**IN THE UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

**Case No. 8:22-cv-1981-TPB-JSS**

STATE OF FLORIDA; and
FLORIDA AGENCY FOR HEALTH
CARE ADMINISTRATION,

*Plaintiffs*,

v.

FOOD AND DRUG ADMINISTRATION;
ROBERT M. CALIFF, *in his official capacity as Commissioner of Food and Drugs*; DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, *in his official capacity as Secretary of Health and Human Services*,

*Defendants.*

# AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

## INTRODUCTION

1. In June 2019, Florida Governor Ron DeSantis signed legislation directing Plaintiff Florida Agency for Health Care Administration ("AHCA"), an arm of Plaintiff State of Florida ("Florida" or "the State"), to establish and administer the Canadian Prescription Drug Importation Program ("Program") as part of an effort to lower prescription drug prices. *See* Fla. Stat. § 381.02035.

2. Certain critical prescription drugs can cost Florida almost $400 per pill, putting a significant strain on its healthcare budget.

3. The United States has some of the highest prescription drug prices in the world. *See* Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons*, Rand Corp. (2021), https://www.rand.org/pubs/research_reports/RR2956.html. On average, those prices are 218% of their Canadian counterparts. *Id.* at xi–xii. The markup is even more drastic for brand-name originator drugs, which are 294% of Canadian prices. *Id.* In other words, prices in Canada are only 46% and 34% of U.S. prices, respectively.

4. Section 804 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 384, and its implementing regulations at 21 C.F.R. part 251, provide for the importation of certain prescription drugs from Canada to save costs. By regulation, the Food and Drug Administration ("FDA") must first approve any importation as part of a Section 804 Importation Program ("SIP"). Florida's Program will operate as a SIP, importing safe and effective prescription drugs from Canada that have the highest potential for cost savings to Florida. These drugs are often the exact same ones already sold (and often manufactured) in the United States, but at substantially lower prices.

5. During the first phase, the Program will import prescription drugs to treat conditions such as HIV/AIDS, diabetes, hepatitis C, and mental illness. The Program will support Florida Medicaid recipients, patients at facilities run

by the Florida Department of Children and Families, individuals under the care of the Florida Agency for Persons with Disabilities, patients at county health departments managed by the Florida Department of Health, and inmates in the custody of the Florida Department of Corrections.

6. Florida estimates the Program could save State taxpayers up to $150 million annually once fully implemented, which can be used to improve access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions.

7. But Florida's ability to begin operating the Program is stuck in the starting blocks because of Defendant FDA, which must first approve the Program.

8. Florida originally provided a Concept Paper to Defendant Department of Health and Human Services ("HHS") in August 2019 detailing the Program. Florida then submitted a formal application to the FDA for approval ("SIP Proposal") in November 2020 after HHS finalized the applicable regulations in 21 C.F.R. part 251. Florida's SIP Proposal details the logistics of the Program—e.g., details on the company that would serve as the importer and distributor, lists of covered drugs, internal compliance plans, laboratory testing procedures, anticipated cost savings, and how the drugs will be relabeled for American use.

9. In the nearly two years while Florida's SIP Proposal has been pending, the FDA has asked for several minor clarifications and supplements but has provided no outward evidence of any substantive progress towards approving the Program.

10. Plaintiffs have long been ready, willing, and able to begin operating the Program immediately upon FDA approval, having already built a refrigerated distribution facility in Lakeland, Florida, procured an approved foreign seller, and contracted with a domestic importer and distributor. Plaintiffs have persistently asked the FDA for movement and for meetings to facilitate and advance the approval process, yet Florida's SIP Proposal still languishes. And the FDA is now refusing to provide even an estimate for any progress whatsoever.

11. In July 2021, President Biden issued Executive Order 14036, declaring we must "act now" and directing the FDA to work with states to implement their importation programs.[1] But that has been yet another empty promise from the Biden Administration, given the FDA's continued inaction for over a year since that Executive Order was issued. This failure is

[1] Exec. Order 14036, §§ 1, 5(q) 86 Fed. Reg. 36987, 36,988 (July 14, 2021).

particularly glaring given President Biden's admission that "prescription drug prices are outrageously expensive in America."[2]

12. Given the near-universal support for programs like Florida's, it seems the FDA's reluctance to approve Florida's SIP Proposal is a nod to the large pharmaceutical companies that oppose these importation programs because they yield increased competition and lower prescription drug prices.

13. As Governor DeSantis has aptly noted, "It may be that [big] pharma has told [the FDA] they don't want this, but you know, we've got to stop doing policy just on the basis of what pharma wants. I mean, we've got to do policy on the basis of what people think is the best."[3]

14. The cost of the FDA's inaction is substantial. The FDA's delay denies vulnerable Floridians access to essential medications at a reasonable cost. Moreover, given the estimate that the Program could save State taxpayers up to $150 million each year once fully implemented, Florida has already suffered an estimated budgetary hit of up to several hundred million dollars—and increasing at the rate of millions of dollars *every single month* that passes without approval of Florida's SIP Proposal. That money could be

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[2] *Remarks by President Biden on How His Build Back Better Agenda Will Lower Prescription Drug Prices*, https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/12/remarks-by-president-biden-on-how-his-build-back-better-agenda-will-lower-prescription-drug-prices/ (Aug. 12, 2021) ("Biden Remarks").

[3] John Davis, *DeSantis Executive Order Takes Aim at Pharmacy Benefit Managers, Prescription Drug Costs*, WGCU, https://news.wgcu.org/2022-07-08/desantis-executive-order-takes-aim-at-pharmacy-benefit-managers-prescription-drug-costs (July 8, 2022).

used to improve access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions. The FDA's delay is costing Floridians their health and wellbeing.

