

## **Citizen Petition**

February 5, 2021

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

Re: Citizen Petition to establish a maximum limit of opiate alkaloid contamination of poppy seeds and ensure the safety of imported poppy seeds.

To Whom It May Concern,

The undersigned respectfully submit this Citizen Petition pursuant to 5 U.S.C. § 553(e); 21 U.S.C. §§ 342(a), 350g, 371, 384a; and 21 C.F.R. § 10.30, to reduce consumer exposure to opiates through contaminated poppy seeds.

Consumption of opiate alkaloid contaminated poppy seeds poses a substantial public health threat that has been overlooked as a component of the larger opioid epidemic. We respectfully request that the Commissioner of Food and Drugs issue regulations and guidance establishing a maximum limit of opiate alkaloid contamination of poppy seeds, as well as issue an import alert and take other necessary actions to ensure the safety of imported poppy seeds.

### **I. Actions Requested**

The undersigned request that the Commissioner of the Food and Drug Administration coordinate with the Drug Enforcement Agency (DEA) and Customs and Border Protection (CBP) to:

1. Issue regulations and guidance establishing a maximum permissible threshold of opiate alkaloid contamination of poppy seeds sold in the United States and describing current good manufacturing practices to reduce the presence of opiate alkaloids in poppy seeds; and
2. Issue import requirements and conduct testing of imports to ensure the safety of imported seeds, including an import alert specifying steps to ensure that imported seeds do not exceed the maximum threshold of opiate alkaloid contamination.

## II. Statement of Grounds

### A. Poppy Seeds Can Be Contaminated with Substantial Amounts of Opiate Alkaloids, a Controlled Substance

Poppy seeds originate from the opium poppy, *Papaver somniferum*, a plant which can produce substantial amounts of naturally occurring opioids called opiate alkaloids including morphine, codeine, and thebaine.<sup>1</sup> There is a wide variety of cultivars of the plant, some grown for primarily pharmaceutical purposes (for which the edible seeds are a byproduct) and, in some cases, specifically for the production of the seeds themselves for food and oil.<sup>2</sup> 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.<sup>3,4</sup> The seeds, however, can become contaminated with the latex, and thus opiate alkaloids, if the seed capsule is damaged or if dust or other plant parts coat the seeds during processing.<sup>5,6</sup> For this reason, producers who grow *Papaver somniferum* primarily for seed production may use “low morphine” cultivars, though there is no generally defined delineation between the opiate alkaloid content of these cultivars and others.<sup>7</sup>

Opiate alkaloids work to inhibit neuronal pain pathways and have substantial analgesic effects, but also can produce euphoria and other potentially unwanted effects including nausea, sedation, respiratory depression, slow heart rate, and constipation.<sup>8,9</sup> Long-term users of opioids may experience quickly increasing tolerance for their analgesic effects, with a slower development of tolerance to the other potentially harmful effects.<sup>10</sup> Their use can lead to addiction and the corresponding psychological and social ramifications, as well as a variety of other health problems, and overdose resulting in serious injury or death, often due to respiratory depression.<sup>11</sup> The risk of overdose death from opioids can be compounded with the concurrent usage of other substances, especially benzodiazepines (benzodiazepines can also cause respiratory depression).<sup>12,13</sup>

Consequently, the DEA lists specific opioids including morphine, codeine, and thebaine, as well as “poppy straw” and “poppy straw concentrate,” as Schedule II controlled substances with “high potential for abuse which may lead to severe psychological or physical dependence.”<sup>14,15</sup>

Notably, the United States banned domestic cultivation of *Papaver somniferum* in the Opium Poppy Control Act of 1942, and trade agreements further limit cultivation of the poppy plant to certain countries.<sup>16,17</sup> Thus, the legal domestic supply of poppy seeds is from trade, with Spain, Turkey, Hungary, France, the United Kingdom, Canada, India, Austria, Poland, the Netherlands, and Germany serving as the top exporters of seeds to the United States in 2019.<sup>18</sup>

