## Contention 1: Innovation

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, Accessed 9/16/21 <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. The share of revenues that drug companies devote to R&D has also grown: On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs, many of which

**Turns case – innovation has widespread impacts on public health and sustainability of health care systems**

**Zozaya et al ’19:** Neboa Zozaya, Bleric Alcala, and Jhon Galindo. “The offset of pharmaceutical innovation: a review study”. Sage Journals. September 14th, 2019. FD.

It is well known that pharmaceutical innovation has improved the health and quality of life of patients. It is however sometimes forgotten that new drugs also have the potential of improving the efficiency and the sustainability of the healthcare system. The objective of this review is to shed light on the magnitude of the offset effect that drugs may have in the realm of the healthcare system and for society as a whole. A narrative literature review was carried out. This review demonstrated that a growing body of literature has tried to measure the magnitude of the offset effect associated with pharmaceutical innovation, both at the aggregate level and for different diseases. There is evidence that the aggregate use of new drugs can generate net savings to the healthcare system and to society, as they may release both healthcare and non-healthcare resources for alternative uses. A high degree of heterogeneity in the magnitude of the effect has been found across different pathologies and different types of drugs. By improving the patients’ health status, the use of new drugs is often translated into a decrease in the utilization of healthcare resources, such as hospitalizations, medical visits, and concomitant medication, leading to financial savings, or releasing resources for other uses within the healthcare system. A growing body of literature has tried to measure the magnitude of this offset effect that is associated with PI, both at the aggregate level and for different concrete pathologies. Lichtenberg was one of the first authors who quantified the offset effect of drugs at the general level, leading to the notion that IP’s economic and social contribution could significantly exceed its costs. In a study published in 2001, the author estimated that if a 15-year-old drug was to be replaced by a 5.5-year-old one, per capita pharmaceutical expenditure in the United States would increase by USD 18 on average, while non-pharmaceutical expenditure would decrease by USD 72, leading to a savings ratio of almost 4 times the cost of the introduction of the newest drug.[4](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) He later updated his analysis for the years 1997 and 1998 and obtained a savings ratio of 7.2 in the entire population and 8.3 for the population covered by Medicare, basically due to savings in hospitalizations.[5](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) In another study, Lichtenberg[6](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) estimated that, even under a most conservative cost methodology, the net cost of new drugs was negative, as they would generate savings in hospitalization and nursing home costs equivalent to 2.4 times the cost of the drugs. Other authors later found that the magnitude of the aggregate offset effect of new drugs in the United States actually amounted to intermediate values. For example, Civan and Koksal focused on Medicare- and Medicaid-covered population and obtained a net per capita savings ratio of 5.5 when using newer drugs (actually, when the average age of the drug being assessed was reduced in 1 year). However, the authors also found significant heterogeneity among different drug classes.[7](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) In another study, Santerre (2011) obtained estimations for the United States and six other Organisation for Economic Co-operation and Development (OECD) countries and found larger offset effects in the long run than in the short run. Indeed, according to the author, the marginal effect of commercializing a new medication was equivalent to net per capita savings in healthcare costs of USD 5.9 in the short run and USD 11.4 in the long run. These findings implied aggregated savings at the national level of USD 1800 million and USD 3400 million in the short and long run, respectively.[8](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Public organizations like the Congressional Budget Office have also validated the offset effect of PI in the United States. Their study highlighted that, in the case of the Medicare-covered population, a 1% increase in the number of annual prescriptions translated into a 0.2% decrease in annual healthcare costs.[9](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Based on this finding and on the volume of prescriptions filled in 2014, Lakdawalla et al.[10](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) estimated that each additional prescription led to savings of USD 94 in DHC in that same year. The existence of an offset effect associated with PI has also been confirmed in other countries. For example, in Canada, Crémieux et al.[11](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) estimated that each additional dollar invested in new drugs yields an average reduction of CAD 4.7 in hospital expenditure and of CAD 1.5 in global healthcare expenditures. In Spain, an increase of 10% in hospital drugs expenditure between 1995 and 2005 led to net per capita savings of EUR 1.1 in total hospital expenditures.[12](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Savings by therapeutic area Many studies have analysed the economic impact that drugs have in specific therapeutic areas, finding that in those cases, PI also often translates into net savings in costs. In what follows, we summarize some examples found in the literature. In the oncology area, drugs that were commercialized between 1980 and 1997 in Canada avoided 1.7 million hospitalization days per year, which translated into savings that approximated CAD 4700 million (base year 2012), a significantly higher amount than the annual expenditure in cancer drugs in that country.[13](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Likewise, in the United States, a study estimated that cancer treatments launched between 1989 and 2005 avoided 1.55 million hospitalization days in 2013, thereby reducing hospitalization costs by USD 4800 million in that same year.[14](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) There is also evidence that oncological IP increased healthcare cost savings in Australia. Multiple examples of offset effects have also been found in the cardiovascular area. In OECD countries, pharmaceutical expenditure in cardiovascular illnesses increased by USD 24 per capita between 1995 and 2004, which in turn led to estimated hospitalization savings of USD 89 per capita.[16](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) A study by the British National Health Service estimated that treating atrial fibrillation patients with anticoagulant therapy was associated with net per capita savings of GBP 412 in the short run and GBP 2408 throughout the patient’s lifetime. This same study found additional savings for society of GBP 94 and GBP 1379 in the short and long run, respectively.[17](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Likewise, according to a clinical trial conducted in the United States, the use of statins has led to a 27% reduction in other healthcare costs related to illness management, thereby allowing for an 11% reduction in total cardiovascular healthcare costs.[18](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Another study found that the use of antihypertensive medication was associated with a benefit–cost ratio of 6:1 in women and of 10:1 in men.[19](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Other examples can be found for other illnesses, such as depression, asthma and HIV/AIDS. In the United States, the total net healthcare cost per patient diagnosed with depression was reduced during the 1990s by 18%, mainly due to the decrease in hospitalization costs that was produced by innovations in drug treatment.[20](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) In Ireland, the use of new monoclonal antibodies in asthmatic patients led to a reduction in exacerbations and allowed for a decrease of 14.5% in net DHC.[21](https://journals.sagepub.com/doi/full/10.1177/2284240319875108) Finally, studies have demonstrated that while the use of antiretroviral therapy has increased drug expenditure in patients with HIV/AIDS, it has also decreased other healthcare costs, leading to net savings of 10%.[22](https://journals.sagepub.com/doi/full/10.1177/2284240319875108)

