Americans for Homeopathy Choice's comment on FDA's proposed Draft Guidance for FDA staff and industry entitled "Drug Products Labeled as Homeopathic."
Docket No. FDA-2017-D-6580
Submission Receipt #: 1k2-939c-c6tk, 1k2-939c-bpwe, 1k2-939c-a1iu, and 1k2-939c-h71a

**ORGANIZATION COMMENTING**: Americans for Homeopathy Choice (AHC)
Americans for Homeopathy Choice is a non-partisan community organization that was formed to support :

- the rights of the 6 million, and growing, Americans who use homeopathy,
- homeopaths and other health professionals who use homeopathic remedies to treat their patients,
- and to support homeopathic pharmacies who manufacture and distribute remedies in the United States.

We are run by volunteers--mostly made up of mothers, and we are funded by donations from people who believe in our mission. Our internet presence is strong and growing with 17 thousand unique visitors monthly on our website and 8 thousand visitors monthly on social media, with 280 new followers each month. These numbers are unprecedented in social media for a genuine grassroots movement run by mothers who simply care about their freedom to access homeopathy.

**COMMENTS ARE FOR:** Dr. Gottlieb, Dockets Management Staff, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and other pertinent FDA Staff.

**ACTION PROPOSED**:
Americans for Homeopathy Choice respectfully requests that the FDA:

1. Withdraw its proposed Draft Guidance entitled "Drug Products Labeled as Homeopathic;"
2. Reaffirm its currently existing FDA Compliance Policy Guide (CPG) Sec. 400.400 "Conditions Under Which Homeopathic Drugs May be Marketed;"
3. Establish an FDA Advisory Committee on Homeopathy made up of experts in the field of Homeopathy such as homeopaths and homeopathic manufacturers, to provide the FDA guidance on homeopathic drugs and "Drug Products Labeled as Homeopathic." Additionally, representation from consumers who use homeopathy as their primary form of medicine should be included as a part of the committee.

*Note: Americans for Homeopathy Choice has already submitted one set of comments to this FDA docket, in the form of a Memorandum: See our submission "Memorandum from Americans for Homeopathy Choice" the Comment Docket No 2017-27157, submission receipt # 1k2-92jv-ju5a. This comment should be seen as part two of that first submission.*

**Table of Contents:**


I. Overview……... 3

a. The FDA Says "About FDA Guidances"……. 3

b. What FDA Says about their proposed Draft Guidance: "Drug Products Labeled as Homeopathic"……. 3

c. Definition of Homeopathy…….. 4

d. Homeopathy is unique, not the same as conventional drugs…….. 4

e. Americans for Homeopathy Choice, Who We Are…… 5

II. Key Points…… 5

a. Why consumers and mothers are turning to homeopathy……..…… 5

b. Mothers use homeopathy as experts in their own homes……...……... 6

c. Draft Guidance inappropriately deals with homeopathy; CPG 400.400 should remain in place …….. 9

d. Americans for Homeopathy Choice's Position on the Draft Guidance…… 9

e. Recommendation in lieu of Draft Guidance…….. 10

III. Our specific comments on the Draft Guidance……... 11

a. Pre-introduction…….. 11

b. Our Comments on the "Introduction" ……..… 11

c. Our Comments on the "Background"…….…… 14

d. Our Comments on the "FDA's Enforcement Policy"……..… 22

IV. Attachments……..……..…… 27

a. Attachment 1: Family Breaks Free from the Medical Cascade Effect…...…… 27

b. Attachment 2: A Mother Using Homeopathy to Deal with Childhood Illness…… 29

c. Attachment 3: Seeking Homeopathy for Interstitial Cystitis……... 31

d. Attachment 4: A Post Surgical Recovery…… 33

**OVERVIEW**:

The FDA Says "About FDA Guidances":

"Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both." [1] In other words, FDA guidance documents indicate how FDA interprets the law; they state how they will enforce by means of their interpretation. Americans for Homeopathy Choice respectfully recognizes and embraces the purpose of guidance documents, and as citizens, we take great concern with interpretations that "do not bind the public." Unlike producers who can ask the FDA to market their products under other interpretations of the law, we know of no way that the public can make such a request. So, if the final interpretation limits our access to homeopathic remedies, we know of no other way we can restore such access. Please let us know if there is one.

FDA's proposed "Drug Products Labeled as Homeopathic" guidance expresses FDA's current, non-binding *opinion*. It is non-binding for both the FDA and the public. Other approaches that satisfy "the requirements of the applicable statute, regulations, or both" advanced by either the FDA or members of the public are acceptable under the law.

What FDA Says about their proposed Draft Guidance - "Drug Products Labeled as Homeopathic"

"This draft guidance describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval….Simultaneous with the issuance of the final guidance, FDA will withdraw Compliance Policy Guide (CPG) 400.400, "Conditions Under Which Homeopathic Drugs May be Marketed", issued on May 31, 1988."[2]

With all due respect, as set out in more detail in the comments below, Americans for Homeopathy Choice believes and asserts that the course of action suggested by FDA in its proposed Guidance "Drug Products Labeled as Homeopathic" is inappropriate and should be withdrawn.

FDA's proposed action unnecessarily disrupts current regulation, deprives consumers of the opportunity to choose Homeopathic remedies, and fails to comply with "the requirements of the applicable statute, (and) regulations" under which the FDA is required to act.

[1] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
[2] Notice of Availability for and Text of "Drug Products Labeled as Homeopathic" proposed Guidance https://www.gpo.gov/fdsys/granule/FR-2017-12-20/2017-27157.

Definition of Homeopathy

Homeopathy is a specific system of medicine based on the principle of "like cures like," as established in 1796 by Samuel Hahnemann. It uses diluted and vigorously agitated (succussed) substances to engage the body in healing itself, and although homeopathic products are often referred to as "drugs," their action on the body is the antithesis of a chemical drug. Homeopathic remedies are not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease nor are they intended to affect the structure or any function of the body of man or other animal. Instead, homeopathic remedies work under this specific system of medicine which is individualized and provides safe and effective alternatives for those caring for their families.

Homeopathic remedies are inherently safe[3] with no documented side effects or deaths in over 200 years of continuous use and, when manufactured according to the existing law, they are completely non-toxic. Homeopathy operates according to sound fundamental scientific principles that have been in place, unaltered for over 200 years, evidencing their accuracy, and does not rely on inherently unsafe substances.

Homeopathy is unique, not the same as conventional drugs

Unlike conventional drugs which contain chemical and potentially toxic ingredients designed to treat a condition, homeopathy is different. Homeopathic remedies seek to engage the body toward healing itself. It may be difficult for those who are unfamiliar to homeopathy to understand how homeopathic remedies trigger healing since they are mostly energetic medicine and there is not any meaningful amount of substance in the final remedy. But indeed, this is the very essence of how homeopathy triggers healing. According to Nobel Laureate Luc Montagnier, "the high dilutions [used in homeopathy] are right. High dilutions of something are *not* nothing. They are water structures which mimic the original molecules...What we have found is that DNA produces structural changes in water, which persist at very high dilutions, and which lead to resonant electromagnetic signals that we can measure."[4] The public is best served by crafting regulations that are respectful to homeopathy as a unique system of medicine; the public is not well served when homeopathy is forced to conform to the standards set in place for conventional drugs. The safeguards for chemical drugs simply do not apply to homeopathy and FDA resources should not be diverted to the misguided enforcement of homeopathic remedies, when there are non-homeopathic and potentially toxic drugs that need such enforcement.

[3] http://homeopathyusa.org/uploads/Homeopathy_Research_Evidence_Base_7-12-2017.pdf

[4] https://www.huffingtonpost.com/dana-ullman/luc-montagnier-homeopathy-taken-seriously_b_814619.html

Americans for Homeopathy Choice, who we are

Americans for Homeopathy Choice is a grassroots, volunteer organization of mostly mothers, which formed in direct response to the Draft Guidance when proposed in December 2017. The mission of Americans for Homeopathy Choice is to raise awareness of the intent of the FDA and to provide a voice for consumers who rely on homeopathy in their homes. We seek to maintain an open and reliable access to safe and well regulated homeopathic remedies, under the standards set forth in CPG 400.400. In the less than 6 months since establishment, Americans for Homeopathy Choice and it's membership has grown exponentially and many more are following the movement. In addition to mothers, fathers, caregivers, and more, our voice has been heard by the greater homeopathic community and has garnered support from homeopathic professionals, pharmacies, manufacturers and consumers worldwide.

