# FW

## [Feser] Commitments to equal human freedom necessitates a minimal state that respects self- ownership

## Professor of Philosophy Edward Feser writes in 2002

(Edward Feser, Robert Nozik (1938 – 2002) www.iep.utm.edu/nozick/)

Nozick takes his position to follow from a basic moral principle associated with Immanuel Kant and enshrined in Kant's second formulation of his famous Categorical Imperative: "Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only." The idea here is that a human being, as a rational agent endowed with self-awareness, free will, and the possibility of formulating a plan of life, has an inherent dignity and cannot properly be treated as a mere thing, or used against his will as an instrument or resource in the way an inanimate object might be. In line with this, Nozick also describes individual human beings as self-owners (though it isn't clear whether he regards this as a restatement of Kant's principle, a consequence of it, or an entirely independent idea). The thesis of self-ownership, a notion that goes back in political philosophy at least to John Locke, is just the claim that individuals own themselves - their bodies, talents and abilities, labor, and by extension the fruits or products of their exercise of their talents, abilities and labor. They have all the prerogatives with respect to themselves that a slaveholder claims with respect to his slaves. But the thesis of self-ownership would in fact rule out slavery as illegitimate, since each individual, as a self-owner, cannot properly be owned by anyone else. (Indeed, many libertarians would argue that unless one accepts the thesis of self-ownership, one has no way of explaining why slavery is evil. After all, it cannot be merely because slaveholders often treat their slaves badly, since a kind-hearted slaveholder would still be a slaveholder, and thus morally blameworthy, for that. The reason slavery is immoral must be because it involves a kind of stealing - the stealing of a person from himself.) But if individuals are inviolable ends-in- themselves (as Kant describes them) and self-owners, it follows, Nozick says, that they have certain rights, in jmparticular (and here again following Locke) rights to their lives, liberty, and the fruits of their labor. To own something, after all, just is to have a right to it, or, more accurately, to possess the bundle of rights - rights to possess something, to dispose of it, to determine what may be done with it, etc. - that constitute ownership; and thus to own oneself is to have such rights to the various elements that make up one's self.

These rights function, Nozick says, as side-constraints on the actions of others; they set limits on how others may, morally speaking, treat a person. So, for example, since you own yourself, and thus have a right to yourself, others are constrained morally not to kill or maim you (since this would involve destroying or damaging your property), or to kidnap you or forcibly remove one of your bodily organs for transplantation in someone else (since this would involve stealing your property). They are also constrained not to force you against your will to work for another's purposes, even if those purposes are good ones. For if you own yourself, it follows that you have a right to determine whether and how you will use your self-owned body and its powers, e.g. either to work or to refrain from working. So far this all might seem fairly uncontroversial. But what follows from it, in Nozick's view, is the surprising and radical conclusion that taxation, of the redistributive sort in which modern states engage in order to fund the various programs of the bureaucratic welfare state, is morally illegitimate. It amounts to a kind of forced labor, for the state so structures the tax system that any time you labor at all, a certain amount of your labor time - the amount that produces the wealth taken away from you forcibly via taxation - is time you involuntarily work, in effect, for the state. Indeed, such taxation amounts to partial slavery, for in giving every citizen an entitlement to certain benefits (welfare, social security, or whatever), the state in effect gives them an entitlement, a right, to a part of the proceeds of your labor, which produces the taxes that fund the benefits; every citizen, that is, becomes in such a system a partial owner of you (since they have a partial property right in part of you, i.e. in your labor). But this is flatly inconsistent with the principle of self-ownership. The various programs of the modern liberal welfare state are thus immoral, not only because they are inefficient and incompetently administered, but because they make slaves of the citizens of such a state. Indeed, the only sort of state that can be morally justified is what Nozick calls a minimal state or "night-watchman" state, a government which protects individuals, via police and military forces, from force, fraud, and theft, and administers courts of law, but does nothing else. In particular, such a state cannot regulate what citizens eat, drink, or smoke (since this would interfere with their right to use their self-owned bodies as they see fit), cannot control what they publish or read (since this would interfere with their right to use the property they've acquired with their self-owned labor - e.g. printing presses and paper - as they wish), cannot administer mandatory social insurance schemes or public education (since this would interfere with citizens' rights to use the fruits of their labor as they desire, in that some citizens might decide that they would rather put their money into private education and private retirement plans), and cannot regulate economic life in general via minimum wage and rent control laws and the like (since such actions are not only economically suspect - tending to produce bad unintended consequences like unemployment and housing shortages - but violate citizens' rights to charge whatever they want to for the use of their own property).

