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

#### **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.

#### **Any plausible moral theory must prioritize extinction**

**Pummer 15** [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015]

**There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now**, whatever general moral view we adopt**: that it is very important to reduce the risk that all intelligent beings on this planet is eliminated by an enormous catastrophe, such as a nuclear war.** How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that **we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world.** According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. **Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here.** If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the worl**d, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people.** Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, **this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake.** **Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter.** Even John Rawls wrote, “**All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.**” **Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view.** **They’d thus imply very strong reasons to reduce existential risk**, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. **Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk.** It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). **To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being.** To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – **suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being**, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But **once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk.** Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. **We should also take into account moral uncertainty.** **What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts?** I’ve just argued that **there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree.** But **even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one** (and 10% sure that one of these other ones is correct), **they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk.** Perhaps most disturbingly still, **even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world.** Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. **It is enough for my claim that there is moral agreement in the relevant sense if**, at least given certain empirical claims about what future lives would most likely be like, **all minimally plausible moral views would converge on this conclusion that we should try to save the world.** While there are some non-crazy **views that place significantly greater moral weight on avoiding suffering than on promoting happiness**, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless **seem to be fairly implausible views.** And **even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living and that things will continue to improve.** Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. **Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast.** We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. **If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period.** Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. **Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.**”(From chapter 36 of On What Matters)

# **Innovation DA**

#### **UQ: Innovation is fragile, any reduction triggers a downward spiral.**

**Charlton 20** Charlton, Emma. Senior Writer for the World Economic Forum, Formative Content. “The looming health catastrophe that could be more deadly than COVID-19.” 2021 World Economic Forum. 20 Nov 2020. https://www.weforum.org/agenda/2020/11/superbugs-health-risk-antimicrobial-resistance/

Resistance is increasing, partly because [antimicrobials have been overused](https://www.who.int/campaigns/world-antimicrobial-awareness-week/2020) since their discovery, and partly because poor sanitation and hygiene allow resistant strains to spread. In farming, antibiotics are often given to animals to boost their growth or to prevent diseases from spreading when livestock are kept in cramped conditions. COVID-19 has added another layer, with antibiotics being prescribed to people around the world, even though it is caused by a virus, not by a bacteria, the [WHO](https://www.who.int/campaigns/world-antimicrobial-awareness-week/2020) says. Tackling resistance matters because the problem has the potential to spiral, with the *AMR Action Fund estimating that* [*deaths from antibiotic-resistant infections*](https://amractionfund.com/amr-innovation-challenge/#page-section-0) *could rise to around 10 million a year by 2050, up from around 700,000 in 2019*. And it could cost the global economy as much as $100 trillion between now and 2050, according to the [International Federation of Pharmaceutical Manufacturers & Associations, IFPMA](https://www.ifpma.org/subtopics/antimicrobial-resistance/). “The coronavirus has really driven home how [vulnerable we are as a society to contagious diseases](https://novonordiskfonden.dk/en/news/lars-rebiens-speech-on-amr/),” says Lars Rebien Sørensen, chairman of the Novo Nordisk Foundation, which helps fund the AMR Action Fund. “2,000 people die every day due to antimicrobial-resistant infections. Even if we start doing everything we can today, this number will increase before it will drop. If we fail to act, a catastrophe is looming.” The WHO [global action plan](https://www.who.int/news-room/feature-stories/detail/an-update-on-the-fight-against-antimicrobial-resistance) seeks to improve awareness of the issue, bolster research, improve sanitization, cut back excessive use of antimicrobial medicines in human and animal health and invest in new medicines to act against the superbugs. **At the moment,** the bacteria are winning the race, morphing faster than drugs are being developed to counter them, the [AMR Action Fund](https://amractionfund.com/amr-innovation-challenge/#page-section-0) says. And that’s partly because of the [poor business case](https://novonordiskfonden.dk/en/news/lars-rebiens-speech-on-amr/): development costs cannot be covered through sales. *While pharmaceutical companies are racing to find a vaccine for COVID-19, research and development of* [*new antibiotics has slowed*](https://www.pewtrusts.org/en/research-and-analysis/reports/2016/05/a-scientific-roadmap-for-antibiotic-discovery)*,* according to Pew research. Now the WHO is calling for a bold, unified agenda focused on prevention and finding new medicines. Seeking to redress this, the AMR Action Fund has raised $1 billion from major pharmaceutical companies to invest in [biotech](https://novonordiskfonden.dk/en/news/major-danish-contribution-to-billion-dollar-global-initiative-to-combat-antimicrobial-resistance/) and plans to bring as many as four new antibiotics to patients by 2030. *“There is currently* [*no viable market for the development of new antibiotics*](https://novonordiskfonden.dk/en/news/major-danish-contribution-to-billion-dollar-global-initiative-to-combat-antimicrobial-resistance/)*,”* says Kasim Kutay, CEO of Novo Holdings, which administers the investment in the AMR Action Fund on behalf of the Novo Nordisk Foundation. “*As a result, antibiotics that are in the early stages of development never reach patients because of a lack of funding for the later stages of clinical research.* The AMR Action Fund is an important part of the solution to this.” Until new antibiotics are found, the US Centers for Disease Control and Prevention advocates good general health practices, like keeping your hands clean, getting vaccinated, only using antibiotics when they’re really needed, and preparing food in a hygienic way. Even so, it’s likely to be a long battle. “*AMR is a complex problem that requires a* [*united multisectoral approach*](https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance),” the WHO says. “*Greater innovation and investment is required in operational research, and in research and development of new antimicrobial medicines, vaccines, and diagnostic tools*.”