Our advocacy for our chosen system of medicine will remain strong and we encourage the FDA to learn and understand homeopathy so that the Agency can effectively continue to ensure the safety and efficacy of homeopathic products.

Homeopathy works for us. As informed consumers, we see a benefit in homeopathy and therefore we should be allowed the freedom to choose it. We believe that our freedom to use homeopathy should not be undermined by unnecessary enforcement guidance.

**KEY POINTS:**

Why consumers and mothers are turning to homeopathy

Consumers, especially mothers, have growing concern over their children's ability to achieve lifelong health. "The number of children with chronic illnesses has quadrupled since the time when some of their parents were kids, portending more disability and higher health costs for a new generation of adults….Doctors and public health officials should be bracing for a wave of chronically ill young adults with weight-related ailments that include diabetes and heart disease."[5] As mothers, it is our experience that such claims are true. Studies indicate that children are impacted by non-communicable illnesses at staggering rates, including autism spectrum disorders, autoimmune diseases, chronic allergies, food intolerances, childhood cancers and more.[6] [7] [8] In addition, the communicable diseases are becoming more and more resistant to the conventional treatment methods.[9] Doctors are prescribing antibiotic variations sometimes as often as every month to children with various bacterial infections such as streptococcus, UTIs, skin infections, etc.[10] Many families have found alternatives to the drug dependency that often

[5] http://archive.boston.com/news/nation/articles/2007/06/27/chronic_illnesses_on_rise_study_says/
[6] http://healthland.time.com/2013/07/16/sick-before-their-time-more-kids-diagnosed-with-adult-diseases/
[7] https://abcnews.go.com/Health/Healthday/story?id=4507708&page=1
[8] https://www.cdc.gov/ncbddd/autism/data.html
[9] https://www.newscientist.com/article/dn25498-antibiotic-resistant-superbugs-now-a-global-epidemic/
[10] https://www.cdc.gov/media/releases/2016/p0503-unnecessary-prescriptions.html

plagues children, through the use of homeopathic remedies, and have been thankful for the freedom to use alternative medical options. We believe that diversity in medical options--which includes homeopathy--is in the best interest of public health.

In addition to the health decline in our children, we are seeing shocking rates of non-communicable illnesses in adults. We also have witnessed increased addiction to medications such as opioids, often in response to prescriptions given after surgeries[11]. The cost of healthcare is on the rise but the overall health of our children and families is not improving with the increased cost. Given that we are a first world nation, the prevalence of disease and theoretically treatable conditions does not compute for those of us looking at the big picture. Homeopathy offers a safe alternative to conventional medicine, and as mothers, we find that it is also a positive adjunct to other medical options. Since homeopathy works well with conventional drugs--homeopathy should be a valued system of medicine that increases the safe options available to the public.[12] [13] [14]

Consumers (especially mothers) want to have choices that are safe and accessible. Homeopathy is inherently safe, and it is our experience as mothers that the more we use homeopathy in safe and appropriate situations, the fewer conventional drugs our children require. We also see a reduction in the prescription cascade effect, where the side effects of drugs are misdiagnosed as symptoms of another problem, resulting in further prescriptions and further side effects and likely unanticipated drug interactions.
*(See Attachment 1: Family Breaks Free from the Medical Cascade Effect)*

Because homeopathy works so well for us, we ask that the FDA keep the CPG 400.400, ensuring that our homeopathic remedies remain as the safely manufactured products we rely on for our families. The public is well served when diverse medical practices such as homeopathy are available to them. With the impending antibiotic resistant strains of bacteria that scientists forecast, it is crucial that diverse medical options such as homeopathy be championed and furthered. [15] [16]

Mothers use homeopathy as experts in their own homes

Typically, mothers who use homeopathy engage in healthy lifestyles at home with their family. They often focus on healthy meals and habits, such as plenty of exercise, and they have proclivity for seeking out natural alternatives. It is often this kind of mother who seeks out an alternative for acute symptoms, such as a cold or sore throat, and finds homeopathy. As

[11] https://www.cdc.gov/drugoverdose/epidemic/index.html
[12] https://www.ncbi.nlm.nih.gov/pubmed/16266440
[13] https://www.ncbi.nlm.nih.gov/pubmed/20175887
[14] https://www.ncbi.nlm.nih.gov/pubmed/8805013
[15] https://www.ncbi.nlm.nih.gov/pubmed/20674839
[16] https://globalhealth.duke.edu/media/blogs/voices-of-dghi/new-threat-public-health-antibiotic-resistant-bacteria

mothers begin to seek out answers to the self-limiting ailments affecting their families and children, they often find homeopathy.

Fortunately, homeopathy has been available in the market over the counter, thanks in part to the guidance of the CPG 400.400, which is in harmony with the Homeopathic Pharmacopoeia of the United States (HPUS) and the Food Drug and Cosmetic Act (FD&CA) and ensures that the manufacturing and marketing of homeopathic remedies are safe and appropriate for consumer consumption. Because homeopathy is inherently safe and non-toxic (as evidenced in zero deaths or disabilities in over 200 years, shown to result from homeopathic remedies) mothers and consumers alike are self-empowered, using remedies that are manufactured, marketed and labeled per FDA's oversight under the CPG 400.400. If the FDA followed the proposed Draft Guidance much of this success would disappear. Because there is no credible danger involved in the use of homeopathy, our freedom to use it should be safeguarded. Additionally, regardless of the fact that homeopathy has much evidence indicating its effectiveness, it is valuable to the consumer that the FDA respect consumers' rights to have access to homeopathy, should they choose to use it.[17] [18] [19] [20]

As mothers (or any consumer) experiences or witnesses shorter healing times and the reduction of symptoms without side effects through the use of homeopathy, she begins to look further into homeopathy. One of the great benefits of today's era is the availability of high-quality information readily available online and in books. Because professional homeopaths recognize that their remedies are inherently safe, and because they have observed the need for mothers to learn how to select appropriate remedies for self-limiting symptoms, homeopaths have created educational books and online platforms where mothers and others learn the science of homeopathy.

In our research, we found that there are hundreds of classes and thousands of books dedicated to the domestic use of homeopathy. These comprehensive educational materials teach mothers and others about Samuel Hahnemann--the father of homeopathy--and his guiding principles; they share the wonderful history of homeopathy in this country as well as around the world. They help mothers learn how to take their own children's cases in appropriate situations and refer them to specialists when necessary. These materials encourage the application of the principle of "like cures like" by introducing the *Materia medica* (i.e. the Clarke *Materia medica*, referenced in the CPG 400.400) as a tool for finding the symptoms which correlate to an appropriate homeopathic remedy.
(See attachment 2: A Mother Using Homeopathy to Deal with Childhood Illness)

Additionally, moms learning homeopathy connect with each other, sharing experiences which further their learning of homeopathy. Mothers often encourage each other to own a kit of

[17] https://www.ncbi.nlm.nih.gov/pubmed/29258191
[18] https://www.ncbi.nlm.nih.gov/pubmed/26275646
[19] https://www.ncbi.nlm.nih.gov/pubmed/25882307
[20] https://www.ncbi.nlm.nih.gov/pubmed/23424755

homeopathic remedies, so that they are prepared in their own homes when the unexpected illness arises. These kits are invaluable to mothers who are able to address the daily bumps, injuries, and illnesses that are common in the life of healthy, energetic children.

Because homeopathy is individualized and engages the body in healing itself, mothers, over time, become experts in finding appropriate homeopathic remedies that are well matched to their family members. Success speaks for itself as evidenced in the increasing number of people who use homeopathy worldwide and in the United States. With this success, many pursue an even deeper experience with homeopathy, seeking out a homeopathic practitioner as their family healthcare provider. This is especially appropriate for the more non-acute and non-self limiting symptoms. (See attachment 3: Seeking Homeopathy for Interstitial Cystitis). Once again, regardless of the fact that homeopathy has much scientific evidence regarding its effectiveness, as consumers we recognize that it works for us, and that we should have access to this inherently safe medicine that has not been evidenced to cause any disabilities or deaths in its 200 years of use.

As mothers, we do not regard conventional, chemical and potentially toxic drugs as unnecessary. Indeed we are grateful for the option of using these inherently dangerous drugs should a situation merit it. However, the success of homeopathy, as currently regulated, is so widespread and well documented that we prefer to use it as our first option. Additionally, because homeopathic remedies work well as an adjunct to the sometimes necessary conventional system, mothers share their knowledge with other fellow moms, and word about homeopathy spreads. It's important to understand that mothers want homeopathy, and we have no desire to stop using it. When we read the new guidance we see ideas that endanger continued access to our desired homeopathic remedies.

