Vaccine Injuries Continue to Rise as Unvaccinated Adults are Targeted by the Federal Government

A Referenced National Vaccine Information Center Article By Theresa Wrangham, NVIC Executive Director

Since its introduction in 2002, the federally recommended adult vaccine schedule has expanded from 53 doses of 9 vaccines to 61 doses of 12 vaccines in 2016. Although the federal Vaccine Injury Compensation Program (VICP) was originally created by Congress to shield drug companies producing government licensed, recommended and mandated vaccines for children, today it is not children but adults injured by influenza vaccine who are receiving most of the compensation. As of March 2016, the VICP has awarded vaccine injury and death victims almost \$3.4 billion.

Notably, adults are being targeted by the federal government with strategies for increased vaccine uptake, while manufacturers are producing vaccines specifically for adults that will not be covered by the VICP for vaccine injury and death compensation.

The vaccine informed consent movement is not about an anti- or pro- vaccine position. It is a battle over freedom, values and beliefs. What is at risk is the ability of parents and individuals to decide what medical risks are acceptable to them and vaccination is the forefront of this battle.

On December 4, 2015 during a meeting of the federal Advisory Commission on Childhood Vaccines (ACCV) the U.S. Department of Justice (DOJ) and Division of Injury Compensation Programs (DICP) reported that the number of vaccine injury claims for this fiscal year will exceed previous years. I have monitored this committee for the past six years and have seen the number of claims and awards rise every year.

Sadly, they are likely to represent only a fraction of the vaccine injured, due to the lack of public awareness¹ of the existence of the federal Vaccine Injury Compensation Program (VICP) created under the National Childhood Vaccine Injury Act of 1986, which has a record of dismissing two-thirds of claims received.²

Expansion of the Adult Vaccine Schedule

Since its introduction in 2002,³ the federally recommended adult vaccine schedule has expanded from 53 doses of 9 vaccines to 61 doses of 12 vaccines in 2016 (see page 3),⁴ a schedule approved by the CDC's Advisory Committee on Childhood Immunization Practices (ACIP). These numbers assume that by the time you have become an adult at age 19, you have stayed up to date with the CDC's recommended childhood vaccine schedule and have received 69 doses of 16 vaccines by 18 years of age, and will continue to get all government recommended vaccines at least until 65 years old.

Adults, Not Children, Get Most Vaccine Injury Compensation Awards



The estimated 1,000 claims for this fiscal year that the VICP anticipates being filed in 2016 are projected to cost \$224 million. Although the VICP was originally created by Congress to shield drug companies producing government licensed, recommended and mandated vaccines for children, today it is not children but adults injured by influenza vaccine who are receiving most of the compensation.

The majority of compensated flu shot injury claims are for nerve inflammation diagnosed as Guillain-Barré syndrome (GBS), an autoimmune disorder that attacks the nervous system and can result in life-long paralysis. Falso on the rise are government conceded claims for shoulder injuries (SIRVA) caused by vaccine providers failing to properly administer vaccinations. GBS and SIRVA are in the process of being added to the federal Vaccine Injury Table 6 to expedite the administrative vaccine injury claims process for those two injuries.

To date the VICP, under the National Childhood Vaccine Injury Act of 1986, paid out nearly \$3.4 billion in federal vaccine injury compensation to victims of vaccine related injuries and death.

Injuries from Some Adult Vaccines not Compensated

Under the 1986 law, the only adult vaccine injury claims that can be compensated by the VICP are for injuries caused by vaccines recommended by the CDC for "universal use" by children. Most, but not all, of the CDC recommended vaccines for adults are also recommended for children. The shingles (herpes zoster) vaccine and 23-valent pneumococcal vaccine (PNEUMOVAX 23) recommended for adults are not eligible for compensation under the VICP9 and federal health officials and the ACCV have wrestled in recent years with how to protect vaccine manufacturers and compensate adult vaccine injuries not covered by the VICP.

Vaccine manufacturers are also expanding their reach and developing vaccines solely for use by pregnant women. Currently, there are two vaccines under development for exclusive use by pregnant women for Respiratory Syncytial Virus (RSV) and group B streptococcal disease.

As a result, the ACCV recommended in 2013 that the U.S. Secretary of the Department of Health and Human Services (DHHS) pursue statutory changes to the 1986 law to extend vaccine injury compensation for injuries caused by vaccines being developed for exclusive use by pregnant women, ¹⁰ as well as for live born infants injured by a these vaccines in utero (before birth). ¹¹ However, during

a December 2015 ACCV meeting, the ACCV's working group recommended not pursuing statutory changes to the 1986 law that would extend coverage to vaccines given to adults but not recommended for children.

