

**National Vaccine Program
and
National Vaccine Advisory Committee:
Beginnings and Highlights**

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Outline

- **Context**
- **National Childhood Vaccine Injury Act**
- **Establishment of NVPO**
- **Establishment of NVAC**
- **First report to Congress**
- **Selected outputs of NVAC 1989-2016**

Context - 1

- **1970s - UK**
 - **DTP and brain damage**
 - **Falling coverage with DTP**
 - **Rising incidence of pertussis**
- **1974 - Reyes v Wyeth**
- **1976 – Swine flu program**
 - **Requirement that HD notify parents of risks and benefits of vaccine**
- **1977 – Immunization Conference calls for no-fault compensation system for those injured by vaccines**

Context -2

- **1982**
 - **DPT – Vaccine Roulette**
 - **Formation of Dissatisfied Parents Together (DPT)**
 - **Formation of National Vaccine Information Center (NVIC)**
- **1980s**
 - **Increasing number of cases brought against DTP makers**
 - **Decreasing number of DTP makers and increasing price**
 - **Increasing demands for some form of compensation system**

DTP – Vaccine Roulette, April 19, 1982

“WRC-TV, the local NBC affiliate in Washington, DC, aired a special titled ‘Vaccine Roulette.’

“...Throughout the hour-long show, Thompson featured heart-breaking interviews with parents who described how their children had been left in near-comatose states after receiving a vaccine that was mandatory for public-school children in the vast majority of states.”

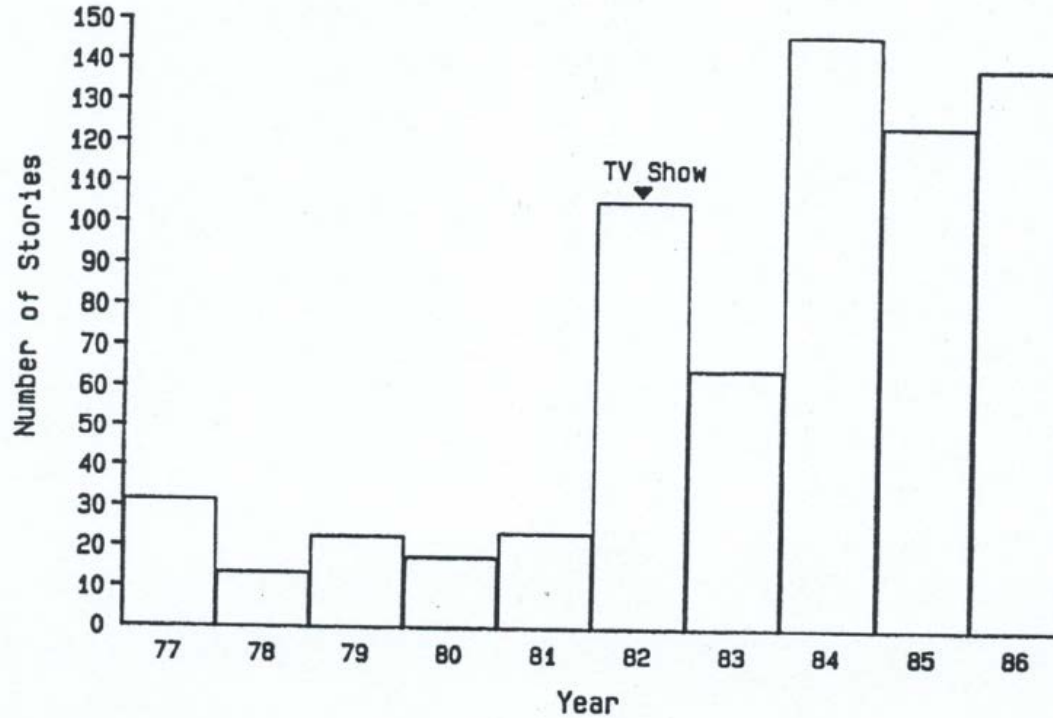
Source: Seth Mnookin, <http://blogs.plos.org/thepanicvirus/2012/09/13/the-whole-cell-pertussis-vaccine-media-malpractice-and-the-long-term-effects-of-avoiding-difficult-conversations/>

DTP - Vaccine Roulette - 2

“In the days after ‘Vaccine Roulette’ aired, Thompson’s employer provided callers with the phone numbers of other people who’d also called looking for more information... and in doing so, helped create the modern-day anti-vaccine movement. Among the parents who met in the days after the airing of ‘Vaccine Roulette’ was Barbara Loe Fisher, who soon formed... the National Vaccine Information Center.”