#### **Link: Plan kills pharma innovation.**

**Akkara et. al. 16** Akkari, Alessandra Cristina Santos et al. “Pharmaceutical innovation: differences between Europe, USA and ‘pharmerging’ countries.” SciELO - Scientific Electronic Library Online. 14 June 2016. https://www.scielo.br/j/gp/a/F66RRXT8N33rmDyV73cGJrk/?lang=en

**para. 3.1 importance of patent protection**

Although the IP system is not the only one to encourage innovation, the absence of such laws would significantly affect innovation in the pharmaceutical industry, unlike some other sectors, since **the patent is an integral part of the company's innovation strategy in the field of medication** (**Binns & Driscoll, 1998**). In fact, **Mansfield (1986)** shows that the absence of patent protection would have a small impact on the innovation efforts of most industries, but the pharmaceutical industry was an obvious exception. According to the author, *this special behavior is a result of a high rate and a high cost of imitation, i.e. the discovery or the development of a new molecule requires a lot of time and investment, but once the drug is obtained, the medicinal product can be easily prepared by different laboratories with the minimal capabilities of developing chemical syntheses.* As such, given that patents are seen as the main means of appropriability available to the pharmaceutical industry, *delaying the development of an IP system that provides the drugs protection,* in addition to maintaining an ineffective and impaired system*, will have damaging consequences for the industry and also for the countries technological progress.* According to **Scherer & Ross (1990)**, the patent is an indicator of technological progress, being one of the possible mechanisms to appropriate innovations as well as the advantages of the pioneering spirit; the benefits obtained by the inventor through the evolution of his learning curve; industrial secrets; and sales and service efforts. According to the so-called Yale Survey by **Levin et al. (1987)**, patents are only seen as the most effective means of ensuring the returns for the release of new products and processes in the pharmaceutical and oil refining industries. In other segments, including R&D intensive sectors, industries have reported that patents are not the most important mechanism to generate profits from their innovations, which means they employ mainly other mechanisms to this purpose*. The information gathered by analyzing patents becomes especially important to guide the decision-making and the acquisition of competitive advantages by an organization, as well as the definition of public policies and strategic sectors of a country, since it enables the investigation of a global, national, regional and sectorial scenario in terms of technological innovation.* According to the Frascati Manual, indicators based on patents provide a measure of a innovative production of a different countries, considering the investments and the other costs linked to the R&D activities as the *input*s of the inventive activities, while patents can be considered as the *output* of the innovation process (**OCDE, 2007**). **Masiakowski & Wang (2013)** state that *information about patents is crucial for many aspects of a successful business,* but its complexity, distribution over several different databases (in a wide variety of formats) and generation of many pure numeric values, place major challenges for their efficient and strategic use. Therefore, studies geared toward the grouping and analysis of innovation indicators (technological mappings, for example) are becoming a facilitating factor to guide organizations or countries, especially in the pharmaceutical segment.

