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Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs

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TRIAGE IN THE NATION'S MEDICINE CABINET: THE PUZZLING SCARCITY OF VACCINES AND OTHER DRUGS

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ABSTRACT

For a variety of reasons, vaccines and other critical pharmaceutical products have become increasingly scarce in the last few years, and persistent shortages involving dozens of essential drugs may imperil the public health. Pressures emanating from regulatory agencies, the courts, and insurers have conspired to make some lines of the pharmaceutical business less than attractive. Although concerns about unpredictable tort liability received most of the blame in the past, two other factors may help to account for the latest round of drug shortages: stringent federal control of manufacturing facilities and aggressive cost-containment efforts that further erode profit margins. Whatever the cause, scarce supplies necessitate efforts at rationing that pose their own difficulties for health care providers. Policymakers could avoid putting physicians to such tough choices in treating patients by focusing on ways to ensure the production of adequate quantities of these highly cost-effective medical technologies. Some commentators have called for greater public sector involvement, but this Article concludes that, in addition to

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bolstering its emergency stockpiles, the federal government instead needs to take steps designed to encourage private manufacturers to continue supplying critical pharmaceuticals. To this end, the government should adopt more flexible regulations governing manufacturing facilities, provide companies with greater protection from the vagaries of tort liability, and avoid pursuing excessive cost-control strategies. Otherwise, patients may continue to lose access to important therapeutic products.

I. INTRODUCTION

The tragic events of September 11, 2001, and the still mysterious mailing of weaponized anthrax spores one month later, awakened this country to the risks of bioterrorism and brought attention to what has become a growing problem: shortages of antibiotics, vaccines, and other medical technologies.¹ Although this situation poses concerns about our readiness in the event of a bioterrorist attack, it has more mundane and potentially serious public health implications. In addition, while it should come as no great surprise that we have inadequate supplies of treatments for smallpox and anthrax, persistent shortages of common childhood vaccines and other critical pharmaceuticals seem inexplicable.

A recent front page story in the *Washington Post* highlighted the problem: “Shots designed to protect children against eight of [eleven] vaccine-preventable infections have been intermittently in short supply everywhere in the United States since last summer. Some will remain hard to get for at least another six months.”² The affected products include a couple of long-used combination vaccines—one to protect against diphtheria, tetanus, and pertussis (DTP), and another one to protect against measles, mumps, and rubella (MMR)—along with two newer vaccines—one to protect against pneumonia, and another one to protect against varicella (chickenpox).³ Although the Centers for Disease Control and Prevention (CDC) have taken interim steps to respond to these temporary supply problems, “physicians are viewing the shortages as an

1. See Rick Weiss, *Bioterrorism: An Even More Devastating Threat*, WASH. POST, Sept. 17, 2001, at A24; see also Raymond J. Baxter et al., *Is the U.S. Public Health System Ready for Bioterrorism? An Assessment of the U.S. Public Health Infrastructure and its Capacity for Infectious Disease Surveillance*, 2 YALE J. HEALTH POL’Y L. & ETHICS 1, 18 (2001) (“While bolstering the nation’s supply of vaccines and pharmaceuticals is important, it is even more critical to shore up the public health infrastructure . . .”).

2. David Brown, *Severe Vaccine Shortages Termed “Unprecedented,”* WASH. POST, Apr. 20, 2002, at A1.

3. See *id.* The DTP vaccine sometimes is designated as “DTaP” to reflect a recent shift to an acellular version of the pertussis component, while the combined tetanus and diphtheria toxoids are designated as “Td” when supplied without the pertussis vaccine component (for instance as a booster shot administered to adults). The shortages eased a few months later. See Liz F. Kay, *Vaccine Shortage Over, CDC Says*, L.A. TIMES, July 12, 2002, at A22. But see Robert Pear, *States Ration Low Supplies of 5 Vaccines for Children*, N.Y. TIMES, Sept. 17, 2002, at A20.

extremely ominous development. Many find it appalling that this could happen in a country that spends more on health care per capita than any other on Earth."⁴ Dozens of other essential pharmaceutical products also have run low in the last couple of years, including the anticoagulant heparin, the antiviral drug ganciclovir, several antiemetics, diuretics, antiepileptic agents, injectable corticosteroids, and neuromuscular blocking agents.⁵

This sort of thing has happened before. In the mid-1980s, manufacturers of pediatric vaccines dramatically increased the prices of their products or left the market altogether. As the California Supreme Court recounted fifteen years ago:

There are only two manufacturers of the [DTP] vaccine remaining in the market, and the cost of each dose rose a hundredfold from 11 cents in 1982 to \$11.40 in 1986, \$8 of which was for an insurance reserve. The price increase roughly paralleled an increase in the number of lawsuits from one in 1978 to 219 in 1985.⁶

Although concerns about unpredictable tort liability provided the primary impetus behind these developments, other factors contributed to the fear of shortages at the time.⁷ In 1986, responding to these developments, Congress

4. Brown, *supra* note 2, at A1 ("‘This is unprecedented,’ said Walter A. Orenstein, a physician who directs the [CDC’s] National Immunization Program . . . ‘I have never seen anything like the supply problems with this many vaccines in the 24 years I’ve worked in immunization.’"); see also Robert Pear, *Shortage of Juvenile Vaccines Worries Doctors and Officials*, N.Y. TIMES, Dec. 2, 2001, at A38.

5. See Am. Soc’y of Health-Sys. Pharmacists, *Drug Product Shortages Management Resource Center*, at <http://www.ashp.org/shortage> (last visited May 23, 2002); Donna Young, *Drug Shortages Frustrate Health Care Providers*, 59 AM. J. HEALTH-SYS. PHARMACY 698, 698 (2002) ("Three months into 2002, FDA had identified 8 ‘medically necessary’ drug products, not including vaccines, as being in short supply and 11 other products . . . as having limited distribution."); Victoria Stagg Elliott, *Changes Sought to Combat Drug, Vaccine Shortages*, AM. MED. NEWS, Dec. 24/31, 2001, at 1 (describing shortages of several critical pharmaceuticals); Sabin Russell, *Critical Vaccines, Medicine Run Low*, S.F. CHRON., Feb. 10, 2002, at A1 ("There is a growing uneasiness about the volume and frequency of drug supply shortfalls."). In the mid-1990s, supplies of fertility drugs ran short. See Tamar Nordenberg, *Drug Supply Restored*, FDA CONSUMER, Jan.-Feb. 1997, http://www.fda.gov/fdac/features/1997/197_fert.html#supply (last visited Nov. 15, 2002).

6. Brown v. Superior Court, 751 P.2d 470, 479 (Cal. 1988) ("One producer of [the DTP] vaccine withdrew from the market, giving as its reason extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance." (internal quotation marks and citations omitted)); see also Gina Kolata, *Litigation Causes Huge Price Increases in Childhood Vaccines*, 232 SCIENCE 1339 (1986); Marjorie Sun, *The Vexing Problems of Vaccine Compensation*, 227 SCIENCE 1012, 1012 (1985) (reporting spot shortages); Philip M. Boffey, *Vaccine Liability Threatens Supplies*, N.Y. TIMES, June 26, 1984, at C1; Stephen Engelberg, *Maker of Vaccine Quits the Market*, N.Y. TIMES, Dec. 12, 1984, at A21.

7. See HOUSE COMMITTEE ON ENERGY & COMMERCE, 99th Cong., CHILDHOOD IMMUNIZATIONS 68-70, 85-87 (Comm. Print 1986) (focusing on liability concerns, but also noting that one manufacturer had experienced production problems); INST. OF MED., VACCINE SUPPLY AND INNOVATION 11, 85, 119 (1985); Georges Peter, Editorial, *Vaccine Crisis: An*

passed the National Childhood Vaccine Injury Act.⁸ The statute helped to stabilize the pediatric vaccine market, but supply problems persist, and experts in the field continue to debate different mechanisms for reducing the threat of future shortages.⁹

Fortunately, past supply interruptions have involved vaccines produced by more than a single company,¹⁰ but “several vaccines now have only one licensed producer.”¹¹ With the shrinking number of companies manufacturing pediatric vaccines, supplies have become more vulnerable:

Given the increased concentration of vaccine producers licensed by the United States, the complexity of the manufacturing processes, and the time-consuming procedures for licensing new production facilities, a serious incident, such as a fire, at a single production facility could disrupt U.S. supplies of some vaccines for months if not years. Any such disruption could rapidly affect public health¹²

In the fall of 2001, something like that happened—the only manufacturer of the MMR and varicella vaccines shut down its sole production facility for a couple of months for scheduled maintenance and upgrades, resulting in spot shortages of these two products.¹³ Earlier that year, one of the last remaining domestic

Emerging Societal Problem, 151 J. INFECTIOUS DISEASES 981 (1985).

8. Pub. L. No. 99-660, 100 Stat. 3743, 3755-84 (1986) (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2000)); see also *infra* notes 91-94 and accompanying text.

9. See David C. Mowery & Violaine Mitchell, *Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives*, 20 J. HEALTH POL. POL'Y & L. 973 (1995).

10. See *id.* at 997 (“Interruptions in the supply of U.S. vaccines have been fairly common during the past decade The effect of these interruptions on U.S. vaccine availability has been limited, however, partly because the most frequent supply interruptions have occurred in a product [DTP] for which there are five licensed U.S. producers.”); see also *id.* at 984 (“Although several (two public and two private sector) domestic sources supply the combined [DTP] vaccine, several recent interruptions occurred in the DTP vaccine supply.”).

11. *Id.* at 980; see also *id.* at 984 (“Both the oral polio vaccine (OPV) and the combination [MMR] vaccine have only one U.S.-licensed supplier”); *id.* at 997 (“[T]he trends toward increased producer concentration increase the likelihood that the number of single-source vaccines on the recommended childhood immunization schedule will increase.”); Brown, *supra* note 2, at A1 (“[O]nly a handful of U.S. companies still make vaccines. A generation ago, there were about 20 producers There’s been nothing short of a stampede away from the business.”).

12. Mowery & Mitchell, *supra* note 9, at 975; see also *id.* at 988 (“Although U.S. single-source vaccine suppliers have avoided production interruptions, there is little reason to discount this possibility in the future. Policies to encourage the development of additional sources of supply therefore merit consideration.”); *id.* at 997 (“If interruptions in the production of OPV or MMR, which are produced by a single U.S. supplier, were comparably frequent [to past DTP supply interruptions], the public health risks would be substantially greater.”); Jonathan Bor, *Shortages Hamper Children’s Vaccination*, BALT. SUN, Mar. 23, 2002, at 1A (“[P]roduction problems at any one factory can cripple the nation’s supply.”).

13. See Brown, *supra* note 2, at A1 (describing repairs and upgrades undertaken at Merck’s vaccine plant).

suppliers of the DTP vaccine announced that it would cease production rather than invest in upgrades to its production facility,¹⁴ leaving only a pair of manufacturers headquartered overseas to supply the market and scrambling to meet the additional demand.¹⁵

Usually, short supplies of drugs do not increase the risks to patient health because effective therapeutic substitutes remain available, but occasionally these shortfalls do endanger patients.¹⁶ Vaccine shortages can interfere with mass immunization efforts,¹⁷ and, with time, they would threaten to unravel some of the remarkable gains made against infectious diseases during the last half century.¹⁸ Even when substitute vaccines exist, they may represent older formulations that offer somewhat reduced safety, efficacy, and/or convenience.¹⁹ Similarly, patients who have come to depend on a particular medication to treat a chronic health condition may suffer if unable to secure

14. See *id.* ("A competitor is working on a vaccine that would combine DTaP with polio and hepatitis B vaccines, potentially making Wyeth's product obsolete. Spending money on a plant to keep making the old vaccine was simply viewed as not worth it.").

15. See *id.* ("The current troubles began with the announcement by the pharmaceutical company Wyeth Lederle in January 2001 that it would stop making vaccines containing tetanus and diphtheria components. . . . Only one company, Aventis Pasteur, [now] makes Td, and only two, Aventis and Glaxo SmithKline, make DTaP. Although each is boosting production, they've been unable to meet demand."). The same thing just happened with vaccines for influenza pneumonia. See Scott Hensley, *Wyeth Stops Making Flu Vaccine; Goal Now Is to Develop Inhalant*, WALL ST. J., Nov. 20, 2002, at D2.

16. See Melody Petersen, *Drug Shortages Become a Worry at Hospitals Around the Country*, N.Y. TIMES, Jan. 3, 2001, at A1.

