Bio Terror Bible

EXPOSING THE COMING BIO-TERROR PANDEMIC

BIOTERRORBIBLE.COM: The following whitepapers were published by think-tanks, universities, NGO's and various governmental agencies and have at the very minimum set the stage psychologically for the impending bio-terror induced pandemic. The simple fact that these whitepapers exists in mass confirms that an upcoming bio-terror attack is in the cards and may be played in a last ditch effort to regain political, economic and militarial control of society.

WHITEPAPERS: Army War College , ASM (American Society for Microbiology), CATO Institute, Center for a New American Security, Center for Biosecurity of UPMC, Center for Counterproliferation Research, Chemical and Biological Arms Control Institute, CRS (Report for Congress), GAO (General Accounting Office), Institute for National Strategic Studies, Institute for Science and Public Policy, Johns Hopkins University, National Academy Of Engineering, National Defence University, PERI (Public Entity Risk Institute), RIS (Research & Information System), Terrorism Intelligence Centre, The Federalist Society, UNESCO (United Nations), University of Laussane, and the WMD Center.

Title: Combating Bioterrorism: The Product Liability Threat
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Abstract: The September 11 attack and recent anthrax scare have shown that our nation is ill-prepared to respond to a large-scale bioterrorist attack. Although lawmakers have introduced a flurry of bills to increase national readiness by improving centralized government planning, no measures encouraging the research, development, manufacture, distribution, or administration of "priority countermeasures"-i.e., drugs and biologics used to counter bioterrorist threats-have been introduced. Yet, such measures are necessary to ensure national preparedness. The fight against bioterrorism will almost certainly require priority countermeasures to be developed and distributed rapidly, but those with the greatest development and distribution ability-private entities-may be discouraged from doing their full part by the threat of massive tort liability. As a result, our nation's ability to effectively counter bioterrorist threats may well be hampered.

Developers and distributors can face massive tort liability if their priority countermeasures are discovered to have harmful long term or late-arising effects, even if those effects could not reasonably have been foreseen at the time they were developed and distributed. The possibility of undiscovered and unwarnable harmful effects is important because developers and distributors will have inadequate time and information to test exhaustively for such effects. Additionally, because they will be unable to adequately assess long term risks, they cannot factor the likelihood of those risks into the prices of their products (and thus insure against the threat of future liability). Even if developers and distributors could somehow assess these risks and increase prices accordingly, it would likely be socially unacceptable for them to sell countermeasures at prices that reflect their full risk premiums. Rather, the government would probably demand that these products be sold at or close to their development and distribution costs (as it did with CiproÔ). Consequently, developers and distributors may well decide that involvement with priority countermeasures would create unacceptable future risks.

Given the urgent public need for the rapid development and distribution of priority countermeasures and the fact that the tort system will act as a hindrance to this goal, the federal government should alter the incentives created by tort law here. The system could be changed in a number of ways, either by shifting all or part of the risk to the individuals who are harmed by the countermeasures or by shifting the risk to

the government. Shifting too much risk to individuals is unworkable because it will decrease individual incentives to take the countermeasures and thus could harm the public as a whole (if enough people decided not to take the countermeasures, the countermeasures' effectiveness would be limited). If the risk is shifted to the government, the appropriate level of risk and the mechanism for risk-shifting must be determined.

This paper summarizes the most prominent legislative proposals to improve government's centralized planning, analyzes the only current plan to alter tort law incentives, and discusses alternative approaches to establish adequate incentives for the development and distribution of priority countermeasures. Once lawmakers understand the strengths and weaknesses of the possible approaches, they can craft an informed and appropriate solution.

Current Legislative Proposals Do Not Establish Adequate Incentivesfor the Development and Distribution of Priority Countermeasures

While the bills that have progressed the farthest in the legislative process-H.R. 3448 (the Tauzin-Dingell bill which passed the House on December 12) and S.A. 2692 (which passed the Senate on December 20 after originating as S.1715, the Frist-Kennedy bill)-propose to create incentives to encourage the development and distribution of priority countermeasures, these measures are inadequate. The primary focus of these bills is improving the government's centralized response to bioterrorist threats by, inter alia, expanding the national pharmaceutical stockpile, improving the Center for Disease Control and Prevention's ability to counter relevant threats, expanding the authority of the Secretary of the Department of Health and Human Services (HHS) to respond to public health emergencies, and establishing a working group to prioritize countermeasure research and development.

