AANP COMMENTS AT "LISTENING SESSION"
FOR FDA STAKEHOLDERS, JUNE 3, 2016

Good afternoon. I'm Mike Jawer, Director of Government and Public Affairs for the American Association of Naturopathic Physicians. AANP represents 4,500 licensed naturopathic physicians who are trained as experts in natural medicine. Their orientation is on finding the underlying cause of a patient's condition rather than solely medicating the symptoms.

I'm here today because compounded medications are an important part of the treatment 'toolkit' of naturopathic doctors – and the FDA's implementation of the Drug Quality and Security Act is going well beyond the letter and intent of the law. The effect on patient care will be significant, and our members' practice of medicine will be hampered. Congress never intended for bulk drug products that have a clear history of safe use to be rejected simply because mass-manufactured drugs are conceivably available to treat the same conditions.

AANP estimates that 2 million patients benefit from naturopathic treatment. These are patients who have not found relief for their health conditions through conventional means. 'Sensitive' patients often have an adverse reaction to mass-manufactured drugs, and require a more individualized treatment regimen in order to boost their immune system and digestive function.

I want to lay out 5 major concerns that AANP has with the FDA's process, and set out ways that the agency can constructively respond to those concerns.

First:

The FDA is incorrectly interpreting DQSA as prohibiting 503(A) office use absent a patient-specific prescription.

- Based on numerous comments inserted into the Congressional Record at the time the law was passed – in addition to directives accompanying the Omnibus Budget Reconciliation Act of 2015 – Congress made clear that it did not intend for state authority to be superseded in this regard.
- Small amounts of compounded medications that can serve the needs of multiple patients, and that can be administered immediately in the office, help these patients receive the products their physicians recommend in a timely fashion. The delay caused by having to fill a patient-specific prescription in every case is detrimental to good patient care.

Second:

The FDA has imposed a complex and expensive nomination process that places an undue burden on healthcare professionals and small pharmacies to submit voluminous clinical evidence and usage data.

- The agency's approach has no basis in the purpose and language of DQSA – particularly for drugs that have been safely used for years. The sheer amount of information required to nominate a bulk drug substance is contrary to the manner in which FDA has

approached such reviews in the past. This documentation burden is unreasonable.

Third:

The agency has failed to recognize the health and economic costs of its proposed regulations.

- No consideration has been given to the harm that will be caused if needed drugs are removed from the market.
- FDA has not performed the analysis required under the Executive Regulatory Flexibility Act.

Fourth:

The standards developed by FDA for evaluating bulk drug products are unduly restrictive; they are being applied unevenly and in a highly subjective manner.

- These standards were never set out for public notice and an opportunity for public comment. The process is improper and constitutes a violation of the Administrative Procedure Act.
- Even when the evidence of patient benefit is ample and well documented – such as with the safety and efficacy of Quinacrine for lupus – the decision is invariably against approval.
- Compounded drug substances are being rejected because the proposed indication is allegedly covered by existing approved drugs, a specious health care policy that is not applied in any other context.

Fifth:

FDA has employed a flawed process for seating and using its Pharmacy Compounding Advisory Committee.

- Only one member of the Committee is a practicing compounding pharmacist. The fact that FDA has made his position non-voting appears plainly prejudicial if not simply unfounded.
- None of the Committee members possesses the extensive training in integrative health and nutrition necessary to fairly evaluate the compounded drugs appropriate to patients of NDs and other integrative healthcare practitioners.
- None of this conforms to the requirements or goals of the Federal Advisory Committee Act.

We call upon the agency to reconsider its regulatory course by taking the following actions:

1. Provide realistic guidelines, under both 503(A) and 503(B), for what would justify continuing access to the safe and effective compounded medications that have been in use for decades;
2. Invite public comment on the appropriate standards to be used in evaluating products for both the approved bulk drug products list and the "difficult to compound list";
3. Broaden the approved monograph list and Interim Guidance safe harbor to include other monographs as have been previously submitted;
4. Commit Agency resources to complete the 390 applications it considered inadequate;

5. Create a list of historically used ingredients and broaden the safe harbor to include this list unless FDA has convincing reason to believe that a given ingredient presents an unreasonable risk;
6. Consider compounded drugs in use before the enactment date of the DQSA to be "grandfathered" until such time as the identified difficulties with the FDA's process are resolved; and
7. Revisit applications for PCAC membership to ensure that professionals who are familiar with the clinical uses of compounded ingredients and with naturopathic, nutritional and integrative medicine are represented on the Committee.

To summarize:

- The FDA's overreach in its implementation of the Drug Quality and Security Act is impeding the ability of naturopathic physicians and other healthcare practitioners to treat their patients.
- Integrative providers were never part of the problem the DQSA sought to remedy.
- The FDA is upending long-established methods of practice, resetting the list of permitted compounded ingredients, and completely rewriting the regulatory structure of how physicians can access and use compounded drugs. The result is enormous disruption and confusion for health professionals and patients alike.

It's important for FDA to recognize that one-third of American adults use some form of complementary, alternative or integrative treatment

according to the most recent NIH figures.[1] These patients have not been able to resolve their health challenges through conventional care nor by mass-manufactured drugs. Indeed, they often react negatively to generic medications. This is where the need for compounded medications comes in. Our patients deserve continuing access to these drugs that have a long history of safe use.

AANP appreciates the Agency's consideration of our concerns. Thank you for this opportunity to dialogue today.

[1] Clarke, Tainya C., Black, Lindsey I., Stussman, Barbara J., et al. Trends in the Use of Complementary Health Approaches Among Adults: United States, 2002-2012. National Health Statistics Reports, No. 79. February 10, 2015. US Departmnt of Health and Human Services. http://www.cdc.gov/nchs/data/nhsr/nhsr079.pdf.