



2020

PUBLIC HEALTH LAW
**VIRTUAL
SUMMIT**

**COVID-19 Response
and Recovery**

September
16-17

**Addressing the
Critical Shortage of
Medical Supplies**

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Assuring Essential Medical Supplies During a Pandemic: Using Federal Law to Measure Need, Stimulate Production, and Coordinate Distribution

Evan Anderson

University of Pennsylvania

&

Scott Burris

Temple University Beasley School of Law

High Level Take-Aways

- We have known that:
 1. a pandemic was coming,
 2. it would deplete essential resources, and
 3. replenishing supply chains would fail.
- The shambolic and shameful PPE situation is a failure to plan and a failure to respond

High Level Take-Aways

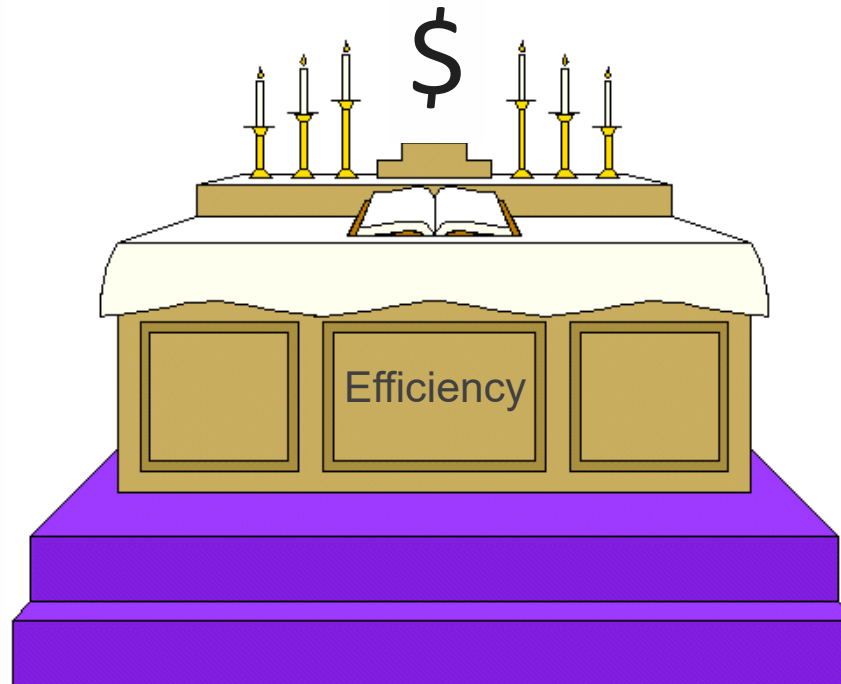
- Key planning failures include:
 1. Stockpile failures (e.g., resupply SNS, 'just-in-time' purchasing at hospitals)
 2. Inability to track inventory,
 3. Confusion about the use of the DPA, and
 4. Limited domestic ability to surge supply.

High Level Take-Aways

- Key responses failures include:
 1. Unwillingness of federal govt. to coordinate tracking, purchasing and allocation,
 2. Tepid use of purchase guarantees and loans to remove risk of retrofitting domestic supply chains, and
 3. Juvenile abdication to broadly lead.

High Level Take-Aways

- The business of healthcare in the U.S.



High Level Take-Aways

- Misunderstanding of the DPA
 - A tool to coordinate, not to coerce
 - Little evidence that govt. could coordinate nationalization and retrofitting of manufacturing



As usual with "this" General Motors, things just never seem to work out. They said they were going to give us 40,000 much needed Ventilators, "very quickly". Now they are saying it will only be 6000, in late April, and they want top dollar. Always a mess with Mary B. Invoke "P".

11:16 AM · Mar 27, 2020 · Twitter for iPhone



General Motors MUST immediately open their stupidly abandoned Lordstown plant in Ohio, or some other plant, and START MAKING VENTILATORS, NOW!!!!!! FORD, GET GOING ON VENTILATORS, FAST!!!!!!

