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**WHAT DEFINES A PUBLIC HEALTH
EMERGENCY? AN ANALYSIS OF THE
STRATEGIC NATIONAL STOCKPILE AND
THE NATIONAL CHILDHOOD VACCINE
INJURY ACT: THE NEED FOR PREVENTION
OF NONTERROR NATIONAL MEDICAL
EMERGENCIES**

*Kapil Kumar Bhanot**

INTRODUCTION

The United States' childhood immunization program has been admired as one of the nation's most successful public health initiatives.¹ Relatively low cost and mass utilization of vaccinations have made immunization an essential component in the nation's medical care system.² Yet, the very industry charged with caring for the nation's children has been compromised by unforeseen flaws within its

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1. Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1854 (1995) ("Over a period of fifty years, the United States has dramatically reduced the annual occurrence of polio, whooping cough, and measles.").

2. Robin J. Strongin, *U.S. Childhood Vaccine Availability: Legal, Regulatory, and Economic Complexities*, NATIONAL HEALTH POLICY FORUM ISSUE BRIEF NO. 785, 2 (November 15, 2002) ("Vaccines have been heralded as one of the most cost-effective public health and biomedical success stories. Protecting against once-dreaded diseases ranging from polio to diphtheria, they are a staple of most U.S. children's routine medical care.").

infrastructure.³ Of particular concern are vaccine shortages.⁴ Terror concerns after September 11, 2001 have only added to the need for stable immunization protection.⁵ Recent congressional and agency actions have shown that the government recognizes that there are childhood immunization issues in the United States that require a response, and that vaccine stockpiling is an effective solution to the problem.⁶

Fear of litigation has created a shortage in vaccine production, compromising child immunization.⁷ Congress responded to the vaccine shortage by enacting legislation to entice private manufacturers to reenter the vaccine market.⁸ Experts, however, are skeptical and want a more comprehensive solution involving federal, state, and private

3. *Id.* at 4 (stating that shortages of vaccines have “undermine[d] the nation’s ability to protect the health of its citizens”). The Brief states that there are other contributing factors to the dangers of public health crisis, including bioterrorism, fears about vaccine safety, and “herd immunity” (where parents rely on the community to be immune instead of vaccinating their own child). *Id.* at 3. The Brief also states that “[m]any health officials are concerned that the very success of vaccine programs actually may contribute to their downfall.” *Id.*

4. *Id.* at 4 (“Recent shortages have made it particularly difficult for physicians and other health providers to keep track of who has been vaccinated and who requires follow-up.”). See also NAT’L VACCINE ADVISORY COMM., STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES: A REPORT 1 (2003) (stating “[a]n unprecedented and unanticipated shortage of routinely recommended vaccines occurred in the United States . . .”).

5. See Strongin, *supra* note 2, at 2 (“The post-September 11 environment, in which the specter of potential bioterror agents such as anthrax and smallpox looms large, has expanded concerns over the nation’s vaccine infrastructure from the largely pediatric arena to the realm of homeland security.”).

6. See generally 42 U.S.C. § 247d-6b (2004).

7. Vaccine production was compromised by a combination of frivolous lawsuits, legitimate liability claims, and malpractice insurance issues. See S. REP. NO. 99-380 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6345 (“[A]s a result of this increase in litigation . . . [t]he number of childhood vaccine manufacturers has declined significantly.”). See also NAT’L VACCINE ADVISORY COMM., *supra* note 4, at 7 (regarding “[p]roblems of Vaccine Supply in 2001-2002 . . . [t]he categories of factors leading to the vaccine supply shortages are two-fold . . .”).

8. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 (2003) (“The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.”).

entities.⁹ This more expansive, coordinated approach should be adopted by Congress through statute.

Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA) in response to vaccine supply shortages and a destabilization of childhood immunization.¹⁰ The NCVIA charged the Department of Health and Human Services (HHS) with the task of overseeing vaccination in the United States through initiatives such as the National Vaccine Program.¹¹ In the early 1990s, with the danger of terrorism looming, President Clinton issued a presidential decision directive ordering HHS to commence the stockpiling of vaccines for terror-related threats.¹²

In 2002, the focus on terrorism threats brought about major realignment to the infrastructure of the U.S. government.¹³ Among many other changes, the administration of government vaccine stockpiling for terror threats shifted from HHS to the Department of Homeland Security (DHS).¹⁴ HHS, however, retained control over vaccine stockpiling for non-terror-related purposes,¹⁵ splitting authority of vaccine stockpiling between the two administrative agencies.

9. NAT'L VACCINE ADVISORY COMM., *supra* note 4, at 18 (2003) ("Current efforts to encourage appropriate use of vaccines should be amplified by a coordinated program involving government, industry, academia, professional societies, and consumers to emphasize the value of recommended vaccines for the individual and the community.").

10. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1-34 (1986).

11. *Id.*

12. Presidential Decision Directive-62, 34 WEEKLY COMP. PRES. DOC. 21 (May 22, 1998) [hereinafter PDD-62]. The full text of PDD-62 is a classified document.

13. See Daniel A. Cotter, *The Homeland Security Act of 2002: A Federal Response to September 11th*, 17-MAR CHICAGO BAR ASS'N REC. 37 (2003) ("The Act restructures the executive branch of the Federal Government, moving all or parts of the 22 existing agencies to the Department, in an effort to more effectively meet the threat to our homeland posed by terrorism.").

14. 42 U.S.C. § 247d-6b (2004). The Secretary of HHS lost autonomous control of terror-related stockpiling to the Secretary of the Department of Homeland Security. Under the Project Bioshield Act, the secretary of Health and Human Services maintains the stockpile, and the secretary of Homeland Security has a secondary, coordinating position. See Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (codified as amended in scattered sections of the U.S.C.). Cf. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 42 U.S.C.).

15. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1-34 (2003).

Despite the work of HHS, vaccine shortages and a decline in childhood immunization remain critical problems in the United States.¹⁶

This Comment first discusses the federal government's response to vaccine shortages caused by market failures in the vaccine industry and specifically to the vaccine supply shortage of 1991. The focus of this Comment then turns to the federal government's response to terror-related public health emergencies, the National Pharmaceutical Stockpile. This Comment then traces the evolution of the National Pharmaceutical Stockpile from its inception under the Centers for Disease Control and Prevention (CDC) to its new form as the Strategic National Stockpile, and the role the Department of Homeland Security plays in its administration. This Comment then explains how this evolution has affected childhood vaccine stockpiling initiatives. This Comment then analyzes recent federal vaccine stockpiling legislation in light of the Supreme Court's view of statutory interpretation by administrative agencies. This Comment further analyzes the need for stockpiling in non-terror-related public health emergencies, and discusses how administrative agencies have proposed to fulfill this need. Finally, this Comment concludes that the Strategic National Stockpile should be a model for government prevention of non-terror-related national medical emergencies and that Congress should implement childhood immunization stockpiling initiatives through statute.

I. RESPONSE TO DANGER: THE FEDERAL GOVERNMENT'S REACTION TO VACCINE INJURY AND SHORTAGE

The federal government has reacted to vaccine shortages by enacting legislation providing for the uninsured and conducting studies that identify the problem.¹⁷ In each action, Congress and HHS acknowledged vaccine stockpiling as an effective solution; however, the federal government has never formally created an effective child immunization stockpiling program through statute.¹⁸

16. *See infra* Part I.B.

17. *See infra* Part I.A.