Although these bills also propose to establish some incentives for manufacturers to produce priority countermeasures by accelerating research, development, and Food and Drug Administration (FDA) approval of countermeasures, it is uncertain how great an incentive these provisions will actually create. It is questionable what effect accelerating this typically 15-year process will have on a manufacturer's ultimate incentives, especially in the likely situation where a manufacturer is pressed by the government to put its product on the market quite rapidly and there is a substantial risk that the product may adversely affect some recipients in the future, thus creating an unusually large product liability risk. In short, while the incentive provisions in the Tauzin-Dingell and Frist-Kennedy bills are laudable, they are likely insufficient to effectively counter a large-scale bioterrorist threat because they fail to adequately protect at risk entities from a threat that looms large on their corporate balance sheets: potentially massive product liability exposure.

Executive Order 10789, as Amended on October 20, 2001, Cannot Provide Comprehensive Protection Against Product Liability Exposure

The only effort that either the executive or legislative branches have made to limit the product liability exposure of responsible entities arising from contact with priority countermeasures is President Bush's October 20, 2001 action amending Executive Order 10789. While the President has taken an important step in moving this issue to the forefront of public debate using all the tools at his disposal, his action is almost certainly insufficient because the scope of the Executive Order is limited and its legal authority is questionable. Accordingly, stronger action is necessary.

President Bush's action authorizes the Secretary of HHS "to enter into contracts . . . whenever . . . the national defense will be facilitated thereby" and to agree by contract to "hold harmless and indemnify the contractor" against otherwise uncompensated claims or losses made by third parties "for death, personal injury, or loss of, or damage to, or loss of use of property," claims for loss or damage to the contractor's or the government's property, and claims for indemnification arising against a contractor and its subcontractors. Exec. Order 10789 1, 2(a), 2(b)(1). In other words, President Bush's action enables the Secretary of HHS to enter into contracts with, and indemnify, private entities for the development and distribution of priority countermeasures.

Even assuming that the indemnification provisions work as intended, the indemnification provided by Executive Order 10789 is limited. Most notably, it applies only to those entities that enter into contracts with the federal government and with whom the federal government elects to enter into an indemnification agreement. Thus, it does not encourage private entities that do not have a contract with the federal government, or whose contract does not contain an indemnification agreement, to develop or distribute priority countermeasures. It would not apply in a situation where a state or locality contracted with a developer or distributor to provide priority countermeasures. Nor would it apply in the event that a developer or distributor of a priority countermeasure sold its countermeasure in large quantities overseas to reduce prices at home and was sued by a foreign claimant. Moreover, if a countermeasure (such as Cipro TM) were on the market at the time of a bioterrorist attack and the Secretary of HHS contracted with-and agreed to indemnify-the manufacturer, distributor, and administrator of such countermeasure, it is unlikely that any entity that previously researched or developed the product could take advantage of the indemnification provisions because it would not likely be a "subcontractor" within the meaning of the Executive Order.

Given this incentive scheme, is unlikely that more than a few entities will develop or distribute priority countermeasures. Thus, a desirable market force, namely, competition, may be weak or nonexistent. Moreover, because indemnification, by its very nature, is uncertain (encouraging disputes over whether particular claims or losses are covered by the indemnification agreement) and provides more limited protection than other possible legal schemes (such as limitation or assumption of liability by the government discussed below), it is uncertain how much practical protection the indemnification regime set forth in Executive Order 10789 will provide.

Perhaps the most serious problem with Executive Order 10789 is its questionable legal basis. The legal authority for the Order arises from 50 U.S.C. §§ 1431, 1432, 1433, 1435. These provisions permit the President, "during a national emergency declared by Congress or the President and for six months after the termination thereof" (50 U.S.C. § 1435), to "authorize any department or agency . . . to enter into contracts . . . whenever he deems that such action would facilitate the national defense" (id. § 1431). Significantly, the contract and indemnification provisions of Executive Order 10789 apply only when Congress or the President has declared a national emergency. They do not apply prior to, or in preparation for, a national emergency. Moreover, the statutory provisions are silent on the President's authority to enter into indemnification agreements. In fact, the only statutory provisions regarding liability (which limit U.S. liability on a contract entered into under these sections to $50,000 without prior approval of an Assistant Secretary or his Deputy, and to $25 million without prior approval of the Committee on Armed Services of the Senate and the House of Representatives), may be inconsistent with the unlimited indemnification authority claimed in the Executive Order. Based upon these potentially significant statutory limitations, Executive Order 10789 may do little to encourage entities that are well-equipped to develop or distribute priority countermeasures to do so.

