

FDA CBER RESEARCH ACTIVITIES  
FUNDING

Mr. BENNETT. Mr. President, the fiscal year 2004 Agriculture, Rural Development and Related Agencies Appropriations Act includes appropriations for the Center for Biologics Evaluation and Review of the Food and Drug Administration to continue important vaccine and biological product research activities. Support of these research activities is essential for keeping CBER scientists and medical reviewers up-to-date and knowledgeable of the breakthrough science of vaccine and biological product research and development. Being involved in this cutting edge research better equips CBER scientists and reviewers with the best scientific-based tools for reviewing and regulating the safety and efficacy of live-saving vaccines and other biological products.

During our subcommittee and Committee deliberations, many colleagues shared my concerns about the emergence of SARS, West Nile Virus, monkey pox, antibiotic resistant staphylococcal infections in hospitals, and other naturally-occurring infectious diseases in the U.S. I believe there is a need to expedite the development and licensing of new vaccines and biologicals to protect our citizens from these naturally-occurring infectious diseases. As with recent efforts and increased appropriations to augment research, regulatory testing and scientific capabilities of the FDA to assist in combating bioterrorism threats, I endorse FDA's continued support of those capabilities at the Center for Biologics Evaluation and Research to combat the public health threats from naturally-occurring diseases. It is my view that continued support of these capabilities will better enable the Center to recruit and retain highly-qualified, motivated scientists and medical reviewers for vaccines and other biological products.

In past years, CBER scientists engaged in laboratory and clinical research, which greatly improved their understanding of the science, their mission of assuring the safety and efficacy of the products under review by FDA, the medical needs of patients, and alternative products available. This understanding resulted in a more efficient and rapid agency licensing processes for many new products, which presented complex scientific, medical and public health issues. For example, CBER reviewers deeply involved in relevant laboratory research were responsible for the complex yet expeditious regulatory review and licensing of the four combination diphtheria-tetanus-acellular pertussis (DTaP) vaccines and the four Hib (meningitis) conjugate vaccines during the last decade.

Past CBER research has significantly contributed to technology transfer and benefited the public through the development of assays and reagents, which would otherwise be too costly and

time-intensive for industry to duplicate. This research has facilitated the expedited testing, development, and availability of several important licensed vaccines for the prevention of life-threatening pediatric diseases and is critical for others currently under development for licensing in the future.

Mr. President, I urge the Administration to provide sufficient funding in fiscal year 2005 for continued CBER research. These appropriations are essential for expediting not only the development and availability of licensed counter-bioterrorism vaccines and biological products, but also for those intended for the prevention and treatment of naturally-occurring infectious diseases, such as SARS, West Nile Virus and HIV-AIDS.

PROTECTION OF LAWFUL  
COMMERCE IN ARMS ACT

Mr. LEVIN. Mr. President, 2 weeks ago, the majority leader indicated that before this session of Congress comes to an end, the Senate may consider the Protection of Lawful Commerce in Arms Act, a bill the New York Times has said "would give gun manufacturers and dealers a courthouse shield that tobacco and asbestos companies never had in being forced to come to terms with some of the damage their products inflict." While it now appears unlikely that the bill will be considered in the Senate this year, I would nevertheless like to express my concerns about it.

The bill would rewrite well-accepted principles of liability law, providing the gun industry legal protections enjoyed by no other industry. Some claim that this bill would prevent frivolous lawsuits and protect firearm manufacturers, dealers, and distributors from being held responsible for the actions of criminals. While most gun dealers and manufacturers may conduct their business responsibly, this bill would shield negligent and reckless gun dealers and manufacturers from legitimate civil lawsuits.

In fact, according to the Brady Campaign to Prevent Gun Violence and the Violence Policy Center, many meritorious cases could be dismissed under the bill. And according to a letter from University of Michigan Law Professor Sherman Clark, the case filed by the Washington, D.C. area sniper victims is among those that would not survive if the legislation were enacted. I ask unanimous consent that a copy of Professor Clark's letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE UNIVERSITY OF MICHIGAN  
LAW SCHOOL,

Ann Arbor, MI, November 6, 2003.

DEAR MEMBERS OF THE UNITED STATES SENATE: As a professor of law at the University of Michigan Law School, I write to make two points regarding the legal implications of S.

1805, the "Protection of Lawful Commerce in Arms Act."

First, S. 1805 would represent a substantial and radical departure from traditional principles of American tort law. Though described as an effort to limit the unwarranted expansion of tort liability, the bill would in fact represent a dramatic narrowing of traditional tort principles by providing one industry with a literally unprecedented immunity from liability for the foreseeable consequences of negligent conduct.

Second, more specifically, and by way of illustration, S. 1805, as currently drafted, would mandate the dismissal of litigation currently pending against the dealer and manufacturer who are alleged to have negligently enabled John Allen Muhammed and Le Boyd Malvo to obtain the assault rifle used in the recent D.C. sniper killings.

S.1805 IS INCONSISTENT WITH TRADITIONAL  
PRINCIPLES OF TORT LAW

S. 1805, described as "a bill to prohibit civil liability actions from being brought or continued against manufacturers, distributors, dealers, or importers of firearms or ammunition for damages resulting from the misuse of their products by others," would largely immunize those in the firearms industry from liability for negligence. This would represent a sharp break with traditional principles of tort liability. No other industry enjoys or has ever enjoyed such a blanket freedom from responsibility for the foreseeable and preventable consequences of negligent conduct.

It might be suggested that the bill would merely preclude what traditional tort law ought to be understood to preclude in any event—lawsuits for damages resulting from third party misconduct, and in particular from the criminal misuse of firearms. This argument, however, rests on a fundamental misunderstanding of American tort law. American law has never embraced a rule freeing defendants from liability for the foreseeable consequences of their negligence merely because those consequences may include the criminal conduct of third parties. Numerous cases from every American jurisdiction could be cited here, but let the Restatement (Second) of Torts suffice:

§49. TORTIOUS OR CRIMINAL ACTS THE PROBABILITY OF WHICH MAKES ACTOR'S CONDUCT NEGLIGENT

If the likelihood that a third person may act in a particular manner is the hazard or one of the hazards which makes the actor negligent, such an act whether innocent, negligent, intentionally tortious, or criminal does not prevent the actor from being liable for harm caused thereby. (emphasis supplied)

Thus, car dealers who negligently leave vehicles unattended, railroads who negligently manage trains, hotel operators who negligently fail to secure rooms, and contractors who negligently leave dangerous equipment unguarded are all potentially liable if their conduct creates an unreasonable and foreseeable risk of third party misconduct, including illegal behavior, leading to harm. In other words, if the very reason one's conduct is negligent is because it creates a foreseeable risk of illegal third party conduct, that illegal conduct does not sever the causal connection between the negligence and the consequent harm. Of course, defendants are not automatically liable for illegal third party conduct, but are liable only if—given the foreseeable risk and the available precautions—they were unreasonable (negligent) in failing to guard against the danger. In most cases, moreover, the third party wrongdoer will also be liable. But, again, the bottom line is that under traditional tort