Policy Statement on Pharmacy Compounding

The current legislative efforts in the House and Senate provide a critical opportunity to address the ongoing harm to public health resulting from unsafe drug manufacturing by compounding pharmacies. The meningitis outbreak, now involving over 700 identified cases of illness and over 60 deaths, is the largest of many documented outbreaks associated with compounded drugs, which are not reviewed or approved by the FDA for safety, efficacy and manufacturing quality.

We urge Congress to enact legislation to close loopholes in the Federal Food, Drug, and Cosmetic Act (FFDCA) that have resulted in patient injuries and deaths.

We recognize the importance of preserving access to compounded drugs when patients cannot be treated with an FDA-approved product for documented medical reasons. To safeguard the public health, we also believe that any final legislation must achieve the following:

1. Restrict manufacturing of medications that do not meet federal safety, efficacy, or quality standards and are produced under the guise of pharmacy compounding outside of FDA oversight.

2. Prohibit the compounding of what are essentially copies of commercial products, unless there is a significant medical rationale for an individual patient.

3. Require disclosure to patients when they are receiving a compounded product that is exempt from FDA evaluation and oversight for safety, efficacy, and manufacturing quality.

Based on the above policy criteria, we also recommend the following specific provisions be retained or added to current bills and legislative proposals:

1. **Labeling and Disclosure**
   Require that labeling and advertisements for compounded drugs include the following:
   - This product is not approved by FDA and has not been verified by the FDA for quality, safety, or effectiveness.
   - For compounded drugs that have an alternative FDA-approved product with a boxed warning or medication guide associated with the same active ingredient, warnings and precautions related to safety and efficacy must be disclosed to patients in labeling and through patient counseling materials reviewed and approved by FDA's Office of Surveillance and Epidemiology and Office of Prescription Drug Promotion. Such statements may be obtained directly by pharmacies or by firms that market active ingredients and product formulas to pharmacies for compounding in advance of marketing such active ingredients.

2. **Variations**
   Traditional compounding pharmacies may not make variations of commercial products in advance of receiving a prescription, and, they may make a variation of an FDA-approved product only if the prescribing physician determines and documents that there is a significant medical difference for the individual between the FDA-approved product and the compounded product. FDA should be instructed to develop guidance and education materials for prescribers based on examples of how the agency has historically applied

enforcement discretion, where benefits to individual patients are expected to exceed risks and warrant exemption to requirements under the FFDCA.

3. **Do Not Compound List**
   The Secretary of HHS should be directed to establish a list of drugs or categories of drugs that cannot be compounded for safety reasons.

4. **New Drug Designation**
   Clarification should be made that compounded drugs are new drugs and subject to enforcement under FFDCA if the public health is threatened.

5. **Inspection Authority**
   FDA's inspection authority of compounding pharmacies should include records inspection and product/ingredient sampling.

6. **Misleading Advertising**
   False or misleading labeling, advertising, or promotion of a drug by both Compounding Manufacturers and Traditional Compounders will result in enforcement under the FFDCA.

7. **Office Use Compounding**
   Sales of compounded prescription drugs by a retail pharmacy to licensed practitioners for office use are considered to be minimal if the total annual volume of compounded prescription drugs sold to licensed practitioners does not exceed 5 percent of the volume of prescription drugs **compounded by the entity** annually.

We believe these criteria and specific policy recommendations are critical to protect the public health and to uphold the integrity of the Federal Food Drug and Cosmetic Act. Legislative language must be carried out in such a way as to leave no room for interpretation or doubt of the legislative intent.

Signatures:

Allergy & Asthma Network Mothers of Asthmatics
American Society for Reproductive Medicine
Blue Ribbon Advocacy Alliance
Caregiver Action Network
CreakyJoints.org
Global Healthy Living Foundation
MD Support
Men's Health Network
North American Menopause Society
Terri Lewis, Meningitis Outbreak FB Community Manager
Society for Women's Health Research
StopAFib.org