



April 3, 2019

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Dear Commissioner Gottlieb, Deputy Commissioner Yiannas, Director Mayne, Attorney General Barr, Acting Administrator Dhillon, and Director Tave:

The Center for Science in the Public Interest (CSPI), a consumer group with more than 45 years of experience advocating for a healthier food system, urges you to take immediate action to stop the illegal importation and sale of contaminated poppy seeds (“unwashed” poppy seeds) and poppy seed pods. These dangerous products can contain high levels of morphine, codeine, thebaine, and other opiate alkaloids. The products pose grave health risks, particularly when the opiates are concentrated by brewing large amounts into a “tea.” The apparently increasing threat they pose has been overlooked for too long as a component of the ongoing opioid epidemic in that addicted patients have been known to use these products as substitutes for other opioids.

Contaminated poppy seeds and poppy seed pods pose a serious and immediate hazard to consumers. As we describe below, these contaminated products have been associated with at least 12 fatalities reported in the United States since 2010, yet the products remain widely available for sale online, including through the popular online shopping platforms Amazon.com and Ebay.com. We urge you to immediately investigate and take enforcement action against the companies that profit from the distribution of these products which, as we demonstrate below, are adulterated and misbranded foods under the Federal Food Drug and Cosmetics Act (FDCA) and contain Schedule II controlled substances, the distribution of which is restricted under the Controlled Substances Act (CSA).

The opium poppy, *Papaver somniferum*, naturally produces opiate alkaloids, including morphine, codeine, and thebaine, which are concentrated in the seed pod and milky sap of the plant. The opiates found in the *Papaver somniferum* plant are highly addictive, leading the Drug Enforcement Administration (DEA) of the U.S. Department of Justice (DOJ) to list “poppy straw,” which is defined as parts of the poppy plant other than the seeds, as a controlled substance under Schedule II of the CSA.^{1,2} As a result of this listing, and under the provisions of several international agreements, *Papaver somniferum* cannot be legally cultivated in the United States, and therefore raw materials must be imported to produce opioids for pharmaceutical use as well as poppy seeds sold as foods.³ While the sale of imported poppy seeds for food is legal, the knowing or intentional distribution of poppy seeds that have been contaminated with poppy straw is a violation of the CSA.⁴

Poppy seeds may become contaminated with poppy straw and sap in the fields or during harvest, necessitating washing and processing to remove the alkaloids.^{5,6} The European Commission has developed guidance on good practices to prevent and reduce the presence of opium alkaloids in poppy seeds and poppy seed products.⁷ These practices begin with selecting seeds from varieties cultivated for food use, which are bred to contain a low level of opium alkaloids. Adequate pest control, prevention of bad harvesting conditions, and proper storage and labeling also help to reduce opiate content. Finally, appropriate processing can be highly effective: the combination of washing and drying can reduce morphine concentrations in highly contaminated batches of raw poppy seeds (original concentration vary from 50 to 220 mg morphine/kg) down to concentrations below 4 mg morphine/kg without loss of quality and organoleptic properties.⁸ Likewise, the United Kingdom has issued guidance setting a target level of 10 mg morphine/kg for the presence in poppy seeds placed on the market destined for the final consumer.⁹

The risk presented by contaminated poppy seeds and poppy seed pods is heightened by the fact that consumers may concentrate the opioid content of these products by brewing the seeds or pods into an herbal tea, often in combination with an acid such as lemon juice. This practice, thought to provide health benefits (and presumably also used by some to induce intoxication or stave off opioid withdrawal), often relies on substantial quantities of seeds for a standard recipe. For example, the website Mercola.com recommends a “Healthy Poppy Seed Tea Recipe” of 200 g (0.44 lbs) poppy seeds in 400 ml water,¹⁰ and the website Chewworld.com offers instructions to brew 300 g of poppy seeds in 400 ml of water, advising consumers: “[t]o prevent overdose, Health And Nutrition Tips suggests ingesting not more than 3 pounds of poppy seeds.”¹¹

¹ 21 U.S.C. §§ 802(17) & 812(c); 21 C.F.R. § 1308.12(b).

² See Appendix. Letter to Senator Cotton from the U.S. Department of Justice, Office of Legislative Affairs. November 2, 2018.

³ *Ibid.*

⁴ *Ibid.*

⁵ European Food Safety Authority. Opium alkaloids in poppy seeds: assessment updated. May 16, 2018. www.efsa.europa.eu/en/press/news/180516.

⁶ Sharma A, Sharma P, Singh N. Reduction of morphine in poppy seeds through food enhancing nutritional quality of food products. *JFAV*. 2015;5(2):9-13.

⁷ 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 (2014/662/EU). Brussels, BE: 2014. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014H0662&from=EN>.

⁸ *Ibid.*

⁹ United Kingdom Food Standards Agency. *Plant toxins*. UK FSA; January 19, 2018. www.food.gov.uk/business-guidance/plant-toxins.

¹⁰ Mercola. *Is Poppy Seed Tea Safe to Drink?* Mercola; n.d. <https://articles.mercola.com/teas/poppy-seed-tea.aspx>.

¹¹ Chew the World. <https://chewtheworld.com/poppy-seed-tea-recipe/>.

Brewing contaminated seeds via these common methods may create substantial risks. One research team at Sam Houston State University recently analyzed samples of poppy seeds purchased online and found that morphine concentrations in some samples were high enough to yield 2788 mg of morphine from 1 kilogram (2.2 lbs) of seeds, in addition to codeine and thebaine.¹² Assuming a batch of seeds with up to 2788 mg/kg of morphine,¹³ brewing 0.44 lbs of seeds per the Mercola recipe instructions could produce up to 557 mg morphine, and 3 lbs of seeds (the maximum suggested by Chewworld.com) could yield up to 3801 mg of morphine. These levels are well above the dose of 50 morphine mg equivalents per day demonstrated to increase the risk of overdose among patients prescribed morphine for pain treatment.¹⁴ These amounts would be dissolved in a certain volume of water, perhaps 1-2 L (see Appendix 1), so the dose to the user would depend upon how much of the liquid was consumed.¹⁵

