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Citizen Petition

Date: July 23, 2018

On behalf of Public Citizen, a consumer advocacy organization with over 500,000 members and supporters nationwide, and Public Citizen's Health Research Group, the undersigned submit this petition under Sections 331(a) and 342(f) of the Federal Food, Drug, and Cosmetic Act (FDCA) and under Food and Drug Administration (FDA) regulations at 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to immediately require the removal from the market of all dietary supplements containing the chemical cesium chloride (CsCl) or any other cesium salt because they present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use.

The basis of this request is a growing body of evidence demonstrating that CsCl or other cesium salt supplementation can cause serious, life-threatening adverse cardiovascular events when taken in amounts recommended or suggested in product labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. In addition to the established harms associated with CsCl or other cesium salt use, it is widely known that this chemical is touted as an alternative cure for cancer[1,2] despite the absence of any sound scientific evidence to support such claims. Further compounding the dangers posed by these supplements is the generalized lack of consumer knowledge of the risks associated with dietary supplements, the inaccessibility of information regarding these risks, the ensuing public perception that all dietary supplements are safe, and the common but incorrect belief that there is any significant health benefit from dietary supplement use. Since the promotion of public health sits at the core of the FDA's mission, it is critical that the agency take the necessary steps to ensure that CsCl is no longer marketed as a dietary supplement.

The FDA previously has taken such essential regulatory action against dietary supplement manufacturers. For example, dietary supplements containing ephedrine alkaloids (ephedra) were marketed prior to October 15, 1994, when the Dietary Supplement Health and Education Act of 1994 took effect and, therefore, were initially grandfathered in and arbitrarily regarded as safe for continued consumer use and could be sold without filing a 75-day premarket notification with the FDA. In 2004, following our 2001 petition to the FDA requesting a ban,[3] dietary supplements containing ephedrine alkaloids were determined by the FDA to "present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of

[1] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed July 20, 2018.
[2] Cancer Tutor. High pH therapy (cesium chloride protocol). https://www.cancertutor.com/cesium-chloride/. Accessed July 20, 2018.
[3] Public Citizen. Petition requesting ban of ephedra. September 5, 2001. https://www.citizen.org/our-work/health-and-safety/petition-requesting-ban-ephedra. Accessed July 20, 2008.

use," and therefore, were deemed adulterated under Section 342(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act" (21 CFR § 119.1) and were banned.[4]

A. ACTIONS REQUESTED

(1) Immediately issue a determination that dietary supplements containing cesium chloride or any other cesium salt present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use and require that all such dietary supplements be removed from the market.

(2) Issue an FDA safety communication advising consumers and health care professionals about the harms that can result from supplementation with CsCl or any other cesium salt.

B. STATEMENT OF GROUNDS

1. Background

Cesium characteristics, half-life, and excretion

Cesium is a member of the group 1 alkali earth metals, which also include lithium, sodium, potassium, rubidium, and francium. Cesium, which has chemical properties similar to lithium, sodium, and potassium, is a trace element in human metabolism.[5] Total body cesium under normal conditions is estimated at about 1.5 milligrams (mg), with the largest quantities found in soft tissues (especially skeletal muscle) at a concentration of 0.009 to 0.02 gram/gram (gm/gm) wet weight.[6] Plasma levels of cesium normally range from approximately 0.00045 to 0.260 gm/gm wet weight.[7]

Cesium chloride is an inorganic chloride salt with the formula CsCl. It is a colorless crystal that is highly soluble in water.[8] CsCl ingested orally is nearly 100 percent absorbed in the small intestine.[9] Kinetic modeling suggests that cesium distribution is extensive, with the greatest concentrations in the kidneys, skeletal muscle, liver, red blood cells, and brain.[10] Because of the long half-life of cesium, it takes approximately 200 days of daily dosing to reach a steady state. The serum half-life of cesium is approximately 70 hours in men and 96 hours in women, and

[4] 69 FR 6853.
[5] Food and Drug Administration. FDA briefing document, Pharmacy Compounding Advisory Committee (PCAC) meeting. June 23, 2016. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf. Accessed July 20, 2018. PDF page 67.
[6] *Ibid*. PDF page 67.
[7] *Ibid*. PDF page 67.
[8] *Ibid.* PDF page 64.
[9] *Ibid.* PDF page 67.
[10] *Ibid.* PDF pages 67-68.

elimination is 85 percent urinary, 13 percent fecal, and 2 percent through sweat.[11] The renal mechanisms for excretion of cesium are thought to be similar to those of potassium.[12]

History of cesium use

CsCl and cesium carbonate administered orally or by intravenous injection has been promoted without FDA approval by doctors and cancer centers as an alternative treatment of cancer known as "high pH therapy" or "cesium therapy." The flawed rationale for promoting such therapy is based on a 1956 paper by Otto Warburg, who postulated that cancer cells rely on non-oxidative glycolysis and ferment even in the presence of adequate oxygen, thus leading to low intracellular pH and subsequent cancer cell survival.[13] Others subsequently theorized that cesium kills cancer cells by increasing the cellular pH of the cells.[14] With no credible evidence to support this theory, some physicians began administering CsCl to a limited number of cancer patients.[15]

In particular, in 1984, Sartori published a case series of 50 cancer patients who had been treated with CsCl over a three-year period.[16] He claimed an "overall 50% recovery from cancer" with CsCl therapy. However, as the FDA itself noted, this case series had "major design flaws including its uncontrolled nature, retrospective design, and probable case selection bias, making its conclusions unreliable."[17]

Claims about the anti-cancer effects of CsCl have never been substantiated in rigorous, well-designed clinical trials. Nevertheless, CsCl is being administered at many different complementary alternative medicine clinics that cite such flawed research as legitimate sources of scientific evidence.

