

Summary of Recommendations for Assuring Access to Medicines and Medical Supplies

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Assuring Access to Medicines and Medical Supplies* address matters related to drug and vaccine development and production and distribution of medical supplies. Recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal and state guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- To prevent and manage shortages of PPE and other essential medical supplies
 - o The president should empower and equip competent career government staff with the necessary resources to fully use federal emergency and DPA authority to
 - Identify and assess the availability of all basic medical equipment required for COVID-19 response
 - Assess domestic and international production capacity and supply chains
 - Use investment and purchasing to incentivize manufacturers to add necessary capacity
 - Develop and implement a strategy for federal procurement and need-based distribution to states (Sinha, PPE; Anderson and Burris, Assuring)
 - o Congress should
 - Fund and require HHS to implement and manage the long-term staff and infrastructure to monitor, track, and proactively address deficiencies in the supply chain for essential medical supplies (Anderson and Burris, Assuring)
 - Fund BARDA and DARPA to conduct research into more sustainable forms of PPE, including N95 masks designed for sterilization and re-use (Sinha, PPE)
 - Mandate that any PPE-related innovation from BARDA and DARPA not be held in confidence as a state secret (Sinha, PPE)
 - Immediately fund the purchase personal protective equipment and test kits—including more accurate, less invasive tests that provide faster results—for distribution to state and local governments (Wiley, Federalism)
 - Reaffirm the enduring role of the SNS as the primary resource for the nation during emergency surges in demand (Anderson and Burris, Assuring), and replace permissive language in the Public Health Services Act with mandatory language to direct the Department of Health and Human Services to support state and local efforts by acquiring and distributing supplies via the Strategic National Stockpile (Wiley, Federalism)
- o HHS should
 - Properly implement and manage the long-term staff and infrastructure to monitor, track, and proactively address deficiencies in the supply chain for essential medical equipment (Anderson and Burris, Assuring)
 - Promulgate, with real attention, new regulations on emergency supply chain management including developing and implementing “stress tests” for supply chains for key products, and reorganize accordingly (Anderson and Burris, Assuring)
 - Immediately and substantially increase stores of traditional and alternative PPE in the SNS (as it has done for potential treatments for COVID-19) (Sinha, PPE)
- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund, and should expand support for the National Hospital Preparedness Program, and the Strategic National Stockpile (Gable, Crisis)
- HHS OCR should develop, expand, and update guidance for the allocation of scarce resources and crisis standards of care consistent with federal antidiscrimination laws (Gable, Crisis)
- To enable the development of high-quality alternative PPE
 - o FDA, NIOSH, and OSHA should finalize (or otherwise make permanent) all draft COVID-19 guidance documents and standards[1][2]. Relevant guidance documents include, but are not limited to:
 - Alternative sources of PPE, especially PPE produced via 3D-printing techniques

- Development and testing of alternative PPE
- Sterilization and reuse of traditional and alternative PPE
- o The FDA should update PPE-related guidance in the following areas:
 - A new premarket evaluation process for alternative PPE to be used in emergent situations, prior to the declaration of an emergency
 - A finalized “Appendix A” list of authorized respirators
 - An amended EUA on imported face masks to penalize identifiable manufacturers of counterfeit products under misbranding authority
 - The role of FDA and NIOSH in testing newly fabricated PAPRs (Sinha, PPE)
- To assure that vaccines and drugs are safe, effective and trusted by the public, FDA should
 - o Decline to authorize EUAs for COVID-19 vaccines
 - o Insofar as FDA considers issuing an EUA for a COVID-19 vaccine, it should be limited to use, on a voluntary basis, to individuals with a documented higher than baseline risk of death or serious injury from COVID-19
 - o Issue EUAs only when they serve public health, as authorized by the FDCA
 - o Clearly communicate and reiterate that EUAs are not “approvals” and that the standard for issuing an EUA does not include a determination that the product has been shown to be safe or effective for its intended purpose
 - o Be as proactively transparent as the law permits it to be in all decisions that FDA makes about COVID-19 countermeasures
 - o Make decisions about which products to authorize or approve for COVID-19 based on the best available public health and scientific evidence, to help ensure better decisions and public trust in those decisions
 - Political pressure on FDA may be particularly acute during pandemics. For this reason, Congress and FDA should consider creating specific processes to protect decision making during pandemics, such as requiring FDA to proactively release detailed information about the basis for its EUA decisions immediately after they are made
 - o Consider routinely requiring patient registries for products that are issued EUAs to help gather information both about patient outcomes and about any disparities in access to such products
 - o Consistent with its obligations under Section 564 of the FDCA, actively and carefully review EUAs, revoking or revising them when needed
 - The results of FDA’s reviews, coupled with a summary analysis of data, should be made public as soon as they are completed
 - In some circumstances, such as COVID-19, a post-market review may be appropriate as frequently as weekly.

