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

Case No. 8:23-cv-877-TPB-TGW

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

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION;
and DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendants.

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF[1]

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 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.

[1] This amended complaint is filed with consent of Defendants. Fed. R. Civ. P. 15(a)(2).

3. Prescription drug prices are often substantially lower in Canada than in the United States. The Program will therefore import safe and effective prescription drugs—like those for treating HIV/AIDS and hepatitis C—from Canada that have the highest potential for cost savings to Florida.

4. The Program was designed to comply with section 804 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 384, and its implementing regulations at 21 C.F.R. part 251, which provide for Canadian drug importation programs. These programs are also known as "Section 804 Importation Programs" ("SIPs").

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 at least $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. Florida is ready, willing, and able to begin operating the Program immediately, having already built a refrigerated distribution facility and procured an approved importer and distributor currently being paid $1.2 million per month.

8. But Florida's ability to begin operating the Program is stuck in the starting blocks because of Defendant Food and Drug Administration ("FDA"). By regulation, the FDA must first approve the Program before Plaintiffs can import prescription drugs. Plaintiffs submitted the required "SIP proposal" for the Program in November 2020.

9. In the nearly 1,000 days while Florida's SIP proposal has been pending, the FDA has asked for several clarifications and supplements but has not adjudicated the SIP Proposal.

10. Given the delay, AHCA submitted a Freedom of Information Act ("FOIA") request to the FDA in July 2022, *see* 5 U.S.C. § 522, seeking relevant documents about Florida's and other states' SIP proposals ("July 2022 FOIA Request").

11. Plaintiffs filed suit in August 2022 challenging Defendants' failure to respond timely to the July 2022 FOIA Request, and Plaintiffs amended the complaint in that case to include claims under the Administrative Procedure Act for Defendants' failure to adjudicate Florida's SIP Proposal. *See Florida v. FDA*, No. 8:22-cv-1981 (M.D. Fla.). Litigation in that case is still ongoing, and

Defendants have only recently begun producing responses to the July 2022 FOIA Request.

12. In March 2023, AHCA submitted another FOIA request, seeking the same scope of materials as the July 2022 FOIA request but with an updated timeline to cover materials created after the July 2022 FOIA request was submitted ("March 2023 FOIA Request").

13. The FDA has acknowledged receiving the March 2023 FOIA Request but did not respond within FOIA's statutory deadline. Plaintiffs accordingly bring this suit to compel the FDA to respond to the FOIA request and provide the requested documents.

14. After submitting the March 2023 FOIA Request, Plaintiffs proposed to Defendants' counsel that the FDA simply run its same search terms from the July 2022 FOIA Request on the expanded timeline (i.e., rather than stopping the search for documents in existence as of July 2022, it would continue to March 2023), given that the FOIA Requests are otherwise identical and also given that the parties were then negotiating the search terms anyway. This would save party and Court resources. Defendants' counsel refused to agree to that proposal, necessitating this additional lawsuit.

15. On April 21, 2023, Plaintiffs filed this suit.

16. In May 2023, AHCA submitted another FOIA request, seeking the same scope of materials as the July 2022 and March 2023 FOIA requests but

with an updated timeline to cover materials created after those requests were submitted ("May 2023 FOIA Request").

17. The FDA has acknowledged receiving the May 2023 FOIA Request but has not responded within FOIA's statutory deadline. Plaintiffs accordingly amend their complaint to compel the FDA to respond to the May 2023 FOIA Request and provide the requested documents.

PARTIES

18. 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.

19. 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.

20. Defendant Food and Drug Administration is the recipient of the FOIA request at issue in this suit.

21. Defendant Department of Health and Human Services is the parent agency of the Food and Drug Administration.

LEGAL STANDARD

22. 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.

23. 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).

24. 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).

25. 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

26. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 2201.

27. 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).

28. Moreover, this Court already has jurisdiction over the related case *Florida v. FDA*, No. 8:22-cv-1981 (M.D. Fla.).

FACTUAL BACKGROUND

29. On July 6, 2022, AHCA submitted the July 2022 FOIA Request to the FDA. The FDA acknowledged the request on July 7, 2022. 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, but the FDA denied that request on July 20, 2022.

30. Plaintiffs filed suit over the July 2022 FOIA Request in August 2022, *see Florida v. FDA*, No. 8:22-cv-1981 (M.D. Fla.), and the FDA produced its first small production of responsive documents in March 2023. Small

batches of productions, largely redacted, have occurred approximately once per month since then.