Marketing of CsCl supplements

Cancer patients represent a particularly vulnerable subset of individuals who are often desperate for a cure, especially if their cancers fail to respond to conventional treatments. Marketers of complementary and alternative medicine have taken advantage of such individuals through the promotion of CsCl treatment. For example, as recently as June 14, 2018, the website for the Montana-based Wolfe Clinic advertised a cesium chloride protocol for patients who have stage IV cancer or fast-growing cancers. Excerpts from the company's online promotional materials included the following:[18]

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[11] *Ibid.* PDF page 68.
[12] *Ibid.* PDF page 68.
[13] Warburg O. On the origin of cancer cells. *Science*. 1956;123(3191): 309-314.
[14] Brewer, AK. The high pH therapy for cancer tests on mice and humans. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):1-5.
[15] *Ibid*.
[16] Sartori HE. Cesium therapy in cancer patients. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):11-13.
[17] Food and Drug Administration. FDA briefing document, Pharmacy Compounding Advisory Committee (PCAC) meeting. June 23, 2016. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf. Accessed July 20, 2018. PDF page 67.
[18] Wolfe Clinic. The cesium chloride protocol. https://www.thewolfeclinic.com/wp/the-cesium-chloride-protocol/. Accessed June 14, 2018.

> With the low pH, cancer cells thrive. However, because the cancer cells are burning glucose (and creating lactic acid), enormous amounts of energy are pulled from non-cancerous cells. In the "cachexia cycle," the liver converts the lactic acid back to glucose, which also consumes enormous amounts of energy. Thus, the cancer cells convert glucose to lactic acid, the lactic acid travels to the liver; the liver converts the lactic acid back to glucose, which then travels back to the cancer cell. This cycle consumes an enormous amount of energy.
>
> Cesium has been proven by Dr. A. Keith Brewer, PhD, to get into cancer cells, when other nutrients cannot. …
>
> Ionic cesium chloride works by making cancer cells highly alkaline, typically 8.0 and above, thus killing the cancer cell. Cesium chloride not only kills cancer cells, but it immediately stops the metastasis of the cancer, can shrink tumor masses within weeks, and almost always stops the pain of cancer within 12 to 36 hours. Many tests on humans have been carried out by H. Nieper in Hanover, Germany, and by H. Sartori in Washington, DC, as well as by a number of other physicians. On the whole, the results have been very satisfactory. It has been observed that all pains associated with cancer disappear within 12 to 24 [hours], except in a very few cases where there was a morphine withdrawal problem that required a few more hours.
>
> Note that it is the CANCER CELL, not the blood that rises to 8.0 or above. The body keeps the blood within a small range of pH.
>
> The Cesium Chloride Protocol directly targets cancer cells. Normal cells do not ingest the cesium chloride.

The Wolfe Clinic's CsCl treatment protocol called for taking no less than 1.5 gm of CsCl orally twice daily. It also recommended taking CsCl concomitantly with potassium, magnesium and increasing water intake. Furthermore, the protocol provided additional options for CsCl intake at doses as high as 15 gm per day in three divided doses.[19]

CsCl also is marketed to the public as dietary supplements in a variety of forms, including aqueous solutions and capsules. For example, Essense of Life markets a CsCl solution containing 1.5 gm of CsCl per tablespoon (15 milliliters [mL]).[20] The recommended serving size is 1.5 gm, and one bottle containing 64 servings is identified as a one-month supply. Online advertisements for the product state that "Cesium Chloride is part of a nutrition plan known as 'High pH Therapy.'" Amazon, on behalf of the Florida Herb House, also markets a CsCl solution containing 1.5 gm per 15 mL.[21] According to the product labeling, a serving size is either 1.5 or 3.0 gm of CsCl. This product also contains rubidium.

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[19] *Ibid.*

[20] Essense of life. Cesium chloride and potassium. https://www.essense-of-life.com/minerals/M-030/cesium-chloride.html. Accessed July 20, 2018.

[21] Amazon. Cesium liquid ionic & super potassium high pH therapy minerals (32 oz). https://www.amazon.com/Cesium-Liquid-Potassium-Therapy-Minerals/dp/B00D8VJTU0/ref=sr_1_5_a_it?ie=UTF8&qid=1528718504&sr=8-5&keywords=cesium+chloride+supplement. Accessed July 20, 2018.

Natural Health Consultants sells CsCl supplements made by Bio-Tech Pharmacal in the form of 500-mg capsules.[22]

Of note, some of these dietary supplement products are marketed with accompanying potassium supplements, indicating manufacturers' awareness of the adverse effects of CsCl on serum potassium.

Finally, at least one website promotes cesium carbonate supplementation as a treatment for cancer.[23]

2. Previous FDA conclusions about cesium toxicity during its evaluation of the nomination of CsCl as a bulk drug substance for use in pharmacy compounding

Nominations of CsCl for inclusion on the 503A bulks list

On September 30, 2014, the American Association of Naturopathic Physicians, Alliance for Natural Health USA, Integrative Medicine Consortium, and McGuff Compounding Pharmacy Services, Inc., nominated cesium chloride for inclusion on the FDA's list of bulk drug substances that, although they are neither the subject of an applicable United States Pharmacopeia or National Formulary monograph nor components of any FDA-approved drugs, can be used to compound drug products under section 503A of the FDCA (the 503A bulks list).[24] The nominators proposed using compounded CsCl in combination with other natural substances in treating individuals with numerous types of cancers, by a presumed alkalinizing effect.[25] The proposed route of administration of compounded CsCl for this use was intravenous infusion. Among the claims made by the nominators about CsCl were the following:

> No existing drug matches the advantages of cesium chloride against cancer: the evident ability to enter the cancer cell together with the pH rise, as well as the high remission rate and lack of observed side effects at therapeutic dose. Generally safe and non-toxic substances such as cesium chloride are a viable alternative.

The nominators' arguments failed to cite any reliable scientific data on the proposed efficacy of CsCl in treating cancer. As discussed below, the FDA expressed strong opposition to this nomination and the arguments supporting it.

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[22] Natural Health Consultants. Cesium 500mg 100 Capsules. https://www.naturalhealthconsult.com/cesium-500-mg-100-capsules-bio-tech.html. Accessed July 20, 2018.

[23] Cesium carbonate & cesium chloride kills cancer cells. http://www.angelfire.com/az/sthurston/cesiumcarbonateforcancer.html. Accessed July 20, 2018.

[24] Food and Drug Administration. FDA briefing document, Pharmacy Compounding Advisory Committee (PCAC) meeting. June 23, 2016. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf. Accessed July 20, 2018. PDF pages 38-60 and 62.

