

# **BOMBING BUREAUCRATIC COMPLACENCY: EFFECTS OF COUNTER-TERRORISM PRESSURES UPON MEDICAL PRODUCT APPROVALS**

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## **I. INTRODUCTION**

The competing risks and rewards of medical products are a constant topic of public debate in America. That debate is a public issue, not merely a private investment choice by pharmaceutical firms, because of the congressional decision to have the federal government act as the gatekeeper of new product entry. This gatekeeper role allows the federal Food & Drug Administration (FDA) to perform cost-benefit analysis and then reject or accept the consequences of the entry of new medical products into the American marketplace. Until recently, these choices were tradeoffs made carefully and based on the cautious balancing of medical, economic, and scientific interests.

That cautious reflection upon concepts of risk lasted until September 11, 2001, when the comfortable passivity of pre-approval debates exploded, along with complacency about Americans' peaceful and secure lifestyles. The aftermath of 9/11 has greatly affected America's health protection bureaucracies. This paper addresses the FDA's responses to the risks of terrorism and war, explains how this impact has been felt in health product approval decisions, and suggests the future course of events for federal reviews of new medical products that offer a counter-terrorism benefit. These products, such as an anthrax vaccine or a ricin poisoning antidote pill, may be referred to as "defensive" products for purposes of their value to homeland defense needs.

After 9/11, counter-terrorism activities became vitally important to U.S. federal agencies. The U.S. government faced the threat of terrorism from several sources: not only the enemies they faced in the 2002 war in Afghanistan and in the 2003 war in Iraq, but also the loosely dispersed organization known as Al Qaeda. The government has employed a wide range of methods to defend against

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these potential terrorist threats, including improving the public health system's ability to deal with sudden epidemics or incidents of infection.

This paper reviews the effects of 9/11 on the FDA's role as gatekeeper of new drugs, vaccines, and diagnostic and blood products. One of the main results has been that the FDA has modified its review and approval mechanisms to hasten the approval of defense-related medical products. For example, FDA rules now allow for the approval of "defensive" drugs without pre-market human testing,<sup>1</sup> a policy unheard of before 9/11. These modifications may have important consequences for the FDA product approval mechanisms that will be felt for years to come.

## II.

### BACKGROUND OF THE FDA

The social policy consensus for the U.S. government to act as a "gatekeeper" in regulating new products is a relatively recent phenomenon. Prior to the twentieth century, the government's role in regulating drugs and vaccines was limited to punishing the vendors of dangerous products *after* consumers had experienced death or injuries. The first pre-approval system for vaccines, adopted by Congress in 1902, was a reaction to an epidemic in which badly-made vaccines created a health emergency by causing death to those who sought immunity by vaccination.<sup>2</sup> In 1938, Congress responded to deaths caused by an untested new drug by passing legislation that controlled the approval and marketing of new drugs. The new drug sponsor was required to prove to the FDA's satisfaction that the drug was safe.<sup>3</sup> Similar approval processes for medical devices were adopted in 1976.<sup>4</sup>

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1. See 21 C.F.R. § 314.610 (2003).

2. "13 children in St. Louis died of tetanus after receiving diphtheria antitoxin (1901) from a horse named Jim. 'This tragedy convinced Congress and the public that producing antitoxin or vaccine was not a simple matter like weighing out a dose of a drug on a scale.'" Dr. Jesse L. Goodwin, Director, FDA Center for Biologics Evaluation and Research, Address at the 2003 DIA Annual Meeting, at <http://www.biologicsconsulting.com/docs/2002/WSP200306E.PDF> (last visited Mar. 16, 2003) (internal citation omitted).

3. See Federal Food, Drug and Cosmetic Act, ch. 675, § 505, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 301 (2003)). The history of this provision is found in CHARLES WESLEY DUNN, FEDERAL FOOD DRUG & COSMETIC ACT (1938).

4. See Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 575 (1976).

The pre-approval processes for drugs,<sup>5</sup> medical devices,<sup>6</sup> and vaccines<sup>7</sup> are each controlled by the FDA under the supervision of distinct operational subgroups.<sup>8</sup> Other parts of the agency regulate food safety<sup>9</sup> and other health-related products.<sup>10</sup> This paper will focus primarily on the administrative adjudication of product license applications by the FDA within the “new drug application” review.<sup>11</sup>

#### A. *Intra-Departmental Mobilization*

The Department of Health & Human Services (HHS) houses three principal components relevant to this paper: the Food & Drug Administration, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDCP). Each is a large and complex public health bureaucracy and each has served a distinct, though interrelated, role in the war on terrorism. For example, when terrorists using biological weapons such as anthrax posed an imminent public health threat, the CDCP tracked the threats and their medical consequences, the NIH stimulated research into protective mechanisms and therapies, and the FDA transformed its cautious protective role into an active advocacy for public access to new medications and new devices.

#### B. *Roles & Responsibilities of the FDA*

The FDA is both a product approval agency, with headquarters scientists and physicians, and an enforcement agency, with field inspection officials at border crossing points. The impact of terrorism has been felt on each of these components to varied degrees,

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5. See 21 U.S.C. § 360(c) (2000).

6. See *id.*

7. See 42 U.S.C. § 262(a) (2000). Note that vaccines are included within the definition of “biological products.” *Id.* § 262(i).

8. The Center for Drug Evaluation & Research is described at <http://www.fda.gov/cder> (last visited Mar. 10, 2004). Many sources have addressed the central role of the FDA drug approval processes in the development of new medical products. See, e.g., 1 JAMES T. O'REILLY, FOOD & DRUG ADMINISTRATION § 13 (2d ed. Supp. 2004).

9. The Center for Food Safety & Applied Nutrition is described at <http://www.cfsan.fda.gov> (last visited Mar. 10, 2004).

10. For example, the radiation detection devices used in counter-terrorism are regulated by the FDA through its radiation safety programs. See Lester M. Crawford, Remarks at the Food and Drug Law Institute Education Conference (Apr. 16, 2002), at <http://www.fda.gov/oc/speeches/2002/fdli0416.html>.

11. See 21 U.S.C. § 355 (2000) (amended 2002); Changes to the adjudication process made after 9/11 can be found at 21 C.F.R. § 314 (2003).

from border surveillance of incoming food containers<sup>12</sup> to rapid approvals of detection kits for anthrax infections.<sup>13</sup> This paper examines the FDA's reaction to bio-terrorism and the eventual consequences of that reaction upon future FDA product approval activities. In particular, it examines the new role that the agency has taken on in promoting emergency response products for marketing.<sup>14</sup> As the FDA itself noted when it rapidly approved a child dose of an antidote for nerve gas exposure, the agency "has placed a high priority in making available safe and effective countermeasures against potential terrorist attacks."<sup>15</sup> Congress facilitated this change by giving the FDA increased statutory power to supervise imports as well as new funding to respond rapidly to public health emergencies and to the military's needs for dealing with weapons of mass destruction.

### III. THE DRUG APPROVAL PROCESS

While pharmaceutical drugs are the most visible of the categories in which FDA pre-market approval has been imposed by Congress, they are not the only category. The pre-market approval requirements also apply to sponsors who prepare applications for FDA review of new vaccines, other biological products,<sup>16</sup> and medical devices, including diagnostic devices.<sup>17</sup> Although there are some variations in the testing requirements and the required data submissions for each of these categories, the common elements of the FDA's product approval procedures are that they take time, cost money, and involve multiple reviewer questions and challenges.