#### **Internal Link: Innovation key to stop super infections**

**Baker 18** Stephen J. Baker, David J. Payne, Rino Rappuoli and Ennio De Gregorio. “Technologies to address antimicrobial resistance.” JSTOR. 18 December 2018.https://www.jstor.org/stable/10.2307/26574193

Some of the challenges that currently face this approach are the conduct of clinical trials, which mostly focus on treating a specific pathogen, and the cost of goods of mAbs. The use of mAbs to protect against many hospital-acquired infections, such as Acinetobacter, P. aeruginosa, or K. pneumoniae, in high-risk patients may be a more pragmatic approach than vaccination for these pathogens, where infection can be a relatively rare event in most people’s lives until they enter a higher risk environment, such as the intensive care unit (48). As antibody engineering and diagnostics technologies advance, coupled with manufacturing approaches that decrease the cost of goods, this could become an area of significant growth in the future. Of all of the approaches described, mAbs probably have the best opportunity to successfully treat AMR, although each mAb treatment will probably be limited to a specific species of bacteria. This will mean these treatments will be reserved for second- or third-line therapy once the infecting organism has been identified. The downside is each mAb will need to have its own clinical development path, which will greatly increase the cost of development. Technology or regulatory changes that reduce the cost or accelerate the development path will certainly catalyze the further development of mAbs. *AMR is eroding our ability to control infections with traditional antibiotics, and there are scientific challenges to develop new treatments at an equivalent rate.* These challenges include the need to kill rapidly growing organisms that are adept at keeping out xenobiotics, lack of rapid diagnostics leading to empirical treatment of infections, and a need to administer high doses to cover worst-case scenarios. However, *new innovations in vaccines and antibacterial approaches have potential to provide new tools to address this public health threat*. Clearly, broader vaccination programs can play a bigger role in preventing bacterial infections and innovative platforms are available to create new vaccines against additional pathogens of concern. Furthermore, *innovative approaches need to be explored for traditional small-molecule antibacterial discovery programs, and alternative approaches need to be robustly validated and progressed.* Together, vaccines and antibiotics have played a key role in our ability to manage bacterial infections, which has enabled the advancement of medical science. However, **this progress has been at risk for some time**, despite the underpinning science and platforms that can address this global threat being available. Significant and coordinated investment is needed to broaden the application of innovative vaccine platforms to additional pathogens and to expand research around novel approaches that will improve the success of traditional and alternative antibacterial discovery. In conclusion, we believe that a coordinated effort in research and development of new antibiotics and vaccines that takes advantage of the opportunities provided by the new technologies, combined with appropriate policy measures, can greatly advance our ability to control AMR.

#### **Impact: If not treated, AMR could cause massive repercussions—twice that of covid per year.**

**Friedman 20** Friedman, Eric. A. Eric A. Friedman is the O’Neill Institute’s global health justice scholar. He works on global health and human rights projects and scholarship, with a focus on equity, empowerment, and accountability. He is also a member of the Executive Committee of the Framework Convention on Global Health Alliance, which advocates for a treaty to improve accountability to the right to health and is aimed at national and global health equity. He also serves on the Steering Committee of the Sustainable Health Equity Movement. Before joining the O’Neill Institute in 2010, Friedman was a senior global health policy advisor at Physicians for Human Rights, where he focused on health systems, the global shortage of health workers, and HIV/AIDS, and sought to increase the extent to which U.S. global health policy, and health workforce and systems policies globally, incorporated the right to health. He also served on the board of the Global Health Workforce Alliance, an international partnership hosted by the World Health Organization, and chaired the Health Workforce Advocacy Initiative. Friedman holds a law degree from Yale Law School and a B.A. from Yale College. “Behind the Headlines: 10 Million Deaths From Antimicrobial Resistance by 2050 (or Not?).” O’Neill Institute for National and Global Health Law or Georgetown University. 12 February 2020. https://oneill.law.georgetown.edu/behind-the-headlines-10-million-antimicrobial-deaths-by-2050-or-not/

