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I negate the resolution, “The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines”.

Since the resolution is dealing with public policy, the value is Utilitarianism

First,

Only consequentialism can justify policy to the public, Woller 97

Gary Woller [BYU Prof., “An Overview by Gary Woller”, A Forum on the Role of Environmental Ethics, June1997, pg. 10]

Moreover, virtually all public policies entail some redistribution of economic or political resources, such that one group's gains must come at another group's expense.Consequently, **public policies** in a democracy **must be justified to the public**, and especially to those who pay the costs of those policies**. Such justification cannot** simply **be assumed a priori by invoking some higher-order moral principle. Appeals to a priori moral principles**, such as environmental preservation, also often **fail toacknowledge that public policies** inevitably **entail trade-offs among competing values.**Thussince policymakers cannot justify inherent value conflicts to the public in any philosophical sense, and since public policies inherently imply winners and losers, **the policymakers' duty to the public interest requires them to demonstrate that** the redistributive effects and **value trade-offs implied by their policies are somehow to the** overall **advantage of society.**At the same time, deontologically based ethical systems have severe practical limitations as a basis for public policy. At best, a priori moral principles provide only general guidance to ethical dilemmas in public affairs and do not themselves suggest appropriate public policies, and at worst, they create a regimen of regulatory unreasonableness while failing to adequately address the problem or actually making it worse. For example, a moral obligation to preserve the environment by no means implies the best way, or any way for that matter, to do so,just as there is no a priori reason to believe that any policy that claims to preserve the environment will actually do so.Any number of policies might work, and others, although seemingly consistent with the moral principle, will fail utterly.That deontological principles are an inadequate basis for environmental policy is evident in the rather significant irony that most forms of deontological based environmental laws and regulations tend to be implemented in a very utilitarian manner by street-level enforcement officials. Moreover, ignoring the relevant costs and benefits of environmental policy and their attendant incentive structures can, as alluded to above, actually work at cross purposes to environmental preservation. (There exists an extensive literature on this aspect of regulatory enforcement and the often perverse outcomes of regulatory policy. See, for example, Ackerman, 1981; Bartrip and Fenn, 1983; Hawkins, 1983, 1984;Hawkins and Thomas, 1984.) Even the most die-hard preservationist/deontologist would, I believe, be troubled by this outcome. The above points are perhaps best expressed by RichardFlathman,The number of values typically involved in public policy decisions, the broad categories which must be employed and above all,the scope and complexity of the consequences to be anticipated militate against reasoning so conclusively that they generate an imperative to institute a specific policy. It is seldom the case that only one policy will meet the criteria of the public interest. It therefore follows that in a democracy,**policy makers have an ethical duty to establish a** plausible **link between policy alternatives and the problems they address, and the public must be reasonably assured that a policy will actually do something about an existing problem; this requires the means-end language and methodology of utilitarian ethics.** Good intentions, lofty rhetoric, and moral piety are an insufficient, though perhaps at times a necessary, basis for public policy in a democracy

Second, All questions of value collapse to how they affect end-states.

Harris ‘10

Sam Harris 2010.[CEO Project Reason; PHD UCLA Neuroscience; BA Stanford Philosophy]. The Moral Landscape: HowScience Can Determine Human Values.``

Here is my (consequentialist)starting point:**all questions of value**(right and wrong, good and evil,etc.)**depend upon the possibility of experiencing such value. Without potential consequences at the level of experience—happiness, suffering, joy, despair, etc.—all talk of value is empty.**Therefore, to say that **an act is morally necessary** or evil, or blameless, is to make (tacit) claims about **[in] its consequences in the lives of conscious creatures** (whether actual or potential). I am unaware of any interesting exception to this rule. Needless to say, if one is worried about pleasing God or His angels, this assumes that such invisible entities are conscious (in some sense) and cognizant of human

behavior. It also generally assumes that it is possible to suffer their wrath or enjoy their approval, either in this world or the world to come. Even Within religion, therefore **consequences and conscious states remain the foundation of values**

Woller and Harris explain that policy makers have a moral duty to use consequentialism when considering policy and that all questions of value depend on the end result of action.

Thus the value criterion is maximizing expected wellbeing.
In order to support the given value and criterion I provide the following contentions

Contention 1- Quality

Generic drugs send their worst quality drugs to LDCs where risk of inspection is the lowest. There, poor quality medication run the risk of not treating the patient and leading to microbial resistance.

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/]

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**. 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**" 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."**

If getting rid of IP protections means generic drug companies produce even more drugs for all illnesses, they are going to keep selling low quality drugs to less developed countries. Not only will this have a negative effect on people who are receiving the low quality drugs, but it will also affect the whole world by creating drug-resistant strains of illnesses, which will ultimately harm less developed countries even more.

