

# Irony Alert: FDA Announces Recall of Homeopathic Products For Harmful Microbes, Not Unproven Health Claims



By *Jamie Wells, M.D.* — August 24, 2018

*A dearth of truth in medical advertising is probably our greatest public health threat. With consumers bombarded by spurious claims, our agencies need to be proactive, not reactive in protecting the public.*



Credit: Pixabay [1]

In a story that speaks for itself, [King Bio](#) [2] has issued a voluntary nationwide recall out of “an abundance of caution” of thirty-two kids and infant products that could be contaminated with harmful microbes that pose a risk for serious infection (see FDA alert [here](#) [2]). Fortunately, so far, there are no reports of such a consequence. That said, as is typical of this extremely lucrative growing market with an ever expanding list of products under the scrutiny-protected often misleading label of “[homeopathy](#) [3],” these items that contain ingredients that cause drug or medicine effects like any other pharmaceutical are not subject to meeting the same standards for safety or efficacy and can do harm.

The company’s [own disclaimer](#) [4] affirms

*“The statements made herein have not been evaluated by the Food and Drug*

*Administration. Products are not intended to diagnose, treat, cure, or prevent disease” or “[These products](#) [5] have not been clinically tested and are not reviewed by the FDA...The information on this website is presented for educational purposes only. The products and information contained herein do not constitute medical or other professional advice and are not intended to replace your doctor's recommendations, advice, diagnosis, or treatment.”*

In a game of constant catch-up, in particular for substances long not supported for children by pediatricians in the first place, the U.S. Food and Drug Administration (FDA) has placed the industry on alert but the slow pace of progress is frustrating.

In May, [in a way overdue action](#) [6], the [FDA](#) [7] informed consumers about the hazards of benzocaine-containing over-the-counter (OTC) oral health products which are typically used by parents for infants and young children to manage teething discomfort (see [here](#) [6]). Not only are they ineffective for teething since they expeditiously wash out of the mouth, but they can do significant harm triggering a condition known as [methemoglobinemia](#) [8]. Oxygen is impaired from getting to vital tissues. When severe, it can be fatal. There have been deaths and serious adverse effects requiring medical treatment as a result of the development of this condition from these products. (To review the FDA warnings and recommendations, see [here](#) [8]). The agency warned companies if they continue to sell it or market it to this population they would be subject to regulatory measures.

[Last January](#) [9] (2017), the FDA advised parents [to stop using and immediately discard certain homeopathic teething products for infants because they contain belladonna](#) [10], a toxic chemical in amounts that cannot be verified as safe. Their [findings](#) [11] revealed inconsistent and sometimes excessive levels of the poison in such products. [The FDA recalled](#) [9] them recognizing they had no proven health benefits nor had they been approved for safety and efficacy.

Consumers were urged to seek immediate medical care if their child experienced

*“seizures, difficulty breathing, lethargy, excessive sleepiness, muscle weakness, skin flushing, constipation, difficulty urinating, or agitation after using homeopathic teething products.”*

When questioned on Twitter by a journalist about this current King Bio situation and the FDA's lack of promotion in their recall statement of these products' absent medical utility, FDA Commissioner Scott Gottlieb, MD responded



**carolyn johnson** ✓ @Carolynyjo... · 22h ✓

FDA warning these homeopathic products might contain harmful microbes. But they don't warn they aren't actually shown to be useful for any known medical condition.

**Scott Gottlieb, M.D.** ✓ @SGottliebFDA

PUBLIC HEALTH ADVISORY: Recall notice: King Bio has recalled some of the Dr. King's homeopathic children and infant products due to potential microbial contamination. A full list is available here: [go.usa.gov/xUuQC](https://go.usa.gov/xUuQC)

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**Scott Gottlieb, M.D.** ✓ @SGottli... · 21h ✓

We've taken aggressive steps [@Carolynyjohnson](#) to implement a new, comprehensive framework for the more vigilant oversight of homeopathic products earlier this year; taking a risk based approach to enforcement to address products making inappropriate claims. [fda.gov/newsevents/new...](https://www.fda.gov/newsevents/new...)

The Commissioner's response references an [FDA announcement](#) [12] made in December 2017 indicating the agency

*"proposed a [new, risk-based enforcement approach](#) [13] to drug products labeled as*

*homeopathic. To protect consumers who choose to use homeopathic products, this proposed new approach would update the FDA's existing policy to better address situations where homeopathic treatments are being marketed for serious diseases and/or conditions but where the products have not been shown to offer clinical benefits. It also covers situations where products labeled as homeopathic contain potentially harmful ingredients or do not meet current good manufacturing practices." (See [here](#) <sup>[12]</sup>).*

In follow-up, the reporter pressed him on whether products that have not done harm but have no proven benefits have also been pulled, Dr. Gottlieb replied as follows



**carolyn johnson**  @Carolynyjo... · 21h 

Thanks! Have any products been pulled solely because there's no evidence they work, in the absence of harm?



 Scott Gottlieb, M.D. Retweeted



**Scott Gottlieb, M.D.** 

@SGottliebFDA 

Replying to [@Carolynyjohnson](#)

The answer is - yes we have. Most recently, in Jan 2018 we issued WLs to 2 homeopathic firms illegally marketing unapproved products with claims about their ability to help in treating opioid addiction and withdrawal. Those companies were King Bio and GUNA [go.usa.gov/xUue6](https://www.fda.gov/xUue6)

At a time when this industry is burgeoning and consumers are routinely bombarded with spurious claims for any and all diseases or conditions, our agencies need to be more proactive, not reactive in protecting the public. A recent study demonstrated cancer patients who use complementary medicine, and refuse conventional, are twice as likely to die (see [here](#) [14]). The stakes are quite

high and the dearth of truth in medical advertising is probably our greatest public health threat.

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**Links**

[1] <https://pixabay.com/en/poison-bottle-medicine-old-symbol-1481596/>

[2] <https://www.fda.gov/Safety/Recalls/ucm617945.htm>

[3] <https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>

[4] [http://www.dkvitamins.com/Nosebleed-Relief-by-King-Bio-2-Ounces\\_p\\_23805.html](http://www.dkvitamins.com/Nosebleed-Relief-by-King-Bio-2-Ounces_p_23805.html)

[5] <https://www.drkings.com/en/>

[6] <https://www.acsh.org/news/2018/05/23/thank-you-fda-action-against-otc-anesthetics-babies-overdue-13004>

[7] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm608325.htm>

[8] <https://www.fda.gov/Drugs/DrugSafety/ucm608265.htm>

[9] <https://www.acsh.org/news/2017/04/14/fda-recall-alert-homeopathic-baby-teething-products%C2%A0-11141>

[10] <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm538684.htm?source=acsh.org>

[11] <https://www.fda.gov/Safety/Recalls/ucm552934.htm>

[12] <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm589243.htm>

[13]

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM589373.pdf>

[14] <https://www.acsh.org/news/2018/07/20/cancer-patients-who-use-complementary-medicine-refuse-conventional-twice-likely-die-says-study-13214>