15. On top of that, Plaintiffs have paid their retained importer and distributor over $24 million thus far—and increasing at the rate of $1.2 million every month—even though not a single prescription pill has been imported, relabeled, or distributed, solely because of the FDA's idleness.

16. As Governor DeSantis has explained, "While Big Pharma and federal bureaucracy have continued to stand in the way, it's past time Florida taxpayers realized savings on these drugs."[4]

17. Plaintiffs accordingly have no choice but to sue the FDA under the Administrative Procedure Act for agency action unlawfully withheld and unreasonably delayed. The Court should compel the FDA to issue a decision on Florida's SIP Proposal. Floridians cannot afford to keep waiting on the FDA.

18. Further, given the substantial delay, AHCA submitted a Freedom of Information Act ("FOIA") request to the FDA, *see* 5 U.S.C. § 522, seeking relevant documents about Florida's and other states' SIP proposals. The FDA has not responded within FOIA's statutory deadline. Plaintiffs accordingly also

[4] *Governor Ron DeSantis Urges Swift Approval of Florida's Canadian Prescription Drug Importation Program*, July 9, 2022, https://www.flgov.com/2021/07/09/governor-ron-desantis-urges-swift-approval-of-floridas-canadian-prescription-drug-importation-program/.

bring suit to compel the FDA to respond to the FOIA request and provide the requested documents.

## PARTIES

19. Plaintiff State of Florida is a sovereign state and has the authority and responsibility to protect its sovereign interests, its public fisc, and the health, safety, and welfare of its citizens.

20. Plaintiff Florida Agency for Health Care and Administration is an agency and arm of the State of Florida and will administer the Program once it is approved by the FDA and also sent the FOIA request at issue in this suit.

21. Defendant Food and Drug Administration has delayed resolving Florida's SIP Proposal for nearly two years and is also the recipient of the FOIA request at issue in this suit.

22. Defendant Robert M. Califf is the Commissioner of Food and Drugs. He is sued in his official capacity.

23. Defendant Department of Health and Human Services is the parent agency of the FDA.

24. Defendant Xavier Becerra is the Secretary of Health and Human Services. He is sued in his official capacity.

## APA LEGAL STANDARD

25. The APA "embodies [a] basic presumption of judicial review." *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967).

26. The APA requires agencies to conclude matters "within a reasonable time." 5 U.S.C. § 555(b). If the agency fails to do so, a "reviewing court *shall* ... *compel* agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1) (emphasis added).

27. The FDA and HHS are required by statute to facilitate the importation of prescription drugs from Canada, including by taking the discrete action of determining whether to grant Florida's SIP Proposal. *See* 21 U.S.C. § 384(b) ("The Secretary … shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."); 21 C.F.R. § 251.4(c)(2) ("FDA will notify a SIP Sponsor in writing whether FDA has decided to authorize or not to authorize the SIP Sponsor's SIP Proposal or supplemental proposal.").

28. In assessing claims of agency delay under the APA, some courts apply a six-factor test articulated in *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) ("*TRAC*"). The Eleventh Circuit has not expressly adopted the *TRAC* factors, but district courts in this Circuit routinely use those factors to assess claims of agency delay.

29. The *TRAC* factors are: (1) "the time agencies take to make decisions must be governed by a rule of reason"; (2) "where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply

content for this rule of reason"; (3) "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake"; (4) "the effect of expediting delayed action on agency activities of a higher or competing priority"; (5) "the nature and extent of the interests prejudiced by delay"; and (6) "the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." *TRAC*, 750 F.2d at 80 (internal quotation marks omitted).

30. As discussed further below, the *TRAC* factors favor Plaintiffs here. Florida's SIP Proposal has been pending for nearly two years with only minor amendments, and the FDA has declined to provide any timeline for future actions. Moreover, the health and wellbeing of Floridians are at issue, and Florida is losing millions of dollars each month that could be used to improve access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions. It seems the most likely explanation for delay in the face of such universal support for these programs is the FDA's longstanding symbiotic relationship with big pharmaceutical companies that stand to lose hundreds of millions of dollars if Florida's SIP Proposal is approved.

31. Courts have found that claims of agency delay state a plausible claim under far less compelling circumstances than those here. *See, e.g.*, *Girges*

*v. Sec'y, Dep't of Homeland Sec.*, No. 6:22-cv-158, 2022 WL 2774211, at *4 (M.D. Fla. June 8, 2022) (Presnell, J.) (denying motion to dismiss where the plaintiffs had alleged: "the Government has, in effect, sat on their [asylum and withholding of removal] application for two years," there was "no reason why the pending application cannot be adjudicated," the "delay is unreasonable," and the government "has not provided any reasonable assurance as to when a decision will be made as to the pending application").

**FOIA LEGAL STANDARD**

32. FOIA requires a federal administrative agency to promptly make available requested, non-exempt agency records in response to a request that (a) reasonably describes such records, and (b) "is made in accordance with published rules stating the time, place, fees, ... and procedures to be followed[.]" 5 U.S.C. § 552(a)(3)(A); *see also* 21 C.F.R. §§ 20.40, 20.41.

33. FOIA requires federal agencies to respond to a valid request within 20 working days (i.e., exempting Saturdays, Sundays, and legal public holidays) after receipt of such request, including notifying the requestor immediately of its determination, the reasons therefor, and the right to appeal any adverse determination. 5 U.S.C. § 552(a)(6)(A)(i); *see also* 21 C.F.R. § 20.41(b).

34. In certain circumstances, a federal agency may provide notice to the requester that "unusual circumstances" merit additional time—up to an

additional 10 working days—to respond to the request. 5 U.S.C. § 552(a)(4)(viii)(II)(aa); *see also* 21 C.F.R. § 20.41(b)(3).

