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Industry

Pharma firms looking for a superbug killer

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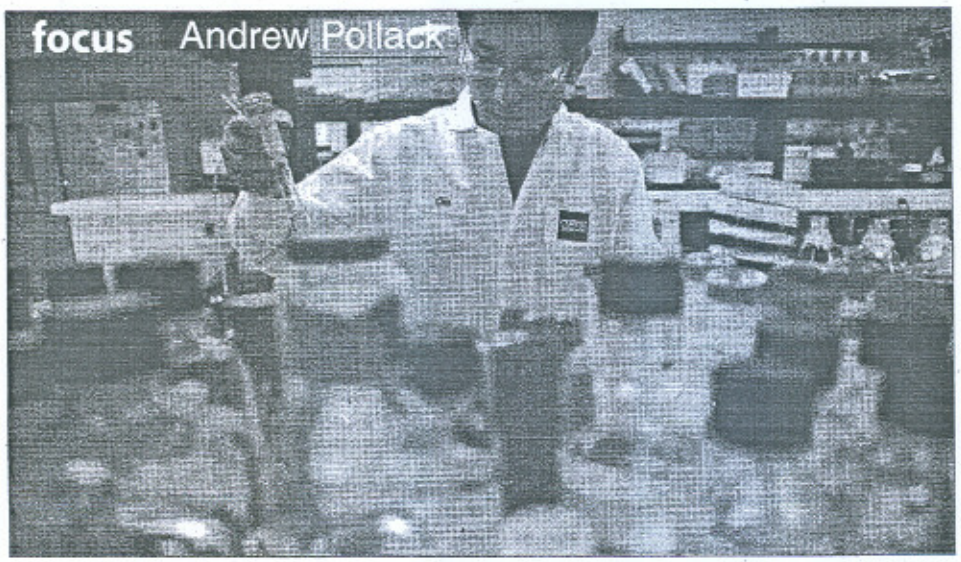

A lab at Cubist Pharmaceuticals in Lexington, Massachusetts, which develops antibiotics. PHOTO: NYT

WORRIED ABOUT an impending public health crisis, government officials are considering offering financial incentives to the pharmaceutical industry, like tax breaks and patent extensions, to spur the development of vitally needed antibiotics.

While the proposals are still nascent, they have taken on more urgency as bacteria steadily become resistant to virtually all existing drugs at the same time that a considerable number of pharmaceutical giants have abandoned this field in search of more lucrative medicines. The number of new antibiotics in development is "distressingly low," Dr Margaret A. Hamburg, commissioner of the Food and Drug Administration, said at a news conference last month. The world's weakening arsenal against "superbugs" has prompted scientists to warn that everyday infections could again become a major cause of death just as they were before the advent of penicillin around 1940.

"For these infections, we're back to dancing around a bubbling cauldron while rubbing two chicken bones together," said Dr Brad Spellberg, an infectious disease specialist at Harbor-UCLA Medical Centre in Torrance, California

For example, scientists have become alarmed by the spread from India of a newly discovered mutation called NDM-1, which renders certain germs like E. coli invulnerable to nearly all modern antibiotics. About 100,000 Americans a year are killed by infections acquired in hospitals, many resistant to multiple antibiotics. Methicillin-resistant staphylococcus aureus, or MRSA, the best known superbug, now kills more Americans each year than AIDS.

While the notion of directly subsidising drug companies may be politically unpopular in many quarters, proponents say it is necessary to bridge the gap between the high value that new antibiotics have for society and the low returns they provide to drug companies.

"There is a market failure," said Representative Henry A. Waxman, a California Democrat and the chairman of the House Energy and Commerce Committee, who said he was considering introducing legislation. "We need to look at ways to spur development of this market."

Mr Waxman will lose his committee chairmanship with the Republicans having won control of the House this week. But the idea of spurring antibiotic development appears to have some bipartisan support. Representative Phil Gingrey, a Georgia Republican and a physician, recently introduced the Generating Antibiotic Incentives Now bill, which would provide certain antibiotics with five extra years of protection from generic competition and speed the reviews of new antibiotics by the Food and Drug Administration.

Besides tax breaks and extra protection from competition, other ideas policymakers are considering would include additional federal funding of research and guaranteed purchases by the government of new antibiotics. Measures like these are already used to encourage the development of drugs for rare diseases, through the Orphan Drug Act, and for illnesses like malaria that primarily afflict poor countries.

The Obama administration is also taking some steps. The federal agency that oversees development of treatments for bioterrorism agents like anthrax is broadening its scope to encompass more common infections. In August, the agency, known as the Biomedical Advanced Research and Development Authority, awarded its first such "multi-use" contract, giving an initial $27 million to a company called Achaogen to develop an antibiotic that could be used for plague and tularemia as well as antibiotic-resistant infections.

The department of health and human services is considering creating an independent fund that would invest in small bio-defense companies.

Antibiotic-resistant germs would be exempt from priority review, according to a report that the department issued in August.

The European Union is also working on a plan, based on proposals from the London School of Economics. A year ago, the United States and the European Union formed a task force on antibiotic resistance.

Despite the activity, there is no consensus on what would work best and little discussion of how much such measures would cost.

A paper issued last month by the Office of Health Economics, a consulting firm owned by the British pharmaceutical industry's trade group, suggested that incentives exceeding $1 billion per drug would be required.

Some critics say the case for incentives is not yet persuasive. There are signs that the drug industry is picking up its efforts on its own, in response to perceived need. The number of antibiotics in clinical trials has climbed sharply in the last three years, reversing a steady decline that began in the 1980s, according to figures from the FDA. The efforts are being led by small companies, which can be satisfied with smaller sales.

Ramanan Laxminarayan, who directs the Extending the Cure project on antibiotic resistance at Resources for the Future, a policy organisation, said the government should focus on conserving the effectiveness of existing antibiotics. That could be done by preventing unnecessary use in people and farm animals and requiring better infection control measures in hospitals.

"There's not a recognition yet that we should think about antibiotics as a natural resource and we should conserve them like we do fish," Mr Laxminarayan, an economist, said. Kevin Outterson, an associate professor of law at Boston University, said one way to encourage both new development and conservation would be to pay drug companies to develop new antibiotics but not to aggressively market them. Incentives, he said, "must be conditioned on the companies' changing their behaviour."

Only five new antibiotics were approved by the FDA from 2003 through 2007, down from 16 in the period from 1983 to 1987. A survey last year by European health authorities found only 15 antibiotics in clinical trials that offered some promise of going beyond what is available today.

Only five of the 13 biggest pharmaceutical companies still try to discover new antibiotics, said Dr David M. Shlaes, a consultant to the industry and the author of a new book *Antibiotics: The Perfect Storm.*

One reason is that antibiotics are typically taken for a week or two and usually cure the patient. While that makes them cost-effective for the health system, it also makes them less lucrative to drug companies than medicines for diseases like cancer or diabetes, which might be taken for months, or even for life, because they do not cure the patient. "There's this perverse disincentive against antibiotics because they work so well," said J. Kevin Judice, chief executive of Achaogen.

Another factor is that new antibiotics are likely to be used only sparingly at first, to stave off the emergence of resistance. While that might be medically appropriate, it reduces the ability of a drug company to recoup its investment, said Dr. Barry I. Eisenstein, a senior vice president at the antibiotic maker Cubist Pharmaceuticals. Another factor discouraging investment, some experts say, is that the F.D.A. recently made it harder for new antibacterial drugs to win approval.

Leading the call for incentives has been the Infectious Diseases Society of America, whose members are infectious disease specialists. It is calling for a "10 by '20" initiative to develop 10 new antibiotics by 2020.

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