**One of the greatest health threats of our time, one that grows by the year, is antimicrobial resistance.** **Bacteria and other microbes develop mutations that protect them against antibiotics and other antimicrobial drugs, meaning that infections, including deadly ones, that we can now treat will become more difficult — even possible — to treat. The**[700,000 or more deaths](https://www.who.int/news-room/detail/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis) **that antimicrobial resistance now causes every year could grow to 10 million by 2050.** It could cause 10 million deaths per year by 2050. But just how likely is this? Read an article or book discussing antimicrobial resistance, and you would think that without more action to combat resistance (such as by developing new antibiotics and other antimicrobials) and slow its spread (such as through more prudent use of existing antibiotics), we are on track to that [truly frightening future](https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf). It would be a future where more people die of antimicrobial resistance than cancer, and today’s routine surgeries become dangerous – even too dangerous to undertake – because of the risk of deadly infections. Bill Bryson’s general excellent book [*The Body: A Guide for Occupants*](https://www.theguardian.com/books/2019/sep/26/the-body-guide-for-occupants-bill-bryson-review) (2019) puts it this way: “At the current rate of spread, antimicrobial resistance is forecast to lead to ten million preventable deaths a year” (p. 46). Bill Bryson cites a [BBC Radio science program](https://www.bbc.co.uk/programmes/b07djvbp), whose host says that “the O’Neill report [to which we will return] suggests that [deaths from antibiotic resistance] will rise to 10 million people per year by 2050.” And he cites [an article from Chemistry World](https://www.chemistryworld.com/features/the-antibiotic-countdown/3008544.article), a news website developed by the United Kingdom’s Royal Society of Chemistry, which reports: “Already, drug-resistant bacterial infections kill 700,000 people every year…and authoritative sources suggest that this figure may rise to 10 million by 2050.” Authoritative indeed. A [*New York Times* article](https://www.nytimes.com/2019/12/25/health/antibiotics-new-resistance.html) in December 2019 that warned of bankruptcies of antibiotic start-ups, threatening an already inadequate pipeline of new antibiotics, states, “**Without new therapies**, **the United Nations says the**[global death toll could soar to 10 million by 2050](https://www.nytimes.com/2019/04/29/health/un-drug-resistance-antibiotics.html)**.”** And indeed, the United Nations said just that – though with emphasis on the word “could.” An April 2019 [report from a UN interagency group](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/final-report/en/) stated: “**Drug-resistant diseases already cause at least 700,000 deaths globally a year**, including 230,000 deaths from multidrug-resistant tuberculosis, a figure that could increase to 10 million deaths globally per year by 2050 under the most alarming scenario if no action is taken” (p. 1). We will return to that key last phase of the UN statement about the most alarming scenario. I could continue along these lines. Enter “10 million deaths antimicrobial resistance” into an Internet search engine, and you will find a plethora of examples like the news articles and programs cited above. The origin of this 10 million figure – what we’re on track to reach “at the current rate of spread”, what “will” happen, what “may” or “could” happen – is a 2014 report by panel, the Review on Antimicrobial Resistance (AMR Review), that then-UK Prime Minister David Cameron had established earlier that year, chaired by Jim O’Neill. And it certainly gives that impression. A figure taking up an entire page (p. 5) of its [December 2014 report](https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf) (several more reports would follow) is labeled “Deaths attributable to AMR every year compared to other major causes of death,” with AMR in 2050 and its 10 million figure highlighted. And the report states, “Initial research, looking only at part of the impact of AMR, shows that a continued rise in resistance by 2050 would lead to 10 million people dying every year” (p. 6). Without looking more carefully, the way this figure has been reported in the press seems more or less accurate with respect to how the AMR Review characterizes its findings. But keep reading, and the picture quickly becomes quite murky. The 10 million figure is drawn from two studies, which of which created possibly but hypothetical scenarios of what could happen in 2050. [One study](https://www.rand.org/pubs/research_reports/RR911.html), by the RAND Corporation, looked to three major infectious diseases and three bacteria where resistance is already a concern – AIDS, tuberculosis, and malaria, and *Escherichia coli* (*E. coli*), *Klebsiella pneumoniae* (*K. pneumoniae*), and *Staphylococcus aureus* (*S. aureus*) – and assumed in 15 years we would have no drugs to combat them. While resistance is a problem with all of these, there is no particular reason to believe that all drugs against them will cease to work, much less in fifteen years, which seems extremely unlikely – a “most alarming scenario” indeed, to use the UN interagency group’s words. The [other study](https://home.kpmg/content/dam/kpmg/pdf/2014/12/amr-report-final.pdf), by KPMG, was similarly limited to the same six diseases and bacteria, and considered four different scenarios, varying by degree of resistance (40% or 100%) and rate of infection (as now, or all except for malaria doubling). Among the two studies and multiple scenarios, the AMR Review fails to say exactly where its 10 million figure comes from. Review the two studies themselves, and you will not find that number. [One analysis](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5127510/) in *PLoS Medicine*, referring to the 10 million figure, observes: “The scenario that seems to be underlying the most often quoted line entails a sharp initial rise of current resistance rates by 40 percentage points, after which rates remain stable until 2050, and doubled infection rates.” This scenario, one of those from KPMG, does appear the most likely source to me as well; along with the RAND study, it is the scenario that the AMR Review itself highlights. Yet is that the most likely scenario? How much more likely is 10 million deaths than 5 million or 2 million – or are these or other lower tolls, in fact, actually (much?) more likely? Notably, contrary to the scenario that seems to underlie the 10 million figure, presently HIV and TB infection rates are falling, not rising. While hardly representative of the world, but indicative of the possibilities of progress even at today’s level of insufficient action, the Center for Disease Control and Prevention’s [best estimates](https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf) (p. 16-17) indicate a slight decrease of annual antimicrobial resistance deaths in the United States, from 36,500 in 2012 to 35,900 in 2018. What are we to make of all of this? First, what is, importantly, not the take-away. That the 10 million death figure hardly reflects either current trends or is particularly more likely than millions fewer deaths (even as more deaths is conceivable as well) hardly means that antimicrobial resistance is not a major threat. It absolutely is, and with **the problem worsening globally, a death toll that reaches into the millions annually is well within the realm of possibility.**