Source: Seth Mnookin, <http://blogs.plos.org/thepanicvirus/2012/09/13/the-whole-cell-pertussis-vaccine-media-malpractice-and-the-long-term-effects-of-avoiding-difficult-conversations/>

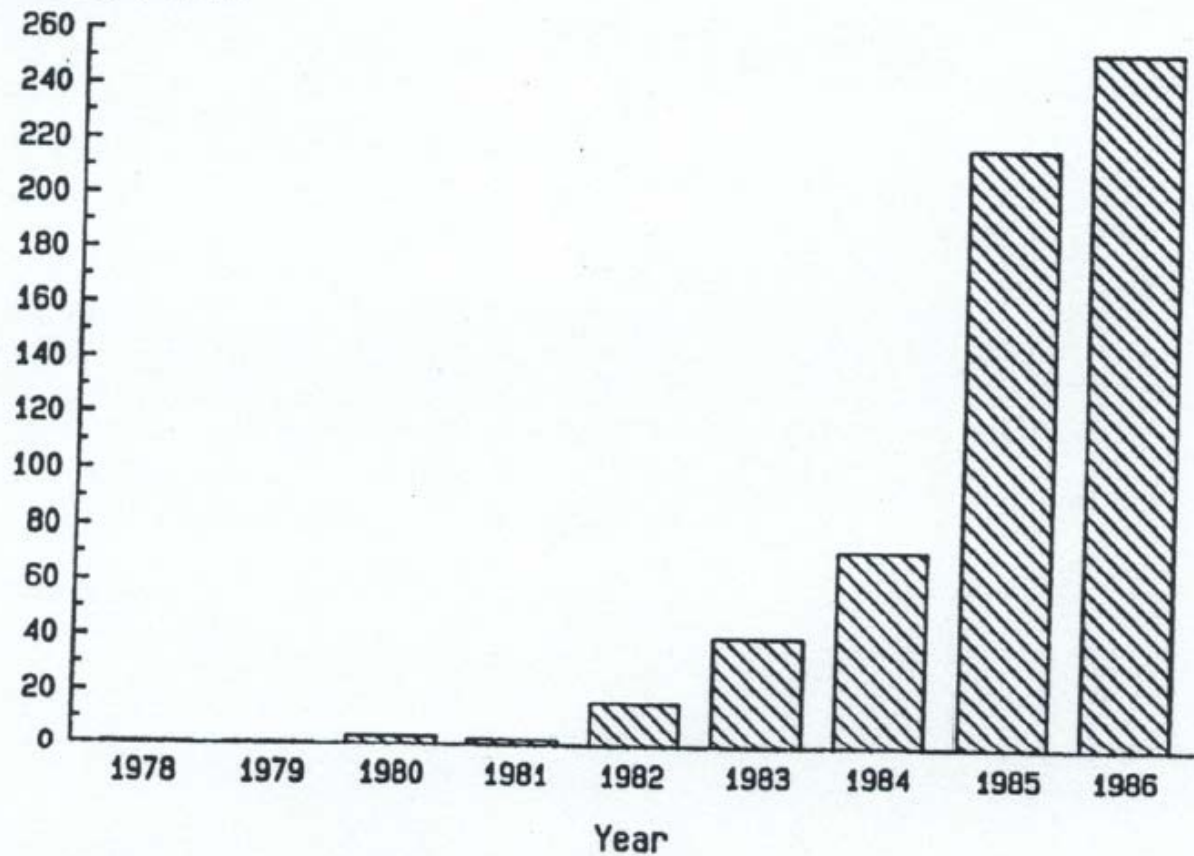
Number of Stories About Pertussis
1977-1986 (Through November 15)
NEXIS Search, OMNI File



