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Has the FDA started to display a little sanity? Two new antibiotics beat down MRSA. One has been approved, and the other is likely.

By ACSH Staff — June 6, 2014

We at ACSH have written frequently about the misguided change in mindset by the FDA two decades ago that brought most antibiotic research to a dead stop.

No one has been deeper in the FDA trenches than ACSH advisor and infectious disease expert Dr. David Shlaes. He has been blogging [1], advising, lobbying, begging, and doing just about everything short of pulling his hair out to convince the infectious disease division of the FDA to reverse the disastrous changes in clinical trial policy that caused almost all drug companies to abandon research in this area.

Nowhere is his frustration more evident than a blog piece [2] where he reports that even as late as 2012 (!) more than a decade after the antibiotic crisis began the FDA s policy on clinical trials still was essentially prohibitive.

Well, perhaps they have started listening, because two new antibiotics dalbavancin [3] and oritavancin [4], which were not only effective against the infamous MRSA infections of the skin, but only required one dose will likely soon be available. Both drugs both were found to perform about as well as vancomycin the standard treatment for serious MRSA skin infections, as highlighted this week two studies, both in the June 5th NEJM.

Oritavancin has had a checkered history. Shlaes explains, Oritavancin is an antibiotic that has been around since the late 1980s or early 1990s. It was rejected by the FDA in 2008, but was picked up by The Medicines Company [5], which conducted additional trials. It would seem that the additional safety data from these trials, the single dose regimen and the return of some sanity to the FDA all combined to give this new antibiotic a much needed nudge.

Dalbavancin was approved last month [6], no doubt due to changes in the antibiotic approval process, as we wrote about earlier this wee [7]k. The drug was categorized as a Qualified Infectious

Disease Product under the new Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act, due the the fact that it is intended to treat serious and potentially life-threatening infections. This ensured that the drug was given priority review, expediting the review process. Oritavancin is expected to receive FDA guidance during their upcoming August meeting.

The approval, according to Dr. Edward Cox, director of the Office of Antimicrobial Products in the FDA s Center for Drug Evaluation and Research, demonstrates the FDA s commitment to encouraging increased development and approval of new antibacterial drugs, providing physicians and patients with important new treatment options.

ACSH s Dr. Josh Bloom comments, The FDA played a huge part in getting us into the current mess. Let s hope that Dr. Cox backs up his statement with action.

Links

[1] http://antibiotics-theperfectstorm.blogspot.com/
[2] http://antibiotics-theperfectstorm.blogspot.com/2012/11/suspending-disbelief-fda-reboot-and.html
[3] http://www.nejm.org/doi/full/10.1056/NEJMoa1310480
[4] http://www.nejm.org/doi/full/10.1056/NEJMoa1310422
[5] http://www.themedicinescompany.com/
[6] http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm398724.htm
[7] http://acsh.org/2014/06/antibiotic-resistance-may-leading-us-pre-antibiotic-era/