



Policy Commentary

The Centers for Disease Control and Prevention (CDC) Report on *Salmonella* Infections Linked to Kratom

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SUMMARY

COMMENTARY

Salmonella causes approximately 1.2 million illnesses, 23,000 hospitalizations, and 450 deaths in the United States every year.ⁱ Nevertheless, CDC only investigates and alerts the public to a small fraction of these cases. The rest remain unexplained.

The CDC's mission is to protect America from health, safety and security threats, such as *Salmonella* illness, both foreign and in the U.S..ⁱⁱ Among the most important role that CDC plays in carrying out its mission is to "track diseases and find out what is making people sick and the most effective ways to prevent it."ⁱⁱⁱ Thus, it is well within CDC's purview to identify disease-causing entities and support communities and individuals in preventing and treating the diseases they cause. In so doing, CDC has pledged "to base all public health decisions on the highest quality scientific data that is derived openly and objectively."^{iv} Unfortunately, in recent years, CDC has displayed a pattern of adopting controversial, unscientific positions influenced in secret meetings by individuals and groups that don't conform to these high standards, and of taking actions that violate its pledge to the American People. CDC's position on prescription opioid drugs is painfully apparent, and its controversial "*Guideline for Prescribing Opioids for Chronic Pain*"^v has been widely criticized as ignoring scientific evidence in favor of biased expert opinion for political purpose.

Is CDC's investigation of alleged *Salmonella* contamination of kratom an objective and scientific inquiry in furtherance of protecting the public or is it yet another example of partiality and predisposition?

2017 *Salmonella* Outbreak History

CDC announced on February 20, 2018 that an outbreak of *Salmonella* strain I 4,[5],12:b- had been identified and publicly stated that kratom was "the likely source" of this outbreak.^{vi} In this initial report, individuals who were infected with *Salmonella* reported purchasing kratom in various forms from both online and retail sources. CDC supplemented this announcement with updates on March 1, 2018.^{vii} and most recently, on March 15, 2018^{viii}.

CDC, in conjunction with state health officials, identified the implicated strain of *Salmonella* in three samples of leftover kratom powder collected from individuals in North Dakota, Utah and California who were affected by *Salmonella*-related illness (“Salmonellosis”).^{ix}

North Dakota. The kratom sample provided by a patient in this case was identified as S.K. Herbalist brand kratom powder purchased from the website soapkorner.com.^x A representative from S.K. Herbalist identified the lot of kratom implicated in this case as Red Maeng Da kratom tea, and removed it from their website.^{xi} SK Herbalist stated that the lot of kratom came with a certificate of analysis indicating no bacterial contamination.^{xii} They also stated that remaining product from this lot will be subjected to independent bacteriology testing.^{xiii} CDC has not stated whether they recovered unopened Red Maeng Da kratom tea from S.K. Herbalist or tested it for *Salmonella*.

Utah. CDC reported that the ill person in Utah purchased kratom powder from the website kratoma.com.^{xiv} Kratoma initially stated that it “would not restock any kratom in future” and would close its online store by March 31, 2018.^{xv} The website was initially down^{xvi} suggesting that it may have suspended sales. However, Kratoma has now issued a statement that they “conducted Lab-Tests on 02/21 and checked all our products for Escherichia coli (AOAC 991.14) and Salmonella spp. (AOAC 998.09). All results came negative as expected.”^{xvii} A copy of the test results for all eighteen kratom products offered by Kratom from Summit Laboratories dated February 26, 2018 was posted along with the statement.

Since samples of Kratoma and S.K. Herbalist kratom collected in the field had been opened and used by individuals with Salmonellosis, but both manufacturers provided evidence that their products were not contaminated prior to distribution, it is possible, if not probable, that the patients contaminated the product rather than the product causing disease.

Test results provided by FDA to one vendor for kratom products purchased by FDA online contradict the vendor’s independent microbiological surveillance. FDA’s test results indicated “adverse results” for *Salmonella*, but provided no information on the test procedure(s) used. Tests CDC performs including whole genome sequencing^{xviii} and pulsed field gel electrophoresis^{xix}, as well as other routine laboratory methods for detecting *Salmonella*, such as polymerase chain reaction and serology, can detect both viable and non-viable bacterial cells. Non-viable, dead bacteria cannot cause Salmonellosis. Moreover, to cause Salmonellosis, an individual must receive a threshold number of viable cells (“infectious dose”), which can be between 259,000 and 14,000,000,000 colony forming units of viable *Salmonella* cells.^{xx} Only laboratory tests that culture *Salmonella* and report detection of a viable infectious dose are relevant to potential for causing disease.