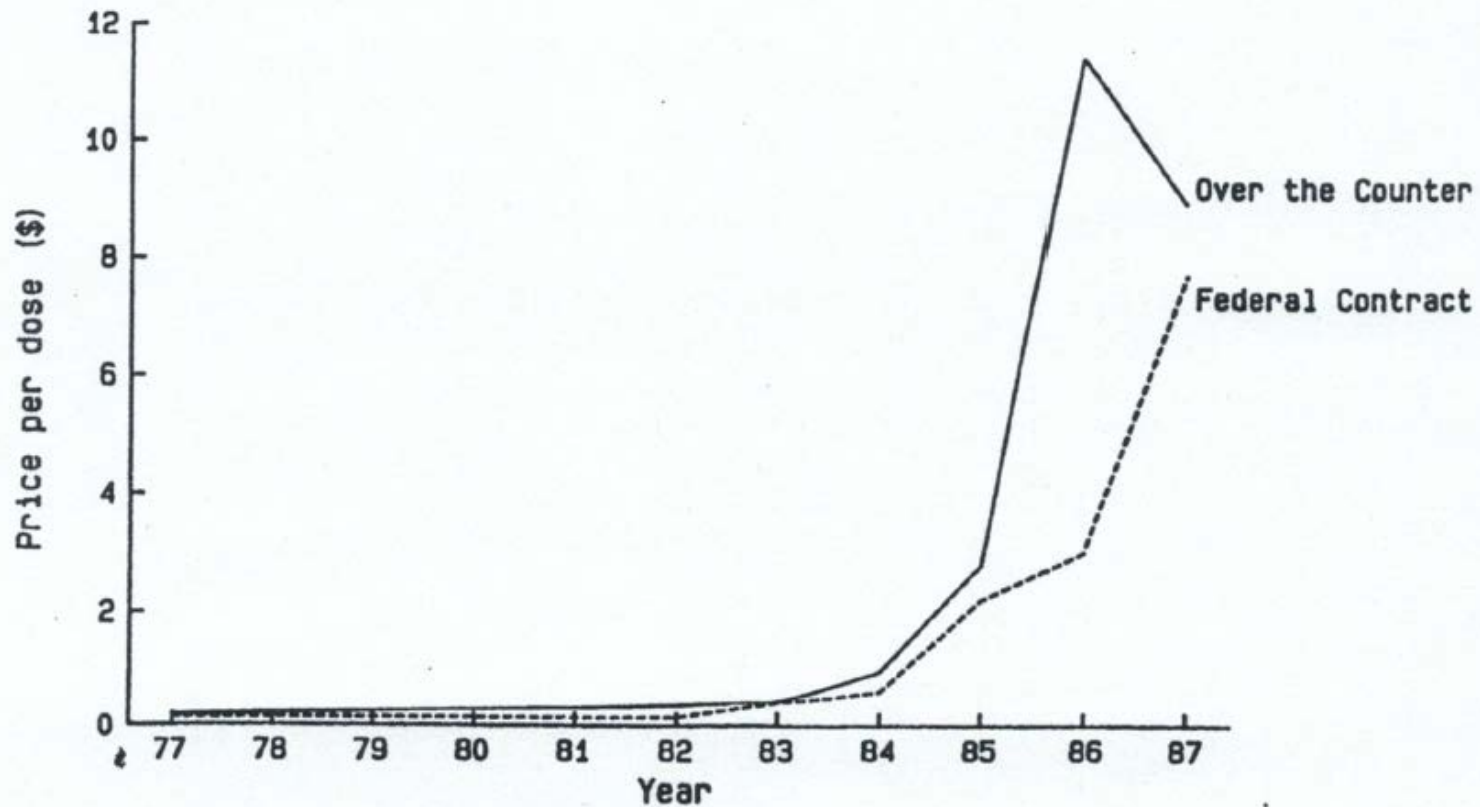
Source: Hinman AR. The National Childhood Vaccine Injury Act of 1986. Proceedings 21st Immunization Conference. CDC publication. 1987:177-182

**DTP Suits Filed
U.S.A., 1978-1986**

Number Suits Filed



DTP Vaccine, U.S. Prices 1977-1987



National Childhood Vaccine Injury Act of 1986 (PL 99-660)

- **Established Vaccine Injury Compensation Program**
- **Established National Vaccine Program Office**
- **Established National Vaccine Advisory Committee**
- **Established Vaccine Adverse Events Reporting System**
- **Mandated a 6-month supply of vaccines**

National Vaccine Program - Establishment

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.

