

**UNITED STATES DISTRICT COURT  
DISTRICT OF COLUMBIA**

**CENTER FOR SCIENCE IN THE PUBLIC  
INTEREST,**

1250 I Street NW, Suite 500  
Washington, DC 20005,

Plaintiff,

v.

**U.S. FOOD AND DRUG  
ADMINISTRATION, and**

**ROBERT M. CALIFF**, in his official capacity  
as Commissioner of Food and Drugs,

Defendants.

Case No. 24-1342

**COMPLAINT FOR  
DECLARATORY AND  
INJUNCTIVE RELIEF**

**INTRODUCTION**

1. Plaintiff Center for Science in the Public Interest (“CSPI” or “Plaintiff”) brings this action against the U.S. Food and Drug Administration and Robert M. Califf, Commissioner of Food and Drugs (collectively, “Defendants” or “FDA”).

2. Plaintiff seeks relief from Defendants’ more than three-year delay in responding to a 2021 petition submitted by Plaintiff, six families impacted by contaminated poppy seeds, and two medical experts. CSPI *et al.*, Citizen Petition to Establish a Maximum Limit of Opiate Alkaloid Contamination of Poppy Seeds and Ensure the Safety of Imported Poppy Seeds (Feb. 5, 2021), <https://bit.ly/47iT3jt> (the “Petition”).

3. The Petition urged FDA to, among other things, establish a maximum limit of opiate alkaloid contamination of poppy seeds and set import requirements to ensure that imported seeds do not exceed the maximum threshold.

4. Opiate alkaloids, also known as opiates, such as morphine and codeine, are naturally occurring substances that inhibit the pain pathways of neurons, the functional unit of the nervous system. Opiates are part of the larger class of drugs known as opioids, which includes opiates and synthetic opiate derivatives, such as fentanyl. Opiate alkaloids are an essential pharmaceutical tool in pain management, but their use can lead to a variety of health problems, including overdose resulting in serious injury or death.

5. Setting a maximum limit of opiate alkaloid contamination of poppy seeds is a commonsense step that can help address the health and safety concerns related to the consumption of contaminated poppy seeds.

6. Both opiate alkaloids and poppy seeds originate naturally from the opium poppy plant. The seeds themselves contain no or negligible levels of opiates, but they can be contaminated by plant sap which does contain high levels of opiates. Proper processing and washing of seeds can substantially reduce contamination.

7. Not all manufacturers adequately process their seeds, however, and some sellers even market poppy seeds using terms such as “unwashed” to convey that they have high levels of opiates to consumers.

8. Consumers may purchase contaminated poppy seeds unwittingly or intentionally for intoxication or claimed health benefits. Some may use these seeds for the purpose of brewing poppy seed tea, which increases the extraction of opiates from the seeds.

9. In the United States, there have been hundreds of exposure calls to poison control centers associated with unintentionally consuming contaminated poppy seeds as well as adverse employment and parental custody consequences from positive drug test results.

10. Moreover, there have been numerous serious adverse events associated with intentionally consuming contaminated poppy seeds, including at least 19 fatalities and 20 non-fatal overdoses.

11. An opiate alkaloid limit is necessary to help prevent future injuries, deaths, and other adverse consequences from contaminated seeds.

12. It has been more than three years since Plaintiff petitioned FDA to take action to address the urgent health threats posed by contaminated poppy seeds, but FDA has failed to act.

13. As a result, Plaintiff's members and their children are forced to choose between foregoing poppy seeds or being at risk of suffering adverse consequences after consuming poppy seeds, including intoxication, addiction, and overdose.

14. They also suffer from stress and anxiety knowing that their family members, friends, and the public at large may be seriously harmed as a result of consuming contaminated poppy seeds.

15. To remedy Defendants' years-long unreasonable delay in acting on the Petition, Plaintiff seeks, among other things, an order from this Court directing Defendants to make a final and definitive decision granting or denying the Petition within sixty days.

#### **JURISDICTION AND VENUE**

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action is a civil action arising under the laws of the United States.

17. Venue properly lies in this Court pursuant to, *inter alia*, 28 U.S.C. § 1391(e)(1)(C) because Plaintiff has its principal place of business in this judicial district.