[25] *Ibid.* PDF page 62.

FDA reviewers identify significant safety risks with compounding cesium chloride

The nomination of CsCl for the 503A bulks list was considered by the FDA's Pharmacy Compounding Advisory Committee (PCAC) on June 23, 2016.[26] In a May 31, 2016, review of cesium chloride, FDA reviewers opposed adding CsCl to the 503A bulks list, in part because there are "serious safety concerns related to the use of cesium chloride."[27] In their discussion of the safety of cesium chloride for use in compounding, FDA reviewers noted the following in their nonclinical assessment of the drug:[28]

> b. Safety pharmacology
>
> In rabbits and dogs, cesium chloride administration, either as intravenous bolus injections (1 mmol/kg [millimoles/kilogram]) or intravenous infusion (0.018 – 0.1 mmol/kg/min), has been **shown to cause ventricular tachycardia** (Takahashi et al., 1998; Nayebpour et al., 1989; Senges et al., 2000). The finding in dogs was associated with **early and delayed afterdepolarizations** (Patterson et al., 1990). In canine cardiac Purkinje fibers, cesium chloride treatment (5 mM) resulted in **prolongation of action potential duration and bradycardia-dependent early afterdepolarizations** (Kinnaird et al., 1991).
>
> c. Acute toxicity
>
> … In mice, single-dose administration with cesium chloride caused **decreased motor activity** and Straub tail in a dose-dependent manner. Clinical signs included **autonomic disturbance, diarrhea, and salivation** (Bose et al., 1984). …
>
> f. Developmental and reproductive toxicity
>
> The effect of pre- and postnatal maternal ingestion of cesium chloride on neonatal growth and development was evaluated in albino mice. In this study, cesium chloride was administered in drinking water at conception and during gestation, lactation, and throughout the 21 days of breast-feeding during weaning. Maternal exposure to cesium chloride **caused a sex-dependent decrease of weanling's body weight**. Decreased brain and testis weights and increased spleen weights were noted when compared to control (Messiha, 1988; Messiha, 1994). Similarly, in a separate study in mice, maternal exposure to 1mEq CsCl solution from birth and through weaning of offspring, resulted in decreased body, kidney, and brain weights in the offspring, which were breastfed until weaning (Messiha, 1998). …
>
> **Conclusions: Nonclinical studies in mice, rats, and dogs identified the cardiovascular and central nervous systems as the major target organ systems of toxicity**. **Major toxicity findings included ventricular tachycardia, decreased motor activities, autonomic disturbances, and salivation**. Genetic toxicology studies with cesium chloride have yielded equivocal results; however, some studies have shown that

[26] *Ibid*. PDF page 5.
[27] *Ibid.* PDF pages 61-73.
[28] *Ibid.* PDF pages 65-66.

> cesium chloride can cause chromosomal aberration in mouse bone marrow cells. Reproductive studies in mice have shown that exposure of offspring through breastfeeding by mothers administered cesium chloride in the drinking water caused decreased body and organ weights (e.g., brain, kidney, spleen, and testis) in the offspring. **The toxicity profile of cesium chloride in animal studies weighs against its inclusion on the 503A list**.
>
> [Emphasis added]

Regarding human safety data on cesium chloride, FDA reviewers reported the following:[29]

> a. Reported adverse reactions
>
> Cesium blocks potassium rectifier channels on atrial and ventricular myocytes, **resulting in prolongation of the QT interval, which can lead to arrhythmias, including torsade de pointes** (Chan et al., 2009, Dalal et al., 2004, Jones et al, 2001, Vyas et al., 2006, Lyon and Mayhew 2003, O'Brien et al., 2008, Pinter et al., 2002, Sessions et al., 2013, Sohn and Vassale, 1995, Wiens et al., 2009.) Because of the long half-life of cesium, it takes approximately 200 days of daily dosing to reach a steady state. It is therefore not surprising that FAERS and CAERS case reports describe arrhythmias occurring after weeks to months of therapy with cesium chloride. **Several case reports describe serious toxicities resulting from cesium chloride ingested as an alternative therapy for cancer, including hypokalemia, seizures, ventricular arrhythmias, syncope, and death**…
>
> **Conclusions: The limited information available about the safety of cesium chloride gives rise to significant concern about its use in compounding. The evidence of cesium chloride causing hypokalemia, seizures, QT prolongation, and cardiac arrhythmias is particularly concerning.** There are numerous FDA-approved agents that have demonstrated safety and efficacy for the treatment of patients with various cancers.
>
> [Emphasis added]

It is also notable that the FDA reviewers concluded the following regarding the efficacy of cesium chloride for treatment of cancer:[30]

> Cesium chloride has **not been shown to be efficacious for the prevention or treatment of any form of cancer**. … evidence of clinical benefit from cesium in human cancer is limited to one case series published in 1984 by Sartori. That case series had major flaws including its uncontrolled nature, retrospective design and probable case selection bias. Therefore, the results cannot be considered reliable.

[29] *Ibid.* PDF page 67-68.
[30] *Ibid*. PDF page 68.

In their recommendation regarding whether cesium chloride should be included on the 503A bulks list, FDA reviewers stated the following:[31]

> **RECOMMENDATION**
>
> We have evaluated cesium chloride as a candidate for the list of bulk drug substances under section 503A of the FD&C Act and **do not recommend** it be included on the list of bulk drug substances allowed for use in compounding [emphasis in original]. …
>
> **There are serious safety concerns related to the use of cesium chloride indicated by the results of both non-clinical and clinical studies**. Non-clinical studies show significant cardiac and central nervous system toxicity including ventricular tachycardia, decreased motor activities, and autonomic disturbances. In addition, studies in mice show reproductive effects of decreased body and organ weights in offspring. **Clinically, numerous reports of serious toxicity following cesium chloride use for the treatment of cancer have been made with effects including hypokalemia seizures, ventricular arrhythmias, syncope, and death.** … [Emphasis added]
>
> **Cesium chloride is not safe for human use and there is no evidence it is effective for the treatment of any cancer. Relying on this type of treatment may have serious health consequences, including ventricular arrhythmias and cardiac arrest.** In addition, use of cesium chloride may cause a patient to delay the use of treatments that have been found to be safe and effective for treating cancer. Based on a balancing of the four evaluation criteria, we find that cesium chloride is not a suitable substance for the bulk drug substance list under 503A of the FD&C Act.
>
> [Emphasis added]

PCAC deliberations and recommendation

On June 23, 2016, the FDA's PCAC discussed and voted on whether cesium chloride should be included on the 503A bulks list. During the meeting, Dr. Michael Brave, Clinical Reviewer in the Division of Oncology Products, Office of Hematology and Oncology Products, presented the FDA's review of the drug. His presentation affirmed the assessment presented in the FDA's May 31, 2016, review of cesium chloride. During his presentation, Dr. Brave noted the following:[32]

> Published literature indicates that cesium chloride used in the treatment of cancer has been taking place since at least the 1980s. Currently, oral cesium chloride is advertised by a number of compounding pharmacies.