[@GeneralMotors](#) [@Ford](#)

♥ 85.4K 3:23 PM - Mar 27, 2020 ⓘ

💬 52.6K people are talking about this >

Stratospheric Take-Aways

- The neo-liberal paradigm of public management has just exploded right before our eyes



Stratospheric Take-Aways

- Premises:
 - Markets and companies are managed best that are managed least
 - Government should steer but leave the rowing to the private sector
- The results:
 - The private sector won't take on the public good
 - Managing health supplies required a serious team of government rowers
 - Agencies lead by steerers who have never rowed were not prepared...



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CRAZY NOTION

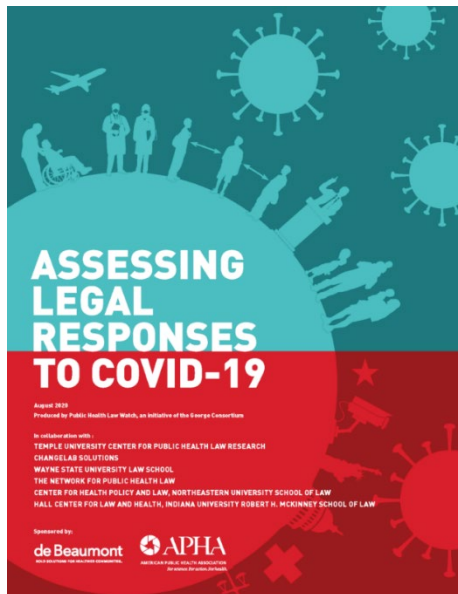
- Public health depends upon a substantial group of well-trained, well-treated, and motivated professionals led by their most excellent peers.
- In good years, the \$20-30 billion annual national price tag may seem like a lot
- This year we'll pay trillions for want of good government

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If you're tweeting from the Summit, remember to use this hashtag to share your insights with Summit attendees and others:
#COVID19PolicyPlaybook

Access the full *Assessing Legal Responses to COVID-19* report or individual chapters at:
COVID19PolicyPlaybook.org



Addressing the Critical Shortage of Medical Supplies

Michael S. Sinha, MD, JD, MPH
Visiting Scholar, NUSL Center for Health Policy and Law

March 2020: #WeNeedPPE

BUSINESS
INSIDER

WHO: The chronic, global shortage of PPE 'is one of the most urgent threats to our collective ability to save lives'

The New York Times

Nurses Die, Doctors Fall Sick and Panic
Rises on Virus Front Lines

STAT

Frustrated and afraid about protective gear shortages, health workers are scouring for masks on their own



#GetMePPE and #GetUsPPE

Esther "STAY HOME" Choo, MD MPH @choo_ek · Mar 17
Personal protective equipment (PPE) helps healthcare workers avoid spreading disease and stay healthy to take care of all of you. Hospitals are already running short. I beg you to help us amplify this need - our administration can mobilize a supply chain ASAP. #GetMePPE

Esther "STAY HOME" Choo, MD MPH @choo_ek · Mar 17
FRONTLINE HEALTHCARE WORKERS

Share a pic of the PPE you're in that you need to stay safe
Tag your congresspeople and @VP

Use the hashtag #GetMePPE
Show this thread

GetUsPPE.org Request Give Make PPE Join Us FAQ Blog About Donate

Getting Personal Protective Equipment (PPE) to Our Healthcare Heroes

Healthcare workers are front line fighters against COVID-19, but they face critical shortages of Personal Protective Equipment nationwide. GetUsPPE is a grassroots coalition of volunteers mobilized to address the PPE shortage and get healthcare heroes the protection they need.

I Need PPE Give PPE

In Pursuit of PPE

The NEW ENGLAND JOURNAL of MEDICINE

THE NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

COVID-19 NOTES

To regularly communicate short reports of innovative responses to Covid-19 around the world, along with a range of current thinking on policy and strategy relevant to the pandemic, the Journal has initiated the Covid-19 Notes series.

