

Why government must negotiate a better deal for publicly funded research

The investigation by *The BMJ* and Cambridge and Bath universities into the availability of breakthrough hepatitis C drugs raises important questions for NHS England about access to lifesaving drugs.<sup>1</sup> But why are medicines so expensive in the first place? The pricing strategy of Gilead for sofosbuvir (Sofaldi) and ledipasvir-sofosbuvir (Harvoni) raises questions that go well beyond the UK.

*The BMJ's* investigation is just an example of a more general problem. What is the right price to pay for a particular drug, and how should this be determined?

Pharmaceutical innovation should be structured to focus on unmet health needs globally and delivers therapeutic advances that are affordable and accessible to all,<sup>2</sup> not just profitable for manufacturers. This requires an approach that directs effort towards therapeutic innovations over “me too” drugs, and a transparent financing and pricing structure, focused on access, and reflecting the collective investment and risk taking involved.

Drug companies have often ignored the collective element of innovation and argued that their research and development investment justifies the extraordinarily high prices for some medicines, despite the lack of transparency. The Drugs for Neglected Diseases initiative has documented much lower drug development costs,<sup>3,4</sup> and several authors have shown the extent to which taxpayer funded investments subsidises those costs.<sup>5</sup> In the US alone, tax payers fund \$32bn a year of research and development expenditure through the National Institutes of Health (NIH).<sup>6</sup>

**Value judgment**

Sofosbuvir and ledipasvir, the drugs on which *The BMJ* investigation is based, relied on early stage funding from the NIH and the Veterans Administration.<sup>7</sup> Sales of the two drugs were around \$12bn in 2014,<sup>8</sup> far in excess of the \$880.3m which Gilead reported for sofosbuvir related trials from 2012 to 2014,<sup>7</sup> showing a complete disconnection between price and development costs.

As high prices are hard to justify based on research and development costs, drug companies have instead argued that their prices are proportionate to the intrinsic value of the drugs—that is, the costs to society if a disease was not treated, or if treated with the second best therapy available. “Price is the wrong discussion,” declared Gilead’s executive vice president, Gregg Alton, responding to criticism over the price of sofosbuvir, “value should be the subject.”<sup>9</sup>

Mariana Mazzucato, R M Phillips professor in the economics of innovation, Science Policy Research Unit, University of Sussex, UK M.Mazzucato@sussex.ac.uk

But there is no consistent link between a drug’s price and the associated medical benefit.<sup>10</sup> A study published in 2015 in the *Journal of Economic Perspectives* examining a sample of 58 cancer drugs approved in the US between 1995 and 2013, shows that the increasing trend in the price of these medicines is not explained by the survival benefits they provide. Over two thirds of new medicines reaching the market do not represent any therapeutic advance for patients, with many patents based on a reshuffling of old combinations or additional uses for existing ones.<sup>11</sup>

**A better way**

An effective pricing system should ensure accessibility and reflect the public contribution so taxpayers don’t pay twice, through publicly subsidised research and high priced medicines. In such a system, drug prices do not need to be so much higher than manufacturing costs. We could, for example, limit patents on new medicines (the current source of company profits) and instead establish a competitive prize system that rewards well targeted pharmaceutical innovation. This would allow widespread access to drugs at competitive prices through generics, while pushing drug companies to focus their energy on delivering innovations that fulfil real medical need. In any case, patents should not be so upstream to affect scientific research, and should remain relatively narrow so as not to close off future discoveries.<sup>12</sup> They should foster innovation, not stifle it.

Importantly, drug pricing must be transparent, so that governments can negotiate for better value and ensure that the prices of new drugs reflect the burden of financial risk borne by the taxpayer. Public funders could retain the lion’s share of intellectual property rights (patents) produced by public research so that spillovers through licensing can be better managed to foster diffusion. In the US, the 1980 Bayh-Dole Act that allowed publicly funded research to be patented includes a clause enabling the government to cap the prices of drugs that are largely publicly funded. The US government has never exercised this right.<sup>13</sup>

The international debate about unsustainable drug prices, including those for hepatitis C drugs, offers an opportunity to rethink the therapeutic innovation ecosystem—the direction and the accessibility of the drugs that result. Realising that government has power to actively shape and create markets, and not just remain on the sidelines fixing broken ones, is the first important step to reaching a better deal.<sup>14 15</sup>

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# A pill too hard to swallow: how the NHS is limiting access to high priced drugs

A joint investigation by *The BMJ* and Cambridge and Bath universities uncovers how NHS England tried to limit access to expensive new drugs.

**Jonathan Gornall,**  
**Amanda Hoey,** and  
**Piotr Ozieranski**  
report