

Innovation Policy and COVID-19

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The spread of COVID-19 has brought into the public consciousness many of the issues implicated in my research on innovation policy. Innovation policy focuses on the ways in which different areas of law – primarily intellectual property law, food and drug regulation, and health law – impact the development of new healthcare technologies and access to those technologies. Public discussions around COVID-19 have dealt extensively with the need to develop new diagnostic tests, pharmaceutical therapies, and vaccines, as well as with the need to ensure access to existing pharmaceuticals and to personal protective equipment (PPE) for healthcare workers. Several colleagues in my field and I have begun a [series](#) of blog posts focusing on particular innovation policy problems related to COVID-19, and I summarize several of those lessons here.

The [lack of sufficient diagnostic testing](#) for COVID-19 in the United States has been a key focus of commentators, policymakers, and journalists. Public health experts agree that an expansive testing program is critical not only to slowing the spread of COVID-19 in the near term, but also to ensuring that future outbreaks can be detected and responded to early. However, the United States was slow to roll out accurate tests for COVID-19.

These failures are traceable to problems of innovation policy. Initially, the Centers for Disease Control (CDC) provided test kits to laboratories around the country, but pulled back once it discovered a mistake in its kits, a mistake which was not corrected for weeks. The Food & Drug Administration (FDA) strictly limited the number of testing providers on the market, meaning that other actors could not fill the space left by the CDC. Additional regulatory requirements imposed by the Centers for Medicare and Medicaid Services (CMS) may have limited the number of labs even eligible to obtain authorization to provide their own tests. Each individual agency therefore contributed to the initial lack of available tests, but the situation also represents a failure of coordination among these agencies. The CDC, FDA, and CMS are all under the control of the Department of Health and Human Services (HHS), which could have exercised a stronger oversight role in identifying and eliminating testing barriers imposed by the interactions of these agencies.

Similarly, a national shortage developed of [specialized PPE](#) needed to protect healthcare workers from exposure to COVID-19, particularly of specialized masks known as N95 respirators. N95 respirators are meant to seal out droplets and particles that include the COVID-19 virus. If widely available and worn correctly, they can help protect their wearer from getting sick with the virus.

Unlike diagnostic testing, N95 respirators already existed before the current pandemic, but the demand for them has skyrocketed, meaning that supply must be scaled up dramatically. But like diagnostic testing, N95 respirators are in scarce supply in part to interagency coordination problems. N95s are regulated both by the FDA and by the National Institute for Occupational Safety (NIOSH), as N95s are also used in the industrial context (such as construction work). N95s approved by NIOSH for industrial work were not necessarily available for healthcare uses. In response to the pandemic, the FDA has used Emergency Use Authorizations (EUAs) to permit healthcare workers first to use NIOSH-approved N95s, and then to use respirators approved in other countries. More recently, innovators have begun to use [3D printing technology](#) to address production shortages. But centralized regulation and incentives, such as in the form of guaranteed purchase commitments from the federal government, may be needed to expand supply further.

Prescription drugs to treat COVID-19 fall into both of these categories. First, the pandemic caused existing essential medications needed to maintain hospitalized COVID-19 patients on ventilators to [fall into shortage](#). Ventilated patients receive a set of medications to keep them comfortable while on the ventilator, but many of those sedatives have experienced shortages as demand now far exceeds typical use.

To increase the supply of these drugs in the near term, manufacturers must expand the production capacity of existing facilities or add new facilities. Each of these options is controlled by innovation policy levers. For instance, the Drug Enforcement Administration operates quotas limiting how much of these medications (which are controlled substances) may be manufactured in the United States annually, a quota which it has [increased](#). The FDA has [expanded](#) compounding pharmacies' ability to repackage some of these products to increase supply in the short term, but will need to inspect new facilities as part of the approval process if new manufacturers seek to enter the market.

Second, new drugs are urgently needed to treat COVID-19 itself. Drugmakers have rushed to identify existing compounds in their libraries for potential efficacy against COVID-19, and to move those products into clinical trials. Some of those products, such as the much-discussed [hydroxychloroquine](#), had already been approved for other uses and are now being repurposed for COVID-19. Other products, such as Gilead's [remdesivir](#), had not yet been approved and were not otherwise available. In both cases, it is critically important that pharmaceutical companies test their products against COVID-19 in high quality clinical trials that will enable physicians and patients to have confidence that approved products are safe and effective against COVID-19.

This distinction between repurposing of existing drugs and the approval of novel products has implications for innovation policy. Existing drugs may be prescribed by physicians for non-approved (known as "off-label") uses, because the FDA does not regulate physicians' practice of medicine. As a result, hydroxychloroquine has fallen into shortage as physicians prescribe it for COVID-19, meaning that patients who need the product for its approved uses (including lupus and rheumatoid arthritis) are having difficulty obtaining it. Many state pharmacy boards have restricted the dispensing of hydroxychloroquine in their state, to protect access for existing patients while clinical trials testing the drug's efficacy against COVID-19 are completed. Unapproved drugs, such as remdesivir, are also being studied in clinical trials for COVID-19 but are not widely available outside of the COVID-19 context. (The FDA initially granted [Emergency Use Authorizations](#) for both hydroxychloroquine and remdesivir for COVID-19, although it has now [withdrawn](#) the authorization for hydroxychloroquine. However, authorization is not the same as full approval, and it conveys much more limited use rights on manufacturers and physicians.)

These different policy levers will continue to be relevant as issues in healthcare technologies arise in the COVID-19 context. The federal government must coordinate across federal agencies to ensure that conflicting policies do not create barriers for patients and healthcare workers, but also to ensure that new products for COVID-19 are supported by clinical evidence.