NVP Responsibilities

- **Coordinate and provide direction for**
 - **Vaccine research**
 - **Vaccine development**
 - **Safety and efficacy testing of vaccines**
 - **Licensing of vaccine manufacturers and vaccines**
 - **Production and procurement of vaccines**
 - **Distribution and use of vaccines**
 - **Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities**
 - **Coordinating governmental and non-governmental activities**
 - **Funding of Federal agencies**

National Vaccine Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa–2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

National Vaccine Advisory Committee Charter

The National Vaccine Advisory Committee shall:

- 1. Study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,**
- 2. Recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,**
- 3. Advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and**
- 4. Identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104**

NVP First Report to Congress, April 1988

- **Assistant Secretary for Health (ASH) appointed Director of NVP in 1987**
- **NVPO established as an independent office in OASH**
 - **National Vaccine Coordinator named**
- **NVP Interagency Group created (building on existing Interagency Group to Monitor Vaccine Development, Production, and Usage)**
- **NVAC Charter developed and in formation**

8 Priority Areas for NVP – 1988

- 1. Improving coordination of vaccine research, development, use, and evaluation**
- 2. Assuring an adequate supply of vaccines**
- 3. Assessing benefits and risks of vaccines and assuring public and practitioner awareness of the benefits and risks**
- 4. Assuring adequate regulatory capacity to evaluate vaccines**
- 5. Improving surveillance of adverse events**
- 6. Establishing research priorities**
- 7. Promoting rapid development and introduction of improved pertussis vaccines**
- 8. Assuring optimal immunization levels in all high risk and target groups**

Priority NVP activities for FY 1988

- 1. Formation and functioning of the National Vaccine Advisory Committee**
- 2. Develop a comprehensive long-term National Vaccine Plan**
- 3. Continue functioning of the NVP Interagency Group**
- 4. Continue liaison with other Advisory Groups**
- 5. Continue promotion of dialogue on vaccine policies**
- 6. Meet with individual manufacturers, researchers, public health agencies, etc.**
- 7. Complete a survey to inventory current vaccine research**

NVP Coordinators/NVPO Directors 1987-2017

- **Alan Hinman**
- **Kenneth Bart**
- **Anthony Robbins**
- **Roy Widdus**
- **Robert Breiman**
- **Martin Myers**
- **Bruce Gellin**

First meeting of NVAC – June 9-10, 1988

NVAC Members

Suzanne Dandoy, MD (Chair)
Barbara Loe Fisher
Donald A. Henderson, MD
Donald P Metzgar, PhD
Georges Peter, MD
Parker A Small, Jr, MD
David H. Smith, MD
Gene H. Stollerman, MD
Catherine Wilfert, MD
Jesse F. Williams, MD

NVPO

Robert E. Windom, MD (Director)
Alan R. Hinman, MD, MPH (Coordinator)
Yuth Nimit, PhD
Daniel Lahn
Sandra Tolpin

Selected major outputs of NVAC 1989-2016 - 1

- **1991 – The measles epidemic: The Problems, Barriers, and Recommendations**
- **1994 – National Vaccine Plan**
- **1994 – Adult Immunization**
- **1996 – Standards for Pediatric Immunization Practices**
- **1997 – US Vaccine Research: A Delicate Fabric of Public and Private Collaboration**
- **1997 – NVAC Adult Immunization Report**
- **1998 – Strategies to Sustain Success in Childhood Immunizations**
- **1999 – Vaccine Safety Action Plan**

Selected major outputs of NVAC 1989-2016 - 2

- **1999 – Vaccines for the 21st Century – NVAC Review of IOM Report**
- **2003 – Strengthening the Supply of Vaccines in the U.S.**
- **2003 – Standards for Child and Adolescent Immunization Practice**
- **2003 – Standards for Adult Immunization Practice**
- **2004 – Financing Vaccines in the 21st Century**
- **2007 – Immunization Information Systems: NVAC Progress Report**
- **2010 – National Vaccine Plan**

Selected major outputs of NVAC 1989-2016 - 3

- **2011 - A Pathway to Leadership for Adult Immunization: Recommendations of NVAC**
- **2012 – Protecting the Public’s Health: Critical Functions of the Section 317 Immunization Program**
- **2012 – Final white Paper on the US Vaccine Safety System**
- **2013 – Standards for Adult Immunization Practice**
- **2013 – Standards for Pediatric Immunization Practice**
- **2014 – Reducing Patient and Provider Barriers to Maternal Immunizations**
- **2015 – Assessing the State of Vaccine Confidence in the US**

Conclusions

- **NVP and NVAC have evolved considerably over the 30 years**
- **The number of vaccines recommended and their cost have risen dramatically**
- **Vaccine hesitancy/opposition has emerged as a major theme but was also an important factor at the beginning**
- **Financial barriers to immunization have been partly solved by Vaccines For Children and the Affordable Care Act (ACA)**
- **Vaccine coverage in children is at an all-time high and most vaccine-preventable diseases are at record low levels**