MEDIA PACK

alliance for natural health USA

ANH-USA/MEDITREND LAWSUIT 10-22-2024

STOP THE FDA BAN ON HOMEOPATHY

FDA guidance published in December 2022 effectively made illegal all homeopathic products in America. The guidance requires all homeopathic drugs, like conventional drugs, to go through a full new drug pre-market approval process, which is neither technically, nor economically, feasible for the vast majority of manufacturers.

If the FDA enforces its own guidance, millions of Americans will lose access to their homeopathic drugs of choice, and an industry valued in excess of $4 billion-a-year will be destroyed.

Alliance for Natural Health USA and leading homeopathic drug maker, Meditrend, are bringing this lawsuit which sets out to reverse the FDA's effective ban, arguing it is unlawful and that it contravenes Congressional decisions.

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PRESS RELEASE

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alliance for natural health USA

ANH-USA FILES LAWSUIT TO REVERSE FDA'S EFFECTIVE BAN ON HOMEOPATHY

ALEXANDRIA, VA: The **Alliance for Natural Health (ANH) USA** filed a complaint yesterday with the United States District Court for the District of Columbia that aims to reverse the FDA's effective ban on homeopathic drugs used by millions of Americans.

FDA guidance published in December 2022 effectively made all homeopathic drugs currently used in America illegal. The guidance requires that all homeopathic drugs go through the same new drug pre-market licensing system used for pharmaceuticals. This system is entirely unjustified and is neither technically, nor economically, feasible for the vast majority of manufacturers.

If the FDA enforces its own guidance, millions of Americans will lose access to their homeopathic drugs of choice, and an industry valued in excess of $4 billion-a-year will be destroyed.

ANH-USA and leading homeopathic drug maker, **Meditrend Inc.**, have brought the lawsuit, arguing the FDA's guidance is unlawful and that it contravenes previous decisions made by Congress.

> "The FDA's guidance is a stunning example of agency overreach", said **Jonathan Emord, Esq.**, General Counsel of ANH. He continued, "Not only has the FDA ignored the careful consideration given to this unique category of drugs by Congress, it has violated the law, notably the Administrative Procedure Act and the Coronavirus Aid, Relief, and Economic Security Act of 2020.
>
> The Supreme Court's decision earlier this year to overturn the Chevron doctrine that has allowed, for some 40 years, government agencies to ignore the rule of law while protecting special interests, gives us a unique opportunity to reset the balance for individual rights, liberty and consumer choice."

The full complaint can be accessed from this link.

> **Rob Verkerk, Ph.D.**, Executive and Scientific Director of ANH added: "The FDA has had to greatly exaggerate safety concerns over homeopathic products to justify its approach. Copious evidence shows that these are among the very safest healthcare products in use. What the FDA should have done is follow the remit given by Congress and develop a new regulatory framework suitable for homeopathics. Fortunately, our friends at Americans for Homeopathy Choice have now created a bill for this purpose and we are hopeful that our lawsuit will give us the momentum needed to ensure the FDA's attacks on homeopathy are eliminated once and for all."

ENDS.

CONTACT

For interviews with Jonathan Emord, Esq. and Robert Verkerk, Ph.D. (ANH) or Richard D. Savage, CEO of Meditrend, and for further information, please contact Michael Ames-Sikora, Editorial Director via telephone 800-230-2762 or email michael@anh-usa.org or office@anh-usa.org.

EDITORS' NOTES

Recent ANH articles covering latest FDA attack on homeopathy:

- *FDA Launches Homeopathy Broadside*, Nov 30, 2023
- *Tell Whole Foods to Stop Limiting Your Homeopathy Access*, Sep 07, 2023
- *Your Advocacy on Homeopathy is Working*, Aug 17, 2023
- *This Might be Your Last Chance to Save Homeopathy*, Mar 30, 2023
- *Explaining the FDA's New Homeopathy Policy*, Dec 15, 2022

BACKGROUNDER:
FDA REGULATION OF HOMEOPATHIC MEDICINES

By Michael Ames-Sikora

The U.S. Food and Drug Administration (FDA) significantly altered its stance on homeopathic medicines, issuing guidance in December 2022 that, in practice, classified all homeopathic drugs as "illegal" under federal law unless they undergo formal drug approval. This shift has sparked concern within the homeopathic and natural health communities that homeopathic medicines may disappear from store shelves entirely.

