

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

principles a failure to take reasonable precautions against foreseeable dangerous illegal conduct by others is treated no differently from a failure to guard against any other risk.

S. 1805 would abrogate this firmly established principle of tort law. Under this bill, the firearms industry would be the one and only business in which actors would be free utterly to disregard the possibility that their conduct might be creating or exacerbating a potentially preventable risk of third party misconduct. Gun and ammunition makers, distributors, importers, and sellers would, unlike any other business or individual, be free to take no precautions against even the most foreseeable and easily preventable harms resulting from the illegal actions of third parties. Under S. 1805, a firearms distributor could park an unguarded open pickup truck full of loaded assault rifles on a city street corner, leave it there for a week, and yet be free from any negligence liability if and when the guns were stolen and used to do harm.

It might appear from the face of the bill that S. 1805 would leave open the possibility of tort liability for truly egregious misconduct, by virtue of several exceptions set forth in Section 4(5)(i). Those exceptions, however, are in fact quite narrow, and would give those in the firearm industry little incentive to attend to the risks of foreseeable third party misconduct.

One exception, for example would purport to permit certain actions for "negligent entrustment." The bill goes on, however, to define "negligent entrustment" extremely narrowly. The exception applies only to sellers, for example, and would not apply to distributors or manufacturers, no matter how egregious their conduct. Even as to sellers, the exception would apply only where the particular person to whom a seller supplies a firearm is one whom the seller knows or ought to know will use it to cause harm. The "negligent entrustment" exception would, therefore, not permit any action based on reckless distribution practices, careless handling of firearms, lack of security, or any of a myriad potentially negligent acts.

Another exception would leave open the possibility of liability for certain statutory violations, variously defined, including those described under the heading of negligence per se. Statutory violations, however, represent just a narrow special case of negligence liability. No jurisdiction attempts to legislate standards of care as to every detail of life, even in a regulated industry; and there is no need. Why is there no need? Because general principles of tort law make clear that the mere absence of a specific statutory prohibition is not *carte blanche* for unreasonable or dangerous behavior. S. 1805 would turn this traditional framework on its head; and free those in the firearms industry to behave as carelessly as they would like, so long as the conduct has not been specifically prohibited. If there is no statute against leaving an open truckload of assault rifles on a street corner, under S. 1805 there could be no tort liability. Again, this represents radical departure from traditional tort principles.

S. 1805 WOULD REQUIRE THE DISMISSAL OF
PENDING D.C. SNIPER LITIGATION

Litigation is currently pending in Washington State against the manufacturer and dealer from whom John Allen Muhammed and Leo Boyd Malvo obtained the assault rifle used in the D.C. area sniper killings. The lawsuit, brought on behalf of victims' families, alleges in essence that the defendants' negligent practices and inadequate security made this weapon available to Muhammed and Malvo. There is nothing in-

novative or cutting edge about this litigation; and it is certainly not based on any new or liability-expanding theory. Rather, it alleges straightforward negligence, and is analogous to the sort of case that might be brought against a contractor who leaves explosives unguarded at a construction site. Allegedly, the firearm in question was so poorly secured that 17-year-old Lee Boyd Malvo was able simply to pick it up and walk out of the store.

S. 1805, as currently drafted, would require the dismissal of this litigation. The lawsuit pending is a "qualified civil action" under the bill, because the harm came about through the "criminal or unlawful misuse of a firearm;" and the bill clearly provides that any such action "pending on the date of enactment of this Act shall be immediately dismissed."

None of the exceptions enumerated in the bill would operate to save the litigation currently pending in Washington State. It is not based on an alleged statutory violation, but on the alleged failure of the defendants to take due care to secure firearms. Nor does the litigation fit the bill's narrow statutory definition of "negligent entrustment." As noted, that theory would not apply in any event to the manufacturer or distributor, and would not apply to a seller in this case, whose alleged negligence consists not of supplying the rifle to a particular person, but in so failing to secure it that it was literally available to anyone who walked in the door.

