



## **The National Vaccine Injury Compensation Program: Awareness, Perception, and Communication Considerations**

### **Developing a Comprehensive National Vaccine Injury Compensation Program Research Report**

Presented by Banyan Communications and Altarum Institute  
For the U.S. Health Resources and Services Administration Division of Vaccine Injury Compensation

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# 1. Introduction and Background

In 2009, Banyan Communications (Banyan), in partnership with Altarum Institute (Altarum), was contracted by the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) Healthcare Systems Bureau’s Division of Vaccine Injury Compensation (DVIC) to develop a comprehensive national marketing and outreach campaign to address the National Childhood Vaccine Injury Act of 1986 legislative mandate for the publicity of the National Vaccine Injury Compensation Program (VICP) (42 USC, Section 300aa-10). With this Developing a Comprehensive National Vaccine Injury Compensation Program contract, DVIC sought support to:

- Conduct formative research with key target audiences,
- Design a multifaceted outreach campaign, and
- Identify key measures of success for the campaign.

The Banyan-Altarum approach to this work includes three distinct phases:

- PHASE I** Formative Research
- PHASE II** Create Marketing and Outreach Plan
- PHASE III** Prepare Final Presentation of Plan

This research report summarizes and provides a synthesis of the formative research activities and addresses the following research areas.

<b>PHASE I: Formative Research</b>
<b>Literature Review</b> <ul style="list-style-type: none"><li>• Vaccine-related legislation</li><li>• Understanding the target audiences</li><li>• Trusted sources of VICP information</li><li>• Current and past VICP messaging</li><li>• Effective communication strategies</li></ul>
<b>Traditional and Online Environmental Scans</b> <ul style="list-style-type: none"><li>• Trusted sources of VICP information</li><li>• Current and past VICP messaging</li><li>• Current and past online VICP discussions</li><li>• Effective communication strategies</li></ul>
<b>Subject Matter Expert Discussions</b> <ul style="list-style-type: none"><li>• Current and past VICP messaging</li><li>• Trusted sources of VICP information</li><li>• Effective communication strategies</li></ul>
<b>Focus Groups</b> <ul style="list-style-type: none"><li>• Understanding of the target audiences</li><li>• Trusted sources of VICP information</li><li>• Effective communication strategies</li></ul>

## a. VICP BACKGROUND: RELATED LEGISLATION

### ***Legislative context of vaccine injury compensation and outreach***

During the early 1980s, vaccine safety gained national attention with a sharp increase in the number of civil lawsuits filed on behalf of children who presumably experienced adverse events (e.g., injury or death) as a result of diphtheria, tetanus, and pertussis (DTaP) vaccine exposure (Evans, 2006). Through the civil tort system, rulings and awards were made in favor of plaintiffs who claimed that they experienced adverse events from DTaP vaccine exposure. Due to the high costs incurred by these lawsuits, several major vaccine manufacturers halted production, which destabilized the entire U.S. vaccine market. In turn, vaccine shortages caused eminent concern about the resurgence of contagious disease epidemics (Anderson, 2003; Mello, 2007; Moreland, 2008; National Vaccine Program Office, 2010).

To simultaneously address these growing public health concerns and reduce liability for vaccine manufacturers and administrators, Congress passed the National Childhood Vaccine Injury Act (the Act) in 1986. The Act, which has since been amended, led to the creation of the VICP, which became operational in October 1988. The VICP is housed within DVIC and is administered by HHS; the Department of Justice (DOJ) and the U.S. Court of Federal Claims (the Court) also have a role in its administration.

The VICP was designed to compensate individuals on a “no-fault” basis, such that vaccine-related injury or death claims must be submitted to the VICP before further litigation directly against vaccine manufacturers and/or health care providers (i.e., vaccine administrators) may be sought (HRSA, n.d.). In addition, individuals who submit claims to the VICP are afforded a reduced burden of proof compared to the level of proof required for civil suits; i.e., presumptive causation versus actual causation may in some cases be sufficient proof to establish vaccine-related injury or death through the VICP (the Court’s Office of Special Masters [OSM], n.d.).

The determination of presumptive causation is dependent on whether a case’s circumstances align with the Vaccine Injury Table (Table) and Qualification and Aids to Interpretation (Aids to Interpretation),<sup>1</sup> which list covered vaccines as well as associated adverse events and prescribed time frames within which the adverse events must occur. If a given claim meets the criteria specified by the Table and Aids to Interpretation, then the requirement for proof substantiating actual causation is waived. Such claims are referred to as “on-Table.” However, if a claim does not directly correspond to the Table and Aids to Interpretation, then proof (e.g., “evidence in the form of scientific studies or expert medical testimony”) must be presented to establish actual causation (OSM, n.d.).

Compensation paid by the VICP may be awarded for (1) past and future un-reimbursable medical, custodial care, and rehabilitation costs; (2) up to \$250,000 for actual and projected pain and suffering or emotional distress; (3) lost earnings; and/or (4) attorneys’ fees and costs. For cases where compensation is being paid for vaccine-related deaths, up to \$250,000 for the estate of the deceased in addition to attorney costs may be awarded. Individuals may be compensated for attorney costs regardless of whether causation is determined for their cases (HRSA, n.d.).

The VICP is funded by the Vaccine Injury Compensation Trust Fund (the Trust Fund). The Trust Fund is primarily used to compensate vaccine-related injury or death claims for covered vaccines on or after October 1988<sup>2</sup> and also to cover VICP administrative costs. For each vaccine dose or disease case

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<sup>1</sup> The Table and Aids to Interpretation is included in Appendix 1.

<sup>2</sup> Retroactive compensation for vaccine-related injuries or deaths, which occurred prior to 1988, was paid from general appropriations (OSM, n.d.).

hypothetically prevented by the vaccine dose, a \$0.75 excise tax is garnered by the Trust Fund. Those vaccines covered under the VICP include those recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), subject to an excise tax by Federal law, and added to the VICP by the Secretary of Health and Human Services. The Department of Treasury collects the excise taxes and manages the Trust Fund. To date, nearly \$2 billion has been paid from the Trust Fund in compensation for claims filed post-1988. There is currently more than \$3 billion in the Trust Fund (OSM, n.d.).

To process the large number of autism-related claims filed around 2002, the OSM began the Omnibus Autism Proceeding (Moreland, 2008). This proceeding was broken down into a two-step process consisting of (1) a general inquiry that tested two different theories of “general causation” and (2) the application of evidence from the general inquiry to the other individual autism cases. The general causation theories tested were “that MMR [measles, mumps, and rubella] vaccines and thimerosal-containing vaccines can combine to cause autism; and that thimerosal-containing vaccines can alone cause autism” (Moreland, 2008; OSM, n.d.). The first of the two general causation theories was tested with respect to three cases during 2007. Two of the three cases were appealed to the Federal Circuit, where they presently remain pending. For the other case, no appeal was made to the Federal Circuit. The three cases for the second theory of general causation were adjudicated in 2008 with decisions issued by the OSM on March 12, 2010. Both of the theories of general causation have been disproven by the Special Masters who initially adjudicated these test cases.

### ***Vaccine injury compensation process<sup>3</sup>***

Individuals who presumably experience adverse events from exposure to vaccines covered in the Table may seek compensation through the VICP. A claim must be filed by or on behalf of the individual who presumably experienced an adverse event as a result of a vaccine covered by the VICP to receive compensation. A claim is made to the VICP by filing a petition, which is a legal document prepared by the claimant or his or her lawyer requesting compensation. Anyone who files a claim is referred to as a petitioner. It is not required to use a lawyer to file a petition, but most individuals choose to do so. If certain minimal income requirements are met, the VICP will subsidize claim-related attorney and other costs. To receive payment through the VICP, a lawyer must file a motion for attorney’s fees. The motion may be filed interim or toward the conclusion of VICP proceedings. The VICP will not pay the fees of petitioners representing themselves.

Once received, the Court then sends one copy of the claim and medical records to the DOJ. An HHS medical professional reviews the medical information included in the claim and makes an initial determination regarding causation. This review is then sent to the DOJ lawyer, who is assigned to represent the Secretary of HHS. The DOJ lawyer reviews the legal aspects of the claim and then writes a report. This report is subsequently combined with the HHS review and sent to the Court and the petitioner. The DOJ lawyer and the petitioner or petitioner’s lawyer then take legal action to resolve the claim, which is followed by the designated Special Master’s decision on whether compensation will be paid and, if so, how much. The petitioner must decide in writing whether to accept or reject the Special Master’s decision. Decisions may first be appealed by the petitioner or HHS to the Court and thereafter to the Federal Circuit Court of Appeals and finally the Supreme Court.

*\*\*Additional information and history on vaccination laws, requirements, and recommendations can be found in Appendix 2.\*\**

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<sup>3</sup> The Process to File Claims With the VICP chart is included in Appendix 3.

## 2. Review of the VICP Literature

### a. METHODOLOGY

This section of this report presents the findings of a review of the peer-reviewed, U.S.-published literature on Vaccine Injury Compensation Program (VICP) perception and Program messaging and promotion. Key questions this literature review investigated included:

- What is the perception and understanding, if any, of the VICP?
- What efforts, if any, have been conducted to educate VICP target audiences?

The search of peer-reviewed literature began in November 2009 and was conducted using electronic journal databases that included MEDLINE, Academic Search Complete, ProQuest, and PubMed. Search engines such as Google were also used in searching for relevant reports and publications. Various combinations of a select set of search terms were used to conduct the search and are included in Appendix 4. Most of the articles and reports reviewed were published within the 10 years preceding the start of this review.

In the previous section, the VICP's legislative history and context were researched and included to provide a solid background for the Program as a VICP outreach and marketing approach is considered. Research on VICP perception and understanding and on messaging and promotion strategies was conducted to inform VICP education in more detail. It asked what the current public opinion of the VICP is and what has been done to reach out to this public based on their perceptions and needs so far. While no VICP-specific peer-reviewed research exists on opinions of the Program or on its outreach efforts, several findings arose from areas such as general vaccine risk/benefit communication, as well as from a previous Altarum Institute (Altarum) study, that might relate to an outreach and marketing plan.

#### Select Literature Review Themes

Clear vaccine risk/benefit and VICP communication target audiences

Vaccine risk/benefit and VICP communication limited

Evident consumer messaging and tone preferences

Timing of communication important

Variety of trusted sources of vaccine risk/benefit information

### b. VICP PERCEPTION AND REACTION

The available literature regarding vaccines and the VICP primarily addresses factors associated with vaccination rates, as well as sociodemographic and other characteristics correlated with perceptions of vaccines and vaccination. Characteristics of un- or under-vaccinated children (and/or children whose parents oppose compulsory vaccination) that are consistently reported in the literature are being of African American or other minority races/ethnicities, coming from a low-income family, being uninsured or experiencing lapses in insurance, and not having continuous primary care in the medical home. Certain family characteristics are also consistently associated with lower vaccination rates, including

being the child of a single mother, having a mother without a college education, having multiple siblings or a higher birth order, and having a younger mother (Smith et al., 2004; Allred et al., 2007; Bundt & Hsou-Mei, 2004; Kennedy et al., 2005; Hutchins et al., 1999; Brenner et al., 2001).

Geography may also play a role in who does and does not get vaccinated. Smith et al. (2004) found lower vaccination rates in children residing outside the Northeast region, while Hutchins (1999) and Bundt & Hsou-Mei (2004) found that children living in an inner city or within a metropolitan statistical area were less likely to be vaccinated. States also vary in the availability of exemptions from mandatory vaccinations based on religious reasons and philosophical or personal beliefs, which can lead to variation in State immunization rates. Even within States, there is often a great deal of heterogeneity with regard to immunization rates and exemptions (Omer et al., 2009).

The more closely the available literature is examined, the more evident it becomes that there are complex interactions between socioeconomic and demographic factors and vaccination rates. Issues of causation, mediation, and interaction come into play. When issues of attitudes, beliefs, and perceptions are overlaid onto the already intricate web of socioeconomic and demographic characteristics, the picture becomes increasingly complex, as is demonstrated in numerous studies on the subject. Prislin et al. (1998)<sup>4</sup> state, “Although valuable, findings on sociodemographic correlates of immunization cannot explain underlying causes of the phenomenon.” Perceptions of vaccine efficacy and safety (including vaccine ingredients, additives, and side effects), the relative risk of disease and severity of the disease, the necessity of immunization as opposed to the development of “natural immunity,” trust in the government and health care system, feelings about the number of immunizations received at one time, and other issues have been studied with regard to their impact on vaccination rates, with varied results.