The 2022 FDA Guidance on Homeopathy

The 2022 guidance document laid out the FDA's current position on homeopathic drugs, based on several key assertions:

1. All homeopathic medicines that are not "generally recognized as safe and effective" (GRAS/E) are now classified as new drugs.
2. The FDA has not deemed any homeopathic products as GRAS/E.
3. Since homeopathic medicines are considered new drugs, they cannot legally be marketed unless they go through the FDA's formal approval process.
4. To date, no homeopathic medicine has completed FDA approval.

Risk-Based Regulatory Approach

Rather than taking immediate action against all homeopathic drugs, the FDA adopted a risk-based enforcement strategy, focusing on products that present higher risks. The FDA's priorities include:

- Safety Concerns: Products with reported safety issues or containing ingredients like belladonna or strychnine that may pose significant risks.
- Non-Oral/Topical Routes: Injectable or ophthalmic (eye-related) products, which bypass some natural bodily defences.
- Serious Conditions: Products claiming to treat serious diseases, such as cancer, heart disease, or opioid addiction.
- Vulnerable Populations: Products targeted at children or other at-risk groups.
- Adulterated Products: Those failing to meet legal standards for quality, purity, or strength.

While outlining its policy of enforcement discretion, the FDA also notes unequivocally in the guidance that no homeopathic medicines are safe. The agency states: "However, this guidance is intended to provide notice that any homeopathic drug product that is being marketed illegally is subject to FDA enforcement action at any time."

Historical Context and Consumer Concerns

Prior to the 2022 guidance, homeopathic medicines were regulated differently. They required a monograph from the Homeopathic Pharmacopoeia of the United States (HPUS), which established standards of efficacy. The FDA's guidance disrupts this model, declaring all homeopathic drugs as technically illegal unless they undergo the same rigorous and expensive drug approval processes as conventional pharmaceuticals. This is not feasible, since homeopathic medicines cannot be patent protected like pharmaceuticals, making it impossible to recoup the costs of FDA approval.

Many advocates argue that homeopathic medicines have a long-standing record of safety and efficacy, citing their widespread use worldwide. For instance, adverse events associated with homeopathic products are extremely rare compared to those from FDA-approved pharmaceutical drugs or even conventional foods. Critics of the FDA's actions suggest the agency is unfairly targeting homeopathy because it competes with conventional pharmaceuticals, which are a significant source of revenue for the FDA through user fees.

Enforcement Actions to Date

In 2019, the FDA issued a warning to consumers about potential dangers of homeopathic teething tablets containing belladonna. The FDA's action was based on hundreds of consumer complaints, yet most of these complaints were not plausible and none were verified. Following the FDA's consumer warning, it is telling that HealthCanada, the Canadian equivalent of the FDA, stated that it would take no action against homeopathic teething tablets because it had received no complaints of belladonna toxicity and considered them safe.

The FDA has taken enforcement actions against companies selling homeopathic injectable and eye care products, sending warning letters due to safety concerns. For injectables, the FDA cited health risks due to the presence of ingredients like belladonna and mercury that could be "potentially toxic." Yet a search of the FDA's adverse event database, for example, shows about 25 adverse events from belladonna between 1969 and 2020. Note that any homeopathic substance is diluted, often extremely diluted. It would seem the FDA's concern about toxicity is more theoretical than based in fact.

Similarly, for homeopathic eye products, the FDA raised concerns about safety risks due to the way these products bypass the body's defenses. Companies such as Boiron, Similasan, Walgreens, and CVS received warnings, with some also cited for manufacturing issues.

Conclusion and Outlook

The 2022 guidance signals the FDA's intention to exert greater control over homeopathic drugs, potentially paving the way for future actions to remove certain products from the market. While not all homeopathic drugs will be pulled from shelves immediately, the guidance grants the FDA broad authority to regulate or restrict homeopathic products more aggressively over time. Consumer and advocacy groups continue to push back, emphasizing the need for continued access to homeopathic treatments and raising concerns about the FDA's motives, given the financial interests tied to pharmaceutical regulation.

SUMMARY OF ANH-USA/MEDITREND LAWSUIT

The court filing is a complaint submitted by the Alliance for Natural Health USA (ANH) and Meditrend, Inc. against the U.S. Food and Drug Administration (FDA) concerning the FDA's regulation of over-the-counter (OTC) homeopathic drug products.

ANH is a non-profit advocacy organization that defends consumers' rights to access natural healthcare and health information. Meditrend is a homeopathic drug company.

As plaintiffs in the complaint, ANH and Meditrend argue that the FDA's recent shift in policy towards a "risk-based approach" to regulating homeopathic drugs, as articulated in its final guidance document issued in December 2022, violates the Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES Act). They assert that the CARES Act expressly exempts homeopathic OTC products from the pre-market approval requirements typically applied to conventional drugs.

