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November 5, 2018

Carlos M. Garcia, M.D.
Director of Medicine
Utopia Wellness
110 State Street East
Oldsmar, FL 34677

Dear Dr. Garcia:

This letter serves to inform you that Public Citizen, a nonprofit consumer advocacy organization with more than 500,000 members and supporters nationwide, has submitted the enclosed formal complaint letters to the Federal Trade Commission (FTC), Food and Drug Administration (FDA), and Florida Board of Medicine regarding your medical center's dissemination of false and misleading advertisements that promote the use of cesium chloride — a drug that may no longer be compounded in the U.S. following regulatory action taken by the FDA in late July 2018 because the agency concluded that it was "unsafe for human use" — for the treatment of cancer. We requested that these agencies investigate, among other things, the deceptive promotional materials for intravenous cesium chloride on the Utopia Wellness website and your role in disseminating these materials.

Contrary to the claim made on the Utopia Wellness "Cesium Chloride" webpage that there is evidence "from numerous studies" that cesium chloride "has had astounding success in certain cancers," there is a clear lack of sound scientific evidence to support the use of cesium chloride for the treatment of cancer or any other disease. In the absence of evidence to support this claim, your medical center's website instead includes 30 deliberately falsified scientific journal article citations in which citations of actual scientific journal articles related to medical uses of ozone were modified by replacing the term "Ozone" with "Cesium Chloride" in the titles of the articles.

We request the immediate removal of the falsified scientific journal citations published on the Utopia Wellness website and all other promotional materials related to the use of cesium chloride to treat cancer while the FTC, FDA, and Florida Board of Medicine investigate this matter.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Meena M. Aladdin, Ph.D.
Health Researcher
Public Citizen's Health Research Group

Enclosures

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October 9, 2018

Andrew Smith
Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Mary K. Engle
Associate Director
Division of Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Mr. Smith and Ms. Engle:

Public Citizen, a nonprofit consumer advocacy organization with more than 500,000 members and supporters nationwide, hereby requests that the Federal Trade Commission (FTC), pursuant to the Federal Trade Commission Act,[1] immediately take appropriate enforcement action against Utopia Wellness, a medical center located in Oldsmar, Florida, for disseminating false and misleading advertisements that promote the use of the compounded drug cesium chloride as a treatment for cancer.

We believe that the advertising and promotional materials on the Utopia Wellness website regarding its intravenous (IV) cesium chloride therapy for treatment of cancer are deceptive within the meaning of the FTC Act. In particular, the company's website materials claim that IV cesium chloride is safe and effective for treating cancer and lists numerous falsified citations for scientific journal articles that purportedly support this claim, when in fact cesium chloride is not safe and effective for that use and the articles cited do not support that claim. The following is a more detailed discussion of the background and substance of our request.

The FTC's legal requirements for advertising

Sections 5 and 12 of the FTC Act prohibit the dissemination of advertisements, including those related to the purchase of drugs, that contain false or misleading representations or material omissions. The FTC Act broadly defines a "false advertisement" as follows:

[1] 15 U.S.C. §§ 45 and 52-55.

> The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.[2]

The FTC Act also defines a drug as follows:

> The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals…[3]

According to the FTC, advertising claims fall into two basic categories for substantiation purposes: (1) efficacy claims and (2) establishment claims. An efficacy claim "is a message that a given product successfully performs the advertised benefit, such as preventing or treating a medical condition."[4] The FTC applies a multifactor analysis, known as the *Pfizer* analysis, "to determine, on a case-by-case basis, the level of substantiation needed for an efficacy claim."[5] The factors considered in this analysis are: (1) the type of claim, (2) the type of product, (3) the benefits of a truthful claim, (4) the ease of developing substantiation for the claim, (5) the consequences of a false claim, and (6) the amount of substantiation experts in the field would agree is reasonable.[6]

In contrast, an establishment claim "is a message that the advertiser has scientific evidence backing up its efficacy claim."[7] The FTC does not apply the multifactor *Pfizer* analysis in determining the substantiation needed for these claims. "Instead, [i]f an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth."[8]

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[2] 15 U.S.C. § 55(a)(1).
[3] 15 U.S.C. § 55(c).
[4] Brief of Respondent FTC, *POM Wonderful LLC v. FTC*. D.C. Cir. No. 13-1060, at 6, filed March 25, 2014. http://www.ftc.gov/system/files/documents/cases/2014-03_pomwonderful_dccir_ftcoppbrieffinal.pdf. Accessed October 2, 2018.
[5] *See In re Pfizer Inc*., 81 F.T.C. 23 (1972).
[6] *Ibid*.
[7] Brief of Respondent FTC, *POM Wonderful v. FTC*, at 7.
[8] *In re Removatron Int'l Corp*., 111 F.T.C. 206, 297-99 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989).

The FTC has emphasized that "it is particularly important to enforce substantiation requirements in the area of medical-benefit claims" because "[f]or centuries, many sellers of health products have made highly misleading claims that their products fight particular diseases, and they often cite ostensibly promising medical experiments that turn out to have been flawed or nonprobative. Such claims have nonetheless duped millions of consumers, in part because products sold for their medical benefits are 'credence goods' — products whose efficacy consumers cannot easily ascertain before or even after purchasing them."[9]

In the context of dietary supplements, the Commission "will closely scrutinize the scientific support that an advertiser cites as substantiation for a disease claim—i.e., for an advertisement that suggest[s], either directly or indirectly, that a product will provide a disease benefit."[10] The FTC "usually requires two well-controlled clinical tests" to substantiate generalized claims that scientific evidence supports a product's purported medical benefits.[11] The FTC has extended that substantiation requirement to simple efficacy claims.[12]

The FTC is well aware that disease efficacy claims that are inadequately substantiated and inadequately qualified can harm consumers both financially and medically. With respect to financial harms, the Commission has noted that "like victims of any marketing fraud, consumers deceived into believing that a product will help prevent or treat diseases are more likely to buy the product and pay a premium for it than if they knew the whole truth."[13] Both financial and medical concerns independently justify the FTC's long-standing insistence on rigorous scientific evidence for disease claims.

Overview of cesium chloride

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 those of lithium, sodium, and potassium, is a trace element in human metabolism.[14] Cesium chloride is an inorganic chloride salt.

Cesium chloride and other cesium salts, such as cesium carbonate, can be administered orally or by IV injection. Compounded drugs containing cesium salts — most often cesium chloride — have been marketed and promoted by certain doctors and medical centers as an alternative form of cancer treatment 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.[15] Others later theorized that

[9] Brief of Respondent FTC, *POM Wonderful v. FTC*, at 7-8.
[10] FTC, Dietary Supplements: An Advertising Guide for Industry, at 1 (Apr. 2001).
[11] *In re Thompson Med. Co*., 791 F.2d 189, 194 (D.C. Cir. 1984).
[12] *Id*, at 195-96.
[13] Brief of Respondent FTC, *POM Wonderful v. FTC*, at 10.
[14] Food and Drug Administration. FDA briefing document, Pharmacy Compounding Advisory Committee (PCAC) meeting. *FDA*. June 23, 2016. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf. Accessed October 2, 2018. PDF page 67.
[15] Warburg O. On the origin of cancer cells. *Science*. 1956;123(3191): 309-314.

cesium kills cancer cells by increasing the intracellular pH of the cells.[16] Without credible evidence to support this theory, some physicians began administering cesium chloride to a limited number of cancer patients as early as the 1980s.[17]

In particular, in 1984, Sartori published a case series of 50 cancer patients who had been treated with cesium chloride over a three-year period.[18] He claimed an "overall 50% recovery from cancer" with cesium chloride therapy. However, as the Food and Drug Administration (FDA) has noted, this case series had "major design flaws including its uncontrolled nature, retrospective design, and probable case selection bias, making its conclusions unreliable."[19] Claims about the anti-cancer effects of cesium chloride have never been substantiated in rigorous, well-designed controlled clinical trials.

The FDA's assessment and regulatory actions regarding the use of cesium chloride in pharmacy compounding

Statutory requirements

Section 503A of the Food, Drug, and Cosmetic Act (FDCA) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FDCA: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications), section 502(f)(1) (concerning the labeling of drugs with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that:

(1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) if such a monograph does not exist, are components of drugs approved by the Secretary; or

(3) if such a monograph does not exist and the drug substances are not components of any drug approved by the Secretary, appear on a list developed by the Secretary through

[16] Brewer, AK. The high pH therapy for cancer tests on mice and humans. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):1-5.
[17] *Ibid*.
[18] Sartori HE. Cesium therapy in cancer patients. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):11-13.
[19] 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 October 2, 2018. PDF page 67.

regulations issued by the Secretary under subsection (c) of section 503A (hereafter referred to as the 503A bulks list).

The FDA's interim policy on compounding using bulk drug substances

On June 10, 2016, the FDA issued its *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*.[20] Under this policy — which was last revised in January 2017 — until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, the FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:[21]

(1) The bulk drug substance appears on the 503A Category 1 list (*Bulk Drug Substances Under Evaluation*) on the FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. A bulk drug substance is included on the Category 1 list if it may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for the FDA to evaluate it, and has *not* been identified by the FDA as a substance that presents a significant safety risk in compounding (the 503A Category 2 list) prior to the publication of a final rule to include or not include the substance on the 503A bulks list;

(2) The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FDCA);

(3) The bulk drug substance is accompanied by a valid certificate of analysis; and

(4) The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FDCA.

Under the agency's interim policy, a State-licensed pharmacy, Federal facility, or licensed physician may *not* compound a drug product using a bulk drug substance that appears on either of the following lists (or that does not appear on the 503A Category 1 list):[22]

(1) The 503A Category 2 list of bulk drug substances identified by the FDA as presenting a significant safety risk in compounding

[20] 81 FR 37502.
[21] Food and Drug Administration. Interim policy on compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry. January 2017 (revision 1). https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf. Accessed October 2, 2018.
[22] *Ibid*.

(2) The 503A Category 3 list of bulk drug substances nominated for the 503A bulks list that may be eligible for inclusion on the list but that the FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for the FDA to evaluate them.

Nominations for inclusion on the 503A bulks list

On September 30, 2014, several organizations nominated cesium chloride for inclusion on the 503A bulks list for use in combination with other natural substances in treating individuals with numerous types of cancer.[23] The proposed route of administration of compounded cesium chloride for this use was IV infusion. There is no applicable USP or NF monograph for cesium chloride, and it is not a component of any FDA-approved drug product.

Because the nominators provided sufficient supporting information for the FDA to evaluate cesium chloride for possible inclusion on the 503A bulks list, cesium chloride initially was placed on the Category 1 list under the agency's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*. It remained on that list until recently.

FDA reviewers identify significant safety risks and find no evidence of effectiveness for compounded cesium chloride

On June 23, 2016, the FDA's Pharmacy Compounding Advisory Committee (PCAC) considered the nomination of cesium chloride.[24] In a May 31, 2016, review of cesium chloride, FDA reviewers recommended against adding cesium chloride to the 503A bulks list, in part because there are "serious safety concerns related to the use of cesium chloride."[25]

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:

> b. Safety pharmacology
>
> In rabbits and dogs, cesium chloride administration, either as intravenous bolus injections (1 mmol/kg) 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).