## [Boaz] Self-ownership provides the basis for action, making it the starting point of ethics.

**Boaz 97**, David Boaz (Executive vice president, Cato Institute). “Libertarianism: A Primer.” Simon & Schuster. pp 61-62. 1997.

Any theory of rights has to begin somewhere. Most libertarian philosophers would begin the argument earlier than Jefferson did. Humans, unlike animals, come into the world without an instinctive knowledge of what their needs are and how to fulfill them. As Aristotle said, man is a reasoning and deliberating animal; humans use the **power of reason** to understand their own needs, the world around them, and how to use the world to satisfy

their needs. So they need a social system that **allows them to use their reason**, to act in the world, and to cooperate with others to achieve purposes that no one individual could accomplish. Every person is a unique individual. Humans are social animals—we like interacting with others, and we profit from it— but we think and act individually. **Each individual owns [themselves]** himself or herself**.** What other possibilities besides self—ownership are there? • Someone – a king or a master race – could own others. Plato and Aristotle did argue that there were different kinds of humans, some more competent than others and thus endowed with the right and responsibility to rule, just as adults guide children. Some forms of socialism and collectivism are—explicitly or im- plicirly—-based on the notion that many people are not compe- _ tent to make decisions about their own lives, so that the more talented should make decisions for them. But that would mean there were no universal human rights, only rights that some have and others do not, denying the essential humanity of those who are deemed to be owned. • [If] Everyone owns everyone, a fully-fledged communist system. In such a system, before anyone could take an action, he [they] would need to get permission from everyone else. But how could each other person grant permission without consulting everyone else? You'd have an **infinite regress**, making any action at all logically impossible. In practice, since such mutual ownership is impossible, this system would break down into the previous one: some- one, or some group, would own everyone else. That is what happened in the communist states: the party became a dictato- rial ruling elite. Thus, either communism or aristocratic rule would divide the world into factions or classes. **The only possibility that is** humane, **logical**, and suited to the nature of human beings **is self-ownership.** Obviously, this discussion has only scratched the surface of the question of self-ownership; in any event, I rather like Jefferson's simple declaration: Natural rights are self-evident.

**[Criterion] Thus, my value criterion is rejecting governmental coercion. It may be morally virtuous to help the poor but that doesn't mean that you can steal money from someone else and give it to the poor so that you help them because that's an act of coercion which violates someone else's freedom.**

# C1 – forced charity

## [Bapanapalli] Forced charity hurts society & violates the right to pursue one's own ends

**Bapanapalli 2020** (Why Forced 'Charity' Is Bad Economics, May 13 2020, Satish Bapanapalli, Foundation for Economic Education, https://fee.org/articles/why-forced-charity-is-bad-economics/) //neth

Fulfillment from Charity I couldn't agree more. Just like freedom is a fundamental desire of every human being, so is the desire to help fellow humans. Individuals express charity in many other forms such as support towards animal welfare, nature conservancy, promotion of arts, incentivizing fundamental research, and environmental causes. Not to be a cynic, but the fulfillment that charity brings to people is just like any other service. We pay a price to watch a movie or have a great time at an amusement park like Universal Studios. In return, we get the satisfaction of great memories. In the case of charity, the price we pay brings us fulfillment. So, why is it important to view fulfillment derived from charity just like any other commodity? Because then economists can apply their theories and have fun! (*huge economist grin*) Let's consider two thought experiments. First, how would you feel if your desire is to buy a Lexus sedan with your money, but you are forced to buy a Hyundai sedan instead for the same price, even though the Hyundai sedan is priced much lower in the market? Second, let's say you get great satisfaction by donating your money to the Wounded Warrior Project. However, you are instead forced to donate that money to help with protection of Indian Rhinoceros' habitat. How does that make you feel? Both thought experiments are similar. Buying a Lexus sedan and donating to Wounded Warrior Project are your personal choices. That is why charity is personal! If you are instead coerced to donate to charities that you do not relate to, then you do not derive equivalent fulfilment out of that donation.