In Search of Comprehensive Incentives To Encourage Development and Distribution of Priority Countermeasures

Given that Congress has not addressed the issue and that the President's tools for handling the issue are limited, lawmakers should consider how to establish incentives encouraging the development and distribution of priority countermeasures. A number of issues are raised by this question, including: (1) the scope and mechanics of the incentive scheme-i.e., creation of an alternate compensation scheme, liability limitation, or partial or total assumption of liability by the government; (2) what products and entities should be covered-i.e., whether researchers, manufacturers, producers, distributors, and/or administrators should be protected for their role in the development and distribution of vaccines, new products developed specifically to combat bioterrorism, and/or marketed products that are used to combat bioterrorism; and (3) whether the incentives should be combined with an existing legislative scheme or whether they should stand alone. In determining which options are best, lawmakers must weigh the value and effectiveness of the incentives against the risk faced by developers and distributors of priority countermeasures to assess the appropriate level of governmental stimulus.

Scope and Mechanics of the Incentive Scheme

The first issue that must be addressed is the scope and mechanics of the incentive scheme. Three obvious options present themselves: (1) restraint on traditional tort liability by the creation of an alternate compensation scheme; (2) limitation of private entities' liability through the creation of a federal cause of action; or (3) partial or total assumption of liability by the government.

Options for Restricting Tort Liability

The National Vaccine Compensation Injury Act

Although Congress does not often oust the tort regime for claims or losses that arise from business entities' performance of certain duties, it nonetheless has adopted a non-judicial compensation scheme in the pharmaceutical context: the National Vaccine Injury Compensation Act of 1986, 42 U.S.C. § 300aa-1 et seq. Congress adopted the Vaccine Compensation Injury Program (VCIP) to stimulate what had become the unprofitable business of developing and distributing vaccines. A prominent reason that manufacturers were ceasing vaccine development and distribution was their very real fear that massive product liability exposure would result from the adverse effects of vaccine administration on patient populations where a number of injuries were inevitable. As one court explained, "an important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacture[r]s in the market." *Schafer v. American Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.).*

The VCIP allays manufacturers' fears and ensures the continuing public availability of vaccines by requiring persons who suffer adverse effects from the administration of authorized vaccines either to file a petition for compensation under the VCIP or to limit their civil actions to damages of $1,000 or less. 42 U.S.C. § 300aa-11(a). If a person opts to file a petition for compensation under the VCIP, their claim is adjudicated by a special master acting under the authority of the United States Court of Federal Claims. Id. § 300aa-11(a)(1). The special master determines the amount of compensation to which the person is entitled by reference to whether the injury falls within the Vaccine Injury Table, which lists common injuries from vaccines and the time frame for manifestation of those injuries, and individual factors. Id. §§ 300aa-13 - 300aa-15. If a person suffers an injury outside the time provided in the Table, compensation may still be awarded, but the amount is usually lower. Id. § 300aa-13(b)(2). Punitive and exemplary damages may never be awarded. Id. § 300a-15(d)(1). Only after the special master has decided the claim may a person reject the determination and file a civil action for damages greater than $1,000. Id. §§ 300aa-11(a)(2), 300aa-21. The detailed procedure by which such actions must be litigated is set forth in the statute. Id. § 300aa-23.

The VCIP has been quite successful in controlling claims against vaccine manufacturers. The fund, which is financed by a 75 cent excise tax on each vaccine dose, has a reserve of approximately $1.5 billion. 26 U.S.C. §§ 4131(b), 9510(b); GAO Report, Vaccine Injury Trust Fund at 3 (March 2000).

The benefits of establishing a program like the VCIP are numerous: the program is financed through an excise paid by those vaccinated and is not financed through general tax revenues, thus ensuring the continued public availability of vaccines. While the benefits of a scheme like the VCIP may be desirable in the bioterrorism context, expanding the actual VCIP to cover priority countermeasures would probably be unworkable. This is because the VCIP protects a known set of entities against known injuries arising from predictably similar events: vaccination by a pre-established category of vaccines against traditional childhood diseases. However, the risks that may arise from a bioterrorist threat and priority countermeasures administered to fight that threat are largely unknown. Even in a simple case-if such countermeasures were administered as vaccines-the risks that might arise from such vaccinations and the time in which injuries might manifest themselves would be largely unknown. Because the factual circumstances created by administering an unknown countermeasure to respond to an unknown threat are complex, it will be difficult-if not impossible-to predict the liability arising from these threats in an actuarially accurate manner.

Unless the scheme were carefully and narrowly drawn, it could potentially provide expansive protection that would outspend the fund created to finance the scheme. Certainly, Congress could not, a priori, draft a table like the Vaccine Injury Table for priority countermeasures: the countermeasures that may be covered and the injuries that may arise are still unknown. On the other hand, if the provisions were narrowly drawn, they might limit too drastically claims arising from the development or distribution of priority countermeasures.

Limitation of Liability

Another possibility for limiting the product liability exposure of developers and distributors of priority countermeasures would be for Congress, in the exercise of its commerce power, to create a federal cause of action encompassing claims and losses arising from contact with priority countermeasures. This is essentially the approach Congress adopted when it passed the Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, 115 Stat. 230 (2000) (ATSSSA). ATSSSA implements a dual mechanism to handle claims arising from the September 11 terrorist attacks. First, it permits qualifying claimants to file for compensation with a Special Master appointed by the Attorney General, and provides that the Special Master's determination is final and not subject to judicial review. Pub. L. No. 107-42 § 405(b)(3); 115 Stat. 239. Payment of the award determined by the Special Master is funded by appropriations and individual contributions. Pub. L. No. 107-42 § 406(b), (c); 115 Stat. 240. Second, ATSSSA establishes an exclusive federal cause of action "for damages arising out of the hijacking and subsequent crashes of American Airlines flights 11 and 99, and United Airlines flights 93 and 175, on September 11, 2001" and provides that "[t]he United States District Court for the Southern District of New York shall have original and exclusive jurisdiction over all actions brought for any [such] claim." Pub. L. No. 107-42 § 408(b); 115 Stat. 240-41. While ATSSSA does not limit the amount that the federal court can award in any individual case, it limits the airlines' aggregate liability to the levels of their insurance coverage. Pub. L. No. 107-42 § 408(a); 115 Stat. 240.

The main advantage of a scheme like ATSSSA is that it encourages claimants to seek speedy resolution of their claims with the Special Master rather than filing a protracted civil action, the final monetary award of which will remain uncertain until all claims filed with the Special Master have been determined. This scheme has obvious benefits in a mass-casualty/mass-tort situation like that of September 11. However, a primary disadvantage of the system is that it is funded largely by insurers and the federal government. While the ex post establishment of such a scheme may do little to alter insurers' behavior, the creation of such a scheme prior to a large-scale bioterrorist event will almost certainly alter insurers' behavior and make it difficult, if not impossible, for the responsible entities to retain the necessary insurance coverage.

Another disadvantage of an ATSSSA-like scheme for claims or losses arising out of contact with a priority countermeasure is that the universe of facts giving rise to such claims or losses will be harder to identify than those arising out of the September 11 attacks. If Congress drafts legislation before a bioterrorist event takes place, it will very likely be either under- or over-inclusive in its identification of covered claims and losses. Under-inclusion will permit claimants to file successful lawsuits outside the scope of the newly-created federal cause of action, thus limiting the effectiveness of the scheme. On the other hand, over-inclusion may sweep in too many claims and lead a court to invalidate the scheme on the ground that Congress impermissibly exercised its power under the Commerce Clause in creating an exclusive federal cause of action for claims and losses that have little relation to the protection of interstate commerce, or for which Congress has made inadequate findings of the relationship to interstate commerce.

Assumption of Liability by the Government

Yet another option for Congress to consider is partial or total assumption of liability by the U.S. of claims or losses arising out of contact with a priority countermeasure. Assumption of liability schemes are, for obvious budgetary and practical reasons, highly disfavored by both Congress and the courts. However, Congress has implemented such schemes in the past. For instance, in 1976, Congress established the National Swine Flu Immunization Program, which authorized the establishment of an emergency national swine flu immunization program and provided an exclusive remedy for personal injury or death arising out

of the manufacture, distribution, and administration of the swine flu vaccine under the program. Pub. L. 94-380, 90 Stat. 1113. The "exclusive remedy" created by the Program provided that all claims for injury or death arising from the manufacture, distribution, and administration of the vaccine would be asserted directly against the United States. Pub. L. 94-380 § 2, 90 Stat. 1114. The Program was funded by congressional appropriations. See id. The Swine Flu epidemic never became the public emergency that was expected, and the Program has since been repealed.

The problems with establishing a scheme that provides either total or partial assumption of liability by the Government are obvious. Given the possible enormity of such liability and the breadth of claims, it is almost certain that total assumption of liability for claims or losses arising from contact with a priority countermeasure would be unworkable. However, partial assumption of liability for the manufacture, distribution, and administration of certain vaccines necessary to combat bioterrorism, such as vaccines for smallpox and anthrax, might well be both workable and serve the public interest. Under such a scheme, Congress might, like the Swine Flu Program, authorize the Secretary of HHS to "establish, conduct, and support (by grant or contract) needed activities" to carry out a national bioterrorism vaccination program. Pub. L. 94-380 § 2, 90 Stat. 1113. Then, Congress could create an exclusive federal cause of action against the United States for specified injuries arising out of vaccination program. This limited assumption of liability scheme would work best if public health experts first determined that there were a limited number of vaccines the national administration of which would serve the public interest, and Congress determined there were inadequate marketplace incentives to encourage the development and distribution of such vaccines.

Covered Products and Entities

Once the basic scope of covered claims and the mechanics of the scheme are established, one must consider what products and specific claims will be covered. While there is no "correct" answer to this question, awareness of the possibilities is necessary to make an informed decision. This paper has referred to coverage for "contact with priority countermeasures." However, the scope of this category must be decided. As suggested in the prior section, a scheme could apply only to injuries arising from administration of vaccines, or it could cover administration of other drug and biologic therapies as well [2]. It could apply only to new drugs and biologics developed or distributed for the purpose of fighting bioterrorism, drugs and biologics that are in the process of being developed but which have not yet been presented to or finally approved by FDA, or already marketed products that are useful for this purpose, such as CiproTM or doxycycline. Whether any one or all of these product categories should be included depends in large part upon Congress's assessment, as a national security matter, of the gravity of the threat faced by the country and the incentive scheme that is established. For instance, it may be unnecessary to limit liability for the production or distribution of marketed products such as CiproTM because market forces do not currently indicate that manufacturers lack an incentive to distribute the drug. Additionally, because FDA has already approved the drug as safe and effective, and the drug has been used without incident in the past, the product liability risk may be significantly less than it would be for a new product developed and approved on an accelerated basis.

In addition, there is a question of whether the scheme will cover researchers, manufacturers, distributors, and administrators of covered products, or only some subset of these individuals. It is important to remember that each of these entities plays a role in product development and that each could be liable for an injury arising out of contact with a covered product. Of course, the liability risk for any one of these entities will increase dramatically if claims against another entity in the product development and distribution chain are limited.

Structure of Incentive Scheme: Stand Alone or Integrated with an Existing Program

Once the mechanics, scope, and coverage of the scheme are decided, the main issue that remains is whether the scheme will stand alone or be integrated into an existing program. No scheme could be integrated into the Swine Flu Program, which has been repealed, and it would not be feasible to amend ATSSSA for this purpose, since ATSSSA is narrowly tailored to respond only to claims arising from the September 11 attack. The only program into which the scheme could realistically be included is the VCIP.

Some of the practical difficulties that would arise from integration have been discussed above: namely, the VCIP deals with known, fairly predictable, and repeated risks that have a specifically enumerated category of associated harms. Because a bioterrorist threat and the priority countermeasures that will be needed to respond to it are unknown and not predictable, assessment of the risks and categorization of the compensable harms will be quite difficult. In any event, these risks and injuries are unlikely to overlap in any meaningful fashion with those set forth in the VCIP. Accordingly, inclusion in the Vaccine Act would be impractical.

Moreover, inclusion in the Vaccine Trust Fund would create enormous cross-subsidization problems: because the risk of a bioterrorist threat is unknown, it is impossible to estimate (with any reasonable likelihood of success) the claims that will arise from covered injuries or to appropriately calibrate the excise tax on covered priority countermeasures. Accordingly, there is a considerable risk that using a single trust fund for both priority countermeasures and traditional vaccines would deplete the monies available for vaccine claims and require Congress to appropriate more funds for this purpose. Additionally, because the special masters who administer the Fund are overburdened, more special masters would have to be appointed. This would heighten the burden on the United States Court of Federal Claims. Thus, it is advisable for Congress-if it decides to implement a system similar to the VCIP for priority countermeasures-to establish separate compensation requirements, a separate administrative scheme, and a separate trust fund.

Conclusion

The issues raised by a bioterrorist threat are difficult to assess, in part because our nation has never faced such a threat before, and in part because the practical effects of such a threat cannot be known at this time. In deciding how to best protect the nation against this threat, Congress should focus not solely on government's centralized response but should also consider the effect of private incentives on those entities in the best position to develop and distribute priority countermeasures. These incentives must adequately protect developers and distributors against an unreasonable product liability threat while at the same time not imposing too great a burden on individual recipients, the federal government, or taxpayers. While a number of viable options for establishing such incentives exist, lawmakers must determine the best course by weighing the value and effectiveness of the proposed incentives against the levels of risk faced by developers and distributors of priority countermeasures (The Federalist Society, 2003).