## PARTIES

18. Plaintiff CSPI is a non-profit, public interest organization headquartered in Washington, D.C., which has worked since 1971 to improve the public's health through better nutrition, safer food, and transparent food labeling. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that foods are safe.

19. CSPI is supported by grants from foundations and its more than 235,000 members, including donors and/or individuals who receive its health and nutrition newsletter, *Nutrition Action*, which is received as a CSPI membership benefit. Through its newsletter and online communications, CSPI engages with its members, who provide a substantial portion of the organization's annual financial support and help shape its priorities.

20. As part of its broader mission, CSPI engages in public education and advocacy related to food safety. This body of work includes developing and disseminating information to CSPI's members regarding the health and safety risks posed by contaminated poppy seeds.

21. CSPI also engages in advocacy urging Defendants and Congress to set a maximum threshold for opiate contamination in poppy seeds.

22. As part of those efforts, among other activities, CSPI has:

- a. Funded and co-authored a study to document adverse events in the United States associated with contaminated poppy seeds, *see* Eva Greenthal *et al.*, *Opioid Exposure Associated with Poppy Consumption Reported to Poison Control Centers and the U.S. Food and Drug Administration*, 59 *Clinical Toxicology* 746 (Jan. 12, 2021), <https://bit.ly/45Wv4pd>;

- b. Championed federal legislation, the Stephen Hacala Poppy Seed Safety Act, that directs FDA to set limits on opioid contamination in poppy seeds. The bill is named after Stephen Hacala, who died in 2016 as the result of a poppy seed tea overdose, *see CSPI, Bill To Protect the Public from Contaminated Poppy Seeds Introduced* (Nov. 29, 2023), <https://bit.ly/4abOqd0>; and
  - c. Produced an educational video on contaminated poppy seeds, featuring Stephen Hacala's parents, Steve and Betty Hacala, who are CSPI members who joined the Petition, *see CSPI, Poppy Seeds*, <https://bit.ly/49j4qso>.
23. CSPI was a petitioner in the Petition at issue in this case.
24. Plaintiff has members who have been harmed by Defendants' delay in acting on the Petition and will continue to be harmed so long as Defendants withhold a decision.
25. Plaintiff's members and their immediate families are forced to choose between foregoing poppy seeds or being exposed to dangerous levels of opiate alkaloids when they consume poppy seeds.
26. They also suffer from stress and anxiety knowing that their family members, friends, and the public at large may be seriously harmed as a result of consuming contaminated poppy seeds.
27. For example, Steve and Betty Hacala, who have been CSPI members and donors since 2019, are the parents of Stephen Hacala, who passed away in 2016 at the age of 24 from morphine intoxication from drinking poppy seed tea.
28. Prior to Stephen's death, he ordered a five-pound bag of poppy seeds online, rinsed them with water, and ingested the rinse. It appears that Stephen was not aware that the seeds' coats were contaminated with a lethal amount of opiates.

29. Stephen had told Ms. Hacala a few weeks before his death that he was having trouble with insomnia and anxiety. Numerous online websites had promoted poppy seed tea as a natural remedy for these and other health issues.

30. Following Stephen's death, Mr. and Ms. Hacala have worked directly with and financially supported CSPI to raise awareness of the dangers of unprocessed poppy seeds and to advocate for changes in policy, control, and enforcement to stop the unlawful and dangerous importation and distribution of contaminated poppy seeds.

31. With their knowledge of the dangers of consuming contaminated poppy seeds, Ms. Hacala avoids poppy seeds entirely in foods, drinks (such as smoothies), and even spices, and Mr. Hacala largely avoids poppy seeds too. While he continues to occasionally eat toasted "everything" bagels because the quantity of seeds is small and he believes the presence of the seeds on the outside of the bagel allows any opiate contamination to be minimized in the baking and toasting process, he avoids other foods, drinks, and spices containing poppy seeds, especially where he does not believe that the processing methods used would eliminate opiate contamination, such as when the poppy seeds are in the interior of the product and would be exposed to less heat.

32. To avoid consuming potentially contaminated poppy seeds, Ms. Hacala must closely read the labels of any items she purchases from the grocery store, Mr. and Ms. Hacala avoid foods and drinks at restaurants that they know contain poppy seeds, and they need to ask whether items at restaurants contain poppy seeds when it is unclear. When foods and drinks contain poppy seeds or they are unable to determine the ingredients of foods and drinks, they both forego such food and drink items that they would otherwise enjoy.