Appropriate preventive controls such as washing the seeds during processing can reduce the presence of opiate alkaloids in poppy seeds to safe levels (discussed *infra*). Processors, however, may not adhere to strict controls, and, in addition, there may be wide-ranging differences in plant opiate alkaloid concentrations depending on plant varietal and growth environment.<sup>19,20,21</sup> While concentrations of individual opiate alkaloids in contaminated seeds can vary by batch, morphine is generally found in the highest concentrations.<sup>22,23</sup>

Between 2012 and 2017, the European Food Safety Authority (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, a median of 13.6 mg/kg, a 95<sup>th</sup> percentile of 253 mg/kg, and a maximum of 596 mg/kg.<sup>24</sup> Lopez analyzed 32 retail samples of blue poppy seeds bought in the Netherlands, Germany, and Italy and found morphine concentrations ranging from 0.2 mg/kg to 241 mg/kg, with a mean and median concentrations of 39.4 and 6.7 mg/kg morphine, respectively.<sup>25</sup> Another study from 2020 found that purchased seeds in the United Kingdom that originated from at least 4 different countries had morphine concentrations ranging from undetectable to 64 mg/kg.<sup>26</sup>

## **B. Contaminated Poppy Seeds Pose a Significant Risk to Public Health**

High concentrations of opiate alkaloids in contaminated poppy seeds lead to the potential for ingestion of therapeutic or toxic doses. In 2011, the EFSA established an acute reference dose of 10 mcg/kg body weight per day (0.7 mg for a 70 kg adult), the equivalent of “the dose of morphine from poppy seed-containing foods for which a person would not be expected to experience effects following consumption of one meal or total consumption within one day.”<sup>27</sup> This acute reference dose was in part based on the lowest known single oral therapeutic dose of 30 mcg/kg body weight (2.1 mg for a 70 kg adult, or 3 times the acute reference dose) with an uncertainty factor of 3 applied.<sup>28</sup>

The lethal dose of morphine can range widely, due to differences in individual tolerance.<sup>29</sup> In general, any increase in daily prescription dose increases the risk of overdose.<sup>30</sup> According to the Centers for Disease Control and Prevention (CDC), even a prescription of 20-50 mg morphine equivalents per day increases the risk of overdose and death.<sup>31</sup> But there is no evidence of a bright-line cutoff for overdose or mortality. For example, a study of the population of North Carolina in 2010 found that the incidence of overdose death for those who were prescribed an average of 100 to 119.9 mg morphine equivalents per day was 6.7 times the rate of those prescribed up to 39.9 mg morphine equivalents per day (the baseline rate).<sup>32</sup> An average daily prescription of 200 to 249.9 mg morphine equivalents per day had an incidence of overdose death 27.4 times the baseline rate.

Consumer practices, such as brewing the contaminated poppy seeds into a tea or other liquid, may concentrate the opiate alkaloid content, increasing the risks of reaching or exceeding effective doses from the consumption of poppy seeds.<sup>33</sup> The opiate alkaloid yield can be further increased with the addition of an acidic ingredient such as lemon juice during brewing.<sup>34</sup> Ingestion of these teas is typically used for the purposes of intoxication and/or claimed health benefits including the treatment of pain, anxiety, and opioid withdrawal. Notably, however, cessation of chronic tea consumption itself can precipitate opioid withdrawal symptoms.<sup>35,36</sup>

Extracting opiate alkaloids from contaminated poppy seeds or poppy into a liquid for consumption is well documented historically, sometimes with resulting adverse events and deaths. Interviews were done of 24 patients in 2000-2001 at an opioid rehabilitation center in New Zealand, 11 of whom reported having tried poppy seed tea.<sup>37</sup> Five of these patients reported that the product was their main source of opioids. A 1990 survey of patients enrolled

in the Cambridge Drug Dependency Unit in the United Kingdom found that 43 out of 46 patients who responded to their questionnaire acknowledged drinking poppy tea, a regional practice that apparently dates to the 19<sup>th</sup> Century.<sup>38</sup> Another review, by Martínez and Ballesteros in 2019, identified historical case reports of both adults and infants with accidental opium intoxication following consumption of drinks brewed with poppy seeds as a folk remedy.<sup>39</sup>