As noted above, contaminated poppy seeds and seed pods can readily be purchased online where they may be labeled and marketed as foods or dietary supplements, or sold for crafting¹⁶ or gardening. Typically, the fact that the seeds may be contaminated with opiates is not clearly indicated in the labeling or advertising materials, and users seeking contaminated seeds instead utilize coded language in product reviews, sometimes offered on third-party blogs, to signal which seeds are most likely to contain high concentrations of opiates. The contaminated seeds thus remain widely available, including through the online shopping platform Amazon.com, despite the fact that the retailer has been informed multiple times of the risks of these products, including on April 25, 2018, by Senator Tom Cotton,¹⁷ on July 13, 2018, by Arkansas Attorney General Leslie Rutledge,¹⁸ and most recently on February 27, 2019, in a letter sent by the family of a victim who died from poppy seeds purchased on the platform.¹⁹

As might be predicted, poppy seed tea consumption has resulted in numerous cases of overdose, dependence, and death, and these cases appear to be more common over time. CSPI identified 15 cases of overdose, dependence, and death associated with the use of poppy seeds or seed pods from the medical literature or that were presented at conferences (see Appendix 1).²⁰ Nine cases involved overdoses, four of which were fatal. The remaining six cases involved addiction to opioids, but not overdose or death.

All but two of the cases involved men (86%; age was unavailable for one case) and the median age was 26 years (range: 6 weeks-82 years). Typically, the product was administered as a tea,

¹² Powers D, Erickson S, Swortwood MJ. Quantification of morphine, codeine, and thebaine in home-brewed poppy seed tea by LC-MS/MS. *J Forensic Sci.* 2017;63(4):1229-1235.

¹³ *Ibid.*

¹⁴ U.S. Centers for Disease Control and Prevention. Calculating total daily dose of opioids for safer dosage. CDC; n.d. www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

¹⁵ For example, if Chewworld.com's 3 lbs of the 2788 mg/kg seeds were dissolved in 2 L of water, and a user drank 100 ml, less than half a cup, they would consume 190 mg of morphine.

¹⁶ Some websites sell poppy seeds are intended for use in soapmaking, and seed pods may be marketed for decorative purposes.

¹⁷ News Release. *Cotton warns of opioid overdoses from unwashed poppy seeds.* April 25, 2018. <https://www.cotton.senate.gov/?p=speech&id=933>.

¹⁸ News Release. *Rutledge asks retailers to remove unwashed poppy seeds from shelves.* July 13, 2018. <https://arkansasag.gov/media-center/news-releases/rutledge-asks-retailers-to-remove-unwashed-poppy-seeds-from-shelves/>.

¹⁹ See Appendix. Letter from Steve and Betty Hacala to the Amazon Board of Directors. February 27, 2019.

²⁰ We did not include reports involving small bowel obstruction *see, e.g.* Schuppener LM, Corliss RF. Death due to complications of bowel obstruction following raw poppy seed ingestion. *J Forensic Sci.* 2018;63:614-8, or acute toxic effects associated with injection of a liquid prepared by boiling poppy seeds in water *see, e.g.* Monaghan D, Peckler B. Parenteral poppy seed tea packs a powerful punch. *NY Med J.* 2013;126:175-8.

usually made from about 1-2 pounds of poppy seeds, but occasionally from the poppy pod. In all but one case, the major opioids in poppy plants, morphine and codeine, were identified either in the product itself or in the blood or urine of the patient. Eight of the cases took place in the United States, including all four deaths. Three case reports, all in the United States, noted that the product was purchased over the internet.

In addition to these case reports, we identified a survey conducted in 2000-2001 of 24 patients at an opioid rehabilitation center in New Zealand, 46 percent of whom reported having tried poppy seed tea. Five of these patients reported that the product was their main source of opioids.²¹ In addition, a survey of patients enrolled in the Cambridge Drug Dependency Unit in the United Kingdom identified 43 patients who acknowledged drinking poppy tea, a regional practice that apparently dates to the 19th Century.²²

CSPI also conducted a review of the FDA Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) using the term “poppy” and going back to 2004. We identified seven adverse event reports possibly linking consumption of contaminated poppy seeds to overdose, dependence, and/or death, all within the past five years. This included three that were associated with deaths.²³ In addition to the deaths, one case involved hospitalization with drug dependence,²⁴ and two others involved ER visits with symptoms of nausea, hypotension, and other signs of possible overdose.²⁵ Based on the ages and event dates reported, it appears that at least one death and the case of hospitalization with drug dependence are not duplicates of the cases reported in Appendix 1.²⁶

Additional cases of overdose, dependence, and death were reported outside the medical literature. For example, the DOJ issued a Drug Alert in 2010 that identified five deaths, all of which appear to be distinct from the reports captured in Appendix 1 and CAERS reports based on their timing and location.^{27,28} Multiple deaths also appeared in lay media reports from other countries, including two in England,^{29,30} one in Canada,³¹ and two in Tasmania.^{32,33}

²¹ Braye K, Harwood T, Inder R, Beasley R, Robinson G. Poppy seed tea and opiate abuse in New Zealand. *Drug Alcohol Rev.* 2007;26(2):215–9.

²² London M, O’Regan T, Aust P, Stockford A. Poppy tea drinking in East Anglia. *Br J Addict.* 1990;85:1345-7.

²³ Report ## 2018-CFS-006187 & 2018-CFS-006553. One additional death involved intestinal obstruction, which may have been due to over-consumption of poppy seeds rather than opiate contamination. Report # 191335.

²⁴ Report # 204829.

²⁵ Report ## 206560 & 210101.

²⁶ We are unable to establish whether any of the other cases are also reported in the medical literature based on the limited identifying information available in the CAERS public database.

²⁷ Drug Alert Watch. U.S. Department of Justice, national Drug Intelligence Center. March 2, 2010. www.justice.gov/archive/ndic/pubs40/40404/sw-Opium_Tea.pdf.

²⁸ Authors reporting fatalities in Appendix 1 are either from states not named in the DOJ report or, in the case of Powers et al. (2017), published their report considerably later than cases in the 2010 DOJ report occurred.

