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THE CONVERSATION

Faster access to new drugs doesn't always mean better treatment

Ghinea, N., Lipworth, W., 15 Mar 2017

US President Donald Trump recently chose an adviser to a large pharmaceutical company to lead the country's drug regulation agency.

Scott Gottlieb – who reportedly sits on the boards of several small drug companies and is an adviser to GlaxoSmithKline – is expected to introduce greater flexibility to the evidence standards used by the Food and Drug Administration (FDA) to evaluate the benefit and risks of new medicines.

This is consistent with Trump's message to pharmaceutical executives in January, when he said:

We're going to be cutting regulations at a level nobody's ever seen before […] You're going to get your products – either approved or not approved – but it's going to be a quick process.

Trump's views might seem extreme but his comments are not entirely out of step with the views of previous US governments. An example is the 21st Century Cures Act, which was passed late last year after heated debate. This aims to speed up innovation and the search for cures by setting lower thresholds for evaluating the safety and effectiveness of new medicines.

The Act is an addition to a range of expedited programs the US already had in place for some time to permit drugs to enter the market based on less robust evidence than traditionally required. So Gottlieb already has the tools to make it easier to get drugs onto the market in the US.

But what does this mean for Australia? A recent comment piece published in the journal Nature noted that weaker regulatory standards in the US can impact health everywhere. One reason is companies will have far less incentive to run the expensive high-quality trials needed to inform decision-making if the biggest market in the world does not demand it.

Dangers of deregulation

Intuitively, it might seem desirable to speed up access to medicines. But this means more drugs will be approved that may subsequently prove unsafe or ineffective.

One could also argue regulatory standards are already lax. For example, one study showed all the cancer drugs approved for solid tumours between 2002 and 2014 had only a minor effect on patients' survival rates – a median increase of just more than two months.

And an FDA report released in January outlined details of 22 drugs with early promise that either proved unsafe or ineffective in subsequent research.

Some may believe easing restrictions for companies to get their drugs to market will make investing in drug development less risky and more attractive, enhancing innovation. But true innovation demands taking greater risks.

If companies can get their drugs approved more quickly and make money off drugs that are less risky to develop, this actually takes away the incentive for innovation. In the case of cancer drugs development, some experts have blamed the marginal improvements in outcomes on regulators and payers being too lax rather than too strict.

Forces at play

There are social and political forces dictating the push to deregulate the drug market. Pressure to speed up access to medicines is framed as being in the best interest of patients. But this debate can't ignore that countries like the US have an economic interest in keeping the pharmaceutical industry producing medicines, and ensuring people buy them at a premium.

These companies also want to get their drugs onto the market as quickly as possible before generic (copycat) drugs come in and drive down prices. A report by consultancy group IMS Health predicted patent-protected medicines will lose US$127 billion in revenue due to generic medicines entering the market by 2016.

In 2004, at the request of the US Congress, the US Commerce Department published a report about the implications of strategies used by other governments to limit medicine prices. If price controls were removed, it concluded, pharmaceutical revenues from patented medicines would increase significantly, including in Australia.

As US firms hold most of the intellectual property rights for new medicines, most of this income would then funnel back into the US and support US jobs. It should not be a surprise, then, that the US leads the way in deregulating pharmaceutical markets.

US Medicare, for instance, cannot negotiate prices and the FDA seems set to make it easier for drugs to enter the market. Trump has been open about his view that foreign countries should pay more for drugs and that foreign price controls are unfair for the United States.

This is understandable because the US economy has the most to lose from the reticence of regulators to approve medicines, and insurers to pay for them. A US biotech industry lobby group reports the industry supports 4.5 million jobs and is responsible for US$1.2 trillion in economic output. It says the average employee in the bio-pharmaceutical sector is paid double the average US wage.

How does all this affect Australians?

When the US is more lenient in its regulatory processes, this creates a dilemma for Australia's Therapeutic Goods Administration – our version of the FDA. It also creates issues for the Pharmaceutical Benefits Advisory Committee, which advises the government which drugs to subsidise.

Patients in Australia may see new drugs becoming available overseas and wonder why they don't have access to the same. Australian regulators and payers are then accused of being old-fashioned, while patients believe they are missing out on the latest and greatest drugs.

This puts immense pressure on Australian regulators and payers to keep up with the rest of the developed world, which means becoming more lenient with evidence standards and prices.

This trend is evident in the case of cancer medicines. Australia's Cancer Drug Alliance claims Australian patients are already falling behind in access to new cancer medicines.

This sentiment was echoed in the Senate inquiry on the availability of new, innovative and specialist cancer drugs in Australia conducted in 2014-2015. This highlighted concerns about "delays" in access to cancer medicines available overseas.

In parallel with this inquiry, the Australian government set up an expert panel in 2014 to review medicines regulation. The panel's conclusion supported expediting access to medicines in Australia.

US pressure to deregulate medicine markets no doubt speeds up access to new drugs. But the rationale isn't always to help patients. It often has more to do with the economic interests of countries with a strong research-based pharmaceutical industry.