In Pursuit of PPE

Andrew W. Aronstein, M.D.
Baystate Health, Springfield, MA

"Two semitrailer trucks, cleverly marked as food-service vehicles, met us at the warehouse. When fully loaded, the trucks would take two distinct routes back to Massachusetts to minimize the chances that their contents would be detained or redirected."

In Pursuit of PPE

The NEW ENGLAND JOURNAL of MEDICINE

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COVID-19 NOTES

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In Pursuit of PPE

Andrew W. Aronstein, M.D.
Baystate Health, Springfield, MA

"Before we could send the funds by wire transfer, two FBI agents arrived, showed their badges, and started questioning me. No, this shipment was not headed for resale or the black market. The agents checked my credentials, and I tried to convince them that the shipment of PPE was bound for hospitals."

September 2020: #WeSTILLNeedPPE

Megan Ranney MD MPH @meganranney

Why do we still face shortages of PPE? Because, simply, supply doesn't match demand - and the supply that is available, is too expensive.

Why don't we have supply?

- * lack of raw material
- * dependence on international supply
- * lead time to ramp up locally
- * lack of gov't support

10:46 PM · Sep 13, 2020 · Twitter Web App

167 Retweets · 11 Quote Tweets · 474 Likes

Esther Choo, MD MPH @choo_ek

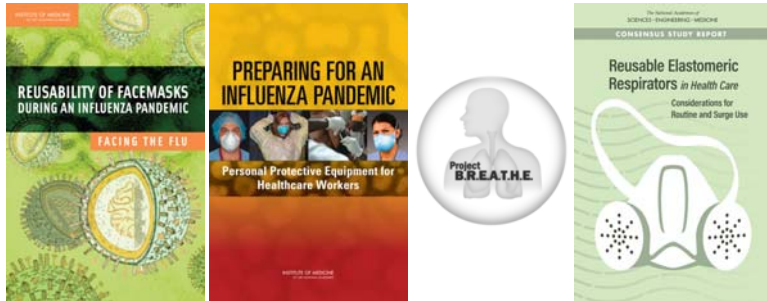
I don't know if people realize, but we're still short on PPE nationally. @getusppe can only meet 10% of the need reported to us. And we're trying to be nimble and pitch in with schools, protests, and other emerging frontline needs. Please donate.

Jonathan Reiner @JReinerMD

Peter Navarro says "we've moved mountains" for PPE. If that's the case, now 9 months later, why are we still reusing N95 masks? @jaketapper

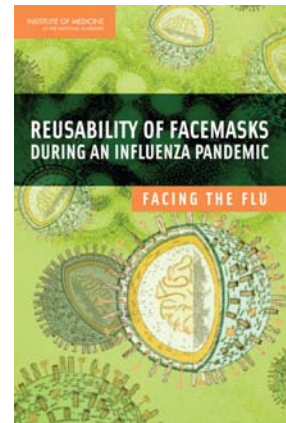
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Several consensus reports have foreshadowed our need for PPE during a pandemic...



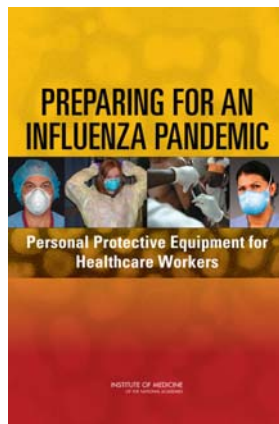
2006

“Disposable medical masks and respirators were not designed for reuse, and there is nearly universal agreement that reuse, even by a single user, should be discouraged except in the most extreme and dire circumstances.”