18. *Id.*

A. *The National Childhood Vaccine Injury Act of 1986*

The government's initial response to vaccine shortages was to protect the vaccine industry from lawsuits. An increase in lawsuits during the 1970s concerning injuries by the diphtheria, pertussis, and tetanus vaccines led to large damage awards for victims' tort claims.¹⁹ Many manufacturers stopped producing vaccines because due to increased liability.²⁰ Simultaneously, states began enacting immunization laws that required parents to have their children vaccinated before entering school.²¹ Soon many essential vaccines were in short supply leading Congress to respond to the increased risk of epidemic disease²² by enacting the National Childhood Vaccine Injury Act of 1986.²³ The NCVIA evidenced Congress' intent to stabilize the private vaccine industry through two federal immunization initiatives,²⁴ the Vaccine Injury Compensation Program and the National Vaccine Program.²⁵

The Vaccine Injury Compensation Program gave victims harmed by adverse reactions to vaccination alternatives to litigation, including immediate compensation based on government-regulated injury determinations.²⁶ Such compensation was given without determining causation on a case-by-case basis, and without having to show negligence on the part of the manufacturer.²⁷ A "Vaccine Injury

19. Ctrs. for Disease Control & Prevention, National Vaccine Program: Overview of Vaccine Safety, at <http://www.cdc.gov/nip/vacsafe>. See also Freed et al, *Safety of Vaccinations: Miss America, the Media, and Public Health*. 276 (23) JAMA 1869-1872 (1996).

20. Freed et al., *supra* note 19.

21. S. REP. NO. 99-380 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6346.

22. *Id.*

23. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1-34 (2003). See also S. REP. NO. 99-380 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344 (stating that the Act "creates a new system for compensating individuals who have been injured by vaccines routinely administered to children").

24. S. REP. NO. 99-380 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6345 ("The number of childhood vaccine manufacturers has declined significantly . . . [this] has led to the Committee's re-evaluation of all current vaccine and vaccine-related activities.").

25. 42 U.S.C. §§ 300aa-1-34 (2003).

26. *Id.*

27. See also S. REP. NO. 99-380 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6353 ("While this bill does not prohibit a vaccine-injured person who has

Table” was placed within the statute listing vaccines and symptoms necessary to receive compensation from the federal government.²⁸ This compensation added an incentive for manufacturers to produce vaccines by shielding them from the potential costs of product liability litigation.²⁹

The National Vaccine Program was created upon what Congress characterized as “advances in biotechnology that could lead to the production of new and improved vaccines, as well as the lack of organization at the Federal [level] in the promotion and use of vaccines.”³⁰ The NCVIA placed the program under HHS control³¹ and gave the Director of the National Vaccine Program several responsibilities, including: 1) coordinating and providing direction for vaccine research; 2) ensuring the safety of vaccines; 3) managing the testing, licensing, production, and procurement of vaccines; and 4) overseeing the distribution and use of vaccines.³² To accomplish these

completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits against manufacturers.”).

28. 42 U.S.C.A. § 300aa-14.

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program.

Id.

29. See *supra* note 27. See also 42 U.S.C. § 300aa-14 (for how compensation program was structured and administered). See also 1 IND. HEALTH L. REV. 1, 20 (2004) (“The National Vaccine Injury Compensation Program (‘NVICP’) exists both to provide compensation to injured vaccines and also to shield the vaccine industry from excessive and unpredictable liability.”). The statutory structure of the Vaccine Injury Compensation Program can be contrasted with policy based compensation, such as the September 11, 2001 Compensation Fund. See Catherine M. Sharkey, *Punitive Damages as Societal Damages*, 113 YALE L.J. 347, 405 (2003) (“There has been a recent surge of interest in the concept of damages funds, prompted in large part by their utilization in successful class action settlements and by the existence of the September 11th Victim Compensation Fund of 2001.”).

30. S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6349.

31. 42 U.S.C. § 300aa-1. See also 20 U.S.C. § 3508 (the enabling statute of HHS).

32. 42 U.S.C. § 300aa-2. See also S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6351 (“The National Vaccine Program will be responsible for determining the vaccine supply needs of the United States.”).

ends, the NCVIA required the Director to work with a number of government agencies including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration's Office of Biologics Research and Review.³³ The NCVIA also charged the Director with allocating funding among the various agencies for the implementation of a vaccine plan.³⁴

The NCVIA provides explicit direction for implementing vaccine initiatives,³⁵ including the preparation of an annual vaccine plan and the establishment of the National Vaccine Advisory Committee (NVAC).³⁶ The plan was established to designate priorities within the National Vaccine Program, provide a roadmap to agency coordination, and describe the optimal use of resources.³⁷ Additionally, the NCVIA authorized the NVAC to perform a number of functions. It charged the NVAC to assist the Director in the implementation of the vaccine plan.³⁸ It also placed responsibility upon the NVAC to recommend research priorities to encourage availability and adequate supply and to assist in devising a plan to make a "supply of safe and effective vaccination products" available to the states.³⁹ The structure of the NCVIA required coordination not only within the designated federal agencies, the NVAC, and the Director, but also between the state and federal governments.⁴⁰ This coordination was essential to create

33. 42 U.S.C. 300aa-2. *See also* S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6352 ("The National Vaccine Program would constitute the central focus in the Federal government for gathering and analyzing information about non-government vaccine and immunization activities.").

34. 42 U.S.C. § 300aa-2. *See also* S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6352 ("These funds would be made available during the year that the Plan is in force to make sure that the failure of one agency to meet an objective does not cripple the whole national vaccine effort.").

35. *See generally* 42 U.S.C. § 300aa-1-5.

36. *Id.* § 300aa-3-5.

37. *Id.* § 300aa-3. *See also* S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6352 ("The annual production of the Plan is to be an integral part of the ongoing process for coordinating and providing direction to collaborating agencies.").

38. 42 U.S.C. § 300aa-3.

39. *Id.* § 300aa-5.

40. S. REP. NO. 99-380 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6346 ("Over the years, State government has become an important adjunct in carrying out the Federal government's responsibility to prevent the spread of infectious diseases."). The Vaccine Act was able to stop production woes in the industry and allow reentry into the vaccine market. Lars Noah, *Triage in the Nation's Medicine*

solutions, albeit temporary ones, to immunization shortfalls. However, while Congress attempted to address these problems, their actions were inconsistent and did not provide proper guidance and support for childhood immunization shortfalls.

B. The Vaccine Supply Shortage of 1991: Implementation of a Vaccine Stockpile

Despite the enactment of the NCVIA, the United States experienced other shortages in vaccines for children.⁴¹ Many experts concluded the shortage was caused by a combination of burdensome government regulations and the rising costs of producing vaccines.⁴² Others contended that the reemergence of personal injury tort claims and production difficulties were responsible.⁴³ Congress attempted to alleviate the problem by authorizing the creation and maintenance of a vaccine stockpile in 1982; however, funding was pulled in 1991 due to the recession.⁴⁴ During its nine-year existence, the vaccine stockpile was effectively used seven times.⁴⁵

By 1993, health care reform and child welfare became central issues of President Clinton's domestic policy agenda.⁴⁶ The Clinton administration proposed that the government provide childhood

Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs, 54 S.C.L. REV. 371, 373-374 (2002) ("The statute helped stabilize the pediatric vaccine market . . .").

41. See Noah, *supra* note 40, at 374 ("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.").

42. Spencer Rich, *Child Vaccine Shortage Seen at Health Centers; Group Disputes HHS on Low Immunization*, WASH. POST, May 22, 1991, at A03. HHS argued that there was a six-month supply, and the real problem was people not coming in. *Id.* See also U.S. GEN. ACCOUNTING OFFICE, NO. GAO-02-987, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges*, 14-19 (2002).

