

February 20, 2020

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

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

Dear Chairman Simons and Commissioner Hahn:

We write to ask the Federal Trade Commission (FTC) and U.S. Food and Drug Administration (FDA) to take swift enforcement action against the televangelist and convicted fraudster¹ James Bakker. On his program, The Jim Bakker Show, he appeared on several occasions over the week of 2/09/2020 to promote sales of a colloidal silver product labeled as Silver Solution for the prevention and treatment of novel coronavirus (Covid-19), among other ailments.



One example of such an exchange referring to Silver Solution occurred in a 2/12/2020 episode entitled "A Close Look at What's Not Being Said About the Coronavirus (Day 1)" (at 41:50), following a long discussion of the risks of the coronavirus.³ The conversation occurred between Bakker and contributor Sherrill Sellman, while an advertisement and 1-800 number for buying the product was displayed across the bottom of the screen:⁴

Bakker: Here's the only product—and this is insanity, God gave us this product, I believe...and we have it at our home, we have it in cases, we use it all the time. I have

this, and uh, I don't think I would have made it without silver. This is amazing.... [Turning to Sellman] Would you recommend, as a doctor, people to have silver in their house for a pandemic?

Sellman: You never want to be without silver. Never. So many reasons. This is a staple. Staple. This is a staple for your family. And we can talk more about it.[] All I can say is that it has been proven by the government that it has the ability to kill every pathogen it has ever been tested on, including SARS and HIV—which you may or may or may not want to get into—as a part of this concern with this virus. And it can kill any of these known viruses like SARS. It has been tested on SARS. It has been tested on the bird flu, the H5N1. And it is 99% kill within 12 hours of exposure to the silver. I mean, you get kill earlier but 99% kill within 12 hours. So we know that it has been able to deactivate this—these viruses successfully.

While Sellman was speaking, a scrolling list of health conditions that the silver could allegedly treat was displayed:



Sellman also said (at 45:50):

Sellman: Ok. So if you want to take it as a maintenance dose, it's taking 1, its taking 2-3 teaspoons a day. That's maintenance dose. And you can put it in anything. You can put it in any drink. You can put it in your soups. You can, you know, just take a slurp of it. ...[]

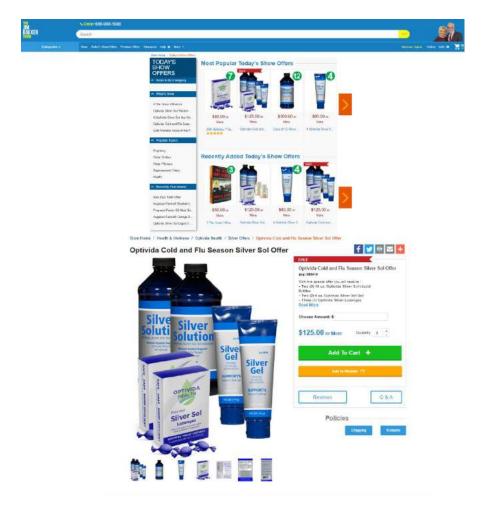
Another commentator, Zach Drew, then discussed how he let his "little daughter" "just drink it right from the bottle." Sellman went on after a little more discussion:

Sellman: So what you want to know: it's used for any age group. You can give it to babies. It has been tested. There are no side effects from it. And you can't overdose on it. The body will use it efficiently and whatever it doesn't need, it's gone.





According to news reports, Bakker had claimed previously on his show, which is broadcast through a range of national and local TV networks, that the same product could cure *all* sexually transmitted diseases. Silver Solution is labeled as a "dietary supplement" and sold on The Jim Bakker Show Website for between \$80 and \$300 for varying amounts. A set of this and related products (including skin care gel and lozenges) is also sold as a "Optivida Cold and Flu Season Silver Sol Offer." Silver Solution makes a labeling claim to have been "clinically tested" and indicates that it is an "immune system support." The Website indicates also that a Proposition 65 warning for cancer or reproductive health toxicity concerns is required on the product.



The Silver Solution products, according to the label, contain only "nano-silver" and water. Silver Gel contains "silver solution," TEA (Triethylamine) and carbomer. The "Silver Sol" lozenges labeling indicates that its "[p]roprietary nano-silver formula works faster, longer and more efficiently than colloidal silvers to help promote natural healing." While commentators on the show touting the product made a marketing distinction between so-called "ionic" silver and colloidal silver, colloidal silver is commonly understood to be a "term used to describe tiny particles of silver suspended in a liquid," which can include nano-particles.⁸

According to the National Center for Complementary and Integrative Health (NCCIH), colloidal silver is both ineffective for any known health condition and dangerous to consumers.