33. Thus, in the absence of FDA action, Mr. and Ms. Hacala must choose between largely or entirely foregoing poppy seeds or putting their health at risk.

34. The Hacalas also suffer from stress and anxiety knowing that their friends, family members, and the general public may be injured from consuming contaminated poppy seeds.

35. They try to educate their friends and family about the risk of contaminated poppy seeds, but they live in nearly constant fear that other families will suffer from a preventable tragedy as the result of FDA's failure to act.

36. These are actual and concrete injuries that are traceable to Defendants' failure to act on the Petition. If Defendants are required to act and make a final decision granting the Petition, Plaintiff's members and supporters could eat poppy seeds without the risk of suffering adverse events. Alternatively, even if FDA made a final decision denying the Petition, that would allow Plaintiff to pursue remedies before the agency and in the courts that are not available so long as Defendants withhold a final decision.

37. Defendant FDA is the federal agency charged with implementing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, including its provisions to ensure food safety.

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

### **LEGAL BACKGROUND**

39. FDA has legal authority to issue regulations to control poppy seed contamination.

40. FDA's authority to regulate contaminated poppy seeds derives from 21 U.S.C. §§ 331 and 342(a), which prohibit the sale of adulterated food and define a food as "adulterated" if, among other things, it:

contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health . . . .

21 U.S.C. § 342(a)(1).

41. Among other reasons, opiate alkaloids are a “substance” “added” to poppy seeds because they are not naturally present in the seeds themselves. Instead, their presence on poppy seeds is the result of contamination that occurs during harvesting or processing. *See infra* Factual Background, Section II.

42. This commonsense interpretation of the term “added substance” has received significant support from the U.S. Department of Agriculture (“USDA”), which recently issued a proposed threshold for *Salmonella* in raw stuffed poultry products. As the basis for that proposal, the agency said it had tentatively concluded that *Salmonella* is an added substance in such products because it is not ordinarily found in the muscle of live birds and only contaminates the edible muscle tissue during processing. 88 Fed. Reg. 26,249. 26,260 (Apr. 28, 2023), <https://bit.ly/3FOcS6w>.

43. Opiate alkaloid contaminated poppy seeds are thus adulterated if they “may [be] injurious to health.”

44. That safety standard is easily satisfied where the quantity of opiates in poppy seeds is such that consumers could experience effects from opiate alkaloids while consuming poppy seeds.

45. That safety standard is currently far exceeded by poppy seeds in the marketplace. As discussed below, consumers can easily exceed the acute reference dose (“ARfD”) for opiate alkaloids (*i.e.*, the dose at which a person would not be expected to experience effects when



consumed at one time) by consuming common baked goods manufactured with contaminated poppy seeds. *See infra* Factual Background, Sections I, III.

46. More, there have been hundreds of exposure calls to poison control centers associated with the unintentional consumption of contaminated poppy seeds and numerous serious adverse events associated with the intentional consumption of contaminated poppy seeds, including 19 fatal and 20 non-fatal overdoses. *See infra* Factual Background, Section III.

47. Finally, FDA has general authority to issue regulations to prevent the sale of imported adulterated seeds under 21 U.S.C. § 371(a), which authorizes the agency to “promulgate regulations for the efficient enforcement” of the FDCA, 21 U.S.C. § 384a, which requires importers to perform risk-based foreign supplier verification activities for the purpose of ensuring the safety of imported food, and 21 U.S.C. § 381, which authorizes FDA to sample imported foods and “refuse[] admission” of imported foods that “appear[]” to be adulterated.

## FACTUAL BACKGROUND

### I. Opiate Alkaloids

48. Opiate alkaloids, such as morphine and codeine, have substantial analgesic effects and are an essential pharmaceutical tool in pain management. But, they also can produce euphoria and other unwanted effects, including nausea, sedation, respiratory depression, slow heart rate, and constipation. *Opioid Basics: Prescription Opioids*, Centers for Disease Control and Prevention (“CDC”) (Aug. 29, 2017), <https://bit.ly/3JbC4WD>; *Opioid Basics: Commonly Used Terms*, CDC (Jan. 26, 2021), <https://bit.ly/4aq9P2c>.