Looking at the drug approval process in particular, the FDA seeks to determine if the drug is safe for humans in light of its bene-

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12. See 21 U.S.C.A. § 381(h)-(o) (West Supp. 2003).

13. The rapid approvals are authorized under 21 U.S.C.A. § 360(c) (West Supp. 2003).

14. If Congress adopts proposed legislation, emergencies will trigger a new FDA power to authorize marketing without product approval. See Project Bioshield Act of 2003, H.R. 2122, 108th Cong. § 564 (2003) (adding new material to 21 U.S.C. § 360bbb-3 (2000)).

15. Press Release, Food & Drug Administration, FDA Approves Pediatric Doses of Atropen (June 30, 2003) (on file with the author).

16. See 42 U.S.C. § 262 (2000).

17. See 21 U.S.C. § 360 (2000). Diagnostic devices are classified as medical devices under 21 U.S.C. § 321(h). The testing is conducted under common standards for the quality of data and for informed patient consent, institutional review board oversight, etc., but the approval groups and their specific standards for acceptability will vary.

fits and whether it will have the effectiveness that is claimed on its label.<sup>18</sup> Thus, federal law requires the manufacturer of a new drug to obtain FDA approval of a product's formula, manufacturing process, and label.<sup>19</sup> The process is an administrative adjudication<sup>20</sup> with the burden of proof upon the manufacturer to demonstrate to the FDA's satisfaction that the new drug is "safe and effective."<sup>21</sup>

Drug approval by the FDA is intentionally arduous and meticulously detailed in its specific evidentiary requirements in order to screen out products that may pose health risks.<sup>22</sup> The New Drug Application (NDA) approval process at the FDA's Center for Drug Evaluation & Research is the ultimate stage of a new product's evidence development process: a new chemical entity that appears to have benefits for human health will undergo many years of study before its sponsor can even apply for product approval by submitting an NDA. In fact, the need to develop a full set of robust testing results in order to satisfy FDA approval requirements means that testing of the new chemical will take many more years than the actual processing of the application within the FDA. The FDA's "gatekeeper" role includes the power to set the preconditions for applicants, and the completion of very detailed reports on successful human studies is expected before the NDA filing can hope to pass through the scrutiny of FDA career medical staff and reach approval.<sup>23</sup> Similar stages exist before a new vaccine can be licensed<sup>24</sup> and before a new medical device can be approved for marketing<sup>25</sup>.

#### A. *Ambiguity and Delay are Normal*

Once a product has reached the NDA phase of the process, it is reviewed by an FDA staffer who, when acting as a safety-focused

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18. The procedural steps required for the applicant are described at 21 C.F.R. § 314.50(c) (2003).

19. See 21 U.S.C. § 355(b)(1) (2000).

20. See 5 U.S.C. § 551(7) (defining adjudication as the "agency process for the formulation of an order").

21. See 21 U.S.C. § 355(b)(1)(a); 1 JAMES T. O'REILLY, FOOD & DRUG ADMINISTRATION § 13.1–13.21 (2d ed. Supp. 2003).

22. Mechanisms of approval are addressed in detail at O'REILLY, *supra* note 21, at § 13. Additional information is available on the FDA website at <http://www.fda.gov/cder/biologics/default.htm> (last visited Mar. 23, 2004).

23. The FDA provides extensive non-technical explanations of this process at <http://www.fda.gov/cder/regulatory/applications/default.htm> (last visited Mar. 23, 2004).

24. See 42 U.S.C. § 262(a)(2) (2000); 21 C.F.R. § 601.2 (2003).

25. See 21 U.S.C. § 360(c)–(f) (2000).

product approval gatekeeper, employs a style that might be called conscious ambiguity. While sophisticated drug companies attempt to predict what the agency will require of them at future stages of product development, this is difficult to do. Although, the FDA has made efforts to improve its guidance process,<sup>26</sup> the challenge of product approval is that it is an art, not a science; a perfectly effective and reasonably safe product may fail if its sponsor makes an inadequate presentation of data to the FDA staff, while a marginally acceptable product, whose NDA documents explaining its risks are well-presented, may win approval.

The ambiguity of the FDA approval mechanism works against those who seek to press for faster approval. The FDA does not often squarely deny a new drug application; instead, it often sends the sponsor a veiled disapproval suggesting the need for additional data regarding the new drug. If, after receiving these suggestions, the sponsors do not improve the test data to the FDA's satisfaction, the sponsors will be forced to "recycle" the application to obtain additional supportive data. When this happens, the time allotted for product review recommences so that the FDA can still be deemed to have completed a "timely" review of the application as required by law.<sup>27</sup> A sponsor may be forced to recycle an NDA multiple times.

### *B. The Conservative Paradigm*

One of the reasons for the challenges faced by new drug sponsors is the conservative ethos that the FDA has cultivated over time. The agency's culture and conservative stance toward evaluating acceptable risks and rewards has much more impact on product approval decisions than the words used in statutes or executive commands will ever have. Moreover, politics, public opinions about risk, and drug approval applications are inherently interrelated. The nature of any risk acceptability decision is inherently political, for a particular drug's known set of risks relative to its benefits may be acceptable in some political environments but unacceptable in others. For example, some drugs are placed on a fast

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26. See Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 7321 (Feb. 14, 2000).

27. Timely action on pending reviews is required by the legislation which granted the FDA additional funding and staff. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 § 406 (1997). FDA drug review officials must demonstrate in annual reports to Congress that they can satisfy time requirements for efficient reviews of completed applications. 21 U.S.C.A. § 379h(g)(2)(A)(ii) (West Supp. 2003).

track for approval because of societal perceptions of need, and the “defensive” drugs necessary for the war on terrorism appear to fall within this category.

FDA drug approval has historically been subject to cyclical critiques claiming that approval is too easy or too difficult. People argue that “bad” drugs that were approved too easily are used by people who should have been protected, while “good” drugs whose approval was too difficult are kept away from dying patients who need those drugs to survive. Both of these critiques may be correct at the same time since several hundred applications are pending at any particular time for new drugs or for the expanded uses of existing ones.

The approval process may sometimes be too difficult as a result of the long-time paradigm of caution and conservatism within the FDA. In the past, FDA staff sometimes have been rewarded for their refusal to approve a drug that later caused a high rate of adverse effects in other countries. The icon of this phenomenon is Frances Kelsey, an FDA physician who refused to approve the drug thalidomide. After the drug’s distribution in Europe was connected to birth defects in children, Kelsey won the Presidential Medal of Freedom and remained active at the FDA for decades as a living symbol of the conservative handling of risk issues.<sup>28</sup>

### *C. Other Challenges Involved in New Drug Development and Approval*

Until 9/11, the drug approval process was largely hidden from the public. Because new drug applications are not publicly disclosed, the strategies and negotiation tactics employed by corporate sponsors in dealing with the FDA proceeded with little public awareness from the outside.

