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Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Docket No. FDA-2017-D-6580

Re: Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry; Availability

The Center for Science in the Public Interest (CSPI) provides these comments supporting the Food and Drug Administration Draft Guidance for Drug Products Labeled as Homeopathic ("the Draft Guidance"), which will enhance consumer safety by appropriately describing how the agency will prioritize enforcement and regulatory actions for these drug products.

CSPI generally advises consumers to avoid spending money on homeopathic drugs. At best, these products are drugs whose ingredients have been diluted to a point that renders them both harmless and ineffective. At worst, the products may be contaminated, divert patients from effective medical treatment, or contain dangerous levels of improperly diluted poisonous ingredients that can lead to toxic overdose.

The Draft Guidance will lead to appropriate targeting of FDA resources towards homeopathic products that create these types of public health risks. In general, we find the priority categories identified in the Draft Guidance to be appropriate. However, we suggest that the FDA also take into account the size of the population potentially affected by a homeopathic drug in considering whether to invest enforcement resources. Specifically, a problematic homeopathic product may warrant higher prioritization when marketed to a larger population.

In particular, we are concerned with widespread marketing of homeopathic drugs alongside over-the-counter treatments for common diseases or conditions in grocery and drugstores. These products may be confused with safe and effective treatments, creating a risk of consumer fraud. In addition, symptoms for these common conditions may sometimes be confused with symptoms of more serious conditions warranting medical attention, increasing the potential for patients to be harmed when they are diverted from effective care.

As an additional minor point, we suggest that the agency identify reported safety concerns by assessing reports in the medical literature or National Poison Data System (NPDS), in addition to reviewing MedWatch reports.

We recognize that some of the individuals who have commented on the public docket for the Draft Guidance have expressed concerns that the new guidance misinterprets the FDA's authority over homeopathic drugs and will result in unreasonable enforcement action against homeopathic products that have not been linked to safety risks. We disagree with both points.

First, we agree with the FDA that homeopathic products are subject to federal oversight because they have been recognized as "drugs" regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) since that law was enacted in 1938. The guidance does not alter this underlying legal status. Instead, the Draft Guidance indicates that the FDA will prioritize enforcement actions against homeopathic drugs that pose higher risks to the public health. This will include products that have caused injuries, products that contain potentially dangerous ingredients (such as viruses, bacteria, toxins or controlled substances), as well as products used to treat serious or life-threatening medical conditions. As such, the guidance effectively puts homeopathic drug makers on notice that if they fail to implement quality controls in their manufacturing, or market products irresponsibly to create risks for consumers, they may face action from federal regulators.

Second, we do not expect that this guidance will result in unreasonable enforcement action by the FDA against the homeopathic drug industry. Rather, we believe that FDA oversight over homeopathic drugs to date has been overly lax, permitting the industry to engage in manufacturing and marketing practices that expose the public to unreasonable levels of risk. In one particularly high-profile instance, hundreds of reports were submitted to the FDA over a 10-year period alleging that babies were harmed by homeopathic teething remedies containing belladonna, including reports of 10 deaths.[1] Other homeopathic drug safety issues identified by the agency have included a zinc cold remedy associated with potentially permanent loss of the sense of smell[2] and a product that included undeclared penicillin, creating risks for consumers with allergies to that drug.[3] In other instances, homeopathic products have been marketed to treat

[1] Kaplan, S. Hundreds of babies harmed by homeopathic remedies, families say. STAT. February 21, 2017. www.scientificamerican.com/article/hundreds-of-babies-harmed-by-homeopathic-remedies-families-say/.
[2] Food and Drug Administration. FDA advises consumers not to use certain Zicam cold remedies, Intranasal zinc product linked to loss of sense of smell. June 16, 2009. https://wayback.archive-it.org/7993/20170113083934/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm167065.htm.
[3] Food and Drug Administration. Pleo homeopathic drug products by Terra-Medica: recall - potential for undeclared penicillin. March 20, 2014. https://wayback.archive-it.org/7993/20170406123829/https:/www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm390002.htm.

serious conditions, such as acute asthma attacks, potentially leading sick patients to avoid effective medical care.[4]

Most consumers, including those who have commented on the Draft Guidance, assume that homeopathic products are safe because they are widely available over the counter and are marketed as "natural" alternatives to more closely regulated pharmaceuticals. This assumption makes it even more important for the FDA —and the homeopathic drug industry— to ensure that consumer safety expectations are met, and that homeopathic products do not expose their users to serious risks.

We therefore welcome the Draft Guidance, and hope that it appropriately signals that the FDA intends a swifter and more forceful enforcement response when dangerous homeopathic products are identified. We further hope that this increased regulatory scrutiny will curb potential abuses within the homeopathic drug industry, which is now worth $3 billion a year and growing rapidly. Ultimately, this can only result in a safer and more transparent marketplace for consumers.

Sincerely,

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[4] Food and Drug Administration. FDA warns consumers about the potential health risks of over-the-counter asthma products labeled as homeopathic. March 20, 2015. www.fda.gov/Drugs/DrugSafety/ucm438976.htm.