49. Their use can lead to addiction and the corresponding psychological and social ramifications, a variety of health problems, and overdose resulting in serious injury or death. *Opioid Basics: Prescription Opioids*, CDC (Aug. 29, 2017).

50. Consequently, the Drug Enforcement Administration (“DEA”) lists specific opioids as Schedule II controlled substances. DEA, Controlled Substances by CSA Schedule (Apr. 24, 2024), <https://bit.ly/3QEXdNI>.

51. The lethal dose of opiates is difficult to accurately estimate, due in part to differences in individual tolerance. Deborah Powers *et al.*, *Quantification of Morphine, Codeine, and Thebaine in Home-Brewed Poppy Seed Tea by LC-MS/MS*, 63 J. Forensic Sci. 1229, 1229 (Oct. 3, 2017), <https://bit.ly/40nEzfX>.

52. In general, any increase in daily prescription dose raises the risk of overdose. While there is no bright-line cutoff for overdose or mortality, according to CDC, even “relatively low dosages” of 20–50 mg of morphine equivalents per day increase the risk of overdose and death. CDC, Calculating Total Daily Dose of Opioids for Safer Dosage, <https://bit.ly/3sgmOCU> (last visited May 1, 2024); *see also* Department of Health and Human Services (“HHS”), Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors (2020), <https://bit.ly/3Owhwul> (“Morphine equivalents” are a measure of opiate alkaloids converted to an equivalent level of morphine (*e.g.*, 10 mg of codeine is equivalent to 1.5 mg of morphine)).

53. Based on the overdose risk, CDC recommends that physicians “avoid or carefully” justify prescriptions of over 90 mg of morphine equivalents per day. CDC, Calculating Total Daily Dose of Opioids for Safer Dosage, <https://bit.ly/3sgmOCU> (last visited May 1, 2024).

54. The ARfD for opiates is considerably lower.

55. The European Food Safety Authority (“EFSA”) has established an ARfD of 10 mcg of morphine equivalents/kg body weight per day. This ARfD was in part based on the lowest known single oral therapeutic dose of morphine for pain (1.9 mg for an adult weighing 60

kg) with an uncertainty factor of three applied. EFSA Panel on Contaminants in the Food Chain, *Scientific Opinion on the Risks for Public Health Related to the Presence of Opium Alkaloids in Poppy Seeds*, 9 EFSA J. 1, 1 (2011), <https://bit.ly/43SGhYx>.

56. For a 70-kg or approximately 154-pound adult, the ARfD is only 0.7 mg of morphine equivalents. EFSA Panel on Contaminants in the Food Chain, *Update of the Scientific Opinion on Opium Alkaloids in Poppy Seeds*, 16 EFSA J. 1, 1 (May 16, 2018), <https://bit.ly/3St2xVh>.

## **II. Poppy Seed Contamination with Opiate Alkaloids**

57. Poppy seeds originate from the opium poppy, a plant which can produce substantial amounts of naturally occurring opiates, including morphine and codeine. *Id.* at 3.

58. There is a wide variety of cultivars of the plant, some grown for primarily pharmaceutical purposes (*i.e.*, to produce opiates) and some grown for the seeds themselves (*i.e.*, to produce food and oil). *Id.*

59. Opiate alkaloids are found in the latex (milky sap) that permeates all parts of the plant other than the seeds, which consequently either contain negligible amounts, or are free, of opiate alkaloids. *Id.* at 15.

60. The seeds, however, can become contaminated with the latex, and thus with opiates, if the seed capsule is damaged or if dust or other plant parts coat the seeds during processing. *Id.*

61. The risk of contaminating poppy seeds with high levels of opiate alkaloids before they reach the consumer can be largely mitigated through appropriate preventive controls by producers, such as selecting seeds from varieties bred to contain a low level of opiate alkaloids, using harvesting technology to minimize damage to the seed pods, and washing and baking seeds

post-harvest. European Commission, Commission Recommendation of 10 September 2014 on Good Practices to Prevent and to Reduce the Presence of Opium Alkaloids in Poppy Seeds and Poppy Seed Products, 662 Official J. EU 96 (Dec. 9, 2014), <https://bit.ly/3sgGjLs>.