The overwhelming number of studies on factors associated with vaccination perceptions and rates are contrasted by the complete dearth of information on the perception and understanding of the VICP by the general public, either in aggregate or by demographic group. However, several studies do address health care providers’ views of the Program. This is important, as physician characteristics and recommendations have been shown to influence vaccination decisions and physicians are often a source of information for patients (Daley et al., 2006; Ma et al., 2006; Freed et al., 1998; Kimmel et al., 2007).

The literature regarding the VICP addresses two primary issues: (1) physicians’ communication with patients regarding the program and (2) physicians’ perceptions of the program’s ability to protect them from litigation. With regard to the latter, in a survey of family physicians, pediatricians, and general practitioners, Zimmerman et al. (1998) found that while most physicians surveyed were aware of the VICP (85% of respondents), only 41% believed that it offered them a high level of liability protection, 22% believed that it gave little protection, and 37% gave an intermediate response. Of the types of providers surveyed, pediatricians were most likely to know about the VICP (95%), followed by family practitioners (71%) and general practitioners (61%). Of note, the likelihood of encouraging vaccination varied by perceived level of protection afforded by the VICP. In a similar survey of pediatricians and family physicians, Freed et al. (1998) found that only 30% of respondents believed that Federal and State programs protected them against vaccine-related lawsuits; pediatricians were significantly more likely (30%) than family physicians (21%) to believe that these programs offered adequate protection. However, only 12% of pediatricians and 13% of family physicians believed that providing pediatric

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<sup>4</sup> Several references in this section are outside of the 10-year time frame established for the literature search (Freed et al., 1998; Prislin et al., 1998; Zimmerman et al., 1998) but are included here because they are some of the only peer-reviewed articles available that reference the VICP.

immunizations increased their chances of a malpractice suit; and overall, liability issues were not significantly associated with physicians' immunization practices (Freed et al., 1998).

With regard to physicians' communication with patients regarding the VICP, Davis et al. (2001) found a "mismatch between the legal mandate for Vaccine Information Statement (VIS)<sup>5</sup> distribution and the actual practice in private office settings." Sixty-nine percent of pediatricians and 72% of family physicians reported distributing VISs—an important finding given that the VIS contains information regarding the VICP. Even more telling, only 10% of physicians reported discussion of the VICP with patients, citing time as the primary limiting factor in overall vaccine risk/benefit communication. When asked what they felt that patients needed to know with regard to vaccines, only 20% indicated information on the VICP, and only 11% indicated that they felt that patients wanted to know about the VICP. Kimmel & Wolfe (2005) and Kimmel et al. (2007) further note the importance of distributing the VIS as a way of facilitating discussion between patient or parent and physician, particularly when time is cited as the most common barrier to adequate discussions. In a time-motion study of two public health clinics, Davis et al. (2004) found that while compliance with the distribution of VISs was high (VISs were given with every dose of vaccine administered in 89% of visits) and issues such as potential vaccine side effects, treatment of side effects, and the vaccine schedule were routinely discussed (in 91%, 91%, and 93% percent of visits, respectively), the VICP was never discussed during any visit observed during the study. The authors suggest that the VICP may not be discussed because State or clinic policy does not require such discussion.

Discussion of VICP messaging and promotion will continue in the following section. It is at this point useful to note that the only available data regarding the public's perception of the VICP were obtained through a study conducted by Altarum in 2008 for the Health Resources and Services Administration (HRSA) Division of Vaccine Injury Compensation (DVIC). As it was a voluntary survey of former petitioners of the VICP, even these data do not accurately reflect the perception of the VICP by the general public. They do, however, highlight some interesting findings regarding how petitioners learned of the VICP and their suggestions for increasing the public's knowledge and understanding of the VICP. Many respondents learned about the Program through unofficial sources. One-quarter of respondents (25.23%) learned about the Program from a Web site other than the one maintained by the VICP. However, the VICP Web site was the second most frequently reported source (17.76%). Common health care-related sources of VICP information included the health care provider who gave the vaccine (12.15%), another health care provider (13.08%), and the VIS (7.48%) that is given to the patient, parent, or guardian with each vaccination. Relatively few respondents found out about the Program through advertising: 6.54% had read about it in a newspaper or magazine, 5.61% heard about it on the radio or television, and 2.80% saw a flyer or brochure from the VICP. Four respondents (3.74%) found out about the VICP when they were contacted by the Centers for Disease Control and Prevention (CDC). Other sources of information included other parents or adults who had been involved with the VICP (12.15%); attorneys (11.22%); and the National Vaccine Information Center (2.80%), a private advocacy organization (Altarum Institute, 2009).

Respondents had differing opinions on the perceived ease of obtaining information about the VICP. More than one-third of respondents (35.24%) felt that the process was very or somewhat easy, and nearly the same proportion (37.15%) found the process very or somewhat difficult. The remaining respondents (27.62%) felt neutral about the ease of obtaining information about the VICP. Respondents most commonly suggested that health care providers should be made more aware of the VICP and be

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<sup>5</sup> CDC-published vaccine risk/benefit statements, to be discussed further in the following sections.



responsible for providing information about it to patients. Fourteen respondents felt that the VICP should be more widely advertised. Their suggestions included distributing pamphlets (e.g., in doctor's offices), advertising on television and in magazines, and maintaining a telephone hotline. Respondents felt that VICP outreach materials should be easy to read and include Program contact information (Altarum Institute, 2009).

The complete lack of peer-reviewed studies on the perception of the VICP, particularly by the general public, suggest that the target audiences for a marketing and outreach campaign by the VICP should not be restricted to any particular group, but rather address all primary audiences for whom vaccination is an important issue, including but not limited to parents of vaccine-age children, adults for whom vaccination is recommended, and health care providers. The only available literature regarding VICP perceptions underscores the importance, in particular, of reaching the provider population as they are one of the primary avenues through which the public receives information regarding vaccines and the VICP.

### **c. VICP MESSAGING AND PROMOTION**

#### ***Existing communication***

Currently, four primary sources of information and communication for the VICP exist: the DVIC National Vaccine Injury Compensation Program (VICP) brochure; the *What You Need to Know About the National Vaccine Injury Compensation Program (VICP)* booklet; the VICP Web page; and the CDC VISs.<sup>6</sup> The National Childhood Vaccine Injury Act (the Act) (as amended [42 USC, Section 300aa-10]), provides the legislative mandate for publicity of the VICP. It states, "The [Department of Health and Human Services (HHS)] Secretary shall undertake reasonable efforts to inform the public of the availability of the Program." Division of Vaccine Injury Compensation materials were developed in response. Centers for Disease Control and Prevention materials were developed in response to the Act as well, in response to the requirement that individuals administering vaccines purchased with government grants or covered by the VICP provide patients with appropriate vaccine information materials with the administration of each dose of vaccine. Division of Vaccine Injury Compensation materials were most recently updated in February 2006 and VISs are regularly amended with the input of several stakeholders, including HHS's Advisory Commission on Childhood Vaccines (ACCV). Table 1 details these materials further.

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<sup>6</sup> In 1992, the CDC created Vaccine Information Pamphlets, but simplification of these complex materials was soon required. The VISs followed in 1994 and are regularly amended.

**Table 1.**

Primary Sources of VICP Communication <sup>7</sup>			
Source	Format	Title	Brief Description and Availability
HRSA, DVIC	Trifold brochure	<i>The National Vaccine Injury Compensation Program (VICP)</i>	The brochure includes introductory sections titled “What is the VICP?”, “What vaccines are covered by the VICP?”, “What do you need to file a claim?”, “What is the Vaccine Adverse Event Reporting System (VAERS)?”, and “How do you obtain more information?” It includes some color and photos of a variety of populations (e.g., children, adults, older adults) on the cover. Available for download and order in English and Spanish on the VICP Web page (URL below).
	Approximately 10-page booklet, plus appendices	<i>What You Need to Know About the National Vaccine Injury Compensation Program (VICP)</i>	The booklet includes detailed information on “What is the VICP?”, “Why and when was the VICP created?”, “What is the process for filing a claim?”, and “How do I obtain more information?”; a summary of the Vaccine Injury Table and Qualification and Aids to Interpretation; and a “Description of the Diseases Prevented by VICP Covered Vaccines.” It includes some color and the same photos as the brochure on cover. Available for download and order in English and Spanish on the VICP Web page (URL below).
	Web page	<i>National Vaccine Injury Compensation Program (VICP)</i>	The page has brief information “About the VICP” and “Additional HHS Vaccine Information”, such as Countermeasures Injury Compensation and the CDC National Center for Immunization and Respiratory Diseases. It also includes VICP news feeds and sidebar links to the Omnibus Autism Proceeding, “Covered Vaccines”, “Filing a Claim with the VICP”, ACCV, Frequently Asked Questions, and Contact Information, among other things. Accessible on the HRSA Web site at <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a> .
CDC	Two-page flyers, front and back; majority also available in audio recordings	<i>Vaccine Information Statements (VISs)</i>	These information sheets (or, in some cases, audio recordings) explain to vaccine recipients, their parents, and/or their legal representatives both the benefits and risks of a vaccine. <sup>8</sup> Print VISs are in black and white and include no more than one image, if any; traditionally a graphic related to the vaccine-preventable disease (e.g., doctors treating patients, insects, animals). Vaccine Information Statements are divided into seven sections, including what the vaccine-preventable disease is, who should get vaccinated, and what the vaccine risks are. Section 6 contains the contact information for the VICP. Distribution by all providers who administer vaccines is mandated. Accessible on the CDC Web site at <a href="http://www.cdc.gov/vaccines/pubs/vis/">http://www.cdc.gov/vaccines/pubs/vis/</a> . Available languages depend on the vaccine and date updated but may include Chinese, Korean, Russian, Somali, Spanish, Tagalog, Thai, and Vietnamese, among others.

<sup>7</sup> Primary Sources of VICP Communication are included in Appendices 5–8.

<sup>8</sup> Per the CDC VIS Web site, VISs cover: Anthrax; Diphtheria and tetanus toxoids and acellular pertussis (DTaP); Hepatitis; Haemophilus influenzae type b conjugate (Hib); Influenza; Human papillomavirus (HPV); Japanese encephalitis (JE); Measles, mumps, and rubella (MMR); Meningococcal; Pneumococcal conjugate (PCV13); Pneumococcal polysaccharide (PPSV23); Polio; Rabies; Rotavirus; Shingles; Smallpox; Tetanus, diphtheria, and acellular pertussis (Td/Tdap); Typhoid; Varicella; Yellow Fever; and a VIS for “Multiple (birth-6 month) Vaccines” (DTaP, Inactivated poliovirus [IPV], Hib, PCV, Hepatitis B, and Rotavirus).

### **Communication research**

Within this research report's search criteria, no peer-reviewed literature was found that examined any DVIC materials and/or previous or current public education plans specifically for the VICP. When VICP communication is mentioned in the research, it is most often included in the larger context of general vaccine risk/benefit communication and/or health care provider provision of VISs, as mentioned in the Perception and Reaction section, and is only addressed if individual physicians discuss the Program with patients. In addition, much of this research discusses vaccine risk/benefit communication issues in the light of increasing and/or supporting vaccination rates.

A study of U.S. vaccine risk communication interventions from 1996 to 2006, found rigorous evaluation of general vaccine risk/benefit communication efforts lacking in the literature as well (Irving, Salmon, & Curbow, 2007). However, as VICP-specific public outreach and education has never been studied, there are several vaccine risk/benefit communication findings in the research that does exist of potential relevance to a VICP outreach plan.

