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Safety Rules Can't Keep Up With Biotech Industry

By **ANDREW POLLACK** and **DUFF WILSON**

They are the highly trained, generally well-paid employees in the vanguard of American innovation: people who work in biotechnology labs. But the cutting edge can be a risky place to work.

The casualties include an Agriculture Department scientist who spent a month in a [coma after being infected](#) by the E. coli bacteria her colleagues were experimenting with.

Another scientist, working in a New Zealand lab while on leave from an American biotechnology company, lost both legs and an arm [after being infected](#) by meningococcal bacteria, the subject of her vaccine research.

Last September, a [University of Chicago](#) scientist [died after apparently being infected](#) by the focus of his research: the bacterium that causes plague.

Whether handling deadly pathogens for biowarfare research, harnessing viruses to do humankind's bidding or genetically transforming cells to give them powers not found in nature, the estimated 232,000 employees in the nation's most sophisticated biotechnology labs work amid imponderable hazards. And some critics say the modern biolab often has fewer federal safety regulations than a typical blue-collar factory.

Even the head of the federal [Occupational Safety and Health Administration](#) acknowledges that his agency's 20th-century rules have not yet caught up with the 21st-century biotech industry.

"Worker safety cannot be sacrificed on the altar of innovation," said David Michaels, OSHA's new director. "We have inadequate standards for workers exposed to infectious materials."

The current OSHA rules governing laboratories, for example, were not written with genetic manipulation of viruses and bacteria in mind. "The OSHA laboratory standard deals with

chemicals," Mr. Michaels said. "It doesn't deal with infectious agents."

Earlier this month, as a first step toward possible new regulations, the agency issued a sweeping request for information on occupational risks from infectious agents, and for suggestions on how best to reduce them. The focus is mainly on hospital and other health care workers, but any rules are expected to also cover industry laboratory workers.

Some safety experts in the biotechnology industry argue that there is no big safety problem, and that workers are adequately protected by various voluntary guidelines on safe laboratory practices and by OSHA's general rule that employers provide a safe workplace.

"The OSHA requirement applies to all industries, including the pharmaceutical industry," said John H. Keene, a biosafety consultant to industry and former president of the American Biological Safety Association, a professional society for those involved in biolab safety.

But at least three trends are stoking concern among safety advocates. In the wake of the 2001 [anthrax](#) attacks, the federal government stepped up research involving biowarfare threats, like anthrax, Ebola and many other of the world's deadliest pathogens. Another factor is that the new techniques of so-called synthetic biology allow scientists to make wholesale genetic changes in organisms rather than just changing one or two genes, potentially creating new hazards. Just this month, the genome pioneer [J. Craig Venter](#) announced the creation of a bacterial cell containing totally synthetic DNA, which Dr. Venter described as the first species "whose parent is a computer."

The third trend involves the shifting focus of the [pharmaceuticals](#) industry — potentially the largest source of new biotechnology jobs. Drug makers, responding to competition from cheap generic medications, are moving beyond the traditional business of making pills in chemical factories to focus instead on vaccines and biologic drugs that are made in vats of living cells.

There are currently few good statistics on biolab accidents. One study, reviewing incidents discussed in scientific journals from 1979 to 2004, counted 1,448 symptom-causing infections in biolabs, resulting in 36 deaths. About half the infections were in diagnostic laboratories, where patient blood or tissue samples are analyzed, and half in research laboratories.

But that may be a "substantial underestimation," the study's authors wrote, because many incidents are never made public. The study was done by two biosafety experts and published in the book "Biological Safety: Principles and Practices."

A survey done by the [Bureau of Labor Statistics](#) in 2006 found that the rate of workplace injury and illness in corporate scientific research laboratories was well below the average for all

industries. The survey included labs in industries like information technology as well as biotechnology, and excluded labs handling the most dangerous pathogens.

Allegations about a more recent case came to light only through a lawsuit. It was filed against the drug giant [Pfizer](#) by Becky McClain, a former molecular biologist at the company's largest research center, which employs 3,500 people in Groton, Conn.

Ms. McClain, now 52, says she has suffered bouts of temporary [paralysis](#) after being infected by a genetically engineered virus at the Groton lab. [A jury last month awarded](#) Ms. McClain \$1.37 million, saying Pfizer had fired her for raising questions about laboratory safety.

Pfizer said it went to considerable effort to accommodate Ms. McClain and dismissed her for refusing to return to a safe workplace. The company also pointed out that OSHA had found that Ms. McClain was not fired for raising safety concerns. But [the jury ruled](#) otherwise, saying Ms. McClain was indeed fired for raising safety concerns of public interest.

The jury never actually addressed whether a workplace virus had made Ms. McClain ill, because the judge threw out that claim, in part for lack of evidence. Mr. Michaels, the OSHA director, declined to comment on the McClain verdict, but said the issues under dispute in her case underscored the gaps in regulatory protection for lab workers.

For almost all private businesses, OSHA requires employers to report workplace deaths and serious accidents. But the information is usually kept in-house by employers and given to OSHA only if requested during an annual spot check of 80,000 companies — a small fraction of the approximately seven million employers bound by OSHA regulations.

Moreover, OSHA does not have jurisdiction over many academic and government biolabs, where there have been dozens of known cases of worker illness or at least exposure to harmful agents.

Many laboratories in both the public and private sectors adhere to practices in a safety manual published jointly by the [Centers for Disease Control and Prevention](#) and the [National Institutes of Health](#). Employees of government biolabs and others that receive federal research grants for genetic engineering are covered in part by stricter guidelines from the National Institutes of Health, and some companies voluntarily follow those guidelines. But other private industry workers are dependent on OSHA.

Mr. Michaels said that rather than trying to establish new rules for each infectious agent or for any specific hazards, he expected OSHA to eventually require employers, in consultation with their employees, to identify all potential hazards in their workplaces and to take steps to reduce

them. OSHA would then have the power to cite employers for failure to adequately implement this process.

“OSHA has 2,000 inspectors for 130 million-plus workers in seven million workplaces,” Mr. Michaels said. “We can’t take them on one at a time.”

Despite the fact that some worker advocates are pointing to Ms. McClain’s case as representative of broader problems, they are hard pressed to cite other examples of workers in biotechnology companies being harmed.

But these advocates contend that the reason more cases in private industry are not coming to light is that current rules do not put enough pressure on companies to report them. And OSHA’s general safety requirement is notoriously difficult to enforce.

“We don’t know how many Becky McClains there are,” said Adam M. Finkel, who worked for OSHA both as a regional administrator and a director of health standards. “Everybody knows there’s new stuff being made every day that’s incredibly dangerous, but nobody knows how to get their arms around it.”