My Christmas Wish Came Early: FDA Cracks Down on Homeopathy

By Julianna LeMieux — December 22, 2017

Homeopathic treatments can be bought almost everywhere. They're the ones that are likely labeled as "natural remedies" and have pictures of grass or leaves on them. What they don't have on them is a label that says "FDA approved", which has been the case since 1988.

However, it may be that that is about to change.

The US Food and Drug Administration (FDA) announced earlier this week that it is going to start to crack down on some homeopathic products. This statement is almost three years in the making since they announced in early 2015 that they were considering changing their stance on homeopathic regulation. Now, a new, risk-based enforcement approach has been announced.

The plan is not going to concern itself with all homeopathic products. The new policy will cover "situations where products labeled as homeopathic contain potentially harmful ingredients or do not meet current good manufacturing practices." This will, most certainly, leave many homeopathic products still unregulated. While all homeopathic products are useless, only some are harmless. If people want to waste money on those, that's not the FDA's problem.

Instead, FDA will focus on a subset of homeopathic products - those that have reported safety concerns, contain potentially toxic ingredients, are administered in ways other than orally or topically, are used to prevent or treat serious and/or life-threatening diseases, are used on vulnerable populations or do not meet standards of quality, strength or purity as required under the law.

Why is FDA putting these new regulations out now, after several years of promising them? This
move may have been sparked by the homeopathic teething products that, allegedly, left roughly a dozen infants dead and sickened many more.

In the span of just over a year, FDA issued different forms of pressure to the homeopathic teething world. In September of 2016, they issued a news release cautioning that homeopathic teething tablets and gels may be harmful to babies and children - issuing a strong recommendation not to use them.

One of the main manufacturing companies, Hyland’s, responded one month later, in the form of an open letter on their website, declaring that they would stop producing the teething tablets.

Through an investigation led by FDA, results were released from their testing that there were variable amounts of the toxic compound belladonna in the teething products. The last straw was the FDA’s formal recall request, a strong letter written to the company. Finally, in April, all lots of both the Hyland’s Baby Teething Tablets and Hyland’s Baby Nighttime Teething Tablets were recalled.

They didn’t stop there, though, further investigating the facilities where the products were made and creating a long list of violations.

FDA Commissioner Scott Gottlieb, M.D., (aka Santa) hits the nail on the head in his statement,

“In recent years, we’ve seen a large uptick in products labeled as homeopathic that are being marketed for a wide array of diseases and conditions, from the common cold to cancer. In many cases, people may be placing their trust and money in therapies that may bring little to no benefit in combating serious ailments, or worse – that may cause significant and even irreparable harm because the products are poorly manufactured, or contain active ingredients that aren’t adequately tested or disclosed to patients,”

“Our approach to regulating homeopathic drugs must evolve to reflect the current complexity of the market, by taking a more risk-based approach to enforcement. We respect that some individuals want to use alternative treatments, but the FDA has a responsibility to protect the public from products that may not deliver any benefit and have the potential to cause harm.”

Will anything really change in the regulation of homeopathic products? Time will tell. But, FDA seems serious and the harm that the teething products allegedly caused is tragic. Either way, FDA is taking a step in the right direction and that is enough of a Christmas gift for us - for this year.
Source [8]: FDA News Release: FDA proposes new, risk-based enforcement priorities to protect consumers from potentially harmful, unproven homeopathic drugs

For more on this topic, read our coverage from this past year.

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