The plaintiffs further argue that the FDA's decision to treat OTC homeopathic drugs under the same framework as conventional drugs threatens the homeopathic industry in the United States. They claim that the FDA's policy change, which requires all homeopathic drugs to undergo pre-market approval, would effectively destroy the OTC homeopathic market due to the high cost of such approvals.

ANH and Meditrend also challenge the FDA's denial of a Citizen Petition filed by the Americans for Homeopathy Choice Foundation (AHCF). The petition requested the FDA to establish a final rule setting out regulations for the manufacture and sale of homeopathic drugs in the United States. ANH and Meditrend argue that the FDA's denial of this petition was unlawful and that the FDA is obligated to regulate OTC homeopathic drugs under a different framework than conventional drugs.

The plaintiffs assert that the FDA's final guidance on homeopathic drug products violates the due process clause of the Fifth Amendment of the U.S. Constitution. They argue that the guidance gives the FDA unbridled discretion to remove homeopathic products from the market and fails to provide the regulated class with fair notice of what conduct is prohibited.

Among their grounds of challenge, the plaintiffs are seeking a declaratory judgment from the court that OTC homeopathic drugs are exempt from pre-market new drug approval requirements under the CARES Act. They also ask the court to enjoin the FDA from taking enforcement action against OTC homeopathic products on the grounds that such products require pre-market new drug approval. They request the court reverse the FDA's December 2022 guidance, requiring the FDA to return to the way things were before this guidance was issued, until the agency creates new rules that allow OTC homeopathic drugs to be sold without excessive regulatory burdens.

THE FDA'S ATTACK ON HOMEOPATHY: A THREAT TO PUBLIC HEALTH

By Chimnonso Onyekwelu LL.B, B.L, LL.M, LL.M. and Rob Verkerk. Ph.D.

The FDA's recent crackdown on homeopathic medicine is at risk of overturning a 200-year-old medicinal tradition valued by millions of Americans that currently represents an estimated $6.2 billion industry in the U.S. The FDA crackdown on homeopathy, stemming from the FDA's December 2022 *Compliance Guidance for Homeopathic Drug Products*, undermines patient autonomy and benefits big pharmaceutical companies at the expense of consumer interests and rights.

What is Homeopathy?

Homeopathy is a system of medicine that uses high or extreme dilutions of substances to stimulate the body's self-healing abilities. It is based on the principle of "like cures like", which means that a substance that can cause symptoms of a disease in a healthy person can also be used to treat those symptoms in a sick person.

Homeopathy was developed in the 19th century by German physician Samuel Hahnemann. It became popular in the U.S. in the mid-1800s, but its popularity declined in the early 20th century due to the rise of conventional medicine based on patented drugs.

A History of Homeopathy in the U.S.

In 1938, the Federal Food, Drug, and Cosmetic Act recognized homeopathic products as "drug" products that should be regulated by the FDA. However, due to their difference and low risk of adverse effects compared to conventional drugs, the FDA allowed homeopathic products to be sold without pre-market approval for more than 80 years, as long as they complied with the standards of the Homoeopathic Pharmacopoeia of the U.S. (HPUS).

The FDA's New Guidance

In December 2022, the FDA issued new guidance stating that homeopathic products are now subject to the same pre-market approval requirements as conventional drugs. This means that homeopathic manufacturers will have to submit expensive applications to the FDA in order to sell their products.

The Impact of the FDA's Guidance

The FDA's new guidance creates a number of negative consequences:

- It makes it more difficult for consumers to access homeopathic products.
- It leads to higher prices for homeopathic products making them less accessible to those on lower incomes.
- It will stifle innovation in the homeopathic industry.
- It undermines patient autonomy by restricting access to alternative healthcare options.

To fully grasp the significance of the FDA's crackdown, it is helpful to reflect on the history of homeopathy in other parts of the world.

A Brief History of Homeopathy in....Germany

In 1978, Germany's Medicinal Products Act recognized homeopathy as a therapeutic approach under Section 25(2) and Section 105(4f). Under Law no 2007-248, it adopted the European Union regulations and regulates homeopathic products. Under Article 2 of the German Medicines Act (AMG), homeopathic medicines are classified as a distinct category of human medicinal products. As such, homeopathy remedies are subject to registration and quality control, but do not require clinical trials to demonstrate effectiveness.