43. See Noah, *supra* note 40, at 374.

44. David C. Mowery & Voilaine Mitchell, *Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives*, 20 J. HEALTH POL. POL'Y & L. 973, 991 (1995) ("Although the existing twenty-four-week stockpile of the six vaccines previously listed ha[d] been maintained, no new vaccines . . . have been stockpiled.").

45. *Id.*

46. *Id.* at 996.

vaccines at no charge through a universal purchase program.⁴⁷ Congress, however, did not approve of no-cost vaccines. Eventually a compromise was reached and inserted within the Omnibus Budget Reconciliation Act of 1993.⁴⁸ Under the compromise, no-cost pediatric vaccines were provided for those children who were uninsured or on Medicaid.⁴⁹ The legislation also required the Secretary of HHS to stockpile pediatric vaccines that may be unavailable for purchase or delivery.⁵⁰ While the legislation provided for expanded CDC purchases of vaccines at a negotiated price, it also linked future increases in the cost of vaccines to the rate of inflation. This ultimately proved to be an ineffective provision as the economy was stable and inflation remained flat throughout the 1990s, thereby allocating less money for the government to buy vaccines.⁵¹ As a result, vaccine shortfalls and childhood immunization concerns continued for the remainder of the decade.⁵²

C. It's Not Over: The Government Acknowledges the Continued Problem of Vaccine Shortages

The federal government again acknowledged a vaccine shortage in a report issued by the NVAC in January of 2003.⁵³ HHS requested that the report evaluate vaccine supply shortages and recommend ways to strengthen the supply.⁵⁴ The report found an “unprecedented and

47. *Id.*

48. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (codified as amended in scattered sections of U.S.C.). The relevant portions of the Act concerning vaccines were codified at 42 U.S.C. § 1396s (2003).

49. 42 U.S.C. § 1396s.

50. *Id.* § 1396s(a)(2)(b) (“To the extent that a sufficient quantity of vaccine is not available for purchase or delivery . . . the Secretary shall provide for the purchase and delivery . . . with priority given to federally vaccine-eligible children unless the Secretary finds there are other public health considerations.”).

51. Mowery & Mitchell, *supra* note 44, at 996 (“[B]ut this legislation seems likely to do little to expand the sources of supply of existing vaccines, for which future price growth is capped.”).

52. *Id.*

53. The National Vaccine Advisory Committee released its annual report on the state of immunization. See NAT'L VACCINE ADVISORY COMM., *supra* note 4, at 1.

54. *Id.* at 2. Recent flu vaccine shortages further compromised the nation's immunization in the winter of 2003. See Rob Stein, *Concerns Raised Over Supply*

unanticipated shortage of routinely recommended vaccines . . . beginning in 2001, resulting in significant and extended shortages of routinely administered vaccines”⁵⁵

The NVAC designated several areas of concern directly affecting the supply of children’s vaccines. Their first concern was the length of time required by the FDA’s approval process.⁵⁶ Secondly, low profit margins within the vaccine industry “may have contributed to a reduction in the number of vaccine manufacturers during the past 25 years.”⁵⁷ The NVAC also cited the complexity and uncertainty of developing new vaccines as a direct barrier to entry into the vaccine market.⁵⁸ In addressing the concerns to the shortage problem, the NVAC noted that stockpiles are the most cost-effective solution to overcoming certain vaccine shortages.⁵⁹

II. STOCKPILING IN ACTION: THE STRATEGIC NATIONAL STOCKPILE

With the institution of a pharmaceutical stockpile program in May 1998, the federal government effectively addressed the concern of a potential terror-related public health emergency, something it has failed to do with respect to the inadequate supply of childhood immunization vaccines.⁶⁰ By clearly defining stockpiling through statute and by coordinating between federal and state authorities, the federal government’s terror-related stockpiling program provides an excellent model on how to address vaccine shortages affecting childhood immunization.

A. Terror Pre-9/11: The National Pharmaceutical Stockpile

of Flu Shots; In Year of Brisk Demand, Vaccine Makers Have Shipped Entire Inventories, WASH. POST, Dec. 6, 2003, at A02.

55. NAT’L VACCINE ADVISORY COMM., *supra* note 4, at 1.

56. *Id.* at 4 (“The development of new vaccines may take many years, starting with the pre-clinical work and progressing through clinical studies that are needed to establish the safety and efficacy of the product.”).

57. *Id.* at 5.

58. *Id.*

59. *Id.*

60. *See infra* Part II.A-B.

In May of 1998, after embassy bombings in Kenya, Uganda, and the Philippines, coupled with escalated tension in Saudi Arabia, President Clinton issued a presidential decision directive.⁶¹ The directive ordered the implementation of a plan to coordinate federal and state efforts to deter and respond to terrorist attacks on the United States.⁶² HHS was given leading authority in planning and preparing a response to emergencies related to weapons of mass destruction.⁶³ The President also required both HHS and the Department of Veterans Affairs (VA) to stockpile antidotes and pharmaceuticals “in the event of a weapons of mass destruction incident.”⁶⁴

In 1999 Congress appropriated funding for both the presidential directive and the newly established National Pharmaceutical Stockpile (NPS). The CDC was assigned the task of implementing the stockpile initiative, including buying vaccines and assisting state and city planners in planning for terrorist attacks.⁶⁵

Under the NPS program, federal and state governments were required to collaborate and provide large quantities of medical supplies to those within the U.S. population suffering from terrorist attacks.⁶⁶ The NPS program was organized to provide state and local governments with twelve-hour “push packages” that would arrive in any city in the country within twelve hours through coordination with the United States Postal Service, Federal Express, and United Parcel Service.⁶⁷ These push packages, kept at a dozen undisclosed locations around the country, contain large packages of drugs, antidotes, and other medical supplies, including vaccines to protect against anthrax, plague, tularemia, and nerve agents.⁶⁸ In fact, the first use of the NPS

61. PDD-62, *supra* note 12, at 1. The full text of PDD-62 is a classified document.

62. *Id.*

63. *Id.*

64. *Id.*

65. CTRS. FOR DISEASE CONTROL & PREVENTION, HELPING STATE AND LOCAL JURISDICTIONS PREPARE FOR A NATIONAL EMERGENCY (August 11, 2003), available at <http://www.bt.cdc.gov/stockpile> (last visited September 21, 2004) (“In 1999 Congress charged the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) with the establishment of the National Pharmaceutical Stockpile (NPS).”).

66. CTRS. FOR DISEASE CONTROL & PREVENTION, RECEIVING, DISTRIBUTING, AND DISPENSING THE NATIONAL PHARMACEUTICAL STOCKPILE: A GUIDE FOR PLANNERS 3 (2002).

67. *Id.* at 4.

68. *Id.*

was in New York City immediately after the terrorist attacks on September 11, 2001. The NPS push package arrived within seven hours of the attack.⁶⁹ The program was initially given a budget of \$160 million in 1999. Today the stockpile has a budget of over \$600 million.⁷⁰

Implementation of the NPS Program involved intense collaboration between federal, state, and local government officials.⁷¹ Locally staffed command and control centers were established throughout the country to assist NPS teams and to act as part of a broader state and local bioterrorism response plan.⁷² The CDC designated “Technical Advisory Response Units” to consult with and aid state and local authorities to oversee all NPS functions.⁷³ While the NPS is an important asset in itself, it serves to support a larger bioterrorism response plan among local, state, and federal authorities.⁷⁴

B. R.I.P. NPS: The Creation and Modification of the Strategic National Stockpile

The terrorist attacks of September 11, 2001 had a profound impact on legislation governing pharmaceutical stockpiling, amplifying the importance of an NPS-type program as part of a larger bioterrorism response plan. As a result, Congress soon passed the Public Health

69. *Id.*

70. *Compare Bioterrorism: Hearing Before the Senate Health, Education, Labor & Pensions Committee, Subcommittee on Public Health and Safety*, 106th Cong. (1999) (statement by William Clark, Deputy Director, Office of Emergency Preparedness, U.S. Department of Health and Human Services) (“I must say our medical bioresponse capabilities are limited, but we are using the \$160 million appropriated for Bioterrorism in FY 99 to change that, and the President’s FY 2000 budget . . .”) with 42 USC § 300hh-12 (describing funding “authorized to be appropriated [in the amount of] \$640,000,000 for fiscal year 2002 . . .”).