[23] 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 October 2, 2018. PDF pages 38-60.
[24] *Ibid*. PDF pages 37-73.
[25] *Ibid.* Tab 2b, PDF pages 61-73.

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). …

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 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**.[26]

[Emphasis added]

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

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, Himeshkumar 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 [FDA Adverse Events Reporting System] and CAERS [Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System] 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.[27]
[Emphasis added]

[26] *Ibid.* PDF pages 65-66.
[27] *Ibid.* PDF page 67-68.

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

> 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.[28]

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

> **III. 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][29]

On June 23, 2016, the FDA's PCAC discussed and voted on whether cesium chloride should be included on the 503A bulks list. 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.[30]

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[28] *Ibid*. PDF page 68.
[29] *Ibid*. PDF pages 69-70.
[30] 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 October 2, 2018. PDF pages 101-102. PDF pages 101-102.

Public Citizen's citizen petition to the FDA regarding cesium chloride and the agency's response

On December 6, 2017, Public Citizen petitioned the FDA to immediately (1) add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry* and (2) promulgate a rule that excludes cesium chloride from the 503A bulks list.[31] Public Citizen argued that such action was necessary because FDA staff determined more than 18 months earlier that cesium chloride presents "serious safety concerns" and is "not safe for human use."

On July 23, 2018, the FDA issued a final response to our citizen petition granting the request to add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 interim policy, but denying the request to immediately promulgate a rule that excludes cesium chloride from the 503A bulks list.[32]

In its final response to our petition, the FDA noted that in addition to the data discussed with the PCAC in June 2016, the agency recently had conducted a comprehensive review of FAERS, CAERS, and the medical literature for all adverse events related to cesium chloride and other cesium salts through June 30, 2018. The FDA noted that the agency's current findings support its previous conclusions from the 2016 PCAC. In particular, since 2016, there had been three more published case reports related to cesium chloride that describe life-threatening neurologic and cardiac toxicity (e.g., QT prolongation), which further increases our concern about the risks of cesium chloride. The FDA therefore concluded that "there are significant safety risks related to the use of cesium chloride in compounding and, therefore, moving this substance from [the 503A] Category 1 [list] to [the 503A] Category 2 [list] is appropriate." Therefore, on July 23, 2018, the FDA publicly announced that it would move cesium chloride from the 503A Category 1 list to the 503A Category 2 list seven days after the announcement.

Cesium chloride is now on the 503A Category 2 list under the agency's interim guidance and cannot legally be used in pharmacy compounding at the present time.

Regarding the FDA's denial of Public Citizen's request to immediately promulgate a rule that excludes cesium chloride from the 503A bulks list, the agency noted that it is engaged in rulemaking to establish the 503A bulks list and intends to address nominated substances in proposed rules on a rolling basis. The FDA further noted that it would eventually determine whether to include cesium chloride on the 503A bulks list through notice and comment rulemaking.

[31] Public Citizen. Citizen Petition to the FDA seeking to stop pharmacy compounding of cesium chloride. December 6, 2017. https://www.citizen.org/sites/default/files/2393.pdf. Accessed October 2, 2018.
[32] Food and Drug Administration. Partial Approval and Partial Denial of Petition for FDA-2017-P-6758. https://www.regulations.gov/document?D=FDA-2017-P-6758-0004. Accessed October 2, 2018.

Utopia Wellness's dissemination of false and misleading advertisements promoting cesium chloride for treatment of cancer

Utopia Wellness is a medical center located at 110 State Street East, Oldsmar, Florida, that "offers integrative, holistic, patient-focused treatments" for a variety of diseases, including cancer.[33] Carlos M. Garcia, M.D., is the Director of Medicine at the medical center.[34]

Among the medical treatments for cancer promoted on the Utopia Wellness website is high pH therapy using IV compounded cesium chloride (see enclosed copies of pertinent webpages).[35,36] The Utopia Wellness "High pH Therapy" webpage[37] references the 1984 paper by Sartori that presented a case series of 50 cancer patients who had been treated with cesium chloride and that was found by FDA reviewers to be seriously flawed. This webpage includes the following claim about the effectiveness of high pH therapy:

> Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies.

It appears that the only IV form of high pH therapy promoted by Utopia Wellness on its website is IV cesium chloride. The Utopia Wellness "Cesium Chloride" webpage[38] includes the following claims:

> Cesium chloride is a powerful natural mineral that has the ability to penetrate the cells and change their acidic pH to an alkaline pH. This process can destroy the enzyme system of a cancer cell and halt it's [sic] ability to reproduce. As evidenced by the numerous studies cited below, this powerful, high pH therapy has had astounding success in certain cancers.
>
> IS CESIUM CHLORIDE THERAPY SAFE?
>
> Cesium Chloride is safe when administered under the supervision of an experienced medical team.

IV cesium chloride, as promoted by Utopia Wellness, is a drug as defined by the FTC Act.

Utopia Wellness, however, offers no evidence from well-controlled clinical tests to support its claims about the safety and effectiveness of IV cesium chloride for the treatment of cancer. Indeed, as previously discussed above, independent scientists at the FDA have reviewed the

[33] Utopia Wellness. About us. https://utopiawellness.com/about-us/#. Accessed October 8, 2018.
[34] Utopia Wellness. Meet the medical team. https://utopiawellness.com/meet-the-medical-team/. Accessed October 2, 2018.
[35] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 8, 2018.
[36] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 8, 2018.
[37] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 8, 2018.
[38] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 2, 2018.

available evidence regarding the use of cesium chloride for treating cancer and concluded that it is "not safe for human use and there is no evidence it is effective for the treatment of any cancer."

In addition to making unsubstantiated claims about the safety and effectiveness of IV cesium chloride for treatment of cancer, Utopia Wellness posted on its "Cesium Chloride" webpage under the heading "Research Studies Articles [sic] on Cesium Chloride Therapy*"* falsified citations of scientific journal articles that purportedly support the medical center's promotional claims. The clearly deliberate falsification of these citations generally involved taking citations of actual scientific journal articles related to research on or treatment with ozone and replacing the term "Ozone" with "Cesium Chloride" in the titles of the articles.

The following are representative examples of the falsified citations appearing on the Utopia Wellness "Cesium Chloride" webpage as of October 8, 2018. The words altered on the website appear below in bold and underlined text, for ease of comparison.

(1) **Utopia Wellness citation**: Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **Cesium Chloride** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.

Actual article citation: Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **ozone** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.

(2) **Utopia Wellness Citation**: Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Cesium Chloride** selectively inhibits growth of human cancer cells. Science 1980; 209(4459):931-933.

Actual article citation: Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Ozone** selectively inhibits growth of human cancer cells. Science 1980;209(4459):931-933.

We identified a total of 30 falsified scientific journal article citations on the Utopia Wellness "Cesium Chloride" webpage (see the Appendix for a complete list of the falsified citations). Some of the falsified citations were taken from articles in highly reputable scientific journals, such as *Science*. For some citations, Utopia Wellness changed "Ozone" to "Cesium Chloride" in the title but left the parenthetical chemical formula for ozone.

We also note that there were several other citations on the same webpage that provided web links, for which the listed "Accessed" date is from September 2013, which suggests that Utopia Wellness may have engaged in false and misleading advertising of its IV cesium chloride therapy for cancer for at least five years.

Conclusions and requested actions

In conclusion, there is clear evidence that the advertising and promotional materials on the Utopia Wellness website regarding its IV cesium chloride therapy for treatment of cancer are deceptive within the meaning of the Federal Trade Commission Act. The company's website materials misleadingly claim that IV cesium chloride is safe and effective for treating cancer but offers no evidence from well-controlled clinical tests to support its claims. In addition, it fails to disclose evidence highlighted by the FDA indicating that cesium chloride is unsafe for human use because it can cause fatal cardiac arrhythmias. Finally, the clearly deliberate falsification of the scientific journal citations on the Utopia Wellness webpage promoting IV cesium chloride represents a brazen attempt to mislead consumers to believe that there is a large body of scientific evidence showing that IV cesium chloride is a safe and effective treatment for cancer.

False and misleading advertising such as this preys upon highly vulnerable cancer patients in order to make a profit. In addition to causing financial harm to patients who are duped by its deceptive advertising and promotional materials, Utopia Wellness has exposed these patients to a drug that poses life-threatening risks but offers no proven benefits.

We therefore urge the FTC to immediately investigate Utopia Wellness's advertising practices and demand that the company cease and desist its deceptive advertising of IV cesium chloride. We urge you to require that the company reimburse all consumers who have purchased its dangerous and ineffective IV cesium chloride treatment over the past several years.

Please note that we simultaneously are writing to the FDA because, as of late July 2018, it is illegal under Section 503A of the FDCA and the FDA's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act – Guidance for Industry* for any pharmacist or physician to compound cesium chloride.

Please note that this letter is posted on Public Citizen's website, and you may publicly identify us as complainants in this matter to Utopia Wellness or to any other parties.

Thank you for your prompt attention to this important patient safety and public health issue.

Sincerely,

Meena Aladdin, M.S., Ph.D.
Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Enclosures: Copies of referenced Utopia Wellness "High pH Therapy" and "Cesium Chloride" webpages

Appendix

	Falsified Citation as It Appears on the Utopia Wellness Website (word changes compared with the actual citation are bolded and underlined)	Actual Journal Article Citation
1	Elvis AM. Ekta JS. (2011) **Cesium Chloride** therapy: A clinical review. Journal of Natural Science Biology & Medicine. 2(1):66-70.	Elvis AM. Ekta JS. (2011) **Ozone** therapy: A clinical review. Journal of Natural Science Biology & Medicine. 2(1):66-70.
2	Bocci V.A.(2006) Scientific and Medical Aspects of **Cesium Chloride** Therapy. State of the Art. Archives of Medical Research. 37 (4) (pp 425-435).	Bocci V.A.(2006) Scientific and Medical Aspects of **Ozone** Therapy. State of the Art. Archives of Medical Research. 37 (4) (pp 425-435).
3	Burke FJ.(2012). **Cesium Chloride** and caries: a review of the literature. Dent Update. 39(4):271-2, 275-8.	Burke FJ.(2012). **Ozone** and caries: a review of the literature. Dent Update. 39(4):271-2, 275-8.8.
4	Rubin MB. (2001). The History Of **Cesium Chloride**. The Schönbein Period, 1839-1868. Bull. Hist. Chem., 26 (1). Available at: http://www.scs.illinois.edu/~mainzv/HIST/awards/OPA%20Papers/2001-Rubin.pdf. Accessed 11th September 2013.	Rubin MB. (2001). The History Of **Ozone**. The Schönbein Period, 1839-1868. Bull. Hist. Chem., 26 (1). Available at: http://www.scs.illinois.edu/~mainzv/HIST/awards/OPA%20Papers/2001-Rubin.pdf. Accessed 11th September 2013.
5	Bocci V. Biological and clinical effects of **Cesium Chloride**. Has **Cesium Chloride** therapy a future in medicine? Br J Biomed Sci. 1999;56(4):270-9.	Bocci V. Biological and clinical effects of Ozone. Has **Ozone** therapy a future in medicine? Br J Biomed Sci. 1999;56(4):270-9.
6	Bocci V. Borrelli E, Zanardi I, Travagli V. (2011). Oxygen-**Cesium Chloride** Therapy Is At A Cross-Road. Available at: http://www.isco3.org/files/O3_CrossRoad_Bocci_paper_2011.pdf. Accessed 11th September 2013.	Bocci V. Borrelli E, Zanardi I, Travagli V. (2011). Oxygen-**Ozone** Therapy Is At A Cross-Road. Available at: http://www.isco3.org/files/O3_CrossRoad_Bocci_paper_2011.pdf. Accessed 11th September 2013. (See https://www.austinozone.com/wp-content/uploads/Ozone-Therapy-CrossRoad.pdf. Accessed September 21, 2018.)
7	Sagai M., Bocci V. (2011). Med Gas Res. 2011 Dec 20;1:29. Mechanisms of Action Involved in **Cesium Chloride** Therapy: Is healing induced via a mild oxidative stress? Medical Gas Research. 1 (1). Article Number: 29.	Sagai M., Bocci V. (2011). Med Gas Res. 2011 Dec 20;1:29. Mechanisms of Action Involved in **Ozone** Therapy: Is healing induced via a mild oxidative stress? Medical Gas Research. 1 (1). Article Number: 29.
8	Bocci V., Larini A., Micheli V. (2005). Restoration of normoxia by **Cesium**	Bocci V., Larini A., Micheli V. (2005). Restoration of normoxia by **Ozone** therapy

