IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR BIOLOGICAL DIVERSITY,
P.O. Box 710
Tucson, AZ 85702

Plaintiff,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
1200 Pennsylvania Avenue NW
Washington, DC 20460

and

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendants.

Civil Action No.: 19-cv-2656

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

(Freedom of Information Act, 5 U.S.C. § 552)

INTRODUCTION

1. In this action, Plaintiff Center for Biological Diversity ("Center")—an environmental conservation organization that works to protect native wildlife and their habitats—challenges the failure and refusal of Defendants U.S. Environmental Protection Agency ("EPA") and U.S. Food and Drug Administration ("FDA") to provide records to the Center in response to its March 5, 2019 requests under the Freedom of Information Act ("FOIA") for records related to the use of medically important antibiotics as pesticides.

2. The Centers for Disease Control and Prevention ("CDC") has identified the development of antibiotic resistant bacteria as "one of our most serious health threats."[1] The CDC estimates that more than 2 million people are infected with antibiotic-resistant organisms each year—leading to an estimated 23,000 deaths annually—and has recognized the overuse and misuse of antibiotics as the leading cause of antibiotic-resistant bacterial development.[2] Indeed, the CDC has warned that the use of medically important antibiotics for use as pesticides on plants, and specifically the pesticidal uses of oxytetracycline and streptomycin approved by EPA, can facilitate antibiotic resistance development in bacteria that pose "urgent" and "serious" threats to human health.[3]

3. The World Health Organization recognizes streptomycin and oxytetracyline as antibiotics "critically" and "highly" important for human medicine, respectively, and has determined that resistant infections related to these and other medically important antibiotics could cause up to 10 million deaths globally by 2050.[4] Owing to these concerns, the European

[1] CDC, *Antibiotic Resistant Threats in the United States* (2013), *available at* https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf.
[2] *Id.*; CDC, *Antibiotic Resistance Q&As, Questions about Bacteria, Viruses, and Antibiotics* (Sept. 25, 2017), *available at* https://www.cdc.gov/antibiotic-use/community/about/antibiotic-resistance-faqs.html.
[3] CDC, *Report to EPA: Antimicrobial Susceptibility Testing of Human Bacterial Pathogens to Antibiotics Used as Pesticides* (May 11, 2017), *available at* https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/CDC-study-from-FOIA.pdf.
[4] World Health Organization, *Critically Important Antimicrobials for Human Medicin*e, 5th revision (2016), *available at* https://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf;jsessionid=F18E535C3C3C6EE84F4E301EA550C9D1?sequence=1; World Health Organization, *No Time to Wait: Securing the future from drug-resistant infections* (Apr. 2019), *available at* https://www.who.int/antimicrobial-resistance/interagency-coordination-group/final-report/en/.

Union has banned the agricultural uses of both streptomycin[5] and oxytetracycline.[6]

4. The use of the antibiotics as pesticides has also been shown to harm bee species by altering their immune system functions and leading to a greater susceptibility to pathogen infection. Their use may also lead to negative long-term effects on mammals that forage in treated fields.

5. In the United States, approximately 80,000 pounds each of streptomycin and oxytetracycline were used on plants in 2016.[7] Since 2016, these uses are expected to have increased, with studies estimating an increase to more than 388,000 pounds of oxytetracycline used per year alone—130,000 pounds *more* than all annual domestic tetracycline use in human medicine.[8]

6. The Center's FOIA requests seek records of communications between or among EPA's Office of Pesticide Programs, the CDC, and FDA mentioning or including the use of the antibiotics streptomycin, oxytetracycline HCl, and/or oxytetracycline calcium as a pesticide. Defendants' delays in providing records in response to the FOIA requests at issue illegally suspends the disclosure and dissemination of information that is of utmost public interest regarding public health and the environment, and that relates to EPA's authorization of the use of streptomycin, oxytetracycline HCl, and/or oxytetracycline calcium as a pesticide.

