THE GOVERNMENT CONTRACTOR®

THOMSON WEST

Information and Analysis on Legal Aspects of Procurement

Vol. 45, No. 17 April 30, 2003

Focus

¶ 181

FEATURE COMMENT: Is The Safety Act Safe? Homeland Security And The Politics Of Tort Liability

Driven by growing terrorist threats and increasing government funding, the demand for anti-terrorism technology has never been greater. Such technology has been widely hailed as critical to our efforts to combat terrorism. Indeed, Congress has recognized "technological innovation" as "the Nation's front-line defense against the terrorist threat." H.R. Rep. No. 107-609 at 118 (2002).

While hardly anyone questions the *need* for new and better anti-terrorism technology, the *means* for spurring such technological development does not enjoy the same broad consensus. One of the more controversial initiatives for encouraging such development has arisen out of the Homeland Security Act of 2002 that includes a subsection entitled the SAFETY Act (Pub. L. No. 107-296, §§ 861-65) or "Support Anti-Terrorism by Fostering Effective Technologies Act of 2002." Consistent with its title, the SAFETY Act creates incentives for companies to bring new anti-terrorism technology to the marketplace by limiting the seller's potential liability if such technology fails. Not surprisingly, the SAFETY Act has served as a political lightning rod in sizzling exchanges within Congress and elsewhere over the propriety of tort reform and product liability limitations.

What are the implications of this politically charged debate for the future of the SAFETY Act and its implementation? The stakes are quite high, given the SAFETY Act's enormous potential for quashing liability lawsuits against sellers of "qualified" anti-terrorism technology. This FEATURE COMMENT describes (1) the purpose and liability limitations of the SAFETY Act, (2) the legislative background of, and continuing political opposition to, the Act, and (3) the implications of congressional scrutiny on the ability of the Homeland Security Department to implement the Act.

Purpose and Protections of the SAFETY Act—Finding a terrorist to foot the bill for damages caused by an act of terrorism is extremely unlikely. Consequently, the grim prospects of protracted litigation and potentially catastrophic multi-million-dollar jury awards loom over companies having anti-terrorism technology deployed at the site of a terrorist attack. The SAFETY Act rests upon the simple premise that companies will delay—or even withhold from the market—some anti-terrorism technology due to the specter of bruising product liability litigation:

> Briefly, the SAFETY Act ensures that U.S. companies will be able to develop and provide vital anti-terrorism technologies to help prevent or respond to terrorist attacks without the threat of crippling lawsuits.

148 Cong. Rec. E2079 (Nov. 15, 2002) (statement of Rep. Armey). To spur development of anti-terrorism technology and "to ensure that these important technologies are available," the SAFETY Act establishes "a narrow set of liability protections for manufacturers of these important technologies." H. R. Rep. No. 107-609 at 118 (2002).

What are these "liability protections" under the SAFETY Act? The protections fall into three general categories: (1) limitations on damages, (2) immunity from lawsuits, and (3) liability caps. To achieve such protections, the anti-terrorism technology must be "qualified"—an ill-defined procedure by which the seller submits information and seeks approval from the Department of Homeland Security that must review the information and consider whether to approve and certify the technology.

Damages Limitations—While the SAFETY Act is no model of clarity, the provisions limiting damages are relatively straightforward. First, the Act specifically bars recovery of "punitive damages" (i.e., those "intended to punish or deter, exemplary damages, or other damages not intended to compensate a plaintiff for actual losses") against companies with "qualified" anti-terrorism technology. Pub. L. No. 107-296, § 863(b)(1). Second, the Act cuts off liability for "interest prior to the judgment," a potentially significant element of damages in product liability litigation that may stretch out over as much as a decade. Third, the Act limits "noneconomic damages" to "an amount directly proportional to the percentage of responsibility of such defendant for the harm to the plaintiff." Id. § 863(b)(2)(A). In plain language, the terrorist caused the injury in the first place and should bear nearly all of the "percentage of responsibility" for the act of terrorism, leaving little fault—or "noneconomic damages—to be allocated to others. The Act broadly defines such damages as including "losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses." Id. § 863(b)(2)(B). In combination, these three limitations on damages offer companies with "qualified" anti-terrorism technology the potential for greatly reducing exposure to product liability lawsuits arising out of terrorism attacks.

