April 7, 2020

Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland
20993-0002

Dear Commissioner:

On behalf of the American Society of Anesthesiologists (ASA) and our 54,000 members, I am writing to express continued concern about drug shortages and to share with you, specific critical drugs that our members have the most interest in ensuring FDA addresses. As you know too well, the COVID-19 pandemic has created new drug supply challenges. ASA members are expressing fear about whether we will have the drugs necessary to provide our patients care, especially those most vulnerable and impacted by this virus.

ASA greatly appreciates the work of the FDA drug shortages team. We are in regular communication with them and commend them for their efforts during this unprecedented crisis. We have been able to confirm that some of the highest priority drugs are either on FDA's drug shortages list or are in the category of being monitored closely. This correspondence is to provide you with the most comprehensive information from our physician anesthesiologists and to ensure that the FDA is aware of these drugs crucial to the care provided by frontline physicians during this crisis. We also ask that as demand for critical drugs continues to increase that the FDA facilitate enhanced guidance to physicians on waste reduction, including working with manufacturers to extend expiration dates of critical products.

Of topline concern to our members is propofol, which is used for sedating patients for ventilation. With the increased demand for this drug and the number of COVID-19 positive patients needing ventilators, we can only anticipate that this will soon be in shortage. Similarly, acceptable substitutes include dexmedetomidine and midazolam, and demand will only increase for these drugs as well. Opioids are another class of drugs needed for ICU patients. We have been in touch with the Drug Enforcement Administration (DEA) regarding controlled substances (CII), such as fentanyl, hydromorphone, and morphine, to request that the agency immediately ensure that manufacturers and 503B outsourcing facilities receive increased annual production quota (APQ) allocations to allow them to meet legitimate and critical patient care needs. We would appreciate FDA and DEA's coordination on this matter. Also important in the intensive care unit (ICU), are neuromuscular blocking agents. As you are likely aware, demand is also increasing for these drugs (included in the comprehensive list below).

To reiterate, ASA is already very concerned about shortages of the following sedatives and opioids:

- Propofol
- Methohexital
- Dexmedetomidine
- Midazolam
- Ketamine
- Fentanyl
- Hydromorphone
- Morphine
We anticipate some, if not all of the following, neuromuscular blocking drugs, could also be in shortage:

- Atracurium
- Cisatracurium
- Rocuronium
- Vecuronium
- Succinylcholine

Additionally, with COVID-19 patients, we anticipate an increase in the need for resuscitative drugs:

- Dopamine
- Dobutamine
- Epinephrine
- Norepinephrine
- Phenylephrine
- Ephedrine
- Atropine

Lastly, we’d also flag the reversal agents: neostigmine, glycopyrrolate and sugammadex for the FDA to monitor during this time.

ASA appreciates the work FDA is doing to address the global pandemic and we thank the Drug Shortages team for their dedication and commitment to monitoring and mitigating drug shortages. Please do not hesitate to reach out to me by email (M.Peterson@asahq.org) or to ASA staff member, Ashley Walton (a.walton@asahq.org).

Sincerely,

Mary Dale Peterson, M.D., MSHCA, FACHE, FASA