17. See Mowery & Mitchell, *supra* note 9, at 985 ("A 'brief' supply interruption, that is one lasting fewer than six months, need not immediately increase the burden of vaccine-preventable diseases, although this is a concern in urban areas. . . . Nevertheless, catching up with the cohorts that missed key immunizations would be difficult and costly."); see also CDC, *General Recommendations on Immunization*, 51 MORBIDITY & MORTALITY WKLY. REP. No. RR-2 (2002); CDC, *National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19-35 Months—United States, 2000*, 50 MORBIDITY & MORTALITY WKLY. REP. 637 (2001).

18. See H.R. REP. No. 99-908, at 7 (1986) ("[T]he withdrawal of even a single vaccine manufacturer would represent the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases."), reprinted in 1986 U.S.C.C.A.N. 6344, 6348; Heikki Peltola, *What Would Happen If We Stopped Vaccination?*, 356 LANCET S22 (2000) (estimating that the United States would experience more than 1,000 deaths annually if vaccinations against measles and Hib ceased); see also E.J. Gangarosa et al., *Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story*, 351 LANCET 356, 360 (1998); Julie Appleby & Anita Manning, *Stockpiles Tapped as Supplies of Vaccines Run Short*, USA TODAY, Feb. 18, 2002, at 1B (referring to "an outbreak in 1989-91 that led to 55,000 measles cases, 11,000 hospitalizations and 123 deaths"); Jane E. Brody, *For the Vaccine-Wary, a Lesson in History*, N.Y. TIMES, Oct. 3, 2000, at F8 (describing pertussis epidemics in England and Japan, which resulted in dozens of deaths, after immunization rates plummeted in the mid-1970s).

19. See Mowery & Mitchell, *supra* note 9, at 984 ("[A]n interruption in the U.S. supply of either MMR or OPV could force changes in the immunization schedule, perhaps including a shift to the inactivated polio vaccine or, with MMR, a return to use of single antigens.").

supplies.²⁰ In addition, alternative suppliers may introduce separate safety concerns. For instance, when the manufacturer of betamethasone experienced quality control problems and had to halt production temporarily, physicians and hospitals in one region of the country turned to a local pharmacy with requests to compound this injectable corticosteroid from available bulk materials, but the product became contaminated and resulted in two deaths and dozens of injuries among patients.²¹

What accounts for this state of affairs, and how, if at all, should the government respond? Part II of this Article considers some of the causes of recent shortages—including stringent federal regulation of manufacturing facilities and cost-containment efforts that create a downward pressure on prices—as well as some of the consequences for the public health. Whatever the explanation for scarce supplies, they place patient welfare at risk and present difficult rationing choices for health care providers. Part III of this Article turns to some of the possible remedies—including enhanced protection from tort liability, improved government stockpiles, and compulsory licensing or public sector manufacturing—before concluding that policymakers need to focus on reducing rather than further increasing the economic disincentives against supplying needed vaccines and other drugs.

II. DIAGNOSING THE PROBLEM

For a variety of reasons, shortages of pharmaceuticals have become increasingly common.²² In some cases, a shortage results because of problems with the supply of raw materials or in the manufacture of the finished drug product. For example, the Food and Drug Administration (FDA) shut down the BioPort Corporation, the sole manufacturer of an experimental anthrax vaccine, for several years because of quality control problems.²³ Recently, a nationwide

20. See Shari Roan, *Longtime Drug's New Troubles: Synthroid, Taken by 8 Million People with Thyroid Problems, Is Under FDA Scrutiny*, L.A. TIMES, July 23, 2001, at S1; see also Chris Adams, *FDA Weighs Requests to Return Lotronex to Consumer Market*, WALL ST. J., Apr. 19, 2001, at B10; Denise Grady, *FDA Pulls a Drug, and Patients Despair*, N.Y. TIMES, Jan. 30, 2001, at F1 (describing the withdrawal of the irritable bowel syndrome drug Lotronex); Marc Kaufman, *Panel Suggests Irritable-Bowel Drug Be Sold Again*, WASH. POST, Apr. 24, 2002, at A7.

21. See Fred Gebhart, *Fatal Meningitis Linked to Compounding by Calif. Pharmacy*, DRUG TOPICS, July 2, 2001, at 32.

22. See U.S. GEN. ACCOUNTING OFFICE, No. GAO-02-987, CHILDHOOD VACCINES: ENSURING AN ADEQUATE SUPPLY POSES CONTINUING CHALLENGES 14-19 (2002) [hereinafter GAO]; Brown, *supra* note 2, at A1 ("There's no single cause behind the shortages. Instead, they've arisen from a combination of business decisions, bad luck and greater than expected demand for the vaccines."); Charles Ornstein & Charles Piller, *U.S. Plagued by Chronic Shortage of Key Vaccines*, L.A. TIMES, Oct. 19, 2001, at A1.

23. See Keith Bradsher, *The Only U.S. Laboratory for the Anthrax Vaccine Says Production Will Be Delayed*, N.Y. TIMES, Nov. 12, 2001, at B7; Guy Gugliotta, *No Decision on Anthrax Vaccine Program: Pentagon Weighs Military, Civilian Needs Against Limited Supply*, WASH. POST, May 20, 2002, at A2; see also Thomas V. Inglesby et al., *Anthrax as a Biological*

recall triggered by evidence of product contamination created a serious shortage of anti-venin used to treat snakebite victims.²⁴ The FDA should, of course, protect patients from risks associated with defective therapeutic products, but, if the regulatory infractions do not pose an immediate health threat, then it also must remember the consequences that may flow from decisions to interrupt manufacturing by sole suppliers of critical pharmaceuticals.

Apart from manufacturing problems, drug shortages may arise from deliberate decisions by pharmaceutical companies to cease or drastically reduce production of a product because profits have declined. Compounds that have lost their patent protection typically command far lower prices, and manufacturers often will prefer to focus on a newer product designed to replace its predecessor and generate more substantial revenues. In 1997, in an effort to minimize the short-term supply disruptions caused by corporate decisions to cease marketing critical pharmaceuticals, Congress mandated that sole suppliers of such products notify the FDA at least six months ahead of time so that the agency can alert physician and patient organizations.²⁵ In implementing this provision, the FDA has devoted a section of its official website to the subject, tracking problems with the supplies of particular drugs and offering recommendations to the health care community.²⁶

This Part elaborates on some of the causes of inadequate supplies of critical pharmaceutical products as well as the consequences of such shortages. Although tort liability received most of the blame in the past, two other factors may help to account for the latest round of shortages: stringent federal control of manufacturing facilities and cost-containment efforts that erode profit margins. Whatever the cause, scarce supplies necessitate efforts at rationing that pose their own difficulties for health care providers and their patients. Instead of making tough microallocational judgments involving these highly

Weapon, 2002: *Updated Recommendations for Management*, 287 JAMA 2236, 2244 (2002).

24. See Charles Rabin, *Low Supplies of Antivenin Heighten Snakebite Danger*, MIAMI HERALD, Apr. 28, 2002, at 3B. A few years earlier, concerns about viral contamination of raw materials coupled with unanticipated demand created shortages of intravenous immunoglobulin. See CDC, *Availability of Immune Globulin Intravenous for Treatment of Immune Deficient Patients—United States, 1997-1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 159 (1999).

25. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 131, 111 Stat. 2332 (codified at 21 U.S.C. § 356c (2000)); 65 Fed. Reg. 66,665 (2000) (proposed Nov. 7, 2000) (to be codified at 21 C.F.R. §§ 314.81(b)(3)(iii), 314.91); see also *id.* at 66,669 (estimating that this would happen only once a year on average).

26. See Ctr. for Drug Evaluation & Research, FDA, *Drug Shortages*, at <http://www.fda.gov/cder/drug/shortages> (last visited May 22, 2002). The Centers for Disease Control and Prevention also may disseminate such information. See, e.g., CDC, *Decreased Availability of Pneumococcal Conjugate Vaccine*, 50 MORBIDITY & MORTALITY WKLY. REP. 783 (2001); CDC, *Shortage of Spectinomycin—United States*, 50 MORBIDITY & MORTALITY WKLY. REP. 470 (2001); see also CDC, *Potential Shortage of Supplemental Test Kits for Detecting HIV-1 Antibodies*, 51 MORBIDITY & MORTALITY WKLY. REP. 395 (2002).

cost-effective medical technologies, we need to find ways of avoiding such artificial shortages in the first place.

A. Backdoor “Drug Lag”

In 1962, Congress amended the Federal Food, Drug and Cosmetic Act to strengthen the premarket approval requirements applicable to new drugs, forcing sponsors to provide proof of effectiveness as well as safety.²⁷ Over the years, critics have blamed the FDA’s lengthy and demanding approval process for creating a “drug lag” that delayed pharmaceutical products already approved in Europe and elsewhere from reaching the United States market.²⁸ Commentators have paid far less attention to the other changes wrought by the 1962 amendments, such as the requirement that sponsors comply with good manufacturing practices (GMPs).²⁹ Just as rigorous premarket review has both positive and negative effects, the careful control of manufacturing processes is not an unalloyed good.

In recent years, the agency has improved the speed with which it approves new drugs.³⁰ In the process, however, it has diverted attention from other regulatory tasks. For instance, as it focuses increasingly on reviewing applications for product approval, the FDA may invest fewer resources in its

27. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. § 355 (2000)); see also LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 198-219 (2002) (discussing the FDA’s new drug approval requirements).

28. See U.S. GEN. ACCOUNTING OFFICE, No. HRD-80-64, FDA DRUG APPROVAL—A LENGTHY PROCESS THAT DELAYS THE AVAILABILITY OF IMPORTANT NEW DRUGS (1980); HENRY G. GRABOWSKI & JOHN M. VERNON, THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS (1983); Robert W. Hahn & John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 YALE J. ON REG. 233, 276-77 (1991); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1753-55, 1788-89 (1996); Barry S. Roberts & David Z. Bodenheimer, *The Drug Amendments of 1962: The Anatomy of a Regulatory Failure*, 1982 ARIZ. ST. L.J. 581.

29. See 21 U.S.C. § 351(a)(2)(B) (2000); 21 C.F.R. pts. 210-211 (2002); Nat’l Ass’n of Pharm. Mfrs. v. FDA, 637 F.2d 877 (2d Cir. 1981) (upholding the agency’s authority to adopt binding GMP rules); *United States v. Undetermined Quantities . . . Proplast*, 800 F. Supp. 499, 502 (S.D. Tex. 1992); Nat’l Ass’n of Pharm. Mfrs. v. HHS, 586 F. Supp. 740, 748-63 (S.D.N.Y. 1984) (rejecting numerous substantive and procedural challenges to the FDA’s GMP regulations).

30. See U.S. GEN. ACCOUNTING OFFICE, No. PEMD-96-1, FDA DRUG APPROVAL: REVIEW TIME HAS DECREASED IN RECENT YEARS (1995); David A. Kessler et al., *Approval of New Drugs in the United States: Comparison with the United Kingdom, Germany, and Japan*, 276 JAMA 1826, 1829-31 (1996); Deborah G. Parver, Comment, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 ADMIN. L. REV. 1249, 1266 (1999); Chris Adams & Scott Hensley, *Drug Makers Want FDA to Move Quicker*, WALL ST. J., Jan. 29, 2002, at B12.

periodic inspection activities.³¹ This may result in greater—though perhaps largely undetected—industry noncompliance with GMP requirements.³² When problems eventually come to light, the agency may put a temporary halt to further sales of a manufacturer's drugs.³³ In addition, insufficient resources available for conducting inspections may result in delays when sponsors apply for supplemental new drug approval in order to manufacture a previously approved product in a new facility.³⁴

Manufacturers of vaccines must satisfy not only new drug approval requirements but also a separate set of controls that govern biologics,³⁵ though recent amendments to the regulations have reduced some of these burdensome requirements.³⁶ Vaccines require more complex manufacturing facilities and

31. See Margaret Gilhooly, *The Administrative Conference and the Progress of Food and Drug Reform*, 30 ARIZ. ST. L.J. 129, 141 (1998); Bruce N. Kuhlik, *Industry Funding of Improvements in the FDA's New Drug Approval Process: The Prescription Drug User Fee Act of 1992*, 47 FOOD & DRUG L.J. 483, 500 & n.96 (1992) (explaining that user fees cannot be utilized by the FDA to finance compliance monitoring activities); Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 462-66, 494-95 (2000). The FDA has decided to accept (on a reciprocal basis) inspections of overseas drug manufacturing facilities conducted by its regulatory counterparts among members of the European Union. See 21 C.F.R. pt. 26(A) (2002); see also *id.* § 26.4(b) (excluding biologics); GAO, *supra* note 22, at 23 (suggesting flexibility in case of vaccine shortages).