Standard recipes for tea or other drinks can rely on substantial quantities of seeds for opiate alkaloid extraction. For example, Mercola.com, a supplement sales and marketing website by Dr. Joseph Mercola, recommends a “Healthy Poppy Seed Tea Recipe” of 200 g (0.44 lbs.) poppy seeds in 400 ml water.<sup>40,41</sup> Chewtheworld.com, a food and cooking website, offers instructions to brew 300 g of poppy seeds in 400 ml of water, advising consumers: “[t]o prevent overdose, Health And Nutrition Tips [another advice webpage] suggests ingesting not more than 3 pounds of poppy seeds.”<sup>42</sup>

A 2018 study by Powers, in response to 2 recent cases of fatalities associated with high morphine blood levels and poppy seed tea consumption, brewed tea with samples of poppy seeds purchased online from 22 different vendors and analyzed the opiate alkaloid content of teas brewed with the seeds.<sup>43</sup> Morphine concentrations in some samples were high enough to yield 2,788 mg of morphine in a tea form from 1 kilogram (2.2 lbs.) of seeds, in addition to variable amounts of codeine and thebaine.

Assuming a 1 kg batch of seeds can yield 2,788 mg of morphine, brewing 0.44 lbs. of seeds per the Mercola.com recipe could produce up to 558 mg morphine, and 3 lbs. of seeds (the maximum suggested by chewtheworld.com) could yield up to 3,802 mg of morphine. These amounts would be dissolved in a certain volume of water, approximately 1-2 L, so the dose to the user would depend upon the amount of liquid consumed. One 8 oz. cup of tea (237 ml) brewed from a liter of water could yield 901 mg of morphine according to the maximum chewtheworld.com recipe, which is well above a lethal dose.

Greenthal et al. (2021), in a study published in *Clinical Toxicology* and coauthored by researchers at CSPI and the Connecticut Poison Control Center, confirmed the ongoing occurrence of opiate alkaloid intoxications from poppy consumption. The research documented that intentional exposures to contaminated poppy seeds may have increased among people over 13 years of age in the U.S. between 2000 and 2018, based on cases reported to the American Association of Poison Control Centers’ National Poison Data System (NPDS). There were 591 exposure cases involving poppy reported to NPDS during that period, including 392 in persons aged 13 and over. Among these 392 exposures, 221 were considered “intentional” (a data category that includes use of a substance for intoxication, therapeutic purposes, or self-harm) and 77 involved poppy in liquid form (suggesting consumption of poppy seed tea). Most intentional exposures occurred in males (72 percent) and those in their teens and twenties.

The study also collected reports of ingestion of contaminated poppy seeds that led to major effects or death from NPDS and two FDA databases, the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) and the Adverse Event Reporting System (FAERS). This analysis identified 20 non-fatal overdoses and 7 deaths in the U.S., all since 2004, from exposure to opioids in poppy that had never been reported in the medical

literature. Combined with reports already published in the medical literature or government documents, there are now a total of at least 20 non-fatal overdoses and 19 deaths attributable to opiate-contaminated poppy seeds in the U.S., most of which have occurred since 2016.<sup>44</sup> This may be a significant underestimate, considering underreporting to poison control and FDA.

In addition to the risks of clinical effects, 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.<sup>45,46</sup> Food processing practices such as grinding seeds or baking them within or on products may reduce the opiate alkaloid concentration of poppy seeds, though evidence for this is mixed, and there are anecdotal reports of clinical effects resulting from the consumption of baked goods.<sup>47,48,49,50</sup>

A study by Samano in 2015 found morphine concentrations as high as 1408 ng/ml in urine samples 2 hours after study participants ingested a Ukrainian-style poppy seed roll prepared from approximately 15 g of seeds purchased from a Kansas spice market.<sup>51</sup> This approaches the workplace drug testing cutoff of 2,000 ng/ml morphine in urine established by the Department of Health and Human Services' Substance and Abuse Mental Health Services Administration (SAMHSA), and exceeds the previous federally mandated cutoff of 300ng/ml in 1998 which some institutions may still use.<sup>52,53</sup> Half of study participants who consumed the roll still had urine morphine concentrations exceeding 300ng/ml when samples were collected 20 hours after consumption (the final sample collection of the study).

