholding agency action against plaintiffs' argument that would "transform . . . provisions into nullities" and "strip" statutory text of "its independent meaning") (internal citation omitted). Moreover, this reading is also contrary to the very next phrase in Section 384(c): the parenthetical indicating that compliance with Section 355 must "(include[e] . . . being safe and effective for the intended use of the prescription drug)." There would be no need to explain that the regulatory "safeguards" must include Section 355's provisions on safety and effectiveness, if *all* of Section 355 applied to imports under Section 804. Instead, Congress's specific reference to those safety and effectiveness provisions demonstrates that *only some portions* of Section 355 apply. And whatever those portions encompass besides the provisions related to safety and effectiveness, the one part of

Section 355 *they cannot* include—if Section 384 is to have any meaning at all—are the application procedures.

B. The Final Rule Does Not Violate 21 U.S.C. Section 352.

Plaintiffs additionally argue that the Final Rule is "contrary to law" because "drugs imported under the Final Rule would also necessarily be misbranded," in violation of 21 U.S.C. Section 352. Compl. ¶ 125(b). That Section provides that "[a] drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a). Plaintiffs argue that the labels required by the Final Rule will be both false and misleading because they "(a) use FDA approved labeling on an unapproved new drug; (b) mislead consumers into believing that the drug was identical to the FDA-approved drug; and (c) fail to provide consumers with important information" about how the drug was transported, stored, and imported from Canada. Compl. ¶ 125(b).

As a preliminary matter, once again Congress's specific instructions on labeling in Section 804 must be read to control imports under Section 804, rather than the general labeling provisions of Section 352. *See Morton*, 417 U.S. at 550–51. In 21 U.S.C. Section 384(h), Congress included clear and specific labelling requirements, mandating that "[t]he manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug." Congress further provided that testing of the imported drugs must include "confirm[ation] that the labeling of the prescription drug complies with labeling requirements under this chapter." *Id.* at § 384(e)(2)(A)(ii). Finally, either the importer or the manufacturer of the prescription drug must certify that the prescription drug "(i) is approved for marketing in the United States and is not adulterated or misbranded" and "(ii) meets all labeling requirements under this chapter." *Id.* at § 384(d)(1)(K).

Thus, although Plaintiffs complain of the labeling requirements in the Final Rule, these stem directly from *Congress's own requirements*. And it would be passing strange to suggest that Congress required in Section 384(d)(1)(K)(i) that an importer or manufacturer certify that a drug is not "misbranded" and then also certify in Section 384(d)(1)(K)(ii) that a drug has the requisite label, which would be considered "misbranding" under Plaintiffs' theory of Section 352. *See Taylor v. Fed. Aviation Admin.*, 895 F.3d 56, 67 (D.C. Cir. 2018) ("[W]e decline to strike down a rule that merely implements an unchallenged governing statute."); *see also AT & T Corp. v. Iowa Util. Bd.*, 525 U.S. 366, 396 (1999) ("[I]t is hard to declare the FCC's rule unlawful when it tracks the pertinent statutory language almost exactly.").

The Final Rule also takes great care to prevent any consumer confusion from the label of the imported drugs. *See* 85 Fed. Reg. 62114–15. Among other requirements, the label must include the imported drug's National Drug Code number, 21 C.F.R. § 251.13(b)(3)(i), the name and place of business of the importer, § 251.13(b)(3)(iii), the SIP's website, and the statement that "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program," § 251.13(b)(3)(iv). As HHS has explained, these requirements ensure that the labels are far from misleading, but instead provide "pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients" with the necessary information and education to avoid confusion and maintain pharmacovigilance. 85 Fed. Reg. 62115. The Final Rule thus does not require false or misleading labels; in fact, it ensures just the opposite.

IV. Florida Is Well-Equipped to Ensure the Safety and Quality of Imported Canadian Drugs.

Plaintiffs' Complaint repeatedly alleges that States will be unable to ensure the safety and quality of imported Canadian drugs. These allegations are completely unfounded. First, as

discussed at length above, FDA will engage in a fulsome review process of individual States' SIP plans. And the Rule explicitly provides that FDA may deny a SIP plan "because of the degree of uncertainty that the SIP Proposal or supplemental proposal would adequately ensure the protection of public health." 21 C.F.R. § 251.4(a). In other words, a State's ability to ensure safety is an essential element of the SIP approval process. And to the extent FDA has made a "predictive judgment" about the efficacy of the SIP review process and the capabilities of States to ensure safety and quality of imported Canadian drugs, this Court's review is "particularly deferential" to FDA. *Rural Cellular Ass'n v. F.C.C.*, 588 F.3d 1095, 1105 (D.C. Cir. 2009); *accord Am. Hosp. Ass'n v. Azar*, 983 F.3d 528, 536 (D.C. Cir. 2020) ("[W]hen an agency's decision is primarily predictive, our role is limited; we require only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive." (internal quotation marks omitted)).

Moreover, in addition to Florida's preexisting regulatory framework to "prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs," FLA. STAT. § 499.002; *see also* FLA. ADMIN. CODE. R. 61N-1, Florida's SIP procedures, now in development, show that Florida is ensuring the safety and quality of imported Canadian drugs in compliance with the FDCA and federal standards for drug supply chain security. One of the strengths of Florida's SIP is its co-sponsor, the Department of Business and Professional Regulation ("DBPR"). DBPR has licensed and regulates the SIP's wholesaler and is responsible for enforcing compliance with the FDCA and Florida's Drug and Cosmetic Act.

Additionally, Florida is establishing procedures for the robust testing of imported drugs in compliance with current good manufacturing practices as specified in 21 C.F.R. § 211. Florida's contracted laboratory will test samples pulled directly from shipments or batches of imported drugs. The lab will conduct visual inspections because often counterfeit medications can be

identified based on labeling, pill color and shape, and pill markings. Then the sample of imported drugs will be put through an array of tests to ensure safety and authenticity, including Raman spectroscopy (to identify active ingredients, excipients, and their relative concentrations), high-performance liquid chromatography (to identify any impurities), accelerated stability testing (to assign expiration dates and ensure ingredients do not become toxic before use), and culture media swabbing (to test for biological contamination).

Further, Florida is putting into place a plan to address potential recalls of imported Canadian drugs. If Florida learns a recall has been initiated in one of its daily recall checks, Florida will immediately halt the importation of all recalled prescription drugs. Further, Florida is developing a three-tier strategy (aligning with FDA's recall strategy based on severity of harms associated with the recall) to quickly respond to the recall and prevent recalled drugs from reaching individuals. As part of this strategy, Florida will leverage its existing ability to communicate by email blast and phone with health plans participating in Florida's Medicaid program, pharmacies, state run facilities (e.g., public health clinics, prisons, state mental hospitals), and other state agencies. Florida will also ensure the importer of the recalled Canadian drugs collects, documents, stores, and disposes recalled drugs—all while providing timely updates to Florida health officials.

Notwithstanding Plaintiffs' allegations to the contrary, Florida and other States will be well-equipped to ensure the safety and quality of imported drugs.

CONCLUSION

For the foregoing reasons, Amicus urges the Court to grant Defendants' motion to dismiss.

June 1, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will cause a copy of the document to be served electronically on all parties or their counsel.

Dated: June 1, 2021

s/ Michael W. Kirk
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