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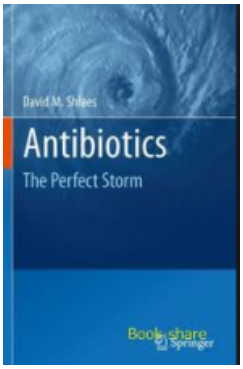
Pharma gingerly returns to antibiotic research: Too little too late?

By ACSH Staff — January 28, 2014



The very good news [1] is that antibiotic research by drug companies is slowly starting up again after a long sabbatical. But almost without exception, the complete story of how we got here is not told.

ACSH s Dr. Josh Bloom explains: The current discussion of this topic is almost always focused on the huge difference in price and profit that can be commanded by cancer drugs, especially compared to that of antibiotics. While this is part of the story, it is certainly not the whole story. To better understand the factors that led to this crisis, you have to go back further in time.

Things started to go downhill in 1992, when the FDA, for no good reason, came up with the idea that antibiotic clinical trials were statistically underpowered. Under their new criteria, clinical trials for new antibiotics became much more difficult, typically requiring twice the number of participants in clinical trials. The FDA also came up with some other ridiculous ideas the best example was the need for a control group that had never taken any antibiotic. But there are other factors involved.

ACSH advisor Dr. David Shlaes, former vice president of infectious disease research at Wyeth, discusses the quadruple whammy that has put us in our current precarious state: In 1999, when Roche dropped their antibiotic R&D effort, there were many reasons behind this move. First, it was the middle of the genomics era and no one was finding any new antibiotics. So the antibiotic pipelines in big pharma were mostly dry.

But there were other factors involved. says Shlaes. This was also the era of the blockbuster mentality in big pharma. A $300-500 million dollar peak year sales drug was no longer acceptable. It had to be $500 million to $1 billion or more like the antidepressants and the statins that you had to take for many years or for the rest of your life. A one week antibiotic course didn t look so good next to chronically administered drugs when you started to look at net present value and return on investment. Then there was the FDA who was starting its lets make antibiotic development harder, longer and more expensive routine that may have been the final nail in the coffin for many of the companies who left the area.

Additionally, explains Dr. Bloom, Companies did not drop antibiotic research simply so that they could sell very expensive cancer drugs in their place. In addition to the reasons above, Gleevec, the prototypical targeted cancer drug was not approved in the US until 2001 after the beginning of big pharma s exodus from antibiotic research. So, there is no way that companies could have anticipated the number of these very expensive (and profitable) drugs that would hit the market a decade later.

That being said, it seems like policy makers are now realizing the value of new antibiotics, as well as the consequences of not having them. With sufficient incentive for companies doing this work, a complete reversal of the FDA s overly stringent policy on clinical trials and a little technological luck, it is at least feasible that this will result in badly-needed new antibiotics.

For a very thorough discussion of this ongoing process, we recommend that you read Dr. Shlaes excellent blog [2], Antibiotics-The perfect storm.

Note: One baby step the US government s unprecedented decision to provide financial support to a private drug company (GlaxoSmithKline) to help pay for clinical trials of new antibiotics to was discussed by Dr. Bloom in his May 31st *Wall Street Journal* op-ed [3] entitled A Welcome Boost in the Race for New Antibiotics.

Links
[1] http://online.wsj.com/news/articles/SB10001424052702303465004579322601579895822
[2] http://antibiotics-theperfectstorm.blogspot.com/
[3] http://online.wsj.com/article/SB10001424127887323728204578513833987142000.htm