31. AHCA submitted the March 2023 FOIA Request on March 21, 2023, and sought expedited processing. *See* Ex. A. The March 2023 FOIA Request is almost identical to the July 2022 FOIA Request but covers records created since July 6, 2022 (i.e., the filing date of the July 2022 FOIA Request). In particular, the March 2023 FOIA Request, like the July 2022 FOIA Request, sought:

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).

32. Given the substantive overlap of the two FOIA requests, and also given that the parties were then negotiating search terms for the July 2022 FOIA Request, Plaintiffs' counsel proposed to Defendants' counsel that the FDA run its search terms for the July 2022 FOIA Request and the March 2023 FOIA Request at the same time, to avoid duplication of efforts. Defendants' counsel rejected that proposal.

33. On March 23, 2023, the FDA acknowledged the March 2023 FOIA Request. Ex. B. And on March 27, 2023, the FDA denied the request for expedited processing. Ex. C.

34. On April 21, 2023, Plaintiffs filed this suit.

35. On May 22, 2023, Plaintiffs submitted the May 2023 FOIA Request. Ex. D. It requested the same records as the March 2023 FOIA Request except covers records created since March 21, 2023 (i.e., the filing date of the

March 2023 FOIA Request), and also sought expedited processing. On May 23, 2023, the FDA acknowledged the May 2023 FOIA Request. Ex. E. And on March 26, 2023, the FDA denied the request for expedited processing. Ex. F.

36. Defendants filed their answer on May 25, 2023. ECF No. 18.

37. More than 20 business days have passed since the FDA acknowledged the March 2023 and May 2023 FOIA Requests. Although the FDA's acknowledgment letters noted that an agency can request an additional 10 business days, the FDA has not actually done so for either Request, and even if such an extension had been requested, it would have expired long ago.

38. To date, the FDA has not provided the required responses to the March 2023 or May 2023 FOIA Requests.

CLAIMS FOR RELIEF

COUNT ONE

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

39. The allegations in paragraphs 1–38 are expressly incorporated herein as if restated in full.

40. The FDA has failed to provide the required responses to the March 2023 and May 2023 FOIA Requests identified above.

41. More than 20 working days have passed since the March 2023 and May 2023 FOIA Requests were received and logged by the FDA.

42. 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).

43. The FDA did not provide a final determination within 20 working days of receiving and logging the March 2023 or May 2023 FOIA Requests, nor has the FDA stated that unusual circumstances exist warranting a 10-day extension. Even if an extension had been requested, it would have long since expired.

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

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

COUNT TWO

(Unlawful Withholding of Agency Records in Violation of FOIA)

46. The allegations in paragraphs 1–38 are expressly incorporated herein as if restated in full.

47. 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).

48. The FDA has neither provided AHCA any responsive documents in response to the March 2023 or May 2023 FOIA Requests, nor has the FDA claimed that responsive records are all exempt from disclosure.

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

COUNT THREE

(Declaratory Judgment)

50. The allegations in paragraphs 1–38 are expressly incorporated herein as if restated in full.

51. For the same reasons described in each of the previous counts, Plaintiffs are entitled to a declaratory judgment that the Defendants have been and are violating the law.

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court:

A. Declare that the FDA failed to make a timely determination on AHCA's March 2023 and May 2023 FOIA Requests, in violation of FOIA, 5 U.S.C. § 552(a)(6)(A)(i);

B. Declare that the FDA failed to promptly provide records responsive to AHCA's March 2023 and May 2023 FOIA Requests, in violation of FOIA, 5 U.S.C. § 552(a)(3);

C. Order the FDA to immediately conduct a reasonable search for all responsive records for the March 2023 and May 2023 FOIA Requests, as required by FOIA, 5 U.S.C. § 552(a)(3)(C);

D. Order the FDA to immediately provide a determination on AHCA's March 2023 and May 2023 FOIA Requests, as required by FOIA, 5 U.S.C. § 552(a)(6)(A)(i);

E. Order the FDA to promptly disclose to AHCA all responsive, non-exempt records for the March 2023 and May 2023 FOIA Requests, as required by FOIA, 5 U.S.C. § 552(a)(3);

F. Award reasonable attorneys' fees and allowable costs, including under 5 U.S.C. § 552(a)(4)(E); and

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

Dated: August 14, 2023

Respectfully submitted,

ASHLEY MOODY
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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2023, 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.

/s/ R. Trent McCotter

R. TRENT MCCOTTER