BRINGING DOWN THE HOUSE ON INTELLECTUAL PROPERTY AND ACCESS

PHARMA LIES, PEOPLE DIE: A MYTH-BUSTING FACT SHEET ON MEDICINE DEVELOPMENT AND PRICING

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The current leaders of the United States manufacture crises, media optics, and catchy sound bites to side step actual responsibility for tackling immensely complex policy issues like extortionately high prescription drug prices. The American Patients First napkin sketch from the Trump administration draws from the Pharmaceutical Research and Manufacturers of America (PhRMA) playbook to spread unfounded myths, deflect blame from companies for price-gouging hijinks, and posit countries that implement price control mechanisms or intellectual property (IP) flexibilities as scapegoats for the U.S.'s dysfunctional pricing schemes. These antics leave patients without access to critical life-saving treatments and diagnostics while bankrupting Americans and payor systems.

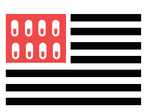
Healthcare and treatment activists have become more well-versed and more coordinated in calling out Pharma lies; with coherent messaging, we can continue to expose the flimsy arguments for stronger IP protection on medicines and monopolistic high pricing, building political momentum toward the systemic policy changes we need. The following fact sheet aims to bust the most common myths spouted by Big Pharma:

MYTH: OTHER COUNTRIES AND MANUFACTURERS OF GENERICS ARE "FREE RIDERS" ON U.S. INNOVATION.

Fact: The free rider argument claims that Americans pay more on research and development (R&D) than people in other countries. There is no evidence to support this claim, and other high-income countries (HICs), such as those in the UK and in Europe, show proportionately equal gross domestic expenditure on R&D (GERD) to the U.S. Furthermore, Pharma still makes substantial profits selling the same medicines for much lower prices in other HICs.

MYTH: PAYING HIGH DRUG COSTS IN THE U.S. TRANSLATES INTO A HIGHER QUALITY OF LIFE AND INCREASED LONGEVITY.

Fact: The U.S. pays the highest prices for medicines in the world; in one 2016 study, the U.S. paid an estimated per capita cost of US$1,443, compared with a range of US$466–US$939 per capita in other HICs. Yet we perform worse on many population health outcomes (including life expectancy) than 10 other HICs. Without federal laws and regulations on medicine prices, Pharma can game the patent and pricing systems in the U.S. Alternatively, other HICs such as Germany and the UK use price review mechanisms and a central negotiating authority. European health systems negotiate medicine prices directly, even refusing to pay excessive prices. But U.S. Medicare, accounting for 29 percent of all U.S. spending on prescription medications, still lacks the authority to negotiate prices (see "Getting Rid of the Boogeyman: the Reality of Prescription Drug Price Controls," page10).



MYTH: PHARMACEUTICAL COMPANIES AND THEIR INDUSTRY GROUPS ARE WORKING WITH GOVERNMENTS TO SUPPORT GREATER DRUG ACCESS.

Fact: Rather than empowering Medicare Part D to negotiate better prices in the U.S., PhRMA and other lobbyists have shifted focus to countries' lower prices due to use of price controls or policy mechanisms that promote generic competition, such as those enshrined in the TRIPS Agreement. The pharmaceutical lobby has influenced the office of the U.S. Trade Representative (USTR) to bully countries into not using TRIPS flexibilities, such as government use licenses, resulting in USTR's threats to place non-compliant countries on its trade watch list, which brings potential penalties, trade sanctions, and loss of economic incentives.

MYTH: THE ESTIMATED COST TO DEVELOP A SINGLE NEW DRUG FROM LABORATORY TO PHARMACY SHELVES IS US$2.6 BILLION. THUS, HIGH DRUG PRICES ARE NEEDED TO FINANCE R&D AND INNOVATION.

Fact: Pharma's prices are chosen to maximize profits and are not based solely, or at all, on R&D costs. By some estimates, U.S. Pharma directs less than 8 percent from sales to R&D.

