### 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, <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? T**he 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 are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The most efficacious mainstream drugs come from Indigenous Knowledge – empirics are on our side.

King 91 Stephen King September 1991 "The Source of Our Cures: A new pharmaceutical company wants to provide reciprocal benefits and recognize the value of indigenous" <https://www.culturalsurvival.org/publications/cultural-survival-quarterly/source-our-cures-new-pharmaceutical-company-wants-provide> //Elmer

**FOR 500 YEARS**, SINCE THE People of South America encountered Europeans on their soil, **the global pharmacopoeia** has been **enriched by a number of important plant-derived medicines discovered and utilized by indigenous people**. The skeletal **muscle relaxant d-tubocurarine** is derived from an Amazonian arrow poison better known as curare, Chonodendron tomentosum. The **antimalarial drug quinine**, obtained from the bark of the several species on Cinchona trees, was first called "Indian fever bark" by the Europeans until the name "Jesuit fever bark" became more popular. Quinidine, also produced from the bark of Cinchona species, is now used as an antiarrhythmic for people with cardiac problems. An important amoebocide and emetic drug **emetine**, obtained from the roots of Cephalis ipecacuana, was utilized by indigenous people in Brazil **to treat dysentery**. One of the world's most important local anesthetics, cocaine is derived from the leaves of Erthroxylum coca and is still used today as medicine by thousands of people in the Andean region of South America. **Pilocarpine**, a drug **used to treat glaucoma**, is derived from the plant Pilocarpups jaborandi and was utilized by indigenous people in Brazil as medicine. These are only a few examples of the mainstream drugs that have been developed based on the - acknowledged - traditional wisdom of indigenous people. Roughly **74 percent of the 121** **plant-derived compounds** currently **used in the global pharmacopoeia** h**ave been discovered through research based on** ethnobotanical information on the **use** of plants **by indigenous people**. It is well known that tropical forest ecosystems contain a tremendous diversity of plant species. Estimates cite a minimum of 250,000 flowering plant species worldwide, at least 90,000 of which are found in the neotropics. Fewer than one percent of these plants have been investigated even superficially for potential pharmacological activity. A surprisingly large proportion of this plant biodiversity is classified, utilized, and actively managed by indigenous and local people of tropical regions. Tropical forest people have a profound knowledge about the utility, of plants found in their environment - an observation confirmed by ethnobotanical and ethnopharmacological research in the past decade (see references). At the same time interdisciplinary research by anthropologists, ecologists, geographers, and tropical agrnomists has shown that indigenous people and rural inhabitants of the neotropics have been - and continue to - actively managing plant genetic resources in their environment (Balee and Posey 1989; Irvine 1987; Denevan and Padoch 1988; Posey 1985); plants used as medicine are often moved and maintained as cultivated or wild/cultivated medical resources.

#### **Chinese Tribal Medicine proves Compatibility and our Innovation Links.**

Erstling 8, Jay. "Using patent to protect traditional knowledge." Tex. Wesleyan L. Rev. 15 (2008): 295. https://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1187&context=facsch (Professor of Law, William Mitchell College of Law, St. Paul, Minnesota.)//Elmer

