

As superbug problem mounts, drug companies slash antibiotics research

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Infectious disease specialists have drawn a causal link between an alarming rise in the number of Quebec hospital patients becoming infected with and dying from *Clostridium difficile*—a bacterium resistant to standard antibiotics—and government budget-cutting. As the *World Socialist Web Site* previously reported, researchers studying the *C. difficile* pandemic in Quebec have linked the bacteria's spread to the unsanitary environment created by decaying infrastructure, patient overcrowding, and reduced staffing. [See "Canada: budget cuts have contributed to spread of super-bug"]

Hospital-based infections and bacteria resistant to standard antibiotics—so-called superbugs—are interlinked and growing problems. In Quebec, more than 3,000 people died last year as the result of infections they contracted while hospitalized, making hospital-contracted infections the fourth most important cause of death in Quebec. While many of the victims were persons who were very old or already seriously ill, a significant number succumbed to bacteria resistant to common antibiotics.

Since the early 1980s, the problem of superbugs has increasingly preoccupied medical specialists and with good reason. It is estimated that currently 20 percent of all bacterial infections in the US involve microbes resistant to one or more antibiotics.

Media reports on the superbug phenomenon typically treat it as exclusively a natural phenomenon. Bacteria that are resistant to antibiotics or that have become resistant due to a mutation survive antibiotic treatments, while the elimination of the non-resistant strain facilitates the rapid proliferation of the "superbug." This explanation, based on the Darwinian principle of natural selection, is certainly scientifically valid. But like the spread of Quebec's *C. difficile*, the

related general problem of superbugs is also linked to social conditions—poverty, the lack of basic hygiene, and the subordination of fundamental health care concerns to the profit needs of big business.

An article published almost 10 years ago in one of the journals of the American College of Physicians observed that in Asia, the Middle East and Latin America, home to more than three quarters of the world's population, there is the greatest concentration of antibiotic resistant bacteria, even though only 20 percent of all antibiotics are consumed there.

The article asked, "Why do countries that can afford so little have so great a problem with resistance to antimicrobial drugs? The situation appears to be due to a combination of a heavy burden of bacterial infectious diseases; huge populations without even the rudiments of primary health care; inappropriate use of the available antimicrobial drugs; and rapid spread through crowding, poor sanitation, and sexual contact. Self-prescribing is common in most developing countries, and the effect is compounded by a bewildering array of proprietary drugs containing irrational mixtures of vitamins, stimulants, and

steroids and by the availability of drugs without prescription for purchase in local pharmacies or open-air markets. Physicians, when available, need to see as many patients as possible in the shortest period of time with minimal, if any, laboratory or radiologic support. They often feel compelled to prescribe antimicrobial drugs to meet patient expectations. The pharmacies work on small mark-ups. The amount of an antimicrobial purchased is often inadequate to treat serious infections....

"In some countries, the political systems are so corrupt, the local business community so venal, and the physicians so disillusioned that the situation seems

hopeless.”

Nevertheless, the author still held out hope that the spread of superbugs could be reversed by the development of new antibiotics and other antimicrobial drugs. However, the situation has changed dramatically over the past decade. Despite the threat posed by bacteria resistant to standard antibiotics, the major pharmaceutical companies are withdrawing from research into antimicrobial drugs.

The number of new antimicrobial drugs approved by the FDA, the US agency responsible for authorizing the marketing of pharmaceuticals, has fallen significantly: 16 were approved between 1983 and 1987; 14 between 1988 and 1992; 10 between 1993 and 1997; and 10 more in the last five-year period, 1998-2003. In 2003, the number of new anti-infection agents submitted to the FDA for testing fell by 10 percent from the year before, an indication that the long-term trend is likely to continue.

In 2001, Eli Lilly and Bristol-Myers Squibb stopped work on developing new antimicrobial drugs. Other major drug companies are reported to be about to do likewise. A major conference of microbiologists, doctors and pharmacists held in Chicago in September 2003 hosted a session devoted to discussing why the major drug companies are withdrawing from antibiotics and antimicrobial research. The session was titled “Why Is Big Pharma Getting Out of Anti-infective Drug Discovery?”

Dr. Henry Masur, one of the session speakers, left no doubt as to the impact of drug makers’ bottom-line on research decisions that will ultimately affect the lives of masses of people: “The cost of drug development is astronomical, the market is not nearly as enticing as markets that involve drugs that must be taken for a lifetime rather than days or weeks, and there is considerable pressure to reduce prices.”

Nature, one of the world’s leading scientific journals, summarized the Chicago session. Its summary read, in part: “Big drug companies are in the financial doldrums, and antibiotics research is easy to cut, said Steven Projan, who directs such work at Wyeth’s facility in Pearl River, New York. Natural selection makes resistance inevitable, rendering any antibiotic less profitable over time. New drugs that combat resistant bacteria are often held in reserve by doctors to treat only the most stubborn infections—so they aren’t

big earners. And unlike drugs for chronic illnesses such as heart disease, antibiotics cure people, eliminating their customers.”

Antibiotic sales are valued at between \$24 and \$26 billion per year and are expected to rise by 10 percent over the next four years. Yet, because they can make larger profits by developing other sorts of drugs, the pharmaceutical companies are cutting back on antibacteria research.

To evaluate the quality of an investment, the pharmaceutical industry uses an index called risk-adjusted net present value or NPV. It takes into account several factors, including expected sales, research costs and costs of the clinical tests needed to get government approval for mass marketing. According to the aforementioned Projan, antibiotics have an NPV of 100, anti-cancer drugs 300, neurological drugs 720 and muscular-skeletal 1150.

The pharmaceutical companies have replied to the criticism of their research decisions by complaining about the costs associated with getting government approval to market new antibiotics. Their standard refrain is that there is too much bureaucracy. FDA records show, however, that since 1964 anti-infection agents have had the highest approval rate of all classes of therapeutics and since 1982 the shortest or second shortest development time.



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