New Regulations for Homeopathic Supplements, FDA Announces

The Food and Drug Administration has announced a new risk-based approach to regulating homeopathic medicines with an increased focus on products administered by injection, intended for children or the elderly, and those marketed for serious diseases. Per the Dietary Supplement and Health Education Act of 1994, homeopathic medicines will not need FDA approval to be on the market, but this proposal brings an increased level of inspection to the 3 billion dollar homeopathy industry.

Among other reasons, these guidelines have been introduced shortly after the discovery of inconsistent amounts of belladonna (otherwise known as deadly nightshade) were found in teething tablets, causing 400 injuries and 10 deaths.

NBC News reported that when Little Blaine Talbott started teething, his mom, Karina, saw homeopathic teething tablets in the store, she grabbed them. “It said homeopathic, all natural, you know, organic stuff, and so you think that stuff is going to be safe for your child.” Coon Blaine began having seizures. Neurologistsdidn’t know what was causing them, but the seizures stopped when Karina ran out of the tablets.

> *Karina Talbott had been giving her baby Hyland’s homeopathic teething tablets, which the Food and Drug Administration has since asked people to stop using. The tablets often contained harmful levels of belladonna, a plant-based poison.” — NBC News*

Even so, most homeopathic treatments on the market will not be affected by this more intense scrutiny. The FDA says it is

primarily concerned with unsafe ingredients and poor manufacturing quality, according to a statement from FDA Commissioner Scott Gottlieb.

Supplements the FDA Will Focus On

While the FDA has made it clear they will not be changing the way the majority of homeopathic are regulated, some medications have been put on notice. These include

- Products that have or are associated with a history of manufacturing errors, adverse health incidences or other safety issues
- Products with infectious agents, controlled substances, and potentially toxic ingredients
- Products administered through non-oral or non-topical method, such as injection
- Products meant to treat serious diseases such as cancer, heart disease, or addiction issues
- Products aimed at children or elderly populations
- Products that have been altered or where the strength, quality, or purity differs from established standards

Mild or Truly Terrifying?

It is possible to see this as the end of being able to treat yourself in the way you see fit. There is some truth in that, and as Americans being told what we can or can't do is unsettling. "It's a slippery slope…" But the good news is that this is on the mild side of medication regulation, and there is certainly an argument made for a greater level of regulation – with the right intentions. The FDA has released guidelines, as opposed to hard and fast rules. It's entirely possible that many supplements will be left alone. If we learned one thing from Nestle's recent acquisition of Pure Encapsulations, Garden of Life, and Douglas Labs,

supplements are big business, and our government is extremely friendly to big business, which brings up the other possibility. We can see a future where large supplement manufacturers, of whom put the profits over our health, could ruin the health of the natural health industry.

Sources:

- *FDA takes more aggressive stance toward homeopathic drugs* – Washington Post
- *Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry* – FDA.gov