It can cause argyria, a usually permanent bluish-gray discoloration of the skin, eyes, internal organs, nails and gums. It can also cause decreased absorption of some drugs, including antibiotics and medications for thyroid conditions. A Mayo Clinic questions and answers post notes that "[r]arely, excessive doses of colloidal silver can cause possibly irreversible serious health problems, including kidney damage and neurological problems such as seizures."

NCCIH makes clear that "there are no legally marketed prescription or over-the-counter drugs containing colloidal silver that are taken by mouth" and that "scientific evidence doesn't support the use of colloidal silver dietary supplements for any disease or condition."

The FDA Can and Should Take Immediate Enforcement Action Against the Marketing of these Mislabeled and Dangerous Products

Any products that are intended to diagnose, cure, treat, prevent, or mitigate a disease by affecting the structure or function of the body are drugs under the Food, Drug, and Cosmetic Act. FDA enforcement policy also makes clear that it is entitled to take marketing claims beyond the label into account in evaluating whether a product is intended to treat disease or makes disease claims. For over-the-counter drugs containing colloidal silver ingredients to be lawfully marketed, they require "an approved application or abbreviated application under section 505 of the [FDCA] and part 314 of this chapter...." None of these products have such an approved application.

Additionally, a product may be deemed misbranded if it is "misleading in any particular." These products are misleadingly labeled because they make unsubstantiated claims about effectiveness that could divert consumers from FDA-approved products and treatment, including seeking medical attention for flu-like symptoms and upper respiratory infections comparable to coronavirus. All of these can be managed symptomatically using FDA-approved drugs, and specific antimicrobials for influenza and are also FDA-approved. Although coronavirus is currently rare in the U.S., officials expect that it will spread here and around the world. Consumers currently watching the program could be misled by the claims into thinking that Silver Solution is a suitable replacement for the flu vaccines or for anti-viral drugs, both of which are identified by the Centers for Disease Control and Prevention as legitimate means to prevent and treat flu. 16

The above claims also constitute "health fraud," as defined by the FDA to mean "[t]he deceptive promotion, advertisement, distribution or sale of articles . . . that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or to provide a beneficial effect on health, but which have not been scientifically proven safe and

effective for such purposes."¹⁷ Bakker has used his position to bilk the public before. In 1989, Bakker was convicted by a jury of 24 counts of felony fraud and conspiracy in federal court for offenses totaling some \$162 million. He served five years of what was originally a 45-year sentence.¹⁸

These products should qualify as an enforcement priority under the FDA's Health Fraud Compliance Policy Guide § 120.500.¹⁹ Under that Compliance Guide, which makes clear the agency's views on enforcement priorities, they would be considered "indirect health hazards" that: (1) claim to treat a condition that is significant, as we are dealing with a rapidly growing epidemic of coronavirus infection; (2) there are no data that adequately support the efficacy or safety of these products; (3) those seeking to prevent themselves from catching the virus are both numerous and vulnerable (and the product is being marketed on the show alongside other "end times" preparation products clearly intended to stir public emotion and give rise to a sense of crisis), and (4) these products directly compete with treatments for flu and upper respiratory conditions that produce symptoms similar to the coronavirus. Accordingly, action to address these misleading products should be a high priority for the FDA.

The FTC Should also Pursue Enforcement Actions against the Misleading Marketing of these Products

The marketing of these products is also violative of the FTC Act. The FTC may bring an action charging that marketing claims are false or unsubstantiated under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to obtain preliminary and permanent injunctive relief, as well as the refund of monies paid, disgorgement of ill-gotten gains and other equitable relief for the Defendant's acts or practices in violation of Sections 5(a) and 12 of the FTC Act. 15 U.S.C. §§ 45(a) and 52.

Over the past several decades, the FTC has taken enforcement action against several companies selling supplements containing colloidal silver, including a 2018 letter in support of such actions against "The Silver Edge" undertaken by the Better Business Bureau's National Advertising Division to pursue its claims about flu prevention, among others. ²⁰ In addition, the FTC took actions against multiple marketers of bogus SARS treatment and prevention products in 2003. ²¹

There are also misleading product endorsements made by regular, promoted commentators on The Jim Bakker Show. Although Bakker's co-host is identified as "Doctor Sherrill Sellman" on the screen during the show and on the show's website, it appears that Sellman does not hold a medical degree, except as described below.

On 2/12/2020, while a hotline for calling to buy the product was depicted at the bottom of the screen, Sellman and Bakker had the following exchange:²²

Bakker: "This influenza that is now circling the globe, you're saying that Silver Solution would be effective?"