When information about a drug’s approval process did become publicly known, the FDA’s signaling of difficulty with a drug’s approval sometimes had severe consequences for investor confidence in the sponsoring company’s stock price. This is illustrated by the problems experienced by Imclone Corporation in 2003, when the FDA recycled the application for the company’s anti-can-

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28. See Linda Bren, *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History*, FDA CONSUMER, Mar.–Apr. 2001, at 24–25:

Although pressured by the manufacturer to quickly approve a drug already in widespread use throughout the rest of the world, Kelsey held her ground. When she repeatedly asked for more data and effectively forestalled the approval of thalidomide, Kelsey did more than keep a dangerous drug off the market. She set into motion a series of events that would forever change the way drugs are tested, evaluated, and introduced in America.

cer drug Erbitux.<sup>29</sup> As a result of the “recycling,” Imclone lost investor support among shareholders such as Martha Stewart,<sup>30</sup> and its chief executive went to federal prison for securities violations.<sup>31</sup>

Finally, although the economics of pharmaceutical innovation are beyond the scope of this article, two significant barriers can be posited that have inhibited the *development* of defensive drugs, before they even make it to the approval process. First, because the likely purchasers of defensive drugs are governmental agencies, they have the ability to control the pricing. When terrorists launched anthrax attacks in late 2001, the federal government forced the maker of Cipro, the first product to be used in defense of anthrax infections, to cut its price to one-fourth the normal selling price under threat of antitrust challenges. That drastic pricing power deters profit-oriented investors from supporting the development of defensive drugs.<sup>32</sup> Second, some defensive drugs cannot ethically be tested on humans without exposing the test subjects to smallpox, anthrax, or similar harmful substances for which the antidote or preventive product is intended.<sup>33</sup> This makes it more difficult for investors to determine whether the FDA will reject the drug for lack of adequate testing and also deters companies from developing these drugs for fear of being held liable for their ultimate effects.<sup>34</sup>

#### IV. EFFECTS OF WAR: THE FDA ADAPTS TO NEW PRESSURES

On September 11, 2001, both the FDA’s cautious approach and the public’s lack of awareness about new product approvals drastically changed. The incentives felt by FDA managers shifted when it suddenly found itself thrust into a new role in the war against terrorism. Instead of simply acting as a “gatekeeper” to prevent the approval of dangerous drugs, the FDA suddenly felt “a

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29. See Andrew Pollack, *Biotechnology Company’s Shares Plummet 62%*, N.Y. TIMES, Oct. 4, 2002, at C6.

30. See Andrew Pollack, *Prosecuting Martha Stewart: The Drug Company; Product at Center of the Trading Case Shows New Promise*, N.Y. TIMES, June 5, 2003, at C4.

31. See Christopher Rowland, *Imclone founder gets over 7 years in jail, fine: Harsh sentence sends a warning to executives*, BOSTON GLOBE, June 11, 2003, at D1.

32. See Terri Somers, *Biotechs seen as a key in fight vs. terrorism: But industry asks: Will it be profitable?*, SAN DIEGO UNION-TRIBUNE, June 26, 2003, at C1.

33. See *id.* This uncertainty is inherent in the antidote research effort, but it makes the investor less willing to support the development costs and expands the company’s liability concerns.

34. See *id.*



high priority in making available safe and effective countermeasures against potential terrorist acts.”<sup>35</sup> That re-prioritization will influence FDA decision-making for years to come.

A. *The BioShield Program*

The events of 9/11 and the subsequent war in Iraq precipitated a widespread patriotic fervor to oppose the forces that posed new threats of terror. Weapons of mass destruction alleged to have been ready for use were expected to pose threats to American forces invading Iraq. At the same time, terrorist use of smallpox or anthrax weapons could have been possible methods for attacking Americans at home.<sup>36</sup> Regulatory agency approvals of the products needed to support the war effort were simply one part of the larger mobilization of efforts against a common enemy. If a risk to the lives of U.S. soldiers or citizens could be prevented by a vaccine, then the expedited development and approval of such a vaccine should be a war-related imperative.

With this goal in mind, President Bush chose to bring FDA expertise into the fight against terrorism. Shortly after 9/11, the FDA’s Deputy Commissioner, its second most senior manager, told the drug industry that “the FDA has been put on a war footing and charged with the responsibility of helping deter or minimize the effects of a bioterrorist attack on our population.”<sup>37</sup> In his 2003 State of the Union address, the President announced Project BioShield, an effort to expedite approvals and to fund further research in antidote and vaccine products for likely biological attack materials such as anthrax.<sup>38</sup> The Project would authorize the spending of nearly six billion dollars over the next ten years “on developing vaccines and treatments for biodefense.”<sup>39</sup> The inclusion of the BioShield counter-terrorism program in the President’s address gave an extraordinary level of visibility to the FDA’s role in promoting rapid product development initiatives for defensive products.

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35. Press Release, Food & Drug Administration, FDA Approves Pediatric Doses of Atropen (June 30, 2003) (on file with the author).

36. The smallpox defense programs are discussed in VICTORIA SUTTON, LAW & BIOTERRORISM 266 (2003).

37. FDA Deputy Commissioner Lester Crawford, Address at the Financial Times’ of London Global Pharmaceutical Conference (Nov. 6, 2002), at <http://www.fda.gov/oc/speeches/2002/London.html>.

38. See President George W. Bush, State of the Union Address (Jan. 28, 2003), <http://www.whitehouse.gov/news/releases/2003/01/print/20030128-19.html>.

39. Somers, *supra* note 32, at C1.

The BioShield program is an effort to bring together the FDA and other federal health agencies with the drug and vaccine development industries to promote rapid development of counter-terrorism products.<sup>40</sup> This cooperation seems to have made the FDA more merciful toward innovative drug companies and more supportive of industry efforts to expedite reviews than it was in its peacetime “gatekeeper” role: the antidotes and preventive products developed in this climate of urgency received the most rapid FDA clearance of any medical products in recent history. For example, prior to the anthrax scare in 2001, the FDA had been disputing the license for an anthrax vaccine for several years. Immediately after the anthrax scare, the FDA approved the distribution of doses of the vaccine that had been made.<sup>41</sup> Similarly, smallpox vaccines received their license for distribution in October 2002.<sup>42</sup>

### *B. Changes to the Drug Approval Process*

#### 1. FDA Changes

In order to defend U.S. citizens against biological weapons such as anthrax, the FDA recognized that drugs would need to be developed that could not ethically or feasibly be tested on humans prior to their approval. In May 2002, in a major departure from past prior approval requirements, the FDA amended its rules and waived human clinical trials for drugs if “the very nature of what

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40. See President George W. Bush, State of the Union Address, (Jan. 28, 2003), *supra* note 38:

I ask you tonight to add to our future security with a major research and production effort to guard our people against bioterrorism, called Project Bioshield. The budget I send you will propose almost \$6 billion to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague. We must assume that our enemies would use these diseases as weapons, and we must act before the dangers are upon us.

41. See Press Release, Food & Drug Administration, FDA Approves License Supplements for Anthrax Vaccine (Jan. 31, 2002), at <http://www.fda.gov/bbs/topics/news/2002/new00811.html>.

