AANP Files Citizen's Petition to Protect Patient Access to Compounded Medicine

On March 20th, the AANP filed a Citizen's Petition with the FDA as the next step in challenging the FDA's unprecedented attack on physician-prescribed compounded nutrients which is on track to reject fully 95 percent of the 300+ nominated natural ingredients often used by patients as compounded medications.

To quickly learn more about what you can do, skip to the end or visit our Protect Patient Access to Compounded Medications page. For more background, keep reading!

MSM, curcumin, resveratrol, quercetin, and acetyl-L-carnitine are some of the valuable substances that pharmacies won't be able to compound – with glutathione and methylcobalamin among the substances next to be considered (and likely to be rejected).

For over 240 substances that were nominated, the FDA determined that there was insufficient evidence to warrant a hearing. If the FDA final rule published on February 19, 2019 is not stopped, these substances will automatically become illegal to compound, without even having had a hearing.

The majority of these substances are natural medicines, such as: Lactobacillus acidophilus, alfalfa, anise seed, certain types of copper, certain types of magnesium, a lot of minerals, a number of herbal substances. Unchanged, this rule will make it illegal to compound safe, USP-monographed dietary ingredients that are, at the same time, freely sold as lawful dietary supplements in retail outlets.

A Citizen's Petition is the first and required step in the process of establishing standing to bring legal action. Physicians' practice of medicine is being interfered with, and patients' health is being compromised.

Our Citizen's Petition will challenge the FDA's process on several fronts. For example:

- Compounded drug products are being rejected whenever there is an FDA-approved drug that treats the same condition(s) as the given compounded drug.
- The FDA's criteria were never set out for public notice and an opportunity for

public comment. This constitutes a violation of the Administrative Procedure Act.
- The FDA invariably ignores a compounded drug product's history of safe use. Even when the evidence of patient benefit is amply documented, the decision is invariably against approval.
- The FDA's complex and expensive nomination process places an undue burden on healthcare professionals and small pharmacies to submit voluminous clinical evidence and usage data. The amount of information required is unreasonable and burdensome, and mostly ignored.

Despite efforts of a large coalition of pharmacists and providers, legislation to correct FDA's massive overreach has yet to advance. One of our primary DC FLI lobby day priorities in 2018 was to ask Congress to pass HR 2871, a bill to protect patient access to compounded medication. Despite 50 co-sponsors, it has not yet received a hearing, therefore the AANP will lobby on it once again at our June 8-10, 2019 DC FLI. All attempts to clarify that it was not Congress' intent to interfere with the ability of physicians to prescribe medicine have been ignored by FDA.

While I am encouraged to report a growing coalition of stakeholder organizations from all sides of nutritional medicine, including in the supplement industry, are collaborating to fund and fight this fight.

There are three things you can do to help:

1. Donate generously to the Protect Patient Access to Compounded Medications fundraising campaign that supports this legal strategy. Consider sharing this information with your patients and colleagues who would consider supporting the effort.
2. Attend the AANP 2019 DC FLI lobby day! If you use compounded medications in your practice, or if you are a patient who uses compounded medications, we need you to show up to explain why Congress has to pass legislation to stop FDA!
3. Share this with patient advocate organizations and integrative medicine clinics. We need letters of support written to FDA from ***organizations*** that work with patients who use these medications: cancer, Parkinson's, allergy groups, diabetes, etc. Email me at Advocacy@naturopathic.org to help us connect and engage their voices.

Thousands of patients depend on us, and your ability to access safely compounded natural substances is in serious jeopardy. Please take action today!

Sincerely,

Laura Farr
Executive Director
American Association of Naturopathic Physicians