²⁹ Mother warns of poppy tea ‘risks’ after son’s overdose. *BBC.* December 8, 2009.

http://news.bbc.co.uk/2/hi/uk_news/wales/8402748.stm

³⁰ Salkeld, L. DJ died after drinking a PINT of deadly ‘poppy tea’ he made using a recipe he found online. *Daily Mail.* December 31, 2013. <https://www.dailymail.co.uk/news/article-2531688/DJ-died-drinking-PINT-deadly-poppy-tea-using-recipe-online.html>

³¹ N.S. family warns of poppy seed tea dangers. *CBC News.* June 4, 2012. <https://www.cbc.ca/news/canada/nova-scotia/n-s-family-warns-of-poppy-seed-tea-dangers-1.1208439>

³² McMillen, A. Tasmania’s opium poppy growers face trouble ahead. *The Australian.* March 7, 2015. <https://www.theaustralian.com.au/weekend-australian-magazine/tasmanias-opium-poppy-growers-face-trouble-ahead/news-story/a66ff44dc39704bc7d68c65f151e789f>

³³ Teen overdoses after drinking poppy head tea. *ABC News Australia.* September 19, 2013. <https://www.abc.net.au/news/2013-09-19/teen-overdoses-after-drinking-poppy-head-tea/4967422>

The death toll in the U.S. continues to climb. On December 13, 2018, a 44-year-old woman passed away in Utah, with poppy seeds ordered online found at the scene.³⁴ And in March of this year, 46-year-old Todd Eugene Shirley passed away in his home. Several bags of poppy seeds, concentrated lemon juice, and a water bottle with washed seeds were found at the scene. Shipping packages and phone records reflect that the poppy seeds had been ordered online. There was no other evidence of illicit drug use.³⁵ CSPI is working with both families to submit further information about these events to the FDA via CAERS.

These two new deaths, too recent to have appeared in the medical literature, CAERS or the DOJ report, combined with four from Appendix 1, one from the CAERS database, and five from the DOJ report, add up to a minimum of 12 deaths in the United States from contaminated poppy seeds and seed pods. Based on our review of the medical literature and the CAERS reports, the problem appears to be worsening in recent years.

The family members of one poppy seed tea overdose victim created a website, www.poppyseedtea.com, which collects reports of 17 deaths attributed to poppy tea, both in the United States and internationally, gathered from media reports and direct email communications from the families of other victims.³⁶ Many of these may be duplicates of those reported in other sources and so are not included in our total of 12 deaths. The same website also includes numerous emails from consumers describing dependence and withdrawal symptoms, as well as additional non-lethal overdose cases. Some users describe how they began using the product believing it was a relatively harmless natural herbal remedy, not fully realizing the potential for dependence and abuse.

The FDA and DEA are well aware of the sale of contaminated poppy seeds, and in 2018 FDA officials met with the family members of one victim, Stephen Patrick Hacala, a 24-year-old who died after drinking tea made from contaminated poppy seeds purchased on Amazon.com in 2016 (this case is included in Appendix 1).³⁷ In addition, Arkansas Attorney General Leslie Rutledge sent a letter to the FDA on August 6, 2018 asking the agency to ban the sale of unwashed poppy seeds containing controlled substances and to ensure appropriate labeling.³⁸ On September 12, 2018, Senator Tom Cotton of Arkansas sent a letter to Attorney General Jeff Sessions and Acting Administrator Dhillon urging them to stop the sale of these dangerous products.³⁹

³⁴ Communication between CSPI and the family of the decedent on March 31, 2019.

³⁵ Communication between CSPI and the family of the decedent, on March 28, 2019. Toxicology reports are pending from this case.

³⁶ PoppySeedTea.com. Other Deaths from Poppy Seed Tea. <http://poppyseedtea.com/Other%20Deaths%20Page.html>.

³⁷ Poppy seed wash is really a drug, FDA says. *NBC News*. August 14, 2018. www.nbcnews.com/storyline/american-heroin-epidemic/poppy-seed-wash-really-drug-fda-says-n900551. This case was also reported in Appendix 1, *supra*.

³⁸ News Release. Rutledge Asks FDA to Prohibit the Sale of Unwashed Poppy Seeds. August 6, 2018.

<https://arkansasag.gov/media-center/news-releases/rutledge-asks-fda-to-prohibit-the-sale-of-unwashed-poppy-seeds/>

³⁹ Press Release. Cotton Urges the Department of Justice and the Drug Enforcement Agency to Act on Unwashed Poppy Seeds. September 12, 2018. https://www.cotton.senate.gov/?p=press_release&id=1003.

Yet the agencies have to date failed to take enforcement action to stop the sale of these highly dangerous products. The FDA has limited its actions to a single warning letter in July 2018 on a labeling issue.⁴⁰ Similarly, the DOJ has, to our knowledge, done no more than issue the 2010 Drug Alert and send a letter to Senator Cotton indicating that it will be “looking into the matter more closely.”⁴¹

The FDA and Department of Justice have ample authority to take forceful action, because the sale of contaminated poppy seeds and poppy seed pods violates multiple provisions of federal law. Specifically:

When marketed for any purpose:

- Contaminated poppy seeds and poppy seed pods contain poppy straw, the knowing or intentional distribution of which is a violation of the Controlled Substances Act 21 U.S. Code § 841(a).

When marketed as foods:

- Contaminated poppy seeds are adulterated under 21 U.S.C. § 342(a)(1) because the food contains quantities of opiate alkaloids that render the food injurious to health, as evidenced by the numerous cases of overdose and death reported to date.
- Contaminated poppy seeds are adulterated under 21 U.S.C. § 342 (a)(4) because they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.
- Contaminated poppy seeds are misbranded under 21 U.S.C. §§ 343(a) and (i) to the extent that the labeling of the products fails to declare poppy straw and milky sap in addition to poppy seeds in the ingredients list.

When marketed as dietary supplements:

- Contaminated poppy seeds are adulterated dietary supplements under 21 U.S.C. § 342(f) because they contain dietary ingredients (poppy straw and sap) that present a significant or unreasonable risk of injury.
- Contaminated poppy seeds are adulterated dietary supplements under 21 U.S.C. § 342(g) to the extent that they have been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.
- Contaminated poppy seeds are misbranded dietary supplements under 21 U.S.C. §§ 343(s) to the extent that the labeling of the products fails to declare poppy straw and milky sap in addition to poppy seeds in the ingredients list.

⁴⁰ On July 12, 2018, the Food and Drug Administration (FDA) issued a warning letter to the owner of the website www.poppyseedteawash.com, warning the company to remove certain disease treatment claims made on the website. <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm616452.htm>. Subsequently, these claims were removed, but the website continues to market “special, unwashed, unprocessed, organic poppy seeds sourced specifically for strength and great taste” in pre-packaged bottles with instructions for brewing tea.

⁴¹ See Appendix. Letter to Senator Cotton from the U.S. Department of Justice, Office of Legislative Affairs. November 2, 2018.