[31] *Ibid*. PDF pages 69-70.

[32] Food and Drug Administration. Transcript of Pharmacy Compounding Advisory Committee (PCAC). June 23, 2016, morning session. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM563843.pdf. Accessed July 20, 2018. PDF page 75.

When asked by PCAC member Dr. Carome, one of the petitioners, whether it would be fair to say that the FDA has concluded that cesium chloride raises serious safety risk concerns, Dr. Brave answered affirmatively.[33]

PCAC member Dr. John DiGiovanna, Senior Research Physician in the DNA Repair Section, Dermatology Branch, Center for Cancer Research, National Cancer Institute, offered the following comments during the discussion of cesium chloride:[34]

> This substance is a little bit different than the others, I think, that we've discussed in that its indication seems to be for patients who are at end-of-life scenarios because of malignancy.
>
> It occurs to me that these patients are a very vulnerable group that are easily manipulated by anything that offers them hope. I think in that scenario, my perception is that potentially toxic compounds really need to be studied in a controlled environment under an IND [investigational new drug application] to determine if there's any evidence that they offer benefit comparable to the toxicity that they offer. This particular compound raises some concerns to me that the others didn't.

PCAC Chairperson Dr. Jurgen Venitz, Associate Professor at Virginia Commonwealth University School of Pharmacy, Department of Pharmaceutics, noted the following during the discussion of cesium chloride:[35]

> So even if you state the point that the efficacy [of cesium chloride] is not demonstrated, it has a major safety issue, and safe doses have not been established, forget the fact that we know nothing about effective doses.

By a unanimous vote of 11 to 0 (with no abstentions), the PCAC recommended that the FDA **not** place cesium chloride on the 503A bulks list.[36] All members cited concerns about the safety of the drug as one reason for their votes.[37] This unanimous recommendation to exclude CsCl from the 503A bulks list was based on a large body of evidence that demonstrates this chemical has unacceptable toxic effects in humans and a lack of evidence that it offers any health benefits.

Importantly, given the oral bioavailability of CsCl, the same dangers identified by the FDA for the use of CsCl as an intravenous formulation in pharmacy compounding extend to CsCl-containing dietary supplements.

3. Human evidence of cardiovascular toxicity

As the FDA noted in its review of the nomination of CsCl as a bulk drug substance for use in pharmacy compounding, "cesium blocks potassium rectifier channels on atrial and ventricular

[33] *Ibid*. PDF page 77.
[34] *Ibid*. PDF page 99.
[35] *Ibid*. PDF page 100.
[36] *Ibid*. PDF page 102.
[37] *Ibid*. PDF pages 102-104.

myocytes, resulting in prolongation of the QT interval, which can lead to arrhythmias, including torsades de pointes."[38]

We identified 15 published case reports that described a total of 16 patients who experienced serious adverse effects as a result of CsCl or cesium carbonate (Cs_2CO_3) use, including hypokalemia, life-threatening cardiac arrhythmias, cardiac arrest, and death. The following is a summary of key features of these cases (see Appendix for details of these cases):

- The patients ranged in age from 8 to 82 years (median age 45). There were two children, one age 8 and the other age 16.
- Five patients were male, and 11 were female.
- Fourteen patients took cesium chloride and two patients took cesium carbonate.
- Thirteen patients had cancer and had taken either CsCl (11 patients) or Cs_2CO_3 (two patients) in lieu of or concomitantly with conventional cancer treatment. One patient took CsCl for prophylaxis for breast cancer, one received an injection of CsCl administered by a family member for a breast mass in the absence of any formal diagnosis of cancer, and another took CsCl as part of a "detoxification" program for menorrhagia.
- The daily dose of CsCl, which was reported for seven cases, ranged from 3 grams (g) (six patients) to 9 g (one patient). The daily dose of Cs_2CO_3 was 9 g in one case and 10 g in the other. The duration of use, which was reported for 13 cases, ranged from one day to one year prior to onset of the reported adverse events. The reported route of administration was intravenous only in three cases, oral only in ten cases, intravenous for two weeks followed by oral use for two months in one case, and oral use for one year followed by a single injection around a breast mass in one case.
- Two patients died from cardiac arrest in the doctor's office while receiving an intravenous dose of CsCl plus aloe vera. The remaining patients presented to the hospital after collapsing at home (one patient); having a witnessed cardiac arrest (two patients); having syncopal episodes (five patients); having seizures (two patients); having an episode of shaking, unresponsiveness, and urinary incontinence (one patient); or developing pancreatitis and abdominal metastases (one patient).
- Of the 12 patients who were hospitalized, two had a cardiac arrest after presenting to the hospital; 12 had QT interval or corrected QT (QTc) interval prolongation; 10 developed some form of ventricular tachycardia, including five who had torsades de pointes; one had ventricular fibrillation; and two had bradycardia.
- One female patient who was using Cs_2CO_3 had a witnessed cardiac arrest at home and was resuscitated with CPR by her husband. She was found to have a prolonged QTc interval upon presentation to the hospital but had no documented ventricular arrhythmias.
- One female patient who had a pre-hospital cardiac arrest and was found to have a polymorphic ventricular tachycardia was discharged to hospice care on hospital day 7 in a neurovegetative state and died three days later. Her death was plausibly caused by cardiac complications from CsCl exposure.