Additionally, many medical doctors are returning or entering into the the practice of homeopathy (which used to be practiced primarily by medical doctors) because of their lower cost, the reduction in a patient's hospital stay/recovery time, their decreased resistance to pharmaceutical medications, and because homeopathic remedies offer the body a tool for healing. Thus, homeopathy is no longer an alternative on the sidelines, but a growing option for many families and professionals.

A great example of how doctors are using homeopathy in their practice is the growing use of *Arnica montana* by doctors as part of their post-surgical treatment. This is a wonderful example of how protecting diverse medical practices benefits the consumer. When one incorporates inherently safe forms of homeopathy together with conventional practices, it reduces their need for medications such as opioids, and can most certainly have a reduced impact on problems such as the opioid addiction crisis. Considering the fact that *Arnica montana* can reduce or eliminate the need for opiates like percocet, oxycodone, and vicodin it is both prudent and wise to protect the diversity of medical options available to consumers. (See Attachment 4: A Post Surgical Recovery)

As mothers and consumers continue to recognize that homeopathy is a safe option, one that mothers admit work well for their families, it is vital that it continue to be maintained as a safe and effective option. Mothers and consumers want the FDA to ensure the safety and efficacy of homeopathic manufacturing and labeling while understanding the value that it offers to both the consumer and to the broader medical community. The new draft guidance undermines this effort.

Draft Guidance inappropriately deals with homeopathy; CPG 400.400 should remain in place

Since 1988, the FDA Compliance Policy Guidance (CPG) 400.400 has been in place as a guiding document for the FDA, which clearly established conditions under which homeopathic drugs may be marketed. The CPG 400.400 is a comprehensive document that clearly dictates that homeopathic remedies must be in compliance with the manufacturing standards set out in the existing law, the Food, Drug & Cosmetic Act (FD&CA) in harmony with the Homeopathic Pharmacopoeia of the United States (HPUS).

As part of this process under the HPUS, homeopathic remedies go through rigorous "provings," under the direction of the Homeopathic Pharmacopoeia Convention. Additionally, the CPG 400.400 outlines that the strength or "potencies" of homeopathic remedies are specified in terms of dilution, and must only contain diluents commonly used in homeopathic remedies. The CPG 400.400 guides the FDA so the Agency can keep homeopathic remedies under the Agency's oversight. To suggest that homeopathic remedies are not regulated misrepresents the facts.

The proposed Draft Guidance, which we believe is inappropriate and should be immediately withdrawn, is a statement of the FDA's desire to ensure that homeopathy continues to be effectively regulated and enforced by the Agency. We are in agreement that there should be oversight established to ensure that the rapidly growing industry of homeopathy remain safe for the consumer. As such, it is our firm recommendation that with the withdrawal of the proposed Draft Guidance, an FDA Advisory Committee on Homeopathy should be established to ensure the protection of homeopathy for the general public. This committee should be made up of experts in the field of Homeopathy such as homeopaths, homeopathic manufacturers, and expert consumers who use homeopathy as their primary form of medicine. It is of utmost concern that the FDA's future oversight over homeopathy should be done under the advisement of both professionals and consumers who are knowledgeable on homeopathy.

Americans for Homeopathy Choice's Position on the Draft Guidance

The FDA's risk-based approach, as outlined in the proposed Draft Guidance, appears to mean that every single homeopathic remedy that is currently on the market (over the counter or otherwise) is subject to the FDA's pre-approval action and therefore technically illegal until approved. The amount of clinical studies required for pre-approval would be costly and delay market approval significantly thus making it almost impossible for the general population to have

useful access to homeopathic remedies. On March 29, 2018, Americans for Homeopathy Choice had a positive meeting with the FDA where the FDA said they would not make the vast majority of remedies illegal. However, there is nothing we see in the proposed Draft Guidance that limits the FDA from doing so. As stated in the AHC memorandum[21] that was submitted in response to this meeting, the proposed Draft Guidance does not limit the Agency from making all of homeopathy illegal.

The risk-based approach to enforcement suggested by the FDA also indicates the misunderstanding that the FDA has about homeopathic remedies. This approach seeks to apply the standards of the Pharmacopoeia of the United States--which outlines inherently dangerous, pharmacological drugs--with the inherently safe remedies found in the *Homeopathic* Pharmacopoeia of the United States. This intent by the FDA illustrates a clear misunderstanding of the differentiation designated by the law.

Additionally, the expensive risk-based approach is absolutely unnecessary, and diverts precious funds from the FDA that should be used for drug products that are inherently dangerous. Homeopathic remedies are non-toxic and inherently safe, as evidenced in over 200 years of scientific study, research and use.

Recommendation in lieu of Draft Guidance

Due to the unique nature of the homeopathic medical system, experts who are educated and skilled in the use of homeopathic remedies should be called upon by the FDA for advice. We suggest this be done through formation of a Homeopathic Advisory Committee for the FDA. Homeopathic professionals should be consulted regarding enforcement, policy and legislative direction of the FDA regarding homeopathy. Additionally, representation from the consumers who use homeopathy would be a necessary component of the committee.

According to the FDA, “Advisory committees provide FDA with independent advice from outside experts on issues related to human and veterinary drugs, vaccines and other biological products, medical devices, and food.”

“In general, advisory committees include a chair, several members, plus a consumer, industry, and sometimes a patient representative. Additional experts with special knowledge may be added for individual committee meetings as needed. Although the committees provide advice to the agency, FDA makes the final decisions.”[22]

An Advisory Committee of this nature for Homeopathy would go a long way to reassuring consumers, especially mothers, that access to remedies and their quality would be maintained.

[21] See our submission “Memorandum from Americans for Homeopathy Choice” into the Comment Docket No 2017-27157, submission receipt # 1k2-92jv-ju5a.
[22] https://www.fda.gov/AboutFDA/Transparency/Basics/ucm222191.htm

**OUR SPECIFIC COMMENTS ON FDA's GUIDANCE:**

*Note: The material in **bold black** are excerpts directly from the Draft Guidance. The material in red is our comments. The material in underline or italics we have highlighted because we believe it makes very important points that need to be emphasized.*

Pre-Introduction

**"Contains Nonbinding Recommendations Draft — Not for Implementation**
**Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry.**
**This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. "It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page."[23]**

We understand the non-binding nature of this guidance, but that non-binding nature raises serious questions for us. For example how do we as a consumer group "use an alternative approach if it satisfies the requirements of the applicable statutes and regulations"? Also what position does the FDA take when parties to various civil suits or state regulatory actions wish to introduce this guidance as evidence into a legal proceeding outside of the FDA process? In other words, if someone wants to sue a homeopathic manufacturer, does FDA's *Draft Guidance on Homeopathy* carry legal precedence? Can the FDA add to its disclaimer about the non-binding nature of the guidance a note that it is not to be used as either a legal conclusion by the Agency or even as its definitive legal position on any issue concerning homeopathy?

We sincerely hope to receive answers to these questions and the many other questions we ask in our response to the Draft Guidance below. In addition, we believe that our questions underscore why the FDA should withdraw this Draft Guidance and reaffirm CPG 400.400.

Our Comments on the "Introduction"

**"This draft guidance describes how [the FDA intends] to prioritize enforcement and regulatory actions for human drug products labeled as homeopathic and marketed in the United States without the required FDA approval."[24]**

It is important to us for the FDA to clarify two points in this sentence:

[23] FDA Draft Guidance on Homeopathy, 2017: Title page and lines 5-11 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[24] FDA Draft Guidance on Homeopathy, 2017: Lines 17-19 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

1. When the Agency refers to "…required FDA approval" is it referring to the pre-market approval required for all drugs containing pharmacologically active ingredients? To the extent that it is, we believe it is improper and outside of the requirements of the law to require inherently safe homeopathic products to meet requirements in the law that apply to products containing inherently unsafe pharmacologically active ingredients. Additionally, to the extent that the products being referred to in the proposed Draft Guidance fall outside the category of inherently safe homeopathic products, the problem is one of "misbranding" to which FDA pre-market approval does not apply. As noted in our Memorandum[25] to the FDA, we request that the FDA use the powers it already has in the CPG 400.400 to address any misbranding issues.

2. What categories is FDA focusing its attention on in this proposed Draft Guidance? We identify two primary categories from the guidance language:
    a. Products "labeled as homeopathic" which are actual homeopathic remedies. These are listed in the HPUS and include their comparable supplements and products which are marketed in accordance with CPG 400.400 and
    b. products inappropriately "labeled as homeopathic."