### **III. The Public Health Harms of Consuming Contaminated Poppy Seeds**

62. High concentrations of opiates in contaminated poppy seeds lead to the potential for ingestion of therapeutic or even toxic doses. In the United States, there are two somewhat distinct concerns in the market for poppy seeds: manufacturers selling intentionally contaminated seeds and manufacturers selling unintentionally contaminated seeds.

#### **A. Intentionally Contaminated Poppy Seeds**

63. Of significant public health concern, some manufacturers and retailers appear to intentionally produce and market heavily contaminated poppy seeds.

64. While not explicitly indicating the levels of opiate contamination in the labeling or advertising of their products, they may use specific language such as “raw,” “unprocessed,” or “unwashed” to signal that their products contain higher concentrations of opiates than properly processed seeds. *See, e.g.*, DEA, Unwashed Poppy Seeds (Nov. 2019), <https://bit.ly/4a4nETt>.

65. As one indicia of the scope of this problem, the Department of Justice is currently prosecuting the owners of a company, Lone Goose Bakery, for selling unwashed poppy seeds in violation of the Controlled Substances Act. *US v. McCarthy*, 23-cr-00359 (N.D. Okla., Nov. 7, 2023).

66. According to the *McCarthy* Summons, the company sold \$12.5 million dollars in unwashed poppy seeds between 2017 and 2020 and, in 2020 alone, fulfilled 46,000 orders for its unwashed poppy seed product. Summons ¶¶ 39, 42, *US v. McCarthy*, 23-cr-00359, ECF No. 2;

*see also* DEA, Unwashed Poppy Seeds (Nov. 2019) (concluding that poppy seeds contaminated with opiate alkaloids are Schedule II controlled substances).

67. Consumers may purchase such products unwittingly or intentionally for intoxication or claimed health benefits, including the treatment of pain, anxiety, and opioid withdrawal.

68. Even those consumers intentionally purchasing poppy seed for intoxication may not be aware that the effects of the poppy seeds are due to opioids and, in any event, would have no way of knowing the amount of opioids consumed, which can vary widely from batch to batch. Powers *et al.*, *Quantification of Morphine, Codeine, and Thebaine in Home-Brewed Poppy Seed Tea by LC-MS/MS*, 63 J. Forensic Sci. 1229, 1235 (2017).

69. Some may use these seeds for the purpose of brewing poppy seed tea, which increases the extraction of opiates from the seeds, increasing the risks of consumption of poppy seeds. *Id.*

70. Standard recipes for poppy seed tea can rely on substantial quantities of seeds for opiate extraction. For example, [chewtheworld.com](http://chewtheworld.com), a food and cooking website, currently offers instructions on how to brew 300 g of poppy seeds in 400 ml of water. Paula Hughes, *How To Make Poppy Seed Tea Recipe The Right Way: Check It Here*, Chew the World (Jul. 29, 2019), <https://bit.ly/3MryBVN>.

71. A 2017 study, conducted in response to two fatalities associated with poppy seed tea consumption, brewed tea with samples of poppy seeds purchased online from 22 different vendors and analyzed their opiate alkaloid content. Researchers found that producing a poppy seed tea with 1 kg (2.2 lbs.) of seeds yielded as high as 2,788 mg of morphine. Powers *et al.*,

*Quantification of Morphine, Codeine, and Thebaine in Home-Brewed Poppy Seed Tea by LC-MS/MS*, 63 J. Forensic Sci. 1229, 1235 (2017).

72. Using that 2,788 mg per 1 kg figure, brewing 300 g of seeds, per the chewtheworld.com recipe, could yield 836.4 mg of morphine, well above a potentially lethal dose.

73. Eva Greenthal and Dr. Peter Lurie, respectively CSPI's Senior Policy Scientist and CSPI's Executive Director, together with a researcher from the Connecticut Poison Control Center, published a study in *Clinical Toxicology* in 2021 seeking to document the harm caused by opiate-contaminated poppy seeds.

74. Utilizing medical and government publications, the study identified nearly 600 reported adverse events including 18 non-fatal overdoses and 19 fatalities attributed to poppy in the United States, with most fatalities having occurred since 2016. Eva Greenthal *et al.*, *Opioid Exposure Associated with Poppy Consumption Reported to Poison Control Centers and the U.S. Food and Drug Administration*, 58 *Clinical Toxicology* 746 (Jan. 12, 2021).