If marketed for pain cessation or other medical uses:

- Poppy seeds marketed as treatment for opioid addiction, pain cessation, or otherwise making medical claims are unapproved drugs, and are an enforcement priority under Agency guidance because they supplant effective treatments and pose safety risks.⁴²

We urge you to take the following steps to prevent the illegal sale of contaminated poppy products, without any further delay:

1. The FDA and DEA should issue a joint public statement clarifying that it is illegal to import and distribute contaminated poppy seeds and poppy seed pods within the United States, either for food or non-food purposes. The statement should make clear that individuals who introduce these products into interstate commerce are subject to federal prosecution by the Department of Justice.
2. The FDA should issue letters to poppy seed distributors and any online or other retailers, including Amazon.com, that make these products available for sale, explaining that the sale of contaminated poppy seeds is illegal and that any businesses may be subject to enforcement action should they be found to distribute or aid in the distribution of such products.
3. The FDA should conduct random sampling and testing of poppy seed products offered for sale by online or other retailers, prioritizing products associated with adverse event reports and products for which customer reviews indicate that the seeds may contain high levels of opiates. The agency should initiate enforcement action against businesses found to be distributing contaminated poppy seeds.
4. The FDA should prioritize inspections of poppy seed distributors, categorizing distributors as “high risk” based on evidence of distribution of contaminated poppy seeds. The agency should initiate enforcement action against businesses found to have prepared, packed, or held poppy seeds under conditions that allowed for contaminated seeds to enter the food supply.
5. The FDA and DEA, in coordination with U.S. Customs and Border Protection (CBP), should screen poppy seed and seed pod imports, testing incoming shipments for contamination and confiscating shipments found to contain high levels of opiates.
6. The FDA should issue guidance to industry advising on current good manufacturing practices to reduce the presence of opiate alkaloids in poppy seeds. The guidance should establish a safe-harbor level for morphine and/or other opiates, allowing spice companies that reduce contamination to below such levels to avoid prosecution.

We look forward to further communication with you on this important matter.

⁴² Guidance for FDA Staff and Industry Marketed Unapproved Drugs – Compliance Policy Guide. September 19, 2011. www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070290.pdf. Although, as we have emphasized, pursuing distributors of contaminated poppy seeds only based on drug claims would be insufficient to address this public health threat of these products, which pose life-threatening risks regardless of how they are labeled.

Sincerely,

Peter Lurie, M.D., M.P.H.
President
Center for Science in the Public Interest

Laura MacCleery
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Appendix 1: Cases of dependence, overdose, and death associated with the use of poppy seeds or seed pods in the medical literature

Reference	Age (years)	Gender	Method of Administration, Duration	Estimated Dose*	Opioids Detected in Blood/Urine	Other Drugs Mentioned	Outcome	Where Purchased; Case Location
Haber, 2019 ⁴³	42	Male	Tea		Urine: morphine 0.001 mg/L		Entered detoxification	Online US
Poponea, 2018 ⁴⁴	22	Male	Tea	Poppy seed pods	Blood (8 days after ingestion): morphine (0.049 mg/L), codeine (0.15 mg/L)		Admitted to ICU; Anoxic brain injury; Death	“Offline” US
Spyres, 2018 ⁴⁵	33	Male	Tea; Four months	2 lbs/2 L water Morphine (1.09 mg/mL), codeine (62.1 µg/mL), thebaine (not quantified)	Urine: opiates, benzodiazepines	Alprazolam, Escitalopram, Buspirone	Overdose reversed with naloxone; later admitted to ICU; continued using the product and developed apparent addiction	Amazon US
Spyres, 2018 ⁴⁶	17	Male	Tea	1.5 lbs with water	Urine: morphine, codeine, benzodiazepines	Etizolam	Overdose reversed with naloxone	Internet US

* Poppy seeds unless otherwise noted

⁴³ Haber I, Pergolizzi J, LeQuang JA. Poppy seed tea: a short review and case study. *Pain Ther.* 2019; <https://doi.org/10.1007/s40122-019-0113-5>.

⁴⁴ Poponea N, Kashian MT, Vollstaedt J. Opium poppy seed tea: a lesser known but deadly cocktail. *Am J Resp Crit Care Med.* 2018;197:A6895. Poster presentation at American Thoracic Society International Conference, 2018.

⁴⁵ Spyres MB, van Wijk XMR, Lapoint J, Levine M. Two cases of severe opiate toxicity after ingestion of poppy seed tea. *Toxicology Communications.* 2018:102-4.

⁴⁶ Spyres MB, van Wijk XMR, Lapoint J, Levine M. Two cases of severe opiate toxicity after ingestion of poppy seed tea. *Toxicology Communications.* 2018:102-4.

Reference	Age (years)	Gender	Method of Administration, Duration	Estimated Dose*	Opioids Detected in Blood/Urine	Other Drugs Mentioned	Outcome	Where Purchased; Case Location
Powers, 2017 ⁴⁷	24	Male	Tea	Dissolved in 33 fl oz bottle of water (5 lb bag found)	Blood: morphine (0.25mg/L), codeine (0.012 mg/L), thebaine (trace)		Death	US
Powers, 2017 ⁴⁸	21	Male	Tea	Water: Poppy seed “double wash”	Blood: morphine (>0.80 mg/L), codeine (0.26 mg/L)	Adderall	Death; Pulmonary edema; Early acute pneumonia	Grocery store US
Kwicien-Obara, 2016 ⁴⁹ (abstract only)	24	Male	“Brew”	5 kg	Opiates (presumably in blood): >2 mg/L	Dextromethorphan	Overdose with quadriplegia	Poland
Pearson, 2015 ⁵⁰		Male	Tea	Made from 1-2 lbs daily	Urine: morphine (37.6 mg/L), codeine (2.56 mg/L), hydromorphone (1.43 mg/L)	Hydromorphone	Withdrawal symptoms	US

⁴⁷ Powers D, Erickson S, Swortwood MJ. Quantification of morphine, codeine, and thebaine in home-brewed poppy seed tea by LC-MS/MS. *J Forensic Sci* 2017; doi:10.1111/1556-4029.13664.

⁴⁸ *Ibid.*

⁴⁹ Kwicien-Obara E, Szponar J, Krajewska A, Witkowska A, Radoniewicz A, Szponar M. [Morphine (obtained from poppy seeds) and dextrometorfan poisoning– a case report]. *Przegl Lek.* 2016;73(8):596-8.