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[5] European Union, Pesticide Database, Streptomycin (last updated July 4, 2016), https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1896.
[6] European Union, Pesticide Database, Oxytetracycline (last updated July 4, 2016), https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1651.
[7] Nathan Donley, *The USA lags behind other agricultural nations in banning harmful pesticides*, *Environmental Health* 18:44 (2019), *available at* https://link.springer.com/article/10.1186/s12940-019-0488-0#citeas.
[8] *Id.*

7. Prompt access to public records is necessary to effectuate FOIA's purpose of transparency. The Center thus seeks declaratory relief establishing that EPA and FDA have violated FOIA. The Center also seeks injunctive relief ordering EPA and FDA to provide the Center with all responsive records without further delay.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this matter pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

9. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

10. Declaratory relief is appropriate under 28 U.S.C. § 2201.

11. Injunctive relief is appropriate under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 2202.

PARTIES

12. Plaintiff CENTER FOR BIOLOGICAL DIVERSITY is a national, non-profit conservation organization with offices throughout the United States that works to protect native wildlife species and their habitat, public health, and the environment, including from exposure to harmful chemicals and other pesticides. Informing the public about the activities of the federal government is central to the Center's mission. The Center educates and counsels its members and the public on environmental issues, policies, and laws through media, advocacy, its website, and publications that are widely distributed.

13. The Center and its over 67,000 members are harmed by Defendants' violations of FOIA because such violations preclude the Center from obtaining information about the harmful environmental and human health effects of the use of streptomycin, oxytetracycline HCl,

and/or oxytetracycline calcium as a pesticide, as well as understanding issues associated with the federal government's regulatory approach in allowing the expanded use of streptomycin, oxytetracycline HCl, and/or oxytetracycline calcium as a pesticide.

14. Defendants' failure to comply with FOIA harms the Center's ability to provide full, accurate, and current information to the public on a matter of public interest. Absent this information, the Center cannot advance its mission to protect native species and their habitats, and advocate for steps to reduce threats to public health and the environment.

15. Defendant U.S. ENVIRONMENTAL PROTECTION AGENCY is an independent agency of the U.S. government. EPA is in possession and control of the records that the Center seeks, and, as such, it is subject to FOIA pursuant to 5 U.S.C. § 552(f) and is responsible for fulfilling the Center's FOIA request to it.

16. Defendant U.S. FOOD AND DRUG ADMINISTRATION is an agency of U.S. Department of Health and Human Services of the U.S. government. FDA is in possession and control of the records that the Center seeks, and, as such, it is subject to FOIA pursuant to 5 U.S.C. § 552(f) and is responsible for fulfilling the Center's FOIA request to it.

STATUTORY BACKGROUND

17. FOIA requires agencies of the federal government to release records to the public upon request unless one or more specific statutory exemptions applies. 5 U.S.C. § 552.

18. FOIA places the burden on the federal agency to show that it may withhold responsive records from a requester. *Id.* § 552(a)(4)(B).

19. FOIA imposes strict deadlines on federal agencies to respond to requests. *Id.* § 552(a)(6)(A). Within 20 working days of receiving a request, an agency must gather and review responsive records, determine and communicate the scope of the records it intends to produce or

withhold and the reasons for withholding any records, and provide the right to seek assistance from the FOIA Public Liaison and the right to appeal the agency's determination. *Id.; see also Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188 (D.C. Cir. 2013).

20. In "unusual circumstances," an agency may extend the time to make a determination by no more than 10 additional working days, but it must provide written notice to the requester setting forth the unusual circumstances for the extension and "the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i). If the agency provides written notice that the request cannot be processed within the specified time limit, the agency shall provide "an opportunity to limit the scope of the request so that it may be processed within" the statutory time limit or "an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request," and shall make available its FOIA Public Liaison to "assist in the resolution of any disputes between the requester and the agency." *Id.* § 552(a)(6)(B)(ii).

21. FOIA requires each agency to make reasonable efforts to search for records in a manner that is reasonably calculated to locate records that are responsive to the FOIA request. *Id.* § 552(a)(3)(C)-(D).

