We are facing a critical shortage of new antibiotics that may lead to an inability to practice modern medicine, according to Dr. Carl F. Nathan, chairman of the department of microbiology and immunology at Weill Cornell Medical College. He explains, in a New York Times op-ed, how economic and scientific factors are to blame.

In terms of the economic challenge, relatively few people may need a specific antibiotic during its patent life and individuals only take antibiotics for a limited time, making the investment in antibiotics not as likely to generate profits, as compared to drugs for chronic illnesses such as high cholesterol and diabetes, in the eyes of drug companies. Scientifically, bacteria mutate to evade antibiotics, since resistant strains survive, making it difficult to find effective drugs that can fight back.

Further complicating the situation, according to ACSH's Dr. Josh Bloom, the FDA has been setting the bar at such an unattainable level for an antibiotic to be approved, that few companies are willing to invest the kind of money needed to conduct appropriate clinical trials and tests.

And ACSH friend Dr. David Shlaes, the former head of infectious disease at Wyeth, would agree. In his recent blog he notes that the statisticians in the FDA infectious disease advisory committee have absurd (or impossible) requirements for clinical studies of antibiotics that may contribute to the statistical power of the trial, but are prohibitively expensive and clinically meaningless. Regarding proposed trials for treatment of pneumonia, he says, No one will ever run trials in nosocomial (hospital acquired) pneumonia under the FDA's current guidance. No one. Put these three factors together, and it spells a recipe for disaster.

In order to fix this problem, Dr. Nathan proposes creating an environment in which science is done open-lab-style, where academics, the government and drug companies work together and share what they learn. Nathan says that relaxing the traditional insistence on secrecy allows collaboration, and with it, innovation. He further proposed that perhaps there should be a monetary reward given by an intergovernmental fund for new drugs in proportion to their impact on reducing the loss of healthy years of life.

Whatever the solution, the interplay of the science, economics and the FDA needs to change to keep up with modern medicine or we will be soon facing routine infections, such as strep throat that are difficult or impossible to treat.
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