# **Orphan Drugs CP**

#### **CP text: The member nations of the WTO should [insert plan mandate] except for orphan drugs.**

#### **IP protections for orphan drugs are key to the pharma industry – it’s key to their market strategy**

Houldsworth 19 (Adam Houldsworth Author | Life sciences reporter, 29 Oct 2019, “Four key IP implications from the rise of orphan drugs”<https://www.iam-media.com/law-policy/four-key-ip-implications-rise-orphan-drugs>) [Twinz]

A recent report from Clarivate Analytics provides the latest reminder of the growing importance of orphan drug innovation to the life sciences industries. The 2019 Centre for Medicines Research International Pharmaceutical R&D Factbook points out that of the 57 new molecular entities approved by the US Food and Drug Administration in 2018, 22 had an orphan drug designation, signifying that they target a rare disease. Between 2010 and 2018, it notes, the number of addressable patients for each drug approval fell by 15%. This echoes other data that suggests an increasing significance for drugs aimed at treating rare diseases. According to EvaluatePharma’s 2019 Orphan Drug Report, worldwide sales from orphan drugs are forecast to grow by 12.3% CAGR between 2019 and 2024. This is double the rate for non-orphan drugs. Medicines approved for rare diseases will provide 20.3% of global prescription revenues by the end of this period. During this period, they are set to provide a third of the industry’s R&D pipeline sales. Requests for orphan drug designations have risen precipitously over the past decade. In 2009 – itself a record-breaking year – there were 250 applications to the US FDA, compared to 346 in 2013, 467 in 2014, 472 in 2015, 582 in 2016 and just over 500 in both 2017 and 2018. The same period has seen a large increase in the number of designations awarded in the US. No year before 2011 saw more than 200 designations, but every year since 2013 has witnessed more than 250, with over 300 in each year since 2015 - and a record 477 awarded in 2017. What’s more, the number of orphan products (including repurposed products) approved each year in the US has also increased dramatically. It reached record numbers in 2017, when 81 products were approved; and again in 2018, which saw 91 drugs given the green light (there had never been more than 30 orphan drug products approved in a year until 2013). This trend has potentially important implications for intellectual property. 1. Growing importance of regulatory exclusivities for IP professionals One clear consequence for IP strategies is that the regulatory market exclusivities offered by drug administrations in several key jurisdictions will increase in significance. Since the 1983 Orphan Drug Act, the US has awarded seven years’ exclusivity after market approval – as well as tax credits – to innovators of orphan-designated drugs. This applies to drugs that target conditions with fewer than 200,000 sufferers in the country. During these seven years, the FDA will only grant marketing approval to another version of the same drug for the same indication if that newer version can be shown to be to be “clinically superior”. Depending on the term of a product’s patent protection, this exclusivity can significantly extend a drug’s monopoly. The EU adopted similar provisions in 2000, since then it has granted 10 years’ regulatory exclusivity to orphan drugs; while an extra two years’ protection is awarded if the drug is a paediatric product. The European Medicines Agency awards orphan designations to products targeting serious conditions suffered by no more five in 10,000 Europeans, provided that the drug would otherwise produce insufficient returns to justify development costs and no other satisfactory product exists. In Europe, this monopoly excludes all “similar medicinal products” for the same indication, not just versions of the same product. But orphan drug exclusivity can be cut short to six years if by the fifth year the drug has reached a level of profitability that means it no longer qualifies for orphan drug status. And, as in the US, other similar products demonstrating clinical superiority may be approved during the exclusivity period. Similar provisions exist in Japan and Australia. As the orphan drugs gain in commercial importance for the industry and specific companies, gaining and maintaining these exclusivities will become an even more central part of overall IP strategies. The distinctive case law around orphan drug exclusivities will be more important to pharma patent professionals, as will knowledge of relevant regulatory processes and standards. 