32. See GAO, *supra* note 22, at 15-16; Mary K. Olson, *Agency Rulemaking, Political Influences, Regulation, and Industry Compliance*, 15 J.L. ECON. & ORG. 573, 593 (1999); Mary Olson, *Substitution in Regulatory Agencies: FDA Enforcement Alternatives*, 12 J.L. ECON. & ORG. 376, 378-79, 383-84, 387 (1996).

33. See *John D. Copanos & Sons, Inc. v. FDA*, 854 F.2d 510, 514-18, 522-26 (D.C. Cir. 1988); *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 464, 487-91 (D.N.J. 1993).

34. See *infra* note 42; see also 21 C.F.R. § 314.70(b)(2)(vi) (2002). When the agency cites a company for GMP violations, it may prompt compliance by delaying final approval of pending applications for any new drugs slated for manufacturing at the allegedly substandard facilities. See David Barr, *The Changing Approval Process: Preapproval Inspection*, 47 FOOD & DRUG L.J. 359, 361 (1992); Merrill, *supra* note 28, at 1787; Melody Petersen, *Faults Found at a Schering Plant*, N.Y. TIMES, Mar. 2, 2001, at C3.

35. See 42 U.S.C. § 262(a) (2000); Ctr. for Biologics Evaluation & Research, FDA, *Vaccine Product Approval Process*, at <http://www.fda.gov/cber/vaccines/vacappr.htm> (last visited May 28, 2002); William David Hardin, *Poliomyelitis Vaccine—History, Regulations and Recommendations*, 40 FOOD DRUG COSM. L.J. 145, 151-55 (1985); Mowery & Mitchell, *supra* note 9, at 986 (“FDA regulation of vaccines is considerably more stringent than regulation of other pharmaceuticals, because it places greater demands on licensing production facilities and monitoring individual batches of vaccines.”). The agency had issued monographs setting out standards for vaccines, see 21 C.F.R. pts. 620, 630 (1995), but it subsequently decided to repeal these as obsolete, see 61 Fed. Reg. 40,153 (Aug. 1, 1996). It continues to review vaccines licensed by the NIH before the transfer of this responsibility to the FDA in 1972. See 65 Fed. Reg. 31,003 (May 15, 2000).

36. See 64 Fed. Reg. 56,441, 56,441-42, 56,450-52 (Oct. 20, 1999) (codified in scattered sections of 21 C.F.R. pt. 601) (amending the regulations to replace separate applications for product and establishment licensing with a single biologics license application (BLA)); 61 Fed. Reg. 24,227, 24,232-33 (May 14, 1996) (amending the regulations to exempt certain well-characterized biotechnology products from separate establishment licensing application requirement). In 1997, Congress directed the FDA to minimize the differences in product

longer production lead times than other pharmaceutical products,³⁷ and the FDA imposes particularly rigorous GMP requirements on biologics.³⁸ For instance, the agency demands that preapproval clinical trials use batches produced in a commercial-scale manufacturing facility,³⁹ which means that, once those facilities actually begin producing biologics for the market, they may use methods that no longer represent the state-of-the-art.⁴⁰ The FDA allows a limited exception for products that are “in short supply,”⁴¹ but the stringency of GMP requirements applicable to drugs and especially biologics still represents a potential obstacle to the uninterrupted supply of therapeutic products approved for marketing.⁴²

approval requirements applied to drugs and biologics. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 123(f), 111 Stat. 2296, 2324.

37. See Brown, *supra* note 2, at A1 (“Vaccines are also harder to make. They’re derived from bacteria and viruses, which are trickier to handle than inert chemicals. Many require elaborate processing to keep them safe, uncontaminated but still active. It takes Aventis Pasteur almost a year to make a batch of Td.”); see also Mowery & Mitchell, *supra* note 9, at 984-85 (“The effects of vaccine supply interruptions are exacerbated by limited industry inventories. Vaccines have a short shelf life (an average of two years) . . . [E]ven under the most urgent circumstances, a large emergency vaccine order requires several weeks to process.”).

38. See 21 C.F.R. pts. 600-610 (2002); PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 664 (2d ed. 1991) (“Once the specific plant has been approved, . . . it is more difficult to secure approval of an alternative manufacturing site for a biological than for a new drug.”); Gary E. Gamerman, *Regulation of Biologics Manufacturing: Questioning the Premise*, 49 FOOD & DRUG L.J. 213 (1994) (criticizing the FDA’s continued insistence on more intensive scrutiny of manufacturing for biological products as compared to drugs); Edward L. Korwek, *Human Biological Drug Regulation: Past, Present, and Beyond the Year 2000*, 50 FOOD & DRUG L.J. 123, 132-34 (Supp. 1995); see also 42 U.S.C. § 300aa-28 (2000) (imposing special recordkeeping and reporting requirements on manufacturers of childhood vaccines); Berkovitz v. United States, 486 U.S. 531, 540-47 (1988).

39. See NeoRX Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 206 (D.N.J. 1994); Gary B. Ebbert et al., *Overview of Vaccine Manufacturing and Quality Assurance*, in VACCINES 40, 41 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999); Mowery & Mitchell, *supra* note 9, at 986-87; Paul D. Parkman & M. Carolyn Hardegrege, *Regulation and Testing of Vaccines*, in VACCINES, *supra*, at 1131, 1136-37.

40. See Gamerman, *supra* note 38, at 231 (explaining that a biologics manufacturer “face[s] the problem of having to build and staff a facility that will not be state-of-the-art by the time it is needed for full production and distribution”); *id.* at 231-32 n.98 (“[A] manufacturer of a sub-unit vaccine was required to repeat its preclinical and Phase I studies completely when it switched to a purification scheme that permitted greater product yield, purity, homogeneity, and stability.”).

41. See 21 C.F.R. § 601.22 (2002); cf. Mowery & Mitchell, *supra* note 9, at 987 (noting that “this provision is rarely invoked by U.S.-licensed producers of vaccines”).

42. See Brown, *supra* note 2, at A1 (“As with the making of drugs, vaccine production is heavily regulated by the [FDA], and companies must periodically spend large amounts of money on plant improvements to meet the FDA’s requirements. Many complain that they can’t recoup their investment through sales.”); Scott Gottlieb, *Getting Drugs Made Can Be Harder Than Creating Them*, AM. MED. NEWS, Jan 14, 2002, at 19, 22 (describing the lack of adequate manufacturing facilities for monoclonal antibodies such as Enbrel, and blaming the problem on slow and expensive FDA inspections).

B. Cost Containment Backfires

The federal government buys substantial quantities of prescription drugs for use in a variety of programs. By virtue of its sheer size, the government can negotiate for favorable prices, at least if it can coordinate its purchases.⁴³ In addition, state governments have become more active in trying to use their leverage to limit expenditures on pharmaceuticals.⁴⁴ Public and private insurers are more likely to reimburse or supply pharmaceuticals regarded as essential to health, but the desire to guarantee patient access unwittingly may weaken the industry's economic incentives for producing adequate supplies of these therapeutic agents. Bulk purchases by government agencies or pressures exerted by large insurers can depress prices to the point that it makes little business sense for a company to continue manufacturing a particular product.

Vaccines do not represent a terribly lucrative business compared to other pharmaceutical lines.⁴⁵ Indeed, their success in eradicating dreaded infectious diseases of the past creates a risk of eventual obsolescence, as had happened with the smallpox vaccine until very recently. Government-mandated immunizations for children ensure a steady demand for many vaccines, but, in contrast to prevalent chronic diseases that may require daily and indefinite use, individuals may receive a particular vaccine on only a few occasions over the course of their lifetimes.⁴⁶ To make matters worse, many individuals do not

43. See Shankar Vedantam, *HHS's Varying Costs for Cipro Criticized*, WASH. POST, Oct. 26, 2001, at A16 (reporting that the government negotiated a contract to purchase an antibiotic for the treatment of anthrax for 95¢ per dose—far less than the retail price of over \$4 and the manufacturer's original offer of \$1.83 but more than twice the price paid by the federal government under a preexisting program).

44. See *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222–26 (D.C. Cir. 2001) (invalidating the federal government's waiver of certain Medicaid requirements applicable to Vermont's program); *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 71–72, 84–85 (1st Cir. 2001) (refusing to enjoin Maine's program), *cert. granted*, 122 S. Ct. 2657 (2002); Francis B. Palumbo, *The Role of the State as a Drug Purchaser*, 56 FOOD & DRUG L.J. 267, 276–80 (2001). Governments in other countries, such as Canada and the United Kingdom, play an even more central role in drug purchasing.

45. See Brown, *supra* note 2, at A1 (“[V]accines historically have been high-volume, low-profit items in drug companies' catalogues. This is still true of older vaccines.”); *id.* (“Only the newer, still under-patent products such as the chickenpox vaccine (\$39 a dose, at the government discounted price) and the pneumococcal vaccine (\$46) offer the kind of profit margins pharmaceutical companies are accustomed to.”); *id.* (“[T]he field generally isn't viewed as a money-maker. Vaccines account for only 1.5 percent of the global pharmaceutical market.”).

46. See *id.* (“Among the economic disincentives is the fact that vaccines are given on a rigid schedule and only occasionally—far different from products such as antidepressants and cholesterol-lowering drugs, which are taken for years and whose ‘target’ populations are constantly expanding.”); *id.* (“Moreover, vaccine hazards stand out starkly in populations in which the diseases the vaccines prevent are no longer visible.”); Terence Chea, *Vaccines Are Hot Topic, but Not Hot Investment*, WASH. POST, Dec. 13, 2001, at E1 (“The drug industry would rather develop pills that people take every day for years than a vaccine taken once in a lifetime.”).

purchase vaccines, relying instead on supplies made available by public health departments.⁴⁷

In 1993, Congress created the Childhood Immunization Initiative, which ensured free vaccines to all eligible children.⁴⁸ This statute directed the CDC to increase their purchasing of pediatric vaccines but limited price increases on government contracts to the rate of inflation.⁴⁹ These and other efforts to secure deep discounts or otherwise control prices could, however, backfire by “accelerat[ing] the exit of U.S. producers from the industry, further reducing the number of suppliers of critical vaccines.”⁵⁰ One might understand the problem as the flipside of rationing expensive health care interventions: if prices become sufficiently depressed as a result of government efforts to ensure inexpensive access for patients, manufacturers may no longer bother to produce the product or at least devote fewer resources to it than more lucrative lines of business,⁵¹ which then creates a problem of scarcity. Along similar lines, declining insurance reimbursements for mammograms, which may no longer cover the cost of performing this diagnostic test, have caused several mammography centers to close their doors.⁵²

47. See Brown, *supra* note 2, at A1 (“[B]ecause the federal government buys so much, discount pricing is the rule, not the exception, in the vaccine market.”).

48. See 42 U.S.C. § 1396s(a)(1)(A) (2000); see also Walter A. Orenstein et al., *Public Health Considerations—United States*, in VACCINES, *supra* note 39, at 1006, 1013 (“Approximately 60% of vaccines routinely recommended for children are purchased with public funds through federal contracts negotiated by the CDC with the vaccine manufacturers. . . . The typical discount has been approximately 50% off the published catalog prices.”).

49. See 42 U.S.C. § 1396s(d)(3)(B).

50. Mowery & Mitchell, *supra* note 9, at 984; see also *id.* at 980 n.8 (The statute “may well cause established U.S. vaccine producers to focus future development efforts on vaccines for adults rather than for children.”); Ira Carnahan, *Blame the Government for the Vaccine Shortage*, FORBES, Mar. 18, 2002, at 50. Conversely, the assured demand and government-run distribution network may help stabilize the market and perhaps attract new entrants. See Mowery & Mitchell, *supra* note 9, at 988; Kathleen Day, *Vaccine Maker Gets a Shot in the Arm*, WASH. POST, Mar. 11, 1996, at F17 (noting that “federal and state government buy 60 percent of vaccines”); see also Hurley v. Lederle Labs., 863 F.2d 1173, 1177 (5th Cir. 1988); GAO, *supra* note 22, at 6 n.5 (noting that the manufacturer of the Td booster vaccine refuses to sell it to the CDC at the capped price).

51. See Barry R. Bloom, *The United States Needs a National Vaccine Authority*, 265 SCIENCE 1378, 1378 (1994) (conceding that the public “interest is best served by multiple manufacturers and competition, not by monopsonistic or universal government purchase”); see also Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 319 (2000) (“The lower the originator product’s price when the patent expires, the lower the potential profit margin for a generic competitor pursuing a price competition strategy, and hence the less attractive is the market for competitive generic entry.”); Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT’L L. 149, 167-71 (2000); Vanessa Fuhrmans & Gautam Naik, *Drug Makers Fight to Fend Off Cuts in European Prices*, WALL ST. J., June 7, 2002, at A1 (reporting that companies may “withhold innovative new treatments from European markets” if governments there insist on unprofitable pricing).

52. See Barbara Martinez, *Screening Crunch: As More Women Seek Mammograms, Many Have to Wait Months*, WALL ST. J., Oct. 30, 2000, at A1.

In the field of organ transplantation, federal and state statutes prohibit the sale of most human tissues,⁵³ which several commentators have criticized given the serious scarcity of donated organs.⁵⁴ The prohibition on commercialization represents an extreme version of the cost containment measures used by governments in an effort to ensure affordable drugs, and it may create scarcity in much the same way.⁵⁵ Imagine that the government prohibited drug manufacturers from generating any profit on sales of vaccines and other critical pharmaceuticals, allowing them to recoup only their expenses for raw materials and counting on their corporate public-spiritedness to continue supplying the market. Although members of the pharmaceutical industry participate in a variety of charitable activities,⁵⁶ altruism alone will not maintain product lines that generate little or no profit.⁵⁷

53. See 42 U.S.C. § 274e (2000); see also Susan H. Denise, Note, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1022-32 (1985) (discussing the origins of this prohibition and parallel state legislation).

54. See Roger D. Blair & David L. Kaserman, *The Economics and Ethics of Alternative Cadaveric Organ Procurement Policies*, 8 YALE J. ON REG. 403, 408-10 (1991); Lloyd R. Cohen, *Increasing the Supply of Transplant Organs: Virtues of a Futures Market*, 58 GEO. WASH. L. REV. 1 (1989); Shelby E. Robinson, Comment, *Organs for Sale? An Analysis of Proposed Systems for Compensating Organ Providers*, 70 U. COLO. L. REV. 1019, 1035-50 (1999); see also Deborah Josefson, *AMA Considers Whether to Pay for Donation of Organs*, 324 BRIT. MED. J. 1541 (2002); Susan Okie, *Surgeons Back Study of Payment for Organs: Plan Aimed as Boosting Donor Rates*, WASH. POST, Apr. 30, 2002, at A3.

55. See Gregory S. Crespi, *Overcoming the Legal Obstacles to the Creation of a Futures Market in Bodily Organs*, 55 OHIO ST. L.J. 1, 19, 76 (1994); see also James F. Blumstein, *The Use of Financial Incentives in Medical Care: The Case of Commerce in Transplantable Organs*, 3 HEALTH MATRIX 1, 19 (1993) ("If people are not inclined to donate [organs], then that means they will require more in the way of an inducement. Prospective buyers would have to raise the price."); *id.* at 21-24 (distinguishing between supply-side and demand-side issues); Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 174-85, 192-200, 221 (2000) (explaining that, even if donors act altruistically, other participants in the organ transplant business do not).

56. See Theresa Agovino, *Private Groups Subsidizing Medicines for World's Sick*, HOUS. CHRON., Feb. 17, 2002, at 8; Bruce Japsen, *Abbott, Rivals Offer a Discount Drug Card*, CHI. TRIB., Apr. 10, 2002, § 3, at 1 ("Abbott, for example, donated more than \$40 million in pharmaceutical products to 85,000 people free of charge last year under a patient assistance program in place since 1996."); *Seven Drug Companies Offer Discount Card to Elderly*, L.A. TIMES, Apr. 10, 2002, at C3 ("Under its long-standing Patient Assistance Program, Merck . . . offers many of the company's medicines free of charge to any patient without prescription drug coverage who has an annual individual income less than \$18,000 . . .").

57. See Vanessa Fuhrmans, *Public Health Groups Act Like Companies in Bid to Fight Diseases in Poor Nations*, WALL ST. J., Nov. 16, 2001, at B3 ("The same dilemma stands in the way of investing in treatments for diseases caused by bioterrorism agents—the uncertain market discourages private investment."); Donald G. McNeil, Jr., *Cosmetic Saves a Cure for Sleeping Sickness*, N.Y. TIMES, Feb. 9, 2001, at A1 ("It has been known for more than 10 years that eflornithine is a virtual miracle cure for trypanosomiasis, but stocks have run out because early hopes that it would help fight cancer have been dashed and medical production has stopped."); see also Justin Gillis, *Drugmakers Step Forward in Bioterror Fight*, WASH. POST, Oct. 31, 2001, at A18 (explaining public relations benefit and other motivations behind company offers to provide free supplies of antibiotics against anthrax); Charles Ornstein, *Drug Firms Rush to Offer*

C. Rationing Finite Supplies

A vast literature exists about health care rationing, but it focuses almost exclusively on scarcity of financial resources that requires trade-offs among patients, choice of interventions, and other uses of the money.⁵⁸ Commentators have paid relatively little attention to the “microallocation” questions that arise when, no matter the ability to pay, there are not enough units of a health care intervention to go around.⁵⁹ The one major exception to this lack of attention is the field of organ transplantation, which actually poses both sets of rationing difficulties.⁶⁰ Given the high costs and sometimes poor chances of success

Free Anthrax Antibiotics, L.A. TIMES, Oct. 27, 2001, at A3 (same).

58. See, e.g., HENRY J. AARON & WILLIAM B. SCHWARTZ, *THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE* (1984); ROBERT H. BLANK, *RATIONING MEDICINE* (1988); PAUL T. MENZEL, *STRONG MEDICINE: THE ETHICAL RATIONING OF HEALTH CARE* (1990); Daniel Callahan, *Transforming Mortality: Technology and the Allocation of Resources*, 65 S. CAL. L. REV. 205, 219-23 (1991); Einer Elhauge, *Allocating Health Care Morally*, 82 CAL. L. REV. 1449 (1994); Mark A. Hall, *Rationing Health Care at the Bedside*, 69 N.Y.U.L. REV. 693 (1994); Symposium, *Caring for the Uninsured and Underinsured*, 265 JAMA 2441 (1991); Symposium, *The Law and Policy of Health Care Rationing: Models and Accountability*, 140 U. PA. L. REV. 1505 (1992).

59. See Maxwell J. Mehlman, *Rationing Expensive Lifesaving Medical Treatments*, 1985 WIS. L. REV. 239, 244-45 (“Allocating medical treatments that are in short supply . . . are difficult and ethically troublesome. Generally, however, the options are circumscribed by the available medical resources. The only question is who should receive them. Economists call this a ‘microallocation’ problem.” (footnotes omitted)). Professor Mehlman’s article, like most others that discuss health care rationing, addresses a different question:

The current debate . . . focuses on a different type of constraint—cost. . . . Under both cost-based rationing and technical or experimental scarcity, microallocation decisions are needed to determine who receives treatment. However, cost-based rationing entails additional decisions on whether, and to what extent, to restrict the availability of treatment on grounds of cost. These are termed “macroallocation” decisions.

Id. at 245; see also Roger W. Evans, *Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions*, 249 JAMA 2047 (1983); David C. Hadorn & Robert H. Brook, *The Health Care Resource Allocation Debate: Defining Our Terms*, 266 JAMA 3328, 3328 (1991) (“Only two types of medical and surgical services are currently scarce relative to demand: organs for transplantation and, sometimes, beds in intensive care units. . . . Use of the word rationing in the contemporary policy debate has clearly transcended [its] original meaning.” (endnotes omitted)); Michael D. Reagan, *Health Care Rationing: What Does it Mean?*, 319 NEW ENG. J. MED. 1149, 1150-51 (1988).

60. See RENÉE C. FOX & JUDITH P. SWAZEY, *SPARE PARTS: ORGAN REPLACEMENT IN AMERICAN SOCIETY* 73-92 (1992); George J. Annas, *The Prostitute, the Playboy, and the Poet: Rationing Schemes for Organ Transplantation*, 75 AM. J. PUB. HEALTH 187, 189 (1985); Roger W. Evans et al., *The Potential Supply of Organ Donors: An Assessment of the Efficiency of Organ Procurement Efforts in the United States*, 267 JAMA 239, 245 (1992); Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, 14 J. HEALTH POL. POL’Y & L. 191, 191-92, 218-21 (1989); John A. Robertson, *Supply and Distribution of Hearts for Transplantation: Legal, Ethical, and Policy Issues*, 75 CIRCULATION 77, 86 (1987); H. Gilbert Welch & Eric B. Larson, *Dealing with Limited Resources: The Oregon Decision to Curtail Funding for Organ Transplantation*, 319 NEW ENG. J. MED. 171, 173 (1988); see also David Mechanic, *Professional Judgment and the Rationing of Medical Care*, 140 U. PA. L. REV. 1713, 1752 (1992) (“The allocation of scarce resources, as in the case of organ transplantation, is not prototypical of the majority of rationing decisions made within our vast health care system. . . .

associated with organ transplantation, some have questioned whether this intervention represents a sensible expenditure of scarce health care resources. If society answers that macroallocational question in the affirmative, then, at least as long as shortages persist, it becomes necessary to face the microallocational question and decide which patients will receive the available organs.

Microallocation problems pose particularly difficult choices.⁶¹ How does one select among various patients when inadequate supplies prevent treating all of those in need? The federal government has established an elaborate allocation system for donated organs,⁶² but no similar framework exists for the rationing of critical pharmaceuticals when shortages arise.⁶³ One could distribute such medications on a first-come, first-served basis or using some other random allocation system. In 1953, for instance, "the British Ministry of Health instituted a national lottery in order to allocate the scarce supplies of polio vaccine."⁶⁴ Half a century later, initial shortages of a new treatment for hepatitis C required the establishment of a special patient registration system.⁶⁵

These decisions detract attention from the far more numerous circumstances under which more routine types of rationing occur.").

61. See JOHN F. KILNER, WHO LIVES? WHO DIES? ETHICAL CRITERIA IN PATIENT SELECTION (1990); AMA Council on Ethical & Judicial Affairs, *Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients*, 155 ARCHIVES INTERNAL MED. 29, 35 (1995); James F. Childress, *Triage in Neonatal Intensive Care: The Limitations of a Metaphor*, 69 VA. L. REV. 547 (1983); Volker H. Schmidt, *Selection of Recipients for Donor Organs in Transplant Medicine*, 23 J. MED. & PHIL. 50 (1998); Basil A. Stoll, *Choosing Between Cancer Patients*, 16 J. MED. ETHICS 71 (1990); Robert D. Truog, *Triage in the ICU*, HASTINGS CTR. REP., May-June 1992, at 13; see also GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 182-90 (1978) (comparing different countries' approaches to allocating scarce dialysis machines); K.M. Boyd & B.T. Potter, *Priorities in the Allocation of Scarce Resources*, 12 J. MED. ETHICS 197 (1986) (discussing a case involving competing needs for a single renal dialysis machine).

62. See 42 U.S.C. §§ 274, 1320b-8 (2000); James F. Blumstein, *Federal Organ Transplantation Policy: A Time for Reassessment?*, 22 U.C. DAVIS L. REV. 451 (1989); Gail L. Daubert, Note, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 463-74 (1998) (summarizing the central features of the federal allocation program). Recently, the federal government issued controversial new rules that altered some of the allocation criteria. See 63 Fed. Reg. 16,296 (Apr. 2, 1998) (codified at 42 C.F.R. pt. 121 (2002)); Laura E. McMullen, Comment, *Equitable Allocation of Human Organs: An Examination of the New Federal Regulation*, 20 J. LEGAL MED. 405 (1999).

63. See *Anthrax Attacks Leave States Little Better Prepared*, USA TODAY, Jan. 3, 2002, at 10A ("With the possible exception of Colorado, no state has rules for rationing antibiotics or vaccines when there are not enough to go around . . ."). A recently drafted model public health law provides authority to ration critical pharmaceuticals and give precedence to health care workers and disaster response personnel. See Model State Emergency Health Powers Act § 505(b), (c) (draft Dec. 21, 2001), <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> (last visited Nov. 15, 2002).

