March 23, 2020

The Honorable Stephen Hahn, M.D.
Commissioner
Food and Drug Administration (FDA)
Room 2217
White Oak Building One
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Re: Pharmacists' Recommendations to the FDA for COVID-19 Response: "Pharmacists as Front-Line Responders for COVID-19 Patient Care"**

Dear Commissioner Hahn:

As the COVID-19 pandemic continues to put an enormous strain on our nation's healthcare system and limits the supply of healthcare providers, our national pharmacy organizations are respectfully urging that FDA take actions that will enable pharmacists to fully and effectively support our nation's COVID-19 response, help ensure that patients get the treatment they need, and safeguard the availability of safe, effective, and quality drugs.

Pharmacists are medication experts, providing patient care in a variety of settings, including hospitals, clinics, community pharmacies, long-term care, the medical home, and physician offices. 90% of Americans live within 5 miles of a community pharmacy, which enables pharmacists to serve on the front lines of the nation's COVID-19 response.

On March 20, 2020, twelve major pharmacy organizations, representing the interests of pharmacists across the United States, released a joint set of policy recommendations critical to addressing the COVID-19 pandemic entitled "Pharmacists as Front-Line Responders for COVID-19 Patient Care." Several of the policy recommendations are directed to FDA. The pharmacy profession urges FDA to immediately implement these measures that are critical to COVID-19 patient care and the availability of safe, effective, quality drugs. The attached document contains a full list of the recommendations, however listed below are those specifically directed to FDA:

- Increased Transparency Regarding Shortages:
    - FDA should be more transparent and timely in reporting drug shortage information under the national emergency, recognizing the sensitivities of preventing hoarding and stockpiling.
    - FDA should provide timely guidance regarding compounding processes and alternative ingredients providers can utilize when ingredients are in shortage.

- Extend Expiration Dates:
    - FDA should proactively identify drugs that are in or at-risk of shortage during the national emergency and urgently work with firms to extend expiration dates for drug products.

- Exercise Enforcement Discretion:
    - FDA should exercise general enforcement discretion over 503A and 503B compounders, except for matters of gross negligence or imminent threat to public health and safety, to allow maximum flexibility during the declared national emergency.

- FDA should waive the restriction on compounding pharmacies to only ship out of state 5% of their overall prescription volume for specific products in shortage for the duration of the emergency.
- FDA should use enforcement discretion for dispenser-to-dispenser transactions when there is no specific patient need under section 581(19) of the Federal Food Drug and Cosmetic Act and allow for transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need during the national emergency.
- Government authorities (DOJ/FDA/FTC) should aggressively enforce laws and regulations against false and misleading claims and adulterated products by entities offering to sell pharmaceutical and medical products to healthcare providers and consumers.

The joint pharmacy statement also includes recommendations to Congress that are within FDA's jurisdiction to improve supply chain security and integrity. We list them below for your information:

- Require manufacturers to provide the FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.
- Require manufacturers to publicly disclose manufacturing sites, including use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs).
- Require manufacturers to conduct periodic risk assessments of their supply chains and establish contingency plans to maintain the supply of a drug in the event of a manufacturing disruption.
- Require HHS and DHS to conduct a risk assessment of national security threats associated with the manufacturing and distribution of critical drugs.
- Incentivize domestic, advanced manufacturing capacity.

Including these recommendations in FDA's COVID-19 emergency response will ensure pharmacists can provide patients with safe, effective and quality drugs in their time of need.

The pharmacy community stands ready to work with the FDA to address this critical public health crisis. On behalf of the twelve pharmacy organizations, please contact Michael Baxter, Senior Director, Regulatory Policy at mbaxter@aphanet.org with any questions.

Sincerely,

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Enclosure: PHARMACISTS AS FRONT-LINE RESPONDERS FOR COVID-19 PATIENT CARE