Commentary

Title:

"Pharmaceutical Regulation is at the Root of the Antibiotic Resistance Crisis"

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With the raging COVID-19 pandemic, it is easy to overlook other public health issues. Antibiotic resistance (i.e., when bacteria evolve to avoid being killed by human made antibiotics) is one of these. Drug resistant bacteria infect about three million Americans each year, claiming the lives of about 50,000. Globally the death toll is around 700,000 each year and is expected to hit 10 million annually by 2050. If the United States can produce multiple COVID-19 vaccines that are safe and effective about a year after the pandemic started, one might reasonably wonder why there hasn't been some innovation to kill a much older, but soon to be more deadly, problem. Antibiotics are one of the most stagnant pharmaceutical fields.

Adding to the embarrassment, these resistant bacterial infections are easily treatable in the Republic of Georgia, a former Soviet Republic, using phage therapy. Phage therapy is an infection treatment that relies on bacteriophages (phages), which are viruses that only target specific bacteria. When properly administered, phage therapy is an excellent remedy for bacterial infections with minimal side effects; it does not even harm beneficial bacteria in the gut microbiome, unlike antibiotics. When overseen properly, it can be evolutionarily stable in the face of evolving bacteria because phages, which are naturally occurring organisms, evolve alongside bacteria.

So why isn't phage therapy, a century-old technique, in widespread use in the United States? Pharmaceutical regulation and intellectual property law interact to prevent its financial viability. Under current rules, each individual phage must be approved as a new drug, a process with costs that can easily exceed one billion dollars. Many phages are needed, and they must be continually discovered. This wouldn't be such an issue if it weren't for the fact that, as naturally occurring substances, phages are ineligible for patent protection. Without patent protection to safeguard a financial return on a successful innovation, securing funding for development of therapeutics is nearly impossible. Adding on to the financial roadblocks is the market size for antibacterial therapeutics, which is far less than the market for chronic lifestyle diseases like heart disease, diabetes, and cancer, which attract much investment.

It is easy to blame the U.S. Food and Drug Administration (FDA) and even the entire concept of Intellectual Property (IP) for this looming disaster of antibiotic resistance. Many criticisms have been leveled at the FDA, and these center on its excessive conservatism and caution in approving new treatments (leading to preventable deaths), along with the astronomical costs that the approval process imposes on drug development. It does not logically follow, however, that abolishing the FDA would eliminate these issues. For one thing, the FDA didn't always exist, and unsafe and ineffective drugs were rampant before it was created. It has been argued that drug companies have an incentive to make only safe and effective drugs because of tort liability. This is true, but only because tort liability is costly. Given the high costs of liability insurance for individual doctors, imagine the costs of insuring against a lawsuit over a recently developed drug. For this reason, pharmaceutical companies may not see their costs substantially decline if the FDA were abolished. Even if private organizations certified drugs, they too would face liability and may be just as conservative and costly as the FDA. Without tort liability, the incentive to make safe and effective drugs disappears.

Right-to-try laws, which permit terminally ill patients to use experimental drugs that could save their lives, are especially pertinent as interest in phage therapy slowly increases. In many cases, terminally ill patients are elderly or have a chronic disease. Antibiotic-resistant infections, in contrast, can afflict the young or otherwise healthy. Phage therapy ought to be permitted and practiced under right-to-try laws because it has value for an increasingly broad segment of the

population. This requires pharmaceutical companies to begin producing phage therapy treatments, and this will not happen without some reforms at the FDA.

To fight antibiotic resistance, rather than abolishing the FDA, a streamlined regulatory regime governing phage therapy should be created. To grant market exclusivity, a form of IP analogous to USDA plant variety protection (not patents) should be granted to newly discovered phages. For drug regulation, a set of rules governing the process of purifying phage therapeutic treatments should be established with a focus on safety, as opposed to both safety and efficacy. Following these rules should grant safe harbor from lawsuits, regardless of efficacy of treatment. Perhaps this could be expanded to other areas of pharmaceutical development. The goal of such a system ought to be to encourage innovation and to bring life-saving treatments to market. Currently, they are stifled by FDA regulation and IP law, but this need not be the case. Importantly, doing away with the FDA and IP may not solve the problem, but a few simple changes could. These reforms could save the lives of tens of thousands of Americans.