	Chloride therapy may control neoplastic growth: A review and a working hypothtesis. Journal of Alternative and Complementary Medicine. 11 (2): pp 257-265.	may control neoplastic growth: A review and a working hypothtesis. Journal of Alternative and Complementary Medicine. 11 (2): pp 257-265.
9	Magalhaes FN, Dotta L, Sasse A, Teixera MJ, Fonoff ET. **Cesium Chloride** therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. Pain Physician. 2012 Mar-Apr;15(2):E115-29.	Magalhaes FN, Dotta L, Sasse A, Teixera MJ, Fonoff ET. **Ozone** therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. Pain Physician. 2012 Mar-Apr;15(2):E115-29.
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29	Faustini A, Capobianchi MR, Martinelli M, Abbate I, Cappiello G, Perucci CA. A cluster of hepatitis C virus infections associated with **Cesium Chloride**-enriched transfusion of autologous blood	Faustini A, Capobianchi MR, Martinelli M, Abbate I, Cappiello G, Perucci CA. A cluster of hepatitis C virus infections associated with **ozone**-enriched transfusion of autologous blood in Rome, Italy. Infect

	in Rome, Italy. Infect Control Hosp Epidemiol. 2005 Sep;26(9):762-7.	Control Hosp Epidemiol. 2005 Sep;26(9):762-7.
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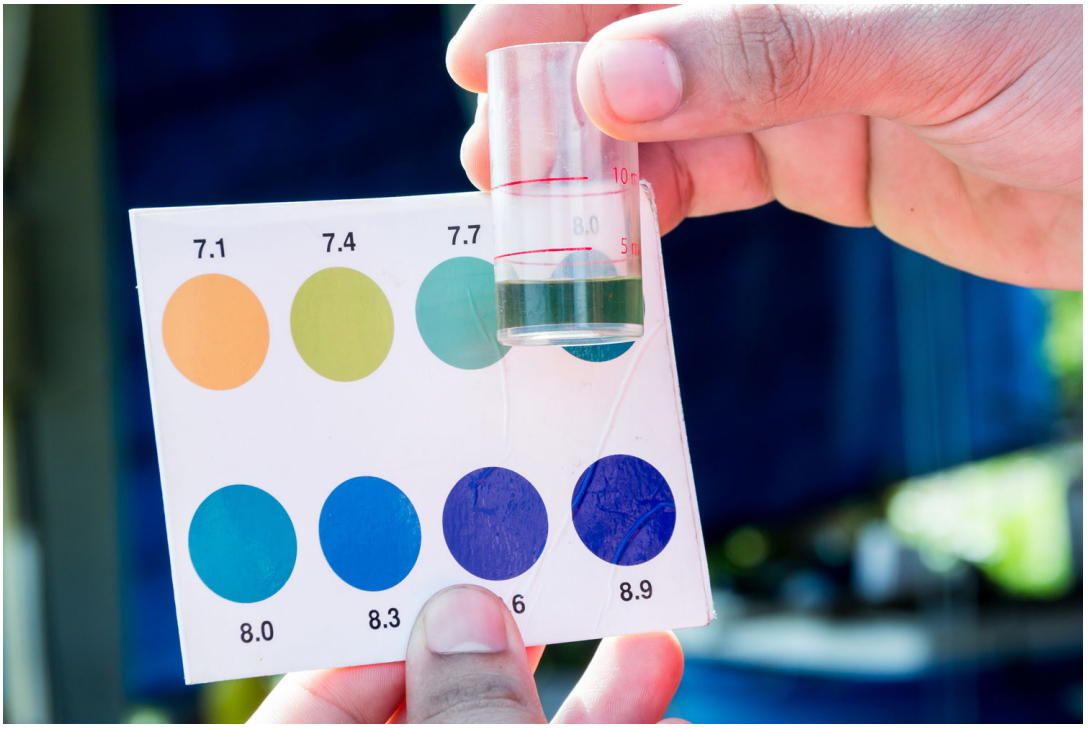
High pH Therapy



Cellular pH is a measure of how acidic, or alkaline, cells are. “pH” is measured on a scale of 0 to 14. A pH of 7 is considered neutral, while numbers below 7.0 are acidic, and numbers above 7.0 are alkaline (or basic).

- Healthy cells – are slightly alkaline with a pH of 7.35 to 7.4
- Cancerous cells – are acidic with a typical pH in the range of 5.5 to 6.5

The research of Dr. Otto Warburg and Dr. H. E. Sartori has demonstrated that most cancer cells prefer an acidic (lower) pH level and thrive in these conditions. Also shown is that cancer growth can be reduced and certain cancer cells may be killed with increased pH levels. That is the purpose of High pH Therapy and why it is an integral part of our Intensive Medical Program.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to drop from between 7.3 to 7.2 down to 7 and later to 6.5; in more advanced stages of cancer and in metastases the pH drops to 6.0 and even 5.7.

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

TOP

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.

More recent research has uncovered another fuel source for cancer cells. In 2008, a team of researchers at Duke University Medical Center and the Université catholique de Louvain (UCL) found that lactic acid is another important energy source for tumor cells. So whether converting lactic acid to glucose or utilizing lactic acid directly as fuel, if you can neutralize the lactic acid, you essentially cut off the fuel supply to cancer.

In addition to providing the fuel for cancer cells, lactic acid is also responsible for one of the most distressing symptoms of cancer; the intense pain that even morphine may not alleviate. This is the same lactic acid secreted by your muscles during a strenuous workout and why you experience pain the day after. For a cancer patient, this pain can be 10 fold. With High pH Therapies, the lactic acid is neutralized.

Dr. H. E. Sartori initiated a cesium cancer therapy program in April 1981 at Life Sciences Universal Medical Clinics in Rockville, Md. Sartori treated 50 terminal patients with widespread tumors. Not only did half of these terminal patients survive their cancer, Sartori found that pain disappeared in all 50 patients within 1 to 3 days after initiating cesium treatments.

Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies:

*Disclaimer: Individual patient results may vary based on a patient's medical history and other factors and these results should not be expected or anticipated. Information on this site is not intended to replace the advice of your physician or healthcare provider. Statements made about products, therapies or services have not been evaluated by the Food and Drug Administration.

Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
- **Individual Counseling**
- **Group Therapy**
- **Touch For Health**
- **Oxygen Therapies**
- **Hyperbaric Oxygen**
- **IV Peroxide Therapy**
- **Nutraceuticals**
- **Nutritional Counseling**
- **Whole Body Detoxification**
- **Colon Therapy**
- **Juicing**
- **Organ Cleanse**
- **Lymphatic Massage**

The Intensive Medical Program at Utopia Wellness focuses not only on the disease, but also on the patient's mind, body, and spirit. If you are looking for a non-toxic alternative that treats you holistically, Utopia Wellness is the facility you are looking for. Call us today at **727-799-9060.** Our Patient Care Coordinator is waiting to tell you more about our innovative approach and schedule your free initial consultation.

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Cesium Chloride

In order for cancer cells to survive and reproduce they have to maintain a high acidic pH – they do this by producing lactic acid as a byproduct of their anaerobic respiration. Cesium chloride is a powerful natural mineral that has the ability to penetrate the cells and change their acidic pH to an alkaline pH. This process can destroy the enzyme system of a cancer cell and halt it's ability to reproduce. As evidenced by the numerous studies cited below, this powerful, high pH therapy has had astounding success in certain cancers.

The pioneer of the Cesium therapy was the highly esteemed American physicist, Dr. Aubrey Keith Brewer (1893 – 1986). He was the chief of the National Bureau of Standards and Mass Spectrometer and Isotope Section and his main interest was in the behavior of cell membranes. He noted during his research that there were areas of the earth where the incidences of cancer were very low. In analyzing the foods from these regions, they were found to be extremely high in cesium and rubidium. The Hopi Indians have water that contains rubidium and potassium while the Hunzas of Northern Pakistan have water high in cesium and potassium. Through his research, he was able to prove that cesium chloride can penetrate cancer cells when other nutrients cannot. Following his research, many studies 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 good.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to

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Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

HOW IS CESIUM CHLORIDE ADMINISTERED?

Utopia Wellness administers Cesium Chloride in an intravenous solution that is infused into a vein in the arm or through a medical port. The solution also contains the "super solvent" with the ability to penetrate every single cell of the body, so whatever its other effects may be, they will be spread systemically through the entire body.

IS CESIUM CHLORIDE THERAPY SAFE?

Cesium Chloride is safe when administered under the supervision of an experienced medical team. While extremely rare, there can be side effects of Cesium Chloride including inflammation, swelling and pain, muscle cramps, feet and your finger tips feeling like needles and pins, or a tingly prickly feeling in your hands or on your face, nausea and vomiting.

Research Studies Articles on Cesium Chloride Therapy

Elvis AM. Ekta JS. (2011) Cesium Chloride therapy: A clinical review. Journal of Natural Science Biology & Medicine. 2(1):66-70.

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Bocci V., Larini A., Micheli V. (2005). Restoration of normoxia by Cesium Chloride therapy may control neoplastic growth: A review and a working hypothtesis. Journal of Alternative and Complementary Medicine. 11 (2): pp 257-265.

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At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
- **Individual Counseling**
- **Group Therapy**
- **Touch For Health**
- **Oxygen Therapies**
- **Hyperbaric Oxygen**
- **IV Peroxide Therapy**
- **Nutraceuticals**
- **Nutritional Counseling**
- **Whole Body Detoxification**
- **Colon Therapy**
- **Juicing**
- **Organ Cleanse**
- **Lymphatic Massage**

The Intensive Medical Program at Utopia Wellness focuses not only on the disease, but also on the patient's mind, body, and spirit. If you are looking for a non-toxic alternative that treats you holistically, Utopia Wellness is the facility you are looking for. Call us today at **727-799-9060.** Our Patient Care Coordinator is waiting to tell you more about our innovative approach and schedule your free initial consultation.