*Clear vaccine risk/benefit communication target audiences.* All reviewed vaccine risk/benefit literature squarely focused on parents of vaccine-age children, and in many cases expecting parents, as the primary and most appropriate recipients of risk/benefit communication. In addition, the vast majority of literature identified health care providers as the primary, and in many cases most trusted, source of parents' vaccine risk/benefit information (Davis et al., 2002; Gellin, Maibach, & Marcuse, 2000; Gust et al., 2008; Irving, Salmon, & Curbow, 2007; Kimmel et al., 2007). While the VICP mandate is to educate the general public of its existence, both parents and providers are clear audiences to whom to bring VICP information to with special attention.

*Risk/benefit communication limited.* What is perceived as little available time during health care visits causes health care providers not to discuss vaccine risks/benefits thoroughly, and in some cases not to provide vaccine risk/benefit information at all (Davis et al., 2001; Irving, Salmon, & Curbow, 2007). If vaccine risks/benefits are communicated, as mentioned in the previous Perception and Reaction section, health care providers rarely if ever mention the VICP (Davis et al., 2001; Davis et al., 2002). In addition to simple lack of time, there is a worry about the conversations that in-depth risk/benefit information would provoke. In focus groups that Davis et al. (2006) conducted with physicians and nurses in six U.S. cities the development of a vaccine risk/benefit communication package, providers felt that discussions of vaccine risks/benefits would not only cause them to be "in the exam room all day" but also "open a can of worms" (p. 788).

*Evident consumer messaging preferences.* Parents clearly desire information from their health care providers on the risks of vaccines out of respect and their growing belief in informed consent (Davis et al., 2002; Davis et al., 2004; Kimmel et al., 2007). Select specific vaccine risk/benefit messaging preferences and recommendations included:

- Provide both written information and the opportunity for direct dialogue with parents (Davis et al., 2001; Davis et al., 2002; Davis et al., 2006; Irving, Salmon, & Curbow, 2007).
- Acknowledge the *right* to ask questions, encourage them, and do not judge or condescend when asked (Davis et al., 2002; Gust et al., 2008).
- Present neutral, honest, science-based information (Gust et al., 2008; Gust et al., 2009).
- Include details and "all the facts," but be direct and practical (Gust et al., 2008; Gust et al., 2009).

*Timing of communication important.* Providing vaccine risk/benefit information to parents at the time of vaccination is mandated and important but may not be the only appropriate timing of communication. For example, in Irving, Salmon, & Curbow's (2007) extensive research, they found that providing information such as a VIS at the time of administering children's vaccines may be problematic, as parents are likely unable to adequately focus on the materials when they are also responsible for making immediate health care decisions for their child(ren). More specifically, it has been reported that along with information at vaccination, parents desire information during the prenatal period and/or before their child's first vaccine (Davis et al., 2001; Davis et al., 2006; Irving, Salmon, & Curbow, 2007).

*Variety of trusted sources of information.* As mentioned before, while health care providers are most often parents' primary source of vaccine risk/benefit information and are frequently their preferred source, some parents do turn to other sources to support their health care provider's guidance (Davis et al., 2001; Gellin, Maibach, & Marcuse, 2000). Several studies have found media coverage can be a key factor in perception of vaccinations and associated risks (Habel, Liddon, & Stryker, 2009; Ma et al., 2009; Woo et al., 2004). Organizations such as the American Academy of Pediatrics (AAP) and the CDC have been recognized by some parents as credible sources of information on vaccinations (Gellin, Maibach, & Marcuse, 2000; Gust et al., 2009). In contrast, parents' opinion of vaccines and/or experience with adverse events has been reported to have a negative impact on trust of Federal government-sponsored health- and vaccine-related communication and requirements (Gust et al., 2009; Woo et al., 2004). For example, 75% of parents questioning immunization in a Gust et al. (2009) study disagree or are neutral the statement "The U.S. government provides complete, accurate info" (p. 294). And in Woo et al. (2004), only 34% of VAERS reporters agreed that "Government immunization requirements protect my children from getting diseases from non-immunized children" (p. 993). Acknowledging that different audiences seek and prefer information from different sources is key to comprehensive communication efforts.

### **Select health communication strategies and considerations**

The following health communication considerations have been well-referenced in the vaccine risk/benefit literature. While these strategies have usually been referenced as a way to support vaccination and/or improve vaccination rates (the focus of much of the vaccine risk/benefit communication research), they could also merit exploration when developing certain phases of a VICP-specific outreach and communications plan.

*Audience Segmentation.* In a Gust et al. (2008) study to develop tailored immunization materials for mothers, *audience segmentation* is described as dividing "people into segments based on shared characteristics so that interventions and educational materials can be tailored to best address their concerns and needs" (p. 499). For example, parents can be divided into five segments based on their attitudes and beliefs about health and immunizations. These segments include those generally supportive of immunizations ("Vaccine Advocate," "Health Advocate," and "Go Along to Get Along") and those less supportive ("Worried" and "Fencesitter").<sup>9</sup> For the purposes of this study to tailor and test educational immunization materials, Worried and Fencesitter mothers were targeted because they "had the most to offer in terms of opinions about what they needed to improve their support of immunizations and they had the most to gain from an intervention" (p. 499). As a result of several phases of educational immunization material development and testing with these mothers, a health care provider toolkit to be used in an office setting was developed that includes (1) a brochure for any

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<sup>9</sup> Segments originally devised in Gust, D.A., Brown, C., Sheedy, K., et al. (2004). Immunization attitudes and beliefs among parents: Beyond a dichotomous perspective. *American Journal of Health Behavior*, 29, 81-92.

parents with questions about immunizations (*The Vaccination Process for Children*), (2) a three-question survey that can identify Worried and Fencesitter segments, and (3) an accompanying tailored brochure for the Worried mothers and one for the Fencesitter mothers (*Facts about Immunizations*). While further evaluation of this toolkit is warranted, the AAP Section on Infectious Diseases's comments have already been incorporated, and responses from Worried and Fencesitter mothers thus far have been generally positive.

**Message Framing.** The implication of *message framing* (or information framing) is mentioned a number of times in vaccine risk/benefit communication literature as well as in literature on general health behaviors. In Irving, Salmon, & Curbow's (2007) risk communication research, they encountered a number of references to the fact that risk perception may be affected by how messages are framed; i.e. the order or context by which a message is delivered. For example, a message that highlights the lives saved by a vaccine may be more effective than one that emphasizes the dangers of the disease that it prevents. Kimmel & Wolfe (2005) and Kimmel et al. (2007) further document that proper communication of vaccine benefits and risks requires an understanding of factors (or heuristic processes) that affect an individual's perceptions of those benefits and risks, and that reframing vaccination messages in response to these factors or processes can be useful. For example, if a parent exhibits omission bias,<sup>10</sup> it may be helpful to reframe vaccination from the child's point of view. The effects of framing on HPV vaccination have also been studied. While in these cases there are conflicting conclusions as to whether gain- or loss-framed messages are most effective, purposefully and appropriately framed messages are clearly important to the reactions or message recipients (Gerend et al., 2008; Leader et al., 2009).

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<sup>10</sup> Omission (not taking action) bias may lead to vaccine refusal by parent who thinks, "If my child gets a vaccine reaction, it's my fault; if my child gets a disease, it's an act of God or nature." The parent feels less liable or guilty from an act of omission than from an act of commission or action (Kimmel & Wolfe, 2005; Kimmel et al., 2007).

### 3. Scan of the Field: VICP Players, Media, and the Online Environment

#### a. METHODOLOGY

This section of the report presents the findings of a scan of the Vaccine Injury Compensation Program (VICP)-related environment, including key stakeholders and media discussion and related events. Details of an online-specific environmental scan that investigated user-generated discussions surrounding the VICP are included in Part C. Key questions the traditional environmental scan investigated included:

- Who is the target audiences' source(s) for information about the VICP?
- What efforts, if any, have been conducted to educate VICP target audiences?
- How has the VICP been presented and discussed in the mainstream media?
- What, if any, upcoming events might impact the perception of the VICP?

A scan of U.S.-published VICP information in print media and professional Web sites began in November 2009 and was conducted using electronic databases that included MEDLINE, Academic Search Complete, ProQuest, and PubMed, but most often using Internet search engines such as Google. Key search terms from the literature review were also used in the environmental scan and are included in Appendix 4. Most of the information reviewed was generated and published within the five years preceding the start of the review.

Like the literature review, research for the environmental scans was conducted here to gather what current VICP public discussion, if any, through print media, stakeholder events and conversations, and online user-generated discussion might inform a VICP marketing and outreach campaign.

Select Environmental Scan Themes
Few VICP-specific experts and sources of information
No VICP-specific media coverage, from an education standpoint
Little integration of VICP into current vaccine-related events

#### b. VICP AND VACCINE-RELATED STAKEHOLDERS, MEDIA DISCUSSION, AND EVENTS

##### **Sources of VICP-related information**

The Health Resources Services Administration (HRSA) Division of Vaccine Injury Compensation (DVIC) is clearly the foremost source of in-depth VICP-specific information. In a search for additional information sources about the VICP, few additional sources that provide a significant amount of detail on the VICP were uncovered. As extensive DVIC- and VICP-specific outreach efforts were unreported in both the peer-reviewed literature and a scan of the environment, and as VICP-specific discussion between health care providers and patients is also little reported, resources with brief links to the VICP, VICP-related information, and stakeholders in the general vaccine field are people and places to which both consumers and providers turn for their vaccine risk/benefit communication. They could be resources for more specific VICP information as a marketing and outreach campaign is developed. These stakeholders and sources of information include Federal government agencies such as the Centers for Disease Control

and Prevention (CDC) (including the Advisory Committee on Immunizations Practices [ACIP], the National Immunization Program, the National Center for Immunization and Respiratory Diseases), and the Department of Health and Human Services (HHS) National Vaccine Program Office; professional associations such as the American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), and American Academy of Physician Assistants; and additional sources such as the Immunization Action Coalition, the National Network for Immunization Information, and the National Vaccine Information Center (NVIC). A more complete listing of approximately 20 agencies and organizations is in Appendix 9, including (1) organization name and URL<sup>11</sup>; (2) organization type (e.g., Federal Government, professional association, nonprofit); (3) leadership; (4) brief description of purpose or activities; and (5) select connection to the VICP, if any. This list is not exhaustive but is a sample of major resources in the vaccine and vaccine injury field, some of which have links to VICP information. This list does not include online resources with primarily user-generated content.

### ***VICP print media trends***

In the last five years, the overwhelming majority of media attention that the VICP has received is in relation to the Omnibus Autism Proceeding. A scan of appropriate publications from the 25 most widely circulated newspapers and magazines<sup>12</sup> reveals a pattern of newspaper articles addressing the VICP around the time of major milestones and decisions in the autism cases. For example, in February 2009, almost every newspaper examined ran an article on the decision of the U.S. Court of Federal Claims regarding the first three test cases (Cedillo, Hazelhurst, and Snyder<sup>13</sup>), all of which were decided in favor of the Department of Health and Human Services (HHS). Headlines during this time included “U.S. Court Finds No Link Between Vaccines, Autism,” “Court Says Measles Vaccine Not to Blame for Autism,” and “Foes of Vaccines Jabbed.”

As with any complex issue presented in the mainstream media, the issues surrounding the VICP tend to become oversimplified in translation. For example, in the case of Hannah Poling, now age nine, who developed autistic symptoms after receiving a number of vaccines when she was 18 months old, the Special Master overseeing the proceedings concluded that vaccines “significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism and manifested as a regressive encephalopathy with features of autism spectrum disorder. Therefore, respondent recommends that compensation be awarded to petitioners.” This decision was generally hailed in the media as a victory for the anti-vaccination movement, with some activists claiming that the decision was the first time that the government has conceded a link between vaccines and autism. The case, of course, was not that simple, involving complex underlying conditions and the development of “autism-like” symptoms. The decision was routinely questioned in the scientific literature, but the coverage in the mainstream media was enough to, in the words of one media outlet, “reopen the furious debate.”

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<sup>11</sup> URLs were accessed most recently on April 26, 2010.

<sup>12</sup> A listing of Major Magazines and Newspapers Searched is included in Appendix 10.