42. See Michele Meadows, *An Update on Smallpox*, 37 FDA CONSUMER 2, 28 (Mar./Apr. 2003), available at [http://www.fda.gov/fdac/features/2003/203\\_smallpox.html](http://www.fda.gov/fdac/features/2003/203_smallpox.html):

In October 2002, FDA approved a license supplement for a 100-dose kit of Dryvax, with a new supply of diluent (the liquid that’s mixed with dried vaccine before it’s administered) and needles for administration . . . . “Before the approval of this supplement, Dryvax was available only under an investigational new drug (IND) application. Now the vaccine can be distributed and used as any other approved product.”

they are designed to treat cannot be safely or ethically tested for effectiveness in humans.”<sup>43</sup>

The FDA showed the depth of its counter-terrorism efforts when it made the extraordinary request, probably unprecedented in its history,<sup>44</sup> for drug companies to submit new drug applications for approval of a drug that would be used only as an emergency antidote to radiation exposure.<sup>45</sup> This request was a dramatic departure from the FDA’s statutory role of gatekeeper, in which it simply approved or rejected new drugs rather than encouraged their development.<sup>46</sup> But in the radiation antidote announcement, the FDA pleaded for sponsors to make submissions for approval. To facilitate such applications, the FDA stated that it already had the safety and efficacy data as well as draft labeling, and implied that approval would be rapid if a drug company would prepare the chemistry and production information needed to take that particular manufacturer’s formulation of the antidote into production.<sup>47</sup> The FDA acted because there was no financial incentive to develop expensive sets of supporting data for a product that could not be patented, and thus could not repay the investment in research.<sup>48</sup>

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43. New Drug and Biological Products; Evidence Needed to Demonstrate Effectiveness of New Drugs when Human Efficacy Studies are not Ethical or Feasible, 68 Fed. Reg. 37987, 38989 (May 31, 2002); *see also* Press Release, Food & Drug Administration, FDA Amends its Regulations to Provide for Approval of Certain New Pharmaceutical Products Based on Animal Efficacy Data (May 30, 2002), at <http://www.fda.gov/bbs/topics/news/2002/new00811.html>.

44. The event has no parallel that could be recalled over the author’s three decades of work in this field.

45. *See* Press Release, Food & Drug Administration, FDA Encourages New Drug Application Submissions for Prussian Blue as a Treatment for Thallium or Radioactive Cesium Contamination (Jan. 31, 2003), at <http://www.fda.gov/bbs/topics/news/2003/new00868.html>.

46. *See* Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,437 (June 26, 1979) (“[T]he final labeling for a drug is often the result of interactions between FDA and the manufacturer when a manufacturer seeks approval for a prescription drug . . . . It is not the intent of FDA to influence the civil tort liability of the manufacturer or of the physician.”)

47. *See* Press Release, Food & Drug Administration, FDA Encourages New Drug Application Submissions for Prussian Blue as a Treatment for Thallium or Radioactive Cesium Contamination (Jan. 31, 2003), at <http://www.fda.gov/bbs/topics/news/2003/new00868.html>.

48. The FDA relies on the submissions made by private drug sponsors and does not issue product decisions *sua sponte* without an application. *See* 21 U.S.C. § 355(b). Information about the radiation drug (as well as the drug itself) is available at <http://www.nukepills.com> (last visited Mar. 10, 2004).

## 2. Congress Delegates Sweeping Powers

Bio-terrorism became a very direct threat to American legislators when the Hart Senate Office Building was contaminated by mailed delivery of anthrax spores.<sup>49</sup> This event was an extremely unconventional attack that precipitated a public panic and highlighted the nation's lack of preparation for the public health consequences of biological forms of terrorism.

Realizing that it was now a target of the anthrax terrorists, Congress responded with new funding and new powers for public health officials to act against such critical vulnerabilities.<sup>50</sup> For example, newly adopted legislation requires anyone importing a drug into the United States to notify the FDA in advance concerning the registration status of the foreign manufacturing plant, and it is a federal crime to fail to give the required set of information to the FDA concerning the imported drug.<sup>51</sup> More importantly for purposes of this paper, the legislation substantially increased funding for the FDA's counter-terrorism efforts.<sup>52</sup> In addition, legislation granting the FDA even greater emergency approval authority had passed the House and was awaiting Senate clearance as this article went to press.<sup>53</sup> Under that legislation, the FDA would have emergency authority to allow the interstate marketing of *unapproved* drugs, devices or vaccines.<sup>54</sup> When an emergency is declared,<sup>55</sup> the FDA would be able to issue an immediate authorization for a product that had not yet received approval for marketing, and the product would be able to remain on the market under specified conditions during the time of the emergency.<sup>56</sup> In effect, this legis-

49. See Sheryl Gay Stolberg & Alison Mitchell, *Letter Containing Anthrax Sent to U.S. Senate Leader*, N.Y. TIMES, Oct. 16, 2001, at A1.

50. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594; Consolidated Appropriations Resolution of 2003, Pub. L. 108-7, 117 Stat. 11.

51. See 21 U.S.C. A. §§ 331(ff), 381(o) (West Supp. 2003).

52. The FDA sought \$20.5 million for counter-terrorism activities. See FDA Talk Paper T03-09, FDA's Budget Proposal for FY 2004 (Feb. 3, 2003); Consolidated Appropriations Resolution of 2003, Pub. L. 108-7, 117 Stat. 11 (2003).

53. See Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 4 (2003).

54. See *id.* § 564(a).

55. Three types of emergencies are recognized: military emergencies (designated by the Secretary of Defense), public health emergencies (designated by the Secretary of Health and Human Services), and national emergencies (designated by the Secretary of Homeland Security). *Id.* § 564(b)(1).

56. See *id.* § 564(a) ("[T]he Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an 'emergency use').").

lation would enable the FDA in certain emergency situations to avoid the drug approval procedures generally required.

## V. IMPACTS ON APPROVALS

The FDA was extraordinarily busy in 2003. Historians may look back at this period as a dynamic response to the pressures to suddenly do more, better, and faster against a determined and criminal enemy. While the FDA worked on implementing its new statutory powers and increased its staff in order to fulfill its expanded duties,<sup>57</sup> its managers considered how to streamline approvals for special defense-related products. As noted above, the FDA departed from its gatekeeper role and stretched its administrative powers by encouraging drug sponsors to develop new materials. In addition, the agency managers used the discretion accorded the FDA to interpret the new drug provisions of the 1938 Act,<sup>58</sup> and simultaneously worked with Congress on the pending legislation that would suspend certain requirements for drug approval in the event of a national emergency.<sup>59</sup>

In addition to the FDA's drug approval process, another one of its roles affected by the war on terrorism is its approval of what are known as "in vitro diagnostics." These are products which are used to detect infection from certain drugs.<sup>60</sup> For example, the ability to detect infection caused by anthrax, a grave environmental infection hazard spread by inhalation or other contact,<sup>61</sup> requires a sophisticated laboratory test that is accurate, relatively stable for use out in the field, and relatively inexpensive because of the large volume of sites that could be infectious. Diagnostic products tend to cross the statutory classification lines because they are medical devices but also are sometimes biologic products. Despite the fact that they are used in a testing device or laboratory (outside of the human body), Congress has included them within the regulatory jurisdiction of

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57. The FDA's plans for implementation are presented at <http://www.fda.gov/oc/bioterrorism/bioact.html> (last visited Mar. 10, 2004).