My aim here is not to make a claim about the merits of the pending D.C. sniper litigation, but rather to illustrate the scope of S. 1805. Whether or not the defendants in that case were in fact so negligent in their keeping of firearms that they should be found liable for negligence under Washington State law is a question for the courts of that State. The important point here is that under S. 1805, those defendants would be free of liability no matter how careless they had been. It is for this reason that the bill would require the dismissal of that case. And it is this light that one can see the true scope and import of S. 1805. The bill, as currently drafted, would not simply protect against the expansion of tort liability, but would in fact dramatically limit the application of long-standing and otherwise universally applicable tort principles by precluding, or requiring the dismissal of, cases alleging traditional negligence liability.

Sincerely,

SHERMAN J. CLARK.

Mr. LEVIN. The two alleged snipers were both legally prohibited from buying guns, but through the apparent negligence of a gun dealer, they were able to obtain the military-style Bushmaster assault rifle. Reportedly, the gun dealer operated in such a grossly negligent manner that 238 guns inexplicably disappeared from its store. Among the missing guns were the alleged snipers' Bushmaster rifle. Several of the snipers' victims have filed a lawsuit against the dealer and others. Their case might not survive if this bill became law.

This bill would set a dangerous precedent by giving a single industry broad immunity from civil liability and depriving many victims with legitimate cases of their day in court. If it is enacted, other industries will almost certainly line up for similar protections.

Every single gun safety organization has expressed its opposition to this bill. This is special interest legislation. It should not be adopted.

THE LONG REACH OF THE HEAVY
BOMBERS

Mr. JOHNSON. Mr. President, I rise today to draw my colleague's attention to an article published in the November 2003 edition of Air Force Magazine entitled "The Long Reach of the Heavy Bombers."

The article outlines the importance of our Nation's long-range bomber fleet, and in particular notes the increasing role the B-1 bomber is having in our national security planning.

I am extremely proud that Ellsworth Air Force Base in my State of South Dakota is home to the B-1 bombers and crews of the 28th Bomb Wing. Their contributions in Operation Iraqi Freedom were critical to our military success. Although B-1s flew fewer than 2 percent of the combat sorties in Operation Iraqi Freedom, they dropped more than half the satellite guided Air Force Joint Direct Attack Munitions, JDAMs, and maintained a 79 percent mission capable rate. The B-1s were assigned against a broad range of targets in Iraq, including command and control facilities, bunkers, tanks, armored personnel carriers, and surface-to-air missile sites. They also provided close air support for U.S. forces engaged in the field.

Given the demonstrated capabilities of the B-1 and its importance to our military, we need to continue to invest in the technological improvements that will maintain the B-1s role as the backbone of our bomber fleet. I am pleased that Congress enacted legislation earlier this year that will return 23 B-1s to the active inventory, and I look forward to working with the Air Force and my colleagues in the Senate to ensure that we provide the resources necessary to fully upgrade these planes.

I close by commending the men and women stationed at Ellsworth Air Force Base and thanking all of the members of our Armed Forces for their sacrifices on behalf of our Nation's security.

I ask unanimous consent that the article be printed in the RECORD.

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

THE LONG REACH OF THE HEAVY BOMBERS

(By Adam J. Hebert)

In mid-2001, the B-1B was in trouble. Years of fiscal stringencies had left the bomber with a \$2 billion modernization backlog, poor reliability, rising upgrade costs, and some major combat deficiencies.

Secretary of Defense Donald H. Rumsfeld, reflecting the prevailing view, charged the B-1 "is not contributing to the deterrent or to the warfighting capability to any great extent." Indeed, the purported backbone of the Air Force heavy bomber fleet seemed destined for the scrap heap.

Then, things changed, and, just two years later, the B-1B became one of the star weapon systems in Operation Iraqi Freedom. Just 11 aircraft deployed to the combat theater. However, commanders set up and maintained B-1B "orbits" that kept at least one of the B-1Bs in the air around the clock, ready to