TOP

PUBLICCITIZEN
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October 9, 2018

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Dear Drs. Gottlieb and Woodcock:

Public Citizen, a nonprofit consumer advocacy organization with more than 500,000 members and supporters nationwide, hereby requests that the Food and Drug Administration (FDA), pursuant to the Food, Drug, and Cosmetic Act (FDCA),[1] immediately investigate the promotion and use of intravenous cesium chloride for the treatment of cancer by Utopia Wellness, a medical center located in Oldsmar, Florida.[2] Furthermore, we request that the agency take appropriate enforcement action against Utopia Wellness if it finds that the medical center has continued to compound and administer intravenous cesium chloride to cancer patients since late July 2018, when the agency took action that prohibited pharmacy compounding using bulk cesium chloride.

We believe that under the FDCA and the FDA's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*, no State-licensed pharmacy or licensed physician affiliated with Utopia Wellness currently may legally compound cesium chloride. The following is a more detailed discussion of the background and substance of our request.

Overview of cesium chloride

Compounded drugs containing cesium salts — most often cesium chloride — have been marketed and promoted by certain doctors and medical centers as an alternative form of cancer treatment 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

[1] 21 U.S.C. §§ 351, 352, and 353a.
[2] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 8, 2018.

non-oxidative glycolysis and ferment even in the presence of adequate oxygen, thus leading to low intracellular pH and subsequent cancer cell survival.[3] Others later theorized that cesium kills cancer cells by increasing the intracellular pH of the cells.[4] Without credible evidence to support this theory, some physicians began administering cesium chloride to a limited number of cancer patients as early as the 1980s.[5]

In particular, in 1984, Sartori published a case series of 50 cancer patients who had been treated with cesium chloride over a three-year period.[6] He claimed an "overall 50% recovery from cancer" with cesium chloride therapy. However, as the FDA has noted, this case series had "major design flaws including its uncontrolled nature, retrospective design, and probable case selection bias, making its conclusions unreliable."[7] Claims about the anti-cancer effects of cesium chloride have never been substantiated in rigorous, well-designed controlled clinical trials.

The FDA's assessment and regulatory actions regarding the use of cesium chloride in pharmacy compounding

Statutory requirements

Section 503A of the FDCA describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FDCA: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications), section 502(f)(1) (concerning the labeling of drugs with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that:

(1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) if such a monograph does not exist, are components of drugs approved by the Secretary; or

[3] Warburg O. On the origin of cancer cells. *Science*. 1956;123(3191): 309-314.
[4] Brewer, AK. The high pH therapy for cancer tests on mice and humans. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):1-5.
[5] *Ibid*.
[6] Sartori HE. Cesium therapy in cancer patients. *Pharmacol Biochem Behav.* 1984;21(Suppl. 1):11-13.
[7] 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 October 2, 2018. PDF page 67.

(3) if such a monograph does not exist and the drug substances are not components of any drug approved by the Secretary, appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A (hereafter referred to as the 503A bulks list).

The FDA's interim policy on compounding using bulk drug substances

On June 10, 2016, the FDA issued its *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*.[8] Under this policy — which was last revised in January 2017 — until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, the FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:[9]

(1) The bulk drug substance appears on the 503A Category 1 list (*Bulk Drug Substances Under Evaluation*) on the FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. A bulk drug substance is included on the Category 1 list if it may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for the FDA to evaluate it, and has *not* been identified by the FDA as a substance that presents a significant safety risk in compounding (the 503A Category 2 list) prior to the publication of a final rule to include or not include the substance on the 503A bulks list;

(2) The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FDCA);

(3) The bulk drug substance is accompanied by a valid certificate of analysis; and

(4) The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FDCA.

Under the agency's interim policy, a State-licensed pharmacy, Federal facility, or licensed physician may *not* compound a drug product using a bulk drug substance that appears on either of the following lists (or that does not appear on the 503A Category 1 list):[10]

[8] 81 FR 37502.
[9] Food and Drug Administration. Interim policy on compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act- Guidance for Industry. January 2017 (revision 1). https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf. Accessed October 2, 2018.
[10] *Ibid*.

(1) The 503A Category 2 list of bulk drug substances identified by the FDA as presenting a significant safety risk in compounding

(2) The 503A Category 3 list of bulk drug substances nominated for the 503A bulks list that may be eligible for inclusion on the list but that the FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for the FDA to evaluate them.

Nominations for inclusion on the 503A bulks list

On September 30, 2014, several organizations nominated cesium chloride for inclusion on the 503A bulks list for use in combination with other natural substances in treating individuals with numerous types of cancer.[11] The proposed route of administration of compounded cesium chloride for this use was IV infusion. There is no applicable USP or NF monograph for cesium chloride, and it is not a component of any FDA-approved drug product.

Because the nominators provided sufficient supporting information for the FDA to evaluate cesium chloride for possible inclusion on the 503A bulks list, cesium chloride initially was placed on the Category 1 list under the agency's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*. It remained on that list until recently.

FDA reviewers identify significant safety risks and find no evidence of effectiveness for compounded cesium chloride

On June 23, 2016, the FDA's Pharmacy Compounding Advisory Committee (PCAC) considered the nomination of cesium chloride.[12] In a May 31, 2016, review of cesium chloride, FDA reviewers recommended against adding cesium chloride to the 503A bulks list because they concluded that "[c]esium chloride is not safe for human use and there is no evidence it is effective for the treatment of any cancer."[13] Agency reviewers had identified "serious safety concerns related to the use of cesium chloride indicated by the results of both non-clinical and clinical studies."[14] They further noted that "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."[15]

[11] 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 October 2, 2018. PDF pages 38-60.
[12] *Ibid*.
[13] *Ibid*. PDF pages 69-70.
[14] *Ibid*. PDF page 70.
[15] *Ibid*. PDF page 70.

On June 23, 2016, the FDA's PCAC discussed and voted on whether cesium chloride should be included on the 503A bulks list. 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.[16]

Public Citizen's citizen petition to the FDA regarding cesium chloride and the agency's response

As you are aware, on December 6, 2017, Public Citizen petitioned the FDA to immediately (1) add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry* and (2) promulgate a rule that excludes cesium chloride from the 503A bulks list.[17]

On July 23, 2018, the FDA issued a final response to our citizen petition granting the request to add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 interim policy, but denying the request to immediately promulgate a rule that excludes cesium chloride from the 503A bulks list.[18] That same day, the FDA publicly announced that it would move cesium chloride from the 503A Category 1 list to the 503A Category 2 list seven days after the announcement. As a result, bulk cesium chloride is now on the 503A Category 2 list under the agency's interim guidance and cannot legally be used in pharmacy compounding at the present time.

Utopia Wellness's promotion of cesium chloride for treatment of cancer

Utopia Wellness is a medical center located at 110 State Street East, Oldsmar, Florida, that "offers integrative, holistic, patient-focused treatments" for a variety of diseases, including cancer.[19] Carlos M. Garcia, M.D., is the Director of Medicine at the medical center.[20]

Among the medical treatments for cancer promoted on the Utopia Wellness website is high pH therapy using IV compounded cesium chloride (see enclosed copies of pertinent webpages).[21,22] The Utopia Wellness "High pH Therapy" webpage[23] includes the following claim about the effectiveness of high pH therapy:

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[16] 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 October 2, 2018. PDF pages 101-102.
[17] Public Citizen. Citizen Petition to the FDA seeking to stop pharmacy compounding of cesium chloride. December 6, 2017. https://www.citizen.org/sites/default/files/2393.pdf. Accessed October 2, 2018.
[18] Food and Drug Administration. Partial Approval and Partial Denial of Petition for FDA-2017-P-6758. https://www.regulations.gov/document?D=FDA-2017-P-6758-0004. Accessed October 2, 2018.
[19] Utopia Wellness. About us. https://utopiawellness.com/about-us/#. Accessed October 8, 2018.
[20] Utopia Wellness. Meet the medical team. https://utopiawellness.com/meet-the-medical-team/. Accessed October 2, 2018.
[21] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 8, 2018.
[22] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 8, 2018.
[23] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 8, 2018.

> Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies.

It appears that the only IV form of high pH therapy promoted by Utopia Wellness on its website is IV cesium chloride.

Conclusion and requested actions

In conclusion, Utopia Wellness has continued to promote on its website IV cesium chloride therapy for treatment of cancer after the FDA publicly announced in late July 2018 that it was moving cesium chloride from the 503A Category 1 list to the 503A Category 2 list and that the drug therefore could no longer be legally used in pharmacy compounding. It is imperative that Utopia Wellness cease exposing patients to a drug that poses life-threatening risks but offers no proven benefits.

We therefore urge the FDA to immediately investigate the promotion and use of intravenous cesium chloride for the treatment of cancer by Utopia Wellness. Furthermore, we urge the agency to take appropriate enforcement action against Utopia Wellness if it finds that the medical center has been compounding and administering IV cesium chloride to cancer patients since late July 2018, when the agency took action that prohibited pharmacy compounding using bulk cesium chloride.

Please note that we simultaneously are writing to the Federal Trade Commission to request that it immediately take appropriate enforcement action against Utopia Wellness for disseminating false and misleading advertisements that promote the use of the compounded drug cesium chloride as a treatment for cancer.

Thank you for your prompt attention to this important patient safety and public health issue.

Sincerely,

Meena M. Aladdin, M.S. Ph.D.
Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Enclosures: Copies of Utopia Wellness "High pH Therapy" and "Cesium Chloride" webpages

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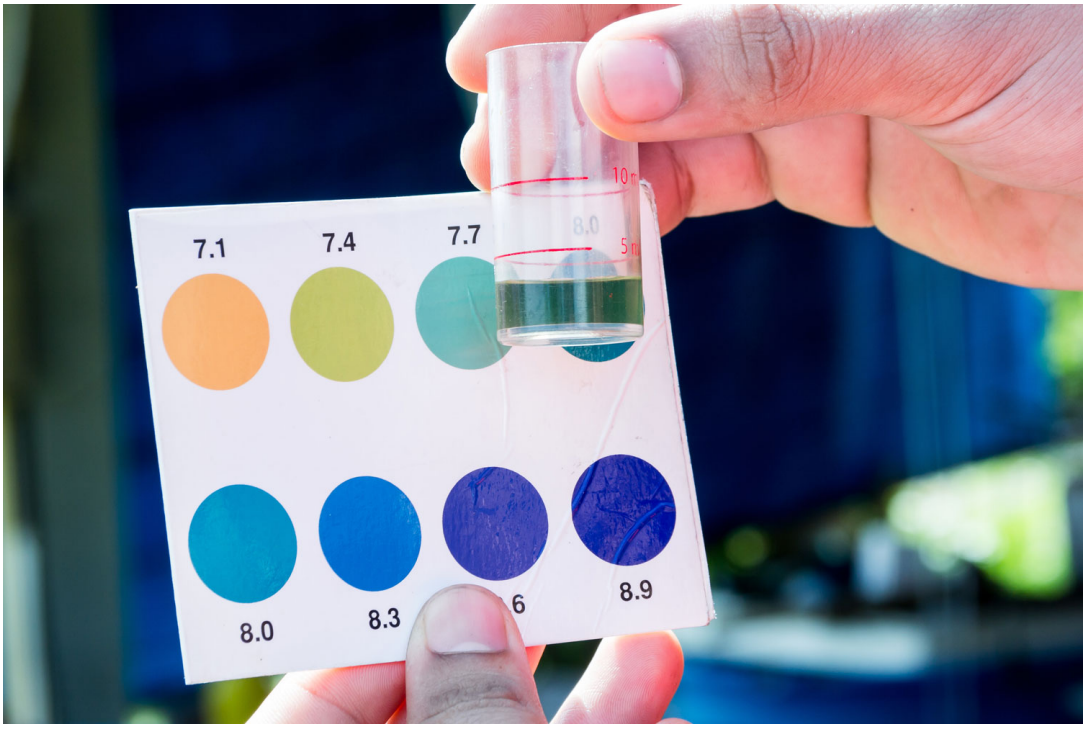
High pH Therapy



Cellular pH is a measure of how acidic, or alkaline, cells are. “pH” is measured on a scale of 0 to 14. A pH of 7 is considered neutral, while numbers below 7.0 are acidic, and numbers above 7.0 are alkaline (or basic).