35. If the federal agency does not respond to a FOIA request by the statutory deadline, the requester is deemed to have exhausted administrative remedies and may immediately pursue judicial review. 5 U.S.C. § 552(a)(6)(C)(i).

**JURISDICTION AND VENUE**

36. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B), 5 U.S.C. §§ 701–706, and 28 U.S.C. §§ 1331, 1346, 1361, and 2201.

37. Venue is proper under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant, and the State of Florida is a resident of every judicial district and division in its sovereign territory, including this judicial district and division. *See Florida v. United States*, No. 3:21-cv-1066, 2022 WL 2431443, at *2 (N.D. Fla. Jan. 18, 2022) ("'It is well established that a state 'resides at every point within its boundaries.'" (alteration omitted) (quoting *Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892))); *see also California v. Azar*, 911 F.3d 558, 569-70 (9th Cir. 2018) ("[A] state with multiple judicial districts 'resides' in every district within its borders."); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005). Venue is also proper because a substantial part of the events at issue occurred in this division, as Florida's state-of-the-art warehouse built for the

Program is in Lakeland and is the subject of an ongoing $14.9 million per year contract for distributing prescription drugs obtained through the Program.

## FACTUAL BACKGROUND

***Section 804 Importation***

38. Section 804 of the FDCA, 21 U.S.C. § 384, provides for the importation of prescription drugs from Canada. Congress added section 804 as part of the Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387, sec. 745, and later amended its provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173.

39. Section 804 is contingent on the Secretary of Health and Human Services certifying to Congress that implementation would (1) pose no additional risk to public health and safety, and (2) result in significant cost savings to American consumers. 21 U.S.C. § 384(*l*). As a result, this statutory authorization was left dormant for nearly 20 years, and still remains unimplemented.

40. In August 2019, Florida submitted a Concept Paper to HHS to demonstrate that Canadian drug importation programs would result in cost savings and not pose additional risk to public health and safety. Ex. 1. The Concept Paper was also intended to provide HHS with a model SIP to guide agency rulemaking.

41. In Fall 2020, after working collaboratively with Governor DeSantis, HHS issued a final rule promulgating 21 C.F.R. part 251 to govern the importation of prescription drugs under section 804. *See Importation of Prescription Drugs*, 85 Fed. Reg. 62,094 (Oct. 1, 2020). Then-Secretary of HHS Alex Azar simultaneously certified to Congress, both in the final rule and by letter, that importation of prescription drugs from Canada pursuant to the final rule "poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer." Ex. 2, Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020).

42. The final rule required a state or Indian Tribe to sponsor each SIP ("SIP Sponsor"), 21 C.F.R. §§ 251.1–251.2, and to submit the following information as part of its proposal to import prescription drugs from Canada:

a. Cover sheet identifying the SIP Sponsor and a person authorized to serve as the point of contact with the FDA, *id.* § 251.3(c)(1);

b. Table of contents, *id.* § 251.3(c)(2);

c. Information on each eligible prescription drug, *id.* § 251.3(d)(3)–(6), (e)(5);

d. Information on a foreign seller that would export the drugs from Canada, *id.* § 251.3(d)(7)–(8), (e)(4); *id.* §§ 251.9–251.11;

e. Information on a domestic purchaser that would import the drugs from Canada into the United States, *id.* § 251.3(d)(9); *id.* § 251.12;

f. Information on a relabeler that would apply labels compliant with U.S. law, *id.* § 251.3(d)(10), (e)(8); *id.* § 251.13;

g. Information on how the SIP Sponsor would satisfy requirements for safety and purity testing, supply chain security, labeling, and recalls, and ensure significant reduced costs to consumers, *id.* § 251.3(d)(11), (e)(7), (9)–(11), (13); *id.* §§ 251.14–16.

*See also* 21 U.S.C. § 384(d).

43. The final rule also provided that two years after the first prescription drugs are imported pursuant to an approved SIP, the Secretary of HHS may authorize private SIP Sponsors (i.e., not states or Tribes) if they can assure the same level of safety. 21 C.F.R. § 251.2.

***Governor DeSantis's Plan to Lower Prescription Drug Prices***

44. Prescription drug spending in the United States surpassed $500 billion in 2020. Benjamin N. Rome et al., Letter, *Trends in Prescription Drug Launch Prices, 2008–2021*, JAMA vol. 327, no. 21, p.2145–46 (June 7, 2022), https://jamanetwork.com/journals/jama/article-abstract/2674663. That figure has more than quintupled since 2003, when spending on prescription drugs was estimated at $99.99 billion. *See* Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey (MEPS) Household Component*

*(HC)*, https://datatools.ahrq.gov/meps-hc?type=tab&tab=mepshcpd (select "Total expenditures ($)," then "Prescribed drug," then "2003," then sum expenditures for all listed drugs for 2003).

45. Since 2008, the median launch price of a new drug treatment has skyrocketed from roughly $2000 per year to over $180,000 per year. Rome, *supra*. By 2021, 47% of new drugs cost over $150,000 per year. *Id.*

46. In response, at the request of Governor DeSantis, the Florida legislature in 2019 directed AHCA to create and begin implementing the Program. *See* Fla. Stat. § 381.02035. The Program will import certain high-cost prescription drugs from Canada for the benefit of Floridians. The Program would start with certain State agencies that purchase and distribute prescription drugs. If the Program is successful, the Florida legislature could expand it to allow for private importation and sale of prescription drugs from Canada.

47. Florida provided a Concept Paper to HHS in August 2019 to demonstrate that Canadian drug importation programs would result in cost savings and not pose additional risk to public health and safety. Ex. 1. The Concept Paper also provided HHS with a model SIP to guide agency rulemaking.

