**FW**

**My value is morality because the use of the word ought the resolution implies moral obligation**

**My standard is maximizing expected wellbeing.**

**Prefer it for …**

**Actor specificity – governments and agents can only evaluate generalities**

**Goodin 90.** Robert Goodin 90, [professor of philosophy at the Australian National University college of arts and social sciences], “The Utilitarian Response,” pgs 141-142 //RS

My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about public officials and their situations that make it both more necessary and more desirable for them to adopt a more credible form of utilitarianism. Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices, but that is all. That is enough to allow public policy-makers to use the utilitarian calculus – assuming they want to use it at all – to choose general rules or conduct.

**Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.**

**Plan Text:**

**Drug Manufacturers should only be allowed to patent a drug once, regardless of any new additions made to the drug, aka “One and Done”**

**One and Done would structure medical patents differently instead of grouping it in with other tech  
Feldman, Robin**. “Drug Patent Protection: It’s Time for a ‘one-and-Done’ Approach.” *STAT*, 11 Feb. **2019**, **Robin Feldman** is a law professor, researcher, and author best known for her contributions to intellectual property and health care law. Feldman is the Arthur J. Goldberg Distinguished Professor of Law at the University of California, Hastings College of Law[1][2] Feldman is a widely cited expert on intellectual property and health care law, particularly as it relates to the pharmaceutical industry, drug policy, and drug pricing[www.statnews.com/2019/02/11/drug-patent-protection-one-done.](http://www.statnews.com/2019/02/11/drug-patent-protection-one-done.)

I believe that **one period of protection should be enough**. We should make the legal changes necessary to prevent companies from building patent walls and piling up mountains of rights. **This could be accomplished by a “one-and-done” approach for patent protection.** **Under it, a drug would receive just one period of exclusivity, and no more.** The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. **The result,** however, **is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity** (in which no generic is allowed to use the original drug’s safety and effectiveness data), **or something else** — **but not all of the above and more.** **Consider Suboxone**, a combination of buprenorphine and naloxone for treating opioid addiction. **The drug’s maker has extended its protection cliff eight times**, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. **The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That** **makes almost two additional decades** in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. **Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals**, **not for all types of technologies**. That way, **one-and-done could be implemented through legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward.

**Advantage 1 - Pricing**

**Exclusive protection for new drugs combined with pharma exploits lead to high prices** – Erin **Fox, 2017** [Erin Fox](https://hbr.org/search?term=erin%20fox&search_type=search-all) is the director of Drug Information at University of Utah Health. A teaching pharmacist, she tracks drug shortages for the American Society of Health-System Pharmacists. https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive

The 1984 [Drug Price Competition and Patent Term Restoration Act](https://blogs.fda.gov/fdavoice/index.php/tag/hatch-waxman-amendments/) **gave pharmaceutical companies exclusive protections for** innovating **a new drug**. If they brought a new therapy to life, they enjoyed patent protection **to effectively monopolize the market**. **That was the payoff for shouldering** **the** high risk and high **costs** **of developing new drugs**. But once the patent and the exclusive hold on the market expires, the legislation encouraged competition to benefit consumers. Any drug company would be able to manufacture non-brand name versions of the very same drug, so-called “generics.” And for a while, the system worked well. Not anymore. **The system intended to reward drug companies for their innovations, but eventually protect consumers**, **is systematically** being **broken**. **Drug companies** **are** **thwarting** competition **through** **a number of tactics**, **and** **the** **result** **is high prices**, little to no competition, and drug quality problems.er

**Patent Expiration allows for new generic manufacturers to enter the market.**

**Pharmexec** 19**98** https://www.pharmexec.com/view/what-happens-when-product-loses-its-patent

**Losing patent protection on a prescription drug** is one certainty in the constantly changing world of pharmaceuticals. Just as surely as a company patents its breakthrough product at the beginning of its development process, that patent will expire approximately 20 years down the road, **leav**ing **the door open for generic products to enter the market.** And the end of a product's life cycle will affect all areas of a pharmaceutical company, including its sales force.er

