BRINGING DOWN THE HOUSE ON INTELLECTUAL PROPERTY AND ACCESS

PHARMA LIKES, 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 sell a step-by-step approach to tackling immensely complex policy issues like extortionately high prescription drug prices. The American Patients First napkin sketch from the Trump administration shows a cartoonous garden of flowers blooming from tax cuts in a U.S.andelusia, in order to obtain medicines that demonstrate little additional clinical benefit, even if these strategies may innovate how to game capitalism. And innovation isn’t valuable if it doesn’t result in useful treatments. Instead of allocating funds for rare and neglected diseases, Pharma pays profits through back-end rebates, lobbying, legal settlements, kickbacks, 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 benefit of innovations at the public’s expense, while patients are denied access to affordable medicines and all of society faces higher long-term healthcare costs.

**Fact:** Median clinical trial costs are more likely US$19 million. The Drugs for Neglected Diseases Initiative uses an alternative costs. By some estimates, U.S. Pharma directs less than 8 percent from sales to R&D.

**Fact:** Pharmaceuticals and 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., Pharma and other lobbyists have drafted bills that would profoundly impact global policies on medicines.

**Fact:** Pharmaceutical and companies are free riders 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 (GDE) to the U.S. Furthermore, Pharma still makes substantial profits selling the same medicines for much lower prices in other HICs.

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

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**Fact:** Medicines are expensive to develop, but R&D costs are exaggerated or undisclosed by Pharma. A concept called deklage shows the usefulness of separating medicine prices from the cost of drug manufacturing. The price of a new drug is the cost of R&D + what we really want to do or do a more affordable access. Calculations for generic production costs of 148 medicines on the World Health Organization Essential Medicines List range from US$0.01 to US$20 per tablet across the ten thousands of dollars that are paid in drug costs and the costs of the failure.

**Fact:** R&D costs, plus substantial profits are the most often recovered from sales within the first few years on the market. From 2012 to 2014, GlaxoSmithKline’s R&D costs for sofosbuvir-based combinations were estimated to be US$880.3 million. Since 2014, global sales amount to over US$50 billion, recouping a 10 percent profit margin. Medicine prices do not reflect the true cost of R&D.

**Fact:** 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).

**Fact:** The history of medical progress is filled with examples (like the polo vaccine) of medicines that were developed outside the patient 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 antiretroviral medicines by at least 90 percent. Moreover, a troubling trend in free-trade agreements, including the renegotiated United States-Mexico-Canada Agreement (USMCA) and the new Latin America trade deal, would prolong the monopolies on medicines or undermine countries’ ability to set their own patentability criteria.

**Fact:** 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, some nonprofits have argued that the high cost of Truvada (which averages US$1,660 per month) may prohibit thousands of dollars out of pocket after the co-pay assistance runs out. Gilead’s Truvada co-pay assistance recently increased from US$148.00 to US$730.00 per year for Federal Community Assistance.

**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 (GDE) to the U.S. Furthermore, Pharma still makes substantial profits selling the same medicines for much lower prices in other HICs.

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**Fact:** U.S. drug prices may be high, but they don’t actually affect access because payors will cover the costs.

**Fact:** 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 until competitors can do it for them. Moreover, a troubling trend in free-trade agreements, including the renegotiated United States-Mexico-Canada Agreement (USMCA) and the new Latin America trade deal, would prolong the monopolies on medicines or undermine countries’ ability to set their own patentability criteria.

**Fact:** The current drug development model will lead to new medicines for rare and neglected diseases, which are prevalent in the developing world.

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**Fact:** The theory of the secret sauce spouts by Big Pharma:

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