WHO 20,

World Health Organization, 13 October, 2020, "Antimicrobial resistance", [https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance]

The emergence of drug-resistant parasites poses one of the greatest threats to malaria control and results in increased malaria morbidity and mortality. **Artemisinin-based combination therapies (ACTs) are the recommended** first-line **treatment for** uncomplicated *P. falciparum* **malaria** and are used by most malaria endemic countries. ACTs are a combination of an artemisinin component and a partner drug. **In the WHO Western Pacific Region and in the WHO South-East Asia Region, partial resistance to artemisinin and resistance to a number of the ACT partner drugs has been confirmed in Cambodia, Lao People's Democratic Republic, Myanmar, Thailand, and Vietnam** through studies conducted between 2001 and 2019. This makes selecting the right treatment more challenging and requires close monitoring. In the WHO Eastern Mediterranean Region, *P. falciparum* resistance to sulfadoxine-pyrimethamine led to artesunate-sulfadoxine-pyrimethamine failures in some countries, necessitating a change to another ACT. **In Africa, evidence has recently been published showing**

emergence of mutations linked to partial artemisinin **resistance in Rwanda**. So far, ACTs that have been tested remain highly efficacious. However, **further spread of resistance** to artemisinin and ACT partner drugs **could pose a major public health challenge and jeopardize important gains in malaria control.**

Contention 2- Cost and Development

Costs of new, high-quality, branded drugs can range from 1-2 billion dollars

Globerman 16 [Steven Globerman- Resident Scholar and Addington Chair in Measurement, Professor Emeritus, Western Washington University, October 14 2016, "Intellectual Property Rights and the Promotion of Biologics, Medical Devices and Trade in Pharmaceuticals," Fraser Institute, [https://www.fraserinstitute.org/sites/default/files/intellectualproperty-rights-and-promotion-of-biologics-medical-devices-and-trade-in-pharmaceuticals-post.pdf]

The 148 countries that are signatories to the Patent Cooperation Treaty (PCT) that was negotiated as the Paris Convention of 1978 allows any resident or national of another signatory country to file a single international application. This has the effect of a national patent application (and certain regional patent applications) in some or all PCT contracting states, including Canada, which became a signatory in 1990. The PCT is administered by the World Intellectual Property Organization, and while the PCT provides a benefit to originators in the form of expedited patent rights recognition, there is no corresponding coordination on regulatory approval. Patent approval processes are similar in most countries that are members of the Organization for Economic Cooperation and Development (OECD)—a group of relatively developed and mature markets that are important consumer markets for pharmaceutical manufacturers. The authorities in these countries will confer a patent for a drug if it meets three criteria: originality (or novelty), meaning that the drug is truly something new; non-obvious (a US term; for the EU the standards it is called an "innovative step"), meaning that there is something inventive in the idea fraserinstitute.org Intellectual Property Rights for Pharmaceuticals and the Global Trade Agenda / 53 or creation or process that is proposed to be patented; and utility, meaning that there is a specified use or purpose to the invention that could have a commercial value, making the certification of ownership significant to the person applying for the patent. Patent examiners may require details of the process or formulation of a drug or specifics concerning the design and functioning of a medical device. This information is provided on a confidential basis by the applicant for a patent, but this information becomes public eventually, either when the patent right is granted or after a period specified by a national statute. Individuals can apply for a patent for a new drug or device, or a new use for an existing drug or device, on the basis of initial evidence of potential utility, such as a study published in a medical journal or a report from a lab. This standard is lower than what is required to convince regulators that a drug is safe to be sold to the public, even when limited by prescription issued by a qualified medical professional. Regulators typically require evidence from clinical trials using humans (rather than animals or another substitute). **The disparity is important and deliberate in order to encourage an innovator who thinks a drug might work to secure the rights to the innovation prior to undertaking the investment of time and resources to conduct trials. Clinical trials can be expensive to conduct. The US regulator, the Food and Drug Administration (FDA), requires a three-stage clinical trial protocol for most pharmaceuticals. One recent estimate placed the cost of clinical trials through all three stages at US$1.3 billion per drug (Roy, 2012). Another study found it cost an average of US$2.558 billion to win regulatory approval for a single drug (Tufts Center for the Study of Drug Development, 2014). The second, larger estimate reflects the time-cost of delays of up to ten years in the regulatory approval process.** Both these figures are for approval in the US market only; regulators in other countries may accept the same clinical trial data used to win US approval, but in some cases will require additional testing before approving a drug for use in their respective markets. Delays in regulatory approval for a drug that has been successfully patented mean that the pharmaceutical company that originated a drug cannot sell it and