48. On November 23, 2020, after HHS finalized its regulations, Plaintiffs submitted their SIP Proposal for the Program to the FDA. Ex. 3. The SIP Proposal included, *inter alia*, specific details on:

a. The SIP Sponsor (AHCA), co-sponsor (Florida Department of Business and Professional Regulation), and the "responsible individuals" at those agencies, *id.* at 5;

b. The entities that would import the drugs into Florida (DOH Central Pharmacy and LifeScience Logistics, LLC), including documentation of government inspections and any disciplinary actions, *id.* at 5, 43–109;

c. The FDA-registered company that would relabel the drugs (LifeScience Logistics), *id.* at 5;

d. The identification, including pricing and numbering, of each prescription drug and dosage that the Program would seek to import, *id.* at 8–14;

e. The precise mechanisms for evaluating drug authenticity, safety, and stability, including the identity of four licensed laboratories already contracted, *id.* at 18–20;

f. Cost savings, using detailed tables showing specific drugs, utilization numbers, net costs, total costs under current pricing,

Canadian cost, and total costs under Canadian pricing, *id.* at 22–23;

g. Storage, handling, supply chain, and issue-reporting guidelines for drugs once they have been imported, including plans for the recall and return of drugs if necessary, *id.* at 24–28, 31–35;

h. An internal compliance plan, including the details on seven specific individuals who would be responsible for various aspects of the Program, *id.* at 35–39;

i. Samples of package relabeling, *id.* at 111–13.

49. The only material information not included was the identity of the foreign seller, which would obtain the drugs in Canada and sell them to the importer (LifeScience Logistics). *Id.* at 5. This omission was consistent with the FDA's regulations, which allow identification of a foreign seller six months after the proposal itself has been submitted. 21 C.F.R. § 251.4; *see* 85 Fed. Reg. at 62,099–100.

50. Aside from information about the foreign seller, the SIP Proposal submitted in November 2020 contained all the substantive information the FDA would need to approve the Program.

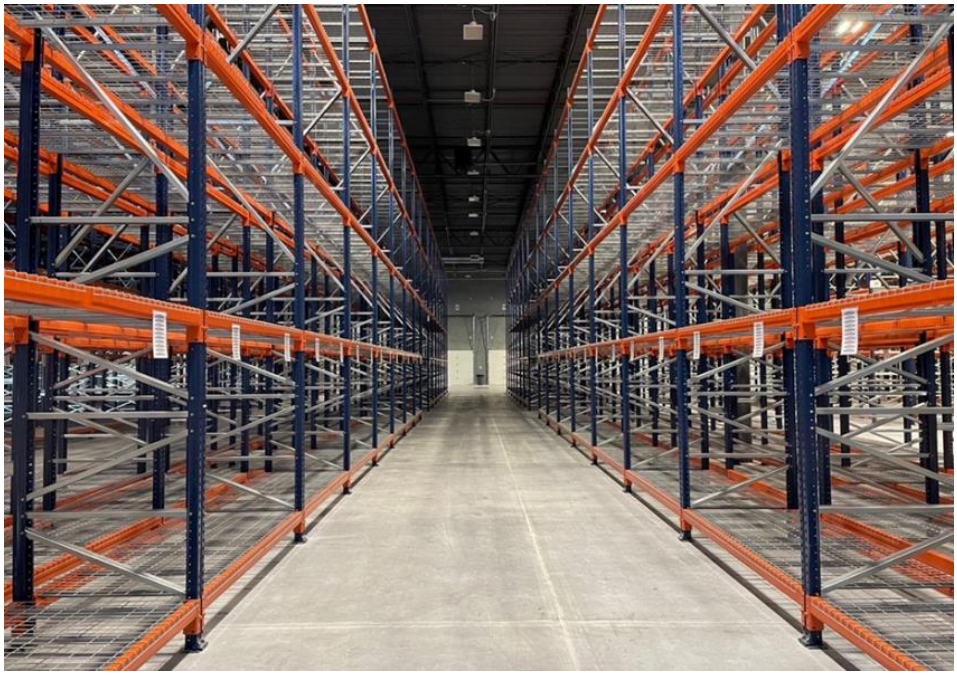
51. In April 2021, Florida selected Methapharm Inc. as its foreign seller.

52. On April 19, 2021—well within the allotted six months—AHCA submitted a revised SIP Proposal adding Methapharm as the foreign seller, along with documentation of Methapharm's licensing, registration, and inspection history. Ex. 4 at 5, 114–25. AHCA also made a minor amendment to revise the list of "responsible individuals." *Id.* at 5.

53. With the April 2021 addition of the foreign seller information, Florida's SIP Proposal contained all material information the FDA would need to approve the Program.

54. In May 2021, Florida finalized a purpose-built distribution center in Lakeland, which has already been inspected and permitted by Florida officials to begin distribution. The warehouse is over 98,000 square feet, almost the same size as an entire city block. Governor DeSantis personally held a press conference at the warehouse to announce Florida's progress, and he called on the FDA to approve Florida's SIP Proposal:


(Governor DeSantis at the Lakeland distribution center, May 2021)



(Lakeland distribution center)


(Lakeland distribution center)

(Lakeland distribution center)

55. On May 28, 2021, Governor DeSantis issued a Tweet noting the skyrocketing cost of prescription drugs and "call[ing] on the Biden Administration to approve Florida's plan to lower prescription costs." Ron DeSantis (@GovRonDeSantis), Twitter, May 28, 2021 (11:11 A.M.), https://twitter.com/GovRonDeSantis/status/1398295948883804164.


