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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

(727) 799-9060 110 State St E, Oldsmar, FL 34677

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

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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.

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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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