DAILY NEWS

To help solve the surgical mask shortage, get the FDA out of the way

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The United States faces a dire shortage of personal protective equipment, especially the surgical masks and respirators that help prevent airborne transmission of the COVID-19 virus from infected patients to the medical professionals treating them. The shortage has left doctors and nurses resorting to desperate measures, like washing and reusing masks intended for single-use and discard.

In early March, Health and Human Services official Dr. Robert Kadlec estimated that 3.5 billion masks would be needed during the pandemic, but the U.S, had merely 1% of that number on hand.

Given that demand for surgical-grade masks has spiked, why hasn't supply followed suit? While this may sound at first like a failure of the market, the blame for this crisis lies with a set of onerous regulations enacted by the Food and Drug Administration. The FDA just took steps to fix this problem, but it took far too long.

At this point, you might want to consider acquiring a new office annex to house the scientists you have begun producing masks to donate to local hospitals, the production falls far short of the billions needed in this crisis. Surely, the manufacture of mask s— some of which cost less than a dollar to purchase — is a relatively simple thing. Shouldn't factories across the county, facing slackened consumer demand for their usual products, easily be able to retool to produce masks in massive quantities?

The barrier to ramping up production is the fact that the FDA considers masks to be medical devices and subjects them to surprisingly strict regulatory standards. For a manufacturer to produce a mask and bring it to market, it must pass through a battery of tests, submit a long and detailed report to the FDA, and then wait potentially months for approval. These rules erect a high barrier against market entry for producing surgical masks, and delays of even weeks or months are significant when the virus replicates on a timeline measured by hours and days.

To understand why these rules are such a problem, consider the FDA's "premarket notification" guidelines for masks. First, you must describe the device and its intended use,

including drawings, for which you will want to hire someone with fluency in bureaucratese and knowledge of the various regulations. Then, you will need to hire a team of materials scientists and medical researchers to perform a series of tests on your prototype masks. They will need to make "side by side" compositional comparisons between your mask and all masks currently on the market. You must prove that each of the hundreds of individual choices made when designing your masks — from any of dozens of different kinds of fibers, patterns of weave, color, type of elastic, and such — will enhance its "comparative safety and performance."

At this point, you might want to consider acquiring a new office annex to house the scientists you have hired to conduct risk analysis of whether the mask allows sufficient fluid and air exchange, is an adequate barrier to bacteria, isn't dangerously flammable, nor is it prone to causing allergic reactions. Each of these steps has its own detailed guidelines to follow, forcing you to wade through documents with titles like the "ASTM F 1215-89" standard or the "MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask."

Then there's the wait. The average wait time for a medical device approval of this kind is half a year, delaying release of the mask until late September. If six months does not seem overly long, consider what damage was done by the FDA delaying COVID-19 testing rollout by about six weeks earlier this year.

These "premarket notification" rules don't prevent manufacturers from making masks for donation. But donation, while commendable, is not a sustainable way to meet spiking demand, to build out a supply chain that lasts for the duration, or to avoid additional worker layoffs.

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Donation stories play well on the 5 o'clock news, but a functioning market for the sale of masks will be necessary to meaningfully address the shortage of surgical masks. The FDA does not hold donated masks to the same standards as masks that are sold, yet many hospitals are greeting these unregulated, donated masks with welcome arms. In our current crisis, any mask is preferable to wearing none at all or being forced to re-wear soiled or secondhand masks. It is important that we not let the perfect be the enemy of the good.

Frustration over the shortages has led some to call for the federal government to use its emergency powers under the Defense Production Act to seize control of the means of mask production, temporarily nationalizing factories and ordering them to produce PPE in sufficient quantities. It might work, but it is a brute force measure that would entail significant economic disruption and political corruption.

On March 26, the FDA announced that it would no longer enforce these premarket notification rules for the duration of the declared public emergency (although the ambiguity in saying that the agency "does not intend to object" to their sale falls short of an actual suspension of the rules). Better late than never, but this likely won't be the last time bureaucracy gets in the way of public health.

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