

Questions over value of new antibiotics to tackle resistance

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In the first installment of a new series, Peter Doshi, Assistant Professor at the University of Maryland School of Pharmacy and Associate Editor at *The BMJ*, asks why authorities are approving drugs with little evidence they do anything to tackle the problem of antimicrobial resistance.

Antimicrobial resistance is a major health care problem worldwide. US president, Barack Obama, has called it "a serious threat to public health and the economy" while in the UK, Sally Davies, chief medical officer for England, declared the problem "as important as global warming," and a "ticking time-bomb."

The Food and Drug Administration (FDA) now offers a series of marketing incentives for [new antibiotics](#), explains Doshi.

Backed by a law passed by Congress in 2012, 61 chemical entities have been granted "qualified infectious disease product" (QIDP) status, promising manufacturers accelerated review of new [drug](#) applications and five additional years of marketing exclusivity.

Another bill introduced this year aims to substantially lower the requirements for FDA approval for certain new antibiotics, he adds.

The FDA told *The BMJ* that a QIDP product is "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections and does not have to show added benefit in terms of efficacy." But if there is no added benefit, what makes the drugs

worth approving, asks Doshi?

He points out that three of the five new antibiotics were approved for skin infections, yet there are already over 30 other drugs approved for these conditions, including treatment for MRSA infections.

Still, both industry and the Infectious Diseases Society of America (IDSA) argue that the new drugs are tackling the problem of antimicrobial resistance, pointing to the fact that the drugs are approved to treat MRSA infections.

So, if the drugs don't directly deal with [antibiotic resistance](#), what about providing additional treatment options for "serious or life threatening infections," as defined in the QIDP regulations, asks Doshi?

But none of the approved drugs were ever tested to evaluate whether they saved lives.

"While the FDA celebrates new drugs approved under the GAIN Act, there remains no evidence the drugs meet unmet medical need, address [antimicrobial resistance](#), or are more effective than pre-existing antibiotics," writes Doshi.

Nevertheless, some US congressmen argue that industry needs further incentives, and in January a new bill was introduced - the Promise for Antibiotics and Therapeutics for Health (PATH) Act.

The bill proposes lowering the requirements for FDA approval of new antibiotics that target unmet medical needs in specific, limited populations of patients.

Proponents argue these changes are necessary to study rare but important pathogens, but Doshi warns that, limited use or not, "the evidentiary

standards set forth in PATH suggest that future patients will be offered drugs with very limited evidence of efficacy."

An accompanying commentary warns that new legislation to further speed the drug approval process while further weakening the standards for safety and efficacy is "a trade-off with potentially deadly consequences."

Diana Zuckerman, president of the National Center for Health Research in Washington DC, and Gregg Gonsalves, lecturer in law at Yale University and a patient living with HIV, say though all drugs are supposed to meet "appropriate standards" for safety and effectiveness, "the standards for most drugs approved through expedited pathways are clearly lower, with smaller and shorter term studies than are otherwise required."

They also point out that, when problems are discovered, "corrective action doesn't happen swiftly" and that medical devices "are subject to even weaker approval criteria."

They conclude that, like the AIDS patients who successfully pushed for a more flexible approach to drug approval decades ago and realized that proof of safety and effectiveness were essential to save lives, today's patients "need knowledge - answers about the drugs they put in their bodies - not just access."

If proposed legislation entitled "21st Century Cures" and similar bills are passed, they "will radically alter the nature of drug, device, and biologics approval in the US, roll back patient safeguards, and leave an FDA that looks more like the one that existed in the mid-20th century, not one worthy of the 21st."

More information: Speeding new antibiotics to market: a fake fix?

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