

Testimony of Laura MacCleery

Policy Director, Center for Science in the Public Interest

“Protecting Americans from COVID-19 Scams”

Senate Committee on Commerce, Science and Transportation
Subcommittee on Manufacturing, Trade and Consumer Protection

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Thank you, Chairman Moran and Ranking Member Blumenthal for the honor of testifying today on this critical topic. I am the Policy Director for the Center for Science in the Public Interest, a nearly fifty-year-old organization that advocates for healthy changes to our food system and for the interests of consumers.

Americans are facing an unprecedented challenge in keeping themselves and their families safe during a pandemic. Public health officials emphasize that we all need to socially distance, wear a mask, and wash our hands. But understandably, many people are looking for more than those measures to protect themselves, and those who lack scruples are actively exploiting consumer fear and anxiety.

In truth, our underregulated marketplace for dietary supplements is a risky place under any conditions. For the past three years, we have been collecting evidence of scams concerning supplements and sending it to the Food and Drug Administration (FDA) and Federal Trade Commission (FTC). These have included the many misleading claims we found on products marketed to vulnerable consumers suffering from opioid¹ and tobacco addiction.²

Last November, we reported to the agencies about 39 supplements selling false hope to women experiencing infertility by making unsupported disease claims, a practice precluded by law.³ Only products approved as drugs may make claims to treat or prevent a disease or health condition, such as infertility or the coronavirus.

It is far too tempting to think that a powder or supplement can help us against a global pandemic. When the coronavirus appeared, we knew the hucksters would not be far behind. We have been tracking and reporting such efforts to appropriate federal authorities since February.

First, we wrote the FDA and FTC about televangelist Jim Bakker, whose show featured experts advancing the claim that products it sold containing colloidal silver could cure the coronavirus “within 12 hours.”⁴ Commentators on the same show previously claimed that the same product cures “all venereal diseases,” as well as HIV.⁵

Yet there’s no evidence that silver supplements prevent or treat *any* condition, according to the National Institutes of Health.⁶ Although experts featured on Bakker show claimed it should be consumed daily in “slurps” and was “safe for babies,”⁷ colloidal silver in large enough amounts can be dangerous to kidneys and other organs.⁸ It can also cause permanent bluish-gray discoloration of a person’s skin and organs.⁹

The FDA and FTC issued warning letters to The Jim Bakker Show,¹⁰ as did the New York¹¹ and Missouri Attorneys General,¹² and the religious group Faithful America is asking for networks to drop the show because of these statements.¹³ In June, the Arkansas Attorney General brought a civil claim against the show, seeking compensation for consumers.¹⁴

Also in June, we sent another request to the FDA and FTC, asking for enforcement on supplements being marketed as “antiviral” products.¹⁵ Any claim that a supplement has antiviral properties is considered an illegal disease claim by the FDA because viruses are, obviously, a form of disease.¹⁶

Our market scan of products on Amazon in late May found at least 46 dietary supplements making illegal antiviral claims, so we sent our findings to the agencies and wrote Amazon directly to ask the company to remove these products.¹⁷ Unfortunately, a subsequent search of Amazon performed on June 29th found that 26 of those supplements are still making antiviral claims on their own websites, Amazon, or other online stores.

While Amazon has already rid its site of many products bearing explicitly illegal COVID claims,¹⁸ others have done little. Because consumers rely on them so much today, platforms such as Amazon, Ebay, Facebook and Etsy must do a far better job of removing misleading claims and products being sold and marketed through their sites, and we urge Congress and the agencies to hold them accountable for doing so.

We continue to be on the look-out for scams related to COVID claims. Just this morning, we sent public letters to the FDA and FTC asking for the agencies to act to address dozens of misleading claims made about at least 23 supplements and medical devices by Dr. Joseph Mercola, a well-known purveyor of dietary supplements over the Internet.

According to Dr. Mercola and his companies’ website, Mercola.com, it is the world’s “#1 most visited natural health website” and is viewed by “millions of people daily.”¹⁹ Working with Justice Catalyst Law,²⁰ and People’s Parity Project,²¹ we documented how he markets these supplements and devices by falsely claiming that they will protect people from, or treat symptoms of, COVID-19.²²

In a pandemic, such untruths pose a clear and urgent danger. Consumers may develop a false sense of security and fail to practice social distancing or use masks, endangering themselves and everyone around them. They may also harm themselves by taking dangerous doses of supplements, or fail to seek effective medical treatment, believing instead in the promises of charlatans.

But it is even worse than that. On a recent episode of Mercola’s podcast, he actually advises consumers to take the immunity-boosting supplements he sells and then attempt to contract the COVID-19 virus deliberately, because his supplements will allegedly reduce their symptoms?²³ Even with all my experience investigating supplement scams, this reckless self-promotion and endangerment of the public took my breath away.