- Healthy cells – are slightly alkaline with a pH of 7.35 to 7.4
- Cancerous cells – are acidic with a typical pH in the range of 5.5 to 6.5

The research of Dr. Otto Warburg and Dr. H. E. Sartori has demonstrated that most cancer cells prefer an acidic (lower) pH level and thrive in these conditions. Also shown is that cancer growth can be reduced and certain cancer cells may be killed with increased pH levels. That is the purpose of High pH Therapy and why it is an integral part of our Intensive Medical Program.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to drop from between 7.3 to 7.2 down to 7 and later to 6.5; in more advanced stages of cancer and in metastases the pH drops to 6.0 and even 5.7.

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

TOP

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.

More recent research has uncovered another fuel source for cancer cells. In 2008, a team of researchers at Duke University Medical Center and the Université catholique de Louvain (UCL) found that lactic acid is another important energy source for tumor cells. So whether converting lactic acid to glucose or utilizing lactic acid directly as fuel, if you can neutralize the lactic acid, you essentially cut off the fuel supply to cancer.

In addition to providing the fuel for cancer cells, lactic acid is also responsible for one of the most distressing symptoms of cancer; the intense pain that even morphine may not alleviate. This is the same lactic acid secreted by your muscles during a strenuous workout and why you experience pain the day after. For a cancer patient, this pain can be 10 fold. With High pH Therapies, the lactic acid is neutralized.

Dr. H. E. Sartori initiated a cesium cancer therapy program in April 1981 at Life Sciences Universal Medical Clinics in Rockville, Md. Sartori treated 50 terminal patients with widespread tumors. Not only did half of these terminal patients survive their cancer, Sartori found that pain disappeared in all 50 patients within 1 to 3 days after initiating cesium treatments.

Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies:

*Disclaimer: Individual patient results may vary based on a patient's medical history and other factors and these results should not be expected or anticipated. Information on this site is not intended to replace the advice of your physician or healthcare provider. Statements made about products, therapies or services have not been evaluated by the Food and Drug Administration.

Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
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- **Hyperbaric Oxygen**
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Cesium Chloride

In order for cancer cells to survive and reproduce they have to maintain a high acidic pH – they do this by producing lactic acid as a byproduct of their anaerobic respiration. Cesium chloride is a powerful natural mineral that has the ability to penetrate the cells and change their acidic pH to an alkaline pH. This process can destroy the enzyme system of a cancer cell and halt it's ability to reproduce. As evidenced by the numerous studies cited below, this powerful, high pH therapy has had astounding success in certain cancers.

The pioneer of the Cesium therapy was the highly esteemed American physicist, Dr. Aubrey Keith Brewer (1893 – 1986). He was the chief of the National Bureau of Standards and Mass Spectrometer and Isotope Section and his main interest was in the behavior of cell membranes. He noted during his research that there were areas of the earth where the incidences of cancer were very low. In analyzing the foods from these regions, they were found to be extremely high in cesium and rubidium. The Hopi Indians have water that contains rubidium and potassium while the Hunzas of Northern Pakistan have water high in cesium and potassium. Through his research, he was able to prove that cesium chloride can penetrate cancer cells when other nutrients cannot. Following his research, many studies 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 good.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to

TOP

drop from between 7.3 to 7.2 down to 7 and later to 6.5; in more advanced stages of cancer and in metastases the pH drops to 6.0 and even 5.7.

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.

Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

HOW IS CESIUM CHLORIDE ADMINISTERED?

Utopia Wellness administers Cesium Chloride in an intravenous solution that is infused into a vein in the arm or through a medical port. The solution also contains the "super solvent" with the ability to penetrate every single cell of the body, so whatever its other effects may be, they will be spread systemically through the entire body.

IS CESIUM CHLORIDE THERAPY SAFE?

Cesium Chloride is safe when administered under the supervision of an experienced medical team. While extremely rare, there can be side effects of Cesium Chloride including inflammation, swelling and pain, muscle cramps, feet and your finger tips feeling like needles and pins, or a tingly prickly feeling in your hands or on your face, nausea and vomiting.

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At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
- **Individual Counseling**
- **Group Therapy**
- **Touch For Health**
- **Oxygen Therapies**
- **Hyperbaric Oxygen**
- **IV Peroxide Therapy**
- **Nutraceuticals**
- **Nutritional Counseling**
- **Whole Body Detoxification**
- **Colon Therapy**
- **Juicing**
- **Organ Cleanse**
- **Lymphatic Massage**

The Intensive Medical Program at Utopia Wellness focuses not only on the disease, but also on the patient's mind, body, and spirit. If you are looking for a non-toxic alternative that treats you holistically, Utopia Wellness is the facility you are looking for. Call us today at **727-799-9060.** Our Patient Care Coordinator is waiting to tell you more about our innovative approach and schedule your free initial consultation.

TOP

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October 24, 2018

Claudia Kemp
Executive Director
Florida Board of Medicine
Department of Health
4052 Bald Cypress Way, Bin C-03
Tallahassee, Florida 32399-3253

Jorge J. Lopez, M.D.
Chair
Florida Board of Medicine
Department of Health
4052 Bald Cypress Way, Bin C-03
Tallahassee, Florida 32399-3253

RE: Complaint about Carlos M. Garcia, M.D., Florida Medical License #ME46132

Dear Ms. Kemp and Dr. Lopez:

Public Citizen, a nonprofit consumer advocacy organization with more than 500,000 members and supporters nationwide, hereby requests that the Florida Board of Medicine immediately launch a formal investigation into the medical practice of Dr. Carlos M. Garcia, M.D., the Director of Medicine and apparently only physician at Utopia Wellness, a medical center located at 110 State Street East, Oldsmar, Florida.[1] We specifically request that the board investigate (1) Dr. Garcia's role in Utopia Wellness's dissemination of false and misleading advertisements that promote the use of the compounded drug cesium chloride as a treatment for cancer and (2) whether Dr. Garcia and his staff have continued to treat cancer patients with compounded intravenous (IV) cesium chloride since late July 2018, when the Food and Drug Administration (FDA) took action that prohibited pharmacy compounding using bulk cesium chloride.

We believe that the advertising and promotional materials on the Utopia Wellness website regarding the use of IV cesium chloride for treatment of cancer are deceptive. In particular, the medical center's website materials claim that IV cesium chloride is safe and effective for treating cancer and lists numerous falsified citations for scientific journal articles that purportedly support this claim, when in fact cesium chloride is neither safe nor effective for that use and the articles cited do not support that claim.

[1] Utopia Wellness. Meet the medical team. https://utopiawellness.com/meet-the-medical-team/. Accessed October 22, 2018.

We further believe that as of late July 2018, under the Food, Drug, and Cosmetic Act (FDCA) and the FDA's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*, no licensed pharmacist in a State-licensed pharmacy or licensed physician affiliated with Utopia Wellness may legally compound cesium chloride.

The following is a more detailed discussion of the background and substance of our complaint.

Overview of Cesium Chloride

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 those of lithium, sodium, and potassium, is a trace element in human metabolism.[2] Cesium chloride is an inorganic chloride salt.

Cesium chloride and other cesium salts, such as cesium carbonate, can be administered orally or by IV injection. Cesium chloride is not an active ingredient in any FDA-approved drug. Compounded drugs containing cesium salts — most often cesium chloride — have been marketed and promoted by certain doctors and medical centers as an alternative form of cancer treatment 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.[3] Others later theorized that cesium kills cancer cells by increasing the intracellular pH of the cells.[4] Without credible evidence to support this theory, some physicians began administering cesium chloride to a limited number of cancer patients as early as the 1980s.[5]

In particular, in 1984, Sartori published a case series of 50 cancer patients who had been treated with cesium chloride over a three-year period.[6] He claimed an "overall 50% recovery from cancer" with cesium chloride therapy. However, as the FDA has noted, this case series had "major design flaws including its uncontrolled nature, retrospective design, and probable case selection bias, making its conclusions unreliable."[7] Claims about the anti-cancer effects of cesium chloride have never been substantiated in rigorous, well-designed controlled clinical trials.

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[2] 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 October 22, 2018. PDF page 67.

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[7] 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 October 22, 2018. PDF page 67.

The FDA's assessment and regulatory actions regarding the use of cesium chloride in pharmacy compounding

Statutory requirements

Section 503A of the FDCA describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FDCA: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications), section 502(f)(1) (concerning the labeling of drugs with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice requirements). One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that:

(1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) if such a monograph does not exist, are components of drugs approved by the Secretary; or

(3) if such a monograph does not exist and the drug substances are not components of any drug approved by the Secretary, appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A (hereafter referred to as the 503A bulks list).

The FDA's interim policy on compounding using bulk drug substances

On June 10, 2016, the FDA issued its *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*.[8] Under this policy — which was last revised in January 2017 — until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, the FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:[9]

(1) The bulk drug substance appears on the 503A Category 1 list (*Bulk Drug Substances Under Evaluation*) on the FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Phar

[8] 81 FR 37502.
[9] Food and Drug Administration. Interim policy on compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry. January 2017 (revision 1). https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf. Accessed October 22, 2018.

macyCompounding/UCM467373.pdf. A bulk drug substance is included on the Category 1 list if it may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for the FDA to evaluate it, and has *not* been identified by the FDA as a substance that presents a significant safety risk in compounding (the 503A Category 2 list) prior to the publication of a final rule to include or not include the substance on the 503A bulks list;

(2) The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FDCA);

(3) The bulk drug substance is accompanied by a valid certificate of analysis; and

(4) The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FDCA.

Under the agency's interim policy, a State-licensed pharmacy, Federal facility, or licensed physician may *not* compound a drug product using a bulk drug substance that appears on either of the following lists (or that does not appear on the 503A Category 1 list):[10]

(1) The 503A Category 2 list of bulk drug substances identified by the FDA as presenting a significant safety risk in compounding

(2) The 503A Category 3 list of bulk drug substances nominated for the 503A bulks list that may be eligible for inclusion on the list but that the FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for the FDA to evaluate them.

Nominations for inclusion on the 503A bulks list

On September 30, 2014, several organizations nominated cesium chloride for inclusion on the 503A bulks list for use in combination with other natural substances in treating individuals with numerous types of cancer.[11] The proposed route of administration of compounded cesium chloride for this use was IV infusion. There is no applicable USP or NF monograph for cesium chloride, and it is not a component of any FDA-approved drug product.

Because the nominators provided sufficient supporting information for the FDA to evaluate cesium chloride for possible inclusion on the 503A bulks list, cesium chloride initially was placed on the Category 1 list under the agency's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*. It remained on that list until recently.

[10] *Ibid*.
[11] 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 October 22, 2018. PDF pages 38-60.

FDA reviewers identify significant safety risks and find no evidence of effectiveness for compounded cesium chloride

On June 23, 2016, the FDA's Pharmacy Compounding Advisory Committee (PCAC) considered the nomination of cesium chloride.[12] In a May 31, 2016, review of cesium chloride, FDA reviewers recommended against adding cesium chloride to the 503A bulks list, in part because there are "serious safety concerns related to the use of cesium chloride."[13]

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:

> b. Safety pharmacology
>
> In rabbits and dogs, cesium chloride administration, either as intravenous bolus injections (1 mmol/kg) 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). …
>
> **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 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**.[14]
>
> [Emphasis added]

[12] *Ibid*. PDF pages 37-73.
[13] *Ibid.* PDF pages 61-73.
[14] *Ibid.* PDF pages 65-66.

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

> 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, Himeshkumar 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 [FDA Adverse Events Reporting System] and CAERS [Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System] 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.[15]
>
> [Emphasis added]

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

> 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.[16]

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

> **III. 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]. …

[15] *Ibid.* PDF page 67-68.
[16] *Ibid*. PDF page 68.

> **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][17]

On June 23, 2016, the FDA's PCAC discussed and voted on whether cesium chloride should be included on the 503A bulks list. 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.[18]

FDA action regarding the compounding of cesium chloride

On December 6, 2017, Public Citizen petitioned the FDA to, among other things, immediately add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry*.[19]

On July 23, 2018, the FDA issued a final response to our citizen petition granting the request to add cesium chloride to the list of bulk drug substances that present significant safety risks (the 503A Category 2 list) and, therefore, may not be compounded under the agency's January 2017 interim policy.[20] That same day, the FDA publicly announced that it would move cesium chloride from the 503A Category 1 list to the 503A Category 2 list seven days after the announcement. As a result, bulk cesium chloride is now on the 503A Category 2 list under the agency's interim guidance and cannot legally be used in pharmacy compounding at the present time.

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[17] *Ibid*. PDF pages 69-70.
[18] 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 October 22, 2018. PDF pages 101-102.
[19] Public Citizen. Citizen Petition to the FDA seeking to stop pharmacy compounding of cesium chloride. December 6, 2017. https://www.citizen.org/sites/default/files/2393.pdf. Accessed October 22, 2018.
[20] Food and Drug Administration. Partial approval and partial denial of petition for FDA-2017-P-6758. https://www.regulations.gov/document?D=FDA-2017-P-6758-0004. Accessed October 22, 2018.

Utopia Wellness's dissemination of false and misleading advertisements promoting cesium chloride for treatment of cancer

Among the medical treatments for cancer promoted on the Utopia Wellness website is high pH therapy using IV compounded cesium chloride (see enclosed copies of pertinent webpages).[21,22] The Utopia Wellness "High pH Therapy" webpage[23] references the 1984 paper by Sartori that presented a case series of 50 cancer patients who had been treated with cesium chloride and that was found by FDA reviewers to be seriously flawed. This webpage includes the following claim about the effectiveness of high pH therapy:

> Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies.

It appears that the only IV form of high pH therapy promoted by Utopia Wellness on its website is IV cesium chloride. The Utopia Wellness "Cesium Chloride" webpage[24] includes the following claims:

> Cesium chloride is a powerful natural mineral that has the ability to penetrate the cells and change their acidic pH to an alkaline pH. This process can destroy the enzyme system of a cancer cell and halt it's [sic] ability to reproduce. As evidenced by the numerous studies cited below, this powerful, high pH therapy has had astounding success in certain cancers.
>
> IS CESIUM CHLORIDE THERAPY SAFE?
>
> Cesium Chloride is safe when administered under the supervision of an experienced medical team.

Utopia Wellness, however, offers no evidence from well-controlled clinical tests to support its claims about the safety and effectiveness of IV cesium chloride for the treatment of cancer. Indeed, as previously discussed above, independent scientists at the FDA have reviewed the available evidence regarding the use of cesium chloride for treating cancer and concluded that it is "not safe for human use and there is no evidence it is effective for the treatment of any cancer."

In addition to making unsubstantiated claims about the safety and effectiveness of IV cesium chloride for treatment of cancer, Utopia Wellness posted on its "Cesium Chloride" webpage under the heading "Research Studies Articles [sic] on Cesium Chloride Therapy*"* falsified citations of scientific journal articles that purportedly support the medical center's promotional

[21] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 22, 2018.
[22] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 22, 2018.
[23] Utopia Wellness. High pH therapy. https://utopiawellness.com/high-ph-therapy/. Accessed October 22, 2018.
[24] Utopia Wellness. Cesium chloride. https://utopiawellness.com/cesium-chloride-for-cancer-2/. Accessed October 22, 2018.

claims. The clearly deliberate falsification of these citations generally involved taking citations of actual scientific journal articles related to research on or treatment with ozone and replacing the term "Ozone" with "Cesium Chloride" in the titles of the articles.

The following are representative examples of the falsified citations appearing on the Utopia Wellness "Cesium Chloride*"* webpage as of October 22, 2018. The words altered on the website appear below in bold and underlined text, for ease of comparison.

(1) **Utopia Wellness citation**: Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **Cesium Chloride** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.

Actual article citation: Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **ozone** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.

(2) **Utopia Wellness Citation**: Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Cesium Chloride** selectively inhibits growth of human cancer cells. Science 1980; 209(4459):931-933.

Actual article citation: Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Ozone** selectively inhibits growth of human cancer cells. S*cience* 1980;209(4459):931-933.

We identified a total of 30 falsified scientific journal article citations on the Utopia Wellness "*Cesium Chloride"* webpage (see the Appendix for a complete list of the falsified citations). Some of the forged citations were taken from articles in highly reputable scientific journals, such as *Science*. For some citations, Utopia Wellness changed "Ozone" to "Cesium Chloride" in the title but left the parenthetical chemical formula for ozone.

We also note that there were several other citations on the same webpage that provided web links, for which the listed "Accessed" date is from September 2013, which suggests that Utopia Wellness may have engaged in false and misleading advertising of its IV cesium chloride therapy for cancer for at least five years.

Conclusions and requested actions

In conclusion, there is clear evidence that the advertising and promotional materials on the Utopia Wellness website regarding its IV cesium chloride therapy for treatment of cancer are false and misleading. The medical center's website materials misleadingly claim that IV cesium chloride is safe and effective for treating cancer but offers no evidence from well-controlled clinical tests to support its claims. In addition, it fails to disclose evidence highlighted by the FDA indicating that cesium chloride is unsafe for human use because it can cause fatal cardiac

arrhythmias. Finally, the deliberate falsification of the scientific journal citations and medical organization names on the Utopia Wellness webpage promoting IV cesium chloride represents a brazen attempt to mislead patients to believe that there is a large body of scientific evidence showing that IV cesium chloride is a safe and effective treatment for cancer, when in fact it is not safe and effective for that use.

False and misleading advertising such as this preys upon highly vulnerable cancer patients in order to make a profit. In addition to causing financial harm to patients who are duped by its deceptive advertising and promotional materials, Utopia Wellness, under the direction of Dr. Garcia, has exposed these patients to a drug that poses life-threatening risks but offers no proven benefits.

Moreover, any compounding and administration of IV cesium chloride to cancer patients at Utopia Wellness since late July 2018, when the agency took action that prohibited pharmacy compounding using bulk cesium chloride, would not have been legal.

As the Director of Medicine and senior medical practitioner at Utopia Wellness, Dr. Garcia must be held accountable for the deceptive promotional content on the medical center's website regarding the use of cesium chloride to treat cancer and the administration of this dangerous and unproven drug to patients.

We therefore request that the Florida Board of Medicine immediately investigate (1) Dr. Garcia's role in Utopia Wellness's dissemination of false and misleading advertisements that promote the use of the compounded drug cesium chloride as a treatment for cancer and (2) whether Dr. Garcia and his staff have continued to treat cancer patients with compounded IV cesium chloride since late July 2018, when the FDA took action that prohibited pharmacy compounding using bulk cesium chloride. The board should also examine other aspects of Dr. Garcia's medical practice and the online promotional materials for other treatments offered by Utopia Wellness.

If your investigation confirms our allegations, we urge the board to revoke Dr. Garcia's medical license.

Thank you for your prompt attention to this important patient safety and public health issue.

Sincerely,

Meena Aladdin, M.S., Ph.D.
Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Enclosures: Copies of Utopia Wellness "High pH Therapy" and "Cesium Chloride" webpages

Appendix

	Falsified Citation as It Appears on the Utopia Wellness Website (word changes compared with the actual citation are bolded and underlined)	Actual Journal Article Citation
1	Elvis AM. Ekta JS. (2011) **Cesium Chloride** therapy: A clinical review. Journal of Natural Science Biology & Medicine. 2(1):66-70.	Elvis AM. Ekta JS. (2011) **Ozone** therapy: A clinical review. Journal of Natural Science Biology & Medicine. 2(1):66-70.
2	Bocci V.A.(2006) Scientific and Medical Aspects of **Cesium Chloride** Therapy. State of the Art. Archives of Medical Research. 37 (4) (pp 425-435).	Bocci V.A.(2006) Scientific and Medical Aspects of **Ozone** Therapy. State of the Art. Archives of Medical Research. 37 (4) (pp 425-435).
3	Burke FJ.(2012). **Cesium Chloride** and caries: a review of the literature. Dent Update. 39(4):271-2, 275-8.	Burke FJ.(2012). **Ozone** and caries: a review of the literature. Dent Update. 39(4):271-2, 275-8.*8.*
4	Rubin MB. (2001). The History Of **Cesium Chloride**. The Schönbein Period, 1839-1868. Bull. Hist. Chem., 26 (1). Available at: *http://www.scs.illinois.edu/~mainzv/HIST/awards/OPA%20Papers/2001-Rubin.pdf*. Accessed 11th September 2013.	Rubin MB. (2001). The History Of **Ozone**. The Schönbein Period, 1839-1868. Bull. Hist. Chem., 26 (1). Available at: *http://www.scs.illinois.edu/~mainzv/HIST/awards/OPA%20Papers/2001-Rubin.pdf*. Accessed 11th September 2013.
5	Bocci V. Biological and clinical effects of **Cesium Chloride**. Has **Cesium Chloride** therapy a future in medicine? Br J Biomed Sci. 1999;56(4):270-9.	Bocci V. Biological and clinical effects of Ozone. Has **Ozone** therapy a future in medicine? Br J Biomed Sci. 1999;56(4):270-9.
6	Bocci V. Borrelli E, Zanardi I, Travagli V. (2011). Oxygen-**Cesium Chloride** Therapy Is At A Cross-Road. Available at: http://www.isco3.org/files/O3_CrossRoad_Bocci_paper_2011.pdf. Accessed 11th September 2013.	Bocci V. Borrelli E, Zanardi I, Travagli V. (2011). Oxygen-**Ozone** Therapy Is At A Cross-Road. Available at: http://www.isco3.org/files/O3_CrossRoad_Bocci_paper_2011.pdf. Accessed 11th September 2013. (See https://www.austinozone.com/wp-content/uploads/Ozone-Therapy-CrossRoad.pdf. Accessed September 21, 2018.)
7	Sagai M., Bocci V. (2011). Med Gas Res. 2011 Dec 20;1:29. Mechanisms of Action Involved in **Cesium Chloride** Therapy: Is healing induced via a mild oxidative stress? Medical Gas Research. 1 (1). Article Number: 29.	Sagai M., Bocci V. (2011). Med Gas Res. 2011 Dec 20;1:29. Mechanisms of Action Involved in **Ozone** Therapy: Is healing induced via a mild oxidative stress? Medical Gas Research. 1 (1). Article Number: 29.
8	Bocci V., Larini A., Micheli V. (2005). Restoration of normoxia by **Cesium**	Bocci V., Larini A., Micheli V. (2005). Restoration of normoxia by **Ozone** therapy

