Topical Essay
Wednesday, November 10 at 3 PM in the Lewes library.

This month, we are going to focus our attention on the public health response to the Covid 19 both during this crisis and in the future. This is a very essential public policy issue that has been under addressed over the last 20 years. We are using the book by Scott Gottlieb "Uncontrolled Spread." The book has been summarized for us by Jordan White, along with his own analysis.

After reading the materials, please write your own response to the issues. Send your responses to aramterzian@aol.com and it will be posted on topical essay website www.lewesseminar.com

Some issues you may want to consider in your response:
Industrial policy during a health crisis.
Consider the relationship between public health practice and the culture of individualism in American society as to the effect on outcomes.
Consider the political and institutional processes and how they affect public health outcomes during periods of crisis.
Assessing the likelihood of a sea change in future public health spending.
What to expect from the international community during such crises.

David and Aram

Document to be read for the seminar.

Jordan White trained in history (BA, World History, Georgetown SFS 2005, MA, World History with a specialty in multi-national governmental systems, Georgetown University SFS Center for German and European Studies, 2007). He addressed his concern and worry over the pandemic by developing instruments to track the disease's progress with use of raw data provided by the US government as reported by various agencies and by the media. He read this book in September and provided me with this overview of its findings, as well as his take on several of the issues. He graciously allowed the use of this document for our next topical essay.

Jordan works in academic publishing. He lives in Arlington, VA, with his wife and two young children.

The following is an outline of Scott Gottlieb's book "Uncontrolled Spread Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic" (Uncontrolled Spread – HarperCollins).

- There's no doubt that the personality of Donald Trump and those around him played a significant role in charting the course of the COVID-19 pandemic, as did the heavily partisan nature of our country's culture wars. Trump fanning the flames of controversy around masking is probably the most visible and egregious error he directly made and lives would have been saved had he not behaved in that manner. But underneath the political theater, there are three fundamental problems with the U.S. federal government that have dogged us throughout the pandemic that were largely independent of Trump and his personality:
    - Since 2005, all the plans and strategies that agencies of the U.S. government trained on to control pandemics were designed using influenza as the standard example, with the

expectation that the playbook could simply be adapted off of that set of tools and expectations to meet any pandemic threat we encountered. The experience of SARS, MERS, Ebola, Zika, et cetera since 2006 did NOT prompt a re-think of the standard playbook. This playbook is the famous document that W and Obama officials were howling that they left for the Trump team. Evidence is that the Trump team WAS using it, but it was a flawed plan in several ways and the Trump team did not exercise good judgment in adapting it to the realities on the ground. The plan needs to be more broad-based, more adaptable, and have contingencies for different types of pathogen built in.

- Our foreign policy paradigm since the end of the Cold War has been built on the ideas that we must promote information sharing, open markets, free movement of people and goods, and that all major international actors are behaving in good faith. China has been the poster child of this effort, where the international community has actively fostered China's participation and rise in the global arena. But over the last decade, China has increasingly adopted a different stance and promoted a competing set of values. We have been slow to realize the impact of this and the COVID-19 pandemic is one consequence of us being totally unprepared for China's behavior and its impact on us. More broadly, there is no agency in the federal government focused on monitoring the world for signs of emergent pathogens, whether through scientific/public health means or intelligence gathering. Our foreign policy community, intelligence community, national security community and related agencies must refocus and be given new tools to account for this going forward.
- Much like the intelligence community and homeland security apparatuses pre-9/11, the federal research and regulatory agencies designated to support and promote public health in the U.S. are fragmented, byzantine, and too frequently impotent and in conflict with one another. They should be re-organized and we should take a good hard look at what tools are needed and where in government they are best deployed to achieve our purposes. The CDC, in particular, needs a reboot as many of the agency's missteps in the COVID pandemic were mirrored in earlier public health emergencies such as Zika in 2016 and will likely be mirrored in the next pandemic if not addressed directly and thoroughly. The federal government should take a close look at its role in organizing the private sector, purchasing biomedical capacity domestically and funding research/innovation to stay ahead of the next pandemic. An empowered FDA, a newly-focused CDC, a new agency focused on health data modeled after the National Weather Service, and clear lines of authority up through HHS is the likely path forward here.

- How?
  - Operation Warp Speed is one of the greatest public health achievements in modern times. But its success only further highlights problems elsewhere in our response because it proved that the government CAN still do big, complex things when it is well designed, well managed, and well-funded, EVEN when the president is as catastrophically bad as Donald Trump. Thus, it is worth it and frankly all the more important to pursue these institutional reforms, because there isn't reason to believe they can't be as successful in achieving other pieces of the puzzle as successfully as we did vaccine creation.
  - To put it simply, with COVID, we did the complex stuff well and the basic stuff poorly. We did amazing scientific research creating vaccines and therapeutics and understanding the transmission patterns and history of the virus and its genome, but we struggled to make enough masks and nose swabs. We struggled to communicate and

share information in a timely and actionable way. Many lives globally have been saved by the fact that we did the complex stuff well. Many lives domestically were lost due to the fact that we did the basic stuff poorly. We can fix this.

- From my own follow-up, the good news here is that the Biden Administration is already pursuing many of the items Gottleib seeks. A "whole-of-government review" is underway now and issued an update on its progress in September.
  - https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/21/national-security-directive-united-states-global-leadership-to-strengthen-the-international-covid-19-response-and-to-advance-global-health-security-and-biological-preparedness/
  - https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf
- However, I've seen shockingly little Congressional action and/or media attention on this.
  - https://thehill.com/opinion/healthcare/572702-time-for-congress-to-make-a-down-payment-to-prevent-future-pandemic
- The administration wants $65 billion to get plans off the ground, of which $15 billion IS PRESENT in the current reconciliation bill being debated by Congress. As of 9/17, the House had included $16 billion in funding, while the Senate was putting its figure around $8 billion.
- But it is worth stating, I found it VERY difficult to find news articles highlighting these figures or these elements. There isn't much public attention on this effort, in my opinion, which is worrisome.
- By comparison, after 3,000 lives were lost on 9/11, the 9/11 Commission began work 14 months later, created by Congressional legislation. It concluded its work in August 2004. Its investigations and findings led to:
  - The Department of Homeland Security was created by Congressional Act in 2002, the largest federal government reorganization since the creation of the DOD post-WWII.
  - The Director of National Intelligence, a Cabinet-level official whose role is to organize the entire intelligence community, created by Congressional Act in 2004.
- We are already 19 months post-March 2020 and 3,000 people are still dying of COVID every couple of days. The Senate is proposing to fund 12% of what the Biden Administration is asking for. Gottlieb's book is considered the best on the subject so far. I found it helpful, but he also is VERY critical of the CDC, and I'd love to hear the CDC's perspective. He loves the FDA and has personal relationships with many former government officials whom he paints in a positive light in this book. I'd love to see Congressional hearings to consider his AND OTHER positions. Why aren't these playing out in public?
- There will be other emergent pathogens this century with the ability to cause global pandemics, exacerbated by globalization. We cannot write off our failures on Trump. We need to be better.

- From here, I share with you my notes on specific themes and policy prescriptions he lays out throughout the book in case you are interested to support the three pillars I describe up top:
- The Flaws of Flu as the Base Model for Epidemic Disease
  - In the summer of 2005, President Bush read a book on the 1918 influenza pandemic. He called upon his team to create a plan to prevent a flu pandemic.

- The H5N1 bird flu was emergent in 2005 and its characteristics became the basis of that plan. The National Security Council's Medical Preparedness Policy director created a national plan to specifically counter the H5N1 bird flu epidemic. This plan forms the basis of all general pandemic planning in the United States government. Again, it was created to counter H5N1, not all pathogens. There is no similar coronavirus plan or Ebola plan, for example.
- The fact that COVID-19 behaved somewhat like flu but not entirely masked its impact early on our surveillance systems and no one was looking for the signal amongst the noise. As media coverage of COVID increased, the population began taking action -- avoiding crowds, washing surfaces, washing hands, et cetera. This actually caused flu and other respiratory viruses to abate, beginning in spring 2020. But if you compared "influenza-like illness" data (or ILI) for Spring 2020 with Spring 2019 at a population level, it would look identical with COVID on the rise while flu and colds were in decline. Meanwhile, the # of positive flu tests was in decline and was at the edge of the historical range. In other words, what had started as a late/intense flu season quickly disappeared if you were looking strictly at flu tests. We had that data at the time. That no one in government was monitoring the data 'holistically,' looking for novel public health threats and seeing that a change in societal behavior was causing positive flu cases to decline whilst ILI reports remained steady or on the increase delayed our recognition of and response to the community spread of COVID-19.
- For example, in the first week of March, there was a 50% increase in ER visits for respiratory illness in NYC, but lab-confirmed cases of flu in NYC were falling sharply in the same period. That ought to have warranted follow-up from the CDC, who receives all of this data. They did not follow up.
- In short, long before we had COVID tests widespread, we could have seen it and took action. We didn't.
- Further, because of a myopic view believing this was like flu, the CDC for too long declared that the spread of COVID was due to 'fomites' or surface transmission, rather than a higher-than-expected asymptomatic spread. COVID transmits primarily through aerosols (in the air). The CDC did not update its guidelines on this until May 2021. This drove lots of expenditures and focus on cleaning surfaces in public spaces in the interim, as well as a sense that we were "doing something,' which in turn may have perversely reduced the will to 'do something else' in many fora.
- Assumption of fomite transmission was what informed the six-feet rule that became the primary policy driver keeping schools closed in Fall 2020. On this last point, there is no actual science behind the six feet. CDC had wanted 8-10 feet, but the federal Office of Management and Budget (OMB) told them that would effectively shut down key functions of the federal government, so they compromised. Meanwhile the WHO recommended 3.3 feet. China and France went with ~4.5 feet while Germany, Italy and Australia went with ~5 feet. Europe's CDC recommended 6.5 feet. When the CDC revised its guideline to 3 feet in spring 2021, this was ultimately the policy trigger that allowed schools to open nationwide.
- Flu has a short incubation period before illness. Establishing that a patient has flu versus another virus isn't so critical because a sick person will begin to quarantine themselves naturally. For COVID, asymptomatic incubation periods are longer, so knowing who is positive and who is negative is more crucial to stopping the pandemic. Assuming COVID was like the flu prevented other parts of government from recognizing the urgency of and prioritizing diagnostics early as part of our national response. The CDC itself didn't

publicly acknowledge the role of asymptomatic cases until fall 2020 when universities reopened and they began population-level testing and the evidence was undeniable. As Trump famously said late last year, if you test more, you find more cases! More on this in the testing section later.
    - Politicians weren't being deliberately naive when they claimed throughout 2020 that COVID was "just like flu;" they were following the lead of our public health professionals!
    - And per Gottlieb, "the application of public health requires public trust. When the tactics to confront a threat don't line up with people's perception of the risks, that trust is eroded." As it became clear that the tactics in place weren't stopping the pandemic, public officials could have and should have done more to adjust early and explain their reasoning. Time and time again, they didn't do this and each time they didn't, trust eroded a little more, making implementation and enforcement of future changes harder.
- Public Health in our Foreign Policy & National Security
    - China & International Law
        - China is a signatory to several international public health treaties, first adopted in 1969, and later updated in 1995 and 2000, under which all parties are required to inform other parties if at least two of four criteria are met that suggest a) an unusual or unexpected health event is occurring, b) public health impact is serious, c) there is significant risk of international spread and/or d) there is significant risk of international travel or trade restrictions. It must notify other parties within 72 hours of the event. Further, all events involving smallpox, poliovirus, novel influenza, and SARS fall under the notification requirements.
        - China historically fulfilled its requirements to these treaties. In February 2003, they helped stop a dangerous pneumonia outbreak that began in Guangdong Province and ultimately became the SARS-1 pandemic, which of course never spilled over globally as a result. But they stopped doing so in 2018 with novel influenza. Those treaties have no enforcement mechanism or punitive measures. China faced no consequences for these violations.
        - There is clear evidence that China failed to fulfill their treaty duties again in December 2019 and January 2020 with COVID-19, and further, there is evidence they actively suppressed information and sequencing in this timeframe.
        - There is possible evidence that China knew it was facing a major outbreak of a novel virus as early as November 2019 and was hoarding medical supplies in early December 2019. There are reports in Chinese state media that suggest the first cases could be traced to November 17.
        - Whilst China has not faced consequences, the director of the WHO (Dr. Tedros Adhanom Ghebreyesus) made excuses for them in this period, refusing to pressure them to release genetic samples in January and February 2020, for instance, by saying it was not fair to pressure them to do so on a technicality (it says SARS not all coronaviruses!) present in one of the treaties.
        - Tedros also praised (!) China publicly in January 2020 and February 2020 for their "commitment to transparency and to supporting other countries" stating they are "setting a new standard for outbreak response, and it's not an exaggeration."

        - WHO describes their reasoning for this praise as trying not to anger China and thus lose what limited information they were getting. The effect, however, was that by the time WHO did declare a public health emergency (March 11), it was too late to trigger international action to contain the spread or temper the pandemic. A majority of countries around the world have laws limiting the legal scope of their public health response until a WHO pandemic declaration. Placating China limited many countries' ability to act.
        - Trump, of course, was also putting out similarly effusive tweets about China in this timeframe, in lock step with the WHO. Here again, Trump was not acting alone nor on his sole judgment. Former HHS Secretary Azar is quoted in the book as suggesting "public praise gets you further than hitting them over the head." By summer, of course, Trump was pulling the U.S. out of the WHO for its "sluggish response" and "indulging of the Chinese government," clearly looking to separate himself from them politically.
        - China's CDC was designed with a high level of input from the U.S. CDC. However, at an early date, the Chinese government sidelined the Chinese CDC. Notably, they put the military head of their bio-warfare program to Wuhan to oversee the initial response. This facet appears to have been ignored and the implications not recognized by the U.S. government.
        - In conclusion, while the Trump administration AND the World Health Organization viewed this as a public health crisis, and behaved accordingly, expecting that international information-sharing and cooperation was key to solving the matter, China believed this was a national security crisis and behaved as such. This asymmetry had profound consequences for the U.S. who was hurt much more deeply than China by the pandemic, given our open society and more limited government.
    - International Monitoring and Cooperation
        - The "lab leak" theory may never be proven definitively due to China's continued obfuscations, but there are hundreds of labs around the world with active pathogen research that must be protected and monitored. A public health equivalent to the International Atomic Energy Agency, an independent global organization that reports to the U.N General Assembly and Security Council is required here.
        - In 2009, Canada and Australia refused to ship the U.S. vaccine for the H1N1 flu virus that the government had purchased. Canada prioritized its own citizens first. During 2021, Italy exercised export controls within the EU to block vaccine shipments to Australia, and then blocked shipments to the UK in 2021. The U.S. refused to send vaccines to Brazil. We cannot rely on international cooperation in a public health crisis *absent strict enforcement mechanisms*. Making public claims of cooperation without these mechanisms is worse than empty rhetoric, because indeed assumptions of international help may dampen domestic resolve to take further action or to become more resilient.
        - Ultimately, in this space, I think Gottlieb is in the Teddy Roosevelt/Reagan camp of speak softly but carry a big stick or trust but verify camp. We pulled out of the WHO, but then re-entered it without demanding reform. The Biden Administration has looked to strengthen the International Health Regulations described in the previous section, which is good, but cannot be the only international angle here. Which brings us to the next point.

- U.S. National Security Apparatus
  - In 1952, the CDC created the "Epidemic Intelligence Service" with the intent to fashion it as part of our national security apparatus. But in the 1960s, its focus was shifted and today it is a fellowship program to train experts and nothing more. It has never returned to its original intent.
  - In April 2000, the Clinton administration designated HIV/AIDS a national security risk, the first such declaration, marked by the first meeting in the White House Situation Room of medical leaders.
  - In 2001, the Bush administration eliminated the role of the person charged with overseeing biothreats on the National Security Council, before quickly reinstating that role after 9/11. In 2009, the Obama administration disbanded this staff, but then reinstituted it after the H1N1 and Ebola epidemics. In 2018, the Trump administration again disbanded it. Over and over, the general theme has been that this function -- when it is deemed worthwhile -- belongs to the CDC, not NSC.
  - As noted again in a later section below, in 2006, Congress funded the Pandemic and All-Hazards Preparedness Act of 2006, under which CDC was required "to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad" that they have yet to implement 15 years later. The CDC understands its mission through a retrospective mindset, not a prospective one, making its utility limited for national security policy. Further, it makes CDC unlikely on its own to prioritize such a capability. In any event, they have been allowed to ignore Congressional statute for 15 years, which is not great.
  - Gottlieb highlights how the intelligence agencies are often wrong, but are willing to take risks as they predict the future. The CDC's culture, as noted, works against this mentality.
  - The Chinese and Russian intelligence services acted throughout 2020 to hack sensitive systems in the U.S. public and private sector to gain insight into our vaccine trials. Later, Russian intelligence launched disinformation campaigns to smear Pfizer's vaccine data, in hopes of winning more market share in the developing world for Sputnik V, the Russian-developed vaccine. The federal government intervened here to protect university and private company computer networks involved in U.S. vaccine development.
  - Further, the previous bullets about international information sharing and cooperation highlight the need for a health focus in our own intelligence community, monitoring and verifying what other nations are or are not doing. Balancing the needs of the scientific method and national security are culturally very difficult issues but should be confronted head on. We need our intelligence agencies to play a key role in identifying and analyzing potential health threats when they emerge in other nations.
  - Gottlieb notes that we can't lose sight of the fact that, irrespective of COVID's origin, nation states and terrorists alike have seen how disproportionately COVID has hurt the U.S. compared to other countries, highlighting the potency of biological warfare here. Viruses are easier to obtain than nuclear

weapons. Confronting biologics (natural or man-made) is a key national security mission.

- U.S. Public Health Governance and Oversight
    - The FDA and the CDC are both part of HHS, a Cabinet-level agency that serves at the pleasure of the president. The FDA's mission is to protect public health via oversight of "safety, efficacy, and security" of products and devices on the market. The CDC's mission is to "protect America from health, safety and security threats." The one has a focus on protecting the individual; the other protects the population. Who reigns supreme in a pandemic, the individual or the community? When should these agencies be allowed to act independently, and when should they be subject to executive pressure?
        - In the past the FDA commissioner has been called in during crises to "quarterback" an industry-wide response, such as during the push to develop HIV/AIDS drugs for Africa in 2004. They were not deputized as such in 2020. In any event, this is not an official, legal role of the FDA chairman; simply an assumed one.
        - At a 1/21 meeting in the Situation Room, the Deputy National Security Advisor Joe Grogan declared that community spread of COVID was underway across the U.S. No less than Anthony Fauci pushed back on this, stating "what would be the epidemiology to justify your question?" In other words, where is your data to prove this? Robert Redfield, head of the CDC, also fought the NSC on this. The National Security Council recognized the threat early, but didn't have the data and were seen as stepping out of their lane, so they weren't listened to. They were not in charge.
        - Not novel, but Gottlieb highlights also that there has never been (and still isn't) a national COVID testing plan that accounts for different layers of tests for different purposes to combat the pandemic. To do so would require leadership from HHS with collaboration across CDC, FDA, BARDA, Centers for Medicare & Medicaid Services, et cetera. Such collaboration does not exist in the federal government public health agencies today. Speaking of testing...
    - Testing Design & Capacity of Manufactured Tests vs. Capacity to Process Tests
        - The FDA claims jurisdiction over regulating tests that are used to diagnose individual patients for a disease. The CDC claims jurisdiction over regulating tests that are being used for public health purposes as part of a pandemic response. Both agencies must be effective independently AND they must be in lock step on approvals and guidance to be effective. In addition to a plan and oversight, you need diagnostic tests that work well enough and you need them in large enough supply to have an impact.
        - Under the Pandemic All Hazards Preparedness Act of 2006, once HHS has declared a public health emergency and section 564 of the Federal Food, Drug and Cosmetic Act has been invoked, all COVID diagnostic tests must be subject to FDA oversight.
        - But the pandemic playbook says that the CDC should be the first mover on *creating* diagnostic tests. They get first access in the U.S. to viral samples in their labs. Once they design a test, they are responsible for creating testing kits to distribute to public health labs. If/when the need for that test exceeds public labs' capacity to process, the CDC are to post blueprints for the test and allow

academic/commercial labs to replicate it. The FDA's job, meanwhile, is to provide EUA for the CDC test.

- Gottlieb also points out much later in the book that the CDC asserts IP rights over its tests and asks for royalty on its design, which it should be obvious could be a major cultural impediment to CDC moving fast to share information with the private sector (and indeed was, per Gottlieb). It takes time to negotiate licenses. Bear that in mind with what follows.
- In 2016, a cluster of Zika cases in Brazil and the Caribbean became a cause for concern. The CDC designed a complex Zika test that could only be used in its facility. The CDC's testing facility got overwhelmed and test results took weeks to return. Dr. Robert Lanciotti, chief of the Fort Collins Arbovirus Diagnostic Laboratory told the Washington Post in 2016 that this insistence on relying solely on CDC's testing facility could prove fatal in a larger pandemic. Lanciotti was placed under investigation and removed from his position by the CDC. In 2017, the GAO issued a report agreeing with Lanciotti's assessment. The Office of the Special Counsel investigated and ultimately agreed with Lanciotti in 2018, restoring him to his position. But no other remediation of the CDC's protocols was done and this situation remained true into 2020.
- The CDC received the COVID-19 virus genetic sequence on 1/11/20 from China and a live sample of the virus on 1/19/20 from Seattle. It had a test designed by 1/18/20. They posted the blueprint on 1/24/20. The CDC submitted validation data to the FDA on 1/27/20. Full authorization was granted by the FDA on 2/4/20. But the CDC's test design and organizational rules stated that only in the CDC's lab and 115 U.S. public health labs could the tests be processed, severely limiting total testing processing capacity as well as the development and deployment of commercial tests for months and months.
- As an outlier on this, the CDC gave permission to the University of Washington to create a COVID PCR test in January 2020 for "research purposes" but they weren't allowed to notify patients if they tested positive, because that would cross a line into that research tool becoming a medical tool, and for this they needed FDA approval, which would not be forthcoming due to CDC's guidance above. UW conducted its first tests on 2/27 and then went rogue and broke the rules by notifying the patient's family (the first positive test was a child) and the local health authorities. This led to that childcare center closing in Seattle that got national attention. But because they broke the rules, CDC shut down the testing immediately and forced them to submit to an ethics committee. It appears they were allowed to resume testing on 3/4 but again these could only be processed in CDC's lab going forward.
- Much like the Zika tests above, the COVID tests that CDC designed are precise but complex. One of the reasons they insist on processing these tests in CDC labs is BECAUSE they are more complex. On 1/27/20, the FDA -- recognizing the challenges with the CDC's test -- contacted all commercial manufacturers with testing platforms to gauge their development timeline for their own tests. They were told that the commercial sector would not develop their own tests absent a guarantee that the U.S. government would purchase these non-CDC tests, which the CDC refused to give. The commercial sector was frozen. The CDC would be the single point of failure, and the FDA would struggle to exercise

authority over a government agency the way it might over a commercial partner.

- Meanwhile, it should be noted that the evidence shows that the decision to make the CDC COVID test more complex was done without consultation or approval by Robert Redfield, the CDC director. Gottleib calls out that the "most crucial task" the CDC has faced in "one of the most epochal moments in its" history did not rise to the level of director awareness/approval, a stunning breakdown in accountability and awareness.
- Through February 2020, the CDC had trouble rolling out implementation of its test due to its complexity. The FDA worked with the CDC to simplify its test but the CDC remained reluctant and opaque. On 2/16, the CDC decided to make replacement testing kits as backup in case they couldn't solve the problems with their first set. The FDA learned of this by reading it in Politico on 2/17. By 2/26, Bill De Blasio stated at a press conference that NYC would do its own testing in NYS labs with a test of its own design, the first to publicly rebuke the CDC. That same day, the FDA was contacting public health laboratories asking them not to follow CDC instructions received the previous day to destroy two sets of tests the CDC had decided were "faulty." On a call that night, the CDC would accede to the FDA on this instruction. Later federal review would reveal that the complexity of CDC's test was masking the fact that quality control anomalies in their manufacturing process had contaminated the tests the CDC produced in those first six weeks and preferred to use, preventing labs from being able to use them. The other two sets that the FDA preferred would indeed turn out to be fine.
- On 2/29, FDA would finally get clearance to issue a guidance document to allow academic and commercial labs to begin developing their own tests. LabCorp and Quest, the two biggest commercial labs in the U.S., moved quickly and announced their services on 3/5. That's a six-day turnaround from the commercial labs, creating tests that would ultimately serve as the majority of testing done in the U.S. On 3/12, the FDA would grant NYS authority to authorize its own tests for use in NYS only from New York State labs. On 3/16, the FDA would grant any state that wanted this authority that approval, which would ultimately be taken up by 8 other states. Meanwhile, in late February (dates unclear), one of the CDC's commercial partners for one component of the tests decided to move ahead and create the tests themselves based on CDC blueprints and convinced the CDC and FDA to allow it to go forward. This was the move that ultimately created the first 10 million tests used widely in the U.S. The FDA had successfully sidelined the CDC.
- In 2021, the FDA would reveal that the CDC was not following standard protocol for separating functions into separate facilities to prevent cross-contamination related to the creation and processing of COVID tests. The CDC likewise acknowledged it had not put in place proper controls and operating procedures. This appears to be what caused the CDC to acquiesce to FDA. Gottleib says however that the HHS report wherein this is acknowledged has not been released to the public.
- As noted earlier, the CDC clung to very tight criteria for who SHOULD be tested for COVID through spring 2020. In so doing, HHS was able -- correctly -- to claim that they had sufficient capacity to process all tests via the CDC. Ultimately,

however, the criteria were being driven as much by testing supply as anything else.

- It takes logistics and manufacturing expertise to rollout a new product to the U.S. market and the CDC is not structured to do this. Its core expertise is "high-science" and "epidemiological investigations and careful research." Commercial device makers value the flexibility that comes from manufacturing test kits that can be run in different labs and on different platforms, for instance. The CDC, by definition, does not have this value ingrained in its culture by design. The CDC, having worked historically mostly with public health labs, didn't even know what equipment was in most commercial or academic labs. The CDC was being asked to be the single point of failure in an area where it was NOT expert. "Into the late spring" CDC was still explaining this to HHS leadership.
- On 3/7, FDA Commissioner Stephen Hahn was stating publicly that there would soon be a capacity of 2.1 million COVID test kits on the market. But a week later at a Congressional hearing, he would acknowledge that only about 16,000 of these tests could be *processed* in a day. Tests on the market don't do a lot of good if you can't process them.
- Staff within the FDA device center were working on this problem. By 3/13, the first commercial manufacturer received FDA authorization to perform PCR tests on their machines, and at least 3 other manufacturers received approval in March. Later, these same staff had to become the 'traffic cops' for where to ship tests, machines and supplies based on who needed them. This was not part of FDA's mission, but they stepped in as HHS had no other process.
- It would still take months for the coordinated capacity of tests, test supplies, testing sites, and testing processing capacity to ramp up to have a meaningful impact on the nation's pandemic. Jared Kushner was put in charge of developing a national plan early but his efforts went nowhere. President Trump announced a plan on 4/27 that Gottlieb advised on. But that plan too would be scrapped by summer 2020. Eventually, Operation Warp Speed took on this role but the majority of its focus and resources was on drugs and vaccines, not diagnostic tests.
- At its peak, the ~100 public health labs in the U.S. could only process 10k tests a day, with the overwhelming majority of capacity coming from the private sector. By my count, in November 2020, the U.S. hit its peak, testing/processing 1.8m samples a day.
- Gottlieb calls on the federal government to a) invest money in expanding the capacity of the ~100 public health labs across the country to do better surveillance when called upon but b) focus primarily on the commercial labs, purchasing capacity so that the labs can maintain more slack in the system than their profit margins would otherwise demand. Additionally, Gottlieb calls for federal investment in state public health labs to ensure facilities are properly spread across the country, reducing bottlenecks.

- Key Supply Chains and Coordination
  - The Chinese chemical industry accounts for 40% of global chemical industry revenue and provides a large number of ingredients for drug products. In many cases, China is the exclusive source of the chemical ingredients used for the manufacture of drug products. The Strategic National Stockpile is the

government's attempt to counter this but was focused primarily on countering bio-weapons. Drugs and vaccines that were stockpiled in large numbers tended to focus on things like anthrax, smallpox and bird flu. Less emphasis was on basic items like masks, ventilators, testing supplies. Historically the stockpile was under the supervision of the CDC. Under the Trump administration, this moved to the Assistant Secretary for Preparedness and Response whose focus is bioweapons, exacerbating this. This office was created after 9/11 to largely have a policy-focused role, not an operational one.

- Further, China is estimated to be 72% of the surgical mask supplier market and 54% of the medical gown supplier market. Clearly this was a key point of failure in the U.S. response to COVID.
- It may make sense instead to over-build manufacturing capacity so that output can be increased quickly when necessary. The federal government could be the primary buyer and then re-sell some portion of these products to the market, similar to how the federal government controls the money supply to better manage the economy, or the Strategic Petroleum Reserve is called upon to alleviate gas prices. Doing so would also involve the creation of a measured distribution system, which would be even more useful in a crisis that would prevent states from acting independently as they were forced to in 2020. FDA attempted to fill this gap at the federal level, though they had no explicit authority to do so.
- Gottlieb outlines the two antibody treatments, from Regeneron and Lilly (the drugs taken by Trump and Christie respectively) as two that never reached the general population primarily because of an inability to ramp up production quickly. (By summer 2021, these treatments would no longer be effective due to the variants.) We did the science but couldn't do the manufacturing.
- South Korea faced similar challenges after the MERS epidemic in 2015 and revamped its CDC, giving that agency this coordination role. South Korea's testing capacity was the model for the world through much of 2020.
- It is not enough simply to purchase/pay for factories. We have to buy capacity to ensure these facilities continue to be maintained, used, upgraded, et cetera so they are ready to go when needed. Gottlieb calls it purchasing right of first refusal on available capacity, with the ability to commandeer volume in an emergency.

- The role of data in public health messaging and policy response
  - The CDC isn't in the business of delivering real-time, actionable information; its culture prefers to provide definitive, reflective analysis. The CDC's frustrated refrain of "follow the science" typically did not reflect a notion that policymakers weren't following the data; it was that policymakers were ignoring or second-guessing CDC's interpretation of the data. But CDC guidance usually takes months to put together. In a pandemic, this doesn't work.
  - Noted in the national security section, under the Pandemic and All-Hazards Preparedness Act of 2006, CDC was required "to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies

that originate domestically or abroad." The CDC didn't do this. In 2017, GAO noted that the CDC still didn't have such a tool.

- One example of where this fell down was in developing clinical recommendations for doctors and medical staff in treating COVID. The CDC's preferred data source was death certificates. That right there creates a time lag of 1-2 months in even GETTING the data, let alone analyzing it. That's not real-time; not actionable.
- Under the flu section, I already listed the revision of the six-foot example and its policy implications. Another one was quarantine time. In spring 2021, the CDC updated its guidance for quarantine from 14 to ten days. They also changed guidance on close contact from 15 consecutive minutes to 15 cumulative minutes, an effectively impossible measure to calculate in the real world. These are examples where sharing the UNDERLYING DATA quickly rather than focusing strictly on in-depth analysis from CDC might have been a better path.
- The New York Times sued the CDC under the FOIA rules to obtain race and ethnicity data on COVID cases, which is the only reason we know Black and Latino Americans were being excessively harmed nationwide in spring 2020, not from any official CDC guidelines issued to this day.2
- The CDC bases its hospitalization data on algorithms, which works when you're looking at flu season and not worried about total hospital utilization nationwide. In a novel nationwide pandemic, it falls flat. For the 2018-2019 flu season, the CDC hospitalization data had a margin of error of about 100k hospital beds! In 2020, Dr. Deborah Birx tried to direct money toward modernizing this model and data reporting, but the CDC refused.
- Perhaps the largest policy impact of this flawed hospitalization model was that immediately after the FDA approval of the drug remdesivir for hospitalized COVID patients, the federal government purchased the entire supply available. HHS then needed to ship it out to hospitals, but the CDC couldn't tell HHS who needed it. Dr. Birx had to sideline the CDC and begin collecting data from hospitals directly. Very quickly, they got 95% of hospitalization data in hand. Dr. Birx offered this data back to the CDC to update their modeling. The CDC declined, claiming they couldn't "assure its provenance" or "fully trust its reliability." In October, Medicare issued a regulation mandating that hospitals report utilization to HHS instead of CDC going forward. At least this step in the process has now been solved.
- The examples above all reflect a failure on CDC's part to capture and analyze data in a timely fashion. They also failed to generate useful data, most notably in failing to sample and sequence the virus at scale so that new variants could be detected. The variants we know of, including delta, were originally called the UK, South Africa, and Indian variants because those countries WERE sampling and sequencing at population levels (in the UK, 10% of all cases, for instance). There may well be New York or Los Angeles variants that became, say, delta, but we don't know because the CDC didn't generate the data until after delta had already become endemic. In spring 2020, Dr. Birx asked CDC to undertake such an operation, beginning in Mississippi to determine the role that urban versus rural communities played in spread. The CDC did not want to engage with outside labs to undertake this mission; as a result, it was impossible to scale up to get this off the ground in a timely fashion and was

abandoned. The U.S. currently ranks 43rd globally in terms of % of cases sequenced.

- Two of CDC's most senior career officials left in spring 2021 due to ongoing friction with the Biden administration over guidance around masks and vaccinated people. Post-print of Gottlieb's book, Rochelle Walensky very publicly overruled her own agency's scientists on boosters. This clearly is not strictly a partisan friction. It's an institutional one.
- That said, the Trump administration, having decided they did not trust the CDC and did not know how to reform it, instead decided to go around it, following FDA's lead in the spring. Per Gottleib, the White House feared in fall 2020 that sharing ANY information about transmission in schools and the conditions that led to outbreaks would create fear and panic, causing more schools to close. So they stifled the CDC from issuing ANY guidance to schools (let alone data). Schools send health data to local health agencies, who in turn provide it to the states. The states, then, send that data to the CDC, and have done so since 2006. The CDC had the data and could have released it, which likely would have opened *more* schools sooner. They didn't.
- Throughout 2020, the CDC was a "peacetime institution in a wartime environment," despite legal calls to change dating back to 2006. The CDC prefers to look retrospectively, doing analysis, rather than generating actionable information for policymakers today. They need a cultural reboot, from top to bottom.

- National Disease Monitoring Service
  - Gottleib references calls for a new agency in the Washington Post and WIRED Magazine, modeled on the National Weather Service to develop "sophisticated disease modeling to help guide public health policy" as a solution. Just as you check with the National Weather Service and their bureaus to learn about blizzards or hurricanes and then take steps to prepare accordingly, so too would you check with this new agency to find out whether you need to mask today.
  - As one element of this, Helen Chu at the University of Washington, whose team invented the COVID PCR test, proposes that we create a national biospecimen repository where certain respiratory samples are routinely held for a few months after routine testing in outpatient settings. If these tests could be stored and linked to a national patient health record (the lack of this item has dogged the U.S. health system for several decades), health officials could look backwards when needed and run additional tests on novel viruses when they appear. At present, such samples are only held for a week. The main constraints are privacy rules and physical freezer space.
  - The CDC did propose such a repository in 2020 in a plan formulated in February. They suggested it would take six months to create. It was initially supported by the Trump White House. But the action was never taken and got bogged down by lack of leadership, and eroding trust in the federal government's response, which would have hindered CDC's ability to overcome the privacy concerns required to get this implemented.
  - We can also identify, sequence and monitor viruses in animals, keeping an eye on those viruses most likely to jump to humans WITHOUT engineering them to do so as may have happened in the Wuhan lab. The US Agency for International Development had the beginnings of such a program globally from 2005-2015,

funding sixty labs globally to identify zoonotic viruses, ultimately identifying 1,000 that hadn't been previously catalogued. Most notably, it identified a coronavirus that was closely related to SARS-1 in 2016 but distinct enough to warrant follow-up. Congress allowed funding for this program to expire in 2019.
        - Gottleib notes that USAID was given the mandate to run the program for identifying zoonotic viruses that spillover, but then CDC is in charge of investigating outbreaks in humans. Further, the NIT researches emerging pathogens and the development of therapeutics, sharing responsibility for the latter with the FDA, BARDA, DARPA, et cetera. There is no one agency or role responsible for coordinating these efforts. Gottlieb calls this the equivalent of a Joint Special Operations Command in the military.
        - Creating such an agency is present in Biden's COVID strategy, but it's on page 115 of the 200-page document.
    - DARPA but for Biomedical Research
        - An estimated 90% of the COVID drug trials run during the pandemic were designed in a way that would not yield actionable results. Clinical trials, involving placebo and double-blind studies, are difficult to enroll. In a crisis, patients prefer the open, off-label tests such as they did in the use of hydroxychloroquine during COVID.
        - The Defense Production Act, enacted in 1950 during the Korean War, exists to help mobilize resources, and would be invoked dozens of times during 2020 to support creation of drugs, vaccines and equipment. However, there is no similar government tool to mobilize clinical trials. The FDA had no means of prioritizing certain trials or steering enrollment towards particular studies. NIH had funding mechanisms for high-priority studies, but limited ability to prioritize enrollment of one study over another. There is also no means to oversee the design of a study to ensure its speed and likelihood of success.
        - As a result, in 2020, most of the key answers on which drugs were providing benefit to COVID hospital patients came not from the THOUSANDS of trials underway in the U.S. but instead a single government-run UK trial called RECOVERY. As of this writing, no therapeutic has been authorized by the FDA on any U.S.-based trial, while remdesivir and dexamethasone approval at the FDA came entirely from the UK data.
        - Meanwhile, of course, in the U.S., the federal government was focused on hydroxychloroquine. Gottlieb walks through his own involvement in this effort, trying to protect the FDA's existing regulatory process, whilst the president and others were promoting its use. Ultimately, he believes the FDA failed to maintain its independence here and again with the EUA around convalescent plasma in summer 2020. They had to earn that back for the remainder of 2020 in the lead-up to the vaccine approval and rollout. FDA scientists layed out a guidance document to govern the review of a COVID vaccine and made it public early, putting political pressure on the FDA chairman and the president to support it. Ironically, once the data from the vaccine trials began to emerge showing overwhelming strong response, that guidance document and the need for earning public trust in the process, the FDA had to move more slowly than they wanted to on approval.
        - Gottlieb believes this episode highlights several points: a) the need for the government to be able to generate and share real data quickly to combat

political pressure, b) the need for a robust and independent process not subject to overtly political actors. We need to have a government agency focused on funding/enrolling/supporting clinical trials for biomedical research, funding not just the most profitable drugs, but the ones we think we'll need, based on our understanding gleaned from elsewhere in this policy prescription.