**Generics reduce cost 85% through competition**

**FDA 2018 https://www.fda.gov/drugs/generic-drugs/generic-drug-facts**

**Generic medicines** tend to **cost less than their brand-name counterparts** because they do not have to repeat animal and clinical (human) studies that were required of the brand-name medicines to demonstrate safety and effectiveness. In addition, **multiple applications for generic drugs are often approved to market a single product**; **this creates competition in the marketplace**, typically **resulting in lower prices. The reduction in upfront research costs means that**, although **generic medicines** have the same therapeutic effect as their branded counterparts, they **are** typically **sold at substantially lower costs**. **When multiple generic companies market a single approved product, market competition typically results in prices about 85% less** **than the brand-name**. According to the IMS Health Institute, **generic drugs saved the U.S. health care system $1.67 trillion** from 2007 to 2016. [[1]](https://www.fda.gov/drugs/generic-drugs/generic-drug-facts#f1)er

**IMPACTS:**

**1 1.5 million US citizens are endangered by high insulin prices, aff solves.**

**Irl B. Hirsch 2016 Aug 29** [**https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5001219/**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5001219/)

Because of the patient population in our hospital (a “disproportionate share” hospital), we had a 340B drug pricing program from the federal government. This had allowed my patients (with or without insurance) to obtain their insulin at extremely low prices. Through this program, patients paid less than their copayments for their insulin—often several hundred dollars less for a 3-month supply. However, we lost this program in early 2016, and now patients have to pay full retail prices. **One woman on an insulin pump noted after she went to pick up her insulin and had to pay the full retail price that “my insulin now costs more than my home mortgage.”** This, to me, seems like a crisis. **Patients literally need to decide if they will pay for their insulin or for their housing and food.** And for patients with type 1 diabetes, there are not many options. Although I acknowledge that the various patient assistance programs can be helpful and are underutilized (but also add a major level of difficult bureaucracy to the system), wouldn’t it make more sense to make the pricing more reasonable in the first place? In early 2015, I was asked to give a talk about insulin pricing in the United States as part of a symposium at the American Diabetes Association (ADA) Scientific Sessions in Boston, Mass. Little could I have imagined the impact that single talk would make on everyone who heard it. The most interesting comment I heard repeatedly after the talk was how “brave” I was to give such a transparent talk against the insulin companies. In reality, at the time, I did not have a good understanding of how the various “middlemen” or “drug channel companies” (pharmacy benefit managers [PBMs], wholesalers, and chain pharmacies) could affect final prices to patients. An article written by Kasia Lipska and published in the New York Times earlier this year provides an important lesson about how PBMs work (7). Dr. Lipska noted that the three largest PBMs bring in more than $200 billion per year in revenue and further explained how the “rebates” from the drug companies “look suspiciously similar to kickbacks.” Another excellent review of this complex system was published recently in Diabetes Forecast, the ADA magazine for people with diabetes (8). So where does all of this leave us now? We were recently told that **insulin pricing increased threefold between 2002 and 2013** and that the expenditure for insulin per patient in the United States was greater than for all other antihyperglycemic medications combined (9). **As a society, how do we rationalize the fact that this elixir, required for survival by ∼1.5 million people and used by another 4.5 million in the United States, has become unaffordable for many?** Is this what the original group from the University of Toronto wanted in 1922? I know this was never the goal of Eli Lilly at that time (10).cs

**2 Price is a major barrier to those wanting to receive HIV/AIDS treatment                   MSF 1 May 20 02** [**https://www.msf.org/patents-prices-patients-example-hivaids**](https://www.msf.org/patents-prices-patients-example-hivaids)