Products in the first category meet all FDA approval requirements. Products in the second category are misbranded and should be regulated as such. There is no need for the proposed Draft Guidance on homeopathy to correct any potential errors in the second category as the CPG 400.400 already guides the FDA in implementing necessary corrections.

To us, the confusion in this opening sentence where the FDA says that it **"intends to prioritize enforcement and regulatory actions for human drug products *labeled as homeopathic*"** makes it very clear why the guidance should be withdrawn and CPG 400.400 reaffirmed.

**"As discussed below, FDA has developed a risk-based approach under which the Agency intends to prioritize enforcement and regulatory actions involving certain categories of such products that potentially pose a higher risk to public health."[26]**

It is appropriate to use a risk-based approach for product categories which **do** in fact present material health risks to consumers, such as conventional, chemical drugs. In contrast, homeopathic remedies, especially when compared to conventional, chemical drugs, are inherently safe with no attributed deaths or disabilities over a 200 year period.

[25] See our submission "Memorandum from Americans for Homeopathy Choice" into the Comment Docket No 2017-27157, submission receipt # 1k2-92jv-ju5a.
[26] FDA Draft Guidance on Homeopathy, 2017: Lines 19-21https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

The approach the FDA has taken in this guidance – to prioritize solely among homeopathic remedies for risk-based enforcement – fails to appropriately prioritize these remedies against materially more risky products that exist across the broader drug product categories.
This approach misplaces limited FDA resources to the risk-based enforcement of inherently safe homeopathic remedies rather than on the more dangerous conventional drug products in the market that have real consumer health risks.

To apply a risk based approach effectively, we feel FDA should apply the risk standards across all drug product categories. This would reinforce that appropriate attention is focused on the products that contain the most risk, whatever their category, rather than placing misguided heightened focus on inherently safe products from one specific category.

Simply stated, applying a risk-based approach on homeopathy shows more of a reactionary impulse to the industry growth rather than a prudent effort to ensure continued safe and effective manufacturing and marketing of homeopathic remedies.

This is a matter we would like very much to hear from the FDA about and if possible to discuss with the FDA. The failure to apply the risk-based approach across all FDA regulatory categories is another reason that we believe that FDA should withdraw this proposed Draft Guidance and reaffirm CPG 400.400.

**"However, the Agency also recognizes that many products labeled as homeopathic will fall outside the risk based categories described below.**
**"Simultaneous with the issuance of the final guidance, we will withdraw Compliance Policy Guide (CPG) 400.400, Conditions Under Which Homeopathic Drugs May be Marketed issued on 27 May 31, 1988."[27]**

These two sentences seem to form a non-sequitur…two statements that seem incompatible if not contradictory. CPG 400.400 has offered a framework in which producers, consumers and regulators of homeopathic products could comfortably work together to provide consumers like us with confidence in the products we purchase from the market. sxRemoval of CPG 400.400 eliminates this working arrangement and results in confusion of authority, mixing categories and unclear expectations.

[27] FDA Draft Guidance on Homeopathy, 2017: Lines 21-27
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

For example, when the FDA says **"…many products labeled as homeopathic will fall outside the risk based categories described below,"**[28] is it saying that this guidance does or does not apply to those **"outside the risk based categories"** products?

This level of imprecision in the guidance give us great pause and reinforces our belief that FDA should withdraw this proposed Draft Guidance and reaffirm CPG 400.400 immediately.

**"In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required."**[29]

We repeat that this statement leaves open the possibility that this proposed guidance will be used as evidence in non-FDA related civil, regulatory and possibly criminal legal proceedings. We request that in addition to withdrawing this guidance and reaffirming CPG 400.400, the agency should add a note to its disclaimers clarifying the legal status of this guidance.

Specifically we request that the FDA include a statement that because of its non-binding nature it is inappropriate for the guidance to be sighted in any proceeding as establishing the legality of any laws enforced by the FDA or as representing the opinion of the FDA on the nature of those laws. The guidance merely states the way FDA staff, including inspectors, intend to apply the law, not that the FDA has chosen a way that the courts will accept.

Our Comments on the "Background"

**"II. BACKGROUND**

**"Homeopathy is an alternative medical practice that has a historical basis in theory and practice first systematized in the late 1700s. Homeopathy is generally based on two main principles: (1) that a substance that causes symptoms in a healthy person can be used in diluted form to treat symptoms and illnesses (known as "like-cures-like"); and (2) the more diluted the substance, the more potent it is (known as the "law of infinitesimals"). Proponents claim that a significantly diluted aqueous solution, consisting mainly of water molecules, retains therapeutic properties due to a "memory" of the substance diluted in it. Historically, homeopathic drugs have been identified through "provings," in which substances are administered to healthy volunteers in concentrations that provoke overt symptoms. Symptoms experienced by volunteers are recorded to indicate possible therapeutic uses for the substances. In other words, if a substance elicits a particular**

[28] FDA Draft Guidance on Homeopathy, 2017: Lines 22-23 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[29] FDA Draft Guidance on Homeopathy, 2017: Lines 29-33 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/

**symptom, individuals experiencing that symptom would be treated with a diluted solution made from that substance."[30]**

**"In 1938, when the Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted, the Bill's senatorial sponsor, Dr. Royal Copeland, himself a homeopathic practitioner, added a provision to the law recognizing the Homeopathic Pharmacopoeia of the United States (HPUS) alongside its counterparts, the U.S. Pharmacopeia and the National Formulary. Recent years have seen an increase in the sale of products labeled as homeopathic. In the past, these products were mostly prepared by homeopathic physicians for individual patients. Today they are frequently mass manufactured and widely marketed as over-the-counter (OTC) products."[31]**

We see homeopathy in a broader context which we present here to help clarify why we are concerned. We think that a broader understanding of Homeopathy's history will help the FDA staff, industry, consumers, legislators and the public better understand what is at issue in the discussion of this guidance.

First, we find it highly unusual that a federal agency would talk about an Act of Congress by saying that one particular Senator introduced a provision to the law. This seems unnecessarily and inappropriately minimizing of the importance of a section of the law that was passed by Congress and signed by the President of the United States. It seems to underscore a bias against homeopathy which the FDA has perhaps unconsciously adopted. As this law recognised, homeopathy has an important role to play in the American Healthcare System.

Homeopathic medicine originated in Germany. By the 1840s the practice was flourishing in the United States. At its height, there were over 14,000 homeopathic physicians and 22 homeopathic medical schools in the United States. Hahnemann hospital in Philadelphia is one of, if not the major hospital in Philadelphia. Sibley Hospital in Washington DC has a Hahnemann Pavilion. In 1900, President William McKinley dedicated a statute to Hahnemann, "the father of modern medicine," at Scott Circle, Massachusetts and 16th St. NW in Washington DC.

Samuel Hahnemann translated over 20 major medical and scientific texts. He authored a four volume set of books called The Pharmaceutical Lexicon, which was considered one of the standard reference texts for apothecaries/pharmacists of his day. In 1796, he wrote about his experiences with the law of similars in Hufeland's Journal, a respected medical journal in Germany. Coincidentally, in 1798, Edward Jenner discovered the value of giving small doses of

[30] FDA Draft Guidance on Homeopathy, 2017: Lines 36-49 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[31] FDA Draft Guidance on Homeopathy, 2017: Lines 51-57 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

cowpox to people in an effort to immunize them against smallpox. *Hahnemann's Homeopathy represents a major systematic, well-grounded approach to health which the FDA guidance treats superficially.*

For example, a compilation of research titled, "*Homeopathy Research Evidence Base: References 2017"* [32] references thousands of pages of homeopathic research. The FDA guidance seems to be based on science that *disregards* the evidence-based science supporting the developed principles of Homeopathy, all of which have been established and have continued to be researched. The existence and application of CPG 400.400 has played a key role in encouraging further scientific development. Removal of the CPG 400.400 as recommended in the Draft Guidance is a great disservice to mothers who use homeopathy and the public at large. We believe that by replacing CPG 400.400 with the proposed guidance, it is likely to cause severe harm to public health. It causes severe harm to public health because it limits the diversification of alternative methods. We are concerned that this would limit homeopathy's potential role in addressing several health crisis' which are growing in the USA, and which homeopathy is evidenced to help. To name a few, these crisis' include:

- the opioid crisis,
- the overuse of antibiotics,
- the impending crisis of antibiotic resistant bugs,
- the problem of weakened immune systems,
- and more.