<sup>13</sup> Originally, three different theories of “general causation”—i.e., how vaccines can cause autism—were to be put forth in the Omnibus Autism Proceeding. Three Special Masters were assigned to resolve the autism cases. Three “test cases” were designated for each of the three theories, for a total of nine test cases. The three theories of “general causation” originally designated were (1) that MMR vaccines and thimerosal-containing vaccines can combine to cause autism, (2) that thimerosal-containing vaccines can alone cause autism, and (3) that MMR vaccines alone can cause autism. However, the third theory was not advanced, since evidence pertaining to that theory was largely presented in the first theory test cases. During 2007, hearings were conducted in the three test cases representing the first general causation theory. Specifically, in June 2007, Special Master George Hastings presided over *Cedillo v. HHS*, No. 98-916V; in October 2007, Special Master Patricia Campbell-Smith presided over *Hazlehurst v. HHS*, No. 03-654V; and in November 2007, Special Master Denise Vowell presided over *Snyder v. HHS*, No. 01-162V.

While newspapers tended to report on milestones and decisions in the test cases before the court (with some exceptions, magazine articles were more likely to highlight the “human factor” (e.g., profiles of families negatively affected by vaccines, such as the Polings). Whether the magazine tended to present the VICP positively, negatively, or neutrally depended on the overriding philosophy of the magazine, with no discernible pattern or overarching viewpoint across publications. Table 2 presents a summary of a select few magazine articles referencing the VICP. The summaries of these articles are emblematic of the wide range of viewpoints presented in the mainstream media regarding the VICP—and in particular the Omnibus Autism Proceeding—as well as the dearth of media coverage of the VICP with an intent to simply educate the public in any detail about its purpose and operation.



**Table 2.**

Sample Print Media References to VICP		
Source	Article Summary	Discussion of VICP
<p>“Why Does the Vaccine/Autism Controversy Live On?” by Chris Mooney, <i>Discover Magazine</i>, June 2009</p>	<p>“Vaccines do not cause autism. That was the ruling in each of three critical test cases handed down on February 12 by the U.S. Court of Federal Claims in Washington, D.C. After a decade of speculation, argument, and analysis—often filled with vitriol on both sides—the court specifically denied any link between the combination of the MMR vaccine and vaccines with thimerosal (a mercury-based preservative) and the spectrum of disorders associated with autism. But these rulings, though seemingly definitive, have done little to quell the angry debate, which has severe implications for American public health.”</p>	<p>“The wave of autism-related claims filed with the U.S. government’s Vaccine Injury Compensation Program is unprecedented. Since 2001 autism claims have outnumbered nonautism cases almost four to one. Following the science, the court has now dismissed many of them, but there is the possibility that civil litigation will follow. ‘I still think it’s going to be another 10 years before this really washes out in litigation,’ Offit says. If the legal atmosphere becomes too difficult for vaccine manufacturers, they could stop producing them or be forced out of business.”</p>
<p>“When Science and Justice Clash” by Matt Ransford, <i>Popular Science Magazine</i>, March 2008</p>	<p>“By conceding the plausibility of an autism-vaccine link, some think a federal claims court unwittingly gave ammo to a dangerous theory... Ultimately, the worry is that the misinformation campaign will take hold and lead more parents to forgo vaccination for their children. While this is not a problem for the population at large when only a small number of children are not immunized, it becomes a serious public health threat when the numbers increase.”</p>	<p>“Paul Offit has written an op-ed in today’s New York Times which hastens to point out what other news stories have largely misrepresented in the Hannah Poling autism lawsuit: The outcome of the court ruling does not mean the government is admitting to a causal link between childhood vaccines and the onset of autism. Rather, it is an indication that a special federal claims court enlisted to hear vaccine-related cases has made a ruling based not on the preponderance of evidence but on biological plausibility.”</p>
<p>“Case Study: Autism and Vaccines” by Claudia Wallis, <i>Time Magazine</i>, March 2008</p>	<p>“What happened to little, red-haired Hannah Poling is hardly unique in the world of autism. She had an uneventful birth; she seemed to be developing normally—smiling, babbling, engaging in imaginative play, speaking about 20 words by 19 months. And then, right after receiving a bunch of vaccines, she fell ill and it all stopped.”</p>	<p>“What’s unique about Hannah’s case is that for the first time federal authorities have conceded a connection between her autistic symptoms and the vaccines she received, though the connection is by no means simple. A panel of medical evaluators at the Department of Health and Human Services concluded that Hannah had been injured by vaccines—and recommended that her family be compensated for the injuries. [Nonetheless] there’s no denying that the court’s decision to award damages to the Poling family puts a chink—a question mark—in what had been an unqualified defense of vaccine safety with regard to autism.”</p>
<p>“Autism and Vaccines: One Family’s Story” by Sharon Cotlier, <i>People Magazine</i>, March 2008</p>	<p>“Terry and Jon Poling argue vaccines are to blame for their daughter Hannah’s autism. A legal decision in their favor reopens the furious debate.”</p>	<p>“While 4,800 claims are backed up in a federal vaccine court, the Polings recently became the first family of the group to receive the promise of a financial settlement and an acknowledgment—albeit of limited scope—that vaccines contributed to Hannah’s symptoms. ‘This concession represents an important victory,’ says attorney Cliff Shoemaker, who represents the Polings. ‘For the first time that I am aware of, the government has conceded that there is a way that vaccines can result in autism.’ Scientists and physicians strongly disagree that the case suggests any such thing. According to a court document leaked on the Internet, it was concluded in the so-called vaccine court that the shots given to Hannah in July 2000 ‘significantly aggravated an underlying mitochondrial disorder,’ a disease that impedes a cell’s ability to generate energy. That, in turn, produced a brain injury that resulted in autistic behavior. While the Polings will now be compensated for Hannah’s care (the amount has not yet been determined), the court stopped short of drawing a link between vaccines and autism. ‘Let me be very clear that the government has made absolutely no statement indicating that vaccines are a cause of autism,’ says Dr. Julie Gerberding, director of the Centers for Disease Control and Prevention.”</p>

**Relevant vaccine-related events**

There are a growing number of vaccine-related events, as well as non-vaccine-related events held by organizations who are key vaccine stakeholders, which may also affect the perception of the VICP. These events may provide a “ready-made” teachable moment for the VICP. It is likely that some of the events, particularly any major decisions in the Omnibus Autism Proceeding, will receive media attention and therefore present an opportunity for the VICP to educate the public about its existence and purpose. Table 3 below presents a summary of these events.

**Table 3.**

Select Vaccine-Related and Vaccine Stakeholder Events			
Event	Sponsor	Description and URL, <sup>14</sup> if available	2010 Date(s)
ACIP Meetings	CDC	“The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the Federal government that makes such recommendations. The overall goals of the ACIP are to provide advice that will lead to a reduction in the incidence of vaccine-preventable diseases in the U.S., and an increase in the safe use of vaccines and related biological products.” <a href="http://www.cdc.gov/vaccines/recs/acip/meetings.htm#dates">http://www.cdc.gov/vaccines/recs/acip/meetings.htm#dates</a>	February 24–25, June 23–24, and October 27–28
Annual Conference on Vaccine Research	National Foundation for Infectious Diseases	“The Annual Conference provides high quality, current reports of scientific progress featured in both invited presentations and submitted abstracts. The disparate fields covered in both human and veterinary vaccinology encourage valuable cross-fertilization of ideas and approaches among researchers otherwise focused on specific diseases or methods. The Conference has become the largest scientific meeting for disease prevention and treatment through immunization.” <a href="http://www.nfid.org/conferences">http://www.nfid.org/conferences</a>	April 26–28
Annual Meeting and Exposition	American Public Health Association (APHA)	“The Annual Meeting and Exposition is the oldest and largest gathering of public health professionals in the world, attracting more than 13,000 national and international physicians, administrators, nurses, educators, researchers, epidemiologists, and related health specialists. APHA’s meeting program addresses current and emerging health science, policy, and practice issues in an effort to prevent disease and promote health.” <a href="http://www.apha.org/meetings/">http://www.apha.org/meetings/</a>	November 6–10
Annual Scientific Assembly	AAFP	<a href="http://www.aafp.org/assembly/2010/index.html">http://www.aafp.org/assembly/2010/index.html</a>	September 29–October 2
International Public Conference on Vaccination	NVIC	<a href="http://www.nvic.org/Events/Vaccine-Conference-2009.aspx">http://www.nvic.org/Events/Vaccine-Conference-2009.aspx</a>	2010 date not yet available

<sup>14</sup> URLs were accessed most recently on April 26, 2010.

Select Vaccine-Related and Vaccine Stakeholder Events (cont'd)			
Event	Sponsor	Description and URL, if available	2010 Date(s)
National Advocacy Conference	American Medical Association (AMA)	<a href="http://www.ama-assn.org/ama/pub/advocacy/get-involved/national-advocacy-conference.shtml">http://www.ama-assn.org/ama/pub/advocacy/get-involved/national-advocacy-conference.shtml</a>	2010 date not yet available
National Conference & Exhibition (NCE)	AAP	“The NCE offers a fresh perspective on your CME [continuing medical education] and lifelong learning, and industry leaders on our exhibit floor guide you through the latest pharmacologic and technologic advances. No matter your role in medicine, if you provide direct patient care for infants, children, or adolescents, you belong at the world’s largest medical educational event in pediatrics.” <a href="http://www.aapexperience.org/">http://www.aapexperience.org/</a>	October 2–5
National Conference on Immunization and Health Coalitions (NCIHC)	Chicago Area Immunization Campaign	“The NCIHC is intended to advance educational and networking opportunities for members of health coalitions and the public health community. NCIHC 2010 will showcase successful ways in which health coalitions can improve immunization protection, prevent disease, improve access to care and health outcomes for underserved populations, reduce racial, ethnic, and geographic health disparities, educate new populations, and build community health infrastructures. The purpose of the conference is to facilitate the sharing of successful strategies by coalitions that address immunization and other health issues in order to strengthen their efforts and thereby, improve the health status of our communities.” <a href="http://www.ilmaternal.org/ncihc2010.html">http://www.ilmaternal.org/ncihc2010.html</a>	May 26–28
National Immunization Awareness Month (NIAM)	CDC	“August observation of NIAM is a great way to rally local organization in your immunization education efforts. Communities are encouraged to plan local health screenings or fairs, media events and other related immunization outreach efforts during the month of August to promote the benefits of immunization.” <a href="http://www.cdc.gov/vaccines/events/niam/default.htm">http://www.cdc.gov/vaccines/events/niam/default.htm</a>	August
National Immunization Conference	CDC	“The goals of the Conference are to provide information that will help participants provide comprehensive immunization coverage for all age groups and explore innovative strategies for developing programs, policy, and research to promote immunization coverage for all age groups.” <a href="http://www.cdc.gov/vaccines/events/nic/default.htm">http://www.cdc.gov/vaccines/events/nic/default.htm</a>	April 19–22
National Immunization Survey (NIS)	CDC	“The NIS is sponsored by the CDC’s National Center for Immunizations and Respiratory Diseases (NCIRD) and conducted jointly by NCIRD and the National Center for Health Statistics (NCHS). The NIS is a list-assisted random-digit-dialing telephone survey followed by a mailed survey to children’s immunization providers that began data collection in April 1994 to monitor childhood immunization coverage.” <a href="http://www.cdc.gov/nis/">http://www.cdc.gov/nis/</a>	Ongoing
National Infant Immunization Week (NIIW)	CDC	“NIIW is an annual observance to highlight the importance of protecting infants from vaccine-preventable diseases and celebrate the achievements of immunization program and their partners in promoting healthy communities. Since 1994, NIIW has served as a call to action for parents, caregivers, and health care providers to ensure that infants are fully immunized against 14 vaccine-preventable diseases.” <a href="http://www.cdc.gov/vaccines/events/niiw/default.htm">http://www.cdc.gov/vaccines/events/niiw/default.htm</a>	April 24–May 1