71. Administrative agencies included in direct implementation included the Department of Health and Human Services, the Centers for Disease Control and Prevention, the Department of Veterans Affairs, and state and local planners. *CTRS. FOR DISEASE CONTROL & PREVENTION*, *supra* note 66, at 4.

72. *See generally id.*

73. *Id.*

74. PDD-62, *supra* note 12, at 1. The full text of PDD-62 is a classified document.

Security and Bioterrorism Response Act of 2002 (Act).⁷⁵ The Act not only granted statutory authority for the NPS, it transformed the NPS into the Strategic National Stockpile (SNS), broadening the program's purpose and increasing its funding to a level above that outlined in President Clinton's 1998 directive.⁷⁶ The Act, for the first time, defined stockpile as the "physical accumulation" of medical supplies or contractual agreements made between the Secretary of HHS and private entities that would provide supplies.⁷⁷ The Act further delineated the purpose of the SNS as "provid[ing] for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency."⁷⁸ Under the broadened purpose of protecting against bioterrorism, the Act initiated development and accumulation of smallpox vaccines as part of the revamped stockpiling program.⁷⁹

The Act enumerated a number of intergovernmental collaboration procedures and security measures for the implementation of the SNS program. The Secretary of HHS was charged with management of the stockpile in consultation with a "working group" of cabinet level officials from various executive departments and agencies.⁸⁰ Congress

75. The Public Health and Bioterrorism Preparedness Response Act of 2001, S.1715. *repealed by* The Public Health Security and Bioterrorism Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 194 (codified as amended in scattered sections of 42 U.S.C.). Although the Act cited in notes 74-89 was repealed, discussion of the changes it made are important to understand the current stockpile regime.

76. 42 U.S.C. § 300hh-12 (2002) (repealed 2004). *See id.* § 247d-6(b) (2004).

77. *Id.* § 300hh-12(d) (repealed 2004).

78. *Id.* § 300hh-12(a)(1) (2002) (repealed 2004). *See also* 149 CONG. REC. E919 (2002) (enacted) (stating "[s]pecific reference to the needs of children and other vulnerable populations is included").

79. 42 U.S.C. § 300hh-12(b) (repealed 2004).

80. *Id.* § 300hh-12(a)(2)(A) (repealed 2004). *See also id.* § 247d-6(a). The Act defines "Working Group" as:

The Secretary, in coordination with the Secretary of Agriculture, the Attorney General, the Director of Central Intelligence, the Secretary of Defense, the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Director of the Federal Emergency Management Agency, the Secretary of Labor, the Secretary of Veterans Affairs, and with other similar Federal officials as determined appropriate, shall establish a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies.

Id. § 247d-6(a).

also delegated to the HHS Secretary the authority to coordinate with state and local agencies in running the program.⁸¹ Specifically, the Secretary is to “devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate federal, state, and local agencies, and the public and private health infrastructure.”⁸² Congress also included a security element which bars any entity from disclosing any information concerning the location of the stockpile.⁸³

On September 11, 2001, terrorists hijacked four American jetliners in a coordinated attack and flew them into the World Trade Center and the Pentagon resulting in the loss of thousands of American lives and the initiation of a global war on terror.⁸⁴ Shortly thereafter, the creation of the Department of Homeland Security (DHS) via the Homeland Security Act of 2003 (HSA) significantly affected the newly created stockpile.⁸⁵ The HSA annexed many functions from the HHS, including the Office of Emergency Preparedness.⁸⁶ It also amended the stockpile in many significant ways, including transferring management of the stockpile to DHS.⁸⁷ Specifically, the measure charged the DHS Undersecretary for Emergency Preparedness and Response with the responsibility for directing the stockpile under the consult of the Secretary of HHS.⁸⁸ Both the revamping of the stockpile

81. 42 U.S.C. § 300hh-12(a)(2) (repealed 2004).

82. *Id.* § 300hh-12(a)(2)(E) (repealed 2004).

83. *Id.* at §300hh-12(a)(2)(F) (repealed 2004).

84. Michael Grunwald, *Terrorists Hijack 4 Airliners, Destroy World Trade Center, Hit Pentagon; Hundreds Dead; Bush Promises Retribution; Military Put on Highest Alert*, WASH. POST, September 12, 2001, at A01.

85. See generally George W. Bush, *The Department of Homeland Security: Executive Brief*, June 2002.

86. Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (codified as amended in scattered sections of the U.S.C.). See also H.R. REP. NO. 99-908 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344.

87. Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (codified as amended in scattered sections of the U.S.C.).

88. 6 U.S.C. § 313(6), Pub. L. No. 107-296 § 1705, 116 Stat. 2316 (repealed 2004). Direction of the stockpile is no longer a responsibility of the Under Secretary, due to the passage of the Project Bioshield Act of 2004. See *infra* note 96. See 42 U.S.C. § 300hh-12 (stating in the amendments to the Code that the Secretary will now work “in coordination with” the Secretary of the Department of Homeland Security), transferred to 41 U.S.C. §247d-6(b) by the Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, July 21, 2004, then amended to transfer the stockpile back to HHS. The Secretary of DHS is now in a consulting position for oversight of the stockpile. *Id.*

program and its transfer to the DHS emphasized the government's commitment to protect against terrorism with stockpiling initiatives.⁸⁹ However, the management and authority of the SNS was significantly altered yet again by Project Bioshield.⁹⁰

C. Project Bioshield

The management of the SNS program was again significantly altered through the creation of Project Bioshield.⁹¹ With the recent passage of the Project Bioshield Act of 2004 ("PBA"), Congress amended the Public Health Security and Bioterrorism Preparedness and Response Act to transfer primary control of the SNS back to the Secretary of HHS.⁹² The Secretary of HHS has regained primary authority regarding the management and maintenance of the stockpile and the Secretary of DHS has a coordinating role.⁹³

The Project Bioshield Act not only transferred control of the stockpile back to HHS, it also expanded that agency's duties to include development of future vaccines.⁹⁴ The PBA funds the research and development of new vaccines and other drugs to protect against biological, chemical, and nuclear national security threats.⁹⁵ It allocates \$5.6 billion to encourage research and development of drugs not yet available⁹⁶ and authorized the Secretary of HHS to stockpile

89. *See supra* Part II.B.

90. Project Bioshield Act of 2004, Pub. L. No. 108-276, 188 Stat. 835 (2004) (codified as amended in scattered sections of the U.S.C.).

91. *Id.*

92. *See supra* note 88.

93. *Id.*

94. *Id.*

95. *See* 42 U.S.C. § 319F-1. *See also* Press Release, Tauzin Applauds House Passage of Project Bioshield Act of 2003, at http://energycommerce.house.gov/108/News/07162003_1042.htm.

[Project Bioshield] will encourage the research and development of new vaccines, drugs, or other countermeasures to deal with those biological, chemical, nuclear, or radiological agents that pose a material threat to our national security. This list includes six dangerous agents: small pox, anthrax, the plague, botulism, hemorrhagic fevers (ebola), and tularemia – many of which lack any effective treatment or antidote today.

Id.