[38] Food and Drug Administration. FDA briefing document, Pharmacy Compounding Advisory Committee (PCAC) meeting. June 23, 2016. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf. Accessed July 20, 2018. PDF page 67.

- Another female patient with breast cancer complicated by brain metastases who was hospitalized for seizures died 48 hours after admission. The role of CsCl use in her death is uncertain.
- Nine patients had hypokalemia (low serum potassium) upon initial presentation to the hospital, and two additional patients developed hypokalemia during hospitalization.
- In at least three patients who had both hypokalemia and QT or QTc interval prolongation, the case reports noted that the QT or QTc interval prolongation persisted for days to weeks despite correction of the hypokalemia.

Importantly, as the FDA recognizes, because of the long half-life of cesium, it is not surprising that case reports have described arrhythmias that occurred after weeks to months of use of cesium chloride.

A search on the FDA's Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) website yielded three reports of patients who experience serious adverse events while using cesium-containing supplements.[39] One report from 2005 involved a 71-year-old male who was hospitalized for syncope and found to have QT interval prolongation. Based on the patient's age and sex, this case was not among the 14 patients reported in the medical literature discussed above. The other two CAERS reports involved women, the first age 39 who was hospitalized for convulsions and the second age 47 who had a cardiac arrest. Based upon the limited data provided in the publicly available CAERS website, we cannot confirm whether these two cases were among the 14 patients reported in the medical literature discussed above.

It is important to note that there likely has been significant underreporting to the FDA of cases of serious adverse events associated with CsCl or Cs_2CO_3 use. Although the Dietary Supplement and Nonprescription Drug Consumer Protection Act mandates that manufacturers, packers, and distributors report adverse effects associated with dietary supplements to the FDA,[40] most of the aforementioned reports of serious adverse effects of cesium supplements have been published in medical journals but not reported to the FDA. Underreporting also may be driven by physicians and patients simply being unaware that they can report adverse events due to dietary supplement intake. Unlike drugs, dietary supplements are considered "safe" until proven otherwise because no safety testing is required by the FDA.

4. *In vitro* and animal evidence of cardiac toxicity

Prior to the adverse health effects being documented in humans, *in vitro* and animal studies had clearly demonstrated the mechanism of these deleterious effects of cesium in laboratory settings. Researchers demonstrated over 40 years ago that cesium blocks potassium ion conductance and

[39] Search performed on June 27, 2018 at: Food and Drug Administration. CFSAN Adverse Event Reporting System (CAERS). https://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm. June 27, 2018.

[40] Food and Drug Administration. Guidance for industry: Questions and answers regarding adverse event reporting and recordkeeping for dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm171383.htm. Accessed July 20, 2018.

affects the rate of sodium pumping in cardiac Purkinje fibers.[41] Furthermore, treatment of canine cardiac Purkinje fibers with cesium resulted in increased action potential duration and early afterdepolarizations.[42]

A number of subsequent animal studies have further established cesium's adverse effects on the heart. Indeed, the well-established, reproducible cesium-induced canine model of cardiac arrhythmias is characterized by QT interval prolongation, ventricular ectopy, and ventricular tachycardia.[43,44,45, 46,47,48] The phenomenon of cesium-induced early afterdepolarizations seen in *in vitro* studies was corroborated in animal studies.[49,50] Furthermore, susceptibility to malignant arrhythmias seen in tachycardia-induced heart failure in dogs was exacerbated by exposure to cesium.[51,52]

The totality of these studies provides substantial and consistent evidence of cesium's ability to block potassium channels in the heart, disrupt normal electrical conduction in the heart, and cause QT prolongation and ventricular arrhythmias.

5. Human and animal evidence of adverse central nervous system (CNS) effects of CsCl

In addition to the detrimental effects on the heart, there is evidence that cesium may adversely affect the brain. While little is known about the effects of cesium on the CNS in humans, a toxicology assessment of the post-mortem tissue of a 42-year old female who had breast cancer that had metastasized to the brain and who had been hospitalized for generalized seizures revealed markedly elevated levels of cesium in the brain (780 mg/kg).[53] In another case report,

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[41] Isenberg G. Cardiac purkinje fibers: Cesium as a tool to block inward rectifying potassium currents. *Pflugers Arch*. 1976;365(2-3):99-106.

[42] Kinnaird AA, Man RY. Electrophysiological effects of cesium and tetraethylammoniumin canine cardiac Purkinje fibers. *J Pharm Exp Ther*. 1991;258(3):778-738.

[43] Brachmann J, Scherlag BJ, Rosenshtraukh LV, Lazzara R. Bradycardia-dependent triggered activity: relevance to drug-induced multiform ventricular tachycardia. *Circulation*. 1983;68(4):846-856.

[44] Levine JH, Spear JF, Guarnieri T, et al. Cesium chloride-induced long QT syndrome: demonstration of afterdepolarizations and triggered activity in vivo**.** *Circulation*. 1985 Nov;72(5):1092-103.

[45] Nayebpour M, Nattel S. Pharmacologic response of cesium-induced ventricular tachyarrhythmias in anesthetized dogs. *J Cardiovasc Pharmacol.* 1990;15(4):552-561.

[46] Patterson E, Szabo B, Scherlag BJ, et al. Early and delayed afterdepolarizations associated with cesium chloride-induced arrhythmias in the dog. *J Cardiovasc Pharmacol*. 1990;15(2):323-331.

[47] Pak PH, Nuss HB, Tunin RS, et al. Repolarization abnormalities, arrhythmia and sudden death in canine tachycardia-induced cardiomyopathy. *J Am Coll Cardiol.* 1997;30(2):576–584.

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post-mortem examination of two cancer patients who had died after treatment with unapproved intravenous injections of CsCl revealed very high levels of cesium in the brain, as well as the liver and kidneys.[54]

Animal studies have also provided evidence of cesium-induced CNS toxicity. For example, studies in Swiss-Webster mice found that single injections of CsCl caused transient excitation and hyperactivity followed by significant suppression of motor activity.[55] Signs of autonomic disturbance also were seen at toxic doses. Another study in rats found that CsCl treatment enhanced 5-hydroxytryptamine (or serotonin-a neurotransmitter) function in the brain.[56] Although more studies of the effects of CsCl on the brain are required, these data clearly indicate that cesium can cross the blood-brain barrier, accumulate in the brain, and alter CNS functions.