begin recouping its costs as quickly as it could with shorter delays. **As a result, pharmaceutical originators have called on governments to provide "patent term restoration," an extension of intellectual property rights (IPR) for the full term (typically 20 years of exclusivity, although this varies by country) effective from the date of regulatory approval.** The asynchronous nature of patent rights and regulatory approval can affect originators in another way**A drug that has secured regulatory approval is the exclusive property of the patent holder for the duration of the patent, giving the patent holder the exclusive right to produce and market that specific drug in that specific market.When the patent term expires, other firms can produce copies of the drug and market them where regulators have approved the drug for use.** Although patent and regulatory approvals processes are parallel, regulatory approval does not expire (although it can be rescinded or altered if new medical evidence warrants, in which case the approval affects the originator and the copier of the drug alike).**Copies of patented medicines are called generic drugs in the case of chemical pharmaceuticals.** A new class of drugs made from genetic material called biologics can also be copied, and the resulting medications are referred to as biosimilars. Biosimilar copies of biologic drugs are just beginning to enter the market and are being treated by US courts like generic drugs (Grant, 2015). **Although the costs of research and development of a new drug are high, as are the added costs of securing patent rights and regulatory approval, the period of patent exclusivity can allow a firm to recoup its initial investments by pricing the drug accordingly**.However, there are obstacles confronting firms seeking to set prices at a level sufficient to recapture their initial investment. The structure of the market for pharmaceuticals is one challenge. In many markets, there are a limited number of customers for a particular medication. First, there may be a limited number of potential patients for whom a drug is appropriate. Second, government health programs, large hospital and health care systems, and private insurers that must approve the purchase of a medication, are often able to exert downward pressure on drug prices (in effect, to act as an oligopsony (i.e., a market in which only a small number of buyers exist for a product). Third, in cases where governments are the exclusive health care provider, drug prices may be regulated with upper limits on unit prices that suppliers may charge. Competition also limits the pricing power of a pharmaceutical originator once its period of patent-secured monopoly has ended. In the most direct case, once a generic or biosimilar alternative is available in the market, the opportunity to recoup the costs of drug development and approvals is constrained. Firms that produce copies of the original drug or medical device do not have to incur the research, development, patent or regulatory approval costs associated with the introduction of a new product, and so are able to price copies at a far lower level. Some insurers and government programs require medical professionals—and even patients— to choose a generic or biosimilar drug if it is available. To forestall the entry of competitors into a market, pharmaceutical originators have in some cases sought a second patent for a drug on the basis of a new use (utility) for which they have an existing patent. The practice of second patenting is known pejoratively as "evergreening" because it can allow an originator to have a second period of exclusivity for the new application, expanding the potential population of users and extending the period during which the originator can engage in monopoly pricing to recoup development costs.

Patents protect revenue for drug manufacturers and allow them to continue to develop new medicines.

CRS 2012 CRS, 10/28/2021, "Drug Patent Expirations: Potential Effects on Pharmaceutical Innovation", Congressional Research Service, [https://www.everycrsreport.com/files/20121128_R42399_8beca70723872957efe4a267a5ae0df4805469ad.pdf]

A critical component of many of these federal efforts concerns patents**Patent ownership can provide an economic incentive for companies to take the results of research and make the often substantial investment necessary to bring new goods and services to the marketplace.**The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for a limited time. In the pharmaceutical industry, patents are perceived as particularly important to innovation due, in part, to the ease of duplicating the invention. **Recently, patents on a significant number of "blockbuster"**4 **drugs have expired.** At the end of 2011, Lipitor, with 2010 retail sales in the United States of $5.8 billion5 and the world's best selling medication, lost patent protection. Between 2012 and 2016, branded pharmaceuticals with an estimated $117.2 billion in U.S. sales are expected to go off patent. **Once patent protection is**

lost, these drugs are expected to lose up to 80% of the revenue generated for the innovator companies. "In the case of the top selling drugs, generics are capturing most of the market within weeks of their launch." Innovator companies depend on the funds generated from sales of blockbuster drugs to invest in additional R&D leading to new products that can improve the health and welfare of the public. At the same time, generic versions of these pharmaceuticals benefit the public due to their lower cost and greater availability; according to one estimate,over the 10 years between 2001 and 2010, generic drugs "saved the U.S. healthcare system more than $931 billion. However, "while consumers and companies [that] provide health benefits could gain from the substantial slashes in costs, big pharma has to look at new ways and strategies to fill the [revenue] gap" created by the unprecedented number of patent expirations on blockbuster drugs.

New drugs can cost up to billions of dollars, and the reduction of Intellectual Property protections will only make research and development even more difficult because it will be harder to recoup money from making the medicines since generic drug-makers will be taking most of the revenue.

Now, I will address the affirmative.