96. Project Bioshield Act of 2004, Pub. L. No. 108-276, 188 Stat. 835 (2004) (codified as amended in scattered sections of the U.S.C.) *See also* *CBO Predicts*

drugs that are integral to national security, but not yet approved by the FDA.⁹⁷ Today the SNS is a joint collaboration effort involving numerous federal agencies, state, and local authorities.⁹⁸ Despite the many changes and modifications since September 11, 2001, this type of coordination is an excellent model for childhood immunization initiatives because of the clarity within the statute and active participation of state and local authorities.⁹⁹ In order for HHS to use stockpiling as a method of addressing childhood immunization concerns, they must do so through statute.

If HHS acts without congressional authority, several parties may object. Potential objectors include Congress, and those within HHS and other administrative agencies who disagree with the disbursement and use of funds for childhood immunization initiatives. Also, current vaccine manufacturers are reluctant to see new entrants in the vaccine market when the current climate allows them to produce vaccines only when there is dire need and without price competition.¹⁰⁰ Without clear language in a federal statute granting such authority, HHS will be

Project Bioshield will Cost Over \$8 Billion in Next 10 Years, 45 No. 19 GOV'T CONTRACTOR P 205 (May 14, 2003) [hereinafter *CBO Predicts*] ("Because several of these vaccines and treatments are not yet available, the cost of purchasing them is uncertain . . . [t]o purchase, store, and replace these counter measures, the Government plans to spend \$5.6 billion during the years 2004-2013.").

97. Project Bioshield Act of 2004, Pub. L. No. 108-276, 188 Stat. 835 (2004) (codified as amended in scattered sections of the U.S.C.) (amending section regarding smallpox vaccine development). This authorization will allow stockpiling of drugs that are integral to national security to circumvent the approval process.

98. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 65.

To conduct this outreach and training, CDC and SNS Program staff are currently working with DHS, HHS agencies, Regional Emergency Response Coordinators at all of the U.S. Public Health Service regional offices, state and local health departments, state emergency management offices, the Metropolitan Medical Response System cities, the Department of Veterans' Affairs, and the Department of Defense.

Id.

99. *See infra* Part V.A.

100. Manufacturers are reluctant to enter the vaccine market because of a "wobbly distribution network" that creates surplus in one region and shortages in another. Industry shortfalls allow manufacturers to only make as much vaccine as is needed to prevent medical disasters. Bernard Wysocki Jr., *Eight Shortages Since 2000; Fewer Shots for Everything from Tetanus to Chickenpox*, WALL ST. J., December 8, 2003, at A1.

forced to rely on the deference granted to the agency when the statute on which such authority is based is determined to be ambiguous.

III. DEGREES OF DEFERENCE: JUDICIAL REVIEW OF ADMINISTRATIVE ACTION

The authority to promote agency action concerning the National Childhood Vaccine Injury Act has been questioned before.¹⁰¹ If the HHS were to act on childhood vaccine stockpiling initiatives, judicial deference may be given to such actions.¹⁰² When reviewing the legitimacy of agency determinations, the Supreme Court has developed an analysis that allows for deference to the agency as an expert in its field.¹⁰³ The following discussion provides a background of the framework underlying the Supreme Court's approach to reviewing agency action.

A. The Early Approach to Administrative Interpretation

In *Skidmore v. Swift & Co.*, the Supreme Court found that light deference should be given to an interpretation of a statute when made by an administrative agency.¹⁰⁴ In *Skidmore*, employees of Swift & Company brought an action under the Fair Labor Standards Act to receive compensation for overtime pay and liquidated damages.¹⁰⁵ The

101. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7679 (Feb. 8, 1995) (codified as 42 C.F.R. § 100) (explaining that “[s]everal commenters suggested that the Department had exceeded its authority in promulgating the regulation”). See also PETER L. STRAUSS ET AL., GELLHORN & BYSE'S ADMINISTRATIVE LAW: CASES AND COMMENTS 902 (10th ed. 2003).

102. See generally *infra* Part III.A-B.

103. See also STRAUSS ET AL., *supra* note 101, at 978 (“Whatever the problems of reviewing findings of fact, the proper standard of review is far more controversial when other kinds of ‘questions’ are under review.”).

104. 323 U.S. 134 (1944).

105. *Id.* at 135. As a condition to their oral agreement to employment, the employees agreed to stay in a fire hall provided by the company to stay on the premises in case of fire or distress. While there, the men were free to use their

point of contention was defining “working time” within the Fair Labor and Standards Act (FLSA).¹⁰⁶ The lower court found that the activities of the employees did not constitute working time as defined by the FLSA.¹⁰⁷ Also, it interpreted congressional intent of the phrase “working time” as a “conclusion of law,” without taking into account the agency’s interpretation.¹⁰⁸

On appeal to the Supreme Court, Justice Jackson stated that the lower court erred by failing to take into account the interpretation that was given by the agency.¹⁰⁹ The Supreme Court held that the agency’s policies and standards are entitled to respect and review by the court, despite the fact that they were not created through an adversarial process.¹¹⁰ The Court further stated that while the agency’s policies were “not controlling upon the courts by reason of their authority, [they] do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.”¹¹¹ The Court remanded the case to the district court with instructions to reevaluate the agency’s interpretation, with some deference to its interpretation, now that it was not restricted by the “notion that waiting time may not be work, an understanding of the law which we hold to be erroneous.”¹¹²

B. Modern Review and Deference in Administrative Action

Modern review of administrative agency action is more deferential than the earlier *Skidmore* review, granting higher deference to agency

time as they saw fit, so long as they were close to the fire hall and were ready to respond to alarms.

106. *Id.* at 163.

107. *Id.* at 162.

108. *Id.*

109. *Skidmore v. Swift & Co.*, 323 U.S. 134, 137 (1944) (“Instead, it put this responsibility on the courts . . . [b]ut it did create the office of Administrator, impose upon him a variety of duties, endow him with powers to inform himself on conditions in industries and employments subject to this Act . . .”).

110. *Id.* at 140.

111. *Id.* (“The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.”).

112. *Id.*

positions.¹¹³ In *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, the Supreme Court created a two-step analysis when reviewing an agency's construction of a statute.¹¹⁴ In *Chevron*, the Clean Air Act Amendments of 1977 enumerated requirements for states that had not "achieved the national air quality standards established by the Environmental Protection Agency . . . pursuant to earlier legislation."¹¹⁵ The case centered on the EPA's interpretation of the statutory term "stationary source."¹¹⁶ The EPA allowed states to treat all devices which emitted pollutants "within the same industrial grouping as though they were encased within a single 'bubble.'"¹¹⁷ The Natural Resources Defense Council, which thought that such a position would enable facilities to avoid stringent emissions limitations and thus hurt the environment, filed suit.

Writing for the majority, Justice Stevens held that when reviewing an agency's construction of a statute, a court engages in a two-step process.¹¹⁸ The first step analyzes whether Congress has "directly spoken to the precise question at issue" or whether congressional intent is unclear.¹¹⁹ The Court found that if Congress' intent was clear, then the analysis is over, and courts should give effect to the "expressed intent of Congress."¹²⁰ However, if Congress explicitly left a gap in the statute, or congressional intent cannot be determined, the reviewing court should give "considerable weight" to agency regulations.¹²¹

In determining whether the agency expressed a proper construction of the statute, the Court allows "considerable weight" unless the agency's construction is "arbitrary, capricious, or manifestly contrary

113. See *infra* Part III.A.

114. 467 U.S. 837, 842 (1984). See also the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (1977). For information concerning the impact of *Chevron* on administrative action see Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 GEO. L.J. 833 (2001) ("[*Chevron* has] dramatically expanded the circumstances in which courts must defer to agency interpretations of statutes."). The *Chevron* decision has been seen as "[o]ne of the most important decisions in the history of administrative law." 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 3.2, at 140 (4th ed. 2004).