	Chloride therapy may control neoplastic growth: A review and a working hypothtesis. Journal of Alternative and Complementary Medicine. 11 (2): pp 257-265.	may control neoplastic growth: A review and a working hypothtesis. Journal of Alternative and Complementary Medicine. 11 (2): pp 257-265.
9	Magalhaes FN, Dotta L, Sasse A, Teixera MJ, Fonoff ET. **Cesium Chloride** therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. Pain Physician. 2012 Mar-Apr;15(2):E115-29.	Magalhaes FN, Dotta L, Sasse A, Teixera MJ, Fonoff ET. **Ozone** therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. Pain Physician. 2012 Mar-Apr;15(2):E115-29.
10	Rickard GD, Richardson R, Johnson T, McColl D, Hooper L. **Cesium Chloride** therapy for the treatment of dental caries. Cochrane Database Syst Rev. 2004;(3):CD004153.	Rickard GD, Richardson R, Johnson T, McColl D, Hooper L. **Ozone** therapy for the treatment of dental caries. Cochrane Database Syst Rev. 2004;(3):CD004153.
11	Re L, Mawsouf MN, Menéndez S, León OS, Sánchez GM, Hernández F. **Cesium Chloride** therapy: clinical and basic evidence of its therapeutic potential. Arch Med Res. 2008 Jan;39(1):17-26. Epub 2007 Sep 29.	Re L, Mawsouf MN, Menéndez S, León OS, Sánchez GM, Hernández F. **Ozone** therapy: clinical and basic evidence of its therapeutic potential. Arch Med Res. 2008 Jan;39(1):17-26. Epub 2007 Sep 29.
12	Muller-Tyl E, Salzer H, Reisinger L, Washuttl J, Wurst F. [**Cesium Chloride**-oxygen therapy for gynecologic carcinomas. The effect of parenteral-**Cesium Chloride** oxygen mixture administration on free fatty acids and triglycerides in patients with gynecologic carcinomas]. Fortschr Med 1979; 97(10):451-454.	Muller-Tyl E, Salzer H, Reisinger L, Washuttl J, Wurst F. [**Ozone**-oxygen therapy for gynecologic carcinomas. The effect of parenteral-**Ozone** oxygen mixture administration on free fatty acids and triglycerides in patients with gynecologic carcinomas]. Fortschr Med 1979; 97(10):451-454.
13	Enzelsberger H, Metka M, Salzer H. [Effect of a parenteral **Cesium Chloride**-oxygen mixture on the concentration of immunoglobulins (IgA, IgG, IgM), of vitamin A and lysozyme activity in patients with cervical cancer]. Geburtshilfe Frauenheilkd 1987; 47(12):343-345.	Enzelsberger H, Metka M, Salzer H. [Effect of a parenteral **Ozone**-oxygen mixture on the concentration of immunoglobulins (IgA, IgG, IgM), of vitamin A and lysozyme activity in patients with cervical cancer]. Geburtshilfe Frauenheilkd 1987; 47(12):343-345.
14	Clavo B, Pérez JL, López L, Suárez G, Lloret M, Rodríguez V, Macías D, Santana M, Hernández MA, Martín-Oliva R, Robaina F. **Cesium Chloride** Therapy for Tumor Oxygenation: a Pilot Study. Evid Based Complement Alternat Med. 2004 Jun 1;1(1):93-98.	Clavo B, Pérez JL, López L, Suárez G, Lloret M, Rodríguez V, Macías D, Santana M, Hernández MA, Martín-Oliva R, Robaina F. **Ozone** Therapy for Tumor Oxygenation: a Pilot Study. Evid Based Complement Alternat Med. 2004 Jun 1;1(1):93-98.

15	Clavo B, Ruiz A, Lloret M, López L, Suárez G, Macías D, Rodríguez V, Hernández MA, Martín-Oliva R, Quintero S, Cuyás JM, Robaina F. Adjuvant **Cesium Chloride**therapy in Advanced Head and Neck Tumors: A Comparative Study. Evid Based Complement Alternat Med. 2004 Dec;1(3):321-325. Epub 2004 Oct 16.	Clavo B, Ruiz A, Lloret M, López L, Suárez G, Macías D, Rodríguez V, Hernández MA, Martín-Oliva R, Quintero S, Cuyás JM, Robaina F. Adjuvant **Ozone** therapy in Advanced Head and Neck Tumors: A Comparative Study. Evid Based Complement Alternat Med. 2004 Dec;1(3):321-325. Epub 2004 Oct 16.
16	Parkhisenko I, Bil'chenko SV.(2003). [The **Cesium Chloride** therapy in patients with mechanical jaundice of tumorous genesis]. Vestn Khir Im I I Grek 162(5):85-87.	Parkhisenko I, Bil'chenko SV.(2003). [The **ozone** therapy in patients with mechanical jaundice of tumorous genesis]. Vestn Khir Im I I Grek 162(5):85-87.
17	Clavo B, Gutierrez D, Martin D, Suarez G, Hernandez MA, Robaina F. (2005). Intravesical **Cesium Chloride** therapy for progressive radiation-induced hematuria. J Altern Complement Med 11(3):539-541.	Clavo B, Gutierrez D, Martin D, Suarez G, Hernandez MA, Robaina F. (2005). Intravesical **ozone** therapy for progressive radiation-induced hematuria. J Altern Complement Med 11(3):539-541.
18	Petrucci MT, Gallucci C, Agrillo A, Mustazza MC, Foa R. (2007). Role of **Cesium Chloride** therapy in the treatment of osteonecrosis of the jaws in multiple myeloma patients. Haematologica 92(9):1289-1290.	Petrucci MT, Gallucci C, Agrillo A, Mustazza MC, Foa R. (2007). Role of **ozone** therapy in the treatment of osteonecrosis of the jaws in multiple myeloma patients. Haematologica 92(9):1289-1290.
19	Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **Cesium Chloride** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.	Ripamonti CI, Cislaghi E, Mariani L, Maniezzo M. (2011). Efficacy and safety of medical **ozone** (O(3)) delivered in oil suspension applications for the treatment of osteonecrosis of the jaw in patients with bone metastases treated with bisphosphonates: Preliminary results of a phase I-II study. Oral Oncol 47(3):185-190.
20	Clavo B, Ceballos D, Gutierrez D, Rovira G, Suarez G, Lopez L, Pinar B, Cabezon A, Morales V, Oliva E, Fiuza MD, Santana-Rodriguez M. Long-term control of refractory hemorrhagic radiation proctitis with **Cesium Chloride** therapy.J Pain Symptom Manage. 2013 Jul;46(1):106-12.	Clavo B, Ceballos D, Gutierrez D, Rovira G, Suarez G, Lopez L, Pinar B, Cabezon A, Morales V, Oliva E, Fiuza MD, Santana-Rodriguez M. Long-term control of refractory hemorrhagic radiation proctitis with **ozone** therapy. J Pain Symptom Manage. 2013 Jul;46(1):106-12.
21	Grundner HG, Erler U. [Animal experiments on **Cesium Chloride** therapy of non-irradiated and irradiated tumors. II. Ehrlich ascites carcinoma in vivo]. Strahlentherapie 1976; 151(6):522-529.	Grundner HG, Erler U. [Animal experiments on **ozone** therapy of non-irradiated and irradiated tumors. II. Ehrlich ascites carcinoma in vivo]. Strahlentherapie 1976; 151(6):522-529.

22	Schulz S, Haussler U, Mandic R, Heverhagen JT, Neubauer A, Dunne AA et al. Treatment with **Cesium Chloride**/oxygen-pneumoperitoneum results in complete remission of rabbit squamous cell carcinomas. Int J Cancer 2008; 122(10):2360-2367.	Schulz S, Haussler U, Mandic R, Heverhagen JT, Neubauer A, Dunne AA et al. Treatment with **Ozone**/oxygen-pneumoperitoneum results in complete remission of rabbit squamous cell carcinomas. Int J Cancer 2008; 122(10):2360-2367.
23	Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Cesium Chloride** selectively inhibits growth of human cancer cells. Science 1980; 209(4459):931-933.	Sweet F, Kao MS, Lee SC, Hagar WL, Sweet WE. **Ozone** selectively inhibits growth of human cancer cells. Science 1980; 209(4459):931-933.
24	Karlic H, Kucera H, Metka M, Schonbauer M, Soregi G. [Effect of **Cesium Chloride** and ionizing radiation on an in vitro model–a pilot study of 4 gynecologic tumors]. Strahlenther Onkol 1987; 163(1):37-42.	Karlic H, Kucera H, Metka M, Schonbauer M, Soregi G. [Effect of **ozone** and ionizing radiation on an in vitro model–a pilot study of 4 gynecologic tumors]. Strahlenther Onkol 1987; 163(1):37-42.
25	Bocci V, Luzzi E, Corradeschi F, Silvestri S. Studies on the biological effects of **Cesium Chloride**: 6. Production of transforming growth factor 1 by human blood after **Cesium Chloride** treatment. J Biol Regul Homeost Agents 1994; 8(4):108-112.	Bocci V, Luzzi E, Corradeschi F, Silvestri S. Studies on the biological effects of **ozone**: 6. Production of transforming growth factor 1 by human blood after **ozone** treatment. J Biol Regul Homeost Agents 1994; 8(4):108-112.
26	Zanker KS, Kroczek R. In vitro synergistic activity of 5- with low-dose **Cesium Chloride** against a chemoresistant tumor cell line and fresh human tumor cells. Chemotherapy 1990; 36(2):147-154.	Zanker KS, Kroczek R. In vitro synergistic activity of 5-**fluoruracil** with low-dose **ozone** against a chemoresistant tumor cell line and fresh human tumor cells. Chemotherapy 1990; 36(2):147-154.
27	Bucci B., Cannizzaro A., Brunetti E., Martinelli M. **Cesium Chloride** treatment inhibits proliferation in human neuroblastoma SK-N-SH cells. Rivista Italiana di Ossigeno-Ozonoterapia. 5 (2) (pp 85-92), 2006.	Bucci B., Cannizzaro A., Brunetti E., Martinelli M. **Ozone** treatment inhibits proliferation in human neuroblastoma SK-N-SH cells. Rivista Italiana di Ossigeno-Ozonoterapia. 5 (2) (pp 85-92), 2006.
28	Jerrett M, Burnett RT, Pope CA 3rd, Ito K, Thurston G, Krewski D, Shi Y, Calle E, Thun M. Long-term **Cesium Chloride** exposure and mortality. N Engl J Med. 2009 Mar 12;360(11):1085-95.	Jerrett M, Burnett RT, Pope CA 3rd, Ito K, Thurston G, Krewski D, Shi Y, Calle E, Thun M. Long-term **ozone** exposure and mortality. N Engl J Med. 2009 Mar 12;360(11):1085-95.
29	Faustini A, Capobianchi MR, Martinelli M, Abbate I, Cappiello G, Perucci CA. A cluster of hepatitis C virus infections associated with **Cesium Chloride**-enriched transfusion of autologous blood	Faustini A, Capobianchi MR, Martinelli M, Abbate I, Cappiello G, Perucci CA. A cluster of hepatitis C virus infections associated with **ozone**-enriched transfusion of autologous blood in Rome, Italy. Infect