56. In July 2021, President Biden issued Executive Order 14036, directing the FDA to work with states wishing to import prescription drugs. *See* Executive Order 14036, § 5(q), 86 Fed. Reg. at 36,997–98 ("To reduce the cost of covered products to the American consumer without imposing additional risk to public health and safety, the Commissioner of Food and Drugs shall work with States and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173, 117 Stat. 2066), and the FDA's implementing regulations."). President Biden acknowledged that "Americans are paying too much for prescription drugs and healthcare services—far more than the prices paid in other countries," and therefore "[w]e must act now to reverse these dangerous trends." *Id.* § 1, 86 Fed. Reg. at 36,988. But this lip service has been nothing more than another empty promise from the Biden Administration.

57. In a letter dated August 20, 2021, *see* Ex. 5, the FDA requested several additional pieces of information for Florida's SIP Proposal, including names and addresses of certain individuals, documents showing the relabeler's FDA registration, more drug information, and additional proposed relabeling graphics. AHCA's response to this request was submitted on September 15, 2021, *see* Ex. 6, and AHCA simultaneously amended its SIP Proposal to include the revised information, *see* Ex. 7. AHCA made clear that "Florida stands ready to immediately begin implementation of its program following FDA approval." Ex. 6 at 3.

58. In an email dated November 8, 2021, *see* Ex. 8, the FDA asked two clarifying questions: (1) confirmation that Plaintiffs had contracted with a foreign seller to provide the prescription drugs (about which Plaintiffs had already submitted information seven months earlier), and (2) confirmation of the precise number of prescription drugs included in the SIP Proposal. On November 11, 2021, AHCA sent its response, *see* Ex. 9, and amended its SIP Proposal to include the clarifications, *see* Ex. 10. AHCA again stated that "Florida stands ready to immediately begin implementation of its program following FDA approval." Ex. 9 at 1.

59. Aside from those few basic information requests in 2021, there has been no outward progress by the FDA on Florida's SIP Proposal since it was submitted in November 2020.

60. Plaintiffs have not sat idle. On February 10, 2022, AHCA's Secretary Simone Marstiller sent a letter to Defendant Becerra, Secretary of HHS, asking him to "direct swift action in approving Florida's Canadian Prescription Drug Importation Program." Ex. 11. The letter reiterated that Florida had long since contracted with a domestic vendor (LifeScience Logistics), a Canadian seller (Methapharm), and had built a distribution center in Lakeland. Secretary Marstiller pointed out that Executive Order 14036 had directed the FDA to work with states seeking to import foreign prescription drugs, making the FDA's delay all the more inexplicable.

61. On March 10, 2022, Secretary Marstiller sent another letter, this time to Defendant Califf, the recently confirmed Commissioner of Food and Drugs. Ex. 12. The letter first noted that the February 10 letter to Secretary Becerra remained unanswered. Secretary Marstiller again made clear that "the only remaining obstacle to operationalizing the [P]rogram in Florida is the FDA," yet "[i]t remains unclear as to why the FDA continues to delay the approval of Florida's [P]rogram." *Id.* at 1. Secretary Marstiller stated that further delay would "deny vulnerable Floridians access to essential medications at a reasonable cost. The pharmaceutical industrial complex and their powerful lobby have long denied Americans access to low-cost drugs," and thus prompt FDA approval is necessary. *Id.*

62. On March 15, 2022, the FDA finally responded to Secretary Marstiller's February 10 letter by sending a letter noting generically that Florida's "information is currently under evaluation." Ex. 13. The FDA provided no sense of timeline for next steps, let alone when the SIP Proposal might be approved.

63. The FDA's letter also noted that the FDA had scheduled a Zoom call on March 31, 2022, with officials from numerous states, but stated the call was intended to "facilitate collaboration and advance … ongoing dialogue" with "states that have demonstrated … interest in developing a …. proposal," and had nothing to do with evaluating or approving Florida's SIP Proposal (or any other proposal). The call ultimately focused on basics like what elements are required for a proposal, including that the FDA wanted two years of cost analysis using pricing that had already been negotiated between a SIP Sponsor's importer and foreign seller.

64. Also on March 31, 2022, the FDA responded to Secretary Marstiller's March 10 letter. Ex. 14. This response simply reiterated the same boilerplate language from the March 15 FDA letter, including the generic claim that Florida's "information is currently under evaluation." *Id.* The FDA provided no sense of timeline for next steps or when the SIP Proposal might be approved.

65. Again, Plaintiffs did not sit idle. On April 4, 2022, Florida officials requested a time for a bilateral meeting with the FDA to discuss Florida's SIP Proposal. Ex. 15 at 3. The FDA did not respond to this request.

66. On April 13, 2022, Florida officials again requested a bilateral meeting with the FDA, and this time the FDA responded but only to state blandly that the FDA "is currently working through the request and will respond as soon as possible." *Id.* at 2.

67. On April 14, 2022, Florida officials asked their FDA contact, "Is there any information Florida can provide that might assist the FDA in working through this request?" *Id.* at 1. The FDA contact's response was again lacking in any specifics: "I understand your concerns, and we will circle back with you as soon as possible." *Id.* at 1.

68. Around April 29, 2022, Politico reporter Arek Sarkissian asked Defendant Califf about Florida's SIP Proposal at a conference in Texas, to which Califf responded, "You know those timelines don't mean anything." Ex. 16 at 1. When Sarkissian asked a follow up, Califf stated, "You know better than to ask those kind of questions." *Id.*

69. On May 9, 2022, the FDA finally emailed Florida officials proposing dates for the bilateral meeting. Ex. 17.

70. On May 19, 2022, the FDA finally held a bilateral call with Florida officials. The FDA stated that it had received Florida's SIP Proposal and

responses to prior requests for information in 2021, and that "review is still ongoing." The FDA indicated it anticipated requesting additional information but declined to provide any specific details on what this supposed request might include, when it might be sent, what the next steps would be, or when approval might occur.