Some Vaccine Injured Adults Can Sue Vaccine Manufacturers

In effect, unlike the legal requirement under the 1986 law that shields vaccine manufacturers from civil liability for government recommended vaccines for children that are also used by adults, vaccine injuries sustained by adults from vaccines used *exclusively* by adults (like shingles and PNEUMOVAX 23 vaccines) *can* pursue civil lawsuits against vaccine manufacturers and negligent physicians in order to obtain vaccine injury compensation.

While the ACCV's recommendations carry no legal authority, it does not appear likely that the DHHS Secretary will pursue legal changes necessary to cover adults. The vaccine manufacturer representative on the working group stated that vaccine manufactures did not support extending VICP coverage to adult-only vaccines, due to a potential risk of "certain groups" weakening the 1986 law's liability protections if legal changes to the law were pursued.

Adults Targeted for More Vaccination

As I reported in March 2015, ¹² the National Adult Immunization Plan (NAIP), which was authored by the federal National Vaccine Advisory Committee (NVAC), cites adults as being delinquent vaccinators and contains strategies to increase adult vaccination. These strategies include close monitoring of adult vaccination status in state vaccine registries, incentivizing vaccine providers with rewards and sanctions, and conducting outreach efforts to churches, employers and other community organizations.

Americans can expect to be hearing a lot more about adult vaccines during 2016, now that the NAIP has officially been launched.

What you need to know - the nutshell.



The basis of the NAIP rests on Healthy People 2020 Goals, ¹³ many of which are arbitrary. ¹⁴ The key fact the plan seems to lose sight of in using these goals as its foundation is ... THEY ARE GOALS. These goals have no legal authority over your healthcare decisions and are being used by government officials to shape public health policy, which in turn is

spurring legal mandates to force you to comply with them. 15

The adult immunization plan also "incentivizes" doctors and other vaccine providers to convert patient data into Electronic Health Record (EHR) formats that can then be shared across state and federal electronic databases to track national vaccine coverage rates and also track and identify who is and is not vaccinated. Many states already have electronic vaccine tracking registries (Immunization Information Systems - IIS) in place, but do not share this information due to laws preventing the sharing of personal medical information and/or limited vaccination data on adults. This is where financial and other types of incentives come in to convince vaccine providers and

state legislators to participate in the gathering of this private medical information on all adults.

NVAC Lays State Mandate Groundwork

Over the past six years of monitoring the NVAC, what I find striking is that for a federal committee with no statutory authority, NVAC recommendations are quickly showing up in strong support of proposed state legislation that will repeal or restrict vaccine exemptions, require parent "re-education," and institute vaccine tracking registries.

Informed Consent Freedom at Risk

You you may not realize that history is about to repeat itself. Government enforced vaccination through identification and door-to-door efforts to make everyone comply, like was seen with smallpox vaccination campaigns a century ago, is a real possibility again in America. Only this time it won't just be about one vaccine – it will be about a lot of vaccines you will be forced to get.

The noose being tightened around the necks of our children is being thrown over the necks of adults as well. The tightening of that noose is growing daily in an attempt to strangle vaccine freedom of choice by eradicating the ethical principle of informed consent.

Adults and their children are being asked to accept a one-size-fits-all vaccine schedule that does not allow for the ability to delay or decline one or more vaccines for religious and conscientious beliefs. This is very dangerous when the medical exemption has been narrowed by government so that almost no health condition qualifies for a medical exemption anymore. Families already personally impacted by vaccine reactions, injuries and deaths will be faced with more loss, including their financial stability if they are forced to be revaccinated.

The human right to protect bodily integrity and autonomy – the core value of the informed consent ethic – is at stake.

This battle is not about an anti- or pro- vaccine position. It is a battle over freedom, values and beliefs. ¹⁶ What is at risk is your ability as a parent and individual to decide what medical risks you are willing to accept and vaccination is the forefront of this battle.

For over three decades NVIC has supported informed consent protections in all U.S. vaccine laws and policies, which means that parents and individuals must receive full and accurate information on vaccine risks and benefits and the right to make voluntary decisions to accept, delay or decline one or more vaccines without being sanctioned for the decision they make.

Now, more than ever before, we must have the courage to stand up and speak to our friends and family, because these attempts to destroy the right to exercise informed consent to medical risk-taking impacts everyone.



About the Author

Theresa Wrangham has been the National Vaccine Information Center's (NVIC) Executive Director since 2010. She actively monitors and analyzes federal advisory committee activities related to vaccine policy-making. Theresa is also a consumer reviewer for systematic reviews and their protocols that are undertaken by the Cochrane Collaboration via NVIC's membership with the Consumers United for

Evidence-based Healthcare (CUE).

