## Substandard Drugs DA

#### Brink: 10% of all drugs in developing countries are substandard; Breman 19

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**Each year, more than 250,000 children with malaria and pneumonia, common illnesses in poor countries, do not survive after treatment with fake and substandard drugs.** While poor quality drugs targeting older individuals are also entering global markets, the World Health Organization says “it is very difficult to quantify [their] impact.” Such useless or harmful drugs once went by the confusing designation “substandard/spurious/falsely labeled/falsified/counterfeit medical products.” A recent move by the WHO aims to simplify this by separating them into three categories: falsified medical products deliberately misrepresent their identity and are distributed with criminal intent substandard medical products fail to meet quality standards unregistered or unlicensed medical products have not been assessed or approved **According to the WHO, 1 in 10 medical products in developing countries is falsified or substandard. The personal and public health tolls are huge, as is the economic burden — up to $200 billion annually.** **Poor-quality antimicrobials are most often found in low-income countries.** In addition to failing to treat infection, **they also contribute to the evolution of antimicrobial resistance, which British researchers have estimated could kill up to 10 million people a year by 2050.**But counterfeit medications in virtually every therapeutic class, from blood pressure pills to treatments for cancer and vaccines, are made and distributed by unscrupulous criminals. **In countries with poor pharmaceutical control systems, such drugs can be made in illicit facilities inside or outside the country and enter the supply stream because no FDA-like system exists for inspection or approval. Expensive analytic equipment generally isn’t available, while simple, accurate, and inexpensive testing systems for use in the field, at pharmacies, and at the point of care remain out of reach in virtually all poor countries. To make matters worse, many countries do not have laws to define and enforce regulations addressing crimes related to counterfeit or substandard medicines, nor do the have well-defined judicial actions once criminals are suspected or identified.**

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#### Link: IP protections are a essential barrier to fight counterfeit medicine and substandard drugs; Lybecker, 16

Lybecker, Kristina M (C. Dr. Kristina M. Lybecker is an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. She has testified numerous times on the economics of the importation of Canadian drugs and the risks of pharmaceutical counterfeiting. Dr. Lybecker has also worked with US Food and Drug Administration, PhRMA, and the World Bank, on a variety of issues relating to the economics of innovation and international trade policies.) “Counterfeit Medicines and the Role of IP in Patient Safety.” IPWatchdog.com | Patents &amp; Patent Law, IPWatchdog, 27 June 2016, [www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/](http://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/).

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and **the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals.** UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] **The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.** While **patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit** **counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.**

#### Internal Link: Lack of IP floods markets with dangerous products; Mercurio, 21

Mercurio, Bryan (C.Bryan Mercurio is the Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.) “The IP Waiver for COVID-19: Bad Policy, Bad Precedent.” *IIC; international review of industrial property and copyright law*, 1-6. 24 Jun. 2021, doi:10.1007/s40319-021-01083-5 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/>

Alan Beattie, writing in the *Financial Times*, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the **leading vaccines** using mRNA **are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production.** Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. **The know-how**and trade secrets **are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals**or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, **instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up.**

#### Impact: Increased presence of substandard drugs and falsified medicines endangers public health and strengthens antimicrobial resistance; Johnston and Holt, 14

Johnston, Atholl (C. Clinical Pharmacology, Barts and The London School of Medicine and Dentistry, Queen Mary, University of London, London, UK) and David W Holt (C. Professor David Holt has more than 47 years’ experience in the measurement of drugs as a guide to therapy, and has been responsible for the development of assays used to monitor a wide variety of therapeutic agents. For over 20 years he was the Director of the Analytical Unit at St George’s, University of London, where he was also responsible for the analysis of illicit and prescription drugs for the Unit’s Forensic Toxicology Services provided to HM Coroners, pathologists and law enforcement agencies. He now advises on proficiency testing schemes for the measurement of immunosuppressive drugs, and on problems associated with substandard pharmaceuticals.

Professor Holt is a frequent speaker on a broad range of issues relating to bioanalytics and clinical toxicology. He is the author of over 400 publications in peer reviewed journals and invited contributions to books. He is a past President of the International Association of Therapeutic Drug Monitoring and Clinical Toxicology and a recipient of the Charles E Pippenger Award for Outstanding Contributions to Therapeutic Drug Monitoring.. “Substandard drugs: a potential crisis for public health.” *British journal of clinical pharmacology* vol. 78,2 (2014): 218-43. doi:10.1111/bcp.12298 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/>

The WHO defines ‘counterfeit’ drugs as ‘medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source’ [[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b8)]. It also states that both branded and generic products may be counterfeited and that ‘counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging’. However, because of the potential misunderstanding of the term ‘counterfeit’ – which, **in the context of intellectual property, refers specifically to trademark infringement – the phrase ‘falsified medicines’ is used** by some authorities, particularly in Europe. The Commission of the European Communities defines these as ‘medicinal products which are falsified in relation to their identity, history or source. These products … usually contain sub-standard or false ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients’ [[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b9)].