**In several Caribbean** **countries, HIV/AIDS has become a leading cause of death**\*. The AIDS epidemic is having major consequences for tropical infectious diseases in the region, such as Chagas disease (American trypanosomiasis) and tuberculosis. **Hundreds of thousands of people with HIV/AIDS in developing countries in the Americas do not have access to antiretroviral therapy** which, in wealthy countries such as the U.S., has dramatically extended and improved the lives of people living with HIV/AIDS, reducing AIDS-related deaths by over 70%\*\* —simply because they cannot afford it. **Price is** not the only reason that people do not get the medicines they need, but it is **a major barrier**. As MSF and other non-governmental organizations have been pointing out for over two years, the high cost of medicines is often linked to patents. **Patents give their owners a monopoly to use, manufacture, sell, and import the patented product and therefore to sell it at the most profitable price, which may not be the most equitable price in most developing countries. Generic competition is crucial to ensuring downward pressure on drug prices**—as we have witnessed in countless instances in the field, particularly with antiretrovirals for the treatment of HIV/AIDS. **Just two years ago, the average cost of a triple combination of antiretrovirals was between $10,000-$15,000 per patient per year, and today it is available for as little as $300 per patient per year. These price reductions were the direct result of international public pressure and generic competition, particularly from Indian and Brazilian manufacturers. Generic competition was possible because of the lack of patent protection in those countries.** In the coming years, such competition will not be possible due to the filing of patents on pharmaceuticals in key developing countries with manufacturing capacity, unless flexible conditions for granting compulsory licenses are available, as per the Doha Declaration, and compulsory licenses are routinely issued to address public health concerns. Compulsory licensing of pharmaceuticals is one of the most important policy tools for ensuring generic competition.cs

**Final card: solvency - rAmin 20 to prove that when we have these restrictions, prices go down.**

We Need to Take On Drug Companies’ Abuse of the Patent System, TAHIR **AMIN 20,** <https://www.jacobinmag.com/2020/12/pharmeceutical-industry-patent-system-antitrust-law> Tahir Amin is the cofounder and co-executive director of I-MAK, a global nonprofit organization building a more just and equitable medicines system for all. /chs niv + ear

Tellingly, **the judge presiding over the case commented that AbbVie** **had exploited advantages conferred on it through lawful practices permitted by the patent system**. He added that, **to the extent this had kept Humira prices high, existing antitrust doctrine does not prohibit it**. In other words, **abuse of the patent system is permitted by law.** The case is currently under appeal. Meanwhile, **Americans will have to wait until 2023 before competitive products can enter the market and bring prices down. In Europe, where AbbVie’s monopoly on Humira ended in 2018, prices have already dropped by 70 percent**. Inaction on patent abuse is rooted in the fear that strong enforcement would harm “innovation.” To that end, antitrust law has become deferential to patent law and also needs a reboot. **The consequence for pharmaceutical companies who behave anti-competitively, if there are any, is usually a fine**. **But the profits reaped through patent abuse typically far exceed the amount of the fine**. As a result, the threat of a fine does little to deter patent shenanigans. **Under our current system, it pays to get as many patents as possible and risk the possibility of a slap on the wrist.**

**Advantage 2  - Innovation**

**Re-patenting drugs has destroyed market competition and innovation**

**Feldman** R. May your drug price be evergreen. *J Law Biosci*. 2018;5(3):590-647. Published 20**18** Dec 7. doi:10.1093/jlb/lsy022 /chsear **Robin Feldman** is a law professor, researcher, and author best known for her contributions to intellectual property and health care law. Feldman is the Arthur J. Goldberg Distinguished Professor of Law at the University of California, Hastings College of Law[1][2] Feldman is a widely cited expert on intellectual property and health care law, particularly as it relates to the pharmaceutical industry, drug policy, and drug pricing

As described in the opening of this article**, the intellectual property system in general and the patent system in particular are designed to provide an opportunity for innovators to garner a return**. Competition may be held in abeyance for a limited time, but those who receive the benefit must pay for the privilege by disclosing sufficient information that competitors will be able to step in. **This design reflects the deeply rooted notion that providing a period of exclusivity for inventors is intended to rebound to the benefit of society as a whole,** not simply to the benefit of the inventors. **The patent protection should end, returning the market to a competitive state**. **This foundational structure of the patent system**—one that delicately balances innovation and competition—**is crumbling, whittled away across time as one good idea after another creates a special carve-out**. **Each carve-out**, standing on its own, **presents an appealing cause**. **Together,** however, **the result is a complete undermining of the system for pharmaceutical innovation** **as** the **repeated addition of protections**, one after another, **pushes competition further into the future**, **threatening innovation** in the process. The behavior is not limited to a few bad apples. Our research reveals that **it is endemic to the pharmaceutical industry**. In short, this is not an image of innovation and competitive entry. It is an image of a system that provides for repeated creation of competition-free zones, pushing a competitive market further and further out into the future. **The problem is not only pervasive and persistent, but it is also growing across time**. **The impact** created by these repeated competition zones **is not some abstract problem that our grandchildren may face.** **Rather, the nation's pharmaceutical system is in crisis today,** with prices soaring to heights that distort both individual and government budgets.[151](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn151) These dire circumstances bring calls for price controls, for government marching in to direct drug production, and for other strong measures.[152](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn152) The US Government's history of directly managing pharmaceutical innovation, however, has been disappointing. In fact, prior to the Bayh-Dole Act of 1980, the federal government took responsibility for handing out licenses for innovation developed through government-funded research. Bayh-Dole shifted that responsibility from the federal government to universities, precisely because the government failed so miserably in this role. There is little reason to expect a different result this time.[153](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn153)