The negative social and behavioral consequences of a failed drug test can be significant. 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 300ng/ml threshold.<sup>54,55</sup>

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. For example, a 2019 report submitted to CAERS described, "After consuming an[] everything bagel with poppy seeds. My son tested positive for morphine use. He is on proba[]tion and may have to go to court for eating a bagel..."<sup>56</sup>

### **C. Better Preventive Practices and Regulation can Protect Consumers**

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. These practices can begin with selecting seeds from varieties of poppy cultivated for food use, which are bred to contain a low level of opiate alkaloids (and acceptable levels should be better defined and enforced as needed by regulation).<sup>57</sup> Additional recommended steps during production include growth regulation to prevent uneven ripening, pest control, and use of appropriate harvesting technology to minimize damage to the seed pods.<sup>58</sup> Post-harvest, seeds can be soaked, washed, and aspirated to remove dust.<sup>59</sup> Baking seeds at high temperature has been shown to remove up to 90 percent of the morphine content.<sup>60</sup>

While higher temperatures may damage the seed, the European Commission, in a 2014 guidance for preventing and reducing opiate alkaloid contamination of poppy seeds, noted that a combination of washing, heating, and if applicable, grinding, at lower temperatures which would not affect the seed quality, can still effectively reduce contamination to “non-detectable quantities.”<sup>61</sup> For example, a combination of pretreatment and heating was shown to reduce seed contamination with morphine at original levels of 50 to 220 mg/kg “to concentrations below 4 mg morphine/kg without loss of quality and organoleptic properties.”<sup>62</sup> The Commission listed a variety of combinations of processes shown to significantly reduce contamination, suggesting poppy seed manufacturers can tailor control plans to meet their needs.<sup>63</sup>

In addition to the guidance it developed on preventive practices, the European Commission is also exploring setting binding opiate alkaloid contamination thresholds for poppy seeds.<sup>64</sup> Other entities have developed recommended thresholds for opiate alkaloid contamination to ensure consumer safety. The German Federal Institute for Risk Assessment recommended a maximum morphine concentration of 4 mg/kg in poppy seeds.<sup>65</sup> Likewise, the United Kingdom has issued guidance setting a target concentration of 10 mg/kg morphine for poppy seeds placed on the market destined for the final consumer.<sup>66</sup>

In the United States, the DEA issued a notice in November 2019 confirming that seeds contaminated with opium alkaloids are considered Schedule II controlled substances pursuant to 21 U.S.C. § 812 of the Controlled Substances Act (CSA).<sup>67</sup> Yet to date, no U.S. agency has issued regulations, guidance, or recommendations identifying a maximum permissible threshold of opiate alkaloid contamination of poppy seeds or describing the manufacturing practices recommended to reduce the presence of opiate alkaloids in poppy seeds.

As a result of this inaction, contaminated poppy seeds are readily available at local retailers and online.<sup>68,69</sup> American consumers have no guarantees that a batch of seeds will not contain high and potentially lethal amounts of opiate alkaloids, if consumed in great enough quantities. Some manufacturers and retailers intentionally market heavily contaminated poppy seeds. 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” or “unwashed” to signal that their products contain higher concentrations of opiates than properly processed seeds. Consumers seeking out contaminated seeds can also search for product reviews that use coded language to describe opiate levels, such as a rating system (“9/10, if you know what I mean...”).

Policies from vendors may help discourage the sale of contaminated poppy seeds. For example, Amazon, Inc. has established a policy to limit the sale of poppy seeds to 1-pound bags or less and requires seeds to be from approved brands.<sup>70</sup> Nevertheless, product postings for “unwashed” poppy persist on online platforms.<sup>71</sup>

#### **D. FDA Has Legal Authority to Act**

The FDA has legal authority to issue regulations to control poppy seed contamination in seeds sold as a food or dietary supplement, and should coordinate with the DEA and CBP to ensure that contaminated seeds are not imported for other purposes that could subsequently be

converted for use as an FDA-regulated food or dietary supplement (*i.e.*, by marketing it as a tea or baking ingredient).