58. *See* *Weinberger v. Hynson, Westcott & Dunning Inc.*, 412 U.S. 609, 627 (1973).

59. Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 4.

60. In vitro diagnostic products are defined as "those reagents, instruments and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae." 21 C.F.R. § 809.3(a) (2003).

61. Explanatory materials on anthrax are available on the CDC website at <http://www.bt.cdc.gov/agent/anthrax/faq/index.asp> (last visited Mar. 10, 2003).

the FDA because their test results have consequences for the health of the patient.<sup>62</sup>

In the past, the development of diagnostic kits and related tools by a small group of companies has been funded by some private investment and by numerous NIH and CDC funding grants. However, financial limitations have inhibited spending on diagnostics for some of the more rare infections that terrorists might seek to generate. Of course, the ideal would be a very accurate test that is also quick and inexpensive enough to be mass-produced for ready use at the scene of a suspected terrorist incident. Since 9/11, the NIH has invested significant funds in the development of diagnostics to detect bio-terrorist infections.<sup>63</sup>

## VI.

### FDA ACTIONS BEYOND PRODUCT APPROVALS

Beyond product approvals, Congress is also concerned about the release of existing supplies of experimental infectious agents. Thus, it has required that all manufacturing facilities holding samples of smallpox, anthrax, animal viruses, or other materials that could be used to cause terrorist effects register their supplies of these high-risk materials with the CDC.<sup>64</sup> This would presumably facilitate criminal law enforcement officials in detecting the source of a disease-related terrorist activity.

Fear among consumers about potential terrorist attacks has also provided opportunity for fraudulent sales promotions by vendors of ineffective products. The FDA and the Federal Trade Commission (FTC) share jurisdiction over drug advertising, and the agencies have been examining a flood of fraudulent product claims relating to the public's fear of anthrax or other terrorism issues. The Internet marketing channel has afforded many of the more aggressive vendors an opportunity to hasten to sale with ideas or

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62. See 21 U.S.C. § 321(h).

63. See Press Release, Nat'l. Inst. of Allergy & Infectious Diseases, Research on Medical Tools to Combat Bioterrorism (Dec. 7, 2001), at <http://www.niaid.nih.gov/factsheets/btmedtools.htm>:

NIAID [part of the NIH] has placed a major emphasis on generating information on the genetic make-up of potential bioterrorism agents. Coupled with knowledge in biochemistry, microbiology, and immunology, genomic information underpins many efforts to make rapid diagnostic tests, antimicrobial therapies, and new vaccines. NIAID has significantly invested in projects to sequence the full genomes of many pathogens, including the bacteria that cause anthrax, plague, Q fever, brucellosis, and glanders.

64. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594, § 201.

products that would not ordinarily have been purchased.<sup>65</sup> In 2003, the FTC forced twenty marketers to modify their claims to remove the exaggerated benefit claims after an Internet surfing exercise found many medical device and dietary supplement products making counter-terrorism claims.<sup>66</sup>

## VII. CONTRASTING THE FDA'S RESPONSES TO PREVIOUS NATIONAL CRISES

Although the FDA's actions in response to terrorism are unprecedented, it is certainly not the first time that the agency has felt pressure to accelerate the approval of drugs in the midst of a national crisis. The examination of two previous "wars"—World War II and the "War" on AIDS (Acquired Immunodeficiency Syndrome)—sheds light on why the FDA's response to terrorism has been more drastic than in previous circumstances.

### A. *The FDA's Role in World War II*

While the FDA felt pressure to expedite the approval of drugs for the military during World War II, the agency's role and structure at the time differed dramatically from its current ones. At the time, the FDA was part of the Federal Security Agency, and its staff of scientists and physicians assigned to drug product review was much smaller since it had only very recently been given statutory authority to review new drug applications.<sup>67</sup> In fact, its approval role under the 1938 Food, Drug & Cosmetic Act was barely three years old when war broke out and suddenly overwhelmed the nation's civilian drug development systems. The peacetime structures for product clearance that we enjoy today were not in place for the military's wartime procurement of drugs needed for battlefield use.<sup>68</sup> Moreover, at the time the FDA was only charged with evaluating the safety of new drugs and not with the more difficult task of

65. The iodine pills sold at [nukepills.com](http://www.nukepills.com) illustrate this unusual marketing pattern. See <http://www.nukepills.com> (last visited Mar. 10, 2004).

66. See Press Release, Food & Drug Administration, FTC and FDA Crack Down on Internet Marketers of Bogus SARS Prevention Products (May 9, 2003), at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00904.html>.

67. See Federal Food, Drug and Cosmetic Act, ch. 675, § 201, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 301 (2003)).

68. In addition, FDA managers told the drug industry that the loss of personnel to the military "and the diversion of the remainder of the force to special wartime tasks" had forced the FDA to stop its routine processing of some drug regulatory matters. Trade Correspondence TC-394 (Nov. 30, 1942), reprinted in FEDERAL FOOD, DRUG & COSMETIC ACT: JUDICIAL AND ADMINISTRATIVE RECORD,

determining whether the drugs were effective (Congress did not require it to evaluate the effectiveness of new drugs until 1962).<sup>69</sup> Finally, because World War II did not pose a direct health danger to civilians in the United States, the FDA's role was limited to the approval of drugs for troops abroad.

By contrast, the current threat of terrorism has required that drugs which once would only have been shipped to distant troops may also be distributed to U.S. civilians in locations where a bio-terrorism attack could arise. In today's environment, it is probable that a rapidly approved "defensive drug" will be directly injected or ingested by civilian first responder personnel such as emergency workers responding to a bio-terrorist's release of smallpox or anthrax in a crowded subway train. So while similar pressures exist as were felt in the 1940s, the fact that "defensive" drugs may be needed by civilians has resulted in more pressure being applied to the FDA.

### *B. The FDA's Response to the War on AIDS*

Another instance where the FDA faced pressure to accelerate the approval of new drugs was in the War on AIDS, which crept slowly into the public consciousness in the late 1980s. That epidemic carried an implied social stigma, because disease transmission for the AIDS virus was associated with sexual transmission and the use of illegal intravenous addictive drugs.<sup>70</sup> Of the HHS agencies, the CDC was the most active early on as the epidemic and its causal factors were being identified. The NIH also gave grants for the research of ways to deal with the virus and its possible prevention. In contrast, the FDA was extremely conservative toward applications for AIDS drugs, reasoning that the approval process required uniformity in the consideration of each new drug, whether for measles, cancer, or AIDS.

FDA approval of AIDS drugs remained slow and particularly difficult in the 1980s and early 1990s, while the disease etiology for the human immunodeficiency virus (HIV) that leads to AIDS was

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1938-49, at 730 (Vincent Kleinfeld & Charles Wesley Dunn, eds., Commerce Clearinghouse 1949).

69. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 781, § 102 (1962).