We are also concerned about the manner in which the FDA guidance chooses to define "drug." As pointed out in the guidance itself, it **"does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible…"** [33] The guidance presents a view of the definition of drugs that may not yet be settled legally. We have pointed our differences in the paragraphs below, in the discussion of "new drug" versus "old drug" as legally defined in the law.

**"The definition of "drug" in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)) includes articles "recognized in the HPUS or any of its supplements. As such, homeopathic drugs are subject to the same regulatory requirements as other old drugs. Generally, a drug, including a homeopathic drug, is considered a "new drug" if it is not generally recognized as safe and effective (GRAS/E) by qualified experts for use under the**

[32] http://homeopathyusa.org/uploads/Homeopathy_Research_Evidence_Base_7-12-2017.pdf
[33] FDA Draft Guidance on Homeopathy, 2017: Lines 7-10 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

**conditions prescribed, recommended, or suggested in the labeling (section 201(p) of the FD&C Act) (21 U.S.C. 321(p)).**"[34]

We believe that Homeopathic remedies are generally recognized as safe and effective (GRAS/E) by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling. **"FDA makes GRAS/E determinations for OTC drugs marketed under the OTC Drug Review. The FDA has not reviewed any drug products labeled as homeopathic under the OTC Drug Review, because the Agency categorized these products as a separate category and deferred consideration of them. 37 FR 9464, 9466 (May 11, 1972)).**"[35]

We also believe, as the FDA said in 1972, and has until now maintained, that homeopathic products are a separate category and they should be review separately by a proper process using the proper standard and the proper expertise. In our view the proposed guidance is decidedly not using the proper standards to address homeopathic products. For example homeopathic products are not "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;…" They claim to and do operate differently than drugs in the United States Pharmacopeia or the official National Formulary and under the law stand equally but distinct from products identified in those two texts.

**"Under section 505(a) of the FD&C Act (21 U.S.C. 355(a)), before any "new drug" is marketed, it must be the subject of an approved application filed pursuant to section 505(b) or section 505(j) of the FD&C Act; however, a biological product with an approved license under section 351(a) of the Public Health Service Act (PHS Act) (42 72 U.S.C. 262(a)) is not required to have an approved application under section 505 of the FD&C 73 Act. Accordingly, absent a determination that a drug product labeled as homeopathic is not a "new drug" under section 201(p), all drug products labeled as homeopathic are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act. There are no drug products labeled as homeopathic that are approved by FDA."[36]**

The problem is that there is an "old drug" definition (1938) and a "new drug" definition (1962). The FDA says in the proposed Draft Guidance that it is going to treat all homeopathic remedies as if they're "new drugs". We believe most, if not all, homeopathic remedies are "old drugs."

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[34] FDA Draft Guidance on Homeopathy, 2017: Lines 59-64 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[35] FDA Draft Guidance on Homeopathy, 2017: Lines 65-68 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[36] FDA Draft Guidance on Homeopathy, 2017: Lines 68-76 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

Therefore premarket approval should not apply to homeopathic remedies since they are "old drugs."

Additionally, placing a double negative in this section confuses the issue at hand. When FDA used this double negative, it established a formal position that it is going to treat homeopathic drugs as if they are "new drugs." Since no homeopathic remedies comply with the "new drug" pre-market approval requirements today, the guidance infers that all homeopathic remedies are in violation and are therefore illegal. FDA says they will enforce these rules about homeopathic remedies with discretion, claiming that we shouldn't worry about their enforcement, since they claim that most homeopathic remedies will remain legal. But, as evidenced with their double negative statement, until a determination is made, the Agency claims that all homeopathic remedies are actually "new drugs" and subject to enforcement--even though homeopathic remedies are in fact "old drugs" and premarket approval should not apply to them.

To correct the problem that the double negative creates, the word "not" should be removed from the following sentence: "absent a determination that a drug product labeled as homeopathic is not a 'new drug'…", so that it reads "absent a determination that a drug product labeled as homeopathic is a "new drug". *It is the responsibility of the FDA to reach a determination that homeopathic remedies are a "new drug" in order to enforce their premarket approval*. But homeopathy is *not* a "new drug," making this enforcement unnecessary. To us this is a further reason why the FDA should withdraw the new guidance and reaffirm CPG 400.400.

**"The FDA's evidence-based systems for the review of drugs under new drug applications (NDAs), biologics license applications (BLAs), and the OTC Drug Review play an essential role in ensuring that drugs are both safe and effective. Drugs marketed without required FDA premarket approval may not meet modern standards for safety, effectiveness, quality, and labeling. The Section 201(g)(1) of the FD&C Act. See 21 CFR part 330. For instance, during the new drug application approval process the applicant must demonstrate that its manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. 21 CFR 314.50(d)(1)(ii)(a). Continued marketing of products that have neither been pre-market approved by FDA nor found to be GRAS/E is a public health concern."**[37]

*This is a very concerning paragraph to us.* The FD&CA says that anything in the Homeopathic Pharmacopoeia of the United States is recognized as a homeopathic remedy under the law. Additionally, the FDA has the authority and uses that authority to ensure that these Homeopathic remedies are "of expected identity, strength, quality, and purity." Evidence of the use of this authority is in the promulgation of the CPG 400.400. The Agency's use of the CPG

[37] FDA Draft Guidance on Homeopathy, 2017: Lines 78-83 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

400.400 indicates that this interpretation of the law is correct: homeopathic remedies in the HPUS are in fact homeopathic remedies as long as they are manufactured according to their "expected identity, strength, quality, and purity." However, it is our understanding that the FDA is totally shifting the accurate interpretation of the law to something that is misguided, and by removing the CPG 400.400, *the proposed guidance destroys the assurance that homeopathic remedies will be manufactured according to their "expected identity, strength, quality, and purity."*

How does this happen? The FDA's effort in saying that a homeopathic remedy is a new drug eliminates the CPG 400.400, and therefore eliminates the structure that homeopathy has been operating under for the last 30 years.

Additionally, if the FDA adopts the proposed guidance, all Homeopathic remedies are thrown into limbo and must seek—by some unspecified process—designation as a "not new drug." So, the FDA is taking away the status that homeopathy had previously under the law as an "old drug", and they are giving homeopathic remedies a new requirement that is: If one does not like the new status, they have to come to the FDA and explain why they don't think a certain remedy should be a "new drug."

This creates the very strange anomaly for the FDA because the wording of the draft guidance sets the FDA up for a conflict: Homeopathic products that the FDA finds to be non-problematic will remain available merely because the FDA chooses not to enforce their rules. This means that, on the one hand, all homeopathic remedies are "new drugs" according to the FDA; it says that if one wants to remove a homeopathic remedy from the new drug category, one should ask the FDA to do so. On the other hand, the FDA says many homeopathic remedies do not pose a safety or efficacy problem, but in spite of that fact, the Agency's proposed guidance is listing them *all* as violators of their proposed rules.

The FDA attempts to solve this conflict by saying that we shouldn't worry because it won't use its enforcement authority against those remedies. But we question: why write a guidance that positions homeopathic remedies to be in constant violation, even when the FDA admits most remedies are not actually in violation? It seems that the FDA should not create guidances that position their enforced products to be perpetual violators.

We think this guidance needs to go back to the Agency for further consideration and action and FDA needs to reaffirm CPG 400.400 which avoids this problem.

**"A. Compliance Policy Guide 400.400**
**In May 1988, the Center for Drug Evaluation and Research issued Compliance Policy Guide 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed." As stated in the 1988 CPG, it delineates the conditions, including ones regarding**

**ingredients, labeling, prescription status, and current good manufacturing practice, under which homeopathic drug products may ordinarily be marketed."[38]**

This is the very point we make. The CPG 400.400 already delineates the ingredients, labeling, prescription status, and current good manufacturing practice under which homeopathic drug products may ordinarily be marketed. All actual problems raised in the Draft Guidance are already addressed in the CPG 400.400 [39], and all the imagined, convoluted, and inaccurately stated problems listed in the Draft Guidance are based on FDA's apparently limited understanding of modern science as it relates to homeopathy. We want to empower the FDA to gain a deeper understanding of the modern science of homeopathy, and the aforementioned homeopathic advisory committee made up of homeopathic professionals and expert consumers would be a step in facilitating this information.