**One and done brings back pharma competition**

**Feldman** R. May your drug price be evergreen. *J Law Biosci*. 2018;5(3):590-647. Published 20**18** Dec 7. doi:10.1093/jlb/lsy022 /chsear **Robin Feldman** is a law professor, researcher, and author best known for her contributions to intellectual property and health care law. Feldman is the Arthur J. Goldberg Distinguished Professor of Law at the University of California, Hastings College of Law[1][2] Feldman is a widely cited expert on intellectual property and health care law, particularly as it relates to the pharmaceutical industry, drug policy, and drug pricing

**One-and-Done** and Ruthless Simplification, **coupled with transparency measures**, **could go a long way towards returning the system of pharmaceutical innovation to its proper competitive pathway**. There will, of course, be much wailing and gnashing of teeth. **The pharmaceutical industry has become comfortably accustomed to working with a system that provides space for creating non-competitive environments. The industry will not relinquish this environment with ease and grace**, and the nation is likely to hear impassioned pleading that pharmaceuticals cannot withstand any reform of the current system.[187](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn187) Along similar lines, the CEO of the pharmaceutical company Allergan published a 2017 Op-Ed in the Wall Street Journal arguing that the 2011 patent reforms, which created a new post-grant review process for patents, left the company with no choice but to transfer their patents to Indian tribes to avoid having the patents reviewed.

**When companies plead with government for benefits by arguing that they cannot withstand competition, one should be deeply skeptical. Our challenge as a society is to restore the balance provided by the patent system** itself, **in which the inventor** **of a** truly innovative **product** **receives** a **limited** period **time** **to** attempt to **garner a return**, **following which, open competition reigns supreme**. The system has strayed far from that ideal.

**Medical Innovation Saves Lives**

**Paranicas** New Brunswick, NJ, December 18, 2014 ― [HealthCare Institute of New Jersey (HINJ)](https://hinj.org/) President and Chief Executive Officer Dean J. has authored the following op-ed on the life sciences and the value of medical innovation.https://hinj.org/the-value-of-medical-innovation-saving-lives-saving-money/ /chsear

**Medical innovations produced by American life sciences companies have vastly improved the human condition. Our pharmaceutical**, biotech, medical technology, device and diagnostics **companies have helped people live longer, with** less pain and **greater quality of life.** **Over the past century**, the life sciences **has eradicated some of the world’s** most dreaded **diseases** **such as polio and smallpox**. More recently, the industry has made other diseases such as breast cancer, HIV/AIDS, heart disease and lung cancer no longer the death sentences that they once were. **Collectively, new therapies are the greatest contributors to increased life expectancy.** According to the [National Bureau of Economic Research](http://www.nber.org/papers/w18235) (NBER), between 1960 and 1997, **new therapies accounted for 45 percent of the increase in life expectancy in 30 developing and high-income countries**. Between 2000 and 2009, new therapies accounted for 73 percent of the increased life expectancy for these countries. Despite the dramatic life-saving advancements that the life sciences sector has made, our work is far from done. Diabetes, Alzheimer’s, Ebola, different types of cancers, and other formidable medical conditions demonstrate the compelling need for America’s medical innovation community to build upon its tremendous achievements to continue saving lives around the world. Toward that goal, every day, teams of scientists from New Jersey companies go to work to research and discover the next generation of medicines, therapies, devices, technologies and diagnostic tools that will alleviate even more of these life-threatening and life-altering diseases.