Select Vaccine-Related and Vaccine Stakeholder Events (cont'd)			
Event	Sponsor	Description and URL, if available	2010 Date(s)
National Influenza Vaccination Week (NIVW)	CDC	<p>“National Influenza Vaccination Week is a national observance that was established to highlight the importance of continuing influenza vaccination, as well as fostering greater use of the flu vaccine after the holiday season into January and beyond.”</p> <p><a href="http://www.cdc.gov/flu/NIVW/index.htm">http://www.cdc.gov/flu/NIVW/index.htm</a></p>	January 10–16
National Influenza Vaccine Summit	CDC	<p>“The National Influenza Vaccine Summit started in the year 2000, is co-sponsored by the AMA and CDC. The Summit is an action-oriented entity with over 400 members who represent over 100 public and private organizations with an interest in addressing and resolving influenza and influenza vaccine issues.”</p> <p><a href="http://www.preventinfluenza.org/nvis.asp">http://www.preventinfluenza.org/nvis.asp</a></p>	2010 not yet available
National Vaccine Advisory Committee (NVAC) Meetings	HHS	<p>“The NVAC recommends ways to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to prevent adverse reactions to vaccines. A sampling of issues that the Committee has recently addressed include: vaccine safety, vaccine financing, adult immunizations, adolescent immunizations, immunization information systems, 2009 H1N1 influenza vaccine, and vaccine stockpiles.”</p> <p><a href="http://www.hhs.gov/nvpo/nvac/meetings/index.html">http://www.hhs.gov/nvpo/nvac/meetings/index.html</a></p>	April 23, May 5, June 2–3, and September 14–15
Omnibus Autism Proceeding	HHS	<p>“The last docket update on the Court’s Web page, dated March 25, 2010, states that on March 12, 2010, the Special Masters overseeing the three test cases (Mead, Dwyer, and King) for the second theory of causation before the Court rendered their decisions. The petitioners in those cases now have the option of seeking review of those cases. Additionally, as reported in an earlier docket update from October 9, 2009, the Hazlehurst and Cedillo case petitioners (two of the three test cases for the first theory of causation) filed an appeal in the U.S. Court of Appeals for the Federal Circuit (no timeframe for the appeal is given).”</p> <p><a href="http://www.uscfc.uscourts.gov/omnibus-autism-proceeding">http://www.uscfc.uscourts.gov/omnibus-autism-proceeding</a></p>	n/a
World Vaccine Congress	Terrapinn, Ltd.	<p>“Officially the longest-running and largest vaccine industry event in North America, World Vaccine Congress continues to deliver a forum where the ever-changing dynamics of an industry in resurgence are discussed and acted upon by the industry’s most senior figures.”</p> <p><a href="http://www.terrapinn.com/2010/wvcdc/index.stm">http://www.terrapinn.com/2010/wvcdc/index.stm</a></p>	April 19–22

### c. ONLINE ENVIRONMENTAL SCAN OVERVIEW

The use of the Internet has evolved significantly over the past two decades and the Web is now a frequently sought source of health information. According to a Pew Internet and American Life Project study, 61% of American adults use the Internet to find health information for themselves or on behalf of another individual. Among the 61% of American adults who go online to seek health-related information, 41% of them have read about health-related topics or experiences on a blog, news group, or Web site.<sup>15</sup>

As the influence of the Internet has evolved, so has that of online user-generated social media.<sup>16</sup> This section of the research report conveys a brief overview of the results of an online environmental scan, the goal of which was to uncover how, and if, user-generated VICP-related discussions are currently occurring online and to identify who is involved in those discussions.

During the scan, user-generated sources were observed over the course of three months. Appendix 11 includes a sampling of the online sources examined.

Significant to the development of the VICP outreach and marketing plan, we found that few individuals are actively creating new content that relates to the VICP. User-generated sites are used sparingly for inquiries and updates. The online conversations that do exist focus primarily on a perceived link between autism and vaccinations.

In addition, we found:

- No clear authority surfaces within the user-generated Web for information relating to VICP, vaccine injury and vaccine risk/benefit communication
- No key stakeholders emerge in the user-generated Web relating to VICP, vaccine injury and vaccine risk/benefit communication
- When vaccines, vaccine injury and vaccine risk/benefit are mentioned in the user-generated Web space, they are not robust relative to DVIC or VICP. When VICP is mentioned within the user-generated Web space, subsequent conversations become focused on issues unrelated to VICP.

With no substantial user-generated content regarding the VICP found online, various approaches may be considered for the VICP communications plan which should be analyzed from the broader perspective of all the research findings.

*\*\*Additional online scan documentation can be found in Appendix 11.\*\**

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<sup>15</sup> Fox, S., & Jones, S. (2009). *The social life of health information*. Pew Internet & American Life Project. Retrieved from <http://www.pewinternet.org/Reports/2009/8-The-Social-Life-of-Health-Information.aspx>.

<sup>16</sup> For the purposes of this scan, the “social Web” and “user-generated media” are defined as the content and conversation present on social media spaces, including social networking sites, blogs and microblogs, video-sharing sites, discussion and comments on traditional news media sites, and forums.

## 4. Conversations with Subject Matter Experts

### a. METHODOLOGY

From February 26 to March 5, 2010, 45-minute semi-structured phone interviews with six diverse vaccine risk/benefit communication Subject Matter Experts (SMEs) were conducted to obtain these experts perspectives about how to best communicate about the Vaccine Injury Compensation Program (VICP) to the public. Subject Matter Experts were identified in consultation with the Health Resources and Services Administration (HRSA) Division of Vaccine Injury Compensation (DVIC) and included representation from varied affiliations, such as government, academia, advocacy, and medicine. Each SME was briefed on the purpose of the Developing a Comprehensive National Vaccine Injury Compensation Program project and the role their responses would play in the development of a VICP marketing and outreach campaign. Subject Matter Experts were asked the same series of 15 questions<sup>17</sup> covering the following topics:

- Experience with vaccine risk/benefit communication research and/or practice;
- Knowledge of the VICP and perceptions of its current visibility and outreach;
- VICP stakeholders and sources of information;
- Suggestions for effective VICP outreach and communication, including target audiences, message format and tone, and images, among other things.

Upon completion of all interviews, several key themes surfaced:

- *Low level of public VICP awareness.* Overall, SMEs shared the perspective that much of the general public is little aware of the VICP and therefore does not have any strong current opinion of the Program. They believed that those that have read a Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) may be aware of the VICP's existence but likely do not know significantly more than the brief information provided therein. The only exception would be persons (or someone in their care) who have been negatively affected (in their perception) by a vaccination.
- *Consistent sources of VICP information.* Several organizations and agencies consistently arose as SMEs' perceived main sources of information about vaccinations and the VICP. This included the CDC, particularly their National Center for Immunization and Respiratory Diseases (NCIRD); associations and private organizations such as the American Academy of Pediatrics (AAP), the Immunization Action Coalition (IAC), and the National Network for Immunization Information (NNII); and advocacy organizations such as the National Vaccine Information Center (NVIC).
- *Consistent target audiences for VICP education.* Two key audiences regularly emerged as those for whom SMEs perceived VICP outreach to be appropriate and relevant: health care providers, including not only primary care physicians but obstetricians and gynecologists (OB/GYNs), nurses, and physician assistants (PAs) in a variety of settings; and parents of vaccine-age children and expecting parents, particularly mothers.
- *Fact-based, neutral VICP communication.* Subject Matter Experts believed that important to VICP outreach that does not advocate for or discourage vaccination is basing communication in science and facts, ensuring consistency and accuracy across sources, and presenting information in a neutral, non-paternalistic manner that empowers audiences to make their own informed choices.

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<sup>17</sup> Semi-Structured Subject Matter Expert Discussion Guide included in Appendix 12.

- *Varied methods and layers of VICP outreach.* The majority of SMEs advised that (1) different audiences prefer and best absorb their information in different formats and (2) health care providers and parents will need different levels of information and at different times. SMEs suggested that VICP information therefore be available in as many formats as possible (e.g., verbal, print, online) and tailored to given audiences.

## **b. EXPANDED INTERVIEW RESULTS**

### ***SME familiarity with the VICP***

Three SMEs worked for the Federal government; two worked for private organizations, specifically a hospital and a philanthropic foundation; and one worked for a State university. All six SMEs were aware of the VICP based on their current or previous work in vaccine risk/benefit communication and/or practice. No SME was familiar with the VICP based on a personal experience or general public education.

The level of familiarity with the VICP among SMEs varied. Half considered themselves very familiar with VICP policies and procedures; the remainder were aware of the Program’s existence by way of their work but did not feel that they knew about it intimate detail. No SMEs were familiar with any peer-reviewed research on the VICP or current VICP communication efforts.

### ***Public VICP awareness***

Most SMEs believed that the public<sup>18</sup> is not very well informed about vaccines in general. All perceived that parents and the public possess a low level of awareness of the VICP, if any. Several suggested even health care providers that give vaccines are not aware of it. The majority therefore believed that the public generally has no current perception or opinion of the VICP, and for those who are at least aware of it, there is “probably a good deal of misunderstanding.” For example, SMEs concluded, “People just don’t understand the purpose of the Program; the little that’s on the VIS just tells that the program exists,” and, “The perception is probably that it is a reporting mechanism or a court system.” Only one SME estimated that parents would be pleased with “an avenue for them to get compensated” if their child experiences an adverse event and would think the VICP is a “good thing.”

The one special population that several SMEs acknowledged would tend to know more of the VICP are those who believe they have experienced an adverse affect from a vaccination or have had exposure to someone who has experienced a negative effect, particularly the “autism community,” since there are several active related lawsuits, and “professional anti-vaccine activists.”

### ***Stakeholders and sources of VICP information***

When asked where the public gets their information about the VICP, in their perception, many SMEs acknowledged HRSA and the DVIC as probable major sources and stakeholders, with a few specifically citing the Department of Health and Human Services’ Advisory Commission on Childhood Vaccines. While SMEs were largely uncertain where the general public would obtain details on the VICP, they did offer a number of other sources from their professional experience, as well as sources that they believed may link the public to VICP information. Table 4 details these sources.

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<sup>18</sup> The majority of SMEs continuously focused on childhood vaccinations & on parents as a major audience; not necessarily the “general public”.

**Table 4.**

SME-Suggested Source of Information	Source’s Communication Method(s), if specified*
<b>Federal and local government</b>	
CDC <ul style="list-style-type: none"> <li>• NCIRD</li> </ul>	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.cdc.gov/vaccines/">http://www.cdc.gov/vaccines/</a></li> <li>• Miscellaneous print materials (e.g., VISs)</li> <li>• <i>The Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases</i>: <a href="http://www.cdc.gov/vaccines/Pubs/pinkbook/default.htm">http://www.cdc.gov/vaccines/Pubs/pinkbook/default.htm</a></li> <li>• Vaccine-related listservs</li> <li>• Health care provider training (e.g., Donna Weaver, RN, MN, Nurse Educator, NCIRD)</li> </ul>
Department of Justice	
Food and Drug Administration (FDA)	
State and local health departments and systems	
<b>Nongovernmental and professional associations**</b>	
American Academy of Family Physicians (AAFP)	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.aafp.org/">http://www.aafp.org/</a></li> </ul>
AAP	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.aap.org/">http://www.aap.org/</a></li> <li>• Red Book® Online: <a href="http://aapredbook.aappublications.org/">http://aapredbook.aappublications.org/</a></li> </ul>
American Medical Association (AMA)	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.ama-assn.org/">http://www.ama-assn.org/</a></li> </ul>
Children’s Hospital of Philadelphia, Vaccine Education Center	<ul style="list-style-type: none"> <li>• Paul Offit, MD, Director</li> </ul>
IAC	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.immunize.org">http://www.immunize.org</a></li> <li>• Deborah Wexler, MD, Founder and Executive Director</li> </ul>
The Johns Hopkins University, Institute for Vaccine Safety	<ul style="list-style-type: none"> <li>• Neal Halsey, MD, Director</li> </ul>
The National Academies	<ul style="list-style-type: none"> <li>• National Academies Press vaccine-related books/reports (e.g., <i>Financing Vaccines in the 21<sup>st</sup> Century: Assuring Access and Availability</i>)</li> </ul>
NNii	<ul style="list-style-type: none"> <li>• Martin Myers, MD, Executive Director and Editor-in-Chief</li> </ul>
Miscellaneous nursing organizations (e.g. American Nurses Association)	
<b>Advocacy and “watchdog” organizations**</b>	
Moms Against Mercury	
NVIC	<ul style="list-style-type: none"> <li>• Web site: <a href="http://www.nvic.org">http://www.nvic.org</a></li> <li>• Barbara Loe Fisher, Co-founder and President</li> </ul>
Miscellaneous autism awareness programs and online social networks	<ul style="list-style-type: none"> <li>• Web sites, blogs, listservs</li> </ul>
Miscellaneous parenting organizations and online social networks	<ul style="list-style-type: none"> <li>• Web sites, blogs, listservs</li> </ul>
<b>Independent vaccination campaigns**</b>	
Every Child By Two	

\* Additional Web sites and other communication methods may exist, but only methods specified by SMEs are included here.

