# **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.**

#### **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.**

# **UHC CP**

#### **CP Text: The member nations of the WTO should implement United Health Care**

#### **Universal Health Care solves for pandemic and covers those who can’t afford. Galvani 20**

[Alison P. Galvani, Burnett and Stender Families Professor of Epidemiology at Yale, 6-1-2020, "The imperative for universal healthcare to curtail the COVID-19 outbreak in the USA," EClinicalMedicine, https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30124-3/fulltext]

The COVID-19 outbreak in the United States is growing steeply and spreading widely. As of March 26, national incidence surpassed every other country, and as of April 28 has reported over a million cases. The COVID-19 crisis is exposing the systemic frailties in our healthcare system. More than 78 million people in America do not have access to adequate health insurance [[1]]. Given that health insurance in the US is typically provided by employers, millions more are at risk of losing their healthcare coverage as unemployment surges. Here we discuss how the pervasive healthcare insecurity in the US hampers control of COVID-19. Further, we argue that universal healthcare would alleviate the cost barriers that are impeding control of this pandemic. Outbreak **mitigation relies on prompt diagnosis and case-isolation**, in which mild cases are quarantined at home and more severe cases are hospitalized. These measures must be implemented **rapidly** in order **to be effective**. However, **for the millions** of people who Are either **uninsured** or underinsured, **concern about** the medical Expenses that could be incurred **delays diagnosis and treatment**. While the Families First Coronavirus Response Act recently approved by Congress stipulates that COVID-19 diagnostic testing is nominally free for everyone, **treatment is not covered. Those who are hospitalized may face major medical expenses**. For instance, the cost of 12 days in the ICU on ventilation would likely exceed US $80,000 [[2],[3]], even without considering the additional hospital care before and after ICU admission. In addition to the burden on the uninsured, the under-insured are obligated to pay substantial out-of-pocket sums, including thousands of dollars in deductibles and copays. Although the Coronavirus Aid, Relief, and Economic Security Act has invested $100 billion into the Public Health and Social Service Emergency Fund for healthcare providers, less than one third of this sum can be used to fund the treatment of uninsured COVID-19 patients. Compounding the crisis, legal action being pursued by the current Administration is jeopardizing the Affordable Care Act, which would lead to the loss of health insurance for as many as 30 million people [[4]]. The COVID-19 pandemic also underscores the precariousness of a system in which insurance is linked to employment. Initial unemployment claims rose from 282,000 for the week ending March 14 to 6.6 million, 5.2 million and 4.4 million, for the weeks ending April 4, April 11, and April 18, respectively, compared with a previous record high of 695,000 from 1982 [[5]]. Many of these newly unemployed individuals will lose their health insurance. Although they are permitted to purchase insurance on the federal exchange, switching networks disrupts continuity of care, which is particularly detrimental for those living with chronic health conditions. Furthermore, the majority of **families are unable to afford health insurance upon becoming unemployed, given that more than half of American families live paycheck to paycheck** [[6]]. Racial and economic disparities in the US healthcare system are being magnified by the pandemic. Rates of adequate health insurance coverage are much lower among people of color [[7]]. With less access to preventative healthcare, people of color are disproportionately affected by comorbidities, such as diabetes, obesity, asthma, and cardiovascular disease. These comorbidities exacerbate the severity of COVID-19 clinical outcomes, including death [[8]], as does delay in seeking care due to concerns about medical bills. COVID-19 is widening socioeconomic fissures facing people of color as well. Since the start of the outbreak, Latino populations have reported much higher rates of job and wage loss than Americans at large [[9]]. The solution to these challenges is the provision of comprehensive healthcare as a human right. Further, universal healthcare will be most cost-effectively achieved by a single-payer system, such as that proposed in the Medicare for All Act [[1]]. Not only would Medicare-for-All save lives, it would resolve costly inefficiencies that currently make our healthcare system the most expensive in the world. Among the major sources of savings, a single-payer system would consolidate administrative costs, reduce overhead, empower pharmaceutical price negotiations, and truncate executive pay. A single-payer system is also incentivized to invest in cost-effective **preventative services** that can avert life-threatening clinical outcomes and expensive downstream treatment. Another advantage of **Medicare-for-Al**l during this pandemic **would** be its **implement**ation of a **standard billing and payment** system, **which would accelerate** COVID-19 case reporting. Billing procedures currently vary across dozens of insurers, and for private insurance is proprietary. Within a consolidated system, patterns in the billing data can signal outbreak hotspots to public health surveillance officials. This consideration is not hypothetical – the single-payer system in Taiwan has facilitated exhaustive COVID-19 data collection and reporting [[10]]. Universal healthcare is fundamental to the continued prosperity of our country in the wake of this and future infectious disease threats. **Obstacles to prompt diagnosis and case isolation** not only impact the individual, but **pose a** broader **societal risk**. A pandemic illustrates an omnipresent truth: that we are each only as safe as the most vulnerable member of our society. We urge investment now in the common good of healthcare security, by extending comprehensive insurance to all who currently lack it. Then, we should move swiftly to create a single-payer system, such as Medicare for All, which is the more efficient way to provide universal coverage [[1]]. **By eliminating financial obstacles to healthcare, we can** pave the way for more efficient outbreak **control**, in both **this pandemic** and the next.

#### **Health Care is affordable. Galvani et al. 20**

[Alison P Galvani, PhD, Alyssa S Parpia, MPH, Eric M Foster, Burton H Singer, PhD, and Meagan C Fitzpatrick, PhD, 02-15-2020, “Improving the prognosis of health care in the USA,” Lancet, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)33019-3/fulltext#%20]

The bottom line of Medicare for All Through the mechanisms detailed previously, we predict that a single-payer **health-care** system **would require $3·034 trillion annually** (figure 3; appendix p 5), $**458 billion less than national** health-care **expenditure in 2017**.40 Even after accounting for the increased costs of coverage expansion, our data-driven base case includes $59 billion savings on hospital care, $23 billion on physician and clinical services, $217 billion on overheads, and $177 billion on prescription drugs (figure 3; appendix p 11). Consequent**ly, annual expenditure per capita would decrease from** $**107396 to** $**9330, equivalent to a 13·1% reduction**. The **expectation of savings is robust** and remains following variation in the input parameters. For example, **if overhead costs only dropped to 6% of total** health **expenditure**—rather than Medicare’s current 2·2%—the **M**edicare **for A**ll Act **would** still **reduce costs by 10·3%**. Conversely, **savings would increase** beyond our base case **if our model overestimates the unfulfilled demand in people who do not have insurance** or are underinsured. Given that $2261 billion is already allocated to health care by existing governmental and philanthropic sources (appendix p 5), a further $773 billion must be collected by the government to fully fund the Medicare for All Act. Restructuring health-care expenditure by employers, individuals, and as a country

#### **UHC ensures wellbeing and increases market size. WHO 21:**

“Universal Health COVERAGE (UHC).” *World Health Organization*, World Health Organization, 1 Apr. 2021, www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc). [Founded in 1948](https://www.who.int/about/who-we-are/history), WHO is the United Nations agency that connects nations, partners and people to promote health, keep the world safe and serve the vulnerable – so everyone, everywhere can attain the highest level of health. WHO leads global efforts to expand universal health coverage. We direct and coordinate the world’s response to health emergencies. And we promote healthier lives – from pregnancy care through old age.

**WHO** contributes to achieving the Thirteenth General Programme of Work 2025 **target** that **1 billion** more **people** **benefit** **from** **UHC**, while **also contributing** **to** the **2** other **billion** **targets** **of** **1 billion** more **people** **better** **protected** **from** **health** **emergencies** and **1** **billion**more **people** enjoying **better** **health** and **well-being**. It also contributes to WHO’s mission of the right to the highest attainable standard of health, to Health for All and the SDGs.

#### **Market size increases lead to increased innovation/this turns the aff. Blume-Kohout et. Al 13:**

Blume-Kohout, Margaret E, and Neeraj Sood. “Market Size and INNOVATION: Effects of Medicare Part D on Pharmaceutical Research and Development.” *Journal of Public Economics*, U.S. National Library of Medicine, Jan. 2013, www.ncbi.nlm.nih.gov/pmc/articles/PMC3711884/. Professor Blume-Kohout is a data scientist *qua* economist who employs theory and quantitative modeling approaches drawn from multiple disciplines—economics, psychology, sociology, statistics, and computer science—to answer public policy questions. Her research examines how government interventions impact STEM workforce participation, higher education, scientific R&D efforts and innovation, and entrepreneurial outcomes. Neeraj Sood, PhD, is professor and vice dean for research at the USC Price School of Public Policy and a founding member the USC Schaeffer Center. His research focuses on economic epidemiology, infectious diseases, pharmaceutical markets, health insurance, economics of innovation, Medicare, and global health. He is currently leading a study on COVID-19 in collaboration with Los Angeles County Department of Public Health. He has published over 100 papers in peer-reviewed journals in economics, medicine, and policy.

**Understanding** the **responsiveness of innovation to expected future revenues** and **market expansions** is **central** **to understanding** the **behavior of private sector innovative firms**, **and** is also critical for **evaluating** the **welfare** **effects** **of** **public policies** such as insurance expansions, price controls, and patent protection. Although **previous** **studies** have **shown** that **increases** **inmarket size** are **significant drivers of pharmaceutical innovation**, If **pharmaceutical** **companies** **respond** **to** the **increases** **in** **market** **size** **as** **predicted**, then all else equal we would **expect** to see an**increase** **in** the **flow** **of** **drugs** **entering** **preclinical** and **clinical** **development**.