



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

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.