71. After another month of silence, Florida officials emailed the FDA on June 14, 2022, asking about the status of this supposed request for information, but the FDA expressly declined to provide any timeline whatsoever and still has not explained what information will supposedly be requested. Ex. 18.

72. For far too long, Florida has been willing, able, and ready to implement the Program *immediately*. The only impediment has been the FDA's lack of approval.

***The FDA's Delay Is Costing Floridians' Health and Wellbeing.***

73. The FDA's inaction is coming at substantial cost. The Program would import critical prescription drugs for conditions like HIV/AIDS, diabetes, hepatitis C, and mental illness. And the prescription drugs would be directed to those Floridians least able to afford them. By sitting on the SIP Proposal, the FDA is denying Floridians that critical access.

74. More, as noted below, Florida estimates the Program could save State taxpayers up to $150 million annually once fully implemented, and those

savings—which the State has been unable to realize due to the FDA's delay—could be used to improve access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions.

75. High prescription drug prices have long been a significant drain on state budgets and a scourge on the neediest individuals. As HHS itself explained in September 2021, "[h]igh drug prices result in access and affordability challenges for many Americans. Twenty-four percent of adults taking prescription drugs say they are hard to afford, and nearly 10 percent of adults report not taking medication as prescribed in order to save money. *Some have died as a result*." HHS, *Comprehensive Plan for Addressing High Drug Prices* 5 (Sept. 9, 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf (emphasis added) ("HHS Comprehensive Plan").

76. Nor does the FDA have any countervailing safety concern when it comes to reviewing the SIP Proposal. As President Biden himself stated, "[t]hese are drugs that the FDA has determined are safe." Biden Remarks, *supra*. That is because the drugs imported through the Program would be the exact same as ones sold in the United States and in any event must pass rigorous purity and safety tests after they are imported to Florida. There is no reason for the FDA to keep dragging its feet and protecting big pharmaceutical companies.

***The FDA's Delay Is Costing Florida Millions of Dollars that Could Be Used for Critical Healthcare Services.***

77. As described in their SIP Proposal, Plaintiffs have estimated that the Program could save Florida up to $150 million per year in budgetary costs once fully implemented. Because the FDA has dragged its feet for nearly two years, Florida has continued to pay high prices for prescription drugs, resulting in an estimated budgetary hit of as much as several hundred million dollars—and increasing at the rate of up to $12 million *every single month* while the FDA declines to act. As noted, that money could have been spent on expanding other State-provided health services, but instead it is being lost (i.e., sent to big pharmaceutical companies) due to the FDA's delay.

78. Florida has also paid over $24 million thus far—and increasing at $1.2 million every month—for a Program it cannot implement while the FDA remains idle. Florida retained LifeScience Logistics to import and distribute the prescription drugs obtained through the Program. The contract is $14,921,196 per year, or roughly $1.2 million per month. Because the FDA requires SIP Sponsors like Florida to estimate cost savings using prices already negotiated between an importer and foreign seller, and because Florida must be ready to start the Program immediately once approval from the FDA is obtained, it was necessary to retain LifeScience Logistics and keep it under contract, including for maintenance of the warehouse needed for

distribution. Florida has already paid over $24.3 million to LifeScience Logistics, which has been unable to deliver a single imported pill to Floridians because of the FDA's foot-dragging.

79. There are other significant, ongoing financial costs of the FDA's delay. For example, several AHCA employees are dedicated to implementation of the Program, and their total salaries and benefits amount to nearly $400,000 per year.

80. Whether measured in human health and wellbeing or in dollars, the FDA's delay has exacted a tremendous toll on Florida and its residents—and that toll is only increasing as each day passes without the FDA approving Florida's SIP Proposal.

***Plaintiffs' FOIA Request***

81. In yet another attempt to spur action at the FDA and help uncover what is causing the unreasonable delay, AHCA submitted a FOIA request and fee waiver to the FDA on July 6, 2022. Ex. 19. The FOIA request sought, *inter alia*:

a. Records relating to Florida's SIP proposal.

b. Records relating to Canadian drug importation programs, including SIP proposals, for Colorado, New Mexico, New Hampshire, Vermont, and Maine.

c. Records relating to Canadian drug importation programs and private pharmaceutical stakeholders, including pharmaceutical companies, lobbying groups, and advocacy groups, including the Pharmaceutical Research and Manufacturers of America.

d. Records relating to the development of the SIP review and approval process, including certain regulatory terms and requirements. 21 C.F.R. §§ 251.3(d)(11)(v), 251.3(e)(9).

e. Records related to an FDA presentation (a copy of which was attached to the FOIA request) titled "Section 804 Importation Program: Overview of Final Rule and Implementation."

f. Records related to an FDA presentation (a copy of which was attached to the FOIA request) titled "Projecting Cost Savings for the American Consumer."

g. Records relating to the basis or bases for denial of a SIP proposal. 21 C.F.R. § 251.4(a).

82. The FDA acknowledged the request on July 7, 2022, and noted "the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." Ex. 20.

83. When it submitted its FOIA request, AHCA requested expedited processing pursuant to 21 C.F.R. § 20.44(e), given the importance of the Program to Floridians who would benefit from life-saving prescription drugs.

*See* Ex. 19 at 2–3. The FDA denied that request on July 20, 2022, because there is allegedly no "urgency to inform the public" about this "Federal Government activity." Ex. 21.

84. To date, the FDA has not responded to the FOIA request, nor provided any responsive materials, nor explained that responsive materials have been or will be withheld.

