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Report urges controversial 'delinkage' to foster new antibiotics

It is conceivable that the day may come when a pandemic bacterial strain emerges with resistance to all of the drugs currently available in our medical arsenal. Given this possible threat, a leading UK think tank has released a report calling for a radical new business model to kickstart the development of new antibiotics.

In the report published in February by the London-based Chatham House, Kevin Outterson, a health policy expert at the Boston University School of Law, argues that revenues for antibiotics need to be separated from sales. The document, titled "New Business Models for Sustainable Antibiotics," explains that this can be achieved by awarding companies upfront payments whenever new drugs are approved, for example, with a patent buyout prize or licensing agreement from the government.

Such a scheme would make infection-fighting agents profitable while removing any incentives that might spur the kinds of inappropriate uses that drive the evolution of antibiotic resistance. "From society's perspective, we want antibiotics to be available and used appropriately," Outterson says, "and from a company's perspective, they want a credible commitment that when they commit funds to antibiotic research

and development, in ten years' time the money will be there." The delinking of sales and profits could provide a solution to both concerns, he says.

Currently, the deck is stacked against antibiotic research and development. To guard against resistance, new antibiotics typically need to be restricted to small populations of patients at high risk from infections that do not respond to other therapies. Not only is the potential market small, but most courses of treatment last only a few weeks, compared with months or even years for more lucrative drugs such as arthritis medications. Crucially, antibiotics have not historically commanded premium prices. "Put all those things together, and you can see that antibiotic development is not an attractive proposition with the current commercial model," says David Payne, head of the Antibacterial Discovery Performance Unit at GlaxoSmithKline (GSK) in Collegeville, Pennsylvania.

Weighing worth

Outterson will be leading a working group at Chatham House throughout the spring to hash out more details regarding the proposal for a new antibiotics funding model. The thorniest issue could be how much money governments and insurers should be prepared

to pay out for a new drug. The global antibiotics market currently generates sales in excess of \$40 billion each year, "so taking just a small percentage of that and bringing it into a new funding mechanism would create a significant fund," says Outterson. Any sum would need to be attractive enough to encourage new companies into the area, says GSK's Payne, who took part in a Chatham House roundtable discussion on the issue.

Exactly how delinked models would work in practice would probably differ from country to country. In Europe, where many countries operate health systems on a single-payer basis, government patent buyouts would be more likely to work than in the US, where a licensing arrangement negotiated between government programs and companies, with provisions for private insurers to join the scheme, would be needed.

"Delinking is a fairly imaginative way to think about the problem, and I think it would have some benefit because it puts the reward for investment relatively close to the actual investment," says Don Ganem, head of infectious diseases at the Novartis Institutes for BioMedical Research, based out of Emeryville, California. However, the delinkage concept faces an uphill battle: "If you're of the persuasion that government intervention in this sort of thing isn't right, then you're going to ask, 'Why are we paying tax dollars to support what is already a profitable industry?'" Ganem says. "Any delinked model is going to suffer from that political problem."

What is indisputable is that the status quo is untenable. An estimated 48,000 people die in Europe and the US each year from infections caused by antibiotic-resistant bacteria, and this number is very likely to increase in years to come. "This is a global issue and a moral issue that needs to be dealt with in collaboration," says Otto Cars, of the Swedish Institute for Communicable Disease Control in Solna. "Delinkage is a necessary element [to] get rid of market-driven overuse. We need simply to find another model, and that is a responsibility for everyone to realize."

David Holmes



Money talks: Experts suggest governments should pay big sums for new antibiotics.