....In India

In India, Dr. John Martin Honigberger, a French traveller and student of Hahnemann introduced homeopathy around 1810. After successfully treating Maharaja Ranjit Singh, the then ruler of Punjab using Dulcamara in 1839, Honigberger was encouraged to establish his practice there, leading to the founding of the Banaras Homeopathic Hospital in 1867. Today, homeopathy is regulated by the National Commission for Homoeopathy under the Ministry for AYUSH.

....In the UK

In the UK, the Human Medicines Regulations 2012 regulates homeopathy under Regulation 102. The law provides for two regulatory schemes; the Simplified Registration Scheme and the National Rules Scheme. The first scheme requires that there are sufficient data to ensure the quality of the product and show that it is sufficiently dilute to ensure safety. The second route is relevant to products used for decades within the UK homeopathic tradition and must include data to demonstrate quality, safety and evidence of UK traditional use.

....In the European Union

In 2004, the European Union (EU) amended the primary legislation regulating drugs, the Human Medicinal Products Directive 2001, and created a so-called "simplified registration procedure" for homeopathic medicines that can be marketed throughout the single market. Given that the requirement borrowed concepts from conventional pharmaceuticals, the regime has been found to be unsuitable and excessively costly for many homeopathic drugs and has presented a significant barrier to products and consumer choice.

What Can Be Done?

Homeopathy is a safe and effective system of medicine that has been used by millions of people around the world for centuries. It is important to protect consumer access to homeopathic products and to ensure that homeopathy remains a viable healthcare option.

There are a number of things that can be done to challenge the FDA's new guidance and protect homeopathy in the USA:

- Support the ANH-USA lawsuit, which is challenging the legality of the FDA's guidance.
- Support a unique, simplified regulatory approach for homeopathic drugs, as proposed by Americans for Homeopathy Choice.
- Educate yourself and others about homeopathy.
- Contact your elected officials and urge them to support homeopathy.

ABOUT THE ALLIANCE FOR NATURAL HEALTH

The Alliance for Natural Health USA is America's leading non-profit organization dedicated to protecting and promoting natural and regenerative healthcare, using the tools of 'good science' and 'good law'. ANH protects the right of natural health practitioners to practice, and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. ANH unites consumers, practitioners, and the natural health industry to speak with a common voice. It has worked since 1992 to help shift the medical paradigm from its primary focus on drugs and surgery to an "integrative" approach that brings together approaches to health that work with, rather than against, natural processes, while enhancing the body's self-healing capacity.

ANH-USA has fought for decades for the right to maintain access to, and communicate about, the many benefits of natural health options. Leading constitutional lawyer, Jonathan Emord (aka the 'FDA Dragon Slayer'), previously as external legal counsel, has brought multiple precedent-setting lawsuits on behalf of ANH in the USA that expanded free speech about the benefits of dietary supplements, including permitting consumers to learn that folate supplementation during pregnancy helped prevent neural tube defects in the unborn child. As of July 2024, Emord was appointed General Counsel of ANH and this is the first of multiple suits that will be filed to prevent unjustified over-regulation by government agencies, facilitated by the recent *LoperBright v Raimondo and Axon Enterprises v FTC* decisions of the Supreme Court. In the US, and through its international arm, Alliance for Natural Health International, ANH has continued to keep the door open to natural health and champion free speech about natural products so more consumers can be empowered to make the best choices for their health.

ABOUT MEDITREND, INC.

Meditrend Inc. was founded in Albuquerque New Mexico by Richard D. Savage in 1980. Mr. Savage has been an entrepreneurial pioneer in the discovery, development and distribution of innovative health solutions. Meditrend's aim is to commercialize and distribute new, creative products and services that improve the quality of health. Its goal is to make health solutions available that are medically sound and economically viable. At the early onset of Meditrend Inc.'s creation, a professional line of nutritional products emerged under the name Progena Professional Formulations.

Since 1984, Progena Professional Formulations has been developing and/or distributing nutritional formulations and homeopathic remedies for alternative and conventional health practitioners across the United States. Development of these formulations is based on scientific rationale that incorporates over 20 years of collaboration and expertise in nutritional medicine. Today, Progena distributes over 150 of its own unique formulas as well as formulas from a handful of other brands.

CONTACT INFORMATION

For interviews with Jonathan Emord, Esq. and Robert Verkerk, Ph.D. (ANH) or Richard D. Savage, CEO of Meditrend, and for further information, please contact Michael Ames-Sikora, Editorial Director via telephone 800-230-2762 or email michael@anh-usa.org or office@anh-usa.org.