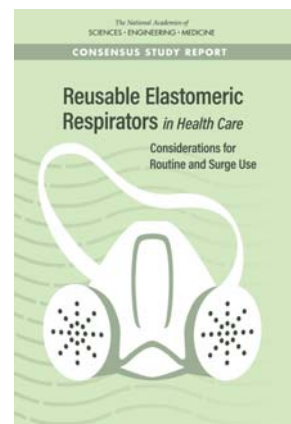
2008

“The varied regulatory, certification, and evaluation requirements for healthcare PPE have largely evolved in a fragmented manner... there has not been a coordinated effort to analyze the entire life cycle of healthcare PPE or the wide spectrum of the user population.”



2019

“The committee concludes that urgent action is needed to resolve gaps in knowledge and leadership on reusable respiratory protection in order to protect the health and safety of health care workers, particularly in an influenza pandemic or an epidemic of an airborne transmissible disease.”



Legal Authority for EUAs during COVID-19

- On February 4th, pursuant to authority in section 319 of the Public Health Service Act, HHS Secretary Alex Azar declared a **public health emergency involving COVID-19**
- Included a declaration that circumstances exist justifying the authorization of emergency use of medical devices, including **alternative products used as medical devices**, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act
- Under section 564, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN (chemical, biological, radiological, and nuclear defense) threat agents when there are no adequate, approved, and available alternatives.



Personal Protective Equipment for COVID-19: Distributed fabrication and additive manufacturing

- Nationwide shortages in PPE have resulted from fragile international supply, just-in-time manufacturing, lean inventories, and limited incentives to innovate
- During the COVID-19 pandemic, local fabricators, “makers,” and 3D printing communities have stepped up to produce PPE for the front line
- EUAs only needed for certain high-risk categories of PPE (sterilization methods, filtering facepiece respirators) and not for other lower-risk categories (face shields, gowns)

Prototyping alternative PPE
Sterilizing to extend PPE use
Rigorously testing potential solutions
Distributing knowledge through website, pre-prints, and publications
Open-source, clinically vetted designs

Face Shields



Mask Frames



PAPRs



Sterilization



ASSESSING LEGAL RESPONSES TO COVID-19

CHAPTER 20 • COVID-19: STATE AND LOCAL RESPONSES TO PPE SHORTAGES

COVID-19: State and Local Responses to PPE Shortages

Michael S. Sinha, MD, JD, MPH, Harvard Medical School Harvard-MIT Center for Regulatory Science

The N95 Mask

- N95: non-oil resistant, filters 95% of particles greater than 0.3 μm in size
- Regulated by the National Institute for Occupational Safety and Health (NIOSH), within CDC



2 Important Considerations:

- **Fit:** whether the mask forms a tight seal around the face
- **Filtration:** whether the mask filters appropriately without affecting the user's ability to breathe normally

PAN-FAB Filtration and Reuse of N95 Masks

- Sterilization of N95 masks using specialized chambers and ionized hydrogen peroxide (Steramist) preserved filtration for up to 10 cycles
- This was more rigorous testing than the Battelle system underwent before receiving its EUA and \$400 million grant
 - Battelle charges \$3.25 per mask to sterilize; pre-pandemic N95s cost \$1.00
- TOMI, the manufacturer of Steramist, has been unsuccessful at obtaining an EUA (application submitted late April)

PAN-FAB Fit of N95 Masks

Filtration may be preserved multiple cycles of sterilization, but other factors may limit reuse

- Elastic band breakage
- Poor seal around face
- Facial injuries from prolonged use
- Differences among manufacturers/sizing and fit



PAN-FAB Quality of Imported FFRs

- Early in the pandemic, an EUA was issued allowing importation of non-NIOSH-approved FFRs
- Seven months after the start of the COVID-19 pandemic, over 100 different makes and models of N95-type masks are in the inventory of local hospitals in Boston, as opposed to 2-5 models under normal circumstances.
- A substantial number of unfamiliar masks are from unknown manufacturers; many did not perform to accepted standards for filtration testing and are likely to be counterfeit.
- Many of the KN95 masks obtained from China on the New England Patriots plane were rumored to be counterfeit

Powered Air Purifying Respirators (PAPRs)

- P100: oil resistant, filters 100% of particles greater than 0.3 μm in size
- Conserves PPE like N95s, does not obstruct the face, easy to sterilize in between uses

Limitations:

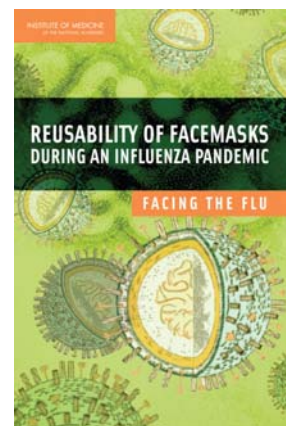
- Cost
- Noise
- Battery life
- Unclear approval process



How do we study and regulate these products going forward?

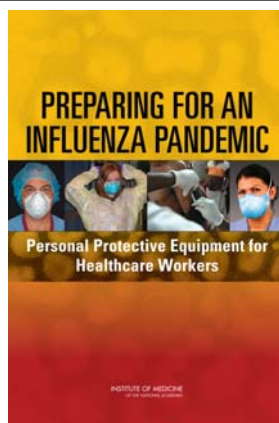
2006

“DHHS should sponsor and/or conduct research on the use of alternative materials, including bioactive fibers, for disposable N95 respirators to allow for extended use (e.g., polyester filter media) and higher durability elastomers for the straps.”



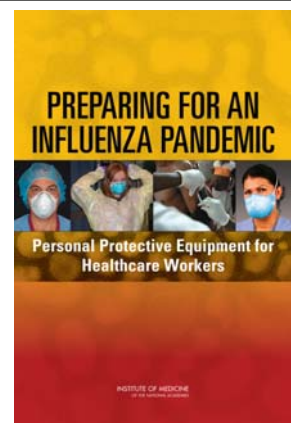
2008

“Federal agencies (e.g., FDA, NIOSH, OSHA) should use standards developed through a consensus-based transparent process that sets specific and clearly defined limits regarding conflicts of interest (financial or other) and involves broad representation of all affected parties.”



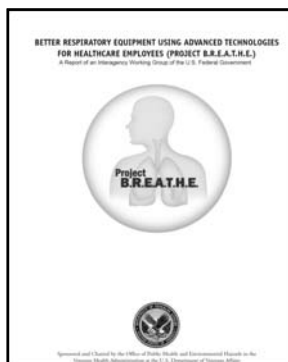
2008

“Congress should expand the resources provided to NIOSH to further research efforts on the next generation of PPE and to coordinate and expedite the approval of effective PPE.”



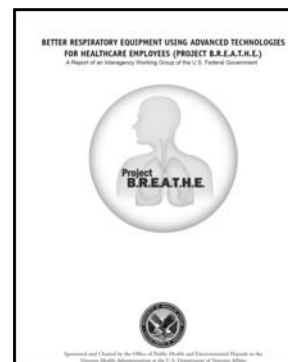
2011

“The Project B.R.E.A.T.H.E. Working Group favors the development of a new respirator class called a ‘B95’ (Biological N95) which connotes protection against biological particulates.”



2011

“Designs should be utilized that prevent respirator-dependent transmission of infectious pathogens, and a test should be developed, validated and standardized that assesses respirator-dependent pathogen transmission in a clinical environment.”



Other recommendations

- FDA should revisit EUAs and remove authorization from those that fail to conduct follow-up studies of safety and efficacy
- CDC should finalize its “Appendix A” to increase certainty over trustworthy vs. counterfeit FFRs
- NIOSH should update guidance related to innovation of both N95s and PAPRs (it has not done so to date)
- Secretary of HHS should issue an OSHA Emergency Temporary Standard (ETS) to protect front-line workers from exposure to aerosol transmissible diseases (states can do this, but federal action would be more expedient)
- BARDA and DARPA, which have been tasked with research into national security, should research more sustainable forms of PPE, but not guard them as state secrets



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