Sellman: "Well, let's say it hasn't been tested on this strain of the coronavirus, but it's been tested on other strains of the coronavirus and has been able to eliminate it within 12

hours. Totally eliminates it. Kills it. Deactivates it. And then it boosts your immune system, so then you can support the recovery."

An online biography of Sellman states that, following a B.A. Degree in Sociology and Psychology from the University of Pittsburgh in 1970, she received her Doctor of Naturopathy from Trinity College of Natural Healing, Warsaw, Indiana in 2004.²³ Trinity School of Natural Health is not federally accredited with the Department of Education according to that school's website.²⁴ Dr. JoAnn Yanez, executive director of the Association of Accredited Naturopathic Medical Colleges (AANMC), told *Newsweek* earlier this week that:

Sellman has not met the educational standards that the organization requires. Sellman "is neither a graduate of an accredited naturopathic medical program, nor has [she] obtained a doctoral level degree from a program recognized by the US Department of Education."²⁵

Yanez wrote in a statement to *Newsweek*:

"[Her] online profile mentions graduating from the Trinity School of Natural Healing (AKA Health), which is not accredited and confers 'degrees' not recognized by any governmental institution. 'Graduates' of these programs are not considered licenseable [sic] medical practitioners." Yanez further requested that *Newsweek* reiterate that Sellman is not a graduate of any institution accredited by AANMC."²⁶

Additionally, there is no evidence that Sellman is a medical doctor with training or experience in flu prevention or treatment. Because viewers are likely to mistake Sellman for a medical doctor, the advertisement is deceptive under FTC rules which state that "whenever an advertisement represents, directly or by implication, that the endorser is an expert with respect to the endorsement message, then the endorser's qualifications must in fact give the endorser the expertise that he or she is represented as possessing with respect to the endorsement."²⁷

The FTC also has made clear that "[a] non-medical 'doctor' (*e.g.*, an individual with a Ph.D. in exercise physiology) or a physician without substantial experience in the area of hearing may endorse a product, but if the endorser is referred to as 'doctor,' the advertisement must make clear the nature and limits of the endorser's expertise." Here, The Jim Bakker Show is violating the FTC's explicit requirement by referring to Sellman as "Doctor" without any further mention of the limitations of her expertise.

Given the nature of the public health threat posed by the coronavirus and the attendant public concern, we urge immediate action by both agencies to halt this fraud on the public. We urge the FDA and FTC to issue warning letters and bring other enforcement actions that require cessation of sales of these and other such products and that would allow inspectors to seize products. In addition, we urge the FTC to pursue refunds for customers who have purchased these products and to alert them of the health risks of consuming them.

Sincerely,

Dr. Peter Lurie, M.P.H., M.D. President and Executive Director

Laura MacCleery Policy Director

Notes

⁷ The Jim Bakker Show. *Optivida Cold and Flu Season Silver Sol Offer*. n.d. https://store.jimbakkershow.com/product/cold-and-flu-season-silver-sol-offer/. Accessed February 19, 2020.

⁸ "All about Colloidal Silver: Is it Healthy or Dangerous?" *Healthline*. https://www.healthline.com/nutrition/colloidal-silver Accessed February 19, 2020.

⁹ National Center for Complementary and Integrative Health. *Colloidal Silver*. n.d. https://nccih.nih.gov/health/colloidalsilver. Accessed February 19, 2020.

¹⁰ Mayo Clinic. Healthy Lifestyle. "My dad takes colloidal silver for his health, but is it safe?" https://www.mayoclinic.org/healthy-lifestyle/consumer-health/expert-answers/colloidal-silver/faq-20058061. Accessed February 20, 2020.

- ¹¹ 21 U.S.C. § 321(g)(1). Federal Food, Drug, and Cosmetic Act- Definitions; generally.
- ¹² 21 C.F.R. §310.548. Drug products containing colloidal silver ingredients or silver salts offered over-the-counter (OTC) for the treatment and/or prevention of disease.
- ¹⁴ Under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling "is false or misleading in any particular." Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)], provides that, in determining whether an article's labeling or advertising "is misleading, there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which labeling or advertising fails to reveal facts material in light of such representations"
- ¹⁵ McKeever A. Here's what coronavirus does to the body. *National Geographic*. February 19, 2020. https://www.nationalgeographic.com/science/2020/02/here-is-what-coronavirus-does-to-the-body/. Accessed February 19, 2020.
- ¹⁶ U.S. Centers for Disease Control and Prevention. *What You Should Know About Flu Antiviral Drugs*. April 22, 2019. https://www.cdc.gov/flu/treatment/whatyoushould.htm. Accessed February 19, 2020.
- ¹⁷ U.S. Food and Drug Administration. *Market Unapproved Drugs- Compliance Policy Guide*. 2011; Sec 440.100. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketed-unapproved-drugs-compliance-policy-guide. Accessed February 19, 2020.

