Dealing with drug pricing: not just one solution

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On Dec 11, US Food and Drug Administration Commissioner Scott Gottlieb announced a set of rules that would change the way insulin production is regulated in the USA, potentially leading to increased accessibility and lower prices for the drug. Those changes will not take effect until 2020. The soaring cost and limited supply of insulin (which has been available for nearly a century) is just one example of an ongoing crisis of global drug prices, from treatments for hepatitis C that cost US$100 000 for a single course to cancer drugs that cost $400 000 per year per patient. According to a WHO report on global public health spending, in 2016, the world spent $7·5 trillion dollars on health, nearly 10% of the world's gross domestic product. Spending per capita on health is also highly unequal, nearly $2000 in high-income countries, versus only $400 and $100 in middle- and low-income countries, respectively.

Drug development and dependence on curative medicine at the expense of primary care, prevention, and public health in high-income countries are a huge driver of that disparity. The average annual cost of pharmaceutical spending in OECD countries in 2016 was $573 per capita, $1208 in the USA. An October report from University College London outlined several potential solutions. In the short term, it calls on governments to start using their powers against dysfunctional drug markets. In the USA, Medicare is legally barred from negotiating drug prices with pharmaceutical companies. States can also ensure that increasing drug prices are not a one-way ratchet by using powers to legally procure generic versions of drugs, even in the face of patents, if companies refuse to drop prices to affordable levels.

Moving forward, the entire system of drug development needs to be rethought to bring the incentives in line with public health goals. Pharma companies argue that drug prices reflect the value that those drugs offer to society above alternative treatments, and that the market prices reflect an appropriate cost against the benefit that the drug provides. This argument is not entirely without merit, but ignores the fundamental fact that intellectual property rights and patent protections that allow pharma companies legal monopolies profoundly distort the market. It is impossible to say if the value of a drug's effectiveness is accurately reflected in the price, because pharma companies currently control too many of the underlying factors for the market to work. It also ignores the fact that pharma companies keep the actual costs of drug research and development closely held secrets, making quantifying the costs and benefits nearly impossible. Biosimilars have opened difficult questions of patent litigation and drugs are routinely reformulated in new, barely different guises: more than half of all drugs approved offer no additional clinically meaningful benefit.

Laws like the US Orphan Drug Act of 1983 (ODA), or programmes like Defense Advanced Research Projects Agency (DARPA), which laid the groundwork for the internet, incentivised private corporations to pursue research and development in line with stated goals, instead of just pursuit of profit. The ODA offered incentives (such as exclusivity periods and tax discounts) to companies that developed drugs for neglected diseases and proved to be an enormous success: 575 treatments for rare diseases have been approved since the law's passage, and similar legislation has been adopted in Japan and the European Union. Indeed, the ODA has become something of a victim of its own success, with pharma companies developing drugs for rare cancers under the auspices of the ODA, slicing the diseases to develop narrowly targeted treatments that are very effective for a very small number of patients, but take advantage of the benefits of the law.

The global market for pharmaceuticals is an artificially constructed one that contains innumerable barriers, restrictions, and loopholes that have developed over decades in different countries and aimed at solving different problems. Addressing drug costs will require a global effort, one that acknowledges that markets are not a panacea, and patents should not be viewed as an immutable contract. There is not a single solution to drug pricing, but any number of efforts: requiring pharma companies to offer a fair accounting of their costs, incentivising development that puts public health goals at the forefront, and ensuring that innovation is not just for innovation's—or profit's—sake. Some of these efforts will require serious, fundamental changes in how we approach drug development; many we could implement tomorrow, if we had the will. ■ *The Lancet*

For the **WHO report, Public spending on health: a closer look at global trends** see http://apps.who.int/iris/handle/10665/276728

For the **OECD data on pharmaceutical spending** see https://data.oecd.org/healthres/pharmaceutical-spending.htm

For the **UCL report** see https://www.ucl.ac.uk/bartlett/public-purpose/publications/2018/oct/peoples-prescription

For more on **orphan drug prices** see **Viewpoint** *Lancet* 2018; **392:** 791–14.