## Contention 2: Generics

#### Reducing IP leads to an increase in the production of low quality generics in third world and developing countries which causes antimicrobial resistance

Hegde 17 Raghuraj S Hegde “Why Branded Drugs Cost Way More than Their Generic Counterparts-India News , Firstpost.” Firstpost, 29 Apr. 2017, Accessed 9/16/21 <https://www.firstpost.com/india/why-branded-drugs-cost-way-more-than-their-generic-counterparts-3412922.html>. AX

In the 1960s, the USA changed it’s laws which then required drug manufacturers to demonstrate that a particular drug works as they claim it would before they could sell on the market. This was the birth of the modern avatar of United States Food and Drug Administration (USFDA) (though the body was originally established in 1906). The evidence of effectiveness demanded by the USFDA gave rise to extensive clinical trials which in turn encouraged scientific rigor through evidence based medicine (EBM). In addition to basic science research to discover new drugs, clinical trials required thousands of patients to be administered the drug to be tested and proof of efficacy of a medicine established scientifically. The results were to be submitted to the regulatory body for approval. Today costs of developing a new drug and conducting clinical trials runs into millions and sometimes billions of dollars- The Cost Of Creating A New Drug Now $5 Billion. So when a successful drug comes through this long winded and expensive process, companies try to recover the R&D costs by selling those drugs at huge profit margins before the drug patent expires (typically about 10–20 years depending on the country and less than that in some countries). This is why branded drugs are expensive when a new drug comes in the market. So the high price of branded drugs comes down to market economics and the society’s need for the invention of new and effective drugs. It is watered down to this simplified axiom- No profits→ no R&D; No R&D→ no new drugs discovered. The new regulations spread to the rest of the world. Most industrialized countries accepted it and evidence based medicine became the global standard. To ensure ethical and safe clinical trials, Helsinki Declaration was drafted in 1964 which brought in new rules to follow with regard to clinical trials. The clinical trials also created a difficult entry threshold for new companies to bring new products to the market since most of the new companies couldn’t afford either good quality basic science research or the ever increasing costs of clinical trials. In 1984, USA changed it’s drug regulatory laws again to regulate those manufacturers who manufacture the proprietary drug after it’s patent had lapsed. The new laws were aimed at simplifying the process, preventing reduplication of established results and for reducing cost threshold for new entrants. These new regulations didn’t require the new manufacturers to repeat the expensive clinical trials of the original molecule but instead mandated that the new companies conduct and submit Bio-equivalence (BE) and Bio-availability (BA) studies to USFDA for approval of the drugs. The USFDA was also proactively involved in the enforcement of the good manufacturing practices in the factories even before BE/BA reports were filed. This ensured that quality was maintained throughout the whole process. These rules were again readily accepted by drug regulatory authorities throughout the world. This was the birth of the generic medicines market. Bio-equivalence studies are tests to show that a generic version of the drug works just as well as the original formerly patented drug. Bio-availability studies conducted to ensure that the available active ingredient of the drug in the body is the same that provided by the original molecule. These studies typically require only a few hundred healthy volunteers. The costs of such studies are obviously much lower than full fledged clinical trials. This is why generics are so cheap. The manufacturers don’t have to spend as much as the big pharma giants to bring these new drugs to the market. It was a win-win for both the pharma companies as well as the consumers- who now had to pay less for their medicines. It seemed like an ideal solution to rising costs of healthcare but a disaster was luzrking in the background waiting to show it’s ugly head. The ugly side of the generic medicine manufacturing and regulation (India perspective) The introduction of generics and its proper regulation (BE/BA reports) ensured that European and American markets received good quality generics at lower costs supplied to their population. However poor laws and regulation in developing countries ensured that corners were cut resulting in low quality generics and contaminated drugs finding their way to patients especially in countries with large populations (India &China) and even poor countries of Africa (where even recording of drug-related deaths were absent). In India, the generic manufacturing boomed in the 80s and 90s due to lax laws and socialistic tendencies of successive governments which were only bothered about reduction in drug prices but not quality of the drugs manufactured. India now is placed 4th in the global generics market but leads the race