2. Political controversies over pharma IP to be exacerbated Another potential consequence of the rise of orphan drugs may be a growth in public concern about drug prices, leading to a heightening of existing political tensions around life sciences patents. As detailed previously by IAM, pharma IP (and patent owner strategies) have been severely criticised in recent years. This is especially so in the United States, where they have been blamed for underpinning high drug prices. As a consequence, we have seen several legislative proposals seeking to rein in pharma IP rights. Orphan drugs risk fuelling these controversies because their mean cost per patient is significantly higher than the mean cost of other drugs. According to EvaluatePharma, the top 100 US orphan drugs cost on average 4.5 times as much per patient as non-orphan drugs, with a mean cost of $150,854 per patient in 2018, compared to $33,654 for other treatments. In general, this is because rights holders are seeking to recover costs and make a profit from what are, by definition, smaller patient populations. But, given the seriousness of the conditions targeted by orphan drugs, and the fact that there are no alternative treatments for many rare diseases, such prices risk calling into doubt public confidence in pharma IP rights. In the US, orphan drug exclusivities themselves have been subjected to serious scrutiny in recent years, with Senator Chuck Grassley announcing an investigation into potential misuses of the orphan drug programme in 2017. In 2018 and 2019, a plethora of news articles (such as this one) have called for reform. And in the UK, the National Health Service’s long-running dispute with Vertex Pharmaceuticals over Orkambi – resolved just last week – led to calls for the use of compulsory licensing. 3. More IP deals and collaborations The growing importance of orphan drugs is likely to accentuate a broader trend towards the acquisition and licensing of products invented by small and medium-sized biotechs by big pharma. Against a background of rising R&D costs, and pressures to replenish pipelines to mitigate the second patent cliff, big pharma has in recent years sought to buy or license-in promising innovations from other companies, usually smaller entities. This trend is especially pronounced in the orphan drug space, where inventions are produced overwhelmingly by small and medium-sized biotechs. Nimbler innovators have traditionally dominated this space because of its requirement for specialised knowledge and laser focus on particular indications. Indeed, the US National Organization for Rare Disorders – which lobbied for the 1983 Orphan Drug Act – claims that the American biotech industry is a “child” of that legislation. If one looks at the EvaluatePharma’s top 20 orphan-designated R&D drugs, all those in the hands of big pharma companies have been either acquired – as with Celgene’s Liso-cel and Novartis’ Zolgensma – or licensed-in (like Roche’s Risdiplam and Sanofi’s Isatuximab) from other companies. The only organically developed products in this list are in the hands of medium sized companies, such as Blueprint Medicines, bluebird bio and Deciphera Pharmaceuticals. And even many of these are being developed in collaboration with larger entities. For example, Galapagos’ GLPG1690, to which Gilead has exclusive licensing options; and bluebird’s bb2121, which is partnered with Celgene. What’s more, it is striking to note that of Roche’s abundant portfolio of orphan-designated drugs – Herceptin, Perieta, Tecentriq, Avastin, Rituxan, Gazyva, Venclexta, Kadcyla and Alensa – none were originally developed in-house. 4. More emphasis on personalised drugs While many orphan drugs are not personalised treatments, they account for a significant chunk of the medicines in this category; and the rise of rare disease treatments is happening hand-in-hand with the growth of personalised and precision medicines – which are also expected to increase their revenue by over 11% CAGR between 2017 and 2024. As such, the increasing significance of understanding the distinctive challenges of, and divergent international rules for, patenting personalised medicines will be an important by-product of the global increase in orphan drugs. This is one of the reasons why issue 98 of IAM magazine will include in-depth guidance on how best to protect personalised medicine innovations from Frances Salisbury of Mewburn Ellis.