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

(1) If it bears or 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...

or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Opioid contamination in poppy seeds is an "added substance" because the opiates are not naturally present in the seeds and are instead the result of contamination that occurs during harvesting or processing.<sup>72</sup> Such contamination renders the seeds "injurious to health" because opiates may cause a range of severe adverse health consequences, including respiratory depression, abdominal pain, addiction, and death.<sup>73</sup>

Similarly, the FDA has authority under 21 U.S.C. § 342(a)(4) to ensure that poppy seeds are not "prepared, packed, or held under insanitary conditions ... whereby [they] may have been rendered injurious to health," including by specifying good manufacturing practices and preventive controls needed to ensure poppy seeds are not contaminated with dangerous levels of opiates.

Finally, the FDA has general authority to issue regulations to prevent the sale of adulterated seeds under 21 U.S.C. § 371 which authorizes the agency to "promulgate regulations for the efficient enforcement of this chapter," as well as the regulatory authorities conferred under 21 U.S.C. § 350g, which requires food facilities to conduct hazard analysis and set in place risk-based preventive controls,<sup>74</sup> and 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.

Our request that the FDA issue regulations and guidance that will further clarify obligations for poppy seed facilities and importers, including by setting a maximum safe level for opiates in poppy seeds. There is precedent for such rules to address specific requirements for individual foods. For example, the FDA recently used its authority under 21 U.S.C. § 342(a)(4) to establish specific binding controls for *Salmonella* Enteritidis in shell eggs during production,<sup>75,76</sup> and has also established specific regulatory controls for bottled drinking water,<sup>77</sup> and infant formula.<sup>78</sup>

We are also requesting that the agency conducting testing of imported poppy seeds to determine the levels of opiate contamination, with sampling targeted based on specific risk

factors, including prior importation of seeds associated with injury to consumers or a history of regulatory noncompliance. Such a testing program would verify the effectiveness of existing controls established by importers as well as inform enforcement activities and the development of additional regulatory requirements.

In addition, we request that the FDA coordinate with the DEA and CBP to take actions to ensure the safety of imported poppy seeds. As noted *supra*, all poppy seeds consumed in the United States must be imported from other countries. Thus, import controls have potential to serve as a key means of ensuring the safety of poppy seeds introduced for sale in the United States.

We are requesting that the FDA coordinate with the DEA and CBP to issue an import alert specifying the conditions under which poppy seeds that appear to be contaminated may be detained at the border for violation of FDA and DEA rules. Such an alert could specify the forms of documentation, including product testing results, as appropriate, that would be required in order to avoid detention of a shipment of pods or seeds at the border. In addition, FDA may place importing firms on a “red,” “green,” or “yellow” list, a practice commonly used for other high-risk imports, which may make a specific company subject to or exempt from detention, or subject to intensified surveillance.<sup>79</sup>

We are concerned that contaminated poppy seeds, ostensibly imported for crafting, gardening, or other purposes, may be diverted for consumption as foods or beverages. FDA can prevent this by coordinating with the DEA to ensure that contaminated seeds are not imported for any purpose, as the DEA has oversight over seeds that have been contaminated with Schedule II controlled substances regardless of the purpose of use for such products.<sup>80</sup> Accordingly, we urge the FDA to coordinate with the DEA and CBP to ensure that any import restrictions developed to limit contamination in poppy seeds are imposed uniformly on imported poppy pods and seeds regardless of the stated purpose for use.

### **III. Environmental Impact Statement**

This petition is categorically excluded from the Environmental Impact Statement requirement under 21 C.F.R. 25.32(m) because this petition is an action to prohibit, restrict, or reduce the contamination of a substance (opiates) in food (poppy seeds).