⁵⁰ Pearson ACS, Eldrige JS, Hooten WM. Interpreting urine drug screen results in the context of poppy seed use. *Mayo Clin Proc.* 2015;90:1734-40.

Reference	Age (years)	Gender	Method of Administration, Duration	Estimated Dose*	Opioids Detected in Blood/Urine	Other Drugs Mentioned	Outcome	Where Purchased; Case Location
Bailey, 2010 ⁵¹	42	Male	Tea	Poppy seed pods	Blood: morphine (0.12 mg/L), codeine (0.085 mg/L), thebaine (0.072 mg/L), phenazepam (0.29 mg/L) Urine: hydrocodone; codeine; thebaine	Phenazepam	Death; Pulmonary and cerebral edema	US
Nanjayya, 2009 ⁵²	82	Female	Afeem (opium) candies, then poppy seeds, then poppy pod solution over a total of 55 years	Poppy pods in 1-2 L of water per day Solution positive for opioids			Withdrawal symptoms; required opioid detoxification	Homeopathic shops India
Hahn, 2008 ⁵³ (also described in Smith ⁵⁴ and EFSA ⁵⁵)	6 weeks		Poppy seed milk mixture	75 cc of 200 g in 500 cc milk In seeds: morphine (0.1%), codeine (0.003%)	Blood: morphine (0.004 mg/L) Urine: morphine		Accidental poisoning; admitted to ICU	

⁵¹ Bailey K, Richards-Waugh L, Clay D, Gebhardt M, Mahmoud H, Kraner JC. Fatality involving the ingestion of phenazepam and poppy seed tea. *J Anal Toxicol.* 2010;34:527-32.

⁵² Nanjayya SB, Murthy P, Chand PK, et al. A case of poppy tea dependence in an octogenarian lady. *Drug Alcohol Rev.* 2010;29:216-8.

⁵³ Hahn A, Michalak H, Begemann K, et al. Severe health impairment of a 6-week-old infant related to the ingestion of boiled poppy seeds. *Clin Toxicol.* 2008;46:607.

⁵⁴ Smith ML, Nichols DC, Underwood P, et al. Morphine and codeine concentrations in human urine following controlled poppy seeds administration of known opiate content. *Forensic Sci Int.* 2014;241:87-90.

⁵⁵ European Food Safety Agency. Scientific opinion on the risks for public health related to the presence of opium alkaloids in poppy seeds. *EFSA Journal.* 2011;9:2405.

Reference	Age (years)	Gender	Method of Administration, Duration	Estimated Dose*	Opioids Detected in Blood/Urine	Other Drugs Mentioned	Outcome	Where Purchased; Case Location
Lloyd-Jones, 2006 ⁵⁶	43	Female	Tea for 10 years	5-6 kg/ week	Urine: opiates		Entered detoxification 3 times	Australia
Lloyd-Jones, 2006 ⁵⁷	26	Male	Tea for 3 years	1-3 kg/day	Urine: morphine, codeine, oxazepam, temazepam, desmethyldiazepam	Heroin, Benzodiazepines, Alcohol	Entered drug treatment 2 times	Supermarket Australia
King, 1997 ⁵⁸	26	Male	Tea	Up to 2 L made from 4 kg Morphine (0.14 mg/mL)	Blood: morphine (3 mg/L)		Seizure; entered detoxification	Australia
Unnithan, 1993 ⁵⁹	37	Male	Tea for 20 years	Poppy heads – 14 heads/day	Urine: morphine, benzodiazepines	Benzodiazepines, Alcohol	Entered detoxification	Florist UK

⁵⁶ Lloyd-Jones DM, Bonoma Y. Unusual presentations for pharmacotherapy—poppy seed dependence. *Drug Alc Rev.* 2006;25:375-6.

⁵⁷ Lloyd-Jones DM, Bonoma Y. Unusual presentations for pharmacotherapy—poppy seed dependence. *Drug Alc Rev.* 2006;25:375-6.

⁵⁸ King MA, McDonough MA, Drummer OH, Berkovic SF. Poppy tea and the baker's first seizure. *Lancet.* 1997;350:716.

⁵⁹ Unnithan S, Strang J. Poppy tea dependence. *Br J Psych.* 1993;163:813-4.



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

NOV 02 2018

The Honorable Tom Cotton
United States Senate
Washington, D.C. 20510

Dear Senator Cotton:

This responds to your letter to Attorney General Jeff Sessions and Drug Enforcement Administration (DEA) Acting Administrator Uttam Dhillon, dated September 13, 2018. The letter asks if the Department of Justice (Department) considers the sale of poppy straw along with poppy seeds a violation of the Controlled Substances Act (CSA); what kind of criminal liability a manufacturer or distributor of unwashed poppy seeds can face for manufacturing, distributing, and dispensing morphine laced unwashed seeds; and what the Department and DEA are doing to address this problem.

The production, cultivation, and distribution of opium are controlled under several international agreements. Under the provisions of these agreements, the United States refrains from engaging in the domestic commercial production of plant material containing opium. Instead, the United States addresses its legitimate need for opium through the importation of this basic material.

The CSA defines "opium poppy" as the plant of the species *Papaver somniferum L.*, except the seed thereof. *See* 21 U.S.C. § 802(19). The CSA defines "poppy straw" as all parts, except the seeds, of the opium poppy, after mowing. *See* 21 U.S.C. § 802(2). Both opium poppy and poppy straw are listed under the definition of a "narcotic drug" in 21 U.S.C. § 802(17) and are listed as a Schedule II controlled substance in 21 U.S.C. § 812(c), Schedule II (a)(3). Further, although *Papaver* species, other than *Papaver somniferum L.*, are not specifically listed as controlled substances in the CSA, if Schedule II opium alkaloids are contained within the product that is being distributed as poppy seeds, the product may be subject to CSA controls.

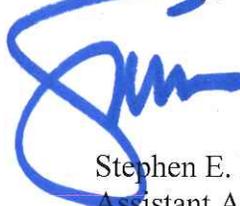
Depending on the specific circumstances of each case, selling poppy straw along with poppy seeds may be a violation of the CSA. *For example see* 21 U.S.C. § 841(a)(1). The CSA prohibits the knowing or intentional manufacture, distribution, dispensation, or possession with the intent to manufacture, distribute, or dispense a controlled substance. *See* 21 U.S.C. § 841(a)(1). Among other potential penalties, a violation of 21 U.S.C. § 841(a)(1) regarding a Schedule II controlled substance may result in a sentence to a term of imprisonment of not more than 20 years, and if death or serious bodily injury results from the use of the substance, a

sentence to a term of imprisonment of not less than twenty years or more than life. *See* 21 U.S.C. § 841(b)(1)(C).

