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Antibiotics: Play or Pay?

By David Shlaes — February 12, 2019

Courtesy: David Shlaes [1]

In my last blog [2] I discussed the potential pull incentive proposed in the UK Plan to tackle antimicrobial resistance. One of the other proposals in the plan was to implement a play or pay policy for companies actively engaged or not in antibiotic research and development. This idea was touted both by Jim O'Neill in the AMR Review and in his recent GARDP blog [3]. I should point out that this is an old idea first proposed (as far as I know) by Dr. Lou Rice at an ICAAC meeting back in 2004. The idea was not included in the 2004 white paper from the Infectious Diseases Society of America, Bad Bugs No Drugs (no longer available on the IDSA website). Dr. Rice's motivation was, in part, related to the marketing of antibiotics by industry that he felt may have helped to foster abuse and, ultimately, increasing resistance. Play or pay was designed as an incentive for companies to engage or to continue to be engaged in antibiotic discovery and development and as a disincentive for disengagement. The proposal occurred at a time when many large pharmaceutical companies had abandoned the area.

As is true for all of these attractive-sounding ideas, the devil is in the details. I have never understood exactly how such a policy could be implemented (but I'm happy to be enlightened).

First, how do we define "company?"I assume that we are targeting large pharmaceutical companies to encourage them to re-engage in antibiotic R&D. I would define them as those with annual revenues of $10 billion or more. Allergan and Celgene would now be included in this group. But, one might ask, what about mid-cap companies like Regeneron, Valeant and others? I am assuming that small companies would be exempt from play or pay.

Secondly, we must define "research" and "development" and decide if companies must carry out both activities to qualify. My view is that both preclinical and clinical research should

be required. What domains must the research include? Is a therapeutic vaccine effort sufficient? Is research on preventative vaccines or therapies OK? My own opinion is that vaccine research would be excluded from play or pay. We need new therapeutics such as small molecules, peptides, proteins, antibodies and other similar approaches. Where does research end and development begin? Research could be defined as anything prior to, say, phase II clinical development. That way, phase I trials would be part of discovery research. If companies were allowed to just claim development activities for new therapies, Pfizer would qualify. But if pre-clinical research into new therapeutic approaches were required, Pfizer might not qualify.

Third, how much should they play or pay? Obviously, this incentive/disincentive has to be large enough that it works as such. One way to do this would be to require that 10% of a company's total R&D budget be dedicated to antibacterial research and development. Many large pharmaceutical companies spend around $5-6 billion on R&D. Roche spent much more in 2017 (around $11 billion). Therefore, the required spend on antibacterial R&D would be between $500 million and $1.1 billion in this scenario. The difference between their actual spend on antibacterial R&D and the 10% number would be the required payment.

What would happen to any monies that came into the treasury based on this scheme?These funds could be used to support antibacterial research in academia and small companies and could be used to support significant pull incentives for new and needed antibiotics.

Where would the money come from? Ahhhh! It is virtually certain that these costs would pass right back to consumers regardless of how any play or pay policy is implemented. And this takes us back to square one. Do we want pharmaceutical consumers to pay or do we want to spread the payments for required antibacterial R&D and pull incentives among all taxpayers? I vote for the latter.