	in Rome, Italy. Infect Control Hosp Epidemiol. 2005 Sep;26(9):762-7.	Control Hosp Epidemiol. 2005 Sep;26(9):762-7.
30	Ripamonti CI, Maniezzo M, Pessi MA, Boldini S. Treatment of osteonecrosis of the jaw (ONJ) by medical **Cesium Chloride** gas insufflation. A case report. Tumori. 2012 May-Jun;98(3):72e-75e.	Ripamonti CI, Maniezzo M, Pessi MA, Boldini S. Treatment of osteonecrosis of the jaw (ONJ) by medical **ozone** gas insufflation. A case report. Tumori. 2012 May-Jun;98(3):72e-75e.

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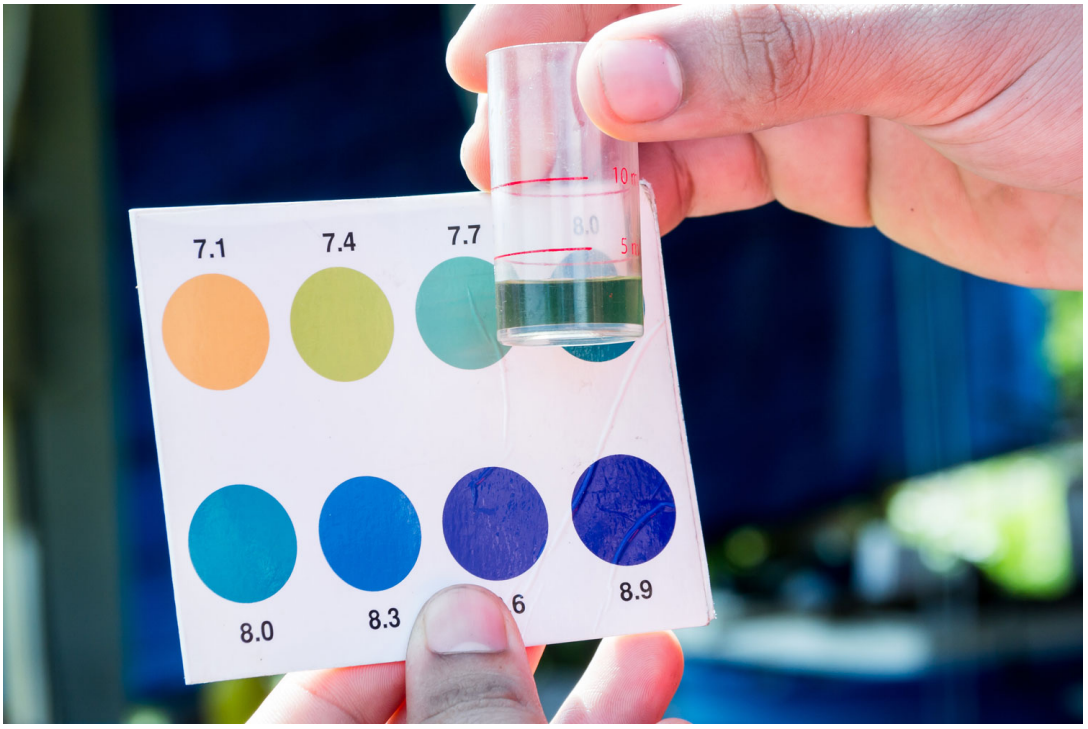
High pH Therapy



Cellular pH is a measure of how acidic, or alkaline, cells are. “pH” is measured on a scale of 0 to 14. A pH of 7 is considered neutral, while numbers below 7.0 are acidic, and numbers above 7.0 are alkaline (or basic).

- Healthy cells – are slightly alkaline with a pH of 7.35 to 7.4
- Cancerous cells – are acidic with a typical pH in the range of 5.5 to 6.5

The research of Dr. Otto Warburg and Dr. H. E. Sartori has demonstrated that most cancer cells prefer an acidic (lower) pH level and thrive in these conditions. Also shown is that cancer growth can be reduced and certain cancer cells may be killed with increased pH levels. That is the purpose of High pH Therapy and why it is an integral part of our Intensive Medical Program.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to drop from between 7.3 to 7.2 down to 7 and later to 6.5; in more advanced stages of cancer and in metastases the pH drops to 6.0 and even 5.7.

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

TOP

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.

More recent research has uncovered another fuel source for cancer cells. In 2008, a team of researchers at Duke University Medical Center and the Université catholique de Louvain (UCL) found that lactic acid is another important energy source for tumor cells. So whether converting lactic acid to glucose or utilizing lactic acid directly as fuel, if you can neutralize the lactic acid, you essentially cut off the fuel supply to cancer.

In addition to providing the fuel for cancer cells, lactic acid is also responsible for one of the most distressing symptoms of cancer; the intense pain that even morphine may not alleviate. This is the same lactic acid secreted by your muscles during a strenuous workout and why you experience pain the day after. For a cancer patient, this pain can be 10 fold. With High pH Therapies, the lactic acid is neutralized.

Dr. H. E. Sartori initiated a cesium cancer therapy program in April 1981 at Life Sciences Universal Medical Clinics in Rockville, Md. Sartori treated 50 terminal patients with widespread tumors. Not only did half of these terminal patients survive their cancer, Sartori found that pain disappeared in all 50 patients within 1 to 3 days after initiating cesium treatments.

Utopia Wellness believes high pH therapy can be beneficial to cancer patients and that is why we include them in our Intensive Medical Program. Utopia Wellness addresses cellular pH through diet and IV therapies:

Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

*Disclaimer: Individual patient results may vary based on a patient's medical history and other factors and these results should not be expected or anticipated. Information on this site is not intended to replace the advice of your physician or healthcare provider. Statements made about products, therapies or services have not been evaluated by the Food and Drug Administration.

At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
- **Individual Counseling**
- **Group Therapy**
- **Touch For Health**
- **Oxygen Therapies**
- **Hyperbaric Oxygen**
- **IV Peroxide Therapy**
- **Nutraceuticals**
- **Nutritional Counseling**
- **Whole Body Detoxification**
- **Colon Therapy**
- **Juicing**
- **Organ Cleanse**
- **Lymphatic Massage**

The Intensive Medical Program at Utopia Wellness focuses not only on the disease, but also on the patient's mind, body, and spirit. If you are looking for a non-toxic alternative that treats you holistically, Utopia Wellness is the facility you are looking for. Call us today at **727-799-9060.** Our Patient Care Coordinator is waiting to tell you more about our innovative approach and schedule your free initial consultation.

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Cesium Chloride

In order for cancer cells to survive and reproduce they have to maintain a high acidic pH – they do this by producing lactic acid as a byproduct of their anaerobic respiration. Cesium chloride is a powerful natural mineral that has the ability to penetrate the cells and change their acidic pH to an alkaline pH. This process can destroy the enzyme system of a cancer cell and halt it's ability to reproduce. As evidenced by the numerous studies cited below, this powerful, high pH therapy has had astounding success in certain cancers.

The pioneer of the Cesium therapy was the highly esteemed American physicist, Dr. Aubrey Keith Brewer (1893 – 1986). He was the chief of the National Bureau of Standards and Mass Spectrometer and Isotope Section and his main interest was in the behavior of cell membranes. He noted during his research that there were areas of the earth where the incidences of cancer were very low. In analyzing the foods from these regions, they were found to be extremely high in cesium and rubidium. The Hopi Indians have water that contains rubidium and potassium while the Hunzas of Northern Pakistan have water high in cesium and potassium. Through his research, he was able to prove that cesium chloride can penetrate cancer cells when other nutrients cannot. Following his research, many studies 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 good.

HOW DOES CANCER AFFECT CELLULAR PH?

Over seventy-five years ago Dr. Otto Warburg published a Nobel Prize winning paper describing the environment of the cancer cell. A normal cell undergoes an adverse change when it can no longer take up oxygen to convert glucose into energy by oxidation. In the absence of oxygen the cell reverts to a primitive nutritional program to sustain itself, converting glucose, by fermentation. The lactic acid produced by fermentation lowers the cell pH (acid/alkaline balance) and destroys the ability of DNA and RNA to control cell division ... the cancer cells begin to multiply unchecked. In the absence of oxygen, glucose undergoes fermentation to create lactic acid. This causes the cell pH to

TOP

drop from between 7.3 to 7.2 down to 7 and later to 6.5; in more advanced stages of cancer and in metastases the pH drops to 6.0 and even 5.7.

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.

Colon Therapy
Juicing
Lymphatic Massage
Organ Cleanse
FAQ's – Cancer Program

HOW IS CESIUM CHLORIDE ADMINISTERED?

Utopia Wellness administers Cesium Chloride in an intravenous solution that is infused into a vein in the arm or through a medical port. The solution also contains the "super solvent" with the ability to penetrate every single cell of the body, so whatever its other effects may be, they will be spread systemically through the entire body.

IS CESIUM CHLORIDE THERAPY SAFE?

Cesium Chloride is safe when administered under the supervision of an experienced medical team. While extremely rare, there can be side effects of Cesium Chloride including inflammation, swelling and pain, muscle cramps, feet and your finger tips feeling like needles and pins, or a tingly prickly feeling in your hands or on your face, nausea and vomiting.

Research Studies Articles on Cesium Chloride Therapy

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At Utopia Wellness, your treatment plan will vary based on your individualized needs and could include:

- **Chelation Therapy**
- **Epigenetic Therapy**
- **High pH Therapy**
- **Cesium Chloride**
- **Alkaline Diet**
- **Hyperthermia – FAR Infrared**
- **Immunotherapy**
- **IV Vitamin C**
- **Mind Body Medicine**
- **Individual Counseling**
- **Group Therapy**
- **Touch For Health**
- **Oxygen Therapies**
- **Hyperbaric Oxygen**
- **IV Peroxide Therapy**
- **Nutraceuticals**
- **Nutritional Counseling**
- **Whole Body Detoxification**
- **Colon Therapy**
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