85. The FDA's FOIA portal listed the "Due Date" for the request as August 4, 2022. Ex. 22.

## CLAIMS FOR RELIEF

### COUNT ONE

### (Agency Action Unreasonably Delayed and Unlawfully Withheld, in Violation of the APA)

86. The allegations in paragraphs 1–85 are expressly incorporated herein as if restated in full.

87. The APA requires agencies to conclude matters "within a reasonable time." 5 U.S.C. § 555(b). If the agency fails to do so, a "reviewing court *shall* ... *compel* agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1) (emphasis added).

88. The FDA and HHS are required to facilitate the importation of prescription drugs from Canada, including by taking the discrete action of determining whether to grant Florida's SIP Proposal. *See* 21 U.S.C. § 384(b); 21 C.F.R. § 251.4(c)(2).

89. The D.C. Circuit's "*TRAC* factors" are routinely used by lower courts in this Circuit to evaluate agency delay. The *TRAC* factors clearly favor Plaintiffs here.

***Rule of Reason***

90. The FDA's delay is patently unreasonable. *First,* Florida's SIP Proposal has been pending for nearly two years with only minor amendments. The application itself largely requires only explanations and documentation of prescription drugs that are already FDA approved and of contractual arrangements between Plaintiffs and their retained contractors—all of which Plaintiffs provided long ago. Despite Plaintiffs' near-constant inquiries and requests for progress, the FDA has made no meaningful forward movement.

91. *Second*, the unreasonableness of this delay is evident from the FDA's own requirements for a SIP Proposal. The FDA has recognized the necessity of approving SIP proposals based on current information, which is defeated by multiple years of delay. *See, e.g.*, 85 Fed. Reg. at 62,101 (explaining that plan sponsors can "compare the current retail case price of the drugs" to determine anticipated cost savings); *Importation of Prescription Drugs*, 84 Fed. Reg. 70796, 70807 (2019) (proposed rule) (same). The FDA also requires two years of cost analysis, which will be lost in the rear-view mirror by the time the FDA decides to act. The FDA cannot ensure cost savings—as required by

statute—if it takes so long to approve proposals that projected benefits are unknown.

92. The FDA further requires SIP Sponsors like Florida to enter agreements with a domestic vendor and foreign seller, and for them to negotiate drug prices, *before* a proposal can be approved. In fact, the contractual arrangements with the importer and distributor must be finalized before the proposal can even be *submitted* to the FDA. The FDA apparently expects SIP Sponsors to hemorrhage money retaining these contractors for indefinite periods while waiting to hear whether the proposal will be approved.

93. *Third*, SIP authorization is valid for only two years maximum (consistent with the required two years of projected cost analysis), at which point Florida would need to file for an extension. 21 C.F.R. § 251.6(a). This timeline gives a sense of how quickly approvals should occur. Plaintiffs have thus waited the equivalent of an *entire* authorization cycle and still have not received approval even to start the Program.

94. *Fourth*, prescription drug prices tend to be most expensive when first introduced to the market, presenting the greatest opportunity for cost savings. The longer approval takes, the less opportunity for cost savings with each drug, defeating the statutory purpose of SIPs, and the more likely Florida will have to request additional approval for new drugs—giving the FDA yet another chance to delay.

95. And *finally*, the FDA has now expressly declined to provide any timeline for future actions. The FDA has repeated this refusal in multiple emails and also during the June 2022 bilateral meeting. In fact, in a separate court proceeding where pharmaceutical trade groups have challenged the HHS final rule, the government insisted that "no timeline exists for the agency to make a decision" on Florida's SIP Proposal, and that the prospect of FDA approval of Florida's SIP was so "speculative" that the trade groups' complaint should be dismissed due to lack of cognizable injury.[5] This delay is inconsistent not only with Executive Order 14036, but also with the FDA's own insistence that proposals be based on up-to-date information projected over two years, which is defeated by multiple years of delay. The FDA's approach was aptly summarized by Defendant Califf, who, in response, to a journalist asking about Florida's SIP Proposal, said "You know those timelines don't mean anything." Ex. 16 at 1.

***Human Health and Welfare Are at Stake***

96. This case involves the health and welfare of Floridians on a grand scale. Florida is forced to pay outrageous prices for critical prescription drugs for its neediest citizens. The FDA's delay thus denies vulnerable Floridians access to essential medications at a reasonable cost. And the inability to

[5] Memorandum in Support of Defendants' Motion to Dismiss the First Amended Complaint for Lack of Subject Matter Jurisdiction and, Alternatively, for Failure to State a Claim Upon Which Relief Can Be Granted at 1–2, *PhRMA v. HHS*, 1:20-cv-03402 (D.D.C. Aug. 27, 2021).

recognize those cost savings is coming at the expense of improved access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions. As HHS itself has acknowledged, high drug prices can be a matter of life and death. HHS Comprehensive Plan, *supra*, at 5.

***Higher or Competing Priorities***

97. Plaintiffs were the first entities to submit a SIP proposal to the FDA. There is no attempt to "jump the line" or undercut other competing priorities. Executive Order 14036 also reaffirmed the importance of processing these proposals.

***Prejudice of Delay***

98. Again, the health and welfare of Floridians is at issue here, representing the highest order of prejudice. Florida is also losing millions of dollars every single month that the FDA fails to act. That money is being wasted on padding the bottom lines of pharmaceutical companies, even though much of it could have been used to help improve access to improve access to services for Medicaid recipients, children, and persons with disabilities or chronic conditions.

***Impropriety***

99. It is telling that the FDA has dragged its feet for so long even though prescription drug importation has near-universal support, and President Biden himself issued Executive Order 14036, declaring we must "act

now" and directing the FDA to facilitate these programs. Although agency impropriety is not required, it seems the most likely explanation for the FDA's delay, in the face of near universal support for importation programs, is the FDA's longstanding symbiotic relationship with big pharmaceutical companies that stand to lose hundreds of millions of dollars if Florida's SIP Proposal is approved.