Immunity from Liability—In one of its boldest strokes, the SAFETY Act took a limited form of liability immunity known as the "government contractor defense" and applied it to "qualified anti-terrorism technologies." *Id.* § 863(d). Recognized by the U.S. Supreme Court in a lawsuit by a Marine copilot's estate against a defense contractor for a helicopter crash (*Boyle v. United Technologies Corp.,* 487 U.S. 512 (1988)), this defense offered Government contractors immunity from third-party lawsuits in some circumstances:

> The Government contractor defense . . . shields contractors from tort liability for products manufactured for the Government in accordance with Government specifications, if the contractor warned the United States about any hazards known to the contractor but not to the Government.

Hercules Inc. v. United States, 516 U.S. 417, 421-22 (1996), 38 GC ¶ 119. However, not all Government contractors have gained protection under this judicially created defense as some courts have limited it to military contractors producing military equipment. *See, e.g., In re Hawaii Federal Asbestos Cases,* 960 F.2d 806, 811-12 (9th Cir. 1992).

The SAFETY Act appears to brush off some of the court-imposed limitations upon the Government contractor defense by extending it to anti-terrorism technology under the following conditions: (1) the lawsuit involves an act of terrorism; (2) the anti-terrorism technology was "deployed" to combat—or respond to—the act of terrorism; (3) the Secretary of Homeland Security approved the technology; and (4) the seller of the technology did not act "fraudulently or with willful misconduct" in seeking such approval. Pub. L. No. 107-296, § 863(d)(1). The Act does not expressly mention other conditions, suggesting that the Act has unshackled the defense from other restrictions imposed by some courts. More importantly, the SAFETY Act expressly extends the defense not just to military procurements, but to any sales to any customer:

> This presumption of the government contractor defense shall apply regardless of whether the claim against the Seller arises from a sale of the product to Federal Government or non-Federal Government customers.

Id. This provision represents an unprecedented expansion of the Government contractor defense not just to state and local government purchases, but even for commercial sales involving private parties. Accordingly, the companies selling anti-terrorism technology may qualify for a level of protection that has not been previously available under the judicial version of the Government contractor defense.

Liability Cap—Perhaps the murkiest of the protections arising out of the SAFETY Act relate to the insurance provisions. The Act specifically requires anyone selling or providing anti-terrorism technology to obtain liability insurance to cover "third-party claims arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed in

defense against or response or recovery from such act." Id. § 864(a)(1). The Act then limits the seller's liability to the amount of such insurance coverage. Id. § 864(c). However, the statutory standards governing the scope, cost, and amount of such insurance coverage raise a host of knotty issues regarding interpretation and compliance that need to be resolved when the Department of Homeland Security issues implementing regulations.

Procedures for Getting Technology "Qualified"—None of the above protections against liability lawsuits becomes available unless the anti-terrorism technology is "qualified" through a somewhat sketchy process requiring approval and certification by the Department of Homeland Security. In short, the SAFETY Act establishes a process by which the seller submits "safety and hazard analyses on such technology" for the Homeland Security Department's review and possible approval. If approved, the "Secretary will issue a certificate of conformance to the Seller and place the anti-terrorism technology on an Approved Product List for Homeland Security." Id. § 863(d). Whether this process will be fast or slow, cooperative or adversarial, or otherwise, remains to be seen. However, the legislative history of the SAFETY Act raises some concerns about the potential for the approval process becoming politicized.

The Contentious Legislative History of the SAFETY Act— The expansive protections potentially available under the SAFETY Act for anti-terrorism technology did not come without a legislative fight. Indeed, recent legislative initiatives suggest that the battle is not over.

The controversy over the SAFETY Act erupted almost as soon as the House of Representatives' sponsor unveiled the bill. In fact, the House "Minority View" complained about being ambushed by having no meaningful opportunity to comment on the draft bill:

> In what was supposed to be a bipartisan process, the majority presented Democratic Members one day prior to the markup with a new Subtitle G of Title VII, entitled the Support Anti-Terrorism by Fostering Effective Technologies Act (the SAFETY Act).