in the global burden of counterfeit medicines as 75% of all counterfeit medicines traces it’s roots to India followed not very closely by Egypt (7%) and China (6%). The greed for cashing in on the foreign developed markets has resulted in reputed Indian pharma giants like Ranbaxy, GVK Biohealthcare, Dr. Reddy’s Laboratories being proven guilty of submitting fabricated BA/BE studies to push generics into the international markets. They pleaded guilty in the courts and had to give millions of dollars in settlements. Only this year ( April 2017) did the Indian government enact amendments to the Drug and Cosmetics Act (1940) which made it mandatory for manufacturers to submit BE/BA reports for approval of generic medicines into the market. How seriously these rules would be enforced remains to be seen. The earlier regime only required BE/BA reports for generics of those patented drugs approved by the Drug Controller General of India (DCGI) within the first four years of introduction of the innovator drug. Beyond that no generics manufacturer required to submit any BE/BA reports to sell their drugs in the markets. Only the finished drugs are sometimes submitted for testing at the Central Drugs Standard Control Organization (CDSCO) and there is no regulation ensuring of good manufacturing practices presently. Currently only 0.01% of the drugs in the Indian market are even tested. Some of the generics are not even tested on basic effectiveness so they don’t even have to put in an active ingredient which gives retailers sometimes 1000% profit margins. Due to such lax rules and regulations- substandard, contaminated and sometimes toxic drugs end up even in government generic medicine supplies. When such generics produced with dubious manufacturing processes fail to pass muster in developed countries due to their strong regulatory authorities, they end up in remote domestic markets in India and several poor African countries. These substandard or fake drugs do not cause direct drug related deaths but by increase in deaths by not curing the disease as well as increase in multi-drug resistant strains in the community. For example in Tuberculosis, if drugs with low effective doses or no active ingredient is given, it doesn't cure the disease and increases incidence of drug resistant tuberculosis in the community. The deaths caused by this is attributed to multi-drug resistant tuberculosis strains while the real culprit is the substandard medicines supplied earlier. Similarly many strains of antibiotic resistant strains of bacteria develop in such countries increasing disease burden in the community as well as making such infections difficult to treat. The Delhi Superbug is the result of such inadequacies as well as rampant unhindered use of antibiotics in the country. There are three types of drugs in the market at present. — Branded drugs which have brand names and is marketed/advertised to doctors and hospitals by reputed established companies. — Branded generic drugs which are also manufactured by reputed companies but are dependent on retailers/chemists to drive sales. — Unbranded generics which are manufactured from lesser known companies and many of them indulging in bad manufacturing processes and even sometimes not putting in the active ingredient of a particular drug. Recently the Medical Council of India (MCI) issued a directive that all registered practitioners of modern medicine should write only chemical names in their prescriptions. On it’s own it is not a bad move and it was intended to fix the physician- pharma nexus that is deeply entrenched in India. However with such a poor regulatory regime in India it probably does more harm than good. The authority to dispense medicines has shifted from the doctor to often unqualified employees/owners of chemist shops and alternative medicine practitioners (because they are not bound to the MCI directive and can do what they want). This in my opinion is quite a dangerous trend. I recently wrote an article about my views on this new directive. Whether a particular drug is branded or generic, it’s efficacy and safety profile should be the same. Often with the intention to reduce costs of medicines, less ethical means are taken to that end. If drug regulation is poor, unethical businessmen will stop at nothing to increase their profit margins. Our focus should not only be in reducing costs of drugs but more on ensuring that quality and reliable safe drugs reach the end consumers-the patients. The Indian government could do well to understand this aspect-so poignantly described this letter to US President Franklin D Roosevelt in 1937 by a woman describing the death of her child after a toxic drug consumption: "The first time I ever had occasion to call in a doctor for [Joan] and she was given Elixir of Sulfanilamide. All that is left to us is the caring for her little grave. Even the memory of her is mixed with sorrow for we can see her little body tossing to and fro and hear that little voice screaming with pain and it seems as though it would drive me insane. ... It is my plea that you will take steps to prevent such sales of drugs that will take little lives and leave such suffering behind and such a bleak outlook on the future as I have tonight."

