

May 24, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2020-N-2123

RE: Public Health Focused Essential Meds, MCM and Their Critical Inputs List to Address Section 3(c) of Executive Order (EO) 13944

Dear Dr. Woodcock:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to provide comments on a provisional list of essential medicines, medical countermeasures, or their critical inputs, as required by Executive Order 13944. ACEP thanks the U.S. Food and Drug Administration (FDA) for putting together this draft list of medications. While we believe that the list includes most of the medications that should be classified as “essential,” we do have some suggestions both about the specific medications on the list and the process for updating the list.

With respect to the list itself, ACEP offers the following comments:

- We respectfully request that FDA consider adding the following medications to the list:
 - Metoclopramide
 - Promethazine
 - Oxytocin
 - Tranexamic acid (TXA)
 - Oral Clindamycin
 - Penicillin VK
 - Oral Prednisone
 - All essential childhood vaccines including Tdap and MMR vaccines
 - Medications for Treatment of HIV/ AIDS
- We have concerns about the inclusion of Andexanet alfa since many health systems do not currently stock it due to cost and supply issues.
- The FDA should consider replacing Nitroprusside with Nicardipine as an antihypertensive infusion since it used more regularly.
- We question whether the medication Mannitol should be placed in the "Antihypertensive / Cardiovascular" category. While the medication can certainly have effects on blood pressure, that is not typically its intended use.
- Rabies Immunoglobulin and the Rabies vaccine are currently listed in different areas but should be grouped together.

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- Although Doxycycline is listed in an antibiotic category, we note that it can be used in cases of bioterrorism as well as endemic treatment of pneumonic tularemia.
- We recommend that the order of the categories within the list be alphabetical or organized by human body system. The FDA should also add a search functionality once the list is posted, allowing individuals to easily find medications on the list.

Going forward, once FDA finalizes this initial list, it will be extremely important for the agency to develop a robust process for keeping it updated. ACEP recommends that the FDA conduct a comprehensive review of the list every five years with a pathway to include new, critical medications, as needed. The FDA should also ensure that the medications on the list align to the extent possible with those on the [World Health Organization's essential medication list](#) (last updated in 2019). Finally, the FDA should carefully track whether the United States or specific regions of the country develop shortages of any of these medications and work to find solutions to these shortages and/or recommend appropriate alternatives.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink that reads "Mark Rosenberg". The signature is written in a cursive style with a large, prominent "M" and "R".

Mark S. Rosenberg, DO, MBA, FACEP
ACEP President