#### **Especially true in the context of the plan – orphan drugs are the only way to ensure pharma stays stable – that’s key to innovation**

Sharma et al. 10 (Aarti, Massachusetts College of Pharmacy and Health Sciences member of Department of Pharmaceutical Sciences and specializes in Medicinal Chemistry, Pharmacology, Organic Chemistry., Abraham Jacob, Manas Tandon, and Dushyant Kumar., December 2010., “Orphan drug: Development trends and strategies”,<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996062/> [twinz])

The growth of pharma industries has slowed in recent years because of various reasons such as patent expiries, generic competition, drying pipelines, and increasingly stringent regulatory guidelines. Many blockbuster drugs will loose their exclusivity in next 5 years. Therefore, the current economic situation plus the huge generic competition shifted the focus of pharmaceutical companies from the essential medicines to the new business model — niche busters, also called orphan drugs. Orphan drugs may help pharma companies to reduce the impact of revenue loss caused by patent expiries of blockbuster drugs. The new business model of orphan drugs could offer an integrated healthcare solution that enables pharma companies to develop newer areas of therapeutics, diagnosis, treatment, monitoring, and patient support. Incentives for drug development provided by governments, as well as support from the FDA and EU Commission in special protocols, are a further boost for the companies developing orphan drugs. Although there may still be challenges ahead for the pharmaceutical industry, orphan drugs seem to offer the key to recovery and stability within the market. In our study, we have compared the policies and orphan drug incentives worldwide alongwith the challenges faced by the pharmaceutical companies. Recent developments are seen in orphan drug approval, the various drugs in orphan drug pipeline, and the future prospectives for orphan drugs and diseases.