Such potentially deadly advice to consumers, and the profiteering from our legitimate fears, must be stopped. While the agencies are working hard to stem the tide of misleading products, the funding and enforcement tools they currently have are woefully inadequate to this task.

Dietary supplements are among the most poorly regulated consumer products. Congress, through the Dietary Supplement Health and Education Act of 1994 (DSHEA), established a bare-bones system of oversight by the Food and Drug Administration (FDA) that was designed to be weak. Today, particularly given the tremendous expansion of products and use by consumers over the intervening 26 years, that system is indisputably failing.

Both the FDA and FTC need more funding, personnel and resources for enforcement. The FDA, in particular, needs far better tools, including a mandatory product registration requirement to make the marketplace transparent for regulators. A modest and graduated registration fee could also be collected to build resources at the agency.

In addition, Congress should authorize state attorneys general to enforce relevant federal laws related to dietary supplements, to improve their accountability and reach. Currently, state AGs can only enforce general consumer protection laws under their own state regime, not federal rules on supplements. Yet the sheer number of products make it practically impossible for one central agency to monitor and enforce compliance with legal requirements.

The FDA should also be given heightened regulatory powers for specific categories of supplements known to pose a “high risk” to consumers because they are marketed to vulnerable groups or are commonly tainted with drugs or synthetic ingredients. Many such products—including sexual-enhancement, weight-loss, and workout supplements—are already identified as high risk because agency testing reveals they often contain drugs such as amphetamines.²⁴

These and other categories of high-risk supplements should be subjected to pre-market product testing and audits in a new, focused safety program authorized and funded by Congress. Ironically, under current law, *because* these are tainted with drugs, they are not subject to mandatory recall—a loophole that should be closed.²⁵

There are other needs as well:

- Companies should be required to report all adverse events that result from their products, not merely the ones they deem “serious.”
- Supplements that interact with common categories of prescription drugs should bear a warning for consumers about the risk of an interaction.
- A loophole that allows new supplements to side-step safety review should be closed.²⁶ A leading trade association representative admitted at a 2018 FDA public meeting that the industry uses this loophole “six to seven times” more than the official safety approval process they are supposed to use under the law, thereby avoid any review for safety at all.²⁷
- Last, rules that have languished unfinished since 1994, including defining what a “new dietary ingredient” is, should be completed by the FDA, and Congress should set deadlines for that completion.²⁸

We would appreciate the opportunity to work with lawmakers on a vision for reform of supplement oversight to ensure that consumers are protected from fraud. It should not take a pandemic to motivate solutions to require that supplements—like any consumer product—are truthfully labeled and marketed, and that consumers are not misled in ways that risk their own and public health.

Notes

¹ Center for Science in the Public Interest (CSPI). *Crackdown Urged on Supplements Marketed as Opioid Withdrawal Aids: CSPI Investigation Shows Manufacturers Can't Support Claims*. December 8, 2017. <https://cspinet.org/news/crackdown-urged-supplements-marketed-opioid-withdrawal-aids-20171208>.

Accessed July 16, 2020.

² CSPI. *FDA Urged to Take Enforcement Action against Manufacturers of Dietary Supplements that Promise to Help Smokers Quit: Companies Produce No Evidence to Support their Claims*. April 23, 2019. <https://cspinet.org/news/fda-letter-dietary-supplements-smoking-cessation>. Accessed July 16, 2020.

³ CSPI. *Manufacturers of "Fertility" Supplements Selling False Hope: CSPI Asks the FDA and FTC to Take Enforcement Action*. November 15, 2019. <https://cspinet.org/news/manufacturers-fertility-supplements-false-hope-20191118>. Accessed July 16, 2020.

⁴ CSPI. *CSPI Urges FDA Enforcement Action on Televangelist Jim Bakker's Fake Coronavirus "Cure": Letter Submitted to FDA and FTC*. February 20, 2020. <https://cspinet.org/news/cspi-urges-fda-enforcement-action-televangelist-jim-bakkers-fake-coronavirus-cure-20200218>. Accessed July 16, 2020.

⁵ *Id.*; 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 July 16, 2020.

⁶ Mayo Clinic. *My dad takes colloidal silver for his health, but is it safe?*. September 6, 2017.

<https://www.mayoclinic.org/healthy-lifestyle/consumer-health/expert-answers/colloidal-silver/faq-20058061>. Accessed July 16, 2020.

⁷ CSPI. *CSPI Urges FDA Enforcement Action on Televangelist Jim Bakker's Fake Coronavirus "Cure": Letter Submitted to FDA and FTC*. February 20, 2020. <https://cspinet.org/news/cspi-urges-fda-enforcement-action-televangelist-jim-bakkers-fake-coronavirus-cure-20200218>. Accessed July 16, 2020.