**"B. FDA's Reexamination of its Enforcement Policies**
**In light of the growth of the industry and passage of more than 2 decades since the issuance of the 1988 CPG, FDA announced on March 27, 2015, that it was evaluating its regulatory framework for these products. In April 2015, FDA held a public hearing to obtain information and comments from stakeholders about the current use of drug products labeled as homeopathic, as well as the Agency's regulatory framework for such products. FDA sought broad public input on its enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health. As a result of the Agency's evaluation, including consideration of the information obtained as a result of the public hearing, FDA has determined that it is in the best interest of public health to issue a new guidance that applies a risk-based enforcement approach to drug products labeled as homeopathic and marketed without the required FDA approval, consistent with FDA's risk-based regulatory approaches generally."[40]**

We appreciate that the FDA may have considered the viewpoint presented by the hundreds of commenters during the 2015 process, which included many of us who support the homeopathy regulation as it was then in place. Unfortunately, the FDA does not explain why it has rejected all of the input supporting the more effective existing FDA regulatory regime, as carried out under the CPG 400.400. Additionally neither in this paragraph nor anywhere else in the Draft Guidance does the Agency explain clearly what issues motivated their restructuring of their guidance documents for homeopathy.

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[38] FDA Draft Guidance on Homeopathy, 2017: Lines 85-91 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[39] See our submission "Memorandum from Americans for Homeopathy Choice" into the Comment Docket No 2017-27157, submission receipt # 1k2-92jv-ju5a.

[40] FDA Draft Guidance on Homeopathy, 2017: Lines 93-105 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

It seems that the FDA generally undergoes this process when a drug product has caused harm to consumers or to public health. But no such harm has actually transpired as a result of homeopathy which would justify this new guidance. The evidence the FDA has presented regarding harm resulting from homeopathic remedies is not conclusive. Speculation about homeopathy being harmful is very different from actual evidence that indicates harm.

What evidence is there which conclusively establishes that someone has been significantly harmed by a homeopathic remedy? Without this conclusive evidence, there is no justification for FDA to issue a risk-based approach, as set out in the new guidelines. The risk-based approach in the new guidelines may not actually be in the best interest of public health. If there is no conclusive harm, there is nothing from which to protect the public.

The CPG 400.400 has effectively guided the safe manufacturing and marketing of homeopathic remedies for 30 years, as evidence by no deaths or disabilities over that time. The longevity of the guidance should not be seen as a reason for changing it. Instead, this longevity is evidence of its effectiveness, not justification for removal. Not only should the CPG 400.400 remain in place, it should be reaffirmed by the FDA.

**"C. FDA's Risk-based Approach**
**In many instances, FDA uses a risk-based approach to carry out its mandates. For example, FDA has generally employed a risk-based enforcement approach with respect to marketed unapproved new drugs. The Agency historically has prioritized compliance actions involving unapproved new drug products that have potential safety risks, lack evidence of effectiveness, are health fraud products, present challenges to the new drug approval or OTC drug monograph systems under the OTC Drug Review, are violative of the FD&C Act in other ways, or that are reformulated to evade an FDA enforcement action."**[41]

This process is a premarket process under which the products can only be marketed if the FDA says so. This premarket approval process is designed for inherently unsafe products, like allopathic drug products that contain pharmacologically active chemical ingredients that can cause damage. FDA uses the risk-based premarket approval process to determine whether the proven benefits outweigh the risks. With inherently safe substances like homoeopathic remedies, premarket approval is not necessary to guard against harm.

Regarding all the other items in this paragraph, the CPG 400.400 has proven its effectiveness by guiding into the marketplace homeopathic remedies which:

- are important to consumers,
- are based on emerging scientific knowledge,
- have as a long history of successful use,

[41] FDA Draft Guidance on Homeopathy, 2017: Lines 107-116
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

- and have no proven instances of harm caused by these products.

Reaffirming CPG 400.400 will continue to expand homeopathy's potential to contribute to the diversification of safe medical options, benefiting public health in America. Homeopathy has a potential role to play in addressing several health crisis' which are growing in the USA. To name a few, these crisis' include:

- the opioid crisis,
- the overuse of antibiotics,
- the impending crisis of antibiotic resistant bugs,
- the problem of weakened immune systems,
- and more.

These are potential areas of development that homeopathy can address, all of which the FDA Draft Guidance on Homeopathy will harm, if not cripple.

**"The Agency generally intends to apply a risk-based enforcement approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic, as described below."**[42]

As a non-binding exercise, the proposed guidance is positioned to undo all the good effect created by CPG 400.400. Though non-binding, the proposed guidance shapes and is intended to shape attitudes and actions taken toward homeopathy—including those held by FDA inspectors. It applies a risk-based enforcement approach ***within*** the category of Homeopathic remedies rather than applying it ***across*** all drugs regulated by the FDA. As such it misdirects FDA resources away from identified significant safety problems contained in useful but inherently dangerous conventional drug products.

Our Comments on the "FDA's Enforcement Policy"

**"III. FDA's ENFORCEMENT POLICY**

**The issuance of this guidance, when finalized, is intended to provide notice that any product labeled as homeopathic that is being marketed illegally is subject to FDA enforcement action at any time."**[43]

We do not believe the law requires such an action. As mothers, we see this as a threat to our freedom to access homeopathic remedies and it concerns us deeply. The Draft Guidance on Homeopathy tells us, as mothers, that at any time, any one of the remedies we rely upon could be snatched from us, arbitrarily enforced and removed from our reach. The Draft Guidance

[42] FDA Draft Guidance on Homeopathy, 2017: Lines 118-119 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[43] FDA Draft Guidance on Homeopathy, 2017: Lines 122-126 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

enforcement policy creates an environment for all homeopathic products to be determined as illegal, based on the definition of "new drug," which does not apply to homeopathy since it is an "old drug."

While CPG 400.400 currently protects us from illegally marketed products, the new guidance does not provide the same security. What the guidance says is: if we disagree with the enforcement of products labeled homeopathic that we have chosen to use, we have no course of action to restore our access to that remedy. The guidance makes no provision for what we should do if we, as consumers, disagree, and we ask: What should we do? Talk to the FDA? Go to court? Congress? Why would the Agency which has successfully managed homeopathic remedies under CPG 400.400 for thirty years in harmony with the FD&CA put such a burden on mothers caring for their children?

We would like you to know that by proposing this guidance, the FDA has shaken our confidence in its ability to properly regulate food and drugs.

**"FDA is not required, and generally does not expect, to give special notice that a drug product may be subject to enforcement action. However, in the listing that follows, we clarify our approach to prioritizing our enforcement actions with regard to drug products labeled as homeopathic and marketed in the United States without the required FDA approval. Enforcement and Regulatory Priorities In developing a risk-based approach, FDA has identified certain categories of drug products labeled as homeopathic and marketed without the required FDA approval as potentially posing 135 higher risks to public health. FDA intends to prioritize enforcement and regulatory actions involving drug *products labeled as homeopathic* and marketed without the required FDA approval in the following categories:"[44]**

We repeat that we do not believe the law allows, let alone requires, premarket approval of homeopathic remedies.

Many other issues raised so far in this guidance discuss and treat homeopathic remedies as defined by the law. However, it's important to create a distinction between actual homeopathic remedies, and *products labeled as homeopathic*. *Products labeled as homeopathic* are not covered by the law in the same way. This is a serious categorization error. The allegedly "bad" products that the FDA identifies in this guidance are ***not*** homeopathic products. They are products mislabeled as homeopathic. This Draft Guidance on Homeopathy is addressing a "misbranding" problem as if it were an "adulteration" problem.

Fortunately, the current CPG 400.400 already addresseses homeopathic "products." The proposed guidance, however, addresses homeopathic "labels." These are two separate issues.

[44] FDA Draft Guidance on Homeopathy, 2017: Lines 126-137 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

We support enforcement of proper labeling of homeopathy "labels". We do not believe that homeopathic "products" need to be made illegal in order to enforce proper homeopathic labeling. This guidance destroys a very workable regimen for ensuring, through the framework set out in CPG 400.400, that both homeopathic labeling and homeopathic products receive proper FDA enforcement. We believe that eliminating the CPG 400.400 and replacing it with this highly flawed Draft Guidance is misguided and will inappropriately limit access to safe homeopathic remedies.

**"Products with reported safety concerns. For example, MedWatch reports or other information submitted to the Agency can indicate or signal a potential association between the product and an adverse event, medication errors, or other safety issues."**[45]

What MedWatch report do you rely on?

**"Products that contain or purport to contain ingredients associated with potentially significant safety concerns. For example, potentially significant safety concerns are raised by products that contain or purport to contain:"**[46]

Properly made homeopathic products as per CPG 400.400 (in harmony with the FD&CA and HPUS) contain no meaningful amount of any substance. If the FDA finds a product labeled as homeopathic that contains meaningful amounts of a dangerous ingredients, it is considered mislabeled, and can be regulated by the enforcement programs for non homeopathic product in place by the Agency.

