

SILENT INVASION

The Untold Story of the
Trump Administration,
Covid-19, and Preventing
the Next Pandemic
Before It's Too Late

DR. DEBORAH BIRX



HARPER

An Imprint of HarperCollinsPublishers

SILENT INVASION. Copyright © 2022 by Deborah Birx. All rights reserved. Printed in the United States of America. No part of this book may be used or reproduced in any manner whatsoever without written permission except in the case of brief quotations embodied in critical articles and reviews. For information, address HarperCollins Publishers, 195 Broadway, New York, NY 10007.

HarperCollins books may be purchased for educational, business, or sales promotional use. For information, please email the Special Markets Department at SPsales@harpercollins.com.

FIRST EDITION

Library of Congress Cataloging-in-Publication Data has been applied for.

ISBN 978-0-06-320423-2

22 23 24 25 26 ISC 10 9 8 7 6 5 4 3 2 1

Appendix

Summary of Issues to Be Addressed with Proposed Solutions that Will Require Legislative Commitment and Funding

Critical issues today that require addressing for this pandemic and future pandemics:

1. **Command and control**—the addition of ASPR to HHS has caused confusion about the division of labor and roles and responsibilities. There needs to be clarity between the CDC and ASPR specific roles. This separation causes more work and confusion for the states.
2. **Lack of definitive laboratory diagnosis of viral diseases—need definitive laboratory diagnosis of all significant respiratory diseases.**
 - a. Flu is tracked and diagnosed by a symptom complex rather than definitive laboratory testing with either nucleic acid testing or antigen testing.
 - b. Many viral respiratory infections, including RSV, parainfluenza, and adenovirus, are diagnosed as a process of elimination or assumptions based on symptom complex.
 - c. Lack of critical sequencing of SARS-CoV-2 and other respiratory viral infectious diseases at a level that is consistent with the pandemic or real-time data collection.
 - d. **Solution:** all respiratory diseases should be definitively diagnosed in the twenty-first century to drive local testing capacity, routine reporting, and development of enhanced antivirals; accountability to Congress with regular reporting on testing and sequencing completed with full analysis.
 - i. Before doctors can prescribe any antivirals or code for specific respiratory infections for reimbursement, insurance companies, Medicaid, and Medicare should require that patients have a definitive laboratory diagnosis of the viral infection. This would incentivize physician's offices, urgent care centers, and all hospitals to have local lab plat-

form capability, thus driving up the number of facilities capable of making these diagnoses in a timely manner.

- ii. This would also create a baseline of known viral disease so new infectious agents could be easily identified.
 - iii. This would create the critical laboratory capacity at all levels that will be useful between and for pandemics.
 - iv. Expand access to quality home rapid testing to empower every American with the knowledge they need to protect themselves and their families.
3. **Data**—there are no comprehensive links of public health data and clinical data and these are two separate and partially overlapping systems and often require duplicate data entry.
- a. The CDC's hospital and ER data was primarily modelled from sentinel reporting sites.
 - b. All reporting was voluntary and sporadic. Specific regions in the United States were either over- or underrepresented with inadequate visibility into all U.S. counties.
 - c. Incomplete: It did not include daily hospital admission nor distinguish on a patient basis confirmed or suspected Covid-19—just generic Covid. It did include an absolute bed count of available ICU and regular hospital beds but again in a modelled methodology.
 - d. Data are in siloed systems across the CDC without a single common system.
 - e. **Solution:**
 - i. Work with all six thousand U.S. hospitals to establish routine, regular, and timely reporting from hospitals that is modular, adaptable, flexible, and electronic, not paper based and that transcends any specific infectious disease but can rapidly build out new modules based on any pandemic.
 - ii. Required regular reporting of already collected codes for specific community-acquired infectious diseases with age bands, race, and ethnicity appropriately blurred at the county level or combined counties to ensure HIPAA compliance.
 - iii. All data, including lab, hospitals, case, mortality, should be integrated at the community level and available internally and externally.

- iv. Use current technology and set up adaptive systems as technology innovates.
- 4. **Guidance without definitive evidence base creates confusion.**
 - a. The CDC must ensure all guidance is accompanied by or linked to the evidence base or clearly state that the evidence base is being developed.
 - i. Masks: when the CDC recommended cloth masks in April 2020, stating it was solely to ensure infected individuals were not spreading the virus this led to significant confusion across the country, as Americans could not understand that cloth fabric only blocked droplets in one direction. Despite repeated requests for the CDC to conduct or commission the conduct of these simple experiments, the CDC waited until the fall of 2020 to brief on the bi-directional protection of cloth masks.
 - b. **Solution:** The CDC must have mechanisms or internal capacity to investigate and provide the proof of all the elements included in guidance in real time.
- 5. **Guidance without evidence base of implementation, mechanisms to conduct implementation science in real time, and continual feedback loops on outcomes and impact of the recommended public health actions.**
 - a. The CDC should have been conducting behavioral research into flu vaccine uptake over the past decade to understand adult vaccine uptake and have developed clear strategies to increase vaccine uptake and show their efficacy, and these would have informed the initial vaccination strategies for states with continuous behavioral implementation research to improve and evolve messaging.
 - b. **Solution:** The CDC must engage in all aspects of timely implementation science in partnership with states to ensure guidance is optimized for execution and with mechanisms to evaluate outcomes and impacts of all guidance and state-level public health funding and continuously improve the outcomes and impact of their public health guidance.
- 6. **Must increase the speed of published data to support evolutions of policy in the MMWR or other public health science journals, or publish in real time within the guidance documents.**

- a. Recent experience in Marin County on the spread of the SARS-CoV-2 in the school situation would have been critical information to school boards; however the incident that occurred in May 2021 was not published until the end of August 2021, long after the Southern schools had made decisions and the students were fully back in school.
7. **The CDC must fully support states with long-term staffing to address both current public health issues and for the next pandemics.**
 - a. 90–95 percent of the CDC domestic staff are in Atlanta and not in the field, where the information dissemination and implementation are occurring.
 - b. 85 percent of the CDC staff worked remotely over the past 2 months.
 - c. Public health involves the public, and their customers are the states and populations in those states.
 - d. **Solution:** The CDC must evolve into a decentralized state presence with continuous feedback loops between the in-state personnel and HQ to ensure timely development and modification of guidance based on the reality on the ground.
8. **Accountability**
 - a. There is no accountability of federal dollars to policies, outcomes, and impacts at the federal or state level.
 - b. The CDC does not have specific annual milestones for their performance or state performance of grant monies.
 - c. There are no annual granular county- and state-level assessments of the health of the country especially among major public health issues facing America.
 - d. The CDC often relies on delayed reporting and delayed publication on a 3- to 5-year basis that doesn't align with the annual funding to ensure continuous public health improvement.
 - e. **Solution:** CDC must develop timely reporting, implementation results, and outcomes linked to the major public health issues of the country translated down to each and every state with timely data and reporting to ensure continuous program improvement for obesity, hypertension, diabetes mellitus, and community-acquired infections in partnership with states and territories, tribal nations and communities to ensure cultur-

ally appropriate and highly impactful programming for dollars invested that looks at incremental improvements through annual reporting and trend lines.

9. **Overarching—we don't need one set of standards and processes for improving the public health of the country and another for pandemic preparedness—they need to be integrated and utilized between pandemics to improve the health of the nation: Next Generation Pandemic Preparedness** as part of our public health response to existing public health issues—health disparities, obesity, diabetes, cardiovascular disease—with data and implementing science.
 - a. **We will be better prepared if we develop definitive diagnosis of viral diseases and there are preexisting equipment, trained technicians, and shared laboratory information systems ready to detect new infectious agents.**
 - b. **We will be better prepared if we continuously conduct behavioral research on the uptake of adult vaccines and year over year address the structural and perception issues that limit vaccine uptake and show year over year progress with programming.**
 - c. **We will be better prepared if we work to address the social determinants of health and the health disparities through trusted partnerships between community and federal, state, and local partners using real-time data to show improved outcomes and impact year over year, not just once or twice a decade.**
 - d. **We need to stop just observing the problem and begin addressing the problem.**
 - e. **We will be better prepared if we listen and actually hear and in deep-partnership address the paternalistic and culturally insensitive manner of service delivery to our tribal nations.**
10. **Deep dive into what held us back from a rapid response at the FDA and NIH and what actually increased responsiveness.**
 - a. Testing—
 - i. **good**—Laboratory Designed Assays (LDA), EUA
 - ii. **bad**—limiting EUA and therefore testing to symptomatic disease—inhibited the aggressive asymptomatic testing

needed to prevent community spread and willingness to try new ways of reporting from the new devices and tests.

b. Treatment—

- i. **Good**—expanded compassion use, rapid review, and EUA—further streamline regular processes.
- ii. **Needs improvement**—lack of pre IRB approved generic protocols for early stage hospitalized and late stage patients, lack of access to these critical study agents with controlled trials at all hospitals across the United States rather than solely the currently established research hospitals—there should have been a national CRO that would surge to states and territories when we first saw an increase in test positivity to ensure all hospitals had access to controlled trial agents and we would have gotten the answers in days to weeks and not months later—this would have also facilitated the objective trial of agents that some proposed, from hydroxychloroquine to ivermectin, in the regions where they were interested in studying efficacy. Community hospitals and rural hospitals must be eligible for research activities.

c. Vaccines Development

- i. **Good**—rapid movement from Phase I to Phase III trials as warranted, adding community-based research sites to established NIH network of sites, parallel GMP production at risk to ensure immediate access to new and effective antivirals, additional therapeutics, and next generation vaccines.
- ii. **Needs improvement**—inadequate education during the summer of 2020 to continually update the American people on the vaccines being developed with Town Halls, children's books for all households, a chat line to answer questions about the science proactively, education at all levels from K–12, higher education, adults through community centers and churches.
- iii. **Enhanced vaccine protection**—increased vaccine induced durability of protection against infection; potential for cross variant vaccine boosting and intranasal vaccines for durable IgA mucosal immunity.

11. **Bring essential medicines and PPE manufacturing back to the United States.**
 - a. The United States ran out of not only protective equipment but essential medication and this is an emergency and needs to be addressed.
12. **Must ensure that full vaccine production and surge fill and finishing capacity exist in the United States to decrease dependence on international facilities.**
13. **Ensure a robust biotech industry for rapid development of new vaccines and viral and fungal treatments.**
14. **Ensure private sector is at the table for all pandemic preparedness planning and response—they can move faster and take risks the federal/state governments won't.**
15. **Ensure the state leaders are in constant communication with the White House and the federal agencies so that their lesson learned can be immediately highlighted to all the states—solutions to many of these issues exist at the state level and we all need to learn from them.**