\*\* Many of these, in particular, were SME assumptions. They may not provide extensive information about the VICP, if any, but SMEs thought that they might.



In addition to the above agencies and organizations, the vast majority of SMEs indicated health care providers, particularly primary care physicians, as a key source of vaccination and VICP information for their patients. For example, “Time and time again, it’s always a health care provider that is [the patients’] most trusted source of information.”

Subject Matter Experts also believed the general press/media and the Internet to be significant lay sources of VICP information, particularly due to coverage of “newsworthy” vaccine injury cases and claims (e.g., Hannah Poling) and advertising by lawyers.

Lastly, SMEs were asked what specific vaccination and VICP stakeholder events, if any, they were aware of and believed might impact an outreach and marketing strategy undertaken by the VICP (e.g., government conferences, professional association meetings, awareness campaigns). This question was posed in an effort to gather information on events and/or campaigns with which it may be appropriate to coordinate VICP education efforts. Table 5 summarizes SME remarks.

**Table 5.**

SME-suggested Relevant Events	
Sponsor	Event(s)
AAFP	Annual Scientific Assembly
AAP	National Conference and Exhibition
AMA	National Advocacy Conference
American Public Health Association	Annual Meeting and Exposition
CDC	National Immunization Conference
	National Immunization Survey
	Immunization Awareness Months/Weeks: <a href="http://www.cdc.gov/vaccines/events/">http://www.cdc.gov/vaccines/events/</a> (e.g., National Immunization Awareness Month, National Infant Immunization Week, National Influenza Vaccination Week)

***Influences on VICP perception***

After discussing their impressions of public knowledge of the VICP and sources of VICP information, SMEs were asked what factors might influence an individual’s perception and understanding of the VICP. Most SMEs found this difficult to answer based on what they perceived to be limited public knowledge of the VICP, as well as their own limited knowledge of existing VICP education and outreach efforts, but several factors did regularly arise:

- *Program complexity.* The VICP and vaccine injury are complicated, technical subjects, particularly if you provide any information beyond “here’s what the program is and here is where you can go if you need more information.”
- *Level of health literacy.* People can process and seek different levels of information. “There are high and low information seekers, and everything in between.”
- *Experience with adverse reactions.* If a person already knows someone with an adverse effect from a vaccine or perceives that person or someone in their care has been adversely affected, it could be difficult to take in any new (or newly presented) information that will change their opinion.

- *Sensationalized media coverage.* Mass media coverage of vaccine injury cases, including those involving the VICP, is often not based in science.
- *Potential government distrust.* There is significant doubt of whether or not the public trusts the government's direction. "If people don't believe they're being listened to, then they aren't going to listen."

### ***VICP communication considerations***

Taking into account their (vaccine) risk/benefit communication experience, their knowledge of current VICP communication, and the factors they thought may affect VICP perception, SMEs were ultimately asked to share what they believed to be key considerations when developing an outreach and marketing strategy for the VICP, including the best strategies to increase knowledge about the VICP, without advocating for or discouraging vaccination. Major considerations included:

- *Recognize that health care providers are both a key audience and communicator.*
- *Layer the communication approach.* As the most appropriate primary conduit of information, consider targeting health care providers for VICP education first and then moving on to parents through providers.
- *Consider different levels of information for different consumers.* "We talk to parents who are great with minimal information and others who research for hours and want an ingredient list of the vaccine; having both levels is important."
- *Keep messaging fact-based and within the perspective of incidence of vaccine injury.* "Make it clear that any kind of medical intervention can result in injuries," but do not provide "misleading information that vaccines are inherently unsafe."
- *Ensure uniformity in information.* Consider that parents often trust the final judgment of their physician but also look to other sources to see whether "everything lines up." Ensure that information seekers will find the same information if they search within different sources.

SME Communication Considerations: Specific Strategies	
<b>Target audiences</b> <sup>19</sup>	<ul style="list-style-type: none"> <li>• Health care providers: primary care physicians, pediatricians, OB/GYNs, nurses, PAs</li> <li>• Parents and expecting parents</li> </ul>
<b>Messaging and Tone</b>	<ul style="list-style-type: none"> <li>• VICP basics: why it was set up, what steps one takes</li> <li>• Fact-/Science-based: include scientific facts on vaccine safety and incidence of injury</li> <li>• Neutral</li> <li>• Simple: “You can’t have a brochure or Web site that is too technical”</li> <li>• Nonpaternalistic and respectful</li> <li>• Understanding: “We understand your child is the most important thing to you...”</li> <li>• Empowerment-based, not fear-based: “An adverse effect is rare, but if something does happen, we want you to have all the information you need”</li> <li>• Positively framed messages that stress informed “choice” and “action”</li> </ul>
<b>Format</b>	<ul style="list-style-type: none"> <li>• Multiple channels: “All the different ways you could possibly afford” <ul style="list-style-type: none"> <li>○ Print: pamphlets, brochures, flyers, VISs</li> <li>○ Internet: Web sites, Web links</li> <li>○ Verbal: interaction with health care provider</li> </ul> </li> </ul>
<b>Timing and Setting</b>	<ul style="list-style-type: none"> <li>• Early <ul style="list-style-type: none"> <li>○ When a pregnant woman visits the OB/GYN</li> <li>○ Anywhere that an expecting parent would visit or receive services: Babies R Us and like stores, midwives</li> </ul> </li> <li>• Repeated <ul style="list-style-type: none"> <li>○ When a parent takes a newborn to the first pediatrician visit</li> <li>○ When a person is receiving a vaccine</li> </ul> </li> </ul>
<b>Images</b>	<ul style="list-style-type: none"> <li>• Varied parents with children: different races or ethnicities, mothers and fathers</li> <li>• Positive images: nothing injury-related or fear-based</li> </ul>

**\*\*Risk Communication Advisory Committee to the FDA\*\***

*One SME spoke of the importance of including risk communication specialists in the long-term development of VICP communication strategies and referenced the FDA’s Risk Communication Advisory Committee as an example of this approach. “The Committee advises the Commissioner of the Food and Drug Administration or designee on methods to effectively communicate risk associated with products regulated by the FDA and in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and any other product for which the FDA has regulatory responsibility. The Committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. It also reviews and evaluates research relevant to such communication to the public by both FDA and other entities, and facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.”*

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm><sup>20</sup>

<sup>19</sup> Along with being sources of vaccine and VICP information, several SMEs indicated that State and local health departments as well as advocacy organizations could be potential audiences for another phase of VICP communication—State and local health departments in particular, as vaccination is a “very local thing, even though we look at it nationally.”

<sup>20</sup> URL most recently accessed on April 29, 2010.

## 5. Target Audience Focus Groups

### a. METHODOLOGY

Throughout April 2010, six one-hour focus groups with target audiences for Vaccine Injury Compensation Program (VICP) communication were held to obtain audiences' familiarity with the VICP, if any, and their opinions on effective VICP messaging and communication strategies. Focus group audiences and locations were identified in consultation with the Division of Vaccine Injury Compensation (DVIC) and were supported by the Centers for Disease Control and Prevention's (CDC) recommended population for a number of vaccinations, the peer-reviewed vaccine risk/benefit literature, and geographical research to reach the best variety in participant demographics. One focus group for each audience was held in each location. Selected audiences and locations follow:

Audiences	Locations
<i>Parents and Parents-to-be:</i> parents and caretakers of vaccine-age children and expecting parents	Charlotte, North Carolina  Chicago, Illinois
<i>Health care providers:</i> primary care pediatricians and physicians, nurses, physician assistants, and more (e.g., private practice, community health center, school-based)	
<i>Older adults:</i> people 50 years of age and older	

Group participants were recruited by the professional focus group facilities<sup>21</sup> at which the focus groups were held, based on specific criteria to ensure diversity in demographics such as race or ethnicity; gender; education level; and, in the case of health care providers, diversity in professions (e.g., physicians, nurses, physician assistants [PAs]) and work settings (e.g., hospital, private practice, community health center [CHC], school).<sup>22</sup> Ten to 12 potential participants were recruited for each group to ensure nine final participants.<sup>23</sup> When more than nine participants appeared, the most appropriate and diverse participants were selected for the group; the others did not participate.

Upon arrival at the focus groups, participants were briefed on the purpose of the Developing a Comprehensive National Vaccine Injury Compensation Program project and the role that their responses would play in the development of a VICP marketing and outreach campaign. Participants were asked a series of approximately 25 questions<sup>24</sup> covering the following topics:

- Knowledge of DVIC and the VICP;
- Trusted sources of vaccine risk/benefit and VICP information;
- Current vaccine injury and VICP communication practices and perceptions; and

<sup>21</sup> MarketWise (<http://www.marketwise-usa.com/>) in Charlotte, NC, and Survey Center Focus (<http://www.surveycenterllc.com/>) in Chicago, IL.

<sup>22</sup> Focus Group Screening Guides are included in Appendices 14a–c.

<sup>23</sup> No more than nine participants were permitted, in accordance with Office of Management and Budget clearance guidelines. Five of the six focus groups had nine participants; only health care providers in Charlotte had eight.

<sup>24</sup> Focus Group Discussion Guides are included in Appendices 15a–c.

- Future considerations for effective VICP outreach and communication, including a review of current DVIC VICP materials, preferred message format and tone, images, and more.

Upon completion of all focus groups, several key themes surfaced:

- *Limited knowledge of VICP among both health care providers and vaccine consumers, if any.*
- *Health care providers are main source of vaccine risk/benefit information for consumers, but variety of supplemental information sources as well.*
- *Limited VICP discussion between health care providers and consumers, if any.*
- *Neutral, fact- and science-based VICP communication materials preferred by both providers and consumers.*
- *Conflicting additional VICP communication expectations between providers and consumers, including level of information, timing of information, and impact on a decision to vaccinate.*

The following focus group results are presented by target audience: (1) health care providers and (2) vaccine consumers.<sup>25</sup> For each target audience, the results are described according to the various research areas addressed in the focus group protocols. Cross-cutting themes that emerged between the two target audiences are summarized in further detail in the section conclusion.

## **b. EXPANDED HEALTH CARE PROVIDER RESULTS**

### ***Participant composition***

The focus group with health care providers in Charlotte was conducted on April 6. The focus group with health care providers in Chicago was conducted on April 12. The group in Charlotte consisted of eight health care providers, including four nurses, three physicians, and one PA, with seven females and one male. These health care providers reported they practice in a variety of settings, such as hospitals, private practices, and schools, with patients of different ages (infants, children, adolescents, and adults). The group in Chicago comprised nine health care providers, including two nurses, four PAs, and three physicians. Health care providers who participated in the Chicago focus group also reported that they practiced in a range of health care settings, such as CHCs, hospitals, and private practices, with patients of different ages. For a detailed summary of the demographic information provided by all participating providers, please see Appendix 16.

### ***Knowledge and perception***

Across both focus groups of health care providers, all expressed they were unaware of DVIC. Similarly, most participants were relatively unfamiliar with the VICP. One provider reported that he had read about the VICP only on an information form provided by his daughter's school. Several providers spoke of how they became aware of the VICP through the mainstream media or "lay press." Only a few providers indicated they had become aware of the VICP from administering certain vaccines and reading Vaccine Information Statements (VISs); through medical societies, such as the American Academy of Pediatrics (AAP); or through journals, such as the *British Medical Journal*.

In general, providers did not express marked perceptions or attitudes regarding the VICP. However, in the Chicago focus group, several providers expressed positive perceptions of the Program. One of these providers stated that the VICP "promotes vaccines by backing them up." Among participants in the

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<sup>25</sup> Given the overwhelming similarities in results from the focus groups comprised of parents/parents-to-be and older adults, these results are described in terms of the encompassing the vaccine consumer target audience.