6. Conclusions

Given the abundance of evidence indicating the dangers associated with ingestion of CsCl or any other cesium salt, it is imperative that the FDA prohibit the marketing of dietary supplements containing these chemicals. There are no data to suggest that CsCl or any other cesium salt has *any* health benefits, nor is there is any evidence demonstrating its proposed cancer-treating properties. It is amply clear from the scientific literature and case reports that the risks of using CsCl or any other cesium salt in any capacity outweigh any claimed benefits.

Finally, the use of alternative and complementary medicine has increased substantially over the years,[57] with about half of cancer patients seeking alternative care.[58] This is particularly alarming, as the number of people lured by false and misleading claims made by the purveyors of cesium as the panacea of cancer may continue to increase. This chemical is endorsed by unscrupulous and dangerous doctors who leach and profit off the hopes of vulnerable patients.

For the reasons stated above, we hereby petition the FDA, pursuant to Sections 331(a) and 342(f) of the Federal Food, Drug, and Cosmetic Act and FDA regulations at 21 C.F.R. § 10.30, to take the following actions:

(1) Immediately issue a determination that dietary supplements containing cesium chloride or any other cesium salt present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use, and require that all such dietary supplements be removed from the market.

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(2) Issue an FDA safety communication advising consumers and health care professionals about the harms that can result from supplementation with CsCl or any other cesium salt.

C. ENVIRONMENTAL IMPACT

We claim categorical exclusion under 21 C.F.R. § 25.31(a) from the environmental assessment requirement. An assessment is not required because the requested action would not increase the use of the active moiety that is the subject of this petition.

D. ECONOMIC IMPACT

Will be submitted upon request.

E. CERTIFICATIONS

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

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Appendix – Case Reports of Adverse Events Linked to Cesium Use							
Case	**Source**	**Pt. Demographics & Medical Hx**	**Reason for CsCl or Cs_2CO_3 Intake**	**CsCl or Cs_2CO_3 Regimen and Other Supplements**	**Reason for Emergency Department Visit or Hospital Admission**	**Clinical Presentation and Findings**	**Intervention/Outcome**
1	Saliba W, Erdogan O, Niebauer. Polymorphic ventricular tachycardia in a woman taking cesium chloride. *Pacing Clin Electrophysiol*. 2001;24(4 Pt 1):515-517.	• Age 47, female • Multiple sclerosis, diabetes mellitus, chronic "bladder spasms" • No family history of long QT interval or sudden death • ECG five years before presentation had normal QT interval	Prophylactic supplement to prevent breast cancer	3 grams (g) of CsCl per day orally over the previous three weeks; also reported taking + $CaCO_3$, MgO, green tea (containing licorice root), garlic, essential fatty acids, coral calcium, pantothenic acid and choline chloride, vitamin C, citrus bioflavonoid, vitamin A with b-carotene, zinc, a multivitamin, melatonin, cholecalciferol, "dots" sublingual	Collapsed at home	• Irregular pulse • QT prolongation (691 milliseconds [ms]) • Episodes of polymorphic ventricular tachycardia • Hypokalemia (3.2 mg/deciliter [dL])	The patient initially was treated with lidocaine to stabilize her rhythm. After lidocaine continuation, potassium and magnesium supplementation and discontinuation of all dietary supplements, ECGs showed improvement in the QT interval and no further arrhythmias during hospitalization. The patient was discharged after 4 days.
2	Pinter A, Dorian P, Newman D. Cesium-induced torsades de pointes. *N Engl J Med*. 2002;346(5):383-384.	• Age 62, male • Prostate cancer • No history of cardiovascular disease, syncope, or palpitations and no family history of sudden death	Naturopathic treatment for prostate cancer	2 g of CsCl four times per day intravenously for two weeks, followed by 1 g of CsCl three times per day for two months	Recurrent syncopal episodes	• QT prolongation (approximately 700 ms) • Ventricular premature beats • Torsades de pointes ventricular tachycardia • Hypokalemia (2.8 milliequivalents/liter [mEq/L])	The patient was treated with intravenous magnesium and potassium. His QT interval remained prolonged and ventricular premature beats persisted after normalization of the serum potassium level. The patient agreed to stop taking CsCl. After six-month follow-up, the patient had not had any further episode of syncope and his corrected QT (QTc) interval had returned to normal.
3	Lyon AW, Mayhew WJ. Cesium toxicity: A case of self-treatment by alternate therapy gone awry. *Ther Drug Monit*. 2003;25(1):114-116.	• Age 52, female • Colon cancer with liver metastasis	Self-treatment for colon cancer	3 g of oral cesium salts daily for several weeks; also reported a vegetarian diet, lecithin, and vitamin supplements	Hypotensive syncope, possible seizure	• Hypotensive (initial BP 60/0) • Long QT interval (596 ms on first presentation to emergency department [ED]; 650 ms on second presentation to ED)	On first ED presentation, the patient was treated with intravenous saline with potassium and self-discharged after 3 hours. The patients was hospitalized after the second ED presentation and during the next 3 days, following discontinuance of cesium, her QT interval gradually