### **IV. Certification**

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

### **V. Description of Petitioners**

**Steve and Betty Hacala of Rogers, Arkansas**, are the parents of Stephen Hacala, who passed away in 2016 at the age of 24 from morphine intoxication from drinking poppy seed tea. Prior to Stephen’s death, he ordered a 5 lb. 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 morphine (opium latex).

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

Following Stephen's death, Mr. and Ms. Hacala worked with Dr. Madeleine Swortwood at Sam Houston State University to conduct a study to evaluate how much morphine could be rinsed off the seed coats of poppy seeds purchased online and in stores. Astonishingly, the study discovered that up to 6300 mg of morphine could be rinsed from the seed coats in a 5 lb. bag of poppy seeds.

Armed with this knowledge and as a direct result of their son's death, it is now the Hacas' strong desire 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 morphine-contaminated poppy seeds.

**Mark and Elizabeth Dominguez of Tonawanda, New York**, are parents who were excited to bring their new son into the world in 2019. Shortly after arriving to the hospital and before giving birth, Ms. Dominguez provided a urine sample and was told that she tested positive for opioids. After initially believing there was a mistake, as Ms. Dominguez had not taken any prescription or illegal opioids during her pregnancy, Mr. and Ms. Dominguez recalled that Ms. Dominguez had consumed an "everything" bagel from Tim Hortons that day and deduced that poppy seeds on the bagel likely caused the positive test results.

After Ms. Dominguez gave birth, the hospital evaluated her son for withdrawal, and called Child Protective Services. Personnel from the agency arrived in her hospital room, and questioned Ms. Dominguez, clearly regarding her as an opioid user.

Child Protective Services visited the Dominguez's home 3 times and went to their older children's school, pulling them from class to speak with them without their parents' knowledge. Ms. Dominguez was discharged from the hospital while their baby remained because results from her urine test were not back from a lab conducting a confirmatory test. After being initially separated from their baby, the hospital eventually discharged him. Days later, the test results came back showing that Ms. Dominguez's initial urine screen had been a false positive.

**Linda Golden of Lexington, South Carolina, and Jeffery Folds of Atlanta, Georgia**, are the mother and cousin, respectively, of Todd Shirley, who passed away in 2019 at the age of 48 due to an opioid overdose from poppy seed tea. Mr. Shirley used the tea to assist with anxiety and sleep issues, apparently unaware that there could be a lethal dose of opioids in the tea. Mr. Shirley had purposely avoided the use of street drugs.

Mr. Folds, his cousin, is a firefighter with first-hand knowledge of how the opioid crisis is ravaging communities. Mr. Folds sees a strong parallel between poppy seeds and his experience with street drugs like heroin, and feels that not enough is being done to stop the distribution of

poppy seeds. Their family has lost three members to the opioid crisis, and they are highly motivated to work to get such products out of circulation in order to prevent other families from dealing with the tragedy of addiction or overdose.

**Dr. Irving Haber** is a physician board certified in both physical medicine and rehabilitation and pain medicine. He has treated dependency disorders for almost 20 years. Dr. Haber discovered the issue of poppy seed tea from working with his patients.

With Dr. Joseph Pergolizzi and Dr. Madeleine Swortwood, he published a paper on poppy seed tea to help make the issue more recognizable as a life-threatening condition alongside other opiate dependency disorders.

**Paul Lancia of St. Louis, Missouri:** Mr. Lancia's wife, Rebecca Lancia, has suffered brain damage due to strokes. Her doctors suspect that these events were caused by heavy poppy seed tea consumption. Her neurological damage has badly reduced the family's quality of life. For example, the Lancias used to hike mountains together, but Ms. Lancia's vision and balance have been severely damaged. Mr. Lancia observes that his wife's personality has also changed, and the family expects that Ms. Lancia will need ongoing treatment for the rest of her life. Mr. Lancia has struggled to describe the effect that the strokes will have on their family and children.

**Bob and Lori Morales of Reno, Nevada and Kristen Harris of Sparks, Nevada,** are the parents and wife, respectively, of Kendall Harris, who passed away in 2019 at the age of 38 following an opioid overdose from unwashed poppy seeds that he bought on Amazon.