75. An additional two non-fatal overdoses, not included in the above study, were documented in medical literature. See Meghan B. Spyres *et al.*, *Two Cases of Severe Opiate Toxicity After Ingestion of Poppy Seed Tea*, 2 *Toxicology Communications* 102 (2018), <https://bit.ly/3xtnerM>.

76. Those fatalities and overdoses are likely a significant undercount due to inconsistency and underreporting in publicly available resources. Eva Greenthal *et al.*, *Opioid Exposure Associated with Poppy Consumption Reported to Poison Control Centers and the U.S. Food and Drug Administration*, 58 *Clinical Toxicology* 746, 754 (Jan. 12, 2021).

77. Several family members of individuals who died or suffered significant adverse health consequences from consuming contaminated poppy seeds joined the Petition.

78. In addition to Steve and Betty Hacala, the Petition was joined by Linda Golden and Jeffery Folds, the mother and cousin of Todd Shirley, who passed away at age 48 in 2019 due to poppy seed tea overdose; Bob and Lori Morales, and Kristen Harris, the parents and wife of Kendall Harris, who passed away at age 38 due to overdose from unwashed poppy seeds; and Paul Lancia, whose wife suffered strokes that her doctor suspected were caused by heavy poppy tea consumption. *See* Petition at 8–11.

### **B. Unintentionally Contaminated Poppy Seeds**

79. In the absence of proper controls, manufacturers may also inadvertently or negligently produce contaminated poppy seeds that enter the United States' market for more typical applications, such as for baked goods.

80. For example, between 2012 and 2017, EFSA collected and tested 1,164 poppy seed samples from 10 countries and detected morphine contamination levels of a mean of 57.8 mg/kg and a maximum of 596 mg/kg. EFSA Panel on Contaminants in the Food Chain, *Update of the Scientific Opinion on Opium Alkaloids in Poppy Seeds*, 16 EFSA J. 1, 55-56, tbl. 9 (May 16, 2018). Although the study did not distinguish between intentionally and unintentionally contaminated poppy seeds, the sample size suggests that the scope of the problem far exceeds those manufacturers that purposefully sell contaminated seeds.

81. These are significant amounts of morphine contamination.

82. When incorporated into baked goods, there is some evidence that opiate concentrations are not impacted by the food preparation process (*e.g.*, while baked in an oven). *See* Shalaka A. Shetge, *Concentrations of the Opium Alkaloids Morphine, Codeine, and*

*Thebaine in Poppy Seeds Are Reduced after Thermal and Washing Treatments but Are Not Affected When Incorporated in a Model Baked Product*, 68 J. Agricultural Food Chemistry 5241 (Apr. 27, 2020), <https://bit.ly/3UqWL7J>.

83. Assuming opiate concentrations are not impacted by food preparation, at the mean morphine concentration (57.8 mg/kg), a 70-kg or approximately 154-pound adult would only need to consume 12 grams (or about one and a half tablespoons) of poppy seeds to reach the ARfD for morphine. See EFSA Panel on Contaminants in the Food Chain, *Scientific Opinion on the Risks for Public Health Related to the Presence of Opium Alkaloids in Poppy Seeds*, 9 EFSA J. 1, 1 (2011); see also USDA, FoodData Central: Spices, Poppy Seed (Apr. 2018), <https://bit.ly/3TeqMyH>.

84. Indeed, the Greenthal study discussed above, *see supra* Factual Background, Section III(A), documented hundreds of exposure calls to poison control centers associated with the unintentional consumption of contaminated poppy seeds. Eva Greenthal *et al.*, *Opioid Exposure Associated with Poppy Consumption Reported to Poison Control Centers and the U.S. Food and Drug Administration*, 58 Clinical Toxicology 746, 749 (Jan. 12, 2021).

85. In addition to the risks of clinical effects these seeds present, the consumption of contaminated poppy seeds also poses a risk for exceeding drug testing thresholds, even in the amounts found on some common popular baked goods.

