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Congress of the United States
House of Representatives

March 3, 2020

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Chairman Joseph J. Simons
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Commissioner Dr. Stephen M. Hahn
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Chairman Simons and Commissioner Hahn:

As the nation grapples with a possible pandemic, I urge the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) to be vigilant in your oversight of bad actors exploiting societal anxiety to defraud Americans. During his web show and on his website, televangelist James Bakker has repeatedly made misleading claims that a nanosilver formula product he sells, Optivida Silver Sol (16 oz.), successfully treats novel coronavirus (COVID-19)¹ and cures venereal disease among a plethora of preposterous assertions by Bakker that threaten the public health.

The negative uses of nanosilver are well-documented. According to the National Institutes of Health's National Center for Complementary and Integrative Health, silver products lack evidence-based health benefits and can cause serious side effects.² In fact, researchers in Denmark studying nanosilver found that nanosilver leads to harmful proliferation of free radicals in human intestinal cells and cause significant damage if ingested.³

On prominent public broadcasts, Bakker has claimed that the Optivida Silver Sol product can cure all sexually transmitted diseases. During his show on February 8, 2020, a list of uses for Silver Solution scrolls up the screen, reading "viruses, wound and skin conditions, anti-inflammatory, sinus infections, allergies, cold and flu, bronchitis."⁴ These claims are not only dangerous, they are false, misleading, and can only steer consumers away from legitimate ways to prevent infections.

According to the Federal Trade Commission Act, a deceptive practice is one that is likely to "mislead consumers and affect consumers' behavior or decisions about the product or service."⁵ Given the documented scientific and medical evidence, Bakker's claims about Optivida Silver Sol misleads consumers by claiming the product has health benefits that are not backed by science. Bakker's assertion that Silver Solution can eliminate the coronavirus is especially nefarious as it has the potential to convince consumers that his product serves is a cure-all as the infectious disease spreads around the globe.

The therapeutic claims made on Bakker's show regarding Optivida Silver Sol also violate the FTC's Substantiation Standard. Defined in FTC case law as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results," the Substantiation Standard sets criteria that Optivida Silver Sol clearly does not meet.⁶

Since the Silver Solution product is currently marketed for prevention or cure of disease on Bakker's show, it should be treated as an unapproved drug by the FDA. Any product intended to "diagnose, cure, treat, prevent, or mitigate a disease" is considered a drug according to the Food, Drug, and Cosmetic Act (FDCA).⁷ For products to be lawfully marketed, they must have an approved application or an abbreviated application under section 505 of the FDCA, in addition to compliance with part 314 of subchapter D in order to market such a product. Without approval, Mr. Bakker's marketed product should be considered misbranded under section 505 of the FDCA. Additionally, under section 502(a) of the FDCA, a drug is misbranded if it is "false or misleading."⁸ Therefore, your course of action here is clear.

The FDA has cracked down on similar products. On May 17, 2018, the FDA sent a warning letter to Silver Armor, Inc., a company selling colloidal silver products that are not generally recognized as safe, but that were marketed with similar health claims as Bakker has made.⁹ In 1999, the FDA issued a final rule establishing that over-the-counter drug products containing colloidal silver ingredients for internal or external use are not generally recognized as safe and are considered misbranded. The FDA stated in this rule that many drug products containing colloidal silver are "being marketed for numerous serious disease conditions and FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients or silver salts for these disease conditions."¹⁰

As our country faces the enormous and growing threat of novel coronavirus, I urge the FDA and FTC to use the ample tools at your disposal to exercise proper regulatory oversight of these and any unproven products that make blatantly fraudulent claims which could cause public panic. Swindlers and mountebanks that seek to profit from the fear that COVID-19 has caused are deceitful and manipulative and their schemes must be restrained lest others seek to emulate them. This is 2020, not the Middle Ages, and we cannot fight an infectious disease with worthless elixirs sold for hundreds of dollars by unscrupulous hucksters that have absolutely no place in the treatment of serious medical conditions.

Sincerely,

A handwritten signature in blue ink that reads "Bill Pascrell, Jr." with a stylized flourish at the end.

Bill Pascrell, Jr.
Member of Congress

¹ Right Wing Watch [rightwingwatch]. (February 21, 2020). This is now the fifth time that Jim Bakker has claimed that the silver solution he sells “kills ever venereal disease that there is,” declaring that the product is “almost like a miracle.” [Tweet]. Retrieved from <https://twitter.com/RightWingWatch/status/1230893113641701377>.

² National Center for Complementary and Integrative Health. (2009). Colloidal silver. Retrieved from <https://nccih.nih.gov/health/colloidalsilver>.

³ University of Southern Denmark. (2014). More dangerous chemicals in everyday life: Now experts warn against nanosilver. Retrieved from <https://www.sciencedaily.com/releases/2014/02/140227115424.htm>.

⁴ See <https://twitter.com/RightWingWatch/status/1230893113641701377>.

⁵ Federal Trade Commission. (2000). Advertising and marketing on the internet: Rules of the road. Retrieved from <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-marketing-internet-rules-road>.

⁶ Center for Food Safety and Applied Nutrition. (2009). Guidance for industry: Substantiation for dietary supplement claims made under section 403(r) (6) of the federal food, drug, and cosmetic act. Retrieved from <http://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food>.

⁷ 21 CFR Part 314. (2012). Applications for FDA approval to market a new drug. Retrieved from <https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf>.

⁸ 21 U.S.C. § 352. (2011). Misbranded drugs and devices. Retrieved from <https://www.govinfo.gov/content/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec352.pdf>.

⁹ Office of Regulatory Affairs. (2018). Silver Armor, Inc. Warning Letter. Retrieved from <http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/silver-armor-inc-543786-05172018>.

¹⁰ 21 CFR Part 310. (1999). Over-the-counter drug products containing colloidal silver ingredients or silver salts. Retrieved from <https://www.govinfo.gov/content/pkg/FR-1999-08-17/pdf/99-21253.pdf>.