Please let us know where you found situations to the contrary of our belief.

- **An infectious agent with the potential to be pathogenic;**
- **A controlled substance, as defined in the Controlled Substances Act, 21 U.S.C. 812;**
- **Multiple ingredients that, when used in combination, raise safety concerns due to possible interactions, synergistic effects, or additive effects of the various ingredients; and,**
- **Ingredients that pose potential toxic effects, particularly when those** ingredients are **ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are** not adequately **controlled in the manufacturing process.**[47]

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[45] FDA Draft Guidance on Homeopathy, 2017: Lines 139-141 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[46] FDA Draft Guidance on Homeopathy, 2017: Lines 143-145 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[47] FDA Draft Guidance on Homeopathy, 2017: Lines 146-154 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

We know of no product properly labeled Homeopathic which contains an agent that:

- has the potential to be pathogenic,
- that could be a controlled substance,
- that combines homeopathic and non-homeopathic ingredients, or dangerously combines amounts of homeopathic ingredients,
- or low dilution products that are not adequately controlled in the manufacturing process.

Any product that contains such an agent or falls into such categories that is labeled homeopathic is improperly labeled and the FDA has ample authority, set out in CPG 400.400, to regulate such a product. This is a key reason why we urge for the agency to withdraw this proposed guidance and reaffirm CPG 400.400.

- **Products for routes of administration other than oral and topical. For example, unapproved injectable drug products and unapproved ophthalmic drug products pose a greater risk of harm to users due to their routes of administration (e.g., bypassing some of the body's natural defenses, differences in absorption) and the potential risk of harm from contamination.[48]**

It is our recommendation that this line of non-oral products be regulated as other non-enteral products are currently regulated: They must comply with industry standards for purity, sterility, and non-adulteration. This goes hand in hand with anything delivered through other than an oral route.

- **Products intended to be used for the prevention or treatment of serious and/or life threatening diseases and conditions. Unapproved products for serious and/or life threatening diseases and conditions raise public health concerns, in part, because they may cause users to delay or discontinue medical treatments that have been found safe and Contains Nonbinding Recommendations Draft — Not for Implementation 5 effective through the NDA or BLA approval processes.[49]**

Homeopathic products treat the individual. If a product labeled homeopathic says otherwise it is subject to FDA regulation as a non-homeopathic drug/product.

- **Products for vulnerable populations. For example, patient populations such as immunocompromised individuals, infants and children, the elderly, and pregnant**

[48] FDA Draft Guidance on Homeopathy, 2017: Lines 156-160 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[49] FDA Draft Guidance on Homeopathy, 2017: Lines 162-166 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

**women 1 may be at greater risk for adverse reactions associated with a drug product, even if it contains only small amounts of an ingredient, due to their varying ability to absorb, metabolize, distribute, or excrete the product or its metabolites. These populations may also be at greater risk of harm as a result of foregoing the use of medical treatments that have been found safe and effective through the NDA or BLA approval processes or under the OTC Drug Review.[50]**

Each of these issues is a matter of information, not product formulation. We feel it is proper to require information that guides and empowers the consumer. We do not feel it is proper for the FDA or any government agency to disempower the consumer. Merely because some consumers require special information to use a product effectively, is no reason why all individuals should be prevented from using that product.

- **Products deemed adulterated under section 501 of the FD&C Act. For example, if a product purports to be or is represented as a product recognized in an official compendium but its strength, quality, or purity differs from the standards set forth in that official compendium (defined by 21 U.S.C. 321 as the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them), or if there are significant violations of current good manufacturing practice requirements. [51]**

This paragraph illustrates our point precisely. Each of the transgressions named[52] falls outside the category of homeopathy. The FDA has ample authority and tools to regulate such products without casting the entire category of homeopathic remedies into a regulatory limbo. The FDA has the authority to regulate any product that falls into the description of this paragraph. It has described that authority in CPG 400.400. We urge the FDA as strongly as we possibly can to withdraw this guidance and reaffirm CPG 400.400.

[50] FDA Draft Guidance on Homeopathy, 2017: Lines 168-175 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[51] FDA Draft Guidance on Homeopathy, 2017: Lines 177-183 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf

[52] See our submission “Memorandum from Americans for Homeopathy Choice” into the Comment Docket No 2017-27157, submission receipt # 1k2-92jv-ju5a.

**Attachments:**

Attachment 1: Family Breaks Free from the Medical Cascade Effect
By: April Nall (Atlanta, GA)

My son was diagnosed with Pediatric Autoimmune Neuropsychiatric Syndrome (PANS) in 2016. According to PandasNetwork.org, this condition is characterized as creating "a misdirected immune response [that] results in inflammation on a child's brain. In turn, the child quickly begins to exhibit life changing symptoms such as OCD, severe restrictive eating, anxiety, tics, personality changes, decline in math and handwriting abilities, sensory sensitivities, and more." [53] This was very overwhelming and heartbreaking for me to witness as a mother.

My son was in constant fight or flight mode, scared of everything, and he thought everyone around him was going to die. He was afraid to put his head under water during swim lessons. He was on a constant stream of conventional medical drugs ranging from antihistamines and steroids to antibiotics. He also suffered from other symptoms: His tonsils and adenoids were removed that same year and we were relieved to finally have no more chronic congestion. Unfortunately, there was no improvement to his anxiety which actually worsened over time. In December of 2016, his recurrent streptococcal (strep) infections began, and he was constantly on antibiotics. It seemed that if he even looked at someone with strep, he would get it.

The only antibiotic that seemed to help my son was Azithromycin, but his cultures almost always came back positive. This antibiotic he took was in addition to all the other medications he was on, and because my son suffered from a corn allergy, I had to order all his prescriptions through a special compounding pharmacy. These specially compounded drugs were extremely expensive and there seemed to be no end to amount of medications he had to take.

Desperate to find another way, I started to research alternatives for the treatment of PANS and strep. Because I had read about the risks of Azithromycin, I was aware that my son could potentially suffer from a heart attack, contract clostridium difficile (C-Diff), or worse, death. This was deeply concerning to me as a mother. Another great concern of mine was that no matter how many medications and conventional drugs my doctors prescribed my son, the result was always that he needed more medications and suffered from more symptoms.

A friend suggested homeopathy, and I began to research this alternative. I spoke with a licensed, professional homeopath, and in June 2017, we began administering homeopathic remedies to my son. Within two weeks of our first dose, he went from being terrified of putting his head under water to jumping in the deep end and touching the bottom of the pool during swim lessons. We also saw many more improvements. The change was incredible!

[53] http://www.pandasnetwork.org/understanding-pandaspans/what-is-pans/

After summer break was over, he returned to school, and within two weeks, he was once again diagnosed with strep. At this point I knew I didn't want to go back down the path of multiple medications, so I contacted our homeopath. Within 7 days of my son taking the recommended homeopathic remedy, his pediatrician ran a culture and the strep was gone. I was amazed! With strep throat running rampant through my son's school, he swabbed another positive culture the next month. We once again used homeopathy and his culture came back negative 7 days later. His homeopath suggested an additional treatment, a 'strep detox' by using homeopathic *nosodes*. We started this regimen in November 2017. As of May 2018, he has not had any positive cultures for strep. Before homeopathy, this was unprecedented. It seems that the chronic cycle of strep infections were fully halted by means of homeopathy. We also haven't even needed to go to the doctor once since starting this homeopathic strep detox.

Additionally, since starting homeopathy, his PANS symptoms have completely melted away. He no longer suffers from vocal tics, from irrational fears such as everyone dying, and more. He is considered totally normal and almost fully recovered.

In the time we have used homeopathy, we have also found success in other areas. In addition to strep, we have overcome influenza, croup, stomach viruses, seasonal allergies, and colds. The beauty of homeopathy is that once the correct homeopathic remedy uproots the condition, one no longer has to keep taking that remedy for the rest of their life. Homeopathy does not have a 'cascade effect'. This is in direct contrast to my experience with conventional drugs, where we fell into the 'cascade effect'—using more and more medications. Additionally, since there are no side effects relating to homeopathy, I felt comfortable using this form of medicine on my son. Also, I did not need to administer additional drugs for any side effects, since homeopathy causes none. Homeopathy has empowered my son's body to address the overall conditions, and without the freedom to choose homeopathy, my son would be a very different person today.