86. For example, a 2015 study found morphine concentrations as high as 1,408 ng/ml in urine samples two hours after study participants ingested a Ukrainian-style poppy seed roll prepared from approximately 15 g (almost two tablespoons) of seeds purchased from a Kansas spice market. Kimberly Samano *et al.*, *Concentrations of Morphine and Codeine in Paired Oral*



*Fluid and Urine Specimens Following Ingestion of a Poppy Seed Roll and Raw Poppy Seeds*, 39 J. Analytical Toxicology 655, tbl. I (Oct. 2015), <https://bit.ly/3wgq1nS>.

87. This approaches the federal workplace drug testing cutoff of 2,000 ng/ml morphine in urine established by HHS in 1998 and exceeds the previous federally mandated cutoff of 300 ng/ml, which some non-federal workplaces and hospitals may still use. *Id.* at 655 & tbl. I; Rachel Rettner. *How Does a Poppy Seed Bagel Trigger a Positive Drug Test?*, Live Science (Aug. 9, 2018), <https://bit.ly/40q544K>.

88. The negative social and economic (including loss of parental custody and employment) consequences of a failed drug test can be significant.

89. Hospitals in some jurisdictions routinely administer urine drug tests to women in labor, and media accounts have documented that mothers have been separated from their newborn infants as a result of testing positive on their urine samples on the day of delivery following consumption of poppy seed-containing baked goods, often at institutions which still use the 300 ng/ml threshold. Rettner, *How Does a Poppy Seed Bagel Trigger a Positive Drug Test?*, Live Science (Aug. 9, 2018); Michael Brice-Saddler, *A Mother Briefly Lost Her Newborn After Failing a Drug Test. Her Doctor Suspects Poppy Seeds*, Seattle Times (Feb. 4, 2020), <https://bit.ly/49vnZiG>.

90. For example, Jamie Silakowski, who joined the Petition, consented to a drug test prior to delivering her son in 2018 and tested positive for morphine. Although Ms. Silakowski had not used opioids during her pregnancy and her baby tested negative, a Child Protective Services case was opened by the hospital, initially preventing her from leaving the hospital with her son. After receiving the positive test results, Ms. Silakowski recalled that she had eaten lemon poppy seed bread before heading to the hospital. As a result of her positive test, Child

Protective Services made house visits, interviewed Ms. Silakowski's two daughters, and visited their school. Ms. Silakowski also underwent drug counseling and testing, paying for it all herself. *See* Petition at 8–11.

91. Mark and Elizabeth Dominguez, who also joined the Petition, had a similar harrowing experience after Ms. Dominguez tested positive for morphine on a drug test administered prior to giving birth. She attributed the positive test to an “everything” bagel she consumed earlier that day. *Id.*

92. Positive drug tests conducted following consumption of poppy-containing baked goods could also result in issues with employment, parole requirements, or other social or economic engagements that require this testing.

#### **IV. The Petition and the Response**

93. On February 5, 2021, CSPI, six families impacted by contaminated poppy seeds, and two medical experts, submitted the Petition to FDA.

94. The Petition requested that the agency establish a safe threshold for opiate contamination in poppy seeds to draw a clear and unambiguous line between seeds that are safe for use in food and those that are dangerously contaminated.

95. The Petition also requested that FDA set import requirements, conduct testing, and issue an import alert to ensure that imported seeds do not exceed the maximum threshold.

96. More than three years have passed since the Petition was filed, but FDA has yet to provide a final response. The agency acknowledged receipt of the petition on February 8, 2021, and on July 16, 2021, provided an interim response advising that it had not reached a decision on the Petition because of other agency priorities and limited resources. Letter from Mark A.

Moorman, Director, Office of Food and Safety, FDA to CSPI (Jul. 16, 2021),

<https://bit.ly/3FGSvrZ>.

97. The Petition has garnered significant public support. For example, of the approximately 3,312 comments on the docket, 3,288 comments are from individual consumers who submitted a form comment developed by CSPI raising concerns about consuming contaminated poppy seeds. FDA, Non-Rulemaking Docket, FDA-2021-P-0168,

<https://bit.ly/3SrXl3Y>.

