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Dump the FDA for a Healthier America

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Even before federal red tape delayed development and deployment of COVID-19 testing and hampered the acquisition of protective gear for medical professionals, the U.S. Food and Drug Administration (FDA) had a reputation as an obstructionist bureaucracy that emphasizes caution over innovation. That caution comes with a price tag in human lives that might have been saved by faster access to new drugs and devices.

Although it's usually been largely invisible, that regulatory price is now on public display. As a result, this may be our best opportunity to abolish, or at least reform, this deadly government agency.

Helen Chu, a Seattle-based infectious disease expert, became a national hero by defying federal rules to test for the presence of COVID-19 in the local population. Chu's February act of defiance gave us confirmation that the coronavirus pandemic was spreading in the United States even as the federal government stood in the way of widespread testing for the disease's presence.

"Stephen Hahn, 60, the commissioner of the Food and Drug Administration, enforced regulations that paradoxically made it tougher for hospitals, private clinics and companies to deploy diagnostic tests in an emergency," reported *The New York Times*.

That means that developers of COVID-19 tests encountered absurd regulatory barriers that slowed efforts to get them to the public. For example, after applying for an emergency use authorization for the test he developed, University of Washington epidemiologist Alex Greninger discovered that he was required to mail physical copies of the application to the FDA. That was only the beginning of a regulatory ordeal that delayed vital testing until COVID-19 was well-established in the state.

While the feds kneecapped academic, commercial, and hospital efforts to detect COVID-19, officials were hard at work to keep testing a federal monopoly. That effort proved disastrous when the test developed by the Centers for Disease Control and Prevention (CDC) proved to

be flawed and essentially unusable. But even after the CDC testing fiasco, the FDA stood in the way of independent testing.

"Hospital lab directors say the FDA validation process is onerous and is wasting precious time when they could be testing in their local communities," ProPublica reported at the end of February.

The FDA played a similarly obstructionist role that contributed to the shortage of protective N95 masks. While high demand inevitably resulted from fear of the spreading virus, red tape required medical facilities to use only approved masks while barring the purchase of essentially identical products made for industrial use, choking off access to millions of perfectly usable masks.

Approval requirements and overlapping rules from multiple agencies are so confusing that even the FDA concedes that "regulation of N95s may create confusion among stakeholders."

Only in mid-March did the FDA ease the way for hospitals to purchase industrial N95 masks. Unfortunately, the preexisting rules limited the market to those few companies willing to run the regulatory gauntlet; it takes time for new sources to get up and running.

And with the FDA hampering widespread testing and the production of protective gear, would it surprise you to know that it also bears some responsibility for the short supply of hand sanitizer?

Distilleries, which have plenty of alcohol on hand, want to venture into the hot market for alcohol-based sanitizer. But even the FDA's pandemic-era *loosened* rules require the addition of a denaturant to the alcohol that renders it—and anything made with that alcohol—undrinkable lest somebody decide to use it as a cocktail substitute.

"If we introduce a denaturant into our lines, it renders them useless for future alcohol production barring extreme cleaning measures, because we cannot have any remnant of the denaturant in our lines, and then sell a consumable product," warns Matt Dogali, the President and CEO of the American Distilled Spirits Alliance. Not surprisingly, distillers hesitate to contaminate their production lines.

That's the crisis-era FDA for you, poisoning us for our own good.

But the FDA threatened Americans' health long before COVID-19 appeared on the scene. If you've ever wondered why it takes so long for promising drugs to come to market, or about the price tags they bear once they do, you can thank food and drug bureaucrats for the roles they play.

The full cost of developing a single new drug and seeing it through to approval by the FDA is roughly $2.6 *billion* dollars in 2013 dollars, according to a 2014 study by the Tufts Center for the Study of Drug Development that was published in the *Journal of Health Economics*.

That's not the end of it, either. The Tufts researchers also found that drugs are having a tougher time than in the past in making it through the FDA approval process. While they couldn't be sure why, they speculated that "regulators have become more risk-averse over time."

Approval of medical devices is cheaper—in the tens of millions of dollars rather than billions—but beset by the same bureaucratic delays that plague pharmaceutical approval.

Medical device companies "viewed current U.S. regulatory processes for making products available to patients (the premarket process) as unpredictable and characterized by disruptions and delays," according to a 2010 survey for the Advanced Medical Technology Association.

Respondents complained that key FDA personnel vanished and were replaced during the review process. Even when faces stayed the same, regulators often failed to show up for key meetings, dragging out the review. As a result, "devices were available to U.S. citizens an average of two full years later than patients in other countries, due to delays with the FDA and/or company decisions to pursue markets outside the U.S. before initiating time-consuming, expensive regulatory processes in their own country."

Much of the problem is that bureaucrats, as the Tufts researchers suggest, are risk averse. They're afraid of being pilloried if a drug or device is approved and people suffer side effects, while they'll never be held accountable for illnesses or deaths that result from a product being delayed or buried entirely. But those lost lives represent very real costs.

"Drug lag costs lives because people suffer and die from disease that might be treatable, if only there were more investment in finding a cure," argues Jessica Flanigan, an associate professor at the University of Richmond, in her book, *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicate*. "Premarket testing conditions also cost lives because patients with conditions that could be treated or cured by unapproved drugs suffer and die while they are waiting for approval," she adds.

If the FDA and other regulatory agencies are to have any role, Flanigan reasons, it should be restricted to informational certification of drugs as being safe, while allowing patients and physicians to abide by or disregard such advisory certification as they please.

There's no particular reason that certification would even require the continued existence of the FDA—it could be handled by private organizations, as advocated by Noel D. Campbell in a 1997 Cato Institute paper. Such certification "provides valuable information to consumers and leaves manufacturers and consumers free to trade with one another—a basic right in a free society," Campbell wrote.

A very limited example of letting people make their own decisions comes in the form of the 2018 "right to try" law that gives terminal patients who have exhausted all other options access to investigational drugs. Giving *everybody* more freedom to make such choices could alleviate a lot of suffering that results from regulatory roadblocks erected by risk-averse bureaucrats.

Who knows, maybe we could even let medical professionals design tests and purchase protective equipment without awaiting federal approval. When you let people make their own decisions, anything is possible.