As your letter points out, our nation is currently fighting the worst drug crisis in our history. We appreciate your support and interest in our work as the Department and DEA fight this crisis head-on. The information you provided regarding the online sales of unwashed poppy seeds is concerning. The Department and DEA will be looking into the matter more closely to determine what actions may be necessary. Specifically, DEA will further investigate available information to include toxicology, overdose, and intelligence data, to determine, in consultation with the Department of Health and Human Services, if further regulatory or enforcement action needs to be taken in regards to unwashed poppy seeds.

We hope this information is helpful. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,



Stephen E. Boyd
Assistant Attorney General
Office of Legislative Affairs

February 27, 2019

Jeffrey Bezos
Tom Alberg
Rosalind Brewer
Jamie Gorelick
Daniel P. Huttenlocher
Judith McGrath
Indra Nooyi
Jonathan Rubinstein
Thomas Ryder
Patricia Stonesifer
Wendell Weeks

Board of Directors
Amazon.com, Inc.
410 Terry Ave. North
Seattle, WA 98109-5210

Re: Amazon's Sales of Unwashed Morphine-Laced Poppy Seeds

Dear Board Members:

We are writing to ensure that you are aware of a dangerous product that Amazon is selling, despite multiple warnings from us, Congress, the Department of Justice, and the Arkansas Attorney General: unwashed morphine-laced poppy seeds. Our son died from a morphine intoxication caused by seeds he purchased from Amazon, we have reports of several other individuals dying from unwashed morphine-laced poppy seeds, and last November, the Department of Justice confirmed that they are investigating the sale of these products. It is our earnest hope that you will take immediate action to remove this product from Amazon based on the dangers of the product, the lack of warnings to consumers, and Amazon's own policies.

Our son, Stephen Hacala, purchased Sincerely Nuts unwashed poppy seeds from Amazon in March of 2016. He was found dead by his roommate on April 3, 2016. The medical examiner later determined that Stephen died of "morphine intoxication." Investigators found no evidence of any other illicit or pharmaceutical sources of the morphine; however, they did find a 5-lb. bag of Sincerely Nuts' unwashed poppy seeds along with a water bottle filled with seeds and water. Stephen purchased these seeds from Amazon and made "poppy seed tea" – just as comments from the Amazon product pages and Amazon reseller pages suggested he do.

The Medical Examiner for the Arkansas State Crime Laboratory investigated and confirmed that unwashed poppy seeds can cause fatal overdoses. The Examiner stated, “It is well characterized in the literature that urine drug screens can become positive from ingesting poppy seeds, but cases of actual intoxication are rare. Further research did reveal several cases of fatal morphine intoxication from poppy seeds around the country, and a poll of my colleagues revealed additional unreported cases.”

We subsequently contacted Dr. Madeleine Swortwood, a toxicologist and Postdoctoral Fellow from the National Institute on Drug Abuse with Sam Houston State University in Texas for additional research related to poppy seeds. Dr. Swortwood and Deborah Powers performed extensive testing related to commercially available unwashed poppy seeds, including seeds purchased from Amazon and offered by several suppliers. They published a peer-reviewed article: *Quantification of Morphine, Codeine, and Thebaine in Home-Brewed Poppy Seed Tea*, in the *Journal of Forensic Sciences*. Their research showed that a 5lb bag of Sincerely Nuts poppy seeds purchased from Amazon contained over 6000mg of morphine, which is more than 30 times a fatal dose.

The article’s stated purpose was “to determine whether lethal amounts of morphine could be extracted from poppy seed coats by home-brewing methods.” The authors stated in the article, “Although some bulk poppy seeds can be more lethal than others due to the variation in morphine concentrations both between vendors and between harvest dates, it should be noted that regardless of sample, it is possible to obtain lethal doses of morphine from poppy seed tea if moderate volumes of tea are consumed.”

Below are the brands of seeds tested in the Dr. Swortwood’s published article where the quantity of morphine, codeine and thebaine were measured. Please note that morphine, codeine, and thebaine are scheduled drugs under the Controlled Substances Act:

1. Terra Vita
2. Poppy Seed Wash
3. Dual Spices
4. Medley Hills Farm
5. International Spice
6. Frontier Co-Op
7. Sincerely Nuts
8. Bob’s Red Mill
9. Natural Traders Co
10. Food to Live
11. Anna and Sarah
12. Nature’s Gourmet Classics
13. Spicy World
14. We Got Nuts
15. Herb Pharm
16. Tasmanian Connoisseurs
17. We Know Seeds
18. Nodding Turtle

- 19. Federal Ingredients
- 20. Sincerely Nuts (Sample 2)
- 21. International Spice
- 23. Sincerely Nuts (Sample 3)

The following charts, taken from a summary presentation of Dr. Swortwood’s study called, *The Morphine in Your Pantry – Understanding the Overdose Risk of Home-Brewed Poppy Seed Tea*, presented at The American Academy of Forensic Sciences Annual Meeting in February 2018, illustrates the morphine levels observed in her study measured in mg/kg (Chart A) and by mixing 150 ml of water with 85 grams of seeds Chart B. The purple bar in Chart B represents a therapeutic dose of morphine. Results indicate that with the majority of the seeds evaluated a therapeutic dose of morphine could be rinsed from seed coats.