100. The pharmaceutical industry's fierce opposition to SIPs is well documented. The Pharmaceutical Research and Manufacturers of America ("PhRMA") and Partnership for Safe Medicines ("PSM"), alongside other commenters like Pfizer, opposed HHS's final rule. PhRMA, PSM, and the Council for Affordable Health Coverage then sued to enjoin implementation of section 804 once HHS promulgated its regulations. *PhRMA v. HHS*, 120-cv-03402 TJK (D.D.C.). They have also filed a citizen's petition directly opposing Florida's SIP Proposal.

101. Protecting the interests of pharmaceutical companies is no excuse for the agency to sit on Florida's SIP Proposal for years.

***Congressional Timetable***

102. Although Congress did not impose an express statutory deadline for approving SIP proposals, such a deadline is not required to state a claim for delayed agency action. *See Gen. Motors Corp. v. United States*, 496 U.S. 530, 539 (1990) ("Although the 4–month deadline does not apply, EPA remains

subject to the Administrative Procedure Act's (APA's) statutory requirements of timeliness."). Moreover, the statutory purpose and requirement that SIPs result in cost savings is undermined when it takes so long to approve a SIP Proposal that the cost estimates are stale and the list of drugs for approval may already require updating.

103. For all of these reasons, as well as those explained throughout this Complaint, Defendants have unreasonably delayed resolving Florida's SIP Proposal and have unlawfully withheld a resolution of the SIP Proposal, in violation of 5 U.S.C. §§ 555(b), 706(1), 21 U.S.C. § 384(b), and 21 C.F.R. § 251.4.

**COUNT TWO**

**(Failure to Comply with Statutory Deadlines in Violation of FOIA)**

104. The allegations in paragraphs 1–85 are expressly incorporated herein as if restated in full.

105. To date, the FDA has failed to respond to the FOIA request identified above.

106. More than 20 working days have passed since that FOIA request was received and logged by the FDA on July 7, 2022.

107. FOIA requires the FDA to have provided a final determination within 20 working days of AHCA's FOIA request. The FDA may extend this 20-day period in the event of "unusual circumstances," as defined by 5 U.S.C.

§ 552(a)(6)(B)(iii), for a maximum of 10 working days, but must provide AHCA with notice of doing so. *See id.* § 552(a)(4)(A)(viii)(II)(aa), (6)(B)(ii).

108. The FDA did not provide a final determination within 20 working days of receiving and logging the FOIA request, nor has the FDA stated that unusual circumstances exist warranting a 10-day extension. Even if the FDA had invoked that extension, 30 working days have passed since the FDA received and logged the FOIA request.

109. The FDA has thus failed to timely make a determination, in violation of FOIA. *See* 5 U.S.C. § 552(a)(6).

110. All administrative remedies required by FOIA have been constructively exhausted. *See* 5 U.S.C. § 552(a)(6)(C)(i).

**COUNT THREE**

**(Unlawful Withholding of Agency Records in Violation of FOIA)**

111. The allegations in paragraphs 1–85 are expressly incorporated herein as if restated in full.

112. FOIA requires the FDA to process records requests and promptly provide the requested records or the reasonably segregable portion of records not subject to a FOIA exemption. 5 U.S.C. § 552(a)(3)(B).

113. The FDA has neither provided AHCA any responsive documents in response to its request, nor has the FDA claimed that any responsive records are exempt from disclosure.

114. Therefore, the FDA's failure to produce requested records or claim applicable exemptions violates FOIA. 5 U.S.C. § 552(a)(3)(B).

**COUNT FOUR**

**(Declaratory Judgment)**

115. The allegations in paragraphs 1–85 are expressly incorporated herein as if restated in full.

116. For the same reasons described in Counts 1 through 3, Plaintiffs are entitled to a declaratory judgment that Defendants have been and are violating the law.

**PRAYER FOR RELIEF**

Plaintiffs respectfully request that the Court:

A. Declare that Defendants have failed to make a timely determination on Florida's SIP Proposal, in violation of 5 U.S.C. §§ 555(b), 706(1); 21 U.S.C. § 384(b); and 21 C.F.R. § 251.4;

B. Order Defendants to immediately review Florida's SIP Proposal and provide a determination of whether it has been approved, as required by 5 U.S.C. §§ 555(b), 706(1); 21 U.S.C. § 384(b); and 21 C.F.R. § 251.4;

C. Declare that Defendants have failed to make a timely determination on AHCA's FOIA request, in violation of 5 U.S.C. § 552(a)(6)(A)(i);

D. Declare that Defendants have failed to promptly provide records responsive to AHCA's FOIA request, in violation of 5 U.S.C. § 552(a)(3);

E. Order Defendants to immediately conduct a reasonable search for all responsive records, as required by FOIA, 5 U.S.C. § 552(a)(3)(C);

F. Order Defendants to immediately provide a determination on AHCA's FOIA request, as required by 5 U.S.C. § 552(a)(6)(A)(i);

G. Order Defendants to promptly disclose to AHCA all responsive, non-exempt records, as required by FOIA, 5 U.S.C. § 552(a)(3);

H. Award reasonable attorneys' fees and allowable costs, including under 5 U.S.C. § 552(a)(4)(E) and the Equal Access to Justice Act; and

I. Grant Plaintiffs such other and further relief to which they are justly entitled at law and in equity.

Dated: August 31, 2022

Respectfully submitted,

ASHLEY MOODY
ATTORNEY GENERAL

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 31, 2022, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action. Copies are also being sent via certified mail to:

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