Mr. Harris had injured his back in high school and was not able to have surgery because he would risk being paralyzed. He began making teas from poppy seeds 18 months before he died, at a time when he was having trouble achieving sufficient pain relief with his opioid prescriptions, which were being reduced (and eventually cut off) by his doctor.

His family was aware of his use of the tea but they were unaware that something that was readily available on Amazon was dangerous. Moreover, the poppy seeds were packaged under a brand Ms. Harris knew to provide products for baking, which further encouraged her to believe that tea made from the seeds could not be harmful.

Mr. Harris increased the amount of poppy seed tea that he consumed as time went on. On the day of his death, Ms. Harris found Mr. Harris unresponsive in their home, and when paramedics tried to resuscitate him, she noticed what looked like poppy seed tea coming out of his nose.

It was not until after his death that his family learned that the seeds he was using contained codeine and morphine. His official cause of death was described as the combined effects of codeine, morphine, and diazepam.

**Jamie Silakowski of Depew, New York,** who consented to a drug test prior to delivering her son in 2018 and tested positive, both on a screening test and a confirmatory test, 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 from Tim Hortons before heading to the hospital.

No one in the hospital believed Ms. Silakowski or appeared to be aware that the test results could occur from poppy seeds. 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. Her life was very disrupted for 8 weeks, at a time when she should have been able to focus on experiencing time with her newborn.

**Dr. Madeleine Swortwood** is an Assistant Professor and Director of Graduate Programs for the Department of Forensic Science at Sam Houston State University. Dr. Swortwood received a bachelor's degree in biochemistry from Duquesne University and a Ph.D. in chemistry from Florida International University. She also completed a postdoctoral fellowship with the National Institute on Drug Abuse, a division of the National Institutes of Health (NIH). Dr. Swortwood's research encompasses drug metabolism, marijuana oral fluid drug testing, in utero drug exposure, novel psychoactive substances, and analytical method development. She has authored and co-authored more than thirty manuscripts and more than fifty peer-reviewed oral and poster presentations at national and international conferences, including recent publications on opiate intoxications from poppy seed tea consumption.

**The Center for Science in the Public Interest (CSPI)** submits this petition on behalf of the undersigned. CSPI is America's Food and Health Watchdog, a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate donations and is supported by donations from individuals and foundations and subscribers to its *Nutrition Action Healthletter*.

Please direct questions related to this petition to James Kincheloe, at [jkincheloe@cspinet.org](mailto:jkincheloe@cspinet.org), or via phone at (202) 777-8316.

Respectfully,

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Tonawanda, New York

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Jeffery Folds  
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CC: Dr. Susan Mayne, Director, Center for Food Safety and Applied Nutrition, FDA  
Mr. Frank Yiannas, Deputy Commissioner for Food Policy and Response, FDA  
Dr. Conrad Choiniere, Director, Office of Analytics and Outreach, FDA

## Notes

- <sup>1</sup> European Food Safety Authority Panel on Contaminants in the Food Chain, Knutsen HK, Alexander J, et al. Update of the Scientific Opinion on Opium Alkaloids in Poppy Seeds. *EFSA J.* 2018; 16(5):5243.
- <sup>2</sup> *Ibid.*
- <sup>3</sup> *Ibid.*
- <sup>4</sup> Sproll C, Perz RC, Lachenmeier DW. Optimized LC/MS/MS analysis of morphine and codeine in poppy seed and evaluation of their fate during food processing as a basis for risk analysis. *J Agric Food Chem.* 2006;54(15):5292-5298.
- <sup>5</sup> European Food Safety Authority Panel on Contaminants in the Food Chain, Knutsen HK, Alexander J, et al. Update of the Scientific Opinion on Opium Alkaloids in Poppy Seeds. *EFSA J.* 2018; 16(5):5243.
- <sup>6</sup> Sproll C, Perz RC, Lachenmeier DW. Optimized LC/MS/MS analysis of morphine and codeine in poppy seed and evaluation of their fate during food processing as a basis for risk analysis. *J Agric Food Chem.* 2006;54(15):5292-5298.
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