Chart A:

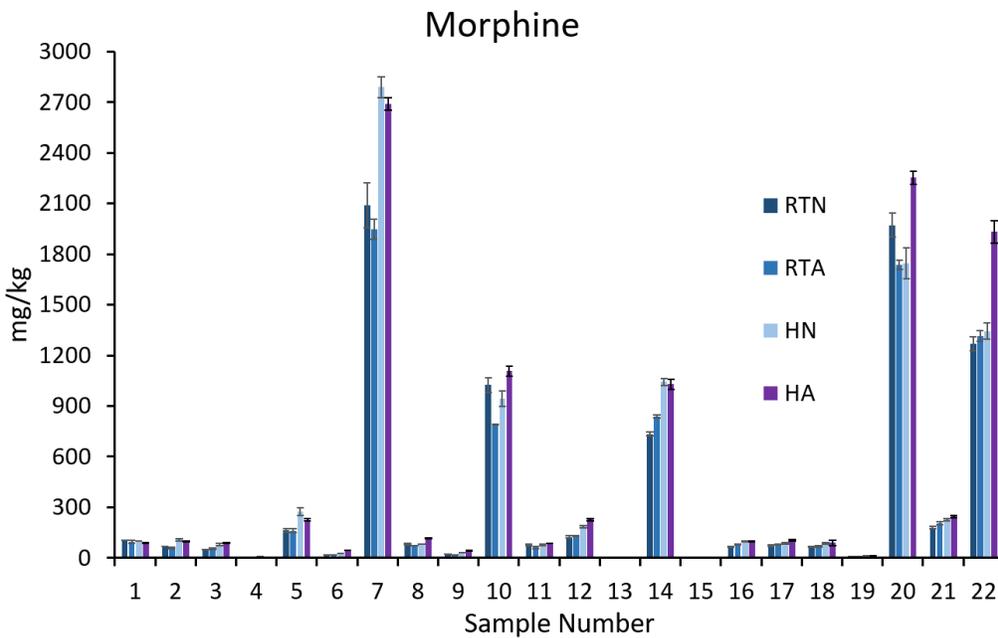
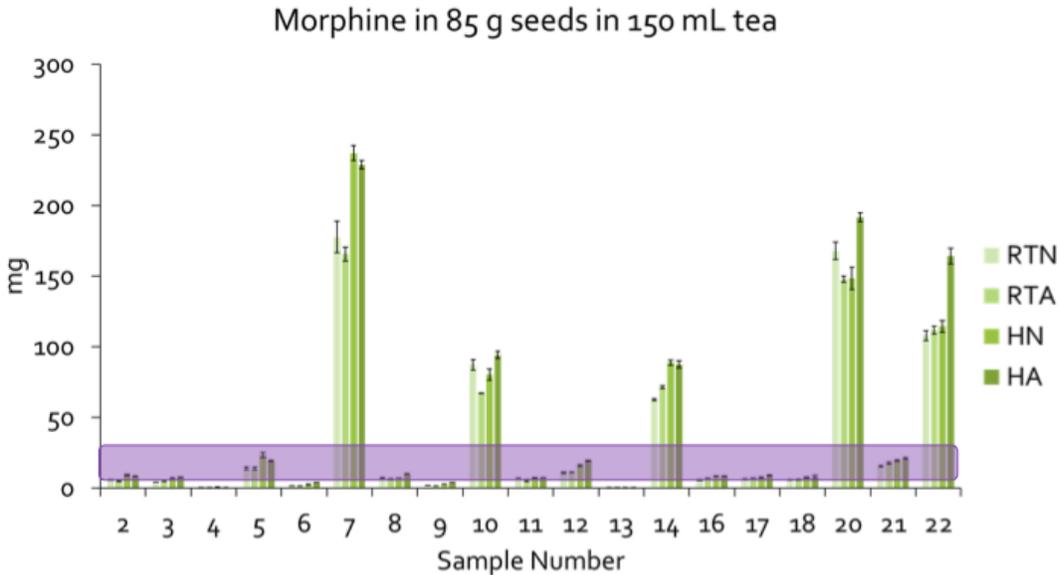


Chart B:



The Sincerely Nuts brand poppy seeds that Amazon sold to our son continue to be sold and contain no warnings of these dangers for consumers. Instead, they are promoted on Amazon.com by use of the Amazon product search bar, the Question/Answer section of the product pages and “customer reviews” with comments including: “Very potent tea, lots of flavor”; “Great for making tea”; “Wonderful seeds for a good poppy rinse ‘tea.’ Very potent. You can get three washes out of each batch. Go slow.”

A recent Amazon user’s comment shockingly stated the following:

DEADLY TEA-AVOID!! DEADLY!!

December 11, 2018 Size: 3 Pounds Verified Purchase

DEADLY TEA!! I AFTER I TRIED IT I ENDED UP IN THE EMERGENCY ROOM!!
2 DAYS IN A ROW!!

Recently, we conducted a search for “unwashed poppy seeds” on the search bar on the Amazon.com website and to our astonishment the search resulted in a list of over 75 different poppy seed products. Furthermore, unwashed seeds are not always marketed as “unwashed”, rather, terms like “natural”, “raw”, “organic”, “kosher”, or “unprocessed” may be used. Suppliers do not indicate whether or not the morphine or other opium alkaloids have been removed from the seed coats. Unwashed poppy seeds are sold in both the Grocery and Lawn and Garden sections of the Amazon.com website.

Further adding to the issue, a website by the name of www.poppyseedtearecipe.com, whose tag line is, “Poppy Seed Tea, A Community Dedicated to this Powerful Tea” is an Amazon reseller, and the website highlights the fact that the owner makes money by encouraging readers to do the following:

Help Support This Website (Hint: It Won’t Cost You Extra Money)

You can help support this community without spending an extra penny. If you are planning on buying something (literally anything) on Amazon, click one of the Amazon links included on this website before your purchase. This website will make a small percentage of your total purchase price for any items purchased within 24 hours of clicking the link. You can purchase anything on Amazon, it doesn’t have to be something advertised on this website. I sincerely appreciate your support, it helps me dedicate a sufficient amount of my time to enhance this free resource!

The reseller and author, known as “Brandon McPoppy,” also has a section of his website where he rates/ranks “The Best Seeds For Tea” - a list that he frequently updates. He also states the following about the best poppy seeds for tea:

The main two things to remember when searching for the best poppy seeds for poppy seed tea are to verify that the seeds are unwashed and obtained from the correct poppy plant.

Below is the current list of poppy seeds being promoted by www.poppyseedtearecipe.com. Note, not all are sold by Amazon presently:

1. Blue Bird Poppy Seeds (English)
2. Sincerely Nuts (UK) – Amazon
3. Nut Cravings (England) – Amazon: marketed as an “Amazon Choice” and “Best Seller”
4. Food To Live (England) – Amazon
5. Sunbest Poppy Seeds – Amazon
6. Anna and Sarah Poppy Seeds (England)

As a result of Stephen’s death, and the deaths of others, Senator Tom Cotton contacted Amazon and Walmart in April 2018, in an effort to convince both Walmart and Amazon to remove unwashed poppy seeds from each site. Walmart has since removed these dangerous products from their website. Below is a quote from Senator Cotton in a speech made on the floor of the US Senate on April 25, 2018:

I put in a call to the leadership of Walmart and Amazon, which at the time both allowed unwashed poppy seeds to be sold on their websites. They listened to our case and quickly agreed to stop selling poppy seeds that are labeled as unwashed. This is important. The two behemoths of online commerce agreeing to take down those seeds was a victory and

a testament to what normal citizens like Steve and Betty can accomplish.