22. FOIA requires federal agencies to promptly disclose requested records. *Id.* § 552(a)(3)(A), (a)(6)(C)(i).

23. In certain limited instances, records may be withheld pursuant to nine specific exemptions. *Id.* § 552(b). These exemptions must be narrowly construed in light of FOIA's dominant objective of disclosure, not secrecy.

24. A requester "shall be deemed to have exhausted his [or her] administrative remedies with respect to such request if the agency fails to comply with the acceptable time limit

provisions" of FOIA. *Id.* § 552(a)(6)(C)(i). In that event, FOIA authorizes the requester to immediately seek relief in federal court. *Id.* § 552(a)(4)(B).

25. FOIA provides this Court jurisdiction "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." *Id.* § 552(a)(4)(B).

STATEMENT OF FACTS

A. Request to EPA (EPA-HQ-2019-003972)

26. On March 5, 2019, the Center submitted to EPA a FOIA request seeking the following records:

> From January 1, 2015 to the date EPA conducts this search, the records of communications between EPA Pesticide Program employees and the Center for Disease Control ("CDC") and/or the Food and Drug Administration ("FDA") mentioning or including the use of streptomycin, oxytetracycline HCl, and/or oxytetracycline calcium as a pesticide.

27. On March 5, 2019, EPA sent an automatic acknowledgement of the receipt of the Center's FOIA request and assigned it EPA FOIA Tracking No. EPA-HQ-2019-003972.

28. On March 8, 2019, EPA responded to the Center's request for a fee waiver, stating that there would be no charges associated with processing FOIA request EPA-HQ-2019-003972.

29. On April 1, 2019, EPA wrote to the Center stating:

> The Agency's IT Staff will be conducting an electronic search for emails and records. We are working with the subject matter experts in developing a comprehensive list of staff that could have responsive records. This includes staff that are no longer employed with the Agency. We will provide you an estimated completion date once we know the number of records that must be reviewed for any applicable exemptions under the Freedom of Information Act, prior to being released.

30. On May 6, 2019, the CDC wrote to the Center regarding a separate FOIA request (#19-00531-FOIA) that was submitted to the CDC and that sought records identical to the records requested in the Center's FOIA request to EPA. The CDC stated that it had located records responsive to FOIA request #19-00531-FOIA, but released to the Center only 19 pages of those records and withheld the remainder, which it stated "belong to the U.S. Environmental Protection Agency (EPA)." The CDC provided that, in accordance with Department of Health and Human Services' FOIA implementing regulations, "CDC does not make decisions on the release or denial of other agencies' documents. We have referred these records along with your request to EPA for their release determination and direct reply to you."

31. The 19 pages that were produced by the CDC included a federal study that concluded that the use of streptomycin and oxytetracycline can select for antibiotic-resistant bacteria that pose serious health threats worldwide—including through MRSA (Methicillin-resistant *Staphylococcus aureus*) and nightmare bacteria (Carbapenem-resistant *Enterobacteriaceae* (CRE)).

32. On June 14, 2019, after receiving no further substantive communications from EPA regarding its production of records responsive to this request, the Center sent a letter notifying EPA that it had violated FOIA by failing to make a lawful determination on the Center's FOIA request within FOIA's statutory deadline, offering to assist the agency in responding to the request, and requesting an estimated date of completion of the FOIA request.

33. On August 1, 2019, the Center emailed EPA's FOIA office at the address given by the CDC to follow-up on the status of the records CDC had referred to EPA. The Center requested a tracking number and an estimate for when the records were expected to be released.

34. EPA did not respond to the Center's August 1, 2019 e-mail, and has not provided the Center with any of the records the CDC referred to EPA in response to the Center's FOIA request to the CDC.

35. EPA has not provided the Center with any records responsive to FOIA request EPA-HQ-2019-003972.

36. EPA has not requested additional information from the Center or notified the Center of any unusual circumstances that prevent it from complying with FOIA's deadline for determination. *See* 5 U.S.C. § 552(a)(6)(A)-(B).

37. EPA has no lawful basis under FOIA for its delay and has provided no lawful basis to withhold or redact the records the Center requested in FOIA request EPA-HQ-2019-003972 or referred to EPA by the CDC.