Charlotte group, responses related to VICP perceptions were generally more ambivalent. As one provider stated, “I don’t think the VICP is going to have an impact on what I tell parents; it’s there for the parents, not me.” Another provider echoed this sentiment, stating that the VICP “is a resource that is there for the parents, but I don’t have a lot of parents ask me about it.”

### **Trusted information sources**

**Government.** For the most part, providers trusted Federal sources as well as some State and local government sources of vaccine-related information. When asked about trusted sources of information specifically regarding vaccine risks and benefits, providers in both groups identified the CDC. In addition, the National Institutes of Health was recognized as a vaccine-related information source, as well as the Food and Drug Administration (FDA), which was repeatedly identified as a trusted source of information particularly with regard to vaccine testing and safety. Some providers additionally identified online State immunization registries (e.g., the North Carolina Immunization Registry), as well as State and local health department Web sites as vaccine-related information sources.

**Medical and health organizations.** Providers identified a variety of medical societies and associations, typically related to their specific health care professions, from which they had obtained vaccine-related information. These organizations included the American Academy of Family Physicians; the American Academy of Physician Assistants; the AAP, including the Red Book®; the American Nurses Association; the Society of Hospital Epidemiologists of America; and the American College of Obstetrics and Gynecology. Several providers additionally mentioned the World Health Organization as an information source more recently associated with the H1N1 pandemic and vaccine.

**Other sources.** To a lesser extent than the aforementioned sources, providers spoke of having received some vaccine-related information from pharmaceutical or “drug” companies. Continuing medical education (CME) courses were mentioned as another vaccine-related information source. Mainstream media sources, such as *Prevention* magazine, Oprah Winfrey, and “television commercials,” were also recognized as sources of information on the risks and benefits of vaccines. The search engine Google was frequently referred to by providers as a means by which vaccine-related information had been sought online.

### **Existing communication practices**

When asked how they currently communicate with their patients about vaccine risks and benefits, many providers responded that their patients are provided with printed materials and/or verbally informed of these issues. However, there was substantive variety in the sources of the printed materials on vaccine risks and benefits that participants referenced. For example, some participants expressed that these materials come from the CDC (e.g., the VISs, whereas others indicated that this information is derived from pharmaceutical companies (e.g., Merck). However, several providers expressed that they have not given VISs to patients who receive vaccines and/or do not have any printed materials concerning vaccine risks and benefits in their offices. Several providers further suggested that the amount of vaccine-related information that they provide to patients is partly contingent on how much patients want to know and

#### **Provider Communication on Vaccine Risks and Benefits**

- “We don’t have [vaccine] information readily available, but patients can print it out if they need it...”
- “We have basic information [on vaccine risks and benefits], and patients can Google the rest.”
- “Usually the nurse gives out a sheet of paper; it has the risks, what the vaccine is for, etc.”
- “I give [parents] the VIS and an office handout with the [vaccine] schedule.”
- “With the flu vaccination, we show [patients] the chart of risks and tell them they are eligible for the vaccine, [but] I’ve never given them... the VIS.”

ask. Although most participants indicated that they communicate with their patients about vaccine risks and benefits, many did not specify whether this communication typically entails mention of the VICP.

### ***Current materials on the VICP and future communication considerations***

During each focus group with health care providers, participants were presented with the National Vaccine Injury Compensation Program brochure (i.e., “trifold” or “pamphlet”), the *What You Need to Know About the Vaccine Injury Compensation Program* booklet, and a snapshot of the Web site homepage, all presently available through the DVIC (please see Appendices 5–8, respectively). All providers indicated that they were unfamiliar with these materials prior to the focus groups. Upon reviewing these materials, providers primarily expressed improvement-oriented feedback from their patients’ perspectives. Importantly, most providers indicated that they thought that these materials would deter patients from vaccination.

*General layout.* Many providers believed that too much information is contained in these materials for the purposes of their patients. With regard to the VICP brochure, one provider stated, “Patients are going to say this information is way too busy.” Moreover, providers commonly thought that patients would find this information difficult to understand. One provider stated, “This [information] is over [patients’] heads.” Another provider affirmed this sentiment, stating, “This is accurate information, but too much information; patients need something they can read speedily and easily.” Several providers suggested incorporating an FAQ or Q&A section into the VICP materials as one way of increasing reader accessibility. Providers also suggested lowering the reading level of these materials to partially remedy this situation. “The ideal [VICP] information would be general and short,” one provider surmised.

*Content and tone.* A more fundamental issue that many providers identified in their initial impressions to the VICP materials was the perceived negative tone of the VICP’s title and description. With regard to the Program’s title, one provider stated, “The name of the Program makes it sound like an expected outcome.” Another provider similarly stated, “I think [the VICP materials are] scary; people will think they can get hurt because of this.” The inclusion of more tangible information on the rarity of vaccine-related injuries, such as vaccine injury incidence statistics, was a common consideration broached among providers. One provider expressed, “When I look [at these materials], I see the word ‘death.’ If you are going to say that, people need to know what percentage and that it’s an incredibly rare event.” Several providers additionally suggested using images and/or brief descriptions to emphasize vaccine safety and benefits rather than risks.

*Dissemination.* In terms of when materials on the VICP should be provided to patients, most providers believe that the VICP information should be provided after vaccination occurs. Providers generally expressed that this preference still promotes VICP awareness among patients while minimizing any vaccine deterrence directly prior to administration. Several providers additionally suggested only providing the VICP materials to patients who think that they or their children have experienced vaccine-related adverse events. One provider stated, “You only need to hand out something like [the VICP materials] if someone comes to you with a definite identifiable adverse reaction. If they came to me and demonstrated a severe complication, then I would give them the information on the VICP after the fact.” The basis of this suggestion was that if patients were aware of the VICP prior to vaccination, then they would be more prone to believe and/or claim that they experienced vaccine-related adverse events. “If people think they could get money [through the VICP], they will come up with symptoms,” one provider stated.

Beyond the potentially negative reactions that providers indicated that their patients may have to the current VICP materials, providers recognized that the negative vaccine climate as portrayed in the mainstream media may also influence how such materials are received by their patients. One provider suggested that a medical organization such as the AAP would be a helpful partner “to give [the VICP] information” once patients have experienced vaccine-related adverse events.

*Vaccine-related information for health care providers.* Although very few providers had patients who had experienced vaccine-related adverse events,<sup>26</sup> several admitted that they would need to seek out additional information from other sources (e.g., pharmacies, textbooks, vaccine manufacturers, government resources) if this were to happen. Several providers indicated that they could also use more specific information regarding these topics than they believe is necessary for their patients. One provider reacted to the VICP brochure by saying, “If I got this as a pediatric provider, just me personally, you need to define what an adverse reaction [is], because as a provider, I have to prescribe everything very specifically. What is an adverse event to me is very different from what adverse is to [patients]...” Another provider supported this response, stating, “General public awareness is one thing, but health care professionals would want more specific [vaccine-related] information that is not for patients.” Several providers suggested that continuing education on these vaccine-related topics becomes more integral to maintaining health care licenses.

### **c. EXPANDED VACCINE CONSUMER RESULTS**

#### ***Participant composition***

The Charlotte focus groups with parents/parents-to-be and older adults were conducted on April 7. The remaining two focus groups with older adults and parents/parents-to-be were conducted in Chicago on April 13. In Charlotte, the focus group with older adults comprised nine individuals ranging in age from 50 to 79 years. The focus group held in Charlotte with parents/parents-to-be was also composed of nine individuals. Eight of the parent group’s participants had at least one child, and only one participant in this group did not presently have a child but was expecting. The focus group of older adults held in Chicago included nine individuals ranging in age from 50 to 74 years. Also in Chicago, the group of parents/parents-to-be was composed of nine individuals. Six of these participants had children, one participant had a child and was expecting, and two participants did not have children but were expecting. For a detailed summary of the demographic information provided by participants from the older adult and parent/parent-to-be focus groups, please see Appendix 16.

#### ***Knowledge and perception***

Nearly all consumers expressed that they were unfamiliar with the VICP and DVIC. Many participants in the parent/parent-to-be focus groups indicated that they had become aware of required vaccinations for their children through schools and/or health care providers. Some of these participants expressed apprehension about childhood vaccines. One participant stated, “I am more leery about the [vaccines] that are not required [for school entry], because of the side effects, so I only [have my child] get the ones that are required...for school.” Furthermore, participants in the parent/parent-to-be groups indicated they were aware of vaccine-related injuries. One participant recounted, “[I] knew someone years ago who had a vaccine[-related] adverse event; he is in his 20s now. I don’t know if he filed a claim, [but] it always leaves a wonder about the odds in the back of my mind.”

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<sup>26</sup> Only in Charlotte were there a (very) few that had patients who had experienced adverse events.



Participants in the two focus groups of older adults expressed considerably less apprehension related to vaccine safety than participants in the parent/parent-to-be groups. This may be associated with the reduced number of vaccines that older adults are required to receive. One participant in an older adult focus group stated, “When you have kids, there is some sort of [vaccine-related] knowledge, because kids have vaccines often. But as you get older, you might only hear about it from friends or when [a vaccine safety issue] is visible.” In addition, many older adults related their knowledge and perceptions of vaccines to their experiences with the “flu” or H1N1 vaccines.

### **Trusted information sources**

Across all four focus groups of vaccine consumers, health care providers were the most commonly identified trusted source of information. Participants also frequently indicated that they obtain vaccine-related information online. Many participants mentioned the search engine Google as a vehicle to seek out vaccine information online. “Vaccine safety,” “vaccine injury,” “childhood vaccines,” and “vaccination and autism” were listed by participants as popular search terms.

Participants identified government Web sites (e.g., the CDC and “health and human services” sites), medical organizations (e.g., the American Medical Association), and several independent health-related Web sites (e.g., WebMD) as familiar online vaccine information sources. Blogs related to vaccines were also referenced as an online source of information by some participants. Mainstream print and television news media (e.g., *Time Magazine*, the *Chicago Sun Times*, *Mothering Magazine*, MSNBC, FOX News, CNN) were additionally listed as vaccine information sources by vaccine consumers.

An important difference between the focus groups of older adults and parents/parents-to-be was that older adults expressed a stronger preference for obtaining vaccine-related information through their health care providers and/or friends or family members, especially if these friends or family members were or had been health care providers. However, participants from the focus groups of parents/parents-to-be consistently expressed a preference to supplement the vaccine-related information received from their children’s health care providers with information sought through alternatives such as the aforementioned online sources.

### **Information Sources Among Vaccine Consumers**

- “My doctor is the best source [of vaccine-related information]. I don’t go on the Internet, because my doctor always knows my conditions.”
- “The best [information] source is my primary care physician, as [she] knows what I should take and not.”
- “I collect [vaccine-related] information from different doctors and sources; then I do what is best for my daughter.”
- “Pediatricians are there for your child but are also biased, so I Google [vaccine information] to get all sides: the good, bad, and ugly.”
- “I do feel confident with [government information sources] but would prefer something with less legal speak. And in those cases, I turn to more plain speak [on] WebMD.”

### **Existing communication practices**

Most focus group participants indicated that they had received some information about the risks and benefits of vaccines from their health care providers. However, when and how this information was provided varied among participants. Among the two focus groups of parents/parents-to-be, participants most commonly indicated that they had received information on vaccine risks and benefits from their children's health care providers on the days of visits when their children were vaccinated. Participants generally did not specify when exactly during these visits their children's providers have given them this information. Participants also expressed that different communication modes (e.g., discussion, printed material) and information sources (e.g., the CDC, health care providers) regarding vaccines had been used during visits when their children were vaccinated. Moreover, all participants expressed that their children's health care providers had not discussed and/or provided them with information on the VICP.

Participants in the two focus groups of older adults similarly expressed that although they had received information concerning vaccine risks and benefits from their providers, they had not received much if any information on the VICP. Nevertheless, many of these participants spoke of how they had raised concerns about vaccine side-effects and injuries with their health care providers. For example, when participants in one older adult focus group were asked, "When you ask about vaccinations, how responsive are your health care providers?", one participant responded, "One hundred percent. We talk about the potential [vaccine] side effects, and then I make my decision." Here again, participants expressed that they generally trust the vaccine-related information that their health care providers give them, but they may feel compelled to do additional research if they have not received what they consider to be sufficient information, especially related to vaccine injuries. "If I were faced with a vaccine-related injury, I would do additional research and my provider would not be the end-all-be-all," one participant in a focus group of older adults succinctly stated.