The rationale underlying the timing of the post-market reviews should be data-driven and publicly disclosed (Zettler et al., Drug and Vaccine Development)

- Congress should reconsider whether EUAs for vaccines intended for widespread use in healthy people are ever appropriate and consider appropriate revisions to Section 564 of the FDCA (21 USC § 360bbb-3)(Zettler et al., Drug and Vaccine Development)
- To achieve some balance between broad access to patented technologies for COVID-19 response and incentives for future technology development
 - o The federal government, acting through the Centers for Disease Control or another appropriate agency, should assess the patent landscape for technologies critical to COVID-19 response, including the licensing practices of key patent holders, and identify any areas in which the combination of patent protection and a demonstrated unwillingness of patent holders to make their rights available to others could plausibly hinder the rapid development and deployment of technologies necessary to combat the pandemic
 - With respect to such patents, the government should develop and publish a plan for asserting governmental use and march-in rights under 28 USC § 1498 and the Bayh-Dole Act, with the proviso that any patent holder that voluntarily pledges its patents for COVID-19 response on a broad, royalty-free basis (eg, the Open COVID Pledge) would not be subject to such measures
 - o In areas key to COVID-19 response, the government should select technology targets requiring further research and development and develop incentive programs (eg, prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (eg, the Open COVID Pledge) for purposes of COVID-19 response
 - o The government should commit to procuring products and supplies only from entities participating in patent pools (Contreras, Expanding Access)

Action at the State Level

- To improve inter- and intra-state coordination of procurement and distribution of medical supplies, states should
 - o In the long term, use legislation, appropriations and long-term contracts to
 - Establish permanent channels for sourcing essential traditional PPE in times of crisis, independent of federal authorities. States may consider establishing their own stockpiles or engaging in long-term procurement contracts
 - Establish robust community networks for fabricating alternative PPE according to need, including makers, designers, and local businesses that can quickly and efficiently ramp up production (Sinha, PPE; Anderson and Burris, Assuring; see also Gable, Crisis)

- o In the near term, as long as federal coordination lags, continue to formalize and extend interstate cooperation in procurement and sharing of resources including, ultimately, vaccines (Anderson and Burris, Assuring; Wiley, Federalism)
- To protect patients from the risks of unapproved drugs and unproven uses
 - o State officials and agencies, including boards of medicine and pharmacy and public health departments, should clearly communicate to health care institutions, health care professionals, and the public that EUAs are not FDA approvals, the difference between approvals and EUAs, and what is known, and not known, regarding the safety and effectiveness of products available under EUAs
 - o State boards of medicine and pharmacy should discourage off-label use of existing products unless strong evidence supports use for COVID-19 (Zettler et al, Drug and Vaccine Development)
- State legislatures or executive agencies should
 - o Review their crisis standards of care protocols to assure compliance with federal and state antidiscrimination law
 - State law should prohibit medical allocation decision making based on social stigma or stereotypes regarding age, color, criminal history, disability, ethnicity, familial status, gender identity, height, homelessness, immigration status, incarceration status, marital status, mental illness, national origin, poverty, race, religion, sex, sexual orientation, socio-economic status, substance abuse disorder, use of government resources, veteran status, or weight
 - o As necessary, develop and enact in law, regulation or guidelines protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies and clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19
 - Developers should seek public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most affected by the consequences of COVID-19 infections and most likely to be disadvantaged by CSC protocols (Gable, Crisis)
- Legislators should
 - o Enact statutory standards and procedures for imposing crisis standards of care that set out when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority
 - o Enact liability shields for health care professionals and institutions following state-adopted and implemented crisis standards of care protocols in good faith for harms arising from decisions allocating scarce medical resources and services (Gable, Crisis)
- To achieve some balance between broad access to patented technologies for COVID-19 response and incentives for future technology development, state governments should
 - o Select technology targets in areas key to COVID-19 response requiring further research and development and develop incentive programs (eg, prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (eg, the Open COVID Pledge) for purposes of COVID-19 response
 - o Commit to procuring products and supplies only from entities participating in patent pools (Contreras, Expanding Access)