38. The Center has exhausted its administrative remedies with respect to claims related to this FOIA request. *Id*. § 552(a)(6)(C)(i).

39. The Center has been required to expend resources to prosecute this action.

B. <u>Request to FDA (FDA1951292; 2019-2064)</u>

40. On March 5, 2019, the Center submitted to FDA a FOIA request seeking the following records:

> From January 1, 2015 to the date FDA conducts this search, the records of communications between FDA employees and the U.S. Environmental Agency ("EPA") Pesticide Program and/or the Center for Disease Control ("CDC") mentioning or including the use of streptomycin, oxytetracycline HCl, and/or oxytetracycline calcium as a pesticide.

41. On March 5, 2019, FDA sent an automatic acknowledgement of the receipt of the Center's FOIA (Confirmation # FDA1951292) and requested that future correspondence refer to

2019-2064.

42. On March 11, 2019, FDA wrote to the Center stating, "[w]e will respond as soon as possible and may charge you a fee for processing your request."

43. On June 14, 2019, after receiving no further substantive communications from FDA regarding its production of records in response to this request, the Center sent a letter notifying FDA that it had violated FOIA by failing to make a lawful determination on the Center's FOIA request within FOIA's statutory deadline, offering to assist the agency in responding to the request, and requesting an estimated date of completion of the FOIA request.

44. On June 17, 2019, FDA responded to the Center's June 14, 2019 letter with an email stating: "Your request is assigned to [Center for Veterinary Medicine] for processing. FDA processes requests on a first in first out basis and your request has about 100 in front of it, we estimate it to be 18-24 months before a response will be sent."

45. FDA has not provided the Center with any records responsive to FOIA request FDA1951292; 2019-2064.

46. FDA has not requested additional information from the Center or notified the Center of any unusual circumstances that prevent it from complying with FOIA's deadline for determination. *See* 5 U.S.C. § 552(a)(6)(A)-(B).

47. FDA has no lawful basis under FOIA for its delay and has provided no lawful basis to withhold or redact the records the Center requested in FOIA request FDA1951292; 2019-2064.

48. The Center has exhausted its administrative remedies with respect to claims related to this FOIA request. *Id*. § 552(a)(6)(C)(i).

49. The Center has been required to expend resources to prosecute this action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Comply with FOIA's Mandatory Determination Deadline)

50. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

51. The Center properly requested records within the control of EPA through its March 5, 2019 FOIA request to the agency, EPA-HQ-2019-003972.

52. The Center has a statutory right to receive a lawful final determination from EPA on its FOIA Request, EPA-HQ-2019-003972, in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3)(A). EPA has violated the Center's rights in this regard by unlawfully delaying its response beyond the deadline that FOIA mandates. *Id*. § 552(a)(6)(A)(i).

53. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to EPA in the foreseeable future.

54. The Center's organizational activities will be adversely affected if EPA is allowed to continue violating FOIA's disclosure provisions.

55. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, EPA will likely continue violating the Center's rights to receive public records under FOIA.

56. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id*. § 552(a)(4)(E).

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SECOND CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Conduct an Adequate Search for All Responsive Records)

57. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

58. The Center has a statutory right to have EPA process its FOIA request in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3)(A).

59. EPA violated the Center's rights in this regard when it unlawfully failed to conduct an adequate search that was reasonably calculated to locate all records that are responsive to the Center's FOIA request, EPA-HQ-2019-003972.

60. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to EPA in the foreseeable future.

61. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, EPA will likely continue violating the Center's rights to receive public records under FOIA.

62. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id*. § 552(a)(4)(E).

THIRD CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Promptly Disclose All Responsive Records)

63. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

64. The Center has a statutory right to the records that it requested. 5 U.S.C. §

552(a)(3)(A). EPA has violated the Center's rights in this regard by failing to promptly provide all responsive records—and reasonably segregable, nonexempt portions of responsive records—related to FOIA request EPA-HQ-2019-003972.

65. EPA has provided no lawful basis to withhold records pursuant to any of FOIA's nine exemptions to mandatory disclosure or to withhold any segregable, nonexempt portion of the records. *See* 5 U.S.C. § 552(a)(3)(A), (a)(8), (b).

66. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to EPA in the foreseeable future.

67. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, EPA will likely continue violating the Center's rights to receive public records under FOIA.

68. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id.* § 552(a)(4)(E).

FOURTH CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Comply with FOIA's Mandatory Determination Deadline)

69. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

70. The Center properly requested records within the control of FDA through its March 5, 2019 FOIA request to the agency, FDA1951292; 2019-2064.

71. The Center has a statutory right to receive a lawful final determination from FDA on its FOIA Request, FDA1951292; 2019-2064, in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3)(A). FDA has violated the Center's rights in this regard by unlawfully delaying its

response beyond the deadline that FOIA mandates. *Id*. § 552(a)(6)(A)(i).

72. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to FDA in the foreseeable future.

73. The Center's organizational activities will be adversely affected if FDA is allowed to continue violating FOIA's disclosure provisions.

74. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, FDA will likely continue violating the Center's rights to receive public records under FOIA.

75. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id*. § 552(a)(4)(E).

FIFTH CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Conduct an Adequate Search for All Responsive Records)

76. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

77. The Center has a statutory right to have FDA process its FOIA request in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3)(A).

78. FDA violated the Center's rights in this regard when it unlawfully failed to conduct an adequate search that was reasonably calculated to locate all records that are responsive to the Center's FOIA request, FDA1951292; 2019-2064. 5 U.S.C. § 552(a)(3)(C)-(D).

79. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to FDA in the foreseeable future.

80. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, FDA will likely continue violating the Center's rights to receive public records under FOIA.

81. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id.* § 552(a)(4)(E).

SIXTH CLAIM FOR RELIEF:
VIOLATION OF THE FREEDOM OF INFORMATION ACT

(Failure to Promptly Disclose All Responsive Records)

82. Plaintiff re-alleges and incorporates by reference the allegations made in all preceding paragraphs.

83. The Center has a statutory right to the records it requested. 5 U.S.C. § 552(A)(3)(A). FDA has violated the Center's rights in this regard by failing to promptly provide all responsive records—and reasonably segregable, nonexempt portions of responsive records—related to FOIA request FDA1951292; 2019-2064.

84. FDA has provided no lawful basis to withhold records pursuant to any of FOIA's nine exemptions to mandatory disclosure or to withhold any segregable, nonexempt portion of the records. *See* 5 U.S.C. § 552(a)(3)(A), (a)(8), (b).

85. Based on the nature of the Center's organizational activities, it will undoubtedly continue to employ FOIA's provisions in records requests to FDA in the foreseeable future.

86. Unless enjoined and made subject to a declaration of the Center's legal rights by this Court, FDA will likely continue violating the Center's rights to receive public records under FOIA.

87. The Center is entitled to reasonable costs of litigation, including attorney fees, pursuant to FOIA. *Id.* § 552(a)(4)(E).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

(1) Declare that each Defendant violated the Freedom of Information Act by failing to lawfully satisfy Plaintiff's March 5, 2019 FOIA requests;

(2) Order each Defendant to search for all responsive records to Plaintiff's March 5, 2019 FOIA requests using search methods reasonably likely to lead to discovery of all responsive records, with the cut-off date for such searches being the date each agency initiates its search;

(3) Order each Defendant to produce, by a date certain, all nonexempt responsive records and reasonably segregable portions of the records, and a *Vaughn* index of any responsive records or portion of responsive records withheld under a claim of exemption, at no cost to Plaintiff;

(4) Enjoin each Defendant from continuing to withhold nonexempt responsive records or segregable portion of the records responsive to Plaintiff's FOIA requests;

(5) Retain jurisdiction of this action to ensure the lawful processing of Plaintiff's FOIA requests;

(6) Award Plaintiff its costs and reasonable attorneys' fees pursuant to 5 U.S.C. § 552(a)(4)(E) or 28 U.S.C. § 2412; and

(7) Grant any such further relief as the Court may deem just and proper.

Dated this 5th day of September, 2019.

Respectfully submitted,

/s/ *Hannah M.M. Connor*

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