64. GERALD R. WINSLOW, TRIAGE AND JUSTICE 147 (1982).

65. See Geeta Anand, *Schering-Plough to Start Wait List for Hepatitis Drug*, WALL ST. J., Jan. 16, 2002, at B14.

Most rationing schemes emphasize relying solely on medical criteria, but even these may point in different directions. Should the scarce resource go to the sickest patient or the one most likely to recover completely if treated at an early stage? When the vaccine against hepatitis B first became available, the combination of limited supplies and high costs led to recommendations for its use only in “high-risk groups.”⁶⁶ Nonetheless, the use of seemingly objective and neutral medical criteria, even if such criteria could be established,⁶⁷ may lead to inequities in access.⁶⁸ Researchers have found, for example, that minorities do not respond as well to certain medications, which may result from the fact that sponsors of investigational new drugs rarely enrolled patients from minority populations in clinical trials.⁶⁹

Although medical ethicists generally reject using social worth criteria, should the patient’s age (or perhaps ability to pay) factor into the choice? In recent years, recurring shortages of the annual vaccines against influenza have resulted in recommendations that otherwise healthy adults delay seeking inoculations so as to ensure adequate doses for the elderly.⁷⁰ In the face of

66. See INST. OF MED., NEW VACCINE DEVELOPMENT: ESTABLISHING PRIORITIES I:267-68 (1985); see also KILNER, *supra* note 61, at 124 (“An imminent-death criterion, for instance, partly determined the distribution of insulin in the days when it was still scarce.”). In the transplantation context, one suggestion for responding to scarcity involves the salvage of diseased or defective (so-called “extended criteria”) organs for patients who otherwise would receive a low priority because of their poor prognosis. See Paul Engstrom, “Marginal” Organs Can Be Another Shot at Life, L.A. TIMES, July 16, 2001, at S6.

67. See Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373 (2002) (discussing endemic medical uncertainty); Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 50 HASTINGS L.J. 241 (1999) (discussing the social construction of disease).

68. For instance, in the context of kidney transplantations, human leukocyte antigen (HLA) matching improves success rates but results in serious distributional inequities for minority patients who do not match the largely non-minority donor supply. See Ian Ayres et al., *Unequal Racial Access to Kidney Transplantation*, 46 VAND. L. REV. 805, 815-36, 849-53 (1993); Robert S. Gaston et al., *Racial Equity in Renal Transplantation: The Disparate Impact of HLA-Based Allocation*, 270 JAMA 1352, 1353-55 (1993); Barbara A. Noah, *The Invisible Patient*, 2002 U. ILL. L. REV. 121, 127-28 (book review).

69. See Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients’ Genetic Profiles*, 43 JURIMETRICS J. (forthcoming Jan. 2003) (explaining that advances in pharmacogenetics may exacerbate these discrepancies in the future). After the anthrax attacks, employees of the United States Postal Service complained that they had received poorer treatment than Senate staffers and suggested that it had something to do with their race and socioeconomic status. See *All Things Considered: Postal Workers Question Equality of Medical Treatment for the Poor* (Nat’l Pub. Radio broadcast, Jan. 15, 2002), available at 2002 WL 3494675.

70. See CDC, *Delayed Influenza Vaccine Availability for 2001-02 Season and Supplemental Recommendations of the Advisory Committee on Immunization Practices*, 50 MORBIDITY & MORTALITY WKLY. REP. 582, 583 (2001) (adding that priority also should be given to other high-risk individuals and health care workers); CDC, *Delayed Supply of Influenza Vaccine and Adjunct ACIP Influenza Vaccine Recommendations for the 2000-01 Influenza Season*, 49 MORBIDITY & MORTALITY WKLY. REP. 619, 620-21 (2000). Physicians also reported incidents of price gouging. See Elliott, *supra* note 5, at 2.

concerns about shortages of the DTP vaccine in the mid-1980s, the CDC recommended that pediatricians delay administering booster shots.⁷¹ It has taken similar steps to cope with the latest round of shortages,⁷² resulting, for instance, in an inability among adults to get tetanus shots.⁷³

Finally, should purely medical criteria give way in the face of a national emergency? During World War II, the inability to synthesize penicillin coupled with a sudden surge in demand resulted in serious supply shortages and required rationing to facilitate the war effort.⁷⁴ At present, some controversy exists about providing initial doses of scarce vaccines to public health and emergency response officials.⁷⁵

Rationing difficulties often arise because of macroallocational decisions or, more typically, indecision. Aside from insuperable technological barriers, we could avoid microallocation problems by devoting greater resources to securing adequate supplies.⁷⁶ For the most part, vaccines and antibiotics do not represent expensive or exotic life-saving technologies. On the contrary, they are among

71. See CDC, *Diphtheria-Tetanus-Pertussis Vaccine Shortage—United States*, 33 MORBIDITY & MORTALITY WKLY. REP. 695, 696 (1984); CDC, *Diphtheria-Tetanus-Pertussis Vaccine Shortage*, 34 MORBIDITY & MORTALITY WKLY. REP. 103, 104 (1985). The agency rescinded its recommendation less than six months later after one of the manufacturers began distributing supplies again. See CDC, *Reinstatement of Regular Diphtheria-Tetanus-Pertussis Vaccine Schedule*, 34 MORBIDITY & MORTALITY WKLY. REP. 231, 232 (1985).

72. See CDC, *Recommended Childhood Immunization Schedule—United States, 2002*, 51 MORBIDITY & MORTALITY WKLY. REP. 31, 33 (2002) (“As a result of the vaccine supply shortage, deferral of some doses of tetanus and diphtheria toxoids (Td), diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), and pneumococcal conjugate vaccine (PCV) has been recommended”); CDC, *Shortage of Varicella and Measles, Mumps and Rubella Vaccines and Interim Recommendations from the Advisory Committee on Immunization Practices*, 51 MORBIDITY & MORTALITY WKLY. REP. 190, 190-91 (2002); Brown, *supra* note 2, at A1 (“[T]he CDC has been rationing supplies and changing immunization schedules to ensure that all children get at least some doses of every vaccine they need.”).

73. See CDC, *Deferral of Routine Booster Doses of Tetanus and Diphtheria Toxoids for Adolescents and Adults*, 50 MORBIDITY & MORTALITY WKLY. REP. 418 (2001); Geraldine M. McQuillan et al., *Serologic Immunity to Diphtheria and Tetanus in the United States*, 136 ANNALS INTERNAL MED. 660, 666 (2002); Brown, *supra* note 2, at A1 (“[T]he classic ‘tetanus shot’ people get when they have dirty wounds . . . is now available only in emergency rooms.”); Andrea Petersen, *Vaccine Shortage Hits Adults*, WALL ST. J., May 15, 2002, at D1 (“Adults needing tetanus-diphtheria boosters—which they should get every 10 years—will probably have to wait until the end of this year.”).

74. See GLADYS L. HOBBY, *PENICILLIN: MEETING THE CHALLENGE* 141-45 (1985); WINSLOW, *supra* note 64, at 7-8; Childress, *supra* note 61, at 551-52; Note, *Scarce Medical Resources*, 69 COLUM. L. REV. 620, 664 n.241 (1969).

75. See Bradley Graham & Mike Allen, *Military Smallpox Vaccinations Planned*, WASH. POST, Nov. 15, 2002, at A16; Guy Gugliotta, *Pentagon to Resume Anthrax Vaccinations*, WASH. POST, June 29, 2002, at A3; see also *supra* note 63.

76. See Mehlman, *supra* note 59, at 245 (“Assuming there is no technological or experimental barrier to providing additional medical resources, availability is a function of cost. Increasing the supply of these resources to avoid the need for rationing would require restrictions on the supply of other resources”).

the most cost-effective health care interventions available today,⁷⁷ but their very success may have bred public complacency, and the resulting failure to give sufficient priority to ensuring the continued availability of these older medical technologies may imperil the public health. In the case of rare diseases, the federal government has extended special incentives designed to encourage the development of so-called “orphan” drugs.⁷⁸ Notwithstanding narrow patient populations, a steady demand for certain orphan drugs coupled with generous market exclusivity provisions have resulted in several commercially successful products.⁷⁹ Off-patent pediatric vaccines, antibiotics, and other critical pharmaceuticals designed for only occasional use by large patient populations may represent the real orphans in need of additional protection.

III. STRATEGIES FOR THE FUTURE

In response to the latest round of vaccine shortages, interested parties have begun serious efforts to find solutions to the problem.⁸⁰ The previous discussion suggests a pair of responses. First, the FDA needs to facilitate rather than impede the production of critical pharmaceuticals.⁸¹ The agency now does a

77. See CDC, *Impact of Vaccines Universally Recommended for Children—United States, 1990-1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 244-45 (1999); Mark A. Miller & Alan R. Hinman, *Cost-Benefit and Cost-Effectiveness Analysis of Vaccine Policy*, in VACCINES, *supra* note 39, at 1074, 1085 (“Economic analyses of immunizations have shown them to be among the best investments in health.”); see also Carolyn Buxton Bridges et al., *Effectiveness and Cost-Benefit of Influenza Vaccination of Healthy Working Adults*, 284 JAMA 1655, 1661 (2000); Craig C. White et al., *Benefits, Risks and Costs of Immunization for Measles, Mumps and Rubella*, 75 AM. J. PUB. HEALTH 739, 740 (1985).

78. See Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. §§ 360aa-360ee (2000)); see also Baker Norton Pharms., Inc. v. FDA, 132 F. Supp. 2d 30, 31 (D.D.C. 2001) (“Since the passage of the Orphan Drug Act, the FDA has approved at least 172 orphan drugs and biological products”); Carolyn H. Asbury, *The Orphan Drug Act: The First 7 Years*, 265 JAMA 893 (1991); Naomi Aoki, *The Price of Success: Orphan Drug Act Has Spurred Advances—and Disputes*, BOSTON GLOBE, July 25, 2001, at F1.

79. See Peter S. Arno et al., *Rare Diseases, Drug Development, and AIDS: The Impact of the Orphan Drug Act*, 73 MILBANK Q. 231, 241-43 (1995); Ann Gibbons, *Billion-Dollar Orphans: Prescription for Trouble*, 248 SCIENCE 678 (1990); Abbey S. Meyers, *The Impact of Orphan Drug Regulation on Patients and Availability*, 47 FOOD & DRUG L.J. 9, 9-10 (1992); Larry Thompson, *The High Cost of Rare Diseases*, WASH. POST, June 25, 1991, at Z10.

80. See GAO, *supra* note 22, at 24-34; Brown, *supra* note 2, at A1 (“[T]here have been numerous meetings among representatives of the federal government, public health departments, drug companies and medical societies to try to come up with ways to avert future shortages. Financial incentives to vaccine makers, changes in regulation, bigger stockpiles and expanded liability protection are all being considered.”); James Collins, *Senate Panel Hears Call for Action on Childhood Vaccine Shortages*, ST. LOUIS POST-DISPATCH, June 13, 2002, at A11; Michael Tackett, *Shortages a Threat to Routine of Immunizations*, CHI. TRIB., Apr. 12, 2002, § 1, at 8; Editorial, *Averting Vaccine Disaster*, WASH. POST, Feb. 22, 2002, at A24.

81. See Mowery & Mitchell, *supra* note 9, at 998 (“Reduction in the stringency of regulation is unlikely, but expanded collaboration between public biomedical research agencies in the United States and foreign or domestic firms in clinical trials and licensure could ease the licensing barriers to entry.”); *id.* at 985 (“[T]he assessment of supply interruption risk and

better job of getting essential drugs to the market, but it needs to help keep them on the market as well. When it initially licenses products, the FDA gives priority to reviewing drugs and biologics intended for the treatment of life-threatening conditions for which effective therapies do not yet exist;⁸² it needs to do the same when it inspects facilities and resolves disputes involving GMP requirements. At the very least, the FDA must demonstrate additional flexibility in case of a serious supply shortage.⁸³ Second, cost-containment strategies need to give way to some mechanism for paying a premium for critical pharmaceutical products or at least providing their manufacturers with generous tax incentives. This Part considers other oft-mentioned solutions to the scarcity problem, in roughly descending order of merit: insulating manufacturers from tort liability, stockpiling supplies, and nationalizing part of the industry.

A. Removing the Liability Cloud

As is true with criticisms of excessive regulatory burdens, commentators usually focus on the disincentives to research and development created by the threat of tort liability,⁸⁴ but these pressures also may have negative impacts on

policies to address this risk must look beyond the number of suppliers to consider policies addressing vaccine stockpiles and FDA licensure of production facilities.”); *cf. id.* at 986 (“The very different product and process technologies associated with vaccines . . . prevent entry by ‘generic vaccine’ producers without extensive clinical trials.”).

82. See 21 U.S.C. § 356 (2000); 21 C.F.R. pts. 314(H), 601(E) (2002). The FDA also simplified the approval requirements for products designed to treat victims of bioterrorism. See 67 Fed. Reg. 37,988 (May 31, 2002).