In 2001 she co-founded the Autism Society of Boulder County (ASBC) in Colorado and serves on advisory board for the US Autism & Asperger Association (USAAA). In 2006, the Boulder County Business Report recognized Theresa as a Health Care Hero and in 2012 she received the Chairman's Award from the US Autism & Asperger's Association.

She has been featured in local, national and international television, radio and print news reports. Ms. Wrangham has also participated in the public engagement process funded by the Centers for Disease Control (CDC) for "Pandemic" H1N1 vaccine, meningococcal vaccine, and Colorado's personal

belief exemption law. She currently represents NVIC in and CDC's Vaccine Information Statement (VIS) Revisions Group.

About NVIC: Founded in 1982, the National Vaccine Information Center (NVIC) is the largest and oldest consumer led charitable non-profit organization advocating for informed consent protections in vaccine related public health policies and laws. NVIC does not promote or advise against the use of vaccines and supports the right of consumers to make educated, voluntary health care choices. Learn more at www.nvic.org.

Recommended Adult Immunization Schedule—United States - 2016

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended immunization schedule for adults aged 19 years or older, by vaccine and age group'

VACCINE ▼	AGEGROUP >	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥65 years
Influenza*2		1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap)*.3		Substitute Tdap for Td once, then Td booster every 10 yrs					
Varicella" ⁴		2 doses					
Human papillomavirus (HPV) Female*5		3 doses					
Human papillomavirus (HPV) Male*5		3 d	oses				
Zoster ⁶						10	dose
Measles, mumps, rubella (MMR)*.7			1 or 2 doses depen	ding on indication			
Pneumococcal 13-valent conjugate (PCV13)*8						10	dose
Pneumococcal 23-valent polysa ccharide (PPS V2 3)8		1 or 2 doses depending on indication 1				1 dose	
He patitis A*9		2 or 3 doses depending on vaccine					
He pati tis B* 10		3 doses					
Meningococcal 4-valent conjugate (MenACWY) or polysaccharide (MPSV4)*.11			ă.	1 or more doses dep	ending on indication	-	
Meningococcal B (MenB) ¹¹		2 or 3 doses depending on vaccine					
Ha emophilus influenzae type b (Hib)". 12		1 or 3 doses depending on indication					
Covered by the Vaccine injury Compensation Program Recommended for all persons who meet the age requirement, lack documentation of vaccination, or lackevidence of past infection; zoster vaccine is recommended regardes of past episide of zoste son as with a risk factor (medical, occupational, lifes byle,		Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS), Reporting forms and instructions on filing a VAERS report are available at www.arsh.hs.gov or by telephone, 800-327-967. In formation on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W. Washington, D.C. 20005; lelephone, 202-357-6400. Additional information a bout the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at a www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m 8:00 p.m. Eastern Time, Monday-Friday, excluding ho lidays. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.					
or other indica		The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG) and the American College of Nurse-Midowyces (ACMN).					

Article & References Updated 2016

¹ Altarum VICP Satisfaction Report

² VICP Data & Statistics Report - Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 02/03/2016

³ Recommended Adult Immunization Schedule – United States 2002-2003. Centers for Disease Control Morbidity and Mortality Weekly Report. Oct. 11, 2002

⁴ http://www.cdc.gov/vaccines/schedules/hcp/adult.html

⁵ NIH GBS Definition

⁶ Federal Register Notice

⁷ Cite NVICA

⁸ Recommended Adult Immunization Schedule - United States 2002-2003. Centers for Disease Control Morbidity and Mortality Weekly Report. Oct. 11, 2002

⁹ http://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

¹⁰ http://www.hrsa.gov/vaccinecompensation/miwgexpandcoverage.pdf

¹¹ http://www.hrsa.gov/vaccinecompensation/miwqeligibility.pdf

¹² http://www.nvic.org/nvic-vaccine-news/march-2015/adults-targeted-for-vaccine-compliance-by-feds.aspx

¹³ Healthy People.gov. <u>Immunization and Infections Diseases</u>.

¹⁴ A Perspective on the Development of the Healthy People 2020 Framework for Improving U.S. Population Health, Public Health Reviews, Vol. 35, No 1, 2013

¹⁵ CDC. Vaccines and Immunizations. State Immunization Laws for Healthcare Workers and Patients. Nov. 19, 2014.

¹⁶ NVIC. The Vaccine Culture War in America: Are You Ready?. NVIC eNewsletter. Barbara Loe Fisher. Mar. 8, 2015.