## [Bapanapalli] Forced charity encourages dependence

**Bapanapalli 2020** (Why Forced 'Charity' Is Bad Economics, May 13 2020, Satish Bapanapalli, Foundation for Economic Education, https://fee.org/articles/why-forced-charity-is-bad-economics/) //neth

And worst of all, people who are being forced by the government to perform this 'charity' do not even get the satisfaction of having helped fellow human beings in need due to the impersonal nature of charity via government welfare programs. And the welfare recipients don't feel grateful, because politicians and activists have convinced them that welfare is a government-given right, not a charitable gift. In countries with highly homogenous populations like Scandinavian countries, charitable people still derive adequate satisfaction from government-enforced 'charity' because they can relate to the recipients of government 'charity'. That is why a large welfare state in such countries does not lead to perceptible public dissatisfaction. As the countries become more non-homogenous, the dissatisfaction levels increase considerably. The US is a good example. Private charities are able to positively discriminate against people who are capable of standing up on their own feet but willfully refuse to do so versus people who are in genuine need of charity. As Jude Blanchette puts it, "aid given without nourishment of a man's character would accomplish little except to demean him". Government 'charity' has little room for such positive discrimination due to the bureaucratic nature of enforcement by rigid rules, and in fact encourages dependency due to bad incentives such as bigger welfare rolls leading to bigger welfare

budgets for the bureaucrats. Here is a quirky way to summarize the 'charity' enforced by US federal and state governments. You want to buy a Lexus sedan for $50,000. But the government is instead taking away $150,000 from you and in return giving you a Hyundai sedan that is priced at $20,000. That is, you are being coerced to spend the difference of $130,000 without deriving any value from it. Bad economics! In free-market economic transactions, both the buyer and seller mutually benefit from a transaction. And that's what happens in voluntary charity too. The charitable people (buyers) voluntarily give their preferred amount of money to causes they believe in. The recipients of charity (sellers) are grateful for the much-needed help. That's good economics. In government-enforced 'charity', the buyers (taxpayers) do not get fulfillment commensurate with their expenditure because they are forced to spend way more money than they intended to and on causes they don't necessarily believe in. Even the sellers (welfare recipients) do not get proportionate satisfaction because they think they have a right to more welfare payments and that they are being short changed by the government and "the system". That's bad economics overall! Bad economic policies result in lackluster economic growth which leads to more poverty. The share of the US population in poverty was declining rapidly until Lyndon Johnson declared his ill-conceived "war on poverty" in the 1960s via a massive expansion of the welfare state. Since then the share of the US population in poverty has stalled around 14 percent. Forced

# C2 - property rights

## [Mercurio] IPP was necessary to produce the vaccine – waiving property rights now will end cooperation for future diseases

**Mercurio 2021** (Bryan Mercurio, June 24 2021, "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/) //neth

When asked if a waiver would improve vaccine availability and equity, Watal responded: "No. It won't. That's clear."21 I share Watal's view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that "what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South"22 I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.23 IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.24 Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

## [PRI] Waiving IPP brings multiple problems – counterfeits, production issues, and lack of innovation, to name a few

**PRI 2021** (Pacific Research Institute, June 21 2021, "Waiving Covid-19 Vaccine Patents Is a Bad Idea and Sets a Dangerous Precedent," WAYNE WINEGARDEN, ROBERT POPOVIAN, PETER PITTS, TOWNHALL.COM, https://medecon.org/waiving-covid-19-vaccine-patents-is-a-bad-idea-and-sets-a-dangerous-precedent/) //neth