83. See Mowery & Mitchell, *supra* note 9, at 985 (“[T]he duration of previous supply interruptions is attributable in large part to the amount of time required by the FDA to license a new production facility. In a crisis, these licensure procedures could be accelerated somewhat without reducing their stringency or public safety.”); see also Freddy A. Jimenez, *Enforcement of the Current Good Manufacturing Practices for Solid Oral Dosage Forms After United States v. Barr Laboratories*, 52 FOOD & DRUG L.J. 67, 71-72 (1997) (discussing a consent decree that enjoined production of Warner-Lambert drugs pending the completion of GMP audits but allowed continued production of “medically necessary” drugs—meaning those without a therapeutic substitute—pending certification of the manufacturing facilities); Tamar Nordenberg, *Inside FDA: When a Drug Is in Short Supply*, FDA CONSUMER, Nov.-Dec. 1997, at 30 (“If shutting down a plant while the manufacturer corrects problems could lead to a shortage of a medically necessary drug, the agency may exempt that drug from the ban to keep it available.”). When it recently ordered a recall of processed tissues distributed by CryoLife because of suspected bacterial contamination, the FDA allowed continuing distribution of heart valves, and it authorized the resumption of shipments of other critical tissue products even before confirming that the company had remedied its GMP problems. See Martha Brannigan, *CryoLife Gains FDA Approval for Some Sales*, WALL ST. J., Sept. 9, 2002, at B6.

84. See, e.g., INST. OF MED., CONTRACEPTIVE RESEARCH AND DEVELOPMENT 21-23 (Polly F. Harrison & Allan Rosenfield eds., 1996); Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 334 (Peter W. Huber & Robert E. Litan eds., 1991); Susan F. Scharf, Note, *Orphan Drugs: The Question of Products Liability*, 10 AM. J.L. & MED. 491, 512-13 (1985).

the supplies of existing therapeutic products. As Professor Richard Epstein explained:

[I]f the number of false positives attributed to a vaccine rises sufficiently, then the private costs imposed upon the manufacturer diverge from the social costs of the vaccine. Systematic underproduction results. . . . If their losses from the line of production exceed the profits that they can make from the sale of vaccines, then they will leave the market.⁸⁵

Subsequent research confirmed these predicted effects of tort liability on drug prices and market concentration.⁸⁶

Tort litigation may drive from the market not just individual manufacturers of multi-source drugs but also entire product lines.⁸⁷ In the case of the antinauseant drug Bendectin, which the FDA continues to regard as safe and effective, the manufacturer withdrew the product rather than continue defending its safety in the courts.⁸⁸ The withdrawal of this drug two decades ago left an unmet therapeutic need for pregnant women suffering from severe nausea, which could result in weight loss and dehydration that sometimes

85. Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1154 (1987); see also *id.* at 1153 (“If in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made. If some net gains survive, then fewer units will be produced to reflect the changes in rules and some marginal consumers must do without.”); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 285-90 (1985). See generally STEVEN GARBNER, *PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES* (1993).

86. See Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J.L. & ECON. 247, 248, 254-58, 273 (1994); Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 234 (1997).

87. See Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs Off the Market*, 40 CASE W. RES. L. REV. 413, 428-29 (1990); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 774-75 (1990); Linda A. Johnson, *Wyeth Won't Resume Norplant Sales*, AP ONLINE, July 26, 2002, available at 2002 WL 24649116; Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. TIMES, May 28, 1995, § 3, at 1; Tamar Lewin, *Searle, Assailing Lawsuits, Halts U.S. Sales of Intrauterine Devices*, N.Y. TIMES, Feb. 1, 1986, § 1, at 1 (“With the company's withdrawal, this type of birth control device [i.e., the IUD] will no longer be available in this country.”).

88. See *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 824 (D.C. Cir. 1988); *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988) (“Ben[de]ctin, the only antinauseant drug available for pregnant women, was withdrawn from sale in 1983 because the cost of insurance almost equalled the entire income from sale of the drug. Before it was withdrawn, the price of Ben[de]ctin increased by over 300 percent.”); Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 318-19 (1992); W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 STAN. L. REV. 547, 584 (2000) (“The risk of juror error coupled with high litigation costs led manufacturers to withdraw Bendectin from the market notwithstanding the continuing assessment by the FDA and the scientific community that Bendectin provides benefits exceeding its risks.”); see also Lars Noah, *Civil Jury Nullification*, 86 IOWA L. REV. 1601, 1656-57 (2001).

necessitated hospitalization.⁸⁹ More recently, in the face of lawsuits and plummeting demand triggered by the resulting adverse publicity, the manufacturer of a vaccine against Lyme disease decided to withdraw its FDA-approved product from the market.⁹⁰

One solution would replace tort liability with alternatives modeled on workers' compensation programs. As mentioned previously, Congress enacted the National Childhood Vaccine Injury Act in response to fears of critical vaccine shortages and dramatic price increases.⁹¹ Manufacturers of listed vaccines must pay an excise tax to fund an administrative compensation system,⁹² and the legislation adds procedural and substantive barriers that are designed to discourage the filing of tort claims.⁹³ This mechanism appears to have succeeded in stabilizing prices and stemming further exit from the market,⁹⁴ though recent litigation involving vaccines or injuries not explicitly covered by the program has shaken some of the confidence that manufacturers have had about the extent of their protection from liability.⁹⁵ Some commentators have proposed similar compensation systems for other types of drug

89. See Gina Kolata, *Controversial Drug Makes a Comeback*, N.Y. TIMES, Sept. 26, 2000, at F1 (adding that a generic version of Bendectin may soon be introduced in the United States market).

90. See *Sole Lyme Vaccine Is Pulled Off Market*, N.Y. TIMES, Feb. 28, 2002, at C5.

91. See H.R. REP. NO. 99-908 (1986), reprinted in 1986 U.S.C.C.A.N. 6344; Victor E. Schwartz & Liberty Mahshagian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 388-89, 394 (1987); Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 151-52, 165 (1988).

92. See 26 U.S.C. §§ 4131-4132 (2000).

93. See *Shalala v. Whitecotton*, 514 U.S. 268, 269-71 (1995); *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2-3 (1st Cir. 1994); see also 42 C.F.R. § 100.3 (2001) (Vaccine Injury Table); *O'Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996) (rejecting challenges to the agency's revisions of the Table); *Beard v. HHS*, 43 F.3d 659 (Fed. Cir. 1994) (holding that an injury to a parent was not covered by the Act); Lisa J. Steel, Note, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?*, 63 GEO. WASH. L. REV. 144, 159-71 (1994) (discussing problems with implementation). See generally Russell G. Donaldson, Annotation, *Construction and Application of National Childhood Vaccine Injury Act*, 129 A.L.R. Fed. 1 (1996 & Supp. 2002).

94. See H.R. REP. NO. 101-247 (1989), reprinted in 1989 U.S.C.C.A.N. 2235; Edmund W. Kitch et al., *U.S. Law, in VACCINES*, supra note 39, at 1165, 1181; Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 76 (1999); see also Edmund L. Andrews, *A Major Revival in Research on Vaccines*, N.Y. TIMES, Aug. 22, 1990, at D7.

95. See Brown, supra note 2, at A1 ("[M]any drug companies now fear that the program won't shield them from a new wave of lawsuits arising from the rumors of new, unproved, vaccine complications."); see also Bruce G. Gellin & William Schaffner, Editorial, *The Risk of Vaccination—The Importance of "Negative" Studies*, 344 NEW ENG. J. MED. 372 (2001); Sandra Blakeslee, *Panel Cautions Against Mercury Preservative*, N.Y. TIMES, Oct. 2, 2001, at A18 (noting concerns about thimerosal used in vaccines). Congress soon may amend the statute to extend its coverage. See Dan Morgan, *Homeland Bill Rider Aids Drugmakers*, WASH. POST, Nov. 15, 2002, at A7.

products,⁹⁶ or, as happened in the case of the swine flu vaccine, the federal government could agree to indemnify manufacturers who supply products used in a mass immunization campaign.⁹⁷

A less cumbersome but equally controversial reform would give pharmaceutical manufacturers the benefit of a regulatory compliance defense.⁹⁸ A couple of states have enacted legislation designed to limit tort claims against pharmaceutical products.⁹⁹ Separately, in response to concerns about maintaining adequate supplies, essentially all jurisdictions exempt blood from strict products liability.¹⁰⁰ These “blood shield” statutes also protect commercial suppliers of blood-derived products from strict liability claims.¹⁰¹ Blood

96. See Andrew R. Klein, *A Legislative Alternative to “No Cause” Liability in Blood Products Litigation*, 12 YALE J. ON REG. 107, 111-35 (1995); H. William Smith, III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207, 246-54 (1992); see also Gregory C. Jackson, Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 235-37 (1992) (suggesting such an approach for all drug products).

97. See National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (repealed 1978); see also *Ducharme v. Merrill-Nat'l Labs.*, 574 F.2d 1307, 1309-10 (5th Cir. 1978) (rejecting constitutional objections to granting tort immunity to vaccine manufacturers); Thomas E. Baynes, Jr., *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U. L.J. 44, 62-74 (1977). This program turned into something of a fiasco. After a number of vaccine recipients reported developing Guillain-Barre syndrome, the immunization program ceased, and the tort litigation against the government commenced. See, e.g., *Novak v. United States*, 865 F.2d 718 (6th Cir. 1989); *Petty v. United States*, 740 F.2d 1428 (8th Cir. 1984); *Unthank v. United States*, 732 F.2d 1517 (10th Cir. 1984); see also Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 180-81, 184-85 (1986). The United States paid out almost \$100 million in claims. See David Brown, *A Shot in the Dark: Swine Flu's Vaccine Lessons*, WASH. POST, May 27, 2002, at A9.

98. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147 (2000); W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1478-80 (1994); see also Carole A. Loftin, Note, *Expansion of the Government Contractor Defense: Applying Boyle to Vaccine Manufacturers*, 70 TEX. L. REV. 1261, 1280-96 (1992).

99. See MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000) (treating FDA drug approval as a conclusive defense absent evidence of fraud), *invalidated by Taylor v. Gate Pharms.*, 639 N.W.2d 45, 53 (Mich. Ct. App. 2001); N.J. STAT. ANN. § 2A:58C-4 (West 2000) (creating a rebuttable presumption of adequate warning). A handful of other states provide an FDA compliance defense against only punitive damage claims. See ARIZ. REV. STAT. ANN. § 12-701(A) (West 2000); OHIO REV. CODE ANN. § 2307.801(C) (West 2001); OR. REV. STAT. § 30.927 (1) (2001); UTAH CODE ANN. § 78-18-2(1) (1996).

100. See Michael J. Miller, Note, *Strict Liability, Negligence and the Standard of Care for Transfusion-Transmitted Disease*, 36 ARIZ. L. REV. 473, 488-90 (1994).

101. See *McKee v. Cutter Labs., Inc.*, 866 F.2d 219, 221-22 (6th Cir. 1989); *Coffee v. Cutter Biological*, 809 F.2d 191, 194 (2d Cir. 1987); *Doe v. Travenol Labs., Inc.*, 698 F. Supp. 780, 784 (D. Minn. 1988); *Rogers v. Miles Labs., Inc.*, 802 P.2d 1346, 1350-52 (Wash. 1991); see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 19(c) (1998) (“Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement.”). But see *JKB v. Armour Pharm. Co.*, 660 N.E.2d 602, 605-06 (Ind. Ct. App. 1996) (holding that state statute did not protect manufacturers).

suppliers remain subject to tort liability in cases of negligence, though many courts define the standard of care as the relevant custom in the industry, which makes it difficult for plaintiffs to recover.¹⁰² Even so, recent litigation involving contaminated blood factor concentrates has created concerns about shortages of a product needed by hemophiliacs.¹⁰³

Suppliers of materials used in medical devices also have encountered litigation that threatened to create scarcity problems. For instance, recipients of defectively designed temporomandibular joint (TMJ) implants sued DuPont, the supplier of the raw material used in the devices, after the finished product manufacturer went bankrupt. The company ultimately prevailed in all of the TMJ lawsuits filed against it for supplying raw materials.¹⁰⁴ DuPont expended significant resources, however, for its string of victories during the decade that this litigation lasted, paying far more in legal fees than it ever earned on this minor application.¹⁰⁵ Similarly, after the largest manufacturer of silicone-gel breast implants filed for bankruptcy protection from the numerous products liability claims,¹⁰⁶ plaintiffs' lawyers began pursuing Dow Chemical as the supplier of the raw silicone.¹⁰⁷ Dow Chemical usually prevailed, and the lawsuits filed against other companies that had supplied silicone to other manufacturers of breast implants have not succeeded.¹⁰⁸ Even so, spooked by

102. See *Smythe v. Am. Red Cross*, 797 F. Supp. 147, 152-53 (N.D.N.Y. 1992); *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1055-60 (D.D.C. 1987), *aff'd in relevant part*, 851 F.2d 437, 439 (D.C. Cir. 1988); *Ward v. Lutheran Hosps. & Homes Soc'y of Am., Inc.*, 963 P.2d 1031, 1036-37 (Alaska 1998); *Spann v. Irwin Mem'l Blood Ctrs.*, 40 Cal. Rptr. 2d 360, 364-66 (Ct. App. 1995); *Brown v. United Blood Servs.*, 858 P.2d 391, 395-99 (Nev. 1993). *But see Doe v. Cutter Biological, Inc.*, 971 F.2d 375, 382-84 (9th Cir. 1992) (denying the defendant's motion for summary judgment); *Doe v. Am. Nat'l Red Cross*, 848 F. Supp. 1228, 1234 (S.D. W. Va. 1994); *Vuono v. N.Y. Blood Ctr., Inc.*, 696 F. Supp. 743, 747-48 (D. Mass. 1988); *United Blood Servs. v. Quintana*, 827 P.2d 509, 521-27 (Colo. 1992); *Advincula v. United Blood Servs.*, 678 N.E.2d 1009, 1027-28 (Ill. 1996). See generally Jay M. Zitter, Annotation, *Liability of Blood Supplier or Donor for Injury or Death Resulting from Blood Transfusion*, 24 A.L.R.4th 508 (1983 & Supp. 2002).

103. See Andrew R. Klein, *Beyond DES: Rejecting the Application of Market Share Liability in Blood Products Litigation*, 68 TUL. L. REV. 883, 918-21 (1994); Eric Nauenberg & Sean D. Sullivan, *Firm Behavior in the U.S. Market for Factor VIII: A Need for Policy?*, 39 SOC. SCI. & MED. 1591, 1593-94 (1994).

104. See *In re TMJ Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1056-59 (8th Cir. 1996) (collecting cases); *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806, 812 (9th Cir. 1995); *LaMontagne v. E.I. du Pont de Nemours & Co.*, 41 F.3d 846, 857-60 (2d Cir. 1994).

105. See Gary Taylor, *A Discovery by DuPont: Hidden Costs of Winning*, NAT'L L.J., Mar. 27, 1995, at B1 (reporting one estimate that the company had spent more than \$40 million defending itself).

106. See *In re Dow Corning Corp.*, 211 B.R. 545, 551-54 (Bankr. E.D. Mich. 1997).

107. See, e.g., *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 106, 114-24 (Nev. 1998) (upholding a compensatory damage award of \$4.2 million, but reversing punitive damage award of \$10 million).

108. See *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F. Supp. 1110, 1113-17 (N.D. Ala. 1997); *Artiglio v. Gen. Elec. Co.*, 71 Cal. Rptr. 2d 817, 822-23 (Ct. App. 1998); see also *White v. Weiner*, 562 A.2d 378, 385-86 (Pa. Super. Ct. 1989) (upholding summary judgment for a company that had supplied bulk active ingredient to another company that

these lawsuits, Dow discontinued supplying silicone for other important medical device applications such as hydrocephalus shunts,¹⁰⁹ and other biomaterials companies have refused to supply implant manufacturers with essential components.¹¹⁰

In response to fears of an emerging shortage of raw materials needed to make life-saving medical devices, Congress enacted the Biomaterials Access Assurance Act of 1998.¹¹¹ Under this statute, a biomaterials supplier that neither manufactured nor sold the allegedly defective implant would face tort liability only if it “failed to meet applicable contractual requirements or specifications” when it furnished raw materials or component parts.¹¹² When named in a lawsuit as a co-defendant, the biomaterials supplier receives certain procedural benefits, including protection from sweeping discovery requests and an opportunity to seek an expedited dismissal with prejudice or summary judgment if the plaintiff cannot establish that the supplier also made or sold the implant or furnished nonconforming biomaterials.¹¹³ It remains to be seen whether this legislation adequately reassures biomaterials suppliers, but the law provides still another model for responding to concerns that unpredictable tort litigation will cause additional shortages of critical pharmaceuticals in the future.

manufactured a prescription drug implicated in a patient’s death).

109. See RAND Sci. & Tech. Policy Inst., *Biomaterials Availability: Potential Effects on Medical Innovation and Health Care*, Issue Paper No. 194, Jan. 2000, at 17, 32.

110. See H.R. REP. No. 105-549, at 10 (1998); Frederick D. Baker, *Effects of Products Liability on Bulk Suppliers of Biomaterials*, 50 FOOD & DRUG L.J. 455, 458 & n.21 (1995); Robert F. Service, *Liability Concerns Threaten Medical Implant Research*, 266 SCIENCE 726, 726 (1994); Barnaby J. Feder, *Implant Industry Is Facing Cutback by Top Suppliers*, N.Y. TIMES, Apr. 25, 1994, at A1; John Stossel, *Protect Us From Legal Vultures*, WALL ST. J., Jan. 2, 1996, at 8 (noting that fears of liability caused the primary supplier of a special type of polyethylene used in artificial joints to stop selling the material to implant manufacturers).

111. Pub. L. No. 105-230, 112 Stat. 1519 (codified at 21 U.S.C. §§ 1601-1606 (2000)).

112. See 21 U.S.C. § 1604. The statute expressly preempts contrary state law. *Id.* § 1603(c).

113. See *id.* § 1605. The biomaterials supplier remains subject to impleader, but only if the claimant or device manufacturer can persuade the trial judge that the negligence or intentionally tortious conduct of the previously dismissed biomaterials supplier caused the harm and that the manufacturer cannot or should not shoulder the full amount of any tort judgment. See *id.* § 1606; see also 66 Fed. Reg. 17,562 (Apr. 2, 2001) (announcing the availability of a draft guidance for implementing a procedure to petition the FDA for a declaration concerning a biomaterials supplier’s compliance with establishment registration requirements); Ann Marie Murphy, Note, *The Biomaterials Access Assurance Act of 1998 and Supplier Liability: Who You Gonna Sue?*, 25 DEL. J. CORP. L. 715, 738 (2000) (explaining that major suppliers remain unconvinced that the statute will afford them meaningful protection).

B. Stockpiling Reserves for a Rainy Day

The creation of emergency stockpiles represents another response to the threat of shortages,¹¹⁴ much like the strategic petroleum reserve established after the OPEC oil embargo.¹¹⁵ In 1982, the federal government began stockpiling childhood vaccines.¹¹⁶ On a couple of occasions, the CDC has tapped into this reserve in order to cover temporary shortfalls caused by production difficulties.¹¹⁷ Although the agency continues to maintain the stockpile at its original levels, the program has stagnated somewhat in the face of resource constraints.¹¹⁸

More recently, the federal government created a National Pharmaceutical Stockpile (NPS) of a range of drugs designed for rapid deployment in the event of public health emergencies.¹¹⁹ When bioterrorism emerged as a threat to civilians, some feared shortages of antibiotics effective in the treatment of

114. See Mowery & Mitchell, *supra* note 9, at 991 ("Another alternative for improving supply reliability is stockpiling of vaccines to prepare for a possible substantial supply interruption.").

115. See Kenneth Bredemeier, *Will Oil Be Cut Off Again?*, WASH. POST, May 16, 2002, at E1 ("[O]il-consuming nations today have amassed strategic petroleum reserves that now total 1.2 billion barrels of crude, led by 566 million barrels of oil in U.S. reserves stored in Louisiana and Texas.").

116. See Mowery & Mitchell, *supra* note 9, at 991 ("[T]he U.S. government contracts with vaccine manufacturers for a vaccine storage and rotation agreement to maintain a twenty-four-week inventory of selected vaccines (tetanus-diphtheria, diphtheria-tetanus, inactivated polio vaccine, OPV, DTP, and MMR)."); Peggy J. Naile, Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 693 (1989) (explaining that, after a shortage of DPT vaccine in 1984, the CDC undertook to stockpile a six month supply).

117. See Mowery & Mitchell, *supra* note 9, at 991 ("Since its inception, the stockpile has been used seven times.").

118. See *id.* ("Congressional funding for the vaccine stockpile ended in 1991. Although the existing twenty-four-week stockpile of the six vaccines previously listed has been maintained, no new [types of] vaccines . . . have been stockpiled, leaving them vulnerable to supply interruptions."); *id.* ("The stockpile of MMR is maintained at a twelve-week level, and that for DTP also is less than the six-month level, because the CDC does not wish to replenish the stockpile with outmoded products."); see also *id.* at 999 ("The stockpiling program mandated by Congress in 1982 provides relatively inexpensive insurance against supply interruptions but requires more stable funding and expansion to cover new vaccines . . . [and] more accurate forecasts of vaccine demand and timely information on conditions of supply and stockpiles.").

119. See Nat'l Ctr. Envtl. Health, CDC, *NPS Synopsis*, <http://www.cdc.gov/nceh/nceh/nps/synopses.htm> (last visited May 21, 2002); see also U.S. GEN. ACCOUNTING OFFICE, GAO-01-463, *COMBATING TERRORISM: ACCOUNTABILITY OVER MEDICAL SUPPLIES NEEDS FURTHER IMPROVEMENT* (2001); Reed Abelson & Robert Pear, *Concerns About How Quickly the U.S. Can Deliver Drugs*, N.Y. TIMES, Oct. 30, 2001, at B8 ("The government's rapid response plan relies on eight so-called push packages, which are pre-assembled sets that contain 84 or more different medical supplies, ranging from antibiotics to intravenous supplies. . . . [E]ach 50-ton set is stored in an undisclosed location around the country . . ."); cf. Scott Hensley & Ron Winslow, *Drug Companies Contemplate New Role as "Biodefense Contractors"*, WALL ST. J., Nov. 12, 2001, at B1.

anthrax.¹²⁰ In addition, the relatively few remaining doses of the vaccine for smallpox, a disease eradicated decades earlier, triggered research into the possibility of diluting the available supplies in order to stretch the doses while waiting for manufacturers to ramp up production under government contracts to purchase 300 million doses.¹²¹ The CDC has added both products to the NPS,¹²² and it also has purchased a large supply of potassium iodide, a drug that provides some protection against thyroid damage from radioactive fallout.¹²³

Stockpiles offer a stopgap measure for covering limited shortfalls in supply, but they do not address the underlying causes of scarcity.¹²⁴ They also present serious logistical difficulties that limit their usefulness, and resource constraints make it unlikely that the federal government would ever manage to establish—much less maintain—a truly comprehensive selection of critical pharmaceuticals for a sizeable patient population. Instead, drug stockpiles will play an increasingly important but still limited role as part of an emergency response strategy.

120. See *supra* note 1; see also Ron Brookmeyer & Natalie Blades, *Prevention of Inhalational Anthrax in the U.S. Outbreak*, 295 SCIENCE 1861 (2002) (concluding that prophylactic use of antibiotics helped limit the number of cases).

121. See Rachel Zimmerman, *Merck, GlaxoSmithKline Are Front-Runners to Produce Smallpox Vaccine for the U.S.*, WALL ST. J., Nov. 2, 2001, at A9. Researchers concluded that diluted vaccine would confer immunity. See Sharon E. Frey et al., *Clinical Responses to Undiluted and Diluted Smallpox Vaccine*, 346 NEW ENG. J. MED. 1265, 1267 (2002). The government has not, however, begun to stockpile an antiviral drug approved for use in AIDS patients even though it may help treat smallpox cases. See Marilyn Chase, *Medical Debate Keeps U.S. from Stockpiling Smallpox Treatment*, WALL ST. J., Mar. 19, 2002, at A24.

122. See M.A.J. McKenna, *Bioterrorism War Changes CDC Role*, ATLANTA J. & CONST., Mar. 23, 2002, at 1A (“Since last fall, enough antibiotics to treat 12 million potential cases of anthrax for 60 days have been added to the stockpile. By the end of this year, enough smallpox vaccine to protect the entire country also will be included.”); see also Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, tit. I(B), 116 Stat. 594; Robert Pear, *Negotiators Reach Compromise on Measure to Strengthen Safeguards Against Bioterror*, N.Y. TIMES, May 22, 2002, at A24 (explaining that Congress crafted this legislation to defend against bioterrorism in part by “expand[ing] government stockpiles of antibiotics and vaccines”).

123. See Justin Gillis, *U.S. Says It Bought Radiation Drug*, WASH. POST, Jan. 3, 2002, at A5.

124. See Mowery & Mitchell, *supra* note 9, at 991 (“In contrast to a preventive strategy to develop more sources of supply for a specific vaccine by encouraging entry, stockpiling is a remedial policy, designed to address supply interruptions once they occur.”).

Stockpiling cannot resolve the consequences of a truly catastrophic supply interruption, such as the complete destruction of a sole-source production facility, because of the limited shelf life of vaccines and the lengthy time needed to license a new production plant. Stockpiling is an important component of a broader strategy to ensure the vaccine supply, one that includes steps to prevent supply interruptions and to address the consequences of a long interruption of supply of a single-source vaccine.

Id. at 992; see also *id.* at 993, 998 (explaining the infeasibility of large emergency procurements from foreign sources).