H. R. Rep. No. 107-609, at 221-22 (2002).

This same House "Minority View" charged that the bill "gratuitously protected irresponsible corporations, including . . . those who knowingly make faulty products." Id. at 217. The House debate also zeroed in on whether Homeland Security legislation should be used to introduce tort reform:

> We are also particularly troubled that the majority has chosen to use the creation of the new Department of Homeland Security as a vehicle to institute broad changes to our tort laws. Under the majority's plan, knowingly shipping tainted anthrax vaccine to our soldiers in harm's way in Afghanistan would not be a cause for legal action. A soldier's widow would not be able to sue the company that created the vaccine even if it had known the product was defective.

Id. at 221.

A hostile reception also awaited the bill in the Senate. Senator Joseph Lieberman (D-Mass.) objected to "last moment" provisions such as the SAFETY Act that would give "protection even to those sellers who knowingly put anti-terrorism products on the market that they know won't work to keep people safe against an attack." 148 Cong. Rec. S11362 (Nov. 19, 2002). Despite these objections, the Homeland Security bill passed by a narrow margin in the Senate after the majority struck an agreement with three Republican Senators to repeal three provisions unrelated to the SAFETY Act during the next legislative session. See Dalrymple, *Deal Reached on Changes to Homeland Law,* Cong. Quarterly Daily Monitor (Jan. 10, 2003).

Continuing Opposition to the SAFETY Act—Even after passage of the Homeland Security Act in November 2002, opposition to the SAFETY Act continued. On January 7, 2003, Senators Daschle and Lieberman introduced S. 41 to "strike certain provisions of the Homeland Security Act of 2002," including the SAFETY Act. Calling the SAFETY Act "unnecessary and overreaching," Senator Lieberman warned that it "would entitle companies selling that technology to broad liability protection from any claim arising out of . . . an act of terrorism, no matter how negligently, or even wantonly and willfully, the company acted." 149 Cong. Rec. S46 (Jan. 7, 2003).

The prospects for S.41 to repeal the SAFETY Act can be predicted no more accurately than the

weather. Nonetheless, the existence of continuing, substantial opposition to the Act within Congress may well bear upon how aggressively and quickly the Department of Homeland Security proceeds with implementation.

Agency Implementation of the SAFETY Act—The Department of Homeland Security has a long trek ahead to implement the many aspects of the Homeland Security Act, including the provisions of the SAFETY Act. As an initial step, the agency must publish regulations providing specific guidance fleshing out the skeletal provisions of the statute. Pub. L. No. 107-296, § 862(c). With the implementing regulations in hand, the Homeland Security Department must then develop the organization, processes, and practices for reviewing "anti-terrorism technology" and deciding whether to approve it.

What does Congressional opposition and resistance mean for purposes of the SAFETY Act? Perhaps nothing, but historical parallels exist. Through means of Congressional hearings, General Accounting Office reviews, and public scrutiny, members of Congress have the capacity to bring a chill to the regulatory approval process. Given the lack of history with the SAFETY Act and the Homeland Security Department, the experience with congressional oversight of the Food and Drug Administration's ("FDA") approval of new drugs may offer some useful analogies for some of the risks in the approval process. Examples of such risks include (1) a bias against approval, (2) delays in the approval process, and (3) demands for submission of excessive information during this process.

Bias Against Approval—Just as the FDA has authority over approval of new drug applications, the Secretary of Homeland Security is "exclusively responsible for the review and approval of anti-terrorism technology" under the SAFETY Act. Id., § 863(d)(2). In particular, the Act states:

> Upon the Seller's submission to the Secretary for approval of anti-terrorism technology, the Secretary will conduct a comprehensive review of the design of such technology and determine whether it will perform as intended, conforms to the Seller's specifications, and is safe for use as intended.

Id. Obviously, Secretary Ridge cannot do this job alone. As with any other regulatory approval process, the responsibility for actual review of the technology will necessarily be delegated to others who have the time and specific expertise for this effort.

Just as every FDA approval of a new drug comes with the risk that unexpected adverse reactions may arise after the drug has been approved for the market, a Homeland Security approval of new anti-terrorism technology poses a risk that the technology will fail during a terrorist attack. Such failure may well spark congressional hearings, causing the civil servant to be grilled about how such defects slipped through the review process undetected. A former FDA Commissioner explained how such oversight chilled the approval process:

> For example, in all the FDA's history, I am unable to find a single instance where a Congressional committee investigated the *failure* of the FDA to approve a new drug. But, the times when hearings have been held to criticize our approval of new drugs have been so frequent that we aren't able to count them. . . . The message to FDA staff could not be clearer. Whenever a controversy over a new drug is resolved in favor of approval, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The Congressional pressure for our *negative* action on new drug applications is, therefore, intense.