But this is more than a labeling problem. In fact, some of the most potent and deadly seeds, which we know about thanks to the work of Steve and Betty, are not labeled as unwashed and are still available for purchase. Therefore, I will work in the Senate and with the Drug Enforcement Agency to ban unwashed seeds entirely, but today I do want to take a moment to thank Amazon and Walmart for taking an important first step-for our country, for our state, and for the Hacalas and families like theirs.

According to Senator Cotton's office, Amazon initially promised to discontinue the sale of unwashed poppy seeds. In fact, Amazon's government affairs representatives told Senator Cotton's office that Amazon acknowledged that the seeds contained morphine and the evidence, in addition to the comments and scientific studies, was the fact that the seeds were being sold for 5X the price of other poppy seeds that contained no morphine.

Our son paid \$29 back in March of 2016 for a 5lb bag of Sincerely Nuts Poppy Seeds; unfortunately, today the same 5lb bag is selling for \$129 on Amazon, still with no warnings.

In July of 2018, Arkansas Attorney General Rutledge wrote to Amazon, eBay and Etsy to highlight dangers of unwashed poppy seeds and requested each retailer remove the seeds. The quotes below were taken from General Rutledge's press release on the matter:

"This letter outlines the unknown dangers of unwashed poppy seeds," said Attorney General Rutledge. "Although washed poppy seeds are approved for consumption for use such as baking ingredients, unwashed poppy seeds can contain substantial amounts of morphine, codeine and thebaine, which are harmful Schedule II controlled substances."

Attorney General Rutledge is asking these online retailers to remove all unwashed poppy seeds from their online catalogs and affiliated stores to help prevent the deaths of consumers in the future. Walmart has already taken action to no longer be part of the problem by removing unwashed poppy seeds from their shelves.

We ask that Amazon remove unwashed morphine-laced poppy seeds from its website to protect the public as this is a dangerous product that contains Schedule II narcotics with no warnings for consumers. We also ask that Amazon follow through on its own policies and remove the product immediately. Amazon's own Product Safety policy states:

Amazon monitors the products sold on our website for product safety concerns. In concerning situations, we may remove the product from the website, reach out to sellers and manufacturers for additional information, place relevant warnings on the product detail page, or take other actions depending on the situation. We may also report product safety concerns to applicable government agencies in order to bolster their safety data and help facilitate any necessary recalls.

The Amazon Services Business Solutions Agreement has policies related to restricted and/or dangerous products. Amazon's policies state:

Customers trust that they can always buy with confidence on Amazon. Products offered for sale on Amazon must comply with all laws and regulations and with Amazon's policies. The sale of illegal, unsafe, or other restricted products listed on these pages, including products available only by prescription, is strictly prohibited. We are constantly innovating on behalf of our customers and working with regulators, third party experts, vendors, and sellers to improve the ways we detect and prevent illegal and unsafe products from reaching our marketplace. Amazon encourages you to report listings that violate Amazon's policies or applicable law by contacting us. We will investigate each report thoroughly and take appropriate action.

The policies also address "Drugs and Drug paraphernalia" under the Restricted Products listing, prohibiting the sale of "Anything listed in Schedules I, II, III, IV or V of the Controlled Substances Act." Morphine is a Scheduled II Controlled Substance.

Amazon also specifically prohibits the sale of "Poppy pods, poppy straw, and poppy straw concentrate." In relation to poppy seeds, the Drug listing policies prohibit:

Listings for poppy seeds that make certain claims, including listings for poppy seeds that reference poppy tea, poppy seeds that are "unwashed," poppy seeds that reference alkaloid content, and poppy seeds that reference opium are prohibited

Listings for products claiming to have psychoactive or hallucinogenic effects are prohibited, including "designer drugs" such as methoxetamine

Listings for products claiming to imitate the effects of a controlled substance, prescription drug, or substance identified by the FDA as an unapproved new drug or tainted supplement are prohibited, including synthetic cannabinoids and bath salts

Under the "Known prohibited products" listing, Amazon policies prohibit certain drug products, including:

Poppy pods, poppy straw, and poppy straw concentrate

Poppy tea (tea brewed from poppy seeds, pods, or straw)

We have listed only some of the Amazon policies under which the sale of unwashed morphine-laced poppy seeds should cease. We request that Amazon take immediate action to end the sale of this dangerous product by removing any poppy seed products where the supplier and Amazon cannot verify that the poppy seeds have been processed consistently with documented, repeatable and measurable quality control standards to remove residual morphine, other opiate alkaloids and poppy straw from the product prior to sale to Amazon customers.

We can only conclude that Amazon is intentionally and willfully selling unwashed poppy seeds by refusing to remove these products after being notified of their dangers, in flagrant disregard of the knowledge that unwashed seeds contain Schedule II narcotics and violate Amazon's own Product Safety policy, Business Services Agreement, and other product policies.

We are heartbroken at the senseless untimely death of our son Stephen, and we implore you – please stop putting profits above the lives of your consumers and remove these dangerous unwashed morphine-laced poppy seed products from the Amazon.com marketplace.

Sincerely,

Steve and Betty Hacala
17 S. Mission Hills Circle
Rogers, AR 72758

CC:

Senator Tom Cotton
Senator John Boozman
Congressman Steve Womack
US Attorney General William Barr
Arkansas Attorney General Leslie Rutledge
Director James Carroll - ONDCP
Dr. Cecilia Spitznagel - ONDCP
Dr. Scott Gottlieb - FDA
Dr. Stephen Erickson – Arkansas Crime Lab
Dr. Madeleine Swortwood – Sam Houston State University
Justin C. King – Assistant Special Agent – DEA
Kimberly J. Daniels – Diversion Group Supervisor – DEA
Jami Cole – Diversion Investigator - DEA

Board of Directors
Amazon.com, Inc.
February 27, 2019
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Attachments:

Senator Tom Cotton Letter to Department of Justice
Department of Justice Response Letter to Senator Tom Cotton
Arkansas Attorney General Letter to Amazon
Arkansas Attorney General Letter to FDA