115. *Chevron*, 467 U.S. at 840.

116. *Id.*

117. *Id.*

118. *Id.* at 842.

119. *Id.*

120. *Chevron*, 467 U.S. at 843.

121. *Id.*

to the statute.”¹²² The Court stated that it is important for courts to show deference to an administrative agency’s construction of a statute as agencies are entrusted by Congress to execute such legislation.¹²³

The Court found that the EPA’s interpretation of the statute was reasonable based on congressional legislation and its history.¹²⁴ As a result, courts after *Chevron* gave far more deference to agency action than did the *Skidmore* decision.¹²⁵

C. Further Defining Deference: Agency Action with the Force and Effect of Law

In *United States v. Mead Corporation*, the Supreme Court found that not all agency action is entitled to *Chevron* deference.¹²⁶ In *Mead*, an importer challenged a custom official’s classification of its day planner notebook products for tariff purposes.¹²⁷ The Secretary of the Treasury authorized customs officials to set tariff classifications for particular imports.¹²⁸ *Mead* challenged the agency’s reclassification of its products from a tariff-free category to one that carried a tariff of four percent.¹²⁹ The agency, relying on *Chevron*, argued that its reclassification was entitled to heavy deference. However, the Court held that the agency’s tariff ruling would not receive *Chevron*

122. *Id.* at 843, 844.

123. *Id.* at 844.

124. *Id.* at 845.

125. See generally *I.N.S. v. Aguirre-Aguirre*, 526 U.S. 415 (1999).

126. 533 U.S. 218, 220 (2001).

127. *Id.* at 224, 225. Modern deference has also been defined by other Supreme Court decisions. See *Christensen v. Harris County*, 529 U.S. 526 (2001). See also Eric R. Womack, *Into the Third Era of Administrative Law: An Empirical Study of the Supreme Court’s Retreat From Chevron Principles in United States v. Mead*, 107 DICK. L. REV. 289, 304 (2002).

The first two major administrative law decisions of the twenty-first century are also, appropriately, the signal of a new era of lessened judicial deference to agency interpretations. *Christensen* and *Mead* confirmed in judicial precedent the signals the Supreme Court had given in earlier cases that it was unprepared to extend *Chevron* deference to informal agency actions.

Id.

128. *Mead*, 533 U.S. at 222.

129. *Id.* at 225.

deference as Congress never intended to “delegate authority to Customs to issue classification rulings with the force of law.”¹³⁰

Justice Souter explained that *Chevron* deference would be triggered only when Congress delegated authority to make rules “carrying the force of law.”¹³¹ Examples of such delegation include “an agency’s power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.”¹³² While the customs rulings fell outside the boundaries of *Chevron*, the Court remanded the case to determine whether the tariff ruling should receive the lower *Skidmore* standard of deference.¹³³ The Court stated that “*Chevron* did nothing to eliminate *Skidmore*’s holding that an agency’s interpretation may merit some deference whatever its form, given the ‘specialized experience and broader investigations and information’ available to the agency, and given the value of uniformity in its administrative and judicial understandings of what a national law requires.”¹³⁴ The *Mead* Court further added that *Chevron* left *Skidmore* intact where the statute does not indicate any intent to delegate general authority to make rules with the force of law.¹³⁵

IV. A SHIFT IN FOCUS: ANALYSIS OF RECENT LEGISLATION AND JUDICIAL REVIEW OF AGENCY ACTION

130. *Id.* at 231-232. *Mead* has been said to resurrect *Skidmore* deference for modern review of agency action. See e.g., Cooley R. Howarth, *United States v. Mead Corp.: More Pieces for the Chevron/Skidmore Deference Puzzle*, 54 ADMIN. L. REV. 699, 702 (2002); Giacomo Gallai, *United States v. Mead Corp.: Will Administrative Transparency Survive the Increasing Demand for National Security?*, 30 PEPP. L. REV. 725, 755 (2003) (“[*Mead*] effectively enlarges the scope of operation of the intermediate standard of judicial review between the well-known de novo standard of review, and the permissive standard adopted in *Chevron*. Such a shift is in direct opposition to the post-modernist idea of the role of the judiciary.”).

131. *Mead*, 533 U.S. at 227.

132. *Id.*

133. *Id.* at 234.

134. *Id.* (citing *Skidmore*, 323 U.S. at 139).

135. *Id.* at 238. For an analysis of the application of *Mead* in the federal circuit, see Adrian Vermeule, *Introduction: Mead in the Trenches*, 71 GEO. WASH. L. REV. 347 (2003).

A. Shifting Stockpiling Resources to Terror-related Public Health Emergencies

While Congress responded quickly to the threat of biological and chemical warfare with enactment of the Public Health Security and Bioterrorism Response Act and the codification of the Strategic National Stockpile, stockpiling efforts for childhood vaccines have fallen behind.¹³⁶ These shortages have led some medical experts to recommend deferrals of vaccine immunization for some in order to give priority to current at-risk patients until supply can meet the demand.¹³⁷ While the CDC has managed to stockpile a few vaccines, many supplies have not been brought up to levels appropriate to ensure adequate immunization protection.¹³⁸

In comparison to the Strategic National Stockpile, HHS's stockpiling of vaccines for childhood immunization has given private industry neither incentives to enter the market nor provided for the expansion of vaccine production. Congress has allocated \$5.6 billion to encourage research and development of terrorism-related vaccines through the Project Bioshield Act, while HHS has received a mere \$700 million for vaccine immunization stockpiling.¹³⁹ Project Bioshield provides manufacturers with security by assuring payment in advance for the development of new terror-related immunization products.¹⁴⁰ Further, the waiver of the FDA approval requirement for drugs and vaccines created for the SNS gives additional incentive for private

136. See CTRS. FOR DISEASE CONTROL & PREVENTION, PROGRAM IN BRIEF: VACCINE STOCKPILE 1 (Feb. 2003) ("These shortages have led [experts] to recommend deferral of certain immunization and to set priorities for high-risk patients until supplies of vaccine return to normal."). See Noah, *supra* note 40, at 374 ("Although the agency continues to maintain the stockpile at its original levels, the program has stagnated somewhat in the face of resource constraints.").

137. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 136. These experts include the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

138. *Id.* Currently, there is no stockpile for Hepatitis B, Hib, DTap, PCV, and Hepatitis A vaccines.

139. *Id.* For an explanation of the projected expenditures on Project Bioshield, see also CBO Predicts, *supra* note 96, at 205.

140. See Project Bioshield Act of 2004, Pub. L. No. 108-276, 188 Stat. 835 (2004) (codified as amended in scattered sections of the U.S.C.).

companies to produce terror-related vaccines.¹⁴¹ None of these incentives exist for the production of childhood vaccines. Relatively predictable market conditions are needed to allow a clear path for the private sector to allocate the necessary time, money, and manpower required for the development of effective childhood immunization techniques.¹⁴²

B. Lack of Federal Action Has Led to Immunization Shortfalls and a Reliance on Herd Immunization

The last federally-initiated program fostering entry into the childhood vaccine market was the Vaccine Injury Compensation Program in 1983.¹⁴³ This twenty year gap in federal assistance has reestablished wariness by private industry to develop and supply childhood vaccines.¹⁴⁴ While the high visibility and sudden nature of the September 11th terrorist attacks and the recent anthrax scare jumpstarted the government into action to address the threat of terrorism,¹⁴⁵ the less conspicuous effects of the shortage of childhood immunization have unfortunately allowed the issue to remain largely below the government's radar screen.