H. Grabowski, *Drug Regulation and Innovation* at 76 (quoting speech by Alexander Schmidt before the National Press Club, Washington, DC (Oct. 29, 1974)) (italics in original). Perhaps the proponents of the SAFETY Act will maintain sufficient power to insulate the Homeland Security Department from such treatment. Nonetheless, the FDA experience offers a cautionary tale about the regulatory approval process.

Delays in the Approval Process—The approval process may drag due to many factors—incomplete data submissions by the seller, complexity of the technology, or need for additional testing and analysis. One of the several factors to be considered in the SAFETY Act approval process is whether the anti-terrorism technology "would be effective in facilitating the defense against acts of terrorism, in-

cluding technologies that prevent, defeat or respond to such acts." Pub. L. No. 107-296, § 862(b)(7). For much of the available anti-terrorism technology, companies will simply be unable to conduct any kind of test—much less double-blind, placebo-controlled scientific studies—to confirm the technology's "effectiveness" during a terrorist attack.

For the FDA, the drug efficacy requirements imposed by the Drug Amendments of 1962 (Pub. L. No. 87-781, 76 Stat. 780) contributed to substantial delays in the approval of new drugs:

> The greatest cause of excessive delay and cost in development of new drugs is the demand for additional proof of efficacy long after scientists would be satisfied that a drug is effective by the data generated.

Oversight—The Food and Drug Administration's Process for Approving New Drugs: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, 96th Cong., 1st Sess 456 (statement of William Wardell). Under the SAFETY Act, the Homeland Security staff should not be applying such a rigorous standard to anti-terrorism technology because the statute does not require *proof* of effectiveness, but simply includes effectiveness as one of several factors to be considered. To do otherwise would be contrary to Congressional intent to "make the [anti-terrorism technology] list as broad and inclusive as possible, so as to insure that the maximum amount of protective technology and services become available." 148 Cong. Rec. E2080 (Nov. 15, 2002) (statement of Rep. Armey).

Demands for Excessive Submission of Data—A couple of provisions of the SAFETY Act might encourage overkill in agency demands for companies to submit data during the approval process. For example, one provision notes that "the Secretary will conduct a comprehensive review of the design of such technology," while another refers to "[e]valuation of all scientific studies that can be feasibly conducted." Pub. L. No. 107-296, §§ 863(d)(2) and 862(b)(6).

Hopefully, no one at Homeland Security will apply these provisions in the way reminiscent of the FDA demands for proof of the whether aspirin would prevent secondary myocardial infarctions. When E. R. Squibb & Sons, Inc. sought approval to investigate aspirin in 1969, the FDA reviewing officer repeatedly demanded additional data and studies, requested the submission of all prior literature on aspirin, and even threatened to shut down Squibb's entire clinical program if the company proceeded with the aspirin project. See Wardell, *Rx: More Regulation or Better Therapies?* Regulation at 25-26 (Sept.–Oct. 1979). Years later, studies confirmed that aspirin substantially reduced secondary myocardial infarctions, thus illustrating how the bureaucratic process could greatly delay the introduction of safe and effective products from the market. See Elwood & Sweetnam, *Aspirin and Secondary Mortality After Myocardial Infarction,* The Lancet at 1313 (1979). How can the Department of Homeland Security reduce the potential for such unreasonable and arbitrary demands for submission of data during the approval process? One approach might be to establish a means for companies to seek independent review (e.g., an ombudsman or independent review panel) of unjustified delays or data demands to assure that a debacle like the FDA aspirin experience does not unreasonably keep highly effective anti-terrorism technology off of the market.

Conclusion—With the implementation of the SAFETY Act, the Department of Homeland Security will embark on a challenging and complex administrative process for reviewing and approving anti-terrorism technology. For both the companies selling such technology and the public needing protection from terrorist attacks, the stakes are too great for the process to be choked by partisan wrangling. As a result, the Homeland Security Department must heed the legislative purpose of the SAFETY Act to "insure that the maximum amount of protective technology and services become available."

This Feature Comment was written by David Z. Bodenheimer, a partner at the law firm of Crowell & Moring LLP in Washington, DC. Mr. Bodenheimer specializes in Government Contracts and Homeland Security.