New drugs: A numbers game or just the wrong number?

By ACSH Staff — January 10, 2014

A the end of every year there is a tally of the number of new drugs that were approved by the FDA during that year. This was recently covered quite thoroughly in a Forbes.com op-ed by Bernard Munos entitled The FDA Approvals of 2012: A Watershed? Munos points out that the number of approvals in 2013 (27) was down sharply from the 37 new drugs that were approved in 2012. While this may be an important number for the pharmaceutical industry, in terms of public health these numbers don’t mean all that much.

ACSH’s Dr. Josh Bloom explains: The number of new approvals is far less important than what these new drugs are designed to treat.

As was the case in 2012, cancer drugs led the pack. Of the 27 new drugs approved in 2013, eight were oncology drugs. The story was similar for 2012 (12 out of 37). But, the focus on oncology drugs, many of which add only months of life to cancer patients, is at the expense of something far more important new antibiotics. In 2012 and 2013 the number of newly approved antibiotics was the same zero.

As Dr. Bloom pointed out in his New York Post op-ed entitled Searching for the Wrong Miracles, drug companies have changed their focus to oncology and orphan drugs both of which are extremely expensive ($100,000 per year is typical), and we are paying the price for this. For example, infections from antibiotic-resistant infections kill more people per year than breast and prostate cancer together.

Just as the FDA approval numbers were released, three related stories highlight the severity of the situation:

In England, the crisis is becoming even more clear. Professor Jeremy Farrar, director of the Wellcome Trust, says "This [the use of antibiotics] is getting to a tipping point where you and your families will start to see this not in infections many many miles away but here in London. Britain is reaching a tipping point in its use of antibiotics beyond which people will start dying of everyday infections.

Driving home this point, several months ago the Government’s Chief Medical Officer Professor Dame Sally Davies said the threat posed by antibiotic resistance was a "ticking time-bomb, which
should be put on the National Risk Register.

To get an idea of how serious this they are taking this threat, just look at another item on this list: Catastrophic terrorist attacks.

And a recent article in the January 8th Wall Street Journal provides little comfort. There was an outbreak of perhaps the most dangerous antibiotic-resistant bacteria, carbapenem-resistant enterobacteriaceae (CRE), in 44 people in a hospital near Chicago last year. The previously largest cluster of CME infection was ten.

Dr. Bloom says, This one is really scary. The mortality rate for CRE is about 50 (!) percent. And if you need proof how quickly this is becoming a problem, in 2001 the first case of this resistant infection was identified at a hospital in North Carolina. Now it has spread to 46 states.

To complete the nightmare trifecta of the week, the Centers for Disease Control and Prevention (CDC) chimed in with a report entitled Threat Report 2013.

Commenting on the report, CDC Director Dr. Tom Frieden noted, "When first-line and then second-line antibiotic treatment options are limited by resistance or are unavailable, health care providers are forced to use antibiotics that may be more toxic to the patient and frequently more expensive and less effective.

ACSH advisor, Dr. Dave Shlaes, an infectious disease expert, writes a blog called Antibiotics- The Perfect Storm. For information on how we got into this mess, and what is being done to remedy this emergency, there is no better place to go.