						• Polymorphic ventricular tachycardia (first ED presentation) • Premature ventricular complexes (second ED presentation) • Bradycardia • Hypokalemia (3.2 millimoles/liter [mmol/L] on first ED presentation; 2.8 mmol/L on second ED presentation)	shortened to 390 ms, and potassium levels remained within the normal range.
4	Centeno JA, Pestaner JP, Omalu BI, et al. Blood and tissue concentration of cesium after exposure to cesium chloride: A report of two cases. *Biol Trace Elem Res*. 2003;94(2):97-104.	• Age 41, male • Metastatic kidney cancer	Treatment for kidney cancer	Intravenous CsCl and aloe vera (dose not reported), daily doses for two days	Never hospitalized. The patient died at doctor's office during treatment.	• Post-mortem toxicological assessments revealed high levels of cesium in the liver, kidney, and brain	No intervention reported; death
5	Centeno JA, Pestaner JP, Omalu BI, et al. Blood and tissue concentration of cesium after exposure to cesium chloride: A report of two cases. *Biol Trace Elem Res*. 2003;94(2):97-104.	• Age 82, male • Metastatic lung cancer	Treatment for lung cancer	Intravenous CsCl and aloe vera therapy (dose not reported); one dose	Never hospitalized. The patient died at doctor's office during treatment.	• Post-mortem toxicological assessments revealed high levels of cesium in the kidney, liver, and brain	No intervention reported; death
6	Dalal AK, Harding JD, Verdino RJ. Acquired long QT syndrome and monomorphic ventricular tachycardia after alternative treatment with cesium chloride for brain cancer. *Mayo Clin Proc*. 2004;79(8):1065-1069.	• Age 43, female • Glioblastoma multiforme • Three weeks prior to presentation, had a QTc interval of 446 ms on a preop ECG • Other history: hypertension, gastroesophageal reflux, irritable	Adjunctive treatment for brain cancer	9 g of CsCl per day orally for 10 days, which she completed one day prior to admission	Two brief witnessed seizures; collapsed with cardiac arrest (during hospital triage) and ventricular tachycardia	• QTc prolongation (624 ms) • Ventricular tachycardia • Hypokalemia (3.1mEq/L)	The patient was treated with intravenous lidocaine (18 hours), potassium, magnesium, and valproic acid (prophylaxis for seizures). She had no further episodes of ventricular tachycardia, but after several days, her QTc interval remained prolonged despite normalization of electrolytes. Two-week follow-up revealed that her QTc interval remained prolonged but shorter

		bowel syndrome, migraines • No history of cardiovascular disease or syncope and no family history of long QT syndrome or sudden death					than admissions; a whole blood cesium level also was 16,000 micrograms (µg)/dL (normal is less than 27 µg/dl). Her QTc was normal six weeks after initial presentation, but she had a whole blood cesium level of 6,100 µg/dL.
7	Vyas H, Johnson K, Houlihan R, et al. Acquired long QT syndrome secondary to cesium chloride supplement. *J Altern Complement Med*. 2006;12(10):1011-1014.	• Age 39, female • Menorrhagia • No history of cardiovascular or neurological disease • No history of syncope or near-syncope • No family history of premature sudden death	"Detoxification program" for menorrhagia	Drinking one to two gallons of water along with cesium salt daily for two weeks	Three episodes of syncope during the preceding week, the last of which required cardiopulmonary resuscitation (consistent with a witnessed cardiac arrest)	• Mild hypokalemia (3.1 mEq/L) • Mild hypomagnesemia (1.4 mg/dL) • QTc prolongation (616 ms)	The patient's detoxification regimen was discontinued and her electrolyte abnormalities were corrected. Daily ECG showed gradual normalization of her resting QTc interval. At discharge, the QTc had decreased to 466 ms, and at 2-month follow-up, the QTc interval was 413 ms (50th percentile QTc for women). This correlated with a reduction in her urine cesium levels over the same period. The patient did well and returned to her asymptomatic, syncope-free state.
8	Curry TB, Gaver R, White RD. Acquired long QT syndrome and elective anesthesia in children. *Paediatr Anaesth*. 2006;16(4):471-478.	• Age 8, male • Osteogenic sarcoma of wrist	Patient's mother administered numerous nutritional supplements as part of alternative cancer treatment regimen.	Nutritional supplements, including coenzyme Q10, coral calcium, bovine colostrum, seal oil, a multivitamin, vitamin D, and cesium mineral salts; dose not reported.	Episodes of shaking, non-responsiveness, and urinary incontinence	• Had cardiac arrest during hospitalization, which spontaneously terminated • Torsades de pointes (degenerated into ventricular fibrillation) • QT prolongation (710 ms) • Sinus bradycardia	After cessation of these agents and treatment with atenolol and potassium supplements, the patient's QT interval normalized to the upper limit of normal before discharge. He had no subsequent cardiac arrests or syncopal episodes.
9	O'Brien CE, Harik N, James LP, et al. Cesium-induced QT-interval prolongation in an adolescent. *Pharmacotherapy*. 2008;28(8):1059-1065.	• Age 16, female • Metastatic hepatocellular carcinoma	Treatment for metastatic hepatocellular carcinoma	1 g of CsCl (capsules), three times daily for two weeks; also reported taking Oxy-Plus multivitamin one tablet three times/day (contains vitamin D3 333 IU,	Two brief episodes of syncope	• Premature ventricular contractions • Monomorphic ventricular tachycardia	The patient was treated with lidocaine therapy. Her initial plasma cesium level was 2,400 µg/dl (normal < 1 µg/dl). After five days, her QTc had decreased to 560 ms, no additional arrhythmias had occurred, and

				vitamin C 69 mg, vitamin E 16 IU, vitamin B2 14 mg, vitamin B3 70 mg, vitamin B5 49 mg, iron 9 mg, CsCl 1 mg, and chlorophyll); coral calcium two capsules three times/day; coenzyme Q10 100 mg/day; dimethyl sulfoxide topical gel applied daily to skin nearest cancer; gold–aloe vera topical gel applied daily to skin nearest cancer; and vitamin D 5,000 IU, two capsules three times/day		• QTc prolongation (683 msec) with R on T phenomenon	lidocaine was discontinued. Two days later, the patient's QTc interval had decreased to 546. The family was counseled not to restart the alternative treatment regimen. During a follow-up visit two months later, the patient's QTc interval was 494 ms and her cesium level was 1,800 µg/dL.
10	Chan CK, Chan MHM, Tse ML, et al.Life-threatening Torsades de Pointes resulting from "natural" cancer treatment. *Clin Toxicol*. 2009;47(6):592-594.	• Age 65, female • Rectal cancer and liver metastasis • History of essential hypertension	Treatment for rectal cancer	Patient was taking anticancer naturopathic drugs for 6 weeks before admission, one of which was confirmed containing 89% CsCl by weight.	Recurrent syncope attacks	• Torsades de pointes polymorphic ventricular tachycardia • QTc prolongation (620 ms) • Hypokalemia (2.8 millimoles [mmol]/L)	The patients initially was treated with intravenous magnesium sulfate and potassium replacement. There was no improvement in her QTc prolongation after this treatment. Prussian blue treatment to shorten the half-life of cesium was started on day 7 of hospitalization and continued for four weeks. Her QTc interval returned to normal baseline at 27 days.
11	Wiens M, Gordon W, Baulcomb D, et al. Cesium chloride-induced torsades de pointes. *Can J Cardiol*. 2009;25(9):e329-e331.	• Age 45, female • Node-positive breast cancer for which she underwent a mastectomy but declined further surgery, radiation, and chemotherapy	Alternative therapy for breast cancer	3 g of oral CsCl regimen daily for approximately 150 days prior to presentation. She also received small doses of molybdenum, indium, rubidium, selenium, germanium, vanadium and daily potassium chloride	Syncopal episode	• QTc prolongation (516 ms) • Narrow complex ventricular tachycardia (240 beats/min) • Pulseless torsades de pointes • Initial normal potassium level (3.9 mmol/L) • Subsequent potassium levels over 6 days	The patient had multiple episodes of torsades de pointes. She was treated with intravenous amiodarone, followed by lidocaine and magnesium sulfate, as well as aggressive potassium supplementation.