California. The source of the kratom sample recovered in this case was traced to products manufactured by PDX Aromatics^{xxi}, which sells kratom under the Soul Speciosa, Phytoextractum and Kraken Kratom brands.^{xxii} PDX Aromatics implemented a voluntary recall of all “potentially contaminated” products; and the supplier identified in their supply chain as the source of the contaminated kratom raw materials was terminated.^{xxiii} The California Department of Public Health (CDPH) notified PDX Aromatics that certain lots of kratom products tested positive for *Salmonella*.^{xxiv} PDX Aromatics subsequently expanded the recall to additional lots of kratom “in response to additional product testing following the initial investigation.”^{xxv} PDX Aromatics, only sells kratom online, while at least three individuals affected in this outbreak reported purchasing kratom from retail locations. PDX Aromatics is not likely the source of *Salomonella* in these individuals.

Thus, in the case of PDX Aromatics, health officials identified the source of contaminants by tracing backwards from an exposure to specific products, retailer, and supplier. Products were recalled voluntarily and future exposures from that source were prevented. This is the template protocol for sound epidemiological surveillance and disease prevention. This is the way it is supposed to be.

Or is it?

AKA has received anecdotal reports of CDC investigators using leading questions biased toward finding kratom as the source of *Salmonella* contamination while dismissing other possible products when interviewing patients. Other reports suggest at least 75 kratom vendors have been raided by FDA, resulting in disruption of business and kratom seizures. Products manufactured and sold nationwide by Divinity Products Distribution were targeted by FDA investigators in the early stages of the outbreak, forced to recall and destroy all kratom inventory and cease sales of kratom despite the fact that no illnesses were connected to their products and FDA's investigation failed to find any indication of *Salmonella* contamination in their products, facilities or workers.^{xxvi}

In the Press Release announcing the recall and destruction of Divinity Products Distribution kratom brands (Botany Bay, Enhance Your Life and Divinity), the FDA focused not on the risk of *Salmonella* contamination, but on "the scientific evidence of the serious risks associated with the use of kratom" including "conclusive evidence that compounds contained in kratom are opioids and are expected to have similar addictive effects as well as risks of abuse, overdose and, in some cases, death."^{xxvii} The FDA further encouraged "all companies currently involved in the sale of products containing kratom intended for human consumption to take similar steps to take their products off the market and submit any necessary evidence, as appropriate, to the FDA to evaluate them based on the applicable regulatory pathway."^{xxviii} *Salmonella* risks were mentioned as an afterthought in the seventh of eight paragraphs. Can there be any doubt that FDA's involvement in this *Salmonella* outbreak was motivated by its opposition to kratom as an "opioid" and embarrassment at having its long-awaited safety report discredited and opposed by journalists and scientists alike, while bearing only a superficial, opportunistic relationship to the risk of bacterial contamination?

Curiously, the I 4,[5],12:b- strain of *Salmonella* had previously been identified as the cause of an outbreak associated with frozen shredded coconut.^{xxix} On March 1, CDC reported that "WGS [whole genome sequencing] performed on isolates from ill people [in the kratom outbreak] were closely related genetically. This means that people in this outbreak are more likely to share a common source of infection."^{xxx} CDC has not provided a comparison of the DNA sequences of isolates from the coconut outbreak to sequences of the same I 4,[5],12:b- strain implicated in the kratom-linked outbreak. However, the kratom outbreak appears to start where the coconut outbreak left off. See attached Figure taken from CDC graphs and maps. Even the distribution of the coconut outbreak seems to bear a geographic and temporal relationship to the kratom outbreak, with the kratom outbreak encompassing all but two of the same states involved in the coconut outbreak as well as additional adjacent states. See Figure, right panels. CDC has not addressed whether these two outbreaks could be related despite their obvious similarities. More recently, CDC identified a new outbreak of *Salmonella* in dried coconut.^{xxxi} One can only wonder whether this new outbreak is related to the previous coconut and kratom cases.

Additional Strains of Salmonella Identified -- March 15, 2018 Update

In the most recent CDC update, three additional strains of *Salmonella* have been linked to kratom: *Salmonella* Javiana, *Salmonella* Okatie and *Salmonella* Thompson.^{xxxii} This is not the typical pattern of a *Salmonella* outbreak linked to plant-based sources. *Salmonella* is most commonly associated with meat, poultry, eggs and domestic live animals, such as pet turtles and other reptiles. Animals may be infected with one or more strains of *Salmonella* without displaying overt signs of disease and thus special care must be taken in processing, handling and preparation for human consumption. Contamination of fruits, vegetables, and prepared foods, on the other hand, is typically attributable to improper hygiene during harvest, packing, processing or end use and infrequently involves multiple strains of *Salmonella*. Linking four different strains of *Salmonella* to a single plant suggests the possibility of up to four unrelated outbreaks.