¹ Applebome P. Bakker Is Convicted on All Counts; First Felon Among TV Evangelists. *The New York Times*. October 6, 1989. https://www.nytimes.com/1989/10/06/us/bakker-is-convicted-on-all-counts-first-felon-among-tv-evangelists.html

² The Jim Bakker Show (homepage). n.d. https://jimbakkershow.com/. Accessed February 18, 2020.

³ The Jim Bakker Show. *A Close Look at What's Not Being Said About The Coronavirus (Day 1)*. Show #3861, Aired on February 12, 2020. https://jimbakkershow.com/watch/?guid=3861. Accessed February 18, 2020.

⁴ The Jim Bakker Show. *A Close Look at What's Not Being Said About The Coronavirus (Day 1)*. Show #3861, Aired on February 12, 2020. https://jimbakkershow.com/watch/?guid=3861. Accessed February 18, 2020.

⁵ The Jim Bakker Show. *Broadcast Listings*. n.d. https://jimbakkershow.com/watch-us-live/broadcast-listings/. Accessed February 18, 2020.

⁶ Smith G. Have an STI? This infamous evangelical preacher wants to sell you a (fake) cure. *LGBTQ Nation*. July 27, 2019. https://www.lgbtqnation.com/2019/07/sti-infamous-evangelical-preacher-wants-sell-fake-cure/. Accessed February 18, 2020. (Viz. "You know, the amazing thing is it's safe for babies," said Bakker while hawking the Silver Solution Combo Pack on *The Jim Bakker Show*. 'It's the most amazing product. It's proven to kill every venereal disease there is."")

¹⁸ Smothers R. Ex-Television Evangelist Bakker Ends Prison Sentence for Fraud. *The New York Times*. December 2, 1994. https://www.nytimes.com/1994/12/02/us/ex-television-evangelist-bakker-ends-prison-sentence-for-fraud.html. Accessed February 19, 2020.

- ¹⁹ U.S. Food and Drug Administration. *Health Fraud- Factors in Considering Regulatory Action;* Sec 120.500. March 1995. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-120500-health-fraud-factors-considering-regulatory-action. Accessed February 19, 2020.
- ²⁰ U.S. Federal Trade Commission. Letter Laura Brett, National Advertising Division, Re: NAD Referral About Advertising for Life & Health Research Group, LLC's Micro-Particle Colloidal Silver Generator. May 14, 2018.
- https://www.ftc.gov/system/files/documents/public_statements/1380295/silver_edge_resolution_letter_5-14-18.pdf. Accessed February 19, 2020.
- ²¹ U.S. Federal Trade Commission. *FTC and FDA Crack Down on Internet Marketers of Bogus SARS Prevention Products*. May 9, 2003. https://www.ftc.gov/news-events/press-releases/2003/05/ftc-and-fda-crack-down-internet-marketers-bogus-sars-prevention. Accessed February 19, 2020.
- ²² Right Wing Watch Twitter Page (@RightWingWatch). February 12, 2020 (1:17pm). https://twitter.com/RightWingWatch/status/1227657884395327489?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1227657884395327489&ref_url=https%3A%2F%2Fwww.lgbtqnation.com%2F2020%2F02%2Ftelevangelist-jim-bakker-claims-silver-solution-std-cure-also-kills-coronavirus%2F. Accessed February 19, 2020.
- ²³ Cancer Control Society. *Sherrill Sellman*, *N.D.* n.d. https://www.cancercontrolsociety.org/bio2006/sellman.htm. Accessed February 19, 2020.
- ²⁴ Trinity School of Natural Health. *About*. https://www.trinityschool.org/about. Accessed February 19, 2020. (Instead, it is accredited only by the American Naturopathic Medical Accreditation Board in Las Vegas, Nevada (www.anmab.org) and the American Association of Drugless Practitioners in Galveston, Texas (www.aadp.net).)
- ²⁵ Moyler H. Televangelist sells \$125 'Silver Solution' as Cure for Coronavirus. *Newsweek*. February 12, 2020. https://www.newsweek.com/televangelist-show-guest-promotes-silver-solution-cure-coronavirus-1487069. Accessed February 19, 2020.

²⁶ *Id*.

²⁷ 16 C.F.R. § 255.3(a). Expert endorsements.

 28 *Id*.