#### Antimicrobial resistsnace is rising now, the increase of antimicrobial resistance from generics pushes us over the brink

Neily 14 Jim O Neily(Jim O Neily is an Honorary Professor of Economics at the University of Manchester.He was appointed Commercial Secretary to the Treasury in the Second Cameron Ministry, a position he held until his resignation on 23 September 2016, He is the current chairman of the Council of Chatham House, the Royal Institute of International Affairs.) “The Review on Antimicrobial Resistance”, 2014, Accessed 9/16/21 <https://amr-review.org/home.html> AX

“The Review on Antimicrobial Resistance (AMR), was commissioned in July 2014 by the UK Prime Minister, who asked economist Jim O’Neill to analyse the global problem of rising drug resistance and propose concrete actions to tackle it internationally. The Review on AMR was jointly supported by the UK Government and Wellcome Trust, although operated with full independence from both. Established as a two-year, time-limited process, the Review engaged widely with international stakeholders to understand and propose solutions to the problem of drug-resistant infections from an economic and social perspective, and produced its final report and recommendations in the summer of 2016. "If we fail to act, we are looking at an almost unthinkable scenario where antibiotics no longer work and we are cast back into the dark ages of medicine" – David Cameron, former UK Prime Minister The real implications of spreading drug resistance will be felt the world over, with developing countries and large emerging nations bearing the brunt of this problem. Routine surgeries and minor infections will become life- threatening once again and the hard won victories against infectious diseases of the last fifty years will be jeopardised. Hospital stays and expenses, for both public health care providers and for out of –pocket payers will increase significantly. Drug resistant infections are already on the rise with numbers suggesting that up to 50,000 lives are lost each year to antibiotic-resistant infections in Europe and the US alone. Globally, at least 700,000 die each year of drug resistance in illnesses such as bacterial infections, malaria, HIV/AIDS or tuberculosis. “We have reached a critical point and must act now on a global scale to slow down antimicrobial resistance” – Professor Dame Sally Davies, UK Chief Medical Officer

#### Antimicrobial resistance leads to extinction

Talkington 20 “The U.S. Is Not Prepared to Combat “Existential Threat” of Antibiotic-Resistant Superbugs.” [https://pew.org/2OZgjNp. Accessed 16 Sept. 2021](https://pew.org/2OZgjNp.%20Accessed%2016%20Sept.%202021). <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/27/the-us-is-not-prepared-to-combat-existential-threat-of-antibiotic-resistant-superbugs> AX

At the July launch of the AMR Action Fund, Admiral Brett P. Giroir, U.S. assistant secretary for health, said the following: "Antimicrobial resistance, I do believe, is the existential threat of this century." Giroir’s warning is dire—but it’s not new. For years, leading public health and national security experts around the world have sounded the alarm about the growing threat posed by antibiotic-resistant bacteria. Commissions led by world-renowned economists, declarations from the United Nations General Assembly, urgent threat reports from the Centers for Disease Control and Prevention, and more have all come to the same conclusion: Antimicrobial resistance is a known and certain danger—and the global level of preparedness does not match the magnitude of the threat. In June, The Pew Charitable Trusts sent a letter to the leaders of the Senate Committee on Health, Education, Labor, and Pensions, providing recommendations for how the U.S. can better prepare for future pandemics. The letter highlighted the urgent need for government incentives to help fix the broken antibiotic market. Pew recently reiterated this call to action in partnership with the World Health Organization. There is widespread and longstanding consensus that such incentives are needed to revitalize and sustain the woefully inadequate antibiotic pipeline. Without them, antibiotic developers will continue to go bankrupt, and innovation will continue to stagnate. Now is the time for action. Policymakers must ensure that the U.S. is not caught flat-footed when the inevitable superbug outbreak hits. Some threats we cannot begin to anticipate, but when it comes to antibiotic-resistant bacteria, there’s no excuse for being unprepared.