CDC Recommendations

Consistent with the suggestion of multiple outbreaks, CDC emphasizes that “[n]o common brands or suppliers of kratom products have been identified at this time.”^{xxxiii} Yet the CDC’s advice is different than that for other products. Instead of recommending safe food handling procedures and thorough cooking, “CDC is recommending against consuming any kratom”.^{xxxiv} This seems an illogical and disproportionate measure considering recommendations for preventing Salmonellosis from other plant and animal sources, which emphasize much less extreme measures including washing, decontamination, cooking, and isolation of uncooked meats and eggs from foods that will be eaten fresh and uncooked. CDC does not even suggest avoiding such frequent sources of bacterial contamination as sprouts, but instead recommends that they be washed thoroughly and lightly cooked to kill bacteria.

The sudden prevalence of multiple strains of *Salmonella* linked to kratom raises questions not only about the timing of these discoveries shortly after FDA all but declared war on kratom, but also whether CDC’s surveillance has, in the past, been adequate. If *Salmonella* is as prevalent in kratom as CDC’s admonitions would have us believe, why has CDC never before traced the disease to kratom in the decades that it has been sold in the US? Did the recent public portrayal of kratom by FDA as a dangerous opioid first bring kratom to CDC’s attention? as a previously unrecognized source of microbial contamination or as the opioid FDA claims it is? Does a product that may be contaminated first need to be on CDC’s radar for it to be identified as the source of an *Salmonella* outbreak? How many other outbreaks evade CDC surveillance because they are linked to less visible products? These are serious questions that CDC and FDA need to answer.

Regulation of Kratom

What is most unfortunate is that the latest attack on kratom moves FDA and CDC in the opposite direction it should go to make Americans safe. The only opportunity to monitor and eliminate microbial threats, other contamination and adulteration with deadly substances such as fentanyl and fentanyl derivatives, is through inspection and efficient removal of contaminated and adulterated products. Communication, cooperation and education involving kratom users and members of the kratom supply chain is a necessary part of that process. If FDA and CDC are successful in driving US vendors out of business and kratom users into the shadows, as it seems they intend, it will simply drive sales underground, to dark web, bitcoin-funded transactions and thousands of little packages arriving

through the USPS for every palletted shipment arriving today. A recent survey of over 6,400 kratom users found that if kratom were banned, almost 50% would find a way to continue using kratom.^{xxxv} Suppliers in Asia have already made many direct contacts with individual consumers and would likely shift from selling to distributors to shipping directly to consumers in the US. Those sales would become virtually invisible to FDA and CDC.

The last thing the American public needs right now is another product shipped direct-to-consumer from Southeast Asia. As the history of the war on drugs has aptly demonstrated, law enforcement is unlikely to be able to prevent importation of kratom even if it is banned. Kratom that escapes surveillance upon entry into this country would completely evade checks on quality, purity and freedom from adulteration, which could otherwise be accomplished through regulation. Black market, adulterated kratom could become the next fentanyl. Regulation that ensures purity, freedom from contamination, and absence of adulteration is the safest and most logical path forward, and the one supported by AKA.

Prevention of Salmonella Infection

As alluded to above, there are steps that Kratom consumers concerned about possible *Salmonella* contamination can take to minimize their risk of becoming ill. Kratom users should engage in frequent hand washing, use of hand sanitizer, thoroughly cleaning surfaces and utensils used with kratom, and decontaminating the outside of kratom packaging with a disinfecting solution (e.g., dilute bleach) prior to opening to minimize transfer of *Salmonella* and any other bacteria from package to contents to user. When consuming kratom, users should make tea using rapidly boiling water and consider bringing the kratom and water mixture to boil together for at least 3-10 minutes to kill viable microbial contaminants that may be present. Avoid adding substances that may promote bacterial growth, such as sugar, syrup or milk, until immediately before drinking. If you plan to store unused kratom tea, refrigerate or freeze as you would any perishable food. Freezing kratom or prepared kratom tea offers the additional advantage of not only prevent *Salmonella* growth but actually killing *Salmonella*, which is subject to cell lysis following freeze-thaw cycles. Adding a squeeze of lemon (pH 2) to steaming hot Kratom tea, as is the custom in many countries where kratom is traditionally used, may further inhibit bacterial growth by providing inhospitable acidity. Finally, consumers may benefit from taking mixed probiotic supplements that have been shown to reduce pathogen loads, improve gut health and ameliorate the outcome of a *Salmonella* challenge in experimental animals.^{xxxvi} CDC has completely abrogated its responsibility to protect consumers from *Salmonella* outbreaks if it fails educate them on such practices that will promote safe handling of bulk herbal supplements and teas such as kratom and prevent disease.

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^{xxviii} *Id.*

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