### **Current VICP materials and future communication considerations**

During the focus groups with vaccine consumers, all participants were presented with the National Vaccine Injury Compensation Program brochure (i.e., "trifold" or "pamphlet"), the *What You Need to Know About the Vaccine Injury Compensation Program* booklet, and a snapshot of the Web site homepage, all presently available through the DVIC (please see Appendices 5–8, respectively). All participants were unfamiliar with these materials prior to the focus groups. Overall, participants' initial reactions to these materials were mixed with positive feedback and constructive criticism. Although some participants expressed that being exposed to these materials may motivate them to seek out additional information, most agreed that receiving these materials would not deter them from being vaccinated or having their children vaccinated.

#### **Perceptions of Existing Communication Practices Among Parents and Parents-to-be**

- "You receive information when it's time to get the vaccine."
- "I get [vaccine information] every vaccine visit from the nurse a few seconds before the vaccine. They print out information from the CDC with a different vaccine on a different color paper each time; that's all they change."
- "You don't receive it until the day you go in, and they tell you that the child needs the shot that day."
- "I am expecting, but my doctor has told me nothing about vaccine injury, and I feel clueless..."
- "I think that [my child's doctor] gives the most current information that she pulls from one of the Web sites, and I also get the information in a pamphlet that the practice makes... but the actual paperwork I don't get until that day."
- "I have never heard anything about what would happen if there was an adverse reaction."
- "Vaccine injury has never been raised."

*General layout.* Several participants provided positive feedback regarding the structure of the VICP brochure (i.e., “trifold” or “pamphlet”), stating, “This is clearly written,” and, “It’s nicely outlined and easy to understand.” Another participant expressed, “[The brochure] is friendly because it’s bullet pointed.” One point of constructive criticism voiced by a participant in the older adult focus group was that the brochure print was too small.

With respect to the VICP booklet structure, participants also provided positive feedback regarding its structure. One participant stated, “It’s laid out beautifully.” Participants also frequently mentioned that the booklet included more detailed information than the brochure and would consequently be used more as a reference material that participants would “file away.” One participant summarized this impression by stating, “The [VICP] brochure is good to get the word out; the booklet is then a follow-up if people need more information.”

Many focus group participants indicated that they would want to receive both the VICP brochure and the booklet. However, several participants spoke of how they would likely use the brochure more than the booklet. One participant reflected, “I’m not a reader and [have attention-deficit disorder], so I wouldn’t read the booklet as much [as the brochure].” Another participant further suggested that the quantity of information contained in the booklet may be overwhelming to some people, stating, “The booklet is the brochure on steroids....”

Overall, participants expressed less satisfaction with the design of the VICP Web site compared to the designs of the brochure and booklet. Participants described the VICP Web site as “poorly organized,” not providing sufficient information and “very claim[s] oriented.” To make the VICP Web site more user friendly, several participants suggested including a more prominent FAQ feature and centrally displaying information and/or Web links to information on vaccine risks and benefits.

*Content and tone.* Many participants from the focus groups of vaccine consumers expressed reactions parallel to those of participants in the focus groups of health care professionals regarding both the content and tone of the VICP materials. Numerous participants expressed that the tone of the VICP materials is very negative. In response to the VICP brochure, participants stated, “It’s well intentioned but very negative, like a warning,” and, “It’s nice until it says ‘death.’” Several participants suggested that the tone of the materials should be “a little more empathetic and mention something about the family, letting [families] know [that the DVIC is] a caring organization.” Several participants also expressed that they would perceive the materials to be a more credible information source if there were a more recent copyright date. In reaction to the VICP booklet, one participant stated, “I’m still taken aback by the 2006 date.”

Many participants also indicated the VICP materials should include more specific information on the incidence of vaccine-related injuries as well as clearer explanations of vaccine benefits. Participants further expressed that if the rarity of vaccine-related injury were more tangibly presented in the VICP materials, then this information would be better received by the public in terms of understanding and perception. “[The VICP brochure] should include statistics and an example of a [vaccine injury] case so people can better relate to the information and see if they qualify...,” stated one participant. Another participant indicated, “Don’t they have statistics that show 1 in 58,000 people [experience vaccine-related injuries]? I think that would help sway a decision [to be vaccinated] instead of people saying, ‘Gosh, I never knew this could happen.’” In reference to the VICP materials more generally, another participant said, “I think the language...is [too] vague. What it should really say is that vaccines, like any medicine, can rarely cause serious problems; that should be front and center...”

*Dissemination.* Across the four focus groups of vaccine consumers, most participants agreed that they would prefer to receive information on the VICP prior to vaccination. That is, participants generally indicated that they would find comfort in better understanding vaccine risks and benefits in relation to the VICP before being vaccinated. As one participant expressed, “I don’t want to be kept in the dark; whether [vaccine injury] is going to happen or not, I want to know [about it].” During this portion of the focus group discussions, most participants reaffirmed that receiving this information would not deter them from being vaccinated or having their children vaccinated.

For the most part, focus group participants indicated that they would prefer to receive the VICP materials from their or their children’s health care providers. In the two focus groups with parents/parents-to-be, participants expressed that they would like to receive the VICP materials during pregnancy. Several of these participants specified that an obstetrician-gynecologist should provide this information to patients who are expecting. “It would be good to receive the booklet around your third trimester but the brochure as a reminder when you pick a pediatrician; I agree some will toss the booklet, but expecting mothers should read it,” one participant in a parent and parent-to-be focus group stated. Although older adults also expressed that they would like to receive the VICP materials prior to vaccination, they generally did not express how far in advance they would prefer to receive these materials.

Many focus group participants also indicated that the VICP information should be made more easily accessible in health care settings (e.g., in the waiting rooms of their doctors’ offices, at the local pharmacy “checkout counter”). To promote public awareness regarding the VICP, focus group participants suggested alternate modes of VICP information dissemination (e.g., television commercials and infomercials, public service announcements and print advertisements in magazines or on public transit). In addition, participants suggested “getting the word out at health fairs sponsored by hospitals and communities” and including information on the VICP with routine bills, insurance statements, and/or prescription drugs to increase public awareness. Online advertisements, such as “pop-ups,” and a greater number of Web sites with VICP information were also suggested as alternate modes of information dissemination among focus group participants.

#### **d. EXPANDED FOCUS GROUP CONCLUSIONS**

The great majority of participants in the focus groups of both health care providers and vaccine consumers indicated they had limited knowledge of DVIC and the VICP. Although this finding was more pronounced among participants in the focus groups with vaccine consumers, many health care professionals similarly expressed that they knew little about the VICP and could benefit from receiving further education on the Program. Even with this limited knowledge, perceptions of the VICP were positive among participants in the focus groups with health care providers. Vaccine consumers, on the other hand, had no preconceived perception of the VICP, but many participants from this target audience expressed positive views of vaccines in general. Participants from the focus groups with older adults were notably forthcoming in articulating the benefits of vaccines throughout the lifespan.

With regard to trusted vaccine-related information sources, participants across focus groups identified government agencies, in particular the CDC. Additional government sources included the FDA and State and local health departments. Health care providers also identified medical societies and professional membership organizations as trusted vaccine-related information sources. In the focus groups with vaccine consumers, participants most often identified their or their children’s health care providers as

their main vaccine information source. Participants in these groups also indicated that they had sought vaccine-related information from alternative sources, including the mainstream news media and Web sites. However, participants in the focus groups of older adults indicated that they have typically sought out less supplemental vaccine-related information beyond what their health care providers provide. Participants from all focus groups spoke of frequently using the search engine Google to obtain vaccine-related information online.

Overall, most focus group participants reported having provided (health care providers) or received (vaccine consumers) some level of information on vaccine risks and benefits. However, substantial variability as to what, how, and when this information was administered and received in health care settings was reported among participants. With respect to information specifically on the VICP, few participants in the focus groups with health providers reported that they had explicitly provided or highlighted this information to patients when they were vaccinated, even if VISs were distributed. Similarly, few participants in the focus groups of vaccine consumers reported that they had overtly received information regarding the VICP during visits when they or their children were vaccinated, even if VISs were distributed.

In reaction to the VICP brochure, booklet, and Web site homepage, participants generally expressed the most criticism regarding the layout of the VICP homepage. Specifically, participants commonly suggested that the information displayed on the Web site should be briefer (e.g., prominent FAQ and Q&A features) and in plainer English (less “legalese”) with more hyperlinks to information on general vaccine safety. However, criticism did arise with regard to the print materials as well. Many participants in the groups of health care providers believed that the information provided in the VICP booklet and brochure would be too disorganized and dense for their patients to easily comprehend. In addition, providers suggested the materials be written at a lower reading level. Together, most participants from both target audiences additionally concurred that the tone and content of the VICP materials could be improved. In specific, participants expressed that the tone of the current VICP materials is somewhat anxiety provoking. Participants across groups suggested that a more empathetic tone in addition to an increased emphasis on the rarity of vaccine-related injuries may lead to more favorable impressions of the VICP materials.

Most health care providers indicated that they thought that the VICP materials would deter patients from vaccination during the focus groups. Consequently, many of these participants expressed that they would not want to administer the VICP materials to patients prior to vaccination. Some providers further indicated that they would want to provide these materials only to patients who had experienced vaccine-related adverse events. In contrast, most participants in the focus groups of vaccine consumers expressed that they would want to review the VICP materials prior to vaccination. Furthermore, many of these participants expressed that reviewing these materials would not deter them from being vaccinated or having their children vaccinated. Although many participants in the vaccine consumers groups indicated that they would use the VICP booklet more as a reference material, most agreed that they would prefer to receive both the brochure and booklet prior to vaccination.

In terms of dissemination preferences, participants from the focus groups with vaccine consumers generally agreed that they would prefer to receive information regarding the VICP as well as vaccine risks and benefits from their or their children’s health care providers. Health care providers who participated in the focus groups primarily indicated that they would like to receive this information through their CME courses, professional membership organization communications, and/or government agencies (Federal, State, or local). Participants across focus groups also suggested that to promote

public awareness of the VICP, alternative communication modes (e.g., television advertisements, mailings, public service announcements) with targeted messages should be pursued. In addition, many participants suggested that alternative information sources (e.g., pharmaceutical companies, medical societies, vaccine watchdog organizations) should be considered as vehicles whereby heightened public awareness of the VICP may be achieved.

## 6. Discussion: Major Themes and Future Considerations

The formative research provides valuable insights about the level of knowledge and awareness certain segments of the general public have about the Vaccine Injury Compensation Program (VICP), preferred communication channels, and feedback about existing VICP informational materials. This information points to several key themes that should be considered in the development of an effective marketing and communication strategy for the VICP.

### MAJOR THEMES

- Knowledge and awareness of the VICP is limited across both consumers (adults over the age of 50 years, parents, and parents-to-be), health care providers, and experts in vaccine-related fields.
- The primary audiences to target for VICP marketing and communication efforts are health care providers and consumers who are the focus of vaccine-related information and education. These consumers include parents of vaccine-age children, expecting parents, and older adults.
- Health care providers are a primary source of information to consumers about vaccines and vaccine-related information. However, the level of information shared about vaccine injury and the VICP is limited. Vaccine-related information provided by the health care provider is often supplemented by other sources of information, which vary by audience segment.
- It is critical that a neutral tone be achieved in any VICP messaging and materials developed. The messaging should be informative, fact-based about vaccine injury and the VICP, and tailored to the intended audience.
- Health care providers and consumers disagree on several aspects of VICP messaging and material dissemination, including the level of detailed information needed, the most appropriate time to disseminate materials to the consumer, and the impact that awareness and knowledge of the VICP will have on the consumer's decision to vaccinate.

### AREAS FOR FURTHER RESEARCH

*Pretesting of communication messages.* A key step in the development of an effective national marketing and outreach campaign for the VICP is to pretest message concepts, messaging, and materials with the intended audiences prior to launching a national outreach effort. Asking selected members of the intended audiences about their impressