For my daughters: August 30, 2020

The Coronavirus Pandemic

Politics Trumps Science

The coronavirus death toll passed 180,000 this week, and the number of confirmed COVID-19 cases reached 6 million today. Not happy numbers, but in the face of them I remain optimistic. As I report today, fast and accurate testing for the virus will soon be possible, and I do not doubt an effective vaccine will emerge from the crowd of potential candidates in development.

As we await happier times, your mother and I are doing our best to take all safety precautions. I mostly stay hunkered down in my office writing, and don't get out except to walk the dog. Your mother calls in her grocery orders, and dons her face mask to do curbside pickup at the grocery store door. Every Tuesday evening we have your mother's high school friend "Aunt Linda" over for wine and pizza on the porch, keeping the proper six feet of social distance between our chairs. I think I miss meeting family and friends nose-to-nose more than almost anything this pandemic has subtracted from our lives. In the meantime your mother shops on the internet for face masks, head shields, and even doggie masks:

And yet, however cheerful your mother and I try to be, sometimes the news defeats all our efforts. This week has been one of those profoundly disturbing times. A series of four awful coronavirus decisions have emanated from the White House, decisions that run directly counter to everything science tells us about the coronavirus (I suspect the goal in each instance has been to minimize the public's concern about COVID-19 in the two months remaining before the presidential election in November). And then, just when my mustache droops down in despair, good news: a new quick and cheap COVID-19 test.

Four wrong turns

I have always told each of you that our family could rely on our federal health institutions to make wise choices that would protect our health in a complex world. The National Institute of Health (NIH) and the Center for Disease Control (CDC) scientists test, analyze and re-test any medical treatment, approving nothing for our use that isn't safe. What concerns me now is a recent pattern of actions that taken together undermine this confidence. I find four decisions particularly troubling:

1. Authorizing Use of Convalescent Plasma

At the beginning of this month I wrote you girls concerning a series of drugs being considered as treatments for COVID-19, one of which was blood plasma collected from people who had recovered from infection. The idea was that a recovered patient's blood plasma would be rich in antibodies directed against the virus, and so could be used to help someone else fight off the virus. I had found very little hard data to back this up--only a few small studies with mixed results. However, I reported to you that a large randomized clinical trial was about to start which would settle the matter. Run by several major universities, this study started last week.

Then, out of the blue, on August 23rd our president announced he had successfully pressed the FDA to "see the light" and immediately authorize emergency use of convalescent plasma as a treatment for COVID-19 patients.

This expedited release has been opposed by Dr Fauci and NIH leaders as premature -- absent the just-started clinical trial, there is no clear evidence that the treatment will work. There have been only two small randomized clinical trials of convalescent plasma reported so far, both unencouraging. One, in China, found no evidence of improvement. The other, in the Netherlands, was halted early.

Why the halt? Because the researchers found that most of the patients seriously ill with COVID-19 *already* had high levels of these antibodies! Their immune systems had already produced anti-COVID-19 antibodies while fighting the infection. This is why plasma transfusions failed for Ebola. Antibodies can only neutralize an infection if produced (or provided) before the virus is able to infect a large number of the patient's cells. After that, the T cell defense must do the work, because antibody proteins cannot enter infected cells. When seriously ill patients have passed this point, adding more antibodies can't help. A reporter described administering convalescent plasma to seriously-ill COVID-19 patients as *giving a fighter a second knife in a gunfight* -- not going to affect the outcome.

But wait! FDA commissioner Stephen Hahn (appointed by the President a year ago) said in response to the outcry in the press about the FDA decision: "*35 out of 100 COVID-19 patients would have been saved because of the administration of plasma*." Can this be right? No. The result Hahn claims to cite refers to a study comparing two small subgroups of patients receiving high and low doses of plasma, <u>not</u> to plasma recipients vs. the vast majority of patients who did not receive plasma. Viewed as a treatment of all COVID-19 patients, the treatment would have saved at the most 3 out of 100 patients, not 35. Hahn is grossly misrepresenting the data.

Still, administering plasma does no harm, right? No. Plasma transfusions are known to often have serious adverse effects. In a recent study of plasma in COVID-19 patients, 25 serious reactions occurred among 5,000 transfusions. That's 1 in 200, an unacceptably high risk for such a small benefit. Hence Dr Fauci's reservations.

So to recap: while the release of convalescent plasma gives the appearance of a White House fighting fiercely against the pandemic, this treatment has in fact not yet been shown to be of any use, and places the patient at risk of serious harm.

2. Implementing New Testing Guidelines

As I have said to you girls often, the core reason the pandemic is far worse in the United States than in other countries is lack of adequate testing. Testing allows us to identify those infected, so they can be quarantined. Last week I described a new saliva test for the virus that will go a long way towards solving the problem, a very hopeful development. Today I will describe another.

But much to my surprise, on August 24th the CDC Director Robert Redfield (appointed 2 years ago by the President) quietly issued new testing guidelines suggesting that asymptomatic people need not be tested for COVID-19, even if they've been in close contact with an infected person! What? The CDC estimates that 40% of people with COVID-19 don't have symptoms, while being quite capable of spreading the disease. We should be testing more people without symptoms, not less. Indeed, we have no hope of controlling the pandemic until we do. How in the world did this happen? Staff at the CDC say the instruction to make the change came down from White House staff. The administration's recently-appointed testing czar, Adm. Brett Giroir, defended the change in the guidelines, saying the new guidelines had the stamp of approval of the White House coronavirus task force. Asked whether Dr. Fauci had signed off on the guidelines, Adm. Giroir said "*Yes, all the docs signed off on this*." Well, not exactly.

Dr. Fauci did indeed approve an earlier revision of the testing guidelines, but the version he approved did not include this change regarding asymptomatic individuals. That change was added at a task force meeting on August 20th, a meeting Fauci did not attend. It would have been impossible for him to have been at that meeting: "*I was under general anesthesia in the operating room* (removal of a nodule on his vocal cord*) and was not part of any discussion or deliberation regarding the new testing recommendations*," Dr. Fauci told a reporter on August 25th. The new guidelines run exactly counter to what Dr. Fauci has been advocating loudly all year: "*I am worried it* (the new guideline) *will give people the incorrect assumption that asymptomatic spread is not of great concern. It is.*" Adm. Giroir is being less than forthright.

Where did this idea come from, anyway? The president has repeatedly complained about widespread testing in the US, falsely claiming increased testing is responsible for the surge in cases since June, and suggesting the US should slow down testing. I find it difficult not to speculate that the CDC's new guidelines were political and not scientific in origin.

3. Seeking Premature Vaccine Approval

During a July 30 meeting, White House chief of Staff Mark Meadows was reported by The Financial Times as raising the possibility of an immediate FDA emergency use authorization of the Oxford University coronavirus vaccine. This is a truly scary development. Our government has given more than $1 billion to the Oxford developers of this vaccine in prepayment for at least 400 million doses. The doses are already being manufactured, even though the vaccine has only just begun phase three clinical trials. That the White House is looking into emergency use authorization hints at the possibility that the vaccine may be approved for distribution before the randomized trials can be completed and analyzed.

Another hint: Today FDA Commissioner Hahn stated that if the developer of the vaccine applies for FDA emergency use authorization *" before the end of phase three, we may find that appropriate*." And another hint: President Trump said at the Republican Convention on August 27 that he expected a vaccine "*before the end of the year – and maybe much earlier*."

Again, I have to emphasize how important it is that we do not skip or skimp on these trials – they are the only way to know which vaccine will work best, and to ensure the "cure" won't be worse than the disease.

4. Failing to Lead By Example

Remember Dr. Fauci's principles? Two of the most critical tools we have to fight the pandemic are social distancing and the wearing of face masks. Yet the president has not helped the nation to see this need by himself wearing face masks. It seemed to me for a few days that he might have come to see their necessity, as he has posed for photographers wearing a face mask at a few recent events.

Then on the morning of August 27th, my hope of presidential leadership evaporated. On television I saw for the first time how the President intended to accept the Republican party's renomination that night. The White House crammed 1,500 chairs onto the South Lawn, each six inches apart. Six inches! So much for 6 feet of social distancing. Face masks? Not required. Look closely at the photo of the event as it was unfolding: in the photo you can see clearly about 130 of the 1,500 people packed tight as sardines in this sea of chairs, straining to hear President Trump speak. Now play *Where's Waldo?:* How many of them are wearing face masks?

Imagine if everyone in the audience was wearing a face mask, with chairs spaced 6 feet apart. Imagine if the President of the United States wore a mask until he reached the podium. What a clear, unambiguous message that could have sent to the American people – that everyone, even the President himself, not only has to, but wants to abide by common-sense precautions that will save lives and make the country a safer place. Instead, what happened made mask wearing and social distancing appear optional and unnecessary. This is not the leadership our country needs in pandemic times.

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The Fauci Meter

Faced with this month's political subversion of what should be by all accounts scientific decisions, I find it difficult to recommend that you maintain full confidence in decisions by government agencies like the FDA and CDC. What do I recommend you do to evaluate government health policy in this uncertain climate? Ask yourself what Dr. Fauci would say.

I like to think of it as consulting The Fauci Meter:

0 ----------10
NO YES

For the events I have talked about in this letter, The Fauci Meter is unambiguous:

POLICY	SCORE	FAUCI
Reduced testing	0	("*must test asymptomatic individuals*")
Plasma use	2	("*utility not yet established*")
Vaccine approval	0	("*clinical trials completed before approving*")
Wearing masks	0	("*face masks are everyone's duty*")
Social Distancing	0	(*"a critical tool in fighting pandemic*")

Now Some Good News: A Rapid Test for COVID-19

Our president has consistently opposed expanded testing for COVID-19, arguing falsely that the reason COVID-19 cases have skyrocketed in the United States this summer is not that the virus is spreading , but simply that we are testing more.

Thus it came as a great surprise to me when, on the morning of August 27th, the White House announced that Abbott Labs had been issued emergency use approval by the FDA the day before for a rapid antigen test for COVID-19, and that the government has purchase of 150 million BinaxNOW rapid COVID-19 tests from Abbott for $750 million! The Abbott rapid antigen test involves a nasal swab and uses the same technology as a flu test. A test kit (see photo) costs $5, and the test takes only 15 minutes.

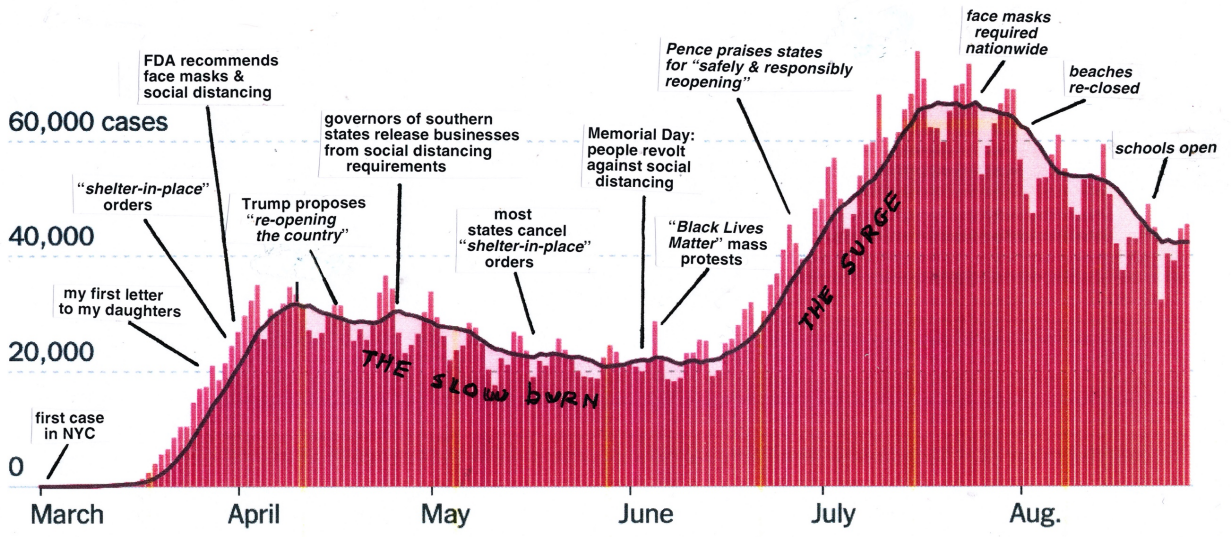
Dubbed BinaxNOW, the Abbott rapid COVID-19 test uses a credit card-sized device to detect COVID-19 antigens. After a health care professional conducts a nasal swab of a patient, the swab is inserted into the device along with a few drops of solution. The solution causes the sample's material to flow across a strip containing antibodies to the COVID-19 spike protein. If the COVID-19 virus is present in the swab sample, it will bind to the antibodies and create a color change to signal the presence of the virus.

Antigen tests have a poor reputation. While faster and cheaper than PCR virus tests, they are famously less accurate. That does not appear to be the case with the BinaxNOW test. According to the FDA's announcement approving its emergency use, the Abbott BinaxNOW test correctly identifies patients with the COVID-19 virus 97.1% of the time, and people without the virus 98.5% of the time. See why it's important to have confidence in the FDA?

While a swab up the nose may not be as pleasant as spitting into a tube, this new rapid COVID-19 test is nothing but good news. The current administration may continue to oppose face masks and social distancing, and to undermine the scientific approaches needed to combat the pandemic, but it got this one right. Interestingly, this very real positive contribution to fighting coronavirus was not mentioned by the President in his address to the Republican Convention that evening. He limited himself to self-congratulations for triggering the approval of convalescent plasma to "*save many, many lives*" in our battle against "*the China virus*."

Where We Stand Today

Where are we, six months into the pandemic? Here's a quick overview of confirmed new COVID-19 cases reported each day in the United States over the last six months, along with a few notes about events that influenced the daily caseload. As you can see, actions have consequences:



Today we are far from out of the woods. While the surge is settling to a lower level (and yet, still about twice the number of new cases seen in early June), further improvement is going to have to wait till our government takes testing seriously. With the new rapid test, that may actually happen in coming months. In the meantime, the political influences seen in the past few weeks suggest we would do well to keep our nose to the wind and our eyes wide open while we wait for those more certain times.

Be safe.

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