⁸ National Center for Complementary and Integrative Health. *Colloidal Silver*. April 2017.

<https://nccih.nih.gov/health/colloidalsilver>. Accessed July 16, 2020.

⁹ *Id.*

¹⁰ US Food and Drug Administration (FDA). *WARNING LETTER: The Jim Bakker Show MARCS-CMS 604820*. March 06, 2020. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jim-bakker-show-604820-03062020>. Accessed July 16, 2020.

¹¹ State of New York, Office of the Attorney General. *Letter RE: CEASE AND DESIST NOTIFICATION*. March 3, 2020. [https://ag.ny.gov/sites/default/files/bakker cease and desist letter notification.pdf](https://ag.ny.gov/sites/default/files/bakker%20cease%20and%20desist%20letter%20notification.pdf). Accessed July 16, 2020.

¹² Missouri State Attorney General. *AG Schmitt Files Suit Against Jim Bakker for Selling Fake "Coronavirus Cure"*. Mar 10, 2020. <https://ago.mo.gov/home/news/2020/03/10/ag-schmitt-files-suit-against-jim-bakker-for-selling-fake-coronavirus-cure>. Accessed July 16, 2020.

¹³ Faithful American. *Tell DirecTV, DISH, and Roku: Drop televangelist for selling fake coronavirus cure*. March 7, 2020. <https://act.faithfulamerica.org/sign/bakker-coronavirus/>. Accessed July 16, 2020.

¹⁴ Arkansas Attorney General. *Rutledge Sues Jim Bakker for Peddling Colloidal Silver Products to Cure COVID-19*. June 16, 2020. <https://arkansasag.gov/media-center/news-releases/rutledge-sues-jim-bakker-for-peddling-colloidal-silver-products-to-cure-covid-19>. Accessed July 16, 2020.

¹⁵ CSPI. *CSPI Letters re: Antiviral Claims by Supplement Manufacturers: Sent to FDA, FTC, Amazon*. June 3, 2020. <https://cspinet.org/resource/cspi-letters-re-antiviral-claims-supplement-manufacturers>. Accessed July 17, 2020.

¹⁶ Agency guidance provides that: "A claim that a dietary supplement fights disease or enhances disease-fighting functions of the body is a disease claim. Under this criterion, context and specificity are important. Claims such as 'supports the body's ability to resist infection' and 'supports the body's antiviral capabilities' are disease claims because the context of the claim is limited to the disease prevention and

treatment capabilities.” FDA. *Small Entity Compliance Guide on Structure/Function Claims*. January 9, 2002. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>. Accessed May 4, 2020.

¹⁷ CSPI. *CSPI Letters re: Antiviral Claims by Supplement Manufacturers: Sent to FDA, FTC, Amazon*. June 3, 2020. <https://cspinet.org/resource/cspi-letters-re-antiviral-claims-supplement-manufacturers>. Accessed July 17, 2020.

¹⁸ US Immigration and Custom Enforcement (ICE). HSI partners with Pfizer, 3M, Citi, Alibaba, Amazon, Merck to protect consumers against COVID-19-related fraud. May 5, 2020.

<https://www.ice.gov/news/releases/hsi-partners-pfizer-3m-citi-alibaba-amazon-merck-protect-consumers-against-covid-19>. Accessed May 6, 2020. (“Since the beginning of the COVID-19 crisis, Amazon has proactively stopped more than 6.5 million products with inaccurate claims, removed over 1 million offers for suspected price gouging, suspended more than 10,000 selling accounts for suspected price gouging and referred the most egregious offenders to federal and state law enforcement across the country. Amazon welcomes HSI’s partnership in holding counterfeiters and bad actors accountable, and we look forward to building on our long-standing relationship to protect customers and ensure a trusted shopping experience,” said Dharmesh Mehta, Amazon vice president, customer trust and partner support.”).

¹⁹ See Dr. Joseph Mercola (Mercola). *Health Website Rankings: Mercola.com is World’s Most Visited Natural Health Site*. <https://www.mercola.com/forms/rankings.htm>. Accessed July 16, 2020.

²⁰ Justice Catalyst Law (JCL) is a nonprofit law firm that focuses on combatting social and economic injustice, working nationally to support cases and policy work in the fields of antitrust, consumer law, employment law and civil rights. See, <https://justicecatalyst.org>. Accessed July 16, 2020.

²¹ People’s Parity Project (PPP) organizes law students and new attorneys nationwide to unrig the legal system and build a justice system that values people over profits. PPP believes that by dismantling the coercive legal tools that enhance corporate power and fighting for a judiciary that is representative of – and thus responsive to – people, not corporations, can reshape the legal profession. See, <https://www.peoplesparity.org>. Accessed July 16, 2020.

²² Such products, sold through its online store, and that Dr. Mercola has endorsed in public statements (See *supra* note 23) for the prevention and/or treatment of COVID-19, include: vitamin C (specifically, liposomal vitamin C); vitamin D; zinc and selenium (which Mercola Group sells together); melatonin; licorice; molecular hydrogen; astaxanthin; n-acetyl cysteine; prebiotics, probiotics, and sporebiotics; saunas; ozone therapy; elderberry extract; spirulina; beta-glucan; lipoic acid; and sulforaphane. See, e.g., Mercola, *Nutrition and Natural Strategies Offer Hope Against COVID-19*. Mar. 29, 2020. <https://articles.mercola.com/sites/articles/archive/2020/03/29/andrew-saul-vitamin-c.aspx>. Accessed July 16, 2020; Mercola. *Coronavirus Resource Page*. <https://www.mercola.com/coronavirus-resources.htm>. Accessed July 16, 2020; Mercola and Andrew Saul, *Nutrition and Natural Strategies Offer Hope Against COVID-19: Discussion Between Drs. Andrew Saul and Mercola*, Dr. Joseph Mercola - Take Control of Your Health. Mar. 29, 2020. <https://podcasts.apple.com/us/podcast/nutrition-natural-strategies-offer-hope-against-covid/id1286870871?i=1000469858840>. Accessed July 16, 2020; <http://Shop.Mercola.com>. Accessed July 16, 2020; <https://bit.ly/2XBFJ9d> (Liposomal Vitamin C). Accessed July 16, 2020; <https://bit.ly/372lcxy> (Liposomal Vitamin D3). Accessed July 16, 2020; <https://bit.ly/2UbOKmX> (Molecular Hydrogen). Accessed July 16, 2020; <https://bit.ly/3gYhzx5> (Melatonin). Accessed July 16, 2020; <https://bit.ly/2UeDlmJ> (Zinc plus Selenium). Accessed July 16, 2020; <https://bit.ly/3758gqA> (Ozone generating air purifiers). Accessed July 16, 2020; <https://bit.ly/3dDE0pk> (Infrared Saunas - temporarily discontinued for “redesign”). Accessed July 16, 2020.

²³ Mercola stated: “When you get a vaccine, you only simulate your humoral immunity, the B-cells. The T-cells are not stimulated. So, scary as it may sound, the best thing is to get the infection, and have a strong immune system to defend against it so you won’t even display any symptoms.” Here, Dr. Mercola made the misleading and false assertion that contracting the virus and recovering will confer a “natural immunity” that will be more effective than the immunity provided by a vaccine. Mercola and Andrew Saul, *Nutrition and Natural Strategies Offer Hope Against COVID-19: Discussion Between Drs. Andrew Saul and Mercola*, Dr. Joseph Mercola - Take Control of Your Health. Mar. 29, 2020.

<https://podcasts.apple.com/us/podcast/nutrition-natural-strategies-offer-hope-against-covid/id1286870871?i=1000469858840>. Accessed July 16, 2020.

²⁴ FDA. *Tainted Dietary Supplements and Foods: Responsibilities of Retailers and Distributors*. October 2010. <https://www.fda.gov/files/drugs/published/Tainted-Dietary-Supplements-and-Foods--Responsibilities-of-Retailers-and-Distributors.pdf>. Accessed July 16, 2020.

²⁵ Such a provision would state that if a product is sold as a dietary supplement and contains an ingredient approved by the FDA for use as a prescription drug, FDA may initiate a recall of the product.

²⁶ The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires companies that introduce novel substances into dietary supplements provide the FDA with information showing that the “new dietary ingredients” (NDIs) in supplements will “reasonably be expected to be safe.” However, FDA draft guidance on NDIs has never been completed, and perhaps three-quarters or more of NDIs evade FDA’s review by following a pathway permitted for secret and unmonitored self-assessment by companies of the safety of ingredients in food, known as “Generally Recognized as Safe,” or “GRAS,” self-determination. *See* 21 U.S.C. § 350b; 62 Fed. Reg. 49886 (September 23, 1997), Premarket Notification for a New Ingredient.); *See also* CSPI *FDA Food Ingredient Approval Process Violates Law, Says CSPI: Flawed ‘GRAS’ System Lets Novel Chemicals Into Food Supply without FDA Safety Review*. April 15, 2015. <http://cspinet.org/new/201504151.html>. Accessed July 17, 2020.

²⁷ FDA. *Public Meeting to Discuss the Development of a List of Pre-DSHEA Dietary Ingredients*. P. 49. October 2017. Transcript available at <https://www.fda.gov/media/108452/download>. Accessed May 11, 2020.

²⁸ The FDA has yet to issue final draft guidance on how companies should show that the “new dietary ingredients” (NDIs) in supplements will “reasonably be expected to be safe.”