70. See Center for Disease Control, *Continued Sexual Risk Behavior Among HIV-Seropositive Drug-Using Men*, 45 MORBIDITY AND MORTALITY WEEKLY REPORT No. 7, Feb. 23, 1996, at 151.



only slowly becoming understood.<sup>71</sup> However, over time political pressures imposed by advocacy groups and sympathetic congressional allies overcame the agency's conservatism and hesitancy. The FDA's support for more rapid drug approval changed as organizations of AIDS-affected communities took strong and visible political action, including sit-ins and demonstrations against the agency.<sup>72</sup> As the former Deputy Commissioner has written, "[n]othing tests the integrity of a regulatory statute or the ability of the regulators like a full blown national crisis . . . . [N]o issue compares to the Acquired Immunodeficiency Syndrome (AIDS) crisis in its unrelenting level of difficulty."<sup>73</sup>

Despite the fact that AIDS was (and remains) a chronic and widespread public health concern, several differences between the war on AIDS and the war on terrorism suggest why the FDA was slower to respond to the need to develop AIDS-related drugs than it has been in reacting to the war on terrorism. First, AIDS poses a fear of infection by having one's actions lead to a chronic disease. This fear is qualitatively different from the fear of becoming a victim of a random attack by bio-terrorism or the use of weapons of mass destruction. In addition, private drug development and sales decisions, such as those involved in the development and marketing of AIDS drugs, are quite different from the governmental decision to develop and purchase defensive drugs for the military and civilians. The defensive need to have a ready supply of a smallpox vaccine or radiation disease-prevention pills in case of infections leads the government to stockpile large bulk purchases. In contrast, the chronic illness problems that AIDS presents are a private marketplace demand in which the individual patient, or his insurer or health clinic, must be prepared to pay for any effective therapeutic drugs.

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71. The first specific approval of an AIDS drug, AZT, came from the FDA in March 1987. Press Release, Food & Drug Administration, Approval of AZT (March 20 1987), at <http://www.fda.gov/bbs/topics/NEWS/NEW00217.html>. For a discussion of how AIDS impacted the FDA's drug approval process, see Ellen C. Cooper, *Changes in Normal Drug Approval Process in Response to the AIDS Crisis*, 45 FOOD DRUG COSM. L.J. 329 (1990). Dr. Cooper was the FDA's Director of Antiviral Drug Products at the time that she authored this article.

72. See James J. Eigo, *Expedited Drug Approval Procedures: Perspectives from an AIDS Activist*, 45 FOOD, DRUG COSM. L.J. 377, 380 (1990) ("The successful efforts of AIDS activists to secure PHS support for a parallel track for investigational AIDS drugs . . . offer the first in a series of programmatic concretizations of the ethical paradigm shift.").

73. William B. Schultz, *Introduction, Panel Discussion on Expedited Drug Approval Procedures*, 45 FOOD, DRUG COSM. L.J. 327 (1990).

Today, the logic of taxpayer funding for research and the prudence of cooperation in developing useful products seems to be broadly accepted in terms of both AIDS and bio-terrorism. Nevertheless, as between these two instances of “war,” Congress reached much more rapid consensus in preventing consequences of terrorism than in responding to the AIDS epidemic. This was likely due in large part to the less unanimous political support for the development of AIDS drugs when the disease first surfaced. Despite the large number of AIDS activists, the disease carried with it a social stigma that prevented unanimous support for devoting public resources to its cure. In contrast, the threat of bio-terrorism affects all people and thus expedited drug approval carries more widespread public support. One could also suggest that the anthrax attack on members of Congress was the perverse stimulus for the appropriations of federal funds to bio-terrorism defense as members of Congress felt a direct threat.

One can speculate that the pending statutory powers that would allow the FDA to bypass the drug approval gateway during a “public health emergency” might be attractive to advocacy groups targeting a particular disease. Just as AIDS groups lobbied the FDA to relax new drug clearance barriers, other advocacy groups may seek to have the accelerated approval mechanisms applied to specific drugs. However, it is important to recognize that the FDA’s recently expanded authority is specifically limited to “defensive” drugs. The agency’s ability to approve new drugs in the absence of human studies applies

only to those new drug products for which: Definitive human efficacy studies cannot be conducted because it would be unethical to deliberately expose healthy human volunteers to a lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substance; and field trials to study the product’s effectiveness after an accidental or hostile exposure have not been feasible.<sup>74</sup>

Most AIDS and cancer drugs do not meet these criteria. Furthermore, the pending legislation limits the public health emergencies to those in which the emergency is one “affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.”<sup>75</sup> In all other circum-

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74. 21 C.F.R. § 314.600 (2003).

75. Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 4.

stances, the FDA new drug clearance process must be used, and its methods for fast-track approval<sup>76</sup> are advocacy groups' best hope.

## VIII. EFFECTS OF CHANGE: FUTURE IMPLICATIONS FOR DRUG APPROVALS

### A. *How Future Approval Processes May Vary*

As a result of the congressional and FDA reactions to the war on terrorism, future FDA decisions on drug approval may become stratified according to the rationale underlying the product's marketing. If the 2003 legislation is passed, "defensive drug" products with a rationale of emergency or national security response will essentially receive waivers from the commonplace delay cycles that new drug applicants generally experience.<sup>77</sup> By waiving key parts of the approval process based upon a public priority for certain products,<sup>78</sup> the FDA will continue to diverge from its conventional role of gatekeeper of human safety and instead will become, for those products, a quasi-promoter of drug and vaccine innovations.<sup>79</sup>

### B. *Likely Supporters and Critics of Expedited Approval Processes*

Faster approvals made under more coherent directives for drug sponsors will be applauded by research-intensive drug manu-

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76. As part of FDA reform legislation in 1997, the FDA created and Congress codified a form of accelerated process for drug reviews known as the "fast track review" for products that had an unmet medical need and which were intended to treat a serious or life-threatening condition. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, § 112. The fast track process is not the subject of this paper, as it is a conventional mechanism unrelated to the terrorism issues addressed here. In the case of the "defensive drugs" for terrorism defense, the FDA has gone beyond rapid review to actual waiver of certain testing requirements. See 21 C.F.R. § 314.600 (2003).

77. See Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 564(b)(1)(C).

78. See 21 C.F.R. § 314.600 (2003).

79. Food & Drug Administration Performance Plan 2002, at <http://www.fda.gov/oc/fy03plan/goals.html> (last visited Mar. 10, 2004). The FDA's strategy for 2003-04 highlights their more active role:

Medical Countermeasures—The purpose of this strategy is to assure drugs, vaccines, blood, medical devices and other medical products are available to prevent, diagnose or treat illnesses or injuries resulting from terrorist attack or battlefield injury. Key objectives are to: 1. Facilitate medical product development—stewarding the development of safe and effective drugs, vaccines and medical devices that can be promptly available to protect the public health and safety in the event of a [sic] attack.

facturers.<sup>80</sup> In particular, the spillover effect of this new urgency may be beneficial for the drug sponsors who can make a case that their drugs provide a special, urgent public benefit by analogy to the counter-terrorist products. The rush of new counter-terrorism products during a public health emergency, permitted under the new legislative proposals,<sup>81</sup> could facilitate the streamlining of some of the approval steps for these other drugs.<sup>82</sup> These drugs would benefit from both faster approval decisions and more coherent directives for their sponsors. Biotech drugs in particular would likely benefit from the streamlined processes, although biotech firms remain cautious about the pace of approvals and the expense of development.<sup>83</sup>

The public's view of the expedited approval process will inevitably vary. Those who confront a particular disease, as well as their families and supporters, are likely to welcome the potential early access to a therapy that might work. Physicians are also likely to favor the new processes as they will provide additional weapons against diseases. Health insurance companies, on the other hand, might prefer that sponsors be required to prove the efficiency of new drugs more extensively before they are forced to provide reimbursement for them (for example, they would want proof that a drug that is three times more costly than prior drugs will reduce hospitalization times by 90 percent). Finally, in litigious America, plaintiffs' counsel will ask juries to compensate those injured where the additional years of experimentation would have revealed the side effect that caused harm to an individual user of the drug.

### *C. Impacts on FDA-Drug Developer Relations*

The post-9/11 climate for drug development and biotech responses to terrorism introduces curious new incentives within the FDA's relationship to drug sponsors. In the past, sponsors pressed new product candidates through the FDA gateway for approval based on economic pressures to sell more drugs and deliver shareholder value. Now the gatekeeper is telling the sponsors what

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80. Pharmaceutical Research and Manufacturers of America (PhRMA), an organization representing pharmaceutical and biotech companies, praised faster approval times resulting from the Prescription Drug User Fee Act, which reduced drug review times from thirty to eighteen months after filing of a complete application. See Pharmaceutical Research and Manufacturers of America (PhRMA) website, at <http://www.phrma.org/publications/quickfacts/01.04.2002.409.cfm>.

81. Project BioShield Act § 4.

82. This might take the form of statutory modification of the current "fast track" processes delineated in 21 U.S.C. § 356 (2000).

83. See Somers, *supra* note 32, at C1.

drugs will be needed for anti-terrorist reasons, and the sponsors must react with redirection of some of their research capabilities toward this public need.

These incentive changes have not been automatically welcomed by sponsors or by FDA staff members. Sponsors of new pharmaceuticals are unaccustomed to having the government, and not the marketplace, establish priorities for new product development. Similarly, FDA staff who have grown accustomed to their gatekeeper role must now confront a switch in priorities that will require them to stimulate rather than resist. This switch is not an easy one for career civil servants to make.

#### *D. Risks of Faster Drug Approval*

There are several negative consequences of the FDA forfeiting the posture of neutral gatekeeper. First, because the FDA's resources are finite, expediting a few drugs through an accelerated system will hold back the remaining products. Delays caused by the favored products' jump to the head of the queue will distort FDA statistics on product approval, which are monitored as part of the FDA user fees legislation.<sup>84</sup> Second, as noted above, the expedited approval of certain drugs for "defensive" purposes may create a slippery slope whereby more and more drugs are approved without going through the usual testing processes. For example, a policy decision not to wait for human clinical studies on a smallpox vaccine was extraordinary when it was taken in 2002.<sup>85</sup> But, once undertaken, policy decisions to waive or eliminate the long and complex human clinical studies phase might be requested by other sponsors of drugs in many, and probably in more benign, circumstances. Although the FDA is likely to resist such pressures, a precedent has been set.

The FDA did not apply conventional risk and benefit analyses to the military defense drugs; unlike the conventional product approval measures, the military drugs are to be used for extraordinary threats not encountered with the natural progression of conventional and commonplace human illnesses.

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84. 21 U.S.C. § 379g (2)(A)(ii) (the FDA collects specialized fees from drug sponsor companies and uses that money to offset federal budget weaknesses by hiring more experts to review drug applications).

85. See Michele Meadows, *An Update on Smallpox*, 37 FDA CONSUMER 2, 28 (March/April 2003), available at [http://www.fda.gov/fdac/features/2003/203\\_smallpox.html](http://www.fda.gov/fdac/features/2003/203_smallpox.html); see also FDA website, at [www.fda.gov/cber/summaries/120600bio05MM.htm](http://www.fda.gov/cber/summaries/120600bio05MM.htm).

While the future emergency mechanisms that could be adopted to hasten drug and vaccine reviews have some merit, they all share a common problem: the failure to test the drugs on humans before their approval means that their potential adverse effects on humans may be unknown. Adverse effects that did not appear in testing may appear in more wide-scale use. Waiving certain testing requirements means that those who receive the rapidly-cleared drug or vaccine, while benefiting from its availability, will become part of a much larger experimental population. Thus, soldiers who receive an emergency vaccine that is not fully licensed are part of the experimental data on which the vaccine later may be approved or rejected.

## IX. THE ROLE OF THE COURTS

All of the above concerns may lead to legal challenges to the FDA's new procedures. However, despite the fact that regulatory agencies are usually tightly bound within the jurisdiction provided by their enabling statute, the Supreme Court has rarely questioned the FDA's authority in decisions regarding new drugs. In 1973, the Supreme Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.* essentially gave the FDA authority to determine the scope of its own jurisdiction by enabling it to construe the term "new drug."<sup>86</sup> The meaning of this power is that the FDA can construe a particular drug to require detailed approval while another drug would not require as much scrutiny; it can deny "fast track" status to one drug and grant it to another.<sup>87</sup> Flexibility in what to review, and how much data to require, allows the FDA to grant the rapid approval for marketing to those products that could assist in counter-terrorism.

When the *Hynson* Court declined to second-guess the FDA's interpretation of whether a product was or was not a "new drug,"<sup>88</sup> the Court signaled that great deference generally should be accorded to FDA decisions. Thus, in the subsequent decision of *United States v. Rutherford*, the Court deferred to the FDA's authority to maintain tight control of drug entry into the marketplace, al-

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86. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973).

87. See 21 U.S.C. § 356(a)(3) (granting the secretary authority to determine whether a drug meets fast track criteria).

88. *Hynson*, 412 U.S. at 627 ("[The FDA's] jurisdiction to determine whether it has jurisdiction is as essential to its effective operation as is a court's like power.").

lowing the agency to insist on risk and benefit evidence even where the patient seeking access to the drug was so close to dying that any risk associated with a particular drug might be deemed by the patient to be a worthwhile bargain.<sup>89</sup> In *Heckler v. Chaney*, the Court refused to require the FDA to take action to prevent a drug from being used for lethal injection even though it had only been approved for medical purposes.<sup>90</sup>

In sum, the circumstances of FDA drug approval are largely discretionary choices for FDA officials. Once decisions are made, they are unlikely to be reversed by judicial review. If the FDA approves a drug sponsor's request, it is unlikely that an outsider would be able to convince a federal court to halt approval of the drug.<sup>91</sup> Thus, if the accelerated approval of a defensive drug either as an emergency exception<sup>92</sup> or as a fast-track item<sup>93</sup> were challenged in the courts, the FDA would be likely to benefit from this pattern of deference.

A side note must be appended to the general discussion concerning judicial deference to FDA approval decisions. Although the FDA would win virtually any challenge to its approval of a drug sponsor's application, the FDA does not win all of its cases. Recently, two lines of cases in particular have been causing troubles for the FDA. The first concerns generic drug approval processes and is an economic quarrel whose consequences may indirectly affect future investment in new drug research.<sup>94</sup> This dispute over generics relates to non-innovative products and so has no role in the homeland security issues (other than as a distraction). The other line of cases concerns FDA controls on labeling claims for drugs, an area in which libertarian ideas and corporate money are combining to assail the FDA's ability to require approval for claims of product benefits.<sup>95</sup> This reflects a deregulatory political climate that could produce an erosion of the FDA's gatekeeper authority. If the libertarian line of reasoning were more widely adopted, the result might deadlock the FDA's ability to deal with fraudulent

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89. See *United States v. Rutherford*, 442 U.S. 544 (1979).

90. See *Heckler v. Chaney*, 470 U.S. 821, 838 (1985).

91. Except in the case of generic copies of approved drugs, a topic beyond the scope of this paper.

92. See Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 4.

93. See 21 U.S.C. § 356 (2000).

94. See generally James T. O'Reilly, *Prescription Pricing and Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patient Exclusivity*, 29 N. KY. L. REV. 413 (2002).

95. See Marc Kaufman, *FDA Eases Rules on Touting Food as Healthful*, WASH. POST, July 11, 2003, at A1, A7.

claims concerning protective effects of a “new anti-anthrax mask” or “radiation protection bracelet.”

*A. Litigation Challenging the FDA’s Expanded Powers*

Some critics who object to the FDA’s fast-track approval of products might sue the FDA, challenging its ability to waive testing requirements in order to have an antidote or vaccine readily accessible. But congressional adoption of the “fast track” in 1997<sup>96</sup> and probable adoption of emergency waiver authority in 2003 legislative proposals,<sup>97</sup> combined with the vast discretion accorded the FDA by the Supreme Court in *Hynson*,<sup>98</sup> *Rutherford*,<sup>99</sup> and *Chaney*,<sup>100</sup> suggest that such suits would be dismissed easily. The objector could assert that the FDA should have done more to require pre-market testing of the products, but a cause of action for inadequate regulatory oversight is hard to sustain in the absence of a statutory mandate. Federal drug user fee laws have a general benefit but do not give rise to a private enforcement right, and the overwhelming case law holds that there is no private right of action to enforce the Food, Drug & Cosmetic Act against an alleged violator of FDA requirements.<sup>101</sup> This was underscored by a 2001 medical device case in which the Supreme Court refused to allow state tort actions asserting that private companies had committed fraud against the FDA through misrepresentations in their product approval applications.<sup>102</sup>

*B. Tort Litigation*

A person injured by a vaccine that was rushed through the FDA process might sue the FDA,<sup>103</sup> asserting claims that are a variation on the Federal Torts Claims Act arguments that were successful in *Berkovitz v. United States*.<sup>104</sup> However, that case allowed a plaintiff to recover damages only because the FDA had locked itself into follow-

96. See Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296, § 112 (1997).

97. See Project BioShield Act of 2003, H.R. 2122, 108th Cong. § 4 (2003).

98. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

99. *United States v. Rutherford*, 442 U.S. 544 (1979).

100. *Heckler v. Chaney*, 470 U.S. 821, 838 (1985) (holding that the FDA’s decision not to take enforcement actions regarding the use of drugs for capital punishment was unreviewable).

101. See 21 U.S.C.A. § 379h(b) (West Supp. 2003).

102. See *Buckman Co. v. Pl.’s*, Legal Comm., 531 U.S. 341 (2001).

103. See 28 U.S.C. § 2680(a) (2000) (stating that governmental functions involving discretion are not subject to liability suits).

104. *Berkovitz v. United States*, 486 U.S. 531 (1988).



ing certain pre-approval steps for a vaccine; the tort action was premised on the FDA's violation of its own rules.<sup>105</sup> No comparable mandate exists in current FDA drug approval, where so much of the product approval process is handled through non-binding Guidance Documents that allow the FDA flexibility.<sup>106</sup>

Tort recovery by injured individuals is also an *ex ante* method of dealing with risk, and does not provide systematic incentives for the FDA to alter its systems. If a special health concern existed about a product that had received accelerated approval, the FDA could perhaps recommend that a vaccine or drug used in homeland defense should have the benefit of statutory indemnification for any losses, paid for by the federal government.<sup>107</sup> In fact, recent legislation offers potential immunity from tort liability for specially recognized anti-terrorist products.<sup>108</sup>

Finally, a challenger would have a difficult time demonstrating legal standing to object to the FDA's discretionary omission of a particular test, since the agency is not required to perform specific types of testing.<sup>109</sup> Several attempts to establish legal standing have been unsuccessful.<sup>110</sup>

Because of the difficulty of challenging FDA actions in court, any criticisms or attempts to change the FDA's new policies likely would be aimed at Congress. This route would be just as challenging for critics, as the current Congress passed the legislation and supports the effort against terrorism. Presumably the majority party

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105. FDA rules require that certain test data be submitted to the FDA prior to the licensing of a vaccine. The vaccine at issue in *Berkovitz* had not been subjected to the required test. Thus, after the vaccine proved to be deficient, the government's claim of discretion was rejected because they had not followed a specific statutory and regulatory directive. *See id.* at 542–44.

106. Guidance Documents are not regulations and do not bind the FDA or the drug sponsor. *See* Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 7,321 (Feb. 14, 2000) (to be codified at 21 C.F.R. pt. 10).

107. *See* Exec. Order No. 13,232, 66 Fed. Reg. 53941 (Oct. 24, 2001) (applying 50 U.S.C. §§ 1431–35).

108. *See* 6 U.S.C. § 442 (2004).

109. The FDA sets no particular testing regimen. *See* 21 U.S.C. § 355(d) (2000) (allowing FDA approval based on “data from one adequate and well-controlled clinical investigation and confirmatory evidence . . . sufficient to establish effectiveness . . . .”); *Berkovitz v. United States*, 486 U.S. 531, 545 (1988) (where the government asserted “that the determination [of a proposed drug’s compliance with safety standards] incorporates considerable ‘policy judgment.’”).

110. *See, e.g., Nat’l Council for Improved Health v. Shalala*, 122 F.3d 878, 883 (10th Cir. 1997) (holding that the council lacked standing to challenge the constitutionality of health claim regulations); *Takhar v. Kessler*, 76 F.3d 995, 1000 (9th Cir. 1996) (finding that plaintiff veterinarian lacked standing to challenge FDA Compliance Policy Guidelines).

would not allow critics of the administration to pass legislation forbidding the FDA to grant waivers where they are deemed necessary for national security.

## X. CONCLUSION

Change generally comes slowly in large, complex bureaucracies. Congressional consensus to impose change generally must develop over time, as competing economic interests play out their rivalries in congressional subcommittees and in legislative reports. However, the sudden, disastrous series of airplane and anthrax attacks in 2001 rapidly caused Congress and the FDA to modify their views toward risk/benefit considerations in the development and approval of new drugs. "Benefit" became more attuned to collective defense than to individual health determinations. One result of this shift will be the hastening of approvals for drug, device and vaccine products that might aid in defending the public against bioterrorism. Given the finite number of approval scientists within the FDA, however, each product that jumps to the head of the line will inevitably retard the progress of other drug products that could have been approved for other diseases.

Ultimately, the approval of medical products involves public choices of risk levels acceptable to society. In the face of terrorism, the acceptable risk levels have been impacted by the need to protect our soldiers and civilians against the possibility of a bio-terrorist attack. The FDA changes that have occurred since 9/11 illustrate how profoundly a crisis can alter the behavioral patterns of a bureaucracy.