The production of these breakthrough Covid-19 vaccines requires sophisticated processes, procedures, staff training, material, and manufacturing. Under typical patent-protected arrangements for new global production facilities, patent-holders voluntarily license their product information to qualified third party-manufacturers. The patent-owners work closely with the licensees to stand up facilities that meet rigorous technological specifications and standards for safety. Even under ideal conditions, it can take a year or longer to build out this infrastructure the right way. The WTO waiver blows up this careful process by allowing pretty much anyone to go into the business of producing Covid-19 vaccines. Suddenly, it's the wild west out there, with legitimate producers trying to compete with aggressive cost and corner-cutters, to say nothing of the outright fraud that has long driven the lucrative counterfeit drug trade. All the research demonstrating the safety and efficacy of the Covid-19 vaccines goes out the window under such conditions. Nor is such a process going to produce faster results. Historically, under compulsory rather than voluntary licensing arrangements, it has taken even legitimate generic manufacturers years to receive the formulas, work out logistical challenges, and scale up production. In one case of compulsory licensing, it took over four

years to bring a generic AIDS drug to Rwanda. The World Health Organization regularly publishes a list of “essential” medications, the vast majority of which patent protections have long expired. Any generic manufacturer can therefore set itself up producing them. Yet the WHO reports that availability of these medicines in many parts of the developing world remains spotty, at best. The quality of many of these essential medicines is also questionable. Yet none of the drugs on the WHO list are in the same universe of complexity as the Covid-19 vaccines. The patent system is not the problem here. But, some ask, why should private companies enjoy the property rights to innovation driven by government funding? This question likewise misses the mark. In a study of 478 drugs less than 10 percent had a public-sector patent associated with it. While providing no gain, compulsory licensing promises lots of pain. Shunting aside patent and intellectual property rights sends a dangerous signal to innovative biopharmaceutical companies and their investors. Biopharmaceutical research is risky. It costs almost $3 billion, on average, to bring a single medicine to pharmacy shelves. Biotech investors take these risks because of strong patent protection like those in the United States. Scientists in America now develop over half of all new drugs worldwide. It’s important to understand the current advocacy for a “temporary” IP waiver. A small but vocal and influential public health policy cohort believes that IP protections are the most significant cause of global healthcare disparities. Their philosophies repeat and reinforce many misconceptions about the problem of improving global access to medicines. The reality is that, in order to save the world, we must all work together as partners. A free-market healthcare paradigm for drug development, although far from perfect, works. A well-appointed armamentarium of Covid-19 diagnostic tools, therapeutics, and vaccines – all invented in under one year, speaks to the power of today’s innovation ecosystem. That ecosystem is built on IP protections. Right now, under voluntary licensing, global production capacity for Covid vaccines and treatments is expanding and accelerating. A move to nullify IP will not result in a single resident of the developing world getting vaccinated one minute sooner.

## [Burger & Nebehay] Open Licensing misses the problem – trade bottlenecks are causing the vaccine delays, not IPP

**Burger & Nebehay 2021** (Ludwig Burger and Stephanie Nebehay, May 6 2021, “Drugmakers say Biden misguided over vaccine patent waiver,” Reuters, ) //neth

