The Economic Conundrum for Antibacterial Drugs

By David Shlaes — October 31, 2019

I just finished writing a commentary for Antimicrobial Agents and Chemotherapy entitled, The Economic Conundrum for Antibacterials. You can find the accepted manuscript (requires subscription) here [1]. Earlier this fall, I was interviewed for a podcast – you can listen here [2]. In both cases, I argued that the numbers of patients with highly resistant infections today are not sufficient (in the developed world) to drive an adequate market for antibacterial drugs active against these resistant pathogens.

I made the point that our pipeline is precarious. Next I tried to show how the economics of commercialization of new antibacterial drugs put companies, especially the small companies that provide the bulk of our antibacterial pipeline today, in the crosshairs of financial failure such as occurred with Achaogen.

Both during the podcast interview and in the review of the manuscript, I was confronted with what seems to be a dominant view outside of our own echo chamber. That view is that the market is not failing – it is working and telling us that there is just not a sufficient medical need today and that it is not guaranteed that the need will be there in 10-20 years.

The reviewer provided additional feedback that I will try and summarize.

They noted that even though the pipeline might be considered to be inadequate by us “experts” it is more robust today than it has been at any time since the 1990s. And, I admit, that is true. But a careful look at the pipeline reveals a number of substantial weaknesses that did not exist in the 1990s. First, the majority of the sponsoring companies are small biotechs with precarious financing. Second, many of the pipeline products, especially those in preclinical and early clinical development are very high risk. I still believe, therefore, that the pipeline is not going to be adequate if resistance to current first line therapy continues to grow and especially if resistance to
second and third line therapies emerges and grows rapidly.

The reviewer also was of the opinion that Achaogen got what it deserved. He argued that they sunk a great deal of money into a product the market for which was probably not what they advertised. And they were critical of Achaogen’s investment in discovery research.

The reviewer was also apparently upset that much of the small molecule pipeline today consists of “me too” products including Achaogen’s plazomicin. My view is that one person’s “me too” is another’s best friend. But it is clear that for plazomicin, the projected medical need and market were just not there.

In my paper, I spent time reviewing post-approval activities that companies undertake and their costs. Some of these are required by the regulatory authorities while others are more focused on education and “marketing.” The reviewer noted that no company should commit to exorbitant post-approval obligations for a product with a very limited market.

Finally, I was accused of being an investor in the industry who is just out to make a “tone” of money.

While it was difficult for me to read the review of my paper and, at times, to hear the podcast interviewers’ views, the experience was eye-opening. I find that us “experts” spend a great deal of time talking among ourselves in a sort of echo-chamber bubble that protects us from these opposing views. And I see that these views are not necessarily those of a small and radical minority, but probably represent a far more substantial set of clinicians, pharmacists and other stakeholders.

One area where everyone seemed to agree (whew!) that action was necessary was at the level of expert societies and automated susceptibility testing devices.

· I suggested that that expert societies step up to the plate and provide a minimum of yearly update on suggested therapies for key infections;

· And that automated susceptibility testing kits be required to provide clinical laboratories with testing capability for such new, high priority drugs within one year of approval.

After all this reflection, though, I find myself back at the starting line. What will we do today to deal with a future of uncertain rates of bacterial resistance? Will we act to protect investments in important potential antimicrobial treatments or will we let market dynamics take over?