Advantages of Affirmative Protection Despite the above-mentioned limitations and challenges, **patents have a place in a TK protection system**. A **prime example is** the use of patents to protect **Traditional Chinese Medicine**. The practice of Traditional Chinese Medicine dates back to the beginning of Chinese history. At its most basic, it is "a systematic practice of distinguishing among various illness-causing imbalances of qi. [It] achieves health by restoring a patient's internal yin-yang equilibrium via herbal remedies and physical manipulation."1'69 Traditional Chinese Medicine is of **enormous importance** not only **to** the **Chinese**-**and** the **world's healthcare systems**, but also to the Chinese economy. 170 It is no surprise, therefore, that the Chinese Government has made it a policy to encourage the patenting of innovative Traditional Chinese Medicinal products. Although most developing countries tend to find disfavor with the **TRIPS** Agreement, the Agreement has proven to be a **boon to** the **protection of T**raditional **C**hinese **M**edicine. Prior to the adoption of Article 27.1 of the TRIPS Agreement, which required China to make patents available "for any inventions, whether products or processes, in all fields of technology . . . " the Chinese Patent Law171 did not protect Traditional Chinese Medicine. Since the Law's amendment, there has been a significant **uptake in patent activity**, particularly related to Traditional Chinese Medicine-based pharmaceuticals, and many supporters of Traditional Chinese Medicine believe that **this** activity has **served to incentivize investment in T**raditional **C**hinese **M**edicine, **increase** the **T**raditional **C**hinese **M**edicine **knowledge base**, and transform Traditional Chinese Medicine into a major global export asset. 172 Since 1992, when the Patent Law was amended, applicants have filed patent applications with the State Intellectual Property Office of China (SIPO) at a rate of 1,400 cases a year, 173 but they have not limited their activity to China alone; they have also filed applications in countries such as Germany, Japan, the United Kingdom, and the United States. Moreover, patent holders have begun to enforce the rights they have been granted. For example, in February 2007, China Business News reported that a Chinese patentee Traditional Chinese Medicine manufacturer won the first Traditional Chinese Medicine infringement case against another Chinese company. The patentee was awarded an injunction prohibiting the infringing company from selling the infringing products as well as damages. 174 The **promotion** of Traditional Chinese Medicine has **led to** the establishment of organizations such as the Shanghai Innovative Research Center of Traditional Chinese Medicine (**SIRC**), 75 **which** in turn has further encouraged patent protection for TK. Founded in 2000 with support from the Chinese Ministry of Science and Technology and the Shanghai Municipal Government, SIRC **seeks to modernize T**raditional **C**hinese **M**edicine **and innovate drug discovery** "**by integrating modern life science, chemistry, and information technology** with [Traditional Chinese Medicine]"1 76 -just the right formula to maximize patenting potential. 177 Although the patent system may not be suited to all types of TK, using patents to protect Traditional Chinese Medicine seems to have achieved some success in encouraging new innovation and invention. Communities working to advance other areas of innovative TK may do well to follow China's example.

#### Innovation checks future disease – extinction

Engelhardt 8 [H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)] Recut Justin

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

### T-Medicines

#### Interpretation: “medicines” is a generic bare plural. The aff may not defend that member nations of the World Trade Organization ought to reduce intellectual property protections for a medicine or subset of medicines.

Nebel 19. [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs. He writes a lot of this stuff lol – duh.] “Genericity on the Standardized Tests Resolution.” Vbriefly. August 12, 2019. <https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/?fbclid=IwAR0hUkKdDzHWrNeqEVI7m59pwsnmqLl490n4uRLQTe7bWmWDO_avWCNzi14> TG

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions.

Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window.

So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why.

“Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons.

First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural.

Second, “colleges and universities” fails the [upward-entailment test](https://plato.stanford.edu/entries/generics/#IsolGeneInte) for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals.

Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universitiesz generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution.

#### It applies to “medicines” – 1] upward entailment test – “member nations of the World Trade Organization ought to reduce intellectual property protections for medicines” doesn’t entail that member nations of the WTO ought to reduce IPP for drugs because it doesn’t prove that marijuana protections should be reduced 2] adverb test – adding “always” to the res doesn’t substantially change its meaning because reduce is permanent.

#### Violation: They spec medicines based on indigenous knowledge

#### Standards:

#### [1] precision – the counter-interp justifies them arbitrarily doing away with random words in the resolution which decks negative ground and preparation because the aff is no longer bounded by the resolution. Independent voter for jurisdiction – the judge doesn’t have the jurisdiction to vote aff if there wasn’t a legitimate aff.

#### [2] Limits and ground – their model allows affs to defend anything from Covid vaccines to HIV drugs to Insulin— there's no universal DA since each has different functions and political implications — that explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible — limits key to reciprocal engagement since they create a caselist for neg prep and it takes out ground like DAs to certain medicines which are some of the few neg generics when affs spec medicines.

#### [3] TVA solves – you could’ve read your plan as an advantage under a whole res advocacy.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – a] deter future abuse and b] set better norms for debate.

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices