

## **PROJECT BIOSHIELD, MORE THAN MEETS THE EYE: A CRITIQUE OF THE U.S.'S PROPOSED SILVER BULLET FOR RESPONDING TO BIOTERRORISM**

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**“Project BioShield, the President declared, is ‘a part of a broader strategy to defend the United States against the threat of weapons of mass destruction.’”<sup>1</sup>**

In the last few years, Americans, through much pain and suffering, have come to realize that they are not invincible to an attack on U.S. soil. In particular, the fear that there is no safe escape from the danger that a terrorist group may use new diseases or chemicals in future attacks, which could facilitate the spread of infection among the people of the United States.<sup>2</sup> The fact that the mass population is not properly vaccinated to protect itself against the introduction of diseases (e.g., small pox) adds to the devastation.<sup>3</sup> Congress has attempted to diminish the panic among Americans by implementing the Project BioShield Act of 2004.<sup>4</sup> This Act aims to disperse funds for the stockpiling of vaccines by streamlining FDA approval of new drugs/medical products.<sup>5</sup>

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\* The author is a graduate from St. Thomas University School of Law and would like to dedicate this piece to Prof. June Mary Makdisi. It was through Prof. Makdisi's encouragement, critique, and inspiration that this article was brought to life.

<sup>1</sup> Sidel, Victor, *Biosword, BioShield*, Gene Watch v.17, n.5/6 Sep-Dec 2004 1sep04 available at <http://www.mindfully.org/GE/2004/Biowarfare-Biosword-BioShield1sep04.htm>.

<sup>2</sup> Steve Schultze and Meg Jones, *Many Americans Fear Another Terror Attack, Poll Finds*, JSONline Milwaukee Journal Sentinel available at <http://www.jsonline.com/news/gen/sep03/167391.asp>.

<sup>3</sup> How Great a Threat? Interview with bioterrorism expert Jonathan B. Tucker, National Review Online (October 2001) available at <http://www.nationalreview.com/interrogatory/interrogatory101501.shtml>.

<sup>4</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

<sup>5</sup> *Id.*

In a momentary glance, Project BioShield appears to be an effective and valuable response to the looming fear of a biological or chemical weapons attack. However, when analyzing the Act with greater scrutiny, the negative points and unrealistic intentions are prominent. For example, the expedited approval of drugs through the Food and Drug Administration (“FDA”), which empowers the FDA with unprecedented authority. Moreover, legislators believe that Project BioShield is a frivolous unnecessary law.<sup>6</sup> The Honorable Jeff Flake stated:

This legislation is another example of the federal government attempting to throw money at a project that is already underway. The Department of Health and Human Services already administer the Strategic National Stockpile, which combat the public health consequences of a terrorist attack or public health emergencies. The Department of Homeland Security currently provides the financing for those efforts ... About \$400 million was appropriated in 2003 for stockpiling activities.<sup>7</sup>

This comment will first explore the meaning, purpose, and objectives of Project BioShield. Second, there will be an overview of how a normal medical product seeks approval under ordinary circumstances. This will include an explanation of the three stages of testing implemented by Pharmaceutical companies, which are seeking FDA approval to market new products. Third, Project BioShield will be compared to the emergency approval section already included within the FDA code of regulations. Fourth, a discussion of bioethical dilemmas which may result from the streamlined approval process allowed under Project BioShield will address concerns of informed consent and allocation of vaccinations, with emphasis on the first contract awarded under the act. Finally, the paper will conclude by examining potential remedies available to individuals harmed from medication administered under Project BioShield.

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<sup>6</sup> 150 Cong. Rec. E1399-01 (July 14, 2004).

<sup>7</sup> *Id.*

## I. PROJECT BIOSHIELD: AN OVERVIEW

On May 19, 2004, the United States Congress accepted the Project BioShield Act of 2004 with a colossal majority vote.<sup>89</sup> In July 2004, President Bush signed the Act into law.<sup>10</sup>

The purpose of the Act is to create a “Strategic National Stockpile” of drugs, vaccines, and other products in such amounts as the Secretary of Health and Human Services (“the Secretary”) deems necessary and realistic in the event of biochemical terrorist attack.<sup>11</sup> In order to ensure that necessary amounts of medical products are available for vaccines, the Secretary may award contracts or enter into agreements with appropriate companies.<sup>12</sup> The contract may require a discounted price, require an availability of the vendor to store the vaccines/products, and the vendor to seek approval from the Secretary.<sup>13</sup> Additionally, any contract entered into by the government is limited to eight years and can only be renewed for periods not exceeding five years.<sup>14</sup>

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<sup>8</sup> Congress.Org, Capital Advantage, *Project BioShield Act Passage of the Bill available at* <http://capwiz.com/congressorg/issues/votes/?votenum=99&chamber=S&congress=1082>

<sup>9</sup> Timeline of Project BioShield: October 2001: “A Letter laced with anthrax was delivered to Capitol Hill, underscoring the nation’s vulnerability to bioterrorism.-January 2003: In his State of the Union address, President Bush announced Project BioShield, an effort to make available new and innovative drugs and vaccines to better protect against biologic attack.- March 2003: Legislation to implement Project BioShield was introduced in Congress- July 2003: The House of Representatives approved 421-2 a version of the legislation; however, consideration slowed in the Senate because of funding authorization and appropriations questions.-May 19, 2004: The Senate approved 99-0 its version of Project BioShield-July 14, 2004: The House approved 414-2 the Senate-passed bill-July 21, 2004: The president signed Project BioShield into law. Sidel, Victor, Biosword, BioShield, Gene Watch v.17, n.5/6 Sep-Dec 2004 1sep04 available at <http://www.mindfully.org/GE/2004/Biowarfare-Biosword-BioShield1sep04.htm>.

<sup>10</sup> President signs Project BioShield Act of 2004, The White House President George W Bush, available at <http://www.whitehouse.gov/news/releases/2004/07/20040721-2.html>

<sup>11</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 319F(a)(1)).

<sup>12</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 319F(b)(1)).

<sup>13</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 319F(C)(ii)(I-VI).

<sup>14</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 319F(C)(ii)(III).

One major emphasis of Project BioShield is to permit the emergency approval of a medical product in the event that of an emergency declaration.<sup>15</sup> A declaration of emergency is defined in three subsections:

- (A) **A determination by the Secretary of Homeland Security** that there is a domestic emergency or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;
- (B) **A determination by the Secretary of Defense** that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- (C) **A determination by the Secretary of a public health emergency** under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agents or agents, or a specified disease or condition that may be attributable to such agents or agents.<sup>16</sup>

An emergency declaration can expire in two ways.<sup>17</sup> The determination of expiration may be made by the Secretary in collaboration with an appropriate government subsidiary or else the declaration will expire one year after the date the declaration was announced.<sup>18</sup>

Under Section 564 of the statute, Authorization for Medical Products for Use in Emergencies, the Secretary may authorize a “drug, device, or biological product intended

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<sup>15</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564).

<sup>16</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564 (b)(1)(A)(B)(C) ).

<sup>17</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564 (b)(2)(A)(i)(ii) ).

<sup>18</sup> *Id.*

for use in an actual or potential emergency” into the medical arena.<sup>19</sup> The emergency authorization allows for the introduction of a drug which has not been approved for distribution and/or a drug that has been approved, but not for the particular intended use.<sup>20</sup>

These criteria are ambiguous as to what constitutes an emergency worthy of approval, though Project BioShield does include a section veered toward the scope of authorization. For an unapproved product, the health care professional administering, as well as the individual receiving the product, must be informed that the product has been authorized for an emergency use.<sup>21</sup> To the extent possible, recipients are to be informed of all the *known* and potential benefits and risks.<sup>22</sup> However, the Act does not require individual recipients of a given product to be informed that the product is generally “unapproved,” they are merely told it is approved by the Secretary for emergency use.<sup>23</sup>

Particularlry striking, Project BioShield bestows upon the FDA an expedited emergency authorization power which overrides the emergency approval process already enacted within the FDA.<sup>24</sup> The reasoning for this expansion of the existing FDA emergency process, is to further streamline approval of medical products. In order to illustrate the differences between the FDA and Project BioShield’s respective approval processes, it is necessary to understand how a new drug typically attains approval. The section that follows will lay out the life and formation of a new drug created by a pharmaceutical company.

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<sup>19</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564 (a)(1)m

<sup>20</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564 (a)(2)(A)(B)),

<sup>21</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564(e)(1)(A)(i)-(ii).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

## II. TYPICAL ROADMAP OF A DRUG/VACCINE'S QUEST FOR APPROVAL

At Alliance Pharmaceutical, a new drug, seeking non-emergency approval, undergoes twelve years of testing before receiving FDA approval.<sup>25</sup> This twelve-year process begins with an initial period consisting of preclinical testing, which examines the safety and biological activity of the new medicine.<sup>26</sup> Preclinical Testing takes place over three and one half years.<sup>27</sup> On average, 5000 compounds enter the preclinical testing stage, which is preceded by the filing of an Investigational New Drug (“IND”) application to the FDA.<sup>28</sup> The FDA endorses an average of five out of the 5000 compounds to advance into the next stage, which is comprised of three phases of human clinical testing.<sup>29</sup>

After successfully completing the preclinical testing stage, Phase One begins.<sup>30</sup> In Phase One testing, the new medical product is tested on twenty-eighty healthy volunteers.<sup>31</sup> Phase One lasts one year.<sup>32</sup> Once the new medicine completes Phase One, Phase Two, consisting of 100-300 patient volunteers, commences.<sup>33</sup> <sup>34</sup> These are the stereotypical type of patients who would be administered the medicine once FDA approval is received.<sup>35</sup> Phase Two is conducted over a period of two years.<sup>36</sup> Finally, the

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<sup>25</sup> Alliance Pharmaceutical Company, *Phases of Product Development*, available at [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

last phase of human testing is Phase Three,<sup>37</sup> comprised of 1000-3000 patient volunteers.<sup>38</sup> This phase lasts for three years.<sup>39</sup> Subsequent to the three phases of human analysis, an additional application (New Drug Application or “NDA”) is processed with the FDA. If the product survives the twelve-year testing process, one drug enters into the final two-year review and approval process from the FDA.<sup>40</sup> However, additional post marketing testing by the pharmaceutical companies is also mandated after the two-year review is completed.<sup>41</sup>

The need for this twelve-year assurance process is clear: The pharmaceutical company’s aim is to benefit individuals and avoid or diminish any potential harmful consequences. Although safety is a principal concern, emergencies do occur and, therefore, the FDA is obligated to allow for a quicker access/approval under certain circumstances for some medications.<sup>42</sup> The following section reviews the differences between previously existing FDA regulations and the expansive approval procedures of Project BioShield.

### **III. PROJECT BIOSHIELD ACT V. FDA**

The FDA has implemented an emergency approval section to respond appropriately when a medical product needs to be available to the public, and, due to the emergency, more expedient testing and research procedures are required. Thus, under extreme emergencies, medical products need not be subjected to the stringent, twelve

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> Food and Drug Administration, Department of Health and Human Services, Treatment use of an investigational new drug, 21CFR § 312.34.

year testing before becoming available for public use. Under section 312.34 of the FDA, a drug not approved for marketing is allowed, but only under clinical investigation.<sup>43</sup> Moreover, the drug will only be approved under 312.34 for treatment of a life threatening condition where there are no other available alternatives.<sup>44</sup>

Therefore, according to 312.34, a drug may conceivably be accessible as early as Phase Three testing, but no earlier than Phase Two.<sup>45</sup> As a result of early approval under 312.34, a drug used for emergency treatment may be available in as little as 6.5-9.5 years.<sup>46</sup> A detailed comparison between 312.34 of the FDA and Project BioShield is illustrated in the following section.

Paragraph 564 of Project BioShield, entitled “Authorization for Medical Products for Use in Emergencies,”<sup>47</sup> represents the Bush administration’s proposed solution to a possible life-threatening terrorist attack. This provision grants the Secretary full discretion to deem a drug, or biological product available for use in an actual or potential emergency.<sup>48</sup> This section further allows the authorization of a drug which is not approved or approved for an alternate diagnosis or remedy.<sup>49</sup> However, this section seems ambiguous because of the absence of any guidelines of what steps, research or advances will be secured before administration to the general public is allowed.

Project BioShield attempts to minimize this ambiguity under a section titled

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<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 ( Section 564 (a) parts (1) and (2) ).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

“Criteria for Issuance of Authorization.”<sup>50</sup> This section states that the Secretary’s authorization of a drug is not to be executed unilaterally, rather, it should be made in conjunction with the Director of the National Institutes of Health and the Center for Disease Control and Prevention.<sup>51</sup> The above parties must determine that the possible threat to the United States MAY cause serious life threatening conditions to the general public and the product to be distributed MAY be effective in diagnosing or treating the condition.<sup>52</sup> The group must also find that the POSSIBLE benefits outweigh the risks, which will be determined by scientific studies if such are available and there are no alternatives to the drug at issue.<sup>53</sup>

The Act is unclear as to what will be designated a life-threatening event or even what extent of certainty is necessary to issue a given product in the case of a possible life-threatening attack. This is very puzzling given the steps the United States has taken in the last four years to designate the possibilities of another terrorist attack. In the last four years, the government has implemented a color scheme to show the likeliness of a terrorist attack, the color rises when there is a possibility of terrorism and the United States is on high alert.<sup>54</sup> After numerous elevations on the scale, with no corresponding attempt taken by a terrorist on US soil, the US population is confused by the color code scheme.<sup>55</sup> Therefore, it would appear that the Bush administration’s credibility of determining a possible life-threatening attack has been diminished.

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<sup>50</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 ( Section 564 (c) ).

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> Kelly Thornton, *Ridge admits upgrade needed in color-coded alert system*, The San-Diego Union Tribune (December 15, 2004) available at [http://www.signonsandiego.com/uniontrib/20041215/news\\_1n15ridge.html](http://www.signonsandiego.com/uniontrib/20041215/news_1n15ridge.html).

<sup>55</sup> *Id.*

In addition, the Project BioShield Act contains a section designated “Conditions of Authorization” as an attempt by the Bush administration to eliminate confusion.<sup>56</sup> The Conditions of Authorization speak to the fact that when an unapproved product is administered, conditions are necessary to protect the public health.<sup>57</sup> These conditions include an order that the health care professionals who are administering the drug and the individuals receiving the drug be informed that this product is authorized by the Secretary for emergency use. The information presented must also make the providers and receivers aware of the known or unknown risks and benefits.<sup>58</sup> Furthermore, the Secretary wants to implement a plan for the monitoring of the newly approved products.<sup>59</sup> Project BioShield appears to be an attempt to further streamline a medical product through the FDA at a higher rate than the emergency approval criteria already enacted under the FDA.

The language of the FDA’s determination of an emergency approval is stated as follows: “Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.”<sup>60</sup> An emergency approval is termed under two phases, a life threatening disease or a serious debilitating illness.<sup>61</sup> Although the FDA, like the Project BioShield Act, does not seem to clarify what constitutes an emergency situation, the FDA has

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<sup>56</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 ( Section 564 (e) ).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> US Food and Drug Administration, *Guidance for Institutional Review Boards and Clinical Investigators 1998 Update available at* <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency> (last visited on October 2004).

<sup>61</sup> *Id.*

established different criteria to determine what constitutes an emergency.<sup>62</sup> For example, if the product is designed to treat a life-threatening biological blood product, its emergency approval status is decided by the Office of Blood Research. Similarly, if the product is delegated as a biological vaccine, its emergency status is reviewed by the Office of Vaccine Research.<sup>63</sup>

After researching section 312.34 of the FDA and comparing it to the Project BioShield Act, many questions remain unanswered: Are these conditions enough to guard the United States population against the possible side effects of products which have not gone through vigorous FDA approval procedures? Under the Project BioShield Act are the risks and benefits known or adequately disclosed to the person receiving the medicine? Shouldn't the mere fact that the drug was streamlined through the investigational stage by FDA authorization be sufficient to warrant a cautionary label indicating the product's status as an "Investigational Drug?"

#### **IV. AMERICAN CITIZENS: UNWITTING HUMAN RESEARCH SUBJECTS UNDER PROJECT BIOSHIELD**

Although under the Project BioShield Act, the Secretary intends to enforce "conditions" to monitor any adverse effect and symptomology related to the use of a drug, the Act essentially treats the United States population as a mass of human test subjects.<sup>64</sup> Presently, the intent of the initial stages of human clinical testing of a non emergency product monitored by the pharmaceutical companies, is to limit dispensation

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<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *See* Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004.

of a new drug to pre-screened individuals who are closely monitored.<sup>65</sup> Under Project BioShield, the administration of a new drug to large numbers will not allow the detailed mechanisms necessary to adequately monitor the effectiveness and possible side effects of new products. The government appears to be ignoring the possibility that tests conducted on animals and preliminary research does not correlate the same results when the drug is ingested by humans. The requirements implemented to monitor adverse effects of new drugs approved under Project BioShield may be ineffective in eliminating unknown risks due to the government's inability to monitor mass amounts of people who may be administered a streamlined drug. In short, Project BioShield does not meet the requirements necessary for informed consent for the following three reasons; individuals administered with the medical product can not effectively be monitored; the exact terms of the emergency authorization are not disclosed; and the risks and benefits are too speculative to gather adequate informed consent.

**A. Informed Consent and the need for Close Monitoring of Human Subjects**

In a recent case, *Lenahan v University of Chicago*, 808 NE 2d 1078, a patient participating in a cancer trial was not taken off the medication at the first adverse sign and died as a result. Her estate filed suit against the University of Chicago and a judgment was awarded in the estate's favor. The court's decision was based in part on the fact that the human subject was not followed with the closeness that is required during an investigational human trial.<sup>66</sup> This case stands for the proposition that the use of unapproved drugs, where the risks are unperceived, is dangerous to the general public. For this reason, continuous monitoring is mandated for human subjects. *Lenahan*, in

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<sup>65</sup> See Alliance Pharmaceutical Company, *Phases of Product Development*, available at [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm).

<sup>66</sup> *Lenahan v. University of Chicago*, 808 N.E.2d 1078.

which the court found that the human subject was not followed closely enough to prevent her death, illustrates that, although the Act appears to have the genuine intent to monitor the actual number of persons administered a streamlined product, such a task may simply not be feasible.<sup>67</sup>

### **B. Informed Consent and Failure to Correctly Term the Product an Investigational Drug**

Furthermore, using the term “emergency authorization,” as opposed to disclosing that the drug is investigational, does not compensate for investigational shortcomings and fails to adequately inform consumers about the product. This non-disclosure creates a problem with general requirements of informed consent. The underlying purpose of informed consent is to give a patient autonomy and choice regarding their health care decisions.<sup>68</sup> Informed consent necessitates that patients be adequately informed of the risks and benefits of a particular study or treatment before agreeing to participate or have the treatment administered.<sup>69</sup> Disclosure of the risk and benefits of a given product or treatment is indispensable because if a patient is not aware of these risks, then the patient can argue that they were not given the necessary information to make an informed decision.<sup>70</sup>

In the case of *Daum v. Spine Medical Group Inc. et. al.*, the California Court of Appeals declared that when a medical product is investigational or experimental, the patient must be informed of the product’s status and written informed consent must be

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<sup>67</sup> *Id.*

<sup>68</sup> Frans C.B. van Wijmen and Frank W.S.M. Verheggen, MYTH AND REALITY OF INFORMED CONSENT IN CLINICAL TRIALS, 16 MEDLAW 53, 1997.

<sup>69</sup> The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine after Schreiber v. Physicians Insurance Co. of Wisconsin, Northwestern University Law Review, 95 NWULR 1029, Spring 2001.

<sup>70</sup> *See Id.*

provided for the patient.<sup>71</sup> This case further supports the contention that, although, Project BioShield makes authorization contingent on notification that the product has been approved for emergency use, this does not compensate for the lax approval process and failure to fully disclose the drug's investigational status.<sup>72</sup>

Individuals may have knowledge of the product's emergency authorization and any *known* risks and benefits, but they are *not* being informed of the product's inherent experimental nature.<sup>73</sup> A recent article explains this dilemma

With experimental procedures . . . the risks are unknown. Therefore, if a patient has consented to a particular medical intervention and has not been made aware of the experimental nature of the treatment, the intervention may be considered a 'substantial variance' from the treatment for which consent had been given.<sup>74</sup>

Under the FDA's own guidelines, informed consent must be acquired before administering an investigational drug unless receiving this consent is not feasible.<sup>75</sup> This problem may only be an issue pertaining to the Project BioShield because under section 312.4, the FDA protects itself from issues arising because of informed consent:

A critical responsibility of the investigator and the IRB has always included ensuring that there is an adequate informed consent process for study subjects. When preclinical teratology and reproductive toxicology studies are not completed prior to the initial studies in humans, male and female study subjects should be informed about lack of full characterization of the test article and the potential effects of the test agent on conception and fetal development. All study subjects should be provided with new pertinent information arising from preclinical studies as it becomes available, and informed consent documents should be updated when appropriate. Study subjects should also be informed about

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<sup>71</sup> Daum v. Spine Medical Group Inc. et al., 52 Cal.App.4th 1285 at 1293.

<sup>72</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 ( Section 564 (e) ).

<sup>73</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

<sup>74</sup> Involuntary Cloning, A Battery Notes 130-134.

<sup>75</sup> 21 CFR 505(i)

any new clinical data that emerge regarding general safety and effectiveness, including relevant gender effects.<sup>76</sup>

As previously noted, Project BioShield only requires that individuals be informed that the drug has been approved for emergency use.<sup>77</sup> A requirement of informing individuals that the product has not been tested on humans or has been streamlined through the approval process, as seen under the FDA, would help to eliminate the problems regarding informed consent that arise from the Act's deficient information disclosure policy.

The terming of a product as 'available for emergency use' does not lead a prudent person to believe that they may be receiving a product which has not formerly been approved by the FDA and has not undergone human clinical testing. Thus, comparing a person being treated with this medication to a human test subject is not such a farfetched analogy. It warrants noting that the government consciously wrote language into the Act which requires that participating patients are monitored and any adverse symptoms recorded.<sup>78</sup> However, this language includes no guidelines and the ability to monitor a mass amount of people is highly impracticable at best and at worst nearly impossible.<sup>79</sup>

### **C. Informed Consent and Unknown Risks and Benefits**

Problems with informed consent are also encountered when the risks and benefits of a particular treatment are unknown.<sup>80</sup> To achieve valid informed consent there needs to be a process whereby the outcomes of the treatment and reactions of treated persons are communicated to the potential user. Further, an outline of the known or potential perils of taking the product must be available.

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<sup>76</sup> US Food and Drug Administration, *Guidance for Institutional Review Boards and Clinical Investigators 1998 Update* available at <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency> (last visited on October 2004).

<sup>77</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

<sup>78</sup> *Id.*

<sup>79</sup> See Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

<sup>80</sup> Daum, 52 Cal.App.4<sup>th</sup> at 1293.

The decision in *Pinnick v. Louisiana State University Medical Center* stands for the proposition that, according to the doctrine of informed consent, a health care provider has a duty to disclose to the patient the known risks, unknown risks, alternatives to the medication, and risks involved if medication is not taking.<sup>81</sup>

In the midst of an emergency situation, Project BioShield obligates health care personnel to acquaint an individual obtaining a vaccine or medication with the potential risks and benefits.<sup>82</sup> The individual will not know that the risks and benefits disclosed to him or her are barely speculative. In some cases, human clinical trials were not completed in a manner to even actualize a rationale for producing possible risks. Therefore, the individual is not consenting to the risks; rather, he or she is only giving consent for the administering of a medication which they believe has achieved FDA emergency approval. A prudent layperson would associate the FDA approval as one that occurred after animal and clinical human trials. Consequently, since the FDA does not know the risks, it is inconceivable that the government sustain that, under these circumstances, an individual can adequately formulate a voluntary and knowing consent. It is unprecedented, and more than arguably unethical, that any unapproved drug, which has not been tested in clinical trials, can meet the elements of informed consent. Even more suspicious is the fact that the government has contoured the regulations set forth within the Act itself, which states emergency authorization grants the administration of medication where the benefits outweigh the risk to circumvent the legal definition of informed consent.<sup>83</sup>

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<sup>81</sup> *Pinnick v Louisiana State University Medical Center*, 707 So.2d 1050 (La.App. 2 Cir.,1998).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

In order to escape liability for informed consent, the government and product manufacturers should impose a consent form stating the drug is experimental and the risks and benefits are unknown and have not been identified through customary emergency testing procedures enforced by the FDA upon Pharmaceutical companies.<sup>84</sup>

## VI. FIRST CONTRACT AWARDED UNDER PROJECT BIOSHIELD ACT

On November 4, 2004, the first contract award under Project BioShield was issued.<sup>85</sup> The contract was awarded to VaxGen, Inc., a biotechnology company located in Brisbane, California.<sup>86</sup> The contract is for five years and pertains to a vaccination for the Anthrax virus.<sup>87</sup> VaxGen, Inc. has agreed to provide enough vaccinations to treat approximately twenty-five million people and anticipates the vaccine will be ready for delivery sometime in 2006.<sup>88</sup> The government plans to put these doses aside for use in the event of an anthrax attack.<sup>89</sup> The contract expressly states that payment for the vaccine will not be received until VaxGen makes delivery to the government for stockpiling.<sup>90</sup> In regards to the payment terms, the president of VaxGen stated: “The company is putting a lot of risk to be involved in this . . . . It’s going to make America a lot safer.”<sup>91</sup>

However, the company must still meet some additional requirements before it can execute the government contract. Specifically, Project BioShield requires that a

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<sup>84</sup> Davis v. Hoffman, 972 F.Supp. 308(E.D.Pa 1997).

<sup>85</sup> Diedra Henderson, U.S. to Buy New Generation Anthrax Vaccine, *available at* [http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&\\_mpc=news%2e10%2e15&cid=474](http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&_mpc=news%2e10%2e15&cid=474) (last visited November 2004).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

vendor such as VaxGen seek licensing, approval or clearance from the Secretary prior to making delivery to the National Stockpile.<sup>92</sup> However, at this point in time VaxGen has not successfully obtained licensing from the FDA.<sup>93</sup>

After animal research and clinical trials on 580 people, the anthrax vaccine developed by VaxGen has been contemplated to be effective in all humans.<sup>94</sup> Interesting to note, the VaxGen product is not a completely new product. Other manufacturers, such as BioPort Corporation, have developed anthrax vaccines similar to VaxGen's.<sup>95</sup> One existing vaccine is manufactured by BioPort Corporation. Bioport is currently under an 877.5 million dollar contract with the Pentagon negotiated before the development of Project BioShield.<sup>96</sup> HHS has decided to include a minimum of five million doses of Bioport's anthrax vaccine in the national stockpile.<sup>97</sup> Many critics of the Act hope to see more of this type of diversification of vaccine providers.<sup>98</sup>

We share Secretary Thompson's stated objective of securing a sufficient stockpile of safe and effective vaccines to protect the American public against a future bioterrorist attack . . . . We believe the most meaningful way to achieve that important goal is for the national stockpile to include products from multiple

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<sup>92</sup> *Id.*

<sup>93</sup> Diedtra Henderson, U.S. to Buy New Generation Anthrax Vaccine, available at: [http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&\\_mpc=news%2e10%2e15&cid=474](http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&_mpc=news%2e10%2e15&cid=474) (last visited November 2004).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* "BioPort's AVA vaccine requires six doses and is derived from cell cultures. The newer generation anthrax vaccine that VaxGen is making is known as a recombinant protective antigen (rPA0 protein and is designed to improve immunity with three doses." BioTech Watch, *Bioterrorism Senators Alter Drug Patent Incentive in 'BioShield II' to Address Concerns*, ISSN 1535-5284 (December 17, 2004) available at: <http://pubs.bna.com/ip/BNA/btb.nsf/is/A0B0E0R9H5>.

<sup>96</sup> Diedtra Henderson, U.S. to Buy New Generation Anthrax Vaccine, available at: [http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&\\_mpc=news%2e10%2e15&cid=474](http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&_mpc=news%2e10%2e15&cid=474) (last visited November 2004); See also BioTech Watch, *Bioterrorism Senators Alter Drug Patent Incentive in 'BioShield II' to Address Concerns*, ISSN 1535-5284 (December 17, 2004) available at: <http://pubs.bna.com/ip/BNA/btb.nsf/is/A0B0E0R9H5>.

<sup>97</sup> *Id.*

<sup>98</sup> BioTech Watch, *Bioterrorism Senators Alter Drug Patent Incentive in 'BioShield II' to Address Concerns*, ISSN 1535-5284 (December 17, 2004) available at: <http://pubs.bna.com/ip/BNA/btb.nsf/is/A0B0E0R9H5>.

suppliers, due to performance risks associated with any single product or single manufacturer.<sup>99</sup>

Due to the fact that there have already been anthrax vaccines developed, the first contract awarded under Project BioShield has a diminished risk because there is more time and resources available to the corporation for clinical trials. However, although this contract should be considered much safer compared to other vaccines which may be streamlined through the FDA without such time and resources, this vaccine's safety is still questioned.<sup>100</sup> Moreover, although the FDA feels this vaccination is safe, the exact effect of the vaccine is still uncertain and, therefore, it is not prudent of the United States to buy so much of the vaccination, which is still in its experimental stage.<sup>101</sup>

An original anthrax vaccination administered to U.S. soldiers has heated much debate. The initial distribution of the vaccine was to troops deployed to Iraq for more than fifteen days.<sup>102</sup> The vaccine caused many health problems, from severe headaches to death.<sup>103</sup> Due to the serious health issues associated with the drug, many military personnel have since refused to be vaccinated.<sup>104</sup> Apart from the side effects, another concern is that the drug is still experimental in nature because it had only completed phase one testing.<sup>105</sup> This is precisely the type of scenario that shows the dangers of forgoing the final phases of clinical testing.

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<sup>99</sup> *Id.*

<sup>100</sup> Justin Gillis, U.S. to buy Anthrax Vaccine, Stockpile Would Permit Mass Inoculations, Washington Post (March 12, 2004) available at: <http://www.washingtonpost.com/ac2/wp-dyn/A51691-2004Mar11?language=printer>.

<sup>101</sup> *Id.*

<sup>102</sup> Meryl Nass, Is the Anthrax Vaccine Really Safe? What You Must Know About "Project BioShield", Washington Post (March 27, 2004) available at [http://www.mercola.com/2004/may/8/anthrax\\_vaccine.htm](http://www.mercola.com/2004/may/8/anthrax_vaccine.htm).

<sup>103</sup> *Id.* This vaccination has also been cited to have caused severe autoimmune deficiencies and neurological disorders. An army surgeon has discussed these problems and has consulted with a vaccine expert for a second opinion. *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

Returning to the VaxGen product, it has been commented that the vaccine is an improvement on the existing products, however, its acceptance within the medical community has met with much hesitation and speculation.<sup>106</sup> Many critics emphasize that the public should not be so quick to assume that improvements upon the existing models will result in a product with no adverse risks.<sup>107</sup>

Also interesting to note, is that an anthrax biochemical attack has been a concern for a number of years.<sup>108</sup> The Clinton administration, in 1998, announced plans to stockpile Anthrax vaccines after the President was informed that the United States was vulnerable to a biological attack.<sup>109</sup> If all the contracts to be awarded pertained to a bacterium that the United States has had notice of for over six years and which has more than one manufacturer, such as in this scenario, then Project BioShield would not be as risky and the emergency approval section would not be crucial. Notwithstanding the fact that the anthrax bacterium has been around for years, there are still serious concerns.

VaxGen rests the safety of its vaccine on humans based on a trial of only 580 human subjects.<sup>110</sup> Under normal testing procedures of a new medical product, human testing lasts for approximately *six years* and constitutes between 1200 and 3200 human subjects. This is more than double the human subjects which have been tested by VaxGen. Clearly, because this bio-terror threat has been known for so long a time, more

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<sup>106</sup> Paula Zahn Now, CNN Security Watch: Anthrax; McCain: No Confidence in Rumsfeld; Interview With Rusty Yates, December 14, 2004 available at: [http://www.thepowerhour.com/news/zahn\\_anthrax.htm](http://www.thepowerhour.com/news/zahn_anthrax.htm). ); See also Peter Gorner, *U.S. war on anthrax has its risk, Rush to stock new vaccine has scientists wary*, Tribune Science (march 28, 2004) available at [http://www.anthraxvaccine.org/tribune\\_article.html](http://www.anthraxvaccine.org/tribune_article.html). This article emphasis's that "Although the vaccine has been tested in animals, testing in humans is in its early phases and the vaccine has not yet demonstrated its effectiveness, making the purchasing plan premature, according to critics." *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> BBC News, Clinton warns against 'cyber attacks,' available at <http://news.bbc.co.uk/1/hi/world/americas/98983.stm> (last visited November 2004).

<sup>109</sup> *Id.*

<sup>110</sup> Jonathan D. Moreno, BIOETHICS AND THE NATIONAL SECURITY STATE, 32 JLMEDETH 198, summer 2004.

human subjects could have and should have undergone testing.<sup>111</sup> Taking this into consideration, the proposition that other products created pursuant to the Act to combat *new* forms of bio-weapons with which the government has had little to no experience could be safe and effective without undergoing full clinical testing and research, seems a hazardous assumption.

Finally, stockpiling only consists of twenty-five to thirty million vaccines stockpiled.<sup>112</sup> The United States has an approximate human population of 294,699,968, with this number growing each day.<sup>113</sup> Therefore, there is greater than ten times more people in the United States than there is anticipated to be of vaccines in the National Stockpile. This can lead to a Bioethical issue analogous to the shortage of the flu vaccine in the United States today.<sup>114</sup>

## V. CONCERNS TO WATCH FOR IN PROJECT BIOSHIELD'S FIRST CONTRACT

During the flu season of 2004-2005, there was not enough of the flu vaccine to go around.<sup>115</sup> Although this is not the first time the United States has had a flu vaccine shortage, the constraint was exacerbated due to 48 million doses which were expected to be available but were contaminated.<sup>116</sup> "These shortages have forced physicians and public health officials to wrestle with who should, and who won't, get the vaccine."<sup>117</sup> Although, the government may mandate that only individuals in the high risk category

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<sup>111</sup> Alliance Pharmaceutical Company, *Phases of Product Development*, available at [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm).

<sup>112</sup> *Supra* note 76.

<sup>113</sup> U.S. Census Bureau, U.S. POPClock Projection available at <http://www.census.gov/cgi-bin/popclock> (Last visited November 2004).

<sup>114</sup> Breaking Bioethics, Flu Shortage poses public health disaster, federal and state governments should declare emergency, available at <http://www.msnbc.msn.com/id/6291712/> (Last visited November 2004).

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> Flu Shot ethics, available at <http://ibb7.ibb.gov/newswire/377b85f5.html> (last visited November 2004).

may receive the vaccine, this doesn't eliminate the possibility of a public disaster.<sup>118</sup> For example, greedy consumers are bribing hospitals to allow them access to the flu shot for eight times the normal price, doctors are administering the flu shot to friends and family members who are not in the high risk category, and in Colorado and Pennsylvania, people have stolen the flu shot from stores.<sup>119</sup>

In the United States, around five to twenty percent of the population become infected with the flu each year.<sup>120</sup> Of this percentage range, each year 36,000 will die.<sup>121</sup> Thus, a low percentage of the infected population runs the risk of having a deadly reaction to the flu. Anthrax is a much more serious disease. Twenty percent of people who contract Anthrax will die from complications of the disease.<sup>122</sup> If people are going through such measures, i.e. stealing the vaccine from stores when dealing with the common flu, then what can be expected in the face of a shortage of a vaccine, for a disease, like Anthrax, that one in five people may die from.<sup>123</sup> Although the flu is more contagious, a terrorist may be able to develop the Anthrax bacterium in such huge amounts as to affect a mass amount of Americans.<sup>124</sup> Therefore, if there is an Anthrax threat where more than twenty-five million have the possibility of being infected, then this shortage of vaccinations may cause the same type of public crisis being seen in

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<sup>118</sup> Breaking Bioethics, Flu Shortage poses public health disaster, federal and state governments should declare emergency, *available at* <http://www.msnbc.msn.com/id/6291712/> (Last visited November 2004).

<sup>119</sup> *Id.*

<sup>120</sup> Centers for Disease Control and Prevention, Influenza: The Disease, *available at* <http://www.cdc.gov/flu/about/disease.htm> (last visited November 2004).

<sup>121</sup> *Id.*

<sup>122</sup> University of Maryland Medicine, Anthrax: What You Should Know, *available at* <http://www.umm.edu/features/anthrax.htm> (last visited November 2004).

<sup>123</sup> *Id.*

<sup>124</sup> *See id.*

today's society in regards to flu.<sup>125</sup> This is to say nothing of the much more difficult questions regarding who will decide which persons receive a dose, and on what basis these preferences may be made. This has the possibility of turning into a bioethical dilemma as seen in human organ allocation.<sup>126</sup>

Health and Human Services set forth new regulations on human organ allocation in 1999.<sup>127</sup> Before these new regulations, the United Network for Organ Sharing (UNOS) had the benefit of deference to its own policies.<sup>128</sup> Now, UNOS must follow more strict and formal regulations, and any departure from the regimen regulations must be approved by HHS.<sup>129</sup> One of the most significant alterations under the new policy is that organs are no longer to be donated with preference going a local contender, rather, the organs are to be allocated nationally.<sup>130</sup> A contender must wait on the list until an organ becomes available, but due to the mass amounts of individuals waiting for each organ, potential recipients are to be identified based on both medical and non medical criteria.<sup>131</sup> Examples of criteria used for organ allocation are "life expectancy, organ failure caused by behavior, compliance/adherence, repeat transplantation, and alternative therapies."<sup>132</sup>

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<sup>125</sup> Breaking Bioethics, Flu Shortage poses public health disaster, federal and state governments should declare emergency, *available at* <http://www.msnbc.msn.com/id/6291712/> (Last visited November 2004).

<sup>126</sup> Barry R. Furrow et. al, *Bioethics: Health Care Law and Ethics* 4<sup>th</sup> ed., West Group Publishing, 2001 pages 394-409.

<sup>127</sup> *Id.* at 392-93.

<sup>128</sup> *Id.* at 393.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 395.

<sup>132</sup> *Id.*

Health and Human Services' new regulation helps to eliminate a lot of problems arising amongst organ allocation, but seven states have enacted laws restricting out of state organ transfers, thus, difficulties are still noticeable in the organ transplant arena.<sup>133</sup>

This area of law has been extremely controversial and volatile throughout the past decade. Because the shortage of organs leads to some individuals not receiving needed transplants, many battles occur over what the proper allocating policies should be. As a result, litigation in this area is constant and public outcry is often overwhelming.<sup>134</sup>

By limiting the number of vaccines stockpiled, the Secretary of Homeland Security is, in essence, paving the pathway to the same quandary seen in organ allocation except that the primary difficulties in organ allocation is caused by limited available organs, whereas the problems of limited vaccinations are caused by poor planning.

As noted earlier the VaxGen contract and Bioport contributions to the stockpile leave enough vaccinations for only ten percent of potential U.S. recipients.<sup>135</sup> Project BioShield provides that the Secretary

“shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.”<sup>136</sup>

How the government determines the vulnerable ten percent earmarked to receive the vaccination is ambiguous, leaving many questions and concerns unanswered.

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<sup>133</sup> *Id.* at 397.

<sup>134</sup> *Id.* at 393.

<sup>135</sup> Diedra Henderson, U.S. to Buy New Generation Anthrax Vaccine, *available at* [http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&\\_mpc=news%2e10%2e15&cid=474](http://aolsvc.news.aol.com/news/article.adp?id=20041104171109990005&_mpc=news%2e10%2e15&cid=474) (last visited November 2004).

<sup>136</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 319 F-2 (a)(1)).

The government asserts that the stockpile of vaccination is enough for an entire city affected with the anthrax virus.<sup>137</sup> For example, the government plans to have enough vaccination for the population of New York City and Washington DC areas, but what if an Anthrax attack covers a wider area? Who will get the vaccination then?<sup>138</sup>

## VI. PROJECT BIOSHIELD PART II

From the Act's beginnings, it was criticized by Senators such as hon. Jeff Flake, who stated that "BioShield would allow a company to spend several million dollars of its own money developing a new drug or vaccine, only to see the government possibly award the contract for producing it to another company."<sup>139</sup> This early criticism has become a reality. Legislators are realizing that pharmaceutical companies are not pushing for contracts under Project BioShield.<sup>140</sup> As a result, legislators have drafted "BioShield II" to further incentivize pharmaceutical companies.<sup>141</sup>

BioShield II is known as the "wild card provision" and was presented to legislation as bill S. 666.<sup>142</sup> The goal of BioShield II is to help induce pharmaceutical companies to do research and produce countermeasure drugs by offering two extra years of patent protection for the drug.<sup>143</sup> However, the two extra years of protection is not mandatory, rather it's the maximum amount of patent protection that the HHS Secretary

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<sup>137</sup> Justin Gillis, U.S. to buy Anthrax Vaccine, Stockpile Would Permit Mass Inoculations, Washington Post (March 12, 2004) available at <http://www.washingtonpost.com/ac2/wp-dyn/A51691-2004Mar11?language=printer>.

<sup>138</sup> *Id.*

<sup>139</sup> 150 Cong. Rec. E1399-01 (July 14, 2004).

<sup>140</sup> BioTech Watch, Bioterrorism *Senators Alter Drug Patent Incentive in 'BioShield II' to Address Concerns*, ISSN 1535-5284 (December 17, 2004) available at <http://pubs.bna.com/ip/BNA/btb.nsf/is/A0B0E0R9H5>.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

may possibly award to a pharmaceutical company.<sup>144</sup> Although this bill is in the embryonic stages, Sen. Orrin G. Hatch (R-Utah) criticized the language of the bill stating that, in essence, the bill allows patent protection “no matter how unrelated [the drug produced is] to addressing bioterrorism and related threats.”<sup>145</sup> Project BioShield only became a bill in July 2004, therefore measures to entice pharmaceutical companies to research and produce countermeasure drugs may be premature and unnecessary at this stage of the game.

## VII. LIABILITY OF THE UNITED STATES UNDER PROJECT BIOSHIELD 2004

Now that potential issues/liabilities of the Project BioShield have been set forth, what are the remedies for those injured? Project BioShield is a law imposed by legislation and because the United States has sovereign immunity in most cases, one possible way of holding the United States as a defendant is through the Federal Torts Claim Act.<sup>146</sup> The Federal Torts Claim Act allows the United States to be liable in tort, for instances such as personal injury and negligence, in the same manner a private individual would be liable to a plaintiff.<sup>147</sup> The substantive law by which the action is decided upon is ruled by the state in which the action took place.<sup>148</sup> The Federal Torts Claim act allows the United States to step in as a defendant when an employee of the government is being charged with numerous claims such as personal injury, medical

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<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> Federal Torts Claim Act, The 'Lectric Law Library's Legal Lexicon *available at* <http://www.lectlaw.com/def/f071.htm> (last visited January 2005).

<sup>147</sup> 27 U.S.C. § 2674; provided in relevant part Section 2 of Pub.L. 100-694 states: “For more than 40 years the Federal Tort Claims Act 28 U.S.C.A. §§ 1346(b), 2671 et seq. has been the legal mechanism for compensating persons injured by negligent or wrongful acts of Federal employees committed within the scope of their employment.” Sec. 2 Pub.L. 10-694.

<sup>148</sup> 28 U.S.C. § 1346(b)

malpractice etc.<sup>149</sup> In an action under the Federal Torts Claim Act, the plaintiff may only seek an award of monetary value.<sup>150</sup>

In *Goodman v. United States*, Goodman sued the United States under the Federal Torts Claim Act.<sup>151</sup> This action commenced when the husband of a diseased patient sought judgment for lack of informed consent on the part of his diseased wives physician.<sup>152</sup> His wife died from a reaction to medication administered during clinical research for an experimental treatment for liver cancer.<sup>153</sup> Although, Goodman was unsuccessful on his claim, the 9<sup>th</sup> Circuit Court of Appeals held that this type of claim, which alleged medical malpractice for failure to obtain patient's informed consent, was broad enough to bring against the United States under the Federal Torts Claim Act.<sup>154</sup> However, this was against one physician employed by the United States.<sup>155</sup> The tricky part will be to construe a claim against a law enacted by the United States. It may be possible to hold the contractor who developed the vaccine liable under the Federal Torts Claim Act, asserting he/she is an employee of the United States. In *Letnes v. United States*, the Court held that the "Government may be sued for actions of government contractor and its employees if Government has authority to control detailed physical performance of contractor and supervise its day-to-day operations."<sup>156</sup> Therefore, a person injured by an experimentally issued vaccination under Project BioShield may creatively bring forth a claim suing the company that developed the vaccination as a contractor alleging that the government had the authority to supervise the physical

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<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Goodman v. United States*, 298 F.3d 1048 (9<sup>th</sup> Cir. 2002).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Letnes v. U.S.*, 820 F.2d 1517, 1519 (9<sup>th</sup> Cir. 1987).

performance of the contractor by the stages and influences detailed within Project BioShield.

## VIII. CONCLUSION

September 11, 2001 changed the life of Americans in many ways and fears of another attack in the near future linger in American minds.<sup>157</sup> The government has sought to eliminate some of this fear by introducing the Project BioShield Act. In July 2004, Project BioShield became a law with George W. Bush's signature of approval.<sup>158</sup> One major emphasis of Project BioShield is to permit the emergency approval of a countermeasure drug in a declaration of an emergency.<sup>159</sup> Under ordinary situations, a new medical product seeking approval is tested through three phases of clinical testing.<sup>160</sup> These phases are easily distinguishable in a chart,<sup>161</sup> such as the one below, shown in relevant part and produced by Alliance Pharmaceutical company;

	<b>Preclinical Testing</b>	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>	<b>FDA</b>
<b>Years</b>	3.5	1	2	3	2.5
<b>Test Population</b>	Laboratory and animal studies	20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers	Review process Approval
<b>Purpose</b>	Assess safety and biological activity	Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness and adverse effects	
<b>Success</b>	5,000 evaluated	5 enter trials			1 approved

<sup>157</sup> Steve Schultze and Meg Jones, *Many Americans Fear Another Terror Attack, Poll Finds*, JSONline Milwaukee Journal Sentinel available at <http://www.jsonline.com/news/gen/sep03/167391.asp>.

<sup>158</sup> President signs Project BioShield Act of 2004, The White House President George W Bush, available at <http://www.whitehouse.gov/news/releases/2004/07/20040721-2.html>

<sup>159</sup> Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004 (Section 564).

<sup>160</sup> Alliance Pharmaceutical Company, *Phases of Product Development*, available at [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm).

<sup>161</sup> *Id.*

However, when emergency approval is needed, a more efficient mechanism of approval is needed. This is what the FDA emergency authorization and Project BioShield have sought to answer. Section 312.34 of the FDA seeks expedited approval for a drug needed to aid in a life threatening condition where there are no alternatives available.<sup>162</sup> Under the FDA, emergency approval can be sought before Phase Three of clinical testing.<sup>163</sup> However, under Project BioShield, clinical testing may never be required or if it is on a level of much lower standards as the FDA's emergency approval section.<sup>164</sup> Project BioShield's main aim is to have vaccines stockpiled in case of a biochemical terrorist attack, where FDA section 312.34 seeks approval for individual life threatening illness.<sup>165</sup> Conversely, even if approval is needed, clinical testing should never be overlooked.

Clinical testing isn't the only way to discover what effects drugs have on people. Unplanned but alert observation and careful scrutiny of experience can often suggest drug effects and lead to more formal study. But such observations are usually not reliable enough to serve as the basis for important, scientifically valid conclusions. Controlled clinical trials, in which results observed in patients getting the drug are compared to the results in similar patients receiving a different treatment, are the best way science has come up with to determine what a new drug really does. That's why controlled clinical trials are the only legal basis for FDA to conclude that a new drug has shown "substantial evidence of effectiveness."

It's important to test drugs in the kind of people they're meant to help. It's also important to design clinical studies that ask, and

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<sup>162</sup> Food and Drug Administration, Department of Health and Human Services, Treatment use of an investigational new drug, 21CFR § 312.34.

<sup>163</sup> *Id.*

<sup>164</sup> See Project BioShield Act of 2004, 108th CONGRESS, 2d Session S. 15, July 16, 2004

<sup>165</sup> *Supra* notes

answer, the right questions about investigational drugs. And that's no easy task.<sup>166</sup>

Due to the importance of clinical testing, approval under Project BioShield is limited. Therefore, it is argued that anyone receiving a vaccine which has gained expedited approval under Project BioShield should be warned of the drug's experimental status and if not there is a lack of informed consent.<sup>167</sup> However, informed consent is not the only bioethical problem under this law. Under the first awarded contract, there is only enough vaccines stockpiled for ten percent of the population. In essence, poor planning is paving the way to the same dilemma as organ allocation, unfortunately organ allocation is unavoidable, stockpiling vaccines is not. After so much discussion, the unanswered question presented; Is Project BioShield a realistic resolution? Due to problems such as informed consent and allocation it seems as though it may not be, but under a more advanced analysis it may be even more unrealistic. Vaccinations such as small pox<sup>168</sup> and anthrax have already been developed, but what if the terrorist organization were to introduce a new biochemical strain, would the United States be able to produce a vaccination for a new agent we aren't prepared for?

National Scientists do not believe so:

"Senior scientists emphasize that they don't really know a straightforward way to create vaccines or antimicrobials, so they can't expect to find out soon. "We do not know the path for developing effective antimicrobial agents," Falkow says. "We just don't know what the right path is." ... Furthermore, scientists have not discovered a new family of antimicrobials in 30 years. "It's not

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<sup>166</sup> Flieger, Ken, *Testing Drugs in People*, FDA Consumer Special Report, January 1995 available at <http://www.fda.gov/fdac/special/newdrug/testing.html>

<sup>167</sup> *Supra*

<sup>168</sup> US pledges smallpox vaccine for world stockpile, CDRAP (December 10, 2004) available at <http://www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/dec1004stockpile.html>.

for lack of trying on the part of the pharmaceutical industry," Falkow says.<sup>169</sup>

Scientists fear that the United States does not have the ability to make an effective vaccine, but what about the vaccines already stockpiled under Project BioShield, are they effective? After the complications that arose from the first vaccine administered to the troops, it can be surmised that the 'new and improved' vaccine may elicit unexpected health problems.<sup>170</sup>

For all the foregoing reasons, it is concluded that Project BioShield seems to be an realistic premature answer to the going threat of Biological or Chemical attacks. The Hon. Flake agrees that Project BioShield is not a realistic solution.<sup>171</sup>

This legislation signifies an expenditure of extraordinary proportions that may be little more than a public relations campaign designed to reassure U.S. citizens that the government cares about bioterrorism. I worry about the programs effectiveness when it is so blatantly ignores the way the market works, and I am not comfortable supporting such an expensive bill when too many questions have gone unanswered.<sup>172</sup>

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<sup>169</sup> John Miller, *Bioterrorism Research: New Money, New Anxieties*, The Scientist (April 2003) available at [http://thescientist.com/yr2003/apr/profl\\_030407.html](http://thescientist.com/yr2003/apr/profl_030407.html).

<sup>170</sup> *Supra* at notes, 102-105.

<sup>171</sup> 150 Cong. Rec. E1399-01 (July 14, 2004).

<sup>172</sup> *Id.*