This oft-cited $2.6 billion figure comes from a problematic study by the Tufts Center for the Study of Drug Development. In keeping with the lack of transparency in companies' actual expenditures on R&D, it does not provide details on the drugs included in the analysis, nor the sample size, nor the costs per patient included in the trials. It also doesn't include the National Institutes of Health (NIH) funding that went into preclinical drug development. The inflated number is a combination of what Tufts spent on the drug that was approved and money spent on projects that failed.

Median clinical trial costs are more likely US$19 million. The Drugs for Neglected Diseases Initiative uses an alternative model of drug development that's even lower in cost. It has reduced overhead through in-kind contributions, pro bono work by scientists, pooled data and libraries, and smaller, faster clinical trials. Thus, combination therapies could be developed for US$10–$45 million; novel drugs from scratch could require just US$110–$170 million in R&D, including the cost of failed therapies.

MYTH: MEDICINES ARE EXPENSIVE TO DEVELOP, SO THEY NEED TO HAVE A HIGH PRICE TO COVER THAT INVESTMENT.

Fact: Medicines are expensive to develop, but R&D costs are exaggerated or undisclosed by Pharma. A concept called delinkage shows the usefulness of separating medicine prices from the cost of manufacturing and investments to R&D, if what we really want to do is ensure affordable access: Calculations for generic production costs of 148 medicines on the World Health Organization Essential Medicines List range between US$0.01 to US$1.45 per tablet, versus the tens of thousands of dollars that payors and/or patients currently pay. For example, a 12-week course of sofosbuvir/ledipasvir can be produced for less than US$100, including a 10 percent profit margin. Medicine prices do not reflect the true cost of R&D.

MYTH: PHARMA NEEDS LONG-TERM PATENTS THAT EXCLUDE GENERICS FROM THE MARKET FOR DECADES SO THEY CAN MAKE BACK THEIR INVESTMENTS IN DRUG DEVELOPMENT.

Fact: R&D costs, plus substantial profits, are most often recovered from sales within the first few years on the market. From 2012 to 2014, Gilead Sciences's R&D costs for sofosbuvir-based regimens were estimated to be US$880.3 million. Since 2014, global sales amount to over US$50 billion, recouping R&D costs *57* times over. In fact, the profits of the largest pharmaceutical corporations are more than double the average of the other Fortune 500 corporations.

Pharma maintains domestic sales profits that exceed R&D costs. For example, in Canada, members of the Innovative Medicines Canada consortium showed domestic profits of US$15.6 billion–20 times higher than R&D costs (US$769.9 million, or a 4.9 percent R&D-to-sales ratio).

MYTH: PHARMA DRIVES INNOVATION THROUGH ITS R&D INVESTMENTS.

Fact: Governments and private philanthropy, not Pharma, drive innovation, particularly in the earlier and riskier stages of R&D. Governments and private philanthropic nonprofit organizations together fund over 40 percent in overall R&D costs, especially in basic science. Pharma then privatizes that work under patent protection, thereby cornering market exclusivity for a medicine for 20 years or longer. In this way, U.S. taxpayers pay twice for patented (originator) medicines: first in the form of government-collected taxes that fund research, and second through payor systems procuring these medicines.

And innovation isn't valuable if it doesn't result in useful treatments. Instead of allocating funds for rare and neglected diseases, Pharma pours profits into marketing, lobbying, legal settlements, stock buybacks, and the creation of "me too" medicines that demonstrate little additional clinical benefit, even if these strategies may innovate how to game capitalism. These practices privatize the benefits of innovation at cost to the public, whereby patients are denied access to affordable medicines and all of society faces higher long-term healthcare costs.

MYTH: STRONGER PATENTS ON MEDICINES PROTECT INNOVATION AND PREVENT THE THEFT OF IDEAS.

Fact: The history of medical progress is filled with examples (like the polio vaccine) of medicines that were developed outside the patent system with the support of public funding. Patents on medicines prevent generic competition, which would dramatically reduce medicine prices. Generic competition dropped the price of HIV antiretrovirals by at least 90 percent.

Moreover, a troubling trend in free-trade agreements, including the renegotiated United States-Mexico-Canada Agreement/North American Free Trade Agreement, is to include TRIPS-plus provisions–those that exceed requirements under the multilateral TRIPS Agreement–that would prolong the monopolies on medicines or undermine countries' ability to set their own patentability criteria.

Data exclusivity under these agreements prevents generic manufacturers from obtaining data on test results for their own studies to show that a medicine is safe and effective. Instead, they must reproduce expensive, time-consuming clinical trials or simply wait longer to introduce their competitor medicine; this delays their ability to bring generic versions to market.

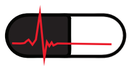
Patent monopolies–defended as incentives for stimulating innovation–actually discourage new ideas because of restrictions on sharing information and the hindrance of access to research. Instead, an open and collaborative approach to biomedical R&D, employing lessons from software development, could accelerate scientific innovation.

MYTH: THE CURRENT DRUG DEVELOPMENT MODEL WILL LEAD TO NEW MEDICINES FOR RARE AND NEGLECTED DISEASES, WHICH ARE PRESSING MATTERS IN PUBLIC HEALTH.

Fact: Pharma directs very little of its R&D funds to addressing rare and neglected diseases. During 2000–2011, only four percent of new medicines and one percent of R&D dollars were for neglected diseases. One model examined 538 candidates for neglected diseases and found significant annual funding gaps–at least US$1.5–$2 billion–over the next five years. Instead, to make a larger profit, Pharma opts to develop "me too" drugs, or identical copies of existing medicines, as well as drugs for non-life-threatening conditions, such as male-pattern baldness, that appeal to consumers in high-income contexts.

MYTH: U.S. DRUG PRICES MAY BE HIGH, BUT THEY DON'T ACTUALLY AFFECT ACCESS BECAUSE PAYORS WILL COVER THE COSTS.

Fact: Extortionate prices contribute to decisions by payors (i.e., public health systems, insurance companies) to restrict or ration treatments, such as direct-acting antivirals. States are then forced to ration these drugs to people living with hepatitis C, which could lead to advanced liver disease and liver cancer. In the U.S., most people living with hepatitis C are on Medicaid or uninsured, and the majority of states restrict treatment according to stage of liver disease, prescriber status, or sobriety requirements. This has resulted in a lack of treatment for 85 percent of people diagnosed with hepatitis C virus in the U.S.



MYTH: PHARMA REBATES WILL REDUCE PRICE AND LOWER OUT-OF-POCKET COSTS.

Fact: Pharma rebates are already calculated in the inflated price as a markup. In order to obtain medicines, health systems (through the Centers for Medicare and Medicaid Services and insurance companies) must pay a huge portion of the list prices. Back-end rebates keep pharmacy prices high, and uninsured and insured patients who are vulnerable to high coinsurance rates experience increasing out-of-pocket costs.

MYTH: U.S. PATIENT ASSISTANCE PROGRAMS COVER THE PRICE OF MEDICINES AND ADDRESS GAPS IN ACCESS.

Fact: Pharma's patient assistance programs enable companies to pass the blame on to insurance companies and do not address root causes of high drug prices. These programs can impose caps, place limits on grants, and require cumbersome application processes. In the case of Truvada for HIV pre-exposure prophylaxis (PrEP), people without healthcare coverage must earn less than 500 percent of the federal poverty level, or US$60,700 for a single-family household, to be eligible for medication assistance programs. Programs may also exclude out-of-pocket costs, such as blood work, that are necessary for monitoring the treatment itself. In the U.S., people using private insurance may have to pay thousands of dollars out of pocket after the co-pay assistance runs out (see TAGline Spring 2016). Gilead's PrEP co-pay assistance recently increased from US$4,800 to US$7,200 per year thanks to community advocacy. It now covers nearly the maximum out-of-pocket cost allowed under the Affordable Care Act for an individual (but not family) plan, potentially mitigating the high cost of Truvada (which averages US$1,600 per month). However, few patients are aware of the program, and some insurers no longer allow the co-pay card to count toward deductibles. Reducing the price and challenging Truvada's unmerited patents would expand affordable access and avoid treatment disruption, particularly among lower-income patients.

TAG
Treatment Action Group