98. The Petition has also received significant governmental support:

- a. On March 3, 2021, the State of Arkansas passed a Referendum (HCR1010) supporting the Petition, a copy of which was submitted by CSPI to the Petition docket, *see* FDA, Comment Letter on Petition from CSPI, Ex. A (Feb. 9, 2022), <https://bit.ly/3UpRjQZ>;
- b. On March 25, 2021, Senators John Boozman, Tom Cotton, and Richard Blumenthal also submitted a letter to FDA expressing support for the Petition and urging the agency to take clear, decisive action to address this risk to consumers, *see* FDA, Comment Letter on Petition from Senator Cotton, Senator Boozman, and Senator Blumenthal (Mar. 31, 2021), <https://bit.ly/3QlvBLK>; and
- c. The House Committee on Appropriations directed FDA to take the actions requested in the Petition in a 2022 report accompanying an appropriations bill. Specifically, that report stated, “[t]he Committee is concerned with reports of positive drug tests, addiction, overdose, and death related to contaminated imported poppy seeds, and directs the agency to establish a maximum

permissible threshold of opiate alkaloid content for poppy seeds and carry out appropriate regulatory or enforcement measures to ensure the safety of poppy seeds,” *see* Report on the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2022, H.R. Rep. No. 117-82 at 102 (2021), <https://bit.ly/4614xXQ>.

99. The Stephen Hacala Poppy Seed Safety Act, that directs FDA to set limits on opioid contamination in poppy seeds, has likewise received significant support.

100. The Attorneys General of 13 states signed a letter of support for the Act, urging Congressional leadership to pass the law to “protect [their] States’ citizens from deadly narcotics marketed under the guise of unassuming poppy seeds” and chastising FDA for “drag[ging] its feet.” Letter from Tim Griffen, Arkansas Attorney General *et al.*, to Congressional Leadership (Feb. 21, 2024), <https://bit.ly/3Jex4jW>.

101. To address the concerns raised in the Petition (although not in direct response to it), in December 2021, the European Union enacted a regulation setting a maximum opiate limit of 20 mg/kg in poppy seeds and 1.5 mg/kg in products derived from poppy seeds. Commission Regulation 2021/2142, 2021 O.J. (L. 433) (EC), <https://bit.ly/3TIgBJE>.

102. Despite the urgent public need, the overwhelming public support, and the adoption of a poppy seed contamination threshold by the European Union, FDA has not provided a substantive response to the Petition in over three years.

### **CLAIM FOR RELIEF**

103. Plaintiff incorporates by reference and re-alleges all allegations set forth in the preceding paragraphs.

104. The Administrative Procedure Act (“APA”) requires that an agency “shall . . . conclude a matter presented to it” “within a reasonable time,” 5 U.S.C. § 555(b), and the reviewing court “shall . . . compel agency action . . . unreasonably delayed,” *id.* § 706(1).

105. Over three years have passed since Plaintiff filed the Petition, yet Defendants failed to issue a final decision granting or denying the Petition.

106. As a result, Plaintiff’s members and supporters and the public at large have had to either forego poppy seeds or have suffered years of unnecessary exposure to foods that are contaminated with dangerous levels of opiate alkaloids.

107. They also suffer from stress and anxiety knowing that their family members, friends, and the public at large may be seriously harmed as a result of consuming contaminated poppy seeds.

108. Defendants have provided no public justification for their failure to act on this urgent public health problem. Defendants’ years-long delay in issuing a decision on the Petition is unreasonable, violates the APA, and warrants relief from this Court. 5 U.S.C. §§ 555(b), 706(1).

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that the Court:

A. Declare that Defendants’ failure to act on the Petition constitutes “unreasonabl[e] delay[.]” in violation of the APA, 5 U.S.C. §§ 555(b), 706(1);

B. Order Defendants to issue a final and definitive decision granting or denying the Petition within 60 days of the Court’s order;

C. Declare that, in the case of a grant of the Petition, to satisfy its obligation to issue a final and definitive decision on the Petition, FDA must issue at the same time as the issuance of

that decision a proposed rule setting a maximum limit of opiate alkaloid contamination of poppy seeds;

- D. Award Plaintiff reasonable attorneys' fees and costs under 28 U.S.C. § 2412; and
- E. Grant such further relief as this Court may deem just and proper.

Date: May 8, 2024

Respectfully submitted,

By: /s/ Lisa S. Mankofsky  
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