GENEVA, May 6 (Reuters) - Drugmakers on Thursday said U.S. President Joe Biden's support for waiving patents of COVID-19 vaccines could disrupt a fragile supply chain and that rich countries should instead share more generously with the developing world. Biden on Wednesday threw his support behind waiving intellectual property rights for COVID-19 vaccines, angering research-based pharmaceutical companies. read more If adopted by the World Trade Organisation, the proposal would invite new manufacturers that lack essential know-how and oversight from the inventors to crowd out established contractors, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) said. "I have heard many (vaccine makers) talking about 'our resources are stretched, our technicians are stretched'," IFPMA Director General Thomas Cueni told Reuters. He warned of a possible free for all if "sort of rogue companies" were allowed to become involved. Vaccine developers echoed his comments that waiving intellectual property rights was not a solution. "Patents are not the limiting factor for the production or supply of our vaccine. They would not increase the global production and supply of vaccine doses in the short and middle term," said Germany's BioNTech, which aims to supply up 3 billion doses together with Pfizer (PFE.N) this year. read more BioNTech said it took more than a decade to develop its vaccines manufacturing process and replicating it required experienced personnel and a meticulous technology transfer, among several other factors beyond patents. Another German company CureVac (5CV.DE), which hopes to release trial results on its messenger ribonucleic acid (mRNA) vaccine as early as this month, said patents were not to blame for supply bottlenecks. "Since mRNA technology has emerged as the key technology in the fight against COVID-19, the world now needs the same raw materials in unfathomable amounts. The biggest problem is how to coordinate this," a spokeswoman said. IFPMA's Cueni said the real bottlenecks were trade barriers, in particular the U.S. Defense Production Act (DPA). The DPA is a decades-old U.S. law that prioritised procurement orders related to U.S. national defence, but it has been widely used in non-military crises, such as natural disasters. Cueni said the way to kickstart low-income countries' vaccination campaigns was for rich countries to donate vaccine, rather than widen eligibility to young and healthy people at home. Moderna (MRNA.O), which on Thursday reported quarterly results, said waiving intellectual property rights would not help to increase supply of its vaccines in 2021 and 2022. The U.S. drugmaker said last year it would not enforce its vaccine patents. CureVac said on Thursday it would also not enforce its patents during the pandemic and that it knew of no other developer that would. Italy's ReiThera which is in late-stage tests on an experimental COVID-19 vaccine, was also critical of patent waivers. "There is proprietary know-how that has to be transferred by the owner. And then there is the problem with process materials, which at the moment have delivery times of almost a year," ReiThera's chief of technology Stefano Colloca said. In contrast to the industry reaction, the GAVI vaccine alliance, which co-leads the COVAX dose-sharing programme with the WHO and faces major supply constraints, welcomed Biden's support for waiving intellectual property rights.

Structral violence

1. No value to life and no reaosn to reduce

structural violenc eunless we reudc eogvnerental coercion. Bc we hav eno autonomy

2. Reducing govenrmental coercion is a prereq to their fwk- if govs are ht ones who are comminting sv, this is solved by my fw bc we only make sure govs provides safety protects rights

## *1-- Lack of IP protection makes medical innovation prohibitively risky and expensive*

**Grabowski et al 15** [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) "The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation," Health Affairs, 2/2015] TDI

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. [5] The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. [6] Only approximately one in eight drug candidates survive clinical testing. [6]

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). [7,8] Once a new drug's patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market**.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians' choices for patient treatment.

Patents play an essential role in the economic "ecosystem" of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. [11] The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

POVERTY

- Medical costs not the problem other ways to solve--- universal healthcare, govermnets providing subsitied, increasing govneremnt welfare, so on.

Access to medicine---

## *2--- Limited manufacturing and poor distribution infrastructure outweigh---their evidence.*

**Khullar 21**. [(Dhruv Khullar is a contributing writer at The New Yorker, where he writes primarily about medicine, health care, and politics. He is also a practicing physician and an assistant professor at Weill Cornell Medical College) "India's Crisis Marks a New Phase in the Pandemic," The New Yorker, May 13, 2021. https://www.newyorker.com/science/medical-dispatch/indias-crisis-marks-a-new-phase-in-the-pandemic] TDI

Jha told me that he **worries less about I.P.** and incentives than about the **practical obstacles to vaccine production.** The primary barriers to vaccine availability, he said, are not rigid intellectual-property

protections but **limited manufacturing capacity and poor distribution infrastructure.** Only a **small number of companies** have the expertise needed to manufacture covid-19 vaccines, especially ones that use new mRNA technology, and **scaling up takes time.** "The world wasn't ready to produce five or ten billion doses of covid vaccines," Jha said. "We don't just have all this excess capacity sitting around. You need raw materials, production capabilities, liner bags, a whole bunch of complex machinery and supplies." Absent "a broader package of funding, supplies, manufacturing, and people with technical know-how," Jha said, **waiving I.P. rights wouldn't help India escape the crisis that it faces today.**

