FDA pushes to fight drug-resistant germs (that they helped cause)

By ACSH Staff — November 19, 2013

In today’s you must be kidding news, the FDA, prodded by the Obama administration, told Congress [1] that they were very concerned about the threat of bacteria that are immune to drugs.

ACSH’s Dr. Josh Bloom, who is rarely at a loss for words, managed to scrape a few together: This is like Donald Trump complaining that his name is on too many buildings. Twenty years too late, the FDA is now concerned about a problem that they helped create.

How did this happen? Beginning in the 1990s statisticians at the FDA decided that clinical trials for new antibiotics were underpowered, and wanted companies to run larger, more expensive, and sometimes impossibly onerous trials. It was even proposed that a control group of patients who had never taken an antibiotic should be required in each trial.

Predictably, most drug companies dropped out of the field entirely. And this is reflected perfectly by looking at the following data of three consecutive decades: [2]

1981-1990: 42 new antibiotics
1991-2000: 18 new antibiotics
2001-2011: 7 new antibiotics

As recently as 2009, the FDA was still recalcitrant about antibiotic development, requiring trials that could never be done [3]. Worse, the supposed FDA reboot [4], proposed by Dr. Janet Woodcock, the director of the FDA’s Center for Drug Evaluation and Research (CDER), which was supposed to facilitate new drug discovery still has gone no place [5].

And given the agency’s attitude about this, it is not surprising. Yesterday Dr. Woodcock said, We feel that a limited pathway for development of antibiotics for drug resistant organisms would address this growing epidemic that we’re seeing.

To which Dr. Bloom simply noted, Duh.
Yet, there may be some hope after all. A July 2013 FDA document entitled Guidance for Industry: Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases, although not yet policy, is at least adding some focus to this discussion. Whether anything comes from this is anyone’s guess.

Hang on folks, it’s going to be a bumpy ride.

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