Attachment 2: A Mother Using Homeopathy to Deal with Childhood Illness

By: Sarah Holmes (Cincinnati, OH)

My son is generally healthy and he has experienced some normal childhood illnesses. Our family has chosen to use homeopathy to treat these illnesses, when possible. When he has a cold, for example, we use homeopathic remedies, which brings relief and shortens the duration of the cold. Homeopathic allergy remedies bring relief when his Springtime allergies emerge. I have been pleased to see that every year, his Springtime allergies improve, and soon I suspect I won't be needing homeopathic allergy remedies anymore. When he was five, he got a case of warts on his hands and these were successfully treated with homeopathy. When we've had a need, homeopathy has been what we've used.

Homeopathic education and study has played a large role in my ability to address these issues and more. When he was three, he accidentally ran into a bookshelf and needed stitches. Right away I gave him homeopathic remedies that fit the description of his injury. In general, when we have an injury or illness such as this in our home, I rely on the information I have learned through the various homeopathic books and homeopathy classes I have attended. At this point as a seasoned mother, I have committed much of this homeopathic education to memory. I often know exactly which remedies to reach for in my homeopathy kit, and when I don't, I reference my educational books and my *Materia medica,* such as the Clarke *Materia medica* that is referenced in the CPG 400.400. In this particular situation where my son needed additional medical attention for the cut on his head--not just homeopathic interventions--we decided to take him to the local children's hospital in our city.

The ER physician was trying to decide if a topical pain relief medication would be sufficient or if they needed to do general anesthesia for my son to receive his stitches. By pairing his injury with homeopathic medicine, we were able to avoid such general anesthesia. The homeopathic medicine played a large role in mitigating my son's pain level while also helping him calm down emotionally. My son was able to take deep belly breaths as instructed, and the doctor stitched him up without any problems. With the use of homeopathy and topical pain relief medication, our son was able to lay completely still while they did the stitches. The ER physician said that he had never seen a three year old who was able to keep his composure and take deep belly breaths in a situation like that. I too was impressed with my son's composure.

I am wary of my son dealing with side effects from conventional medications, and I'm thankful for the homeopathic education I have received so far. At this point as a mother, I have been able to fully rely on homeopathic medicine for any and all at-home injuries or common childhood illnesses. I attribute our ability to avoid conventional medications and their potential life-threatening side effects to the diversity of alternative medical options available to me, especially homeopathy. Educating myself with homeopathic books and courses taught by professionals has been a big part of this empowerment I have as a mother. We choose homeopathy because it is incredibly effective, superior in its safety and track record, and gentle. We rely on homeopathy as our primary form of healthcare, and it is important for our family's health and well being. At our son's age and stage, he is far healthier than my husband and I were at his age. Additionally, by conversing with other moms at my son's school, I have come to realize that he is one of the only, if not only, children in his class who does not take

conventional pharmaceutical drugs on a regular basis.  He was the only child in his whole class who did not miss a single day of school last year.  I attribute his health to homeopathy.

Attachment 3: Seeking Homeopathy for Interstitial Cystitis
By: Paola Brown (Houston, TX)

When I was newly married, I began suffering from chronic urinary tract infections (UTIs), for which I was prescribed antibiotics. After nearly a dozen rounds of antibiotics in only a few short years, my bladder condition went from a series of acute UTI's to developing a chronic condition called Interstitial Cystitis (IC). According to the Mayo Clinic, which I visited in December 2013, IC is a chronic condition causing bladder pressure, bladder pain and sometimes pelvic pain. The pain ranges from mild discomfort to severe," [54] and in my case, my doctors said that my IC was one of the worst cases they had ever seen.

Indeed, my pain and discomfort was so severe that if I didn't limit the foods that I ate to about 12 ingredients, I would suffer from the most excruciating pain, where I could not leave my bed or a scalding hot bathtub which seemed to alleviate symptoms. When asked to describe my pain, I would tell my doctors that it felt like "someone took my bladder, turned it inside out, lit it on fire, and tried to put it out with a track shoe." I had met with urologists, gynocologists, gyno-urologists, and an entire staff of gastroenterologists and pelvic specialists at the Mayo clinic. For treatment, I was given very limited options: I could (a) take a medication that would turn my urine blue and might make all my hair fall out, (b) use a medical device that should be inserted vaginally and then turned on with the intent of electrocuting the pelvis in order to numb the IC symptoms, (c) take opioid painkillers for the rest of my life. For this last option, I would have to join a support group to manage the opioid addiction I did not yet have, but that would surely develop.

I felt none of these options were in any way going to benefit my overall health. I was only 26 years old at the time, and I made the decision to walk away from these conventional medical options. My doctors at the Mayo Clinic applauded this decision because, according to them "I was doing a better job of managing this disease than they would be able to." Because my condition was not self-limiting, but a serious chronic illness, I knew I needed to seek out help from qualified health professionals.

I worked with wonderful health practitioners including chiropractors, licensed acupuncturists, herbalists, naturopaths and others who used alternative medicine. Unfortunately, I had little to no success from these modalities, even though I have witnessed their benefits in the lives of many others. Finally, I stumbled onto homeopathy. I began to work with a qualified homeopath, and within a few short weeks, I noticed a drastic improvement in my symptoms. One remedy in particular, categorized as a nosode, was particularly useful to me. By means of homeopathy's unique system of medicine, the homeopathic remedies administered to me allowed my body recover from this devastating illness. Within a year, I could eat the foods that I once had to

[54] https://www.mayoclinic.org/diseases-conditions/interstitial-cystitis/symptoms-causes/syc-20354357

avoid, I did not have to drink 1 gallon of water a day, and I did not need to travel with a heating pad everywhere I went.

It was important to me that I work with a licensed, professional homeopath.  A chronic condition such as this one is a perfect situation where one can benefit from consulting a homeopathic professional. Today I'm fully recovered from this illness.  I did not have to adapt my lifestyle or diet, and I simply live symptom free from this ugly illness.

Attachment 4: Post-Surgical Recovery
By: Mary P.* (Houston, TX)
**To protect the privacy of the individuals in the story, names have been changed.*

I underwent a surgery that my doctor said would result in a minimum of 6 weeks of recovery. They said that I would suffer "bruising that would make me look like an eggplant," in large portions of my body, and that I needed to have 24 hour, in-home care for at least two weeks post-op. My surgeon had also informed me, as did all the medical forms I had signed, that I would be black and blue from my neck down. My two friends who had the same surgery before me were sure enough black and blue. Because of the nature of this recovery, my doctor prescribed strong opioid painkillers in anticipation to the fairly extreme amount of pain I would experience after my surgery.

With this in mind, I decided to explore alternative options available for my recovery, since I am aware of and concerned over the opioid drug addiction crisis Americans are facing today. I understand that most of these addictions are a result from from receiving postoperative opioid medications for pain management, and I wanted to completely avoid or reduce my need for these medications.

Before going in for my surgery, I decided to take a homeopathic remedy that has a history of encouraging the body to heal itself after surgery: *Arnica montana* 200C. I took one dose the night before the surgery. After the surgery and while in recovery, I dosed *Arnica montana* 200c three times a day until my first post op appointment, which was scheduled 4 days after my surgery.

When I walked into my first post-op appointment, I was still totally bandaged up and had not yet personally seen my body since the surgery. Two nurses were present with my doctor, and they slowly unwrapped me. I was so thoroughly wrapped that I looked like an Egyptian mummy and had no idea what I was about to see. Everyone gasped—not because of the bruising—but because of the *lack of* bruising: I literally had nothing. No bruising or discoloration. NOTHING! The nurses and doctor literally circled me in the room, wondering how to explain that. My surgeon asked what my secret was, and I laughed and said, "homeopathy." She proceeded to bring in other nurses and doctors. She said that in all her years as a doctor, she had never seen recovery like this.

The pain level was also significantly reduced. In the weeks to follow, I recovered exponentially quicker than my doctor had ever witnessed in any of her patients. I did not need at home care, and was already running errands 3 days later. I did not take any sort of opioid painkillers except for a few doses during the first 24 hours after surgery. I literally needed no pain management medication besides homeopathic remedies after that initial 24 hours.

I most definitely feel that conventional medicine is necessary and important, and I was grateful that a qualified surgeon and appropriate anesthesia was available to me for my surgery. My

experience also evidences the importance for consumers to have access to diverse medical practices; diverse medical options empowered me as a consumer to access homeopathy as part of the medicine I used for healing post-surgery. It reduced my risk of developing dependence over opioids and allowed me to recover beautifully. This is only one instance of many where homeopathy empowered me to access better medical options for my health or that of my family. It is important to protect a diversity of medical practice in the United States so that consumers have access to the best medical options available, as they see fit.