Thus, **falsified drugs are highly likely to be of substandard quality, possibly containing no API. However, only a small proportion of substandard drugs are falsified; the rest reach the market as a result of poor manufacturing practices, inadequate quality-control processes, incorrect storage or inappropriate packaging, or a combination of these factors.**This can affect both branded and generic drugs. In many cases, **the reason why a drug product is substandard (i.e. deliberate falsification or poor manufacturing practice) is not stated or is not known. Whether or not a drug product is substandard because of criminal intent or because of failures in manufacturing, storage, etc. is immaterial to the patient because the impact on their health will be the same, regardless of cause** [[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b10)]. In this article, we consider the term ‘substandard’ to apply both to legally approved but poor-quality drugs and to falsified drugs, but we focus on the former with regard to reviewing potential solutions.

**Substandard drugs pose a serious health concern from several perspectives** (Table ​(Table44 [47,48,51,52,57,59,70,95–104]). Although **falsified drugs have** perhaps **received most** of the **attention with respect to causing unnecessary deaths, substandard drug manufacture also leads to morbidity and mortality**. A formulation with insufficient API may lead to a lack of clinical response, and possibly, death. For example, **there are reports of patients failing to respond to antimalarial treatment**[95,96] **because the drugs contained less than the stated dose of API and, in one reported case, contained more paracetamol than antimalarial agent** [95]. In other cases, a reduced therapeutic response has been associated with generic/copy versions of drugs compared with the originator drugs, including antibiotics, tacrolimus and imatinib [70,97,99–102].

**Adverse events also occur due to drug–drug interactions with contaminants, the presence of excess API, contamination with poisonous substances, or allergic reactions to contaminants or substituted excipients.** As mentioned above, some of the most extreme cases involve the (possibly deliberate) contamination of medicines with DEG [[47](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b47),[48](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b48)]. In another case, heparin was found to be contaminated with oversulphated chondroitin sulphate, which was thought to be responsible for the allergic or hypersensitivity-type reactions experienced by a number of patients, some of which proved fatal [[51](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b51)]. At the time of the heparin incident, the oversulphated chondroitin sulphate could not be distinguished from heparin by the standard quality-control tests used. However, the FDA has since implemented changes to the USP standards for heparin, including a new test method that is able to detect such impurities [[105](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b105)].

There are also adverse societal effects arising from the use of substandard drugs.**The inadvertent use of suboptimal doses of drugs is likely to be one of the key factors contributing to antimicrobial resistance and thereby leading to the wider spread of disease. This has been most widely discussed with regard to malaria [**[**106**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b106)**–**[**108**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b108)**]; the repeated administration of subtherapeutic doses of antimalarials will promote the selection and spread of resistant parasites** [[95](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b95),[106](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b106)]. Indeed, artemisinin-resistant malaria has been reported in Cambodia and Thailand [[109](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b109),[110](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b110)], although the extent to which this can be attributed to the use of substandard drugs is unknown. Likewise, poor-quality antibiotics may contribute to the resistance and spread of diseases such as tuberculosis [[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b23),[111](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b111),[112](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b112)]. The use and subsequent failure of substandard narrow-spectrum antibiotics may lead to the unnecessary administration of broad-spectrum antibiotics, thus potentially creating further resistance [[113](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b113)]. **Substandard antihelminthics have been implicated in the development of drug-resistant human helminths** [[114](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b114)], **and substandard antiviral drugs are likely to contribute to the evolution of drug-resistant viruses, including human immunodeficiency virus (HIV)** [[115](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b115)].

#### 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, s tates, “Without new therapies, the United Nations says the global death toll could soar to 10 million by 2050.” 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.**

### CASE

#### Reductions in IP do not improve accessibility, and some protections are necessary for balancing public and private interests

**Krattiger 13** Anatole Krattiger,; Adjunct Professor, School of Integrative Plant Science Plant Breed‐ ing and Genetics Section ; September 2013; ”Promoting access to medical innovation”; https://www.wipo.int/wipo\_magazine/en/2013/05/article\_0002.html, WIP Magazine, accessed 7‐29‐2021 CHS VK

**The rationale** of the intellectual property (IP) **system** in general, and the patent system in particular, **is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in patent applications is accessible to soci‐ ety.** In this way, it seeks to balance competing private and public interests. Anyone **ap‐ plying for a patent is required to disclose the details of their technology so that the pub‐ lic is aware of,** and can eventually use, **the knowledge contained in patent documents.** Patent information available through public databases, such as WIPO′s PATENTSCOPE, offers useful insights about innovation trends and freedom‐to‐operate, and can help shape patenting and licensing strategies. **Data indicate overall long‐term growth in patenting of medical technologies** (a sign of renewed investment in this area) **and that an increasingly diverse range of public and private users** (see Figures 2 and 3), **including from emerging economies, are using the international patent system.** While the patent system is designed to promote innovation by providing an incentive to invest in R&D, **the impact of patents on access to medical technologies is complex** and much debated. Just as the existence of a patent need not be a barrier to access, **the absence of a patent right does not guarantee effective access.** As noted in the WHO′s Framework for Access to Medicines, access to **medicines** is rarely dependent on a single factor; it also **includes rational selection and use of medicines, affordable prices, sustainable financing and reli‐ able health and supply systems, among others.** Striking an appropriate balance **Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector,** since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. **The WTO**′s Doha Declaration on the TRIPs Agreement and Public Health of 2001, **clarified a number of rules specific to IP and helped reassure the global community that IP should not prevent access to the medicines needed in developing countries.** Medical technologies are usually very expensive to develop but relatively cheap to reproduce. Without the protection conferred by a patent it would not be financially viable for companies to continue investing in re‐ search, product development and regulatory approval. If competitors could “free ride” on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby weakening any incentive to develop new products.