With the reliance on "herd immunity," whereby parents perceive that their child is safe from disease because of the immunization of other children, and lack of public awareness of the importance of vaccines, many parents find it unnecessary to immunize their children.¹⁴⁶

Reliance on herd immunity, however, involves inherent dangers. Children have an enormous risk of contracting communicable diseases when not vaccinated.¹⁴⁷ Recent studies have found that

141. Mark B. McClellan, *Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products*, 58 FOOD & DRUG L. J. 191, 204 (2003).

142. *Id.*

143. *See generally* 42 U.S.C. §§ 300aa-1-34 (1986).

144. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 136, at 1 (stating that there is currently no stockpile for Hepatitis B, Hib, DTap, PCV, and Hepatitis A vaccines).

145. Direct government response to terror threats can be seen with the Homeland Security Act, Pub. L. No. 107-296, 116 Stat. 2002; The Strategic National Stockpile, 42 U.S.C. §247d-6(b); and Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835.

146. *See* Stroggin, *supra* note 2, at 3.

147. *Id.*

underimmunization has led to a resurgence of contagious diseases, such as measles, diphtheria, and pertussis, all of which are easily preventable through vaccination.¹⁴⁸ In 1989, an outbreak of measles in the U.S. led to one hundred twenty-three deaths.¹⁴⁹ One hundred eleven of the deceased children were not vaccinated.¹⁵⁰ A shift in the allocation of time and money to terror-related public health emergencies has increased the dangers of vaccine shortages in childhood immunization.¹⁵¹ Vaccines for diphtheria, pertussis, chicken pox, measles, and rubella have all seen supply shortages as recently as last year.¹⁵² All had shortfalls due to heightened demand and production deficiencies.¹⁵³

C. What if the CDC Acts? Analysis of Judicial Deference Given Agency Action

Agency interpretation is limited by the scope of the enabling statute.¹⁵⁴ If the statute has not defined how certain terms should be construed, however, deference is given to the agency.¹⁵⁵ The HHS Secretary's authority has previously been questioned concerning the National Childhood Vaccine Injury Compensation Act.¹⁵⁶ HHS instituted notice and comment rulemaking to add vaccines to the Injury Compensation Table of the NCVIA, thereby compensating patients who experience grave side effects from vaccination.¹⁵⁷

When several vaccines were added to the Injury Compensation Table, vaccine manufacturers commented that HHS had "exceeded its authority in promulgating the regulation."¹⁵⁸ HHS responded negatively to these comments, stating that while HHS is limited to the

148. *Id.*

149. *Id.*

150. *Id.*

151. *See infra* Part V.A-C.

152. *See* Wysocki, *supra* note 100, at A1.

153. *Id.*

154. *See* STRAUSS ET AL., *supra* note 101, at 902.

155. *Id.*

156. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3) (2004).

157. *Id.* *See also* note 29.

158. *Id.* at 7679.

authority delegated to it by Congress, the NCVIA required HHS to “fill the gaps” in the legislation by disseminating regulations based on statutory interpretation.¹⁵⁹ HHS maintained that their actions were entitled to *Chevron* deference of statutory interpretation.¹⁶⁰

This Comment addresses whether the HHS Secretary had legal authority to build a childhood immunization stockpile.¹⁶¹ Such authority is important to combat opposition from other administrative agencies who take issue with the allocation of funding toward childhood vaccine stockpiling as well as from vaccine manufacturers. These manufacturers benefit from the current market through producing just enough vaccines to meet demand without competition from new entrants, which would help provide for stockpiling initiatives.¹⁶²

The CDC, an administrative agency within HHS, has stated its belief that statutory authority comes from the Omnibus Budget Reconciliation Act of 2003.¹⁶³ The relevant language of this statute states:

(6) Assuring adequate supply of vaccines:

The Secretary [of HHS], in negotiations under paragraph (1), shall negotiate for quantities of pediatric vaccines such that an adequate supply of such vaccines will be maintained to meet unanticipated needs for the vaccines. For purposes of the preceding sentence, the Secretary shall negotiate for a 6-month supply of vaccines in addition to the quantity that the Secretary otherwise would provide for in such negotiations. In carrying out this paragraph, the Secretary shall consider the potential for outbreaks of the diseases with respect to which the vaccines have been developed.¹⁶⁴

To determine whether the HHS’s interpretation of the statute is reasonable in the face of potentially ambiguous language, the courts

159. *Id.*

160. *Id.* See also *Chevron*, 467 U.S. 837.

161. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 136, at 1 (“The HHS Office of General Counsel has reviewed the legal authority of the Omnibus Reconciliation Act [of] 1993 legislation and confirmed the Secretary’s authority under current law to build a VFC stockpile equal to the amount needed for the U.S. pediatric population for 6 months for routinely recommended vaccines.”).

162. See *supra* note 100.

163. *Id.* See also 42 U.S.C. § 1396s.

164. 42 U.S.C. § 1396s.

need to first categorize the agency action under a *Chevron* analysis.¹⁶⁵ Here, Congress' clear intent to authorize the promulgation of stockpiling vaccines by HHS is evident in the text of the statute. Congress intended the Secretary of HHS to assure adequate supply to meet an unanticipated need for vaccines for a six-month period. If courts find this to be true, no deference would be granted as Congress has explicitly stated the authority granted to the Secretary.¹⁶⁶

However, if the statute is interpreted to have a "gap" because the word "stockpile" is omitted from the statute, the next step in the analysis would be to define the agency action which in turn determines the degree of deference that would be granted: *Chevron* "high" deference or a "light" *Skidmore* deference.¹⁶⁷ The point of contention then centers around which level of deference applies to this agency action.¹⁶⁸ As the action of stockpiling childhood vaccines is neither formal adjudication nor notice and comment rulemaking, the question becomes whether it falls under the category of "some other indication of a comparable congressional intent" where agency action would have "the force and effect of law."¹⁶⁹

Unless the HHS looks to stockpile through enacting regulations, which would require notice and comment rulemaking procedures, congressional intent could not be construed to have stockpiling carry the "force and effect of law."¹⁷⁰ *Chevron* deference is only given if the agency has gone through notice and comment rulemaking, formal adjudication, or some other type of agency action that was intended to have the "force and effect of law."¹⁷¹ This language would allow for lower *Skidmore* deference, which gives courts the responsibility of taking into account an agency's expertise and function in determining whether the agency's action was appropriate.¹⁷² A court may perceive the nexus too large, thereby increasing the likelihood of the stoppage of childhood immunization programs because of questions concerning statutory authority.

165. See *Chevron*, 467 U.S. at 842.

166. *Id.*

167. See STRAUSS ET AL., *supra* note 101.

168. *Chevron*, 467 U.S. at 842.

169. *Mead*, 533 U.S. 218.

170. *Id.*

171. *Chevron*, 467 U.S. at 842.

172. See *Skidmore*, 323 U.S. at 137.

V. POTENTIAL APPROACHES TO VACCINE STOCKPILING FOR CHILDHOOD IMMUNIZATION

Stockpiling is an excellent solution to childhood immunization concerns, but it is not clearly defined by statute, leaving HHS to speculate on its stockpiling authority.¹⁷³ Without direct authority or a defined organizational structure, child vaccine stockpiling cannot reach its full potential.¹⁷⁴ The Strategic National Stockpile, in contrast, has clearly defined stockpiling through statute and provides an excellent model of how to approach childhood immunization concerns.

