

Antibiotics and the FDA: will the agency reboot its policies?

By ACSH Staff — July 31, 2013



^[1]Former vice president of infectious disease research at Wyeth and

ACSH advisor Dr. David Shlaes knows a thing or two about dealing with the FDA, and its misguided policies regarding approval of new antibiotics. Shlaes, an expert consultant and the author of the sometimes horrifying blog "[Antibiotics the perfect storm](#) ^[2]," has been lobbying the FDA for years, trying to get them to correct their disastrous policies that began in the 1990s and have left us with a public health emergency - antibiotic resistance and the lack of a robust pipeline of new drugs to combat this resistance.

Dr. Shlaes has just had a commentary accepted in the prestigious journal *Antimicrobial Agents and Chemotherapy*, where he discusses the FDA's effort to "reboot" their antibiotic policies.

"They have requirements for prohibiting the use of all prior antibiotics," Dr. Shlaes said. "People get sick, they call their physicians and physicians prescribe antibiotics over the phone, so by the time the patient is sick enough to get to an emergency room where they might be enrolled in a trial, they've already had one or two doses of antibiotics. So some of their requirements simply aren't feasible."

You won't believe some of the obstacles he has faced. In the above interview, he gives an overview of a very serious regulatory problem that could have probably been prevented.

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