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# Superbugs call for super changes in drug-sale rules

By Aaron Kesselheim and Kevin Outterson

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TODAY, THE Centers for Disease Control and Prevention will launch a campaign to stop the overuse of antibiotics, which are fast becoming useless in the war against resistant infections.

The CDC is right on target. We cannot afford to simply wait for new antibiotics to solve this crisis. It takes years to develop new drugs and meanwhile resistant micro-organisms like the one carrying the NDM-1 gene are spreading fast.

Boston is not immune: Last September a patient at Massachusetts General Hospital came down with a resistant infection caused by the NDM-1 gene. Already drug-resistant infections kill tens of thousands of Americans every year and many more worldwide.

As experts in the economics of antibiotic resistance, we've crafted an innovative solution to this public health crisis: developers of new antibiotics should be compensated for the true value that antibiotics bring to society, but such payments should be conditioned on doing everything we can to avoid wasting antibiotics through overuse and overselling. This will preserve the power of antibiotics so that these drugs will still work in the future. In addition, we must increase funding for research that can lead to the development of new antibiotics.

Right now, drug companies have financial incentives to maximize sales to turn a profit as quickly as they can — as soon as a new antibiotic hits the market, it's in a race against the patent clock and competitors.

To maximize profits, some companies market antibiotics for conditions that aren't necessarily proven to respond to that treatment — like minor ear aches in children. And doctors are willing to prescribe them, especially if faced with a patient or parent who is demanding a quick fix.

Hospitals tend to overuse antibiotics, in some cases simply to ward off infections that haven't yet occurred. Wasteful use of these antibiotics in doctors' offices and hospitals has created an environment that gives fast-adapting microbes the advantage. And that overuse has led to a dire situation in which common antibiotics can no longer be relied upon to offer a fast and effective cure. What can we do?

First, we need to price new antibiotics at a higher level that better reflects their value. Antibiotics are valuable to society, but reimbursed as if they were cheap and plentiful. Second, we need incentive-based policies that ensure that antibiotics are not oversold and their usefulness undermined. Under our proposal, payment for new antibiotics would be conditioned on meeting conservation and resistance targets set by the government. The CDC, for example, could use factors such as disease incidence and the rate of emerging resistance to set public health goals, which would then be re-assessed on a regular basis. If the observed data met the target, the manufacturer would maintain its marketing exclusivity. In other words, instead of being subject to the traditional patent period, the manufacturer would earn revenue on the drug

by showing that careful marketing and infection-control activities had slowed the rate at which resistance had developed.

Right now, drug companies derive little financial benefit from acting as responsible stewards of antibiotics — we can't reasonably expect these companies to tell their stockholders that profits are down because of goodwill efforts to protect the public health. But we can expect drug companies to realign their goals if they have economic incentives to act for the common good.

Second, some new antibiotics are very valuable, but only a few patients with highly resistant diseases need them. We should use these antibiotics very sparingly today, saving them for later years when resistance is more widespread. But if we preserve these important new antibiotics for our children, companies complain that their sales are undercut. Why invest in R&D if the product can't be sold to many people?

Under our proposal, outlined with help from the Extending the Cure project in the September issue of Health Affairs, developers of new antibiotics would be incentivized to support the end goal of reducing resistance, including a Strategic Antibiotic Reserve. Finally, we believe that pharmaceutical manufacturers would find it in their interest to provide needed resources to hospitals to adopt strict surveillance and infection-control protocols so that resistant organisms cannot easily jump from one place to the next.

Antibiotic resistance has become an urgent public health problem that requires comprehensive solutions involving action by consumers, drug companies, hospitals, and other key players. If we do nothing, it is only a matter of time before doctors have few available drugs to treat the latest resistant microbe — be it from overseas or the hospital down the street.

Aaron Kesselheim, M.D., J.D., M.P.H., is an instructor in medicine in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and Harvard Medical School. Kevin Outterson, J.D., LL.M., is an associate professor at the Boston University Schools of Law and Public Health.

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