***Reuding ippis insufficient to narrow the structural supply gap between wealthy nations and their developing counterparts – cumbersome licensing measures and lack of technological transfer ensure failure.***

Weak patents
Warrant is more comepition and generics

***Generic drugs send their worst quality drugs to LDCs where risk of inspection is the lowest – this is a form of medical colonialism***

**Eban 19** [Katherine Eban, an investigative journalist and the author of the New York Times bestseller Bottle of Lies: The Inside Story of the Generic Drug Boom, May 17 2019, "How Some Generic Drugs Could Do More Harm Than Good," Time Magazine, https://time.com/5590602/generic-drugs-quality-risk/ ]/Triumph Debate

For the 16 years that Dr. Brian Westerberg, a Canadian surgeon, worked volunteer missions at the Mulago National Referral Hospital in Kampala, Uganda, scarcity was the norm. The patients usually exceeded the 1,500 allotted beds. Running water was once cut off when the debt-ridden hospital was unable to pay its bills. On some of his early trips, Westerberg even brought over drugs from Canada in order to treat patients. But **as low-cost generics made in India and China became widely available through Uganda's government and international aid agencies in the early 2000s, it seemed at first like the supply issue had been solved. Then on February 7, 2013, Westerberg examined a feverish 13-year-old boy who had fluid oozing from an ear infection. He suspected bacterial meningitis, though he couldn't confirm his diagnosis because the CT scanner had broken down. The boy was given intravenous ceftriaxone, a broad-spectrum antibiotic that Westerberg believed would cure him. But after four days of treatment, the ear had only gotten worse**. As Westerberg prepared to operate, the boy had a seizure. With the CT scanner working again, Westerberg ordered an urgent scan, which revealed small abscesses in the boy's skull, likely caused by the infection. When a hospital neurosurgeon looked at the images and confidently declared that surgery was unnecessary and the swelling and abscesses would abate with effective antibiotic treatment, Westerberg was confused. They had already treated the boy with intravenous ceftriaxone, which hadn't worked. His confusion deepened when his colleague suggested that they switch the boy to a more expensive version of the drug. Why swap one ceftriaxone for another? Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it's made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. PAID PARTNER CONTENT 6 Prepaid Funeral Plan Myths: Learn More BY DIGNITY MEMORIAL **But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called "R.O.W. markets" — the generic-drug industry's shorthand for "Rest of World." In swaths of Africa, Southeast Asia and other areas with developing**

**markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive**. But Africa soon became an avenue "to send anything at all," said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. **The poor quality has affected every type of medication, and the adverse impact on health has been "astronomical,"** he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says **that almost all the drugs his patients take are substandard, leading him to increase his patients' doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he'll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams "won't do anything."** Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was "still smiling," Donnir said. Many hospitals also keep a stash of what they call "fancy" drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn't. Confronted with the ailing boy at the Mulago hospital, Westerberg's colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg's Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough "fancy" drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: "It's anesthesia today, ceftriaxone tomorrow, amoxicillin the next day." Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who'd had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy's death. Another of Westerberg's colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson's lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC's Morbidity and Mortality Weekly Report. Although they couldn't say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world's top pharmaceutical standard-setting organizations, calls that argument "totally garbage." For any given drug, he says, "There's only one standard, and that standard was set by the originator," meaning the brand-name company that developed the product. It's not just those in developing markets who should be alarmed. **Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP's chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit**. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like "putting out fire with gasoline." **USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance**. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an "independent pillar" in the global menace of drug resistance. **The low cost of generic drugs makes them essential to global public health. But if those bargain drugs are of low quality, they do more harm than good**. For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. **Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won't be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, "The fact is, pathogens know no borders."**

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