A. *The Strategic National Stockpile: An Ideal Model*

The government construction of the Strategic National Stockpile serves as an excellent model for childhood vaccine stockpiling.¹⁷⁵ Congress provided codification through legislation that gives direct statutory authorization for the administration of the stockpile.¹⁷⁶ The statute also provides for exact standards in terms of duties and responsibilities between the various administrative agencies.¹⁷⁷ Another key feature of the statute is its explicit requirement of cooperation among federal, state, and local entities.¹⁷⁸ The precise definitions and exacting construction contained in the Strategic National Stockpile statute require little need for statutory interpretation.¹⁷⁹ This clear congressional intent has allowed all parties involved to understand their roles in implementing and managing the stockpile. Because Congress has integrated DHS into the management of the stockpile, HHS and the CDC will be hard pressed to use the stockpile's enabling statute as authority for its own childhood vaccine collection measures, as the Stockpile's purpose is for terror-related threats rather than childhood vaccine shortages.¹⁸⁰

173. *See supra* note 161.

174. *See supra* Part IV.C.

175. *See* 42 U.S.C. § 247d-6(b).

176. *Id.*

177. *Id.* These standards include ensuring adequate procedures are followed with respect to inventory management, consultation with federal, state, and local officials, take into consideration the timing and location of special events.

178. 42 U.S.C. § 247d-6(b).

179. *See* Merril & Hickman, *supra* note 114.

180. *Cf.* Homeland Security Act of 2002, *supra* note 86.

In managing the stockpile, federal agencies provide state and local planners the necessary centralization of resources in their preparations for responses to chemical, biological, or nuclear attack. Of particular importance is the statutory requirement to ensure “the emergency health security of the United States, including the emergency health security of children and other vulnerable populations”¹⁸¹ As children and other vulnerable populations that would benefit immensely from federally implemented stockpiling of vaccinations for immunization, the language in the statute underscores the importance of federal vaccine stockpiling initiatives. Federal, state, and local government officials should look to the SNS as a model of how to implement such a program, whether through agency action, regulation or statute.

B. Agency Action

Agency action is currently the method by which the CDC administers stockpiling initiatives.¹⁸² This method could be bolstered through greater involvement from state and local officials, similar to the command and control centers of the Strategic National Stockpile. Private industry already plays a strong role as they have provided the government with estimates of product availability and production procedures.¹⁸³ Experts have recommended additional measures such as compulsory licensing, where the government would force patent holders to allow the use of their drugs by others in exchange for a fixed royalty.¹⁸⁴ While agency action is more quickly implemented than regulation or legislation, it leaves open the possibility for reversal or stoppage of initiatives due to court review or interference from the executive branch. Direct agency action would receive light *Skidmore* deference, as the agency did not undergo notice and comment rulemaking or any other action that would have the force and effect of law, thus leaving a greater chance of program stoppage.¹⁸⁵

181. 42 U.S.C. § 247d-6(b).

182. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 136, at 1.

183. *Id.*

184. See Noah, *supra* note 40, at 344.

185. See Howarth, *supra* note 130, at 701 (“The Court then states that judicial deference is due to agency action only when Congress has authorized the agency to make new rules with the force of law by means of that decisionmaking [sic] format.”) Many experts believe that the Supreme Court can further define the boundaries of deference, as Professor Howarth further states that “the Court

C. Regulation: Notice and Comment Rulemaking

HHS could establish vaccine stockpiles by regulation through notice and comment rulemaking procedures.¹⁸⁶ The question arises, however: from where would they derive their statutory authority? While the National Childhood Vaccine Injury Act makes references to a distribution function within the defined goals of the National Vaccine Program, courts may give minimal deference due to the lack of congressional intent in allowing HHS to promulgate regulations that have “the force and effect of law” concerning the National Vaccine Program.¹⁸⁷ As discussed previously, the 1993 Omnibus Budget Reconciliation Act is cited by the CDC as providing statutory authority for stockpiling. But again, the statute is vague in defining effective purchase and distribution functions with respect to vaccines, and never explicitly states any “stockpiling” initiatives.¹⁸⁸ If HHS is able to show a court that Congress has explicitly left a gap in the statute to allow HHS to create stockpiling initiatives, then *Chevron* “high” deference would apply to the agency’s actions in this regard.¹⁸⁹ However, if no gap exists, lighter *Skidmore* deference would apply.¹⁹⁰

D. Congressional Legislation

Enacting a childhood immunization stockpiling statute is the most direct and efficient way of implementing a stockpiling initiative. Although the CDC currently utilizes the Vaccine for Children Program for childhood vaccine stockpiling, too little funding and too

would do well to clarify whether the ‘force of law’ test is the sole criterion for *Chevron* deference or whether, instead, the interpretation/lawmaking distinction is also relevant, if only in part, to the *Chevron* doctrine.” *Id.* at 717.

186. The Department of Health and Human Services has used regulation before with the National Vaccine Injury Compensation Program. See 42 C.F.R. § 100.

187. 42 U.S.C. §§ 300aa-1-34. See also *Mead*, 533 U.S. at 219.

188. See Project Bioshield Act, *supra* note 140.

189. See *supra* Parts III.A.-C.

190. *Id.*

many responsibilities have rendered the program deficient.¹⁹¹ A congressional mandate explicitly defining the responsibilities of all parties involved and directly authorizing the disbursement of funds is needed to efficiently allocate government and private resources for the purpose of childhood vaccine stockpiling. Such a statute could be codified within the context of the National Vaccine Program, with specific guidelines and procedures involving the National Vaccine Advisory Committee.¹⁹²

A direct congressional mandate with defined terms and goals would also alleviate current concerns regarding legal authority. While the CDC has claimed authority under provisions within the Omnibus Budget Reconciliation Act of 1993 to engage in its childhood vaccine stockpiling activities, the “gap” in the relevant statutory language leaves this authority subject to interpretation.¹⁹³ A well-drafted enabling statute having no “gap” would allow judicial review of an agency action to look to the statute itself for its plain meaning, and if ambiguous, to legislative history and statutory construction for interpretation, thus circumventing the second step of the *Chevron* analysis.¹⁹⁴ Once a court found that Congress’ intent was clear, no further *Chevron* analysis would be necessary. As a result, courts would give effect to the “expressed intent of Congress” and, in doing so, clear the way for the implementation of a much needed childhood vaccine stockpiling initiative.¹⁹⁵

CONCLUSION

The Government’s swift response to terror threats is evidenced by its implementation of the Strategic National Stockpile. This stockpile should serve as a model to address domestic childhood vaccine shortages. After September 11, 2001, the nation redefined a public health emergency to include biological and chemical terror threats, but long-term public health concerns involving the deficiency of non-terror-related immunizations still linger. Although failure to immunize

191. See Vaccine for Children Program, at <http://www.cdc.gov/nip/vfc/Default.htm> (last visited February 23, 2004). See also CTRS, FOR DISEASE CONTROL & PREVENTION, *supra* note 136, at 1.

192. See 42 U.S.C. §§ 300aa-3; 300aa-5.

193. Cf. Omnibus Budget Reconciliation Act of 1993, *supra* note 47.

194. *Chevron* deference only applies when an agency applies notice and comment rulemaking or formal adjudication, where Congress has “delegated” authority to the agency to “promulgate legislative rules implementing a statute . . .” Merrill & Hickman, *supra* note 114, at 874.

195. *Chevron*, 467 U.S. at 843. See also *supra* Part III.B.

does not pose the direct and immediate threat that a terrorist attack does, the long-term ramifications of inadequate childhood immunization could be just as severe. Based on the successful coordination among federal, state, and local authorities in implementing the Strategic National Stockpile, a similar stockpiling initiative, with direct authority from federal statute is needed. Such an initiative would provide an effective solution to the crises of childhood vaccine shortages in America.