						went as low as 3.0 mEq/L	
12	Sessions D, Heard K, Kosnett M. Fatal cesium chloride toxicity after alternative cancer treatment. *J Altern Complement Med.* 2013;19(12):973-975.	• Age 61, female • Right breast mass	Self-treatment of breast mass, but no diagnosis of breast cancer	Oral CsCl for one year; injection of 9 mL of oral CsCl solution (unknown concentration) around breast mass on night before presentation. Patient also had been taking oral selenium, potassium, vitamin D, silymarin, folic acid supplements, and a multivitamin for one year.	Witnessed cardiac arrest approximately 20 hours after CsCl injection into breast mass	• Polymorphic ventricular tachycardia • QTc prolongation (> 700 milliseconds) • Hypokalemia (2.7 mEq/L) • Hyponatremia (sodium 114 meq/L) • Whole blood cesium level (100,000 μg/L)	The patient was treated with amiodarone, lidocaine, magnesium, and rapid correction of hyponatremia and hypokalemia. She also was treated with Prussian blue orally daily beginning on hospital day 2 when her QTc interval was 694 ms. Her QTc interval decreased to the normal range on hospital day 3. The patient was discharged to hospice care on hospital day 7 with a diagnosis of neurovegetative state and anoxic encephalopathy. She died three days after discharge.
13	Khangure SR, Williams ES, Welman CJ. CT brain findings in a patient with elevated brain cesium levels. *Neuroradiol J*. 2013; 26(6):607-609.	• Age 42, female • Metastatic breast adenocarcinoma	Treatment for breast cancer	Intravenous CsCl regimen, dose and duration not reported.	Prior to admission, patient was unwell for 3 days with nausea, vomiting, and diarrhea. Patient was admitted for a generalized seizure.	• Had brain metastases on CT scan	CT scan revealed a right cerebellar mass and attenuation of brain parenchyma. Postmortem examination found elevated levels of cesium in the brain, liver, and kidneys. The patient developed sepsis and had multiple seizures. She died 48 hours after admission.
14	Young F, Bolt J. Torsades de pointes – a report of a case induced by caesium taken as a complementary medicine, and the literature review. *J Clin Pharm Ther*, 2013;38(3):254-257	• Age 46, female • Melanoma diagnosed 2 months prior to admission. • History of hypertension and COPD • No family history of prolonged QT or sudden cardiac death	Alternative treatment for melanomas	10 g of Cs_2CO_3 in water daily for one month; also took a variety of other high-dose multivitamin/mineral solutions and other supplements.	First admission was due to syncope and diarrhea. She declined intravenous rehydration and was discharged home. She continued to feel unwell over the next 2 weeks and presented to the ER again after having several syncopal episodes.	• Developed torsades de pointes and cardiac arrest in emergency department • Initial potassium level was 3.7 mmol/L (normal); subsequently had hypokalemia (3.2-3.4 mmol/L) • QTc prolongation (620 ms)	The patient was resuscitated and administered intravenous amiodarone, potassium, and magnesium. Her post-arrest QTc was 575 ms. She was hospitalized for 35 days with no further recurrence of arrhythmias. On discharge, her QTc was 484 ms.

15	Warsome MO, Gamboa D, Erik Waage Nielsen EW. [A woman in her forties with cancer, syncope and spasms]. *Tidsskr Nor Laegeforen*. 2014;134 (19):1855-1857	• Age forties, female • Advanced incurable rectal cancer • She had no family history of congenital long QT syndrome or of cardiovascular disease.	Alternative treatment for rectal cancer	9 gof Cs_2CO_3 in water daily orally for 11 days; in addition, she used a mineral supplement called "Quentin Marine isotonic" and only ate raw vegetables	Loss of consciousness followed by brief myoclonic jerks in her legs, witnessed cardiac arrest at home, revived with CPR	• A cerebral MRI was normal • QTc prolongation (596 ms) • Hypokalemia (2.8 mmol/L)	The patient was treated with potassium. After 10 days of treatment, the patient's QTc interval had decreased to 456 ms and her serum potassium was 4 mmol/ L. She had no ventricular arrhythmias during her hospital stay. The patient's QTc interval was 413 ms 60 days after ceasing cesium ingestion.
16	Horn S, Naidus E, Alper SL, Danziger J. Cesium-associated hypokalemia successfully treated with amiloride. *Clin Kidney*. 2015;8:335-338.	• Age 45, male • Laryngeal cancer	Treatment for laryngeal cancer after failure to respond to cisplatin	3 g of CsCl daily, usually ingested but occasionally with a topical preparation	Peripheral parethesias and hypokalemia (3.3 mmol/L) developed after two months of CsCl treatment. Pancreatitis and abdominal metastases subsequently developed.	• Hypokalemia (3.3 mmol/L) • Urinary potassium wasting	Normalization of serum potassium required daily potassium supplementation, both intravenous and oral, 60–180 mEq daily. The patient was treated initially with 10 mg amiloride daily, subsequently increased to 20 mg. After one week of amiloride treatment, the patient no longer required extra-dietary potassium supplementation. The patient died in hospice care 18 months after initial presentation.