C. *Compulsory Licensing as an Antidote?*

An even more radical strategy calls for active public sector involvement in the production of critical pharmaceuticals.¹²⁵ Compulsory licensing, which forces a patent holder to allow the use of an invention by others in exchange for a fixed royalty, offers one mechanism for doing so, and some commentators have suggested patent buyouts by the federal government as a mechanism for controlling price and availability problems with critical drug products.¹²⁶ With limited exceptions, however, the United States does not subject pharmaceuticals to compulsory licensing.

In the case of orphan drugs, manufacturers receive an extended period of market exclusivity, but it includes a provision for compulsory licensing in the event of supply shortages.¹²⁷ In addition, pursuant to federal technology transfer laws,¹²⁸ the government enjoys a limited right to call for compulsory licensing of inventions developed with its assistance: it retains so-called "march in" rights that allow it to revoke a previously granted exclusive license if the licensee fails to make a covered invention available to the public.¹²⁹ Finally,

125. See Brown, *supra* note 2, at A1 ("Other possibilities [for averting future shortages] include the creation of a 'National Vaccine Authority' that would help oversee vaccine development, and the construction of a government-owned, contractor-operated production plant. (These two ideas enjoy little support in the pharmaceutical industry.)"); Jon Cohen & Eliot Marshall, *Should the Government Make Vaccines?*, TECH. REV., May 2002, at 39 (discussing same).

126. See Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK Q. 213, 221-25 (1995); Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1163-64 (1998); Evan Ackiron, Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 177-80 (1991).

127. See 21 U.S.C. § 360cc(b)(1) (2000).

128. Under the Bayh-Dole Act of 1980, private entities may commercialize breakthroughs supported by government funding. See Pub. L. No. 96-517, § 6(a), 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000)); see also *Platzer v. Sloan-Kettering Inst.*, 787 F. Supp. 360, 362 (S.D.N.Y.), *aff'd mem.*, 983 F.2d 1086 (Fed. Cir. 1992). See generally Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996). Under the Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, § 2, 100 Stat. 1785 (codified at 15 U.S.C. § 3710 (2000)), agencies could enter into cooperative research and developments agreements (CRADAs), assigning to private entities the patents for any inventions developed in collaboration with government researchers. Until 1995, the NIH imposed a "reasonable pricing" requirement on products that emerged from a CRADA, which it dropped in the wake of criticism that this amounted to the imposition of price controls. See Baruch Brody, *Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being*, HASTINGS CTR. REP., Mar.-Apr. 1996, at 5, 6.

129. See 35 U.S.C. §§ 201(f), 203 (2000); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 647, 659-66 (2001); Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095, 1099, 1115 (1999).

although the United States does not have separate legislation authorizing compulsory licensing of patents for pharmaceutical products, the Tucker Act provides a right of action for the unlicensed use of a patent by the federal government.¹³⁰ To the dismay of the pharmaceutical industry, the government threatened to use this authority in order to acquire inexpensive supplies of the antibiotic Cipro® (ciprofloxacin) for treating persons exposed to anthrax.¹³¹

Several industrialized countries used to have limited compulsory licensing rules applicable to medical technologies either where necessary to combat a threat to public health or after a period of non-use by the patent holder.¹³² In 1993, Canada discontinued its practice of routine compulsory licensing as a mechanism for controlling the prices of pharmaceuticals,¹³³ though it remains available as an option for public health emergencies.¹³⁴ For drugs patented after May 15, 1997, the World Trade Organization (WTO) appears to prohibit routine compulsory licensing, but, in case of a national emergency, a signatory may authorize compulsory licensing of patented pharmaceuticals if necessary to protect the public health.¹³⁵

130. See 28 U.S.C. § 1498 (2000); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1575-76, 1580-81 (Fed. Cir. 1997). In contrast, a few federal statutes provide for compulsory licensing of patents under limited circumstances in other areas. See 7 U.S.C. § 2404 (2000); 30 U.S.C. § 666 (2000); 42 U.S.C. § 2183 (2000); 42 U.S.C. § 7608 (2000). In rare instances, courts may refuse to enjoin infringement by private parties where the patent holder withholds a license to use the invention in a way that would promote the public health. See *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 945-47 (9th Cir. 1944) (holding invalid patents for a process of using irradiation to fortify margarine with vitamin D to combat rickets, but adding that, even if valid, it would not have enjoined the infringing use).

131. See Chea, *supra* note 46, at E1. The government previously has used this power to procure certain needed drugs such as the antibiotic tetracycline from sources other than the patent holder or its licensees. See MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 186-87 (1974); see also *Carter-Wallace, Inc. v. United States*, 496 F.2d 535, 536 (Ct. Cl. 1974) (tranquilizer meprobamate).

132. See Reed Boland, *RU 486 in France and England: Corporate Ethics and Compulsory Licensing*, 20 LAW MED. & HEALTH CARE 226, 230 (1992).

133. See Patent Act Amendment, 1992, ch. 2, § 3 S.C. 11 (Can.); see also Sheldon Burshtein, *Sublicense or Supply Agreement? Supreme Court of Canada Interpretation Benefits Generic Pharmaceutical Industry*, 54 FOOD & DRUG L.J. 73, 74-75 (1999); Mary Atkinson, Comment, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL'Y J. 181, 191-92 (2002); Christopher Scott Harrison, Comment, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L L. & COM. REG. 457, 505-25 (2001).

134. See Shankar Vedantam & Terence Chea, *Drug Firm Plays Defense in Anthrax Scare: For Now, U.S. Declines to Suspend Bayer's Patent and Authorize Generic Cipro*, WASH. POST, Oct. 20, 2001, at A4 (reporting that Canada had invoked its compulsory licensing authority for this antibiotic).

135. See Trade-Related Aspects of Intellectual Property Rights Agreement, art. 31; see also Sara M. Ford, Comment, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 959-67 (2000); Susan Vastano Vaughan, Note, *Compulsory Licensing of Pharmaceuticals Under TRIPs: What Standard of Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87, 96-100 (2001). The WTO eventually

Of course, to the extent that many of the shortages involve products lacking patent protection, the government would not need to exercise an eminent domain power. Some commentators have suggested even more aggressive government involvement in producing critical drugs, but past experience with public control of vaccine manufacturing suggests caution. Early in the nineteenth century, in response to concerns about the sale of fake smallpox vaccine, Congress established an office responsible for providing genuine supplies, but it repealed the law less than a decade later, after an outbreak of smallpox linked to doses from this federal vaccine agent.¹³⁶ A century and a half later, the National Institutes of Health (NIH) faced criticism for authorizing the release of sub-potent doses of polio vaccine, which some commentators ascribed to a conflict of interest arising from the government's commitment to widespread vaccination.¹³⁷ The public health departments in a couple of states produce their own supplies of certain childhood vaccines,¹³⁸ but doing this for numerous critical pharmaceuticals on a national scale seems both impractical and inadvisable.

In 1992, the Institute of Medicine recommended the creation of a "surge" production capacity for critical vaccines under public ownership,¹³⁹ and it

may authorize compulsory licensing of patented drugs for the treatment of a broad range of serious diseases. See Celia W. Dugger, *A Catch-22 on Drugs for the World's Poor*, N.Y. TIMES, Nov. 16, 2001, at W1; Geoff Winestock & Helene Cooper, *Activists Outmaneuver Drug Makers at WTO*, WALL ST. J., Nov. 14, 2001, at A2.

136. See An Act to Encourage Vaccination, ch. 37, 2 Stat. 806 (1813) (repealed 1822); H.R. REP. NO. 17-93 (1822).

137. See Nicholas Wade, *Division of Biologics Standards: The Boat That Never Rocked*, 175 SCIENCE 1225, 1230 (1972) ("[F]ederal responsibility for vaccine development should be clarified, in a way that ensures the DBS does not develop vaccines in-house."); Nicholas Wade, *Division of Biologics Standards: Scientific Management Questioned*, 175 SCIENCE 966, 967 (1972) (reporting allegations that "management has suppressed or ignored scientific findings that would adversely affect the vaccine market"); see also *Berkovitz v. United States*, 486 U.S. 531, 542-48 (1988) (reviewing lawsuit brought against the NIH and FDA alleging negligence in licensing and releasing lots of oral polio vaccine); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 984 F.2d 124, 125-28 (4th Cir. 1993) (concluding that the government had unjustifiably failed to implement the applicable requirements).

138. See Mowery & Mitchell, *supra* note 9, at 981-83 tbl.2, 995 (noting that Massachusetts and Michigan make DTP vaccines); Stephen Smith, *State Plans a \$77M Lab for Vaccines*, *New Drugs*, BOSTON GLOBE, Mar. 21, 2002, at A1.

139. See INST. OF MED., *EMERGING INFECTIONS: MICROBIAL THREATS TO HEALTH IN THE UNITED STATES* 10-12, 150-58 (1992); see also INST. OF MED., *THE CHILDREN'S VACCINE INITIATIVE: ACHIEVING THE VISION* (Violaine S. Mitchell et al. eds., 1993) (elaborating). The 1986 National Childhood Vaccine Injury Act had included provisions designed to promote vaccine innovation and production. See 42 U.S.C. §§ 300aa-1 to -6 (2000); Alan R. Hinman, *The National Vaccine Program and the National Vaccine Injury Compensation Program*, 44 FOOD DRUG COSM. L.J. 633, 633-34 (1989); Phillip K. Russell, *Development of Vaccines to Meet Public Health Needs: Incentives and Obstacles*, 7 RISK: HEALTH, SAFETY & ENV'T. 239 (1996); see also Rachel Nowak, *U.S. National Program Is Going Nowhere Fast*, 265 SCIENCE 1375 (1994).

reiterated this proposal shortly after the latest terrorist attacks.¹⁴⁰ Some commentators have, however, questioned the wisdom of undertaking such an effort: “The costs of establishing a publicly operated standby facility in the United States to provide a secure source of domestic supply are so high, and the resulting facility so limited to specific vaccines, that any such step would be unwise.”¹⁴¹ As with bulk purchasing to create stockpiles, direct government involvement in the production of vaccines and other critical pharmaceuticals is unlikely to succeed on more than a very limited scale. Instead of trying to displace private manufacturers, the federal government should try to help ensure that market conditions are conducive to the production of ample supplies by multiple sources.

IV. CONCLUSION

For a variety of reasons, shortages of vaccines and other critical pharmaceutical products have increased in the last few years. Pressures emanating from regulatory agencies, courts, and insurers have conspired to make this line of the pharmaceutical business less than attractive. The FDA’s implementation of GMP requirements, especially those governing the production of vaccines and other biologics, have created compliance difficulties for manufacturers; the threat of tort liability continues to drive some drug companies from particular markets; and cost-containment pressures resulting from bulk government purchases or declining levels of insurance reimbursement have eroded profit margins. Under these conditions, the pharmaceutical industry’s focus on blockbuster drugs for lifestyle uses or chronic health conditions should come as no great surprise.

This is a multi-faceted problem that does not admit of any single or simple solution, but the government should not respond in ways that further weaken market incentives. Instead, it should try to encourage private manufacturers to continue supplying critical pharmaceutical products. A number of steps would help improve the business climate: more flexible regulation of manufacturing

140. See Council of the Inst. of Med., *Statement on Vaccine Development*, Nov. 5, 2001, <http://www.iom.edu/iom/iomhome.nsf/pages/vaccine+development> (last visited Oct. 3, 2002); *Bioterrorism Risks: Hearing Before the Subcomm. on Nat’l Sec., Veterans’ Affairs and International Relations of the House Comm. on Gov’t Reform*, 107th Cong. (2001) (testimony of Kenneth I. Shine, President, Institute of Medicine).

141. Mowery & Mitchell, *supra* note 9, at 995, 998; see also *id.* (“Cost and feasibility are the key disadvantages of any publicly financed, publicly owned vaccine production facility that could be pressed into service in the event of a catastrophic supply interruption.”); *id.* (“[IOM] estimated the capital costs alone of a vaccine development and pilot production facility to be \$30 million to \$75 million. The capital costs of a full-scale production facility would undoubtedly be higher Moreover, the costs of a multiproduct facility would be higher still.”); *id.* (“[G]aining and retaining an FDA establishment license for vaccine production requires the continuous production of test lots. Thus a licensed standby facility is feasible only if it is nothing of the kind. Any standby facility would have to be engaged in the regular production of vaccines”).

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facilities, greater protection from the vagaries of tort liability, and the avoidance of excessive cost controls. In addition, the government should bolster its emergency stockpiles, but it must take care to avoid suggestions that the public sector should take over the entire operation, because then we really would have only a single supplier that would risk many of the same shortcomings that government-run monopolies have encountered in other fields.