#### **Pharma innovation is the only line of defense from super bugs causing extinction**

Charlton 20 (Emma Charlton, Senior Writer, 20 Nov 2020, “The looming health catastrophe that could be more deadly than COVID-19”<https://www.weforum.org/agenda/2020/11/superbugs-health-risk-antimicrobial-resistance/>) [Twinz]

Superbugs. You’ve probably heard of them, but did you know they’re one of the biggest threats to global public health? Left unchecked, these drug-resistant bugs could kill millions of people every year with the damage to health potentially dwarfing that of COVID-19, according to the AMR action fund. That makes antimicrobial resistance, or AMR, a top 10 global public health threat, according to the World Health Organization, which is raising awareness and promoting ways forward with World Antimicrobial Awareness Week. Have you read? This simple reaction could make antibiotics more effective against drug-resistant bacteria COVID-19 is putting millions of people at risk of blindness Risks arise when bacteria, viruses, fungi and parasites change over time and don’t respond to the drugs that have been developed to keep them in check. Strong resistance Resistance is increasing, partly because antimicrobials have been overused since their discovery, and partly because poor sanitation and hygiene allow resistant strains to spread. In farming, antibiotics are often given to animals to boost their growth or to prevent diseases from spreading when livestock are kept in cramped conditions. COVID-19 has added another layer, with antibiotics being prescribed to people around the world, even though it is caused by a virus, not by a bacteria, the WHO says. AMR Action Fund bacteria viruses fungi drug antimicrobial resistance global public health threat Deaths could increase rapidly if no action is taken. Image: AMR Action Fund Tackling resistance matters because the problem has the potential to spiral, with the AMR Action Fund estimating that deaths from antibiotic-resistant infections could rise to around 10 million a year by 2050, up from around 700,000 in 2019. And it could cost the global economy as much as $100 trillion between now and 2050, according to the International Federation of Pharmaceutical Manufacturers & Associations, IFPMA. “The coronavirus has really driven home how vulnerable we are as a society to contagious diseases,” says Lars Rebien Sørensen, chairman of the Novo Nordisk Foundation, which helps fund the AMR Action Fund. “2,000 people die every day due to antimicrobial-resistant infections. Even if we start doing everything we can today, this number will increase before it will drop. If we fail to act, a catastrophe is looming.” The WHO global action plan seeks to improve awareness of the issue, bolster research, improve sanitization, cut back excessive use of antimicrobial medicines in human and animal health and invest in new medicines to act against the superbugs. What is the World Economic Forum doing about epidemics? Show Prevention focus At the moment, the bacteria are winning the race, morphing faster than drugs are being developed to counter them, the AMR Action Fund says. And that’s partly because of the poor business case: development costs cannot be covered through sales. While pharmaceutical companies are racing to find a vaccine for COVID-19, research and development of new antibiotics has slowed, according to Pew research. Now the WHO is calling for a bold, unified agenda focused on prevention and finding new medicines. AMR Action Fund bacteria viruses fungi drug antimicrobial resistance global public health threat The WHO is calling for action to fill the gap. Image: Pew Charitable Trusts Research Seeking to redress this, the AMR Action Fund has raised $1 billion from major pharmaceutical companies to invest in biotech and plans to bring as many as four new antibiotics to patients by 2030. “There is currently no viable market for the development of new antibiotics,” says Kasim Kutay, CEO of Novo Holdings, which administers the investment in the AMR Action Fund on behalf of the Novo Nordisk Foundation. “As a result, antibiotics that are in the early stages of development never reach patients because of a lack of funding for the later stages of clinical research. The AMR Action Fund is an important part of the solution to this.” Until new antibiotics are found, the US Centers for Disease Control and Prevention advocates good general health practices, like keeping your hands clean, getting vaccinated, only using antibiotics when they’re really needed, and preparing food in a hygienic way. Even so, it’s likely to be a long battle. “AMR is a complex problem that requires a united multisectoral approach,” the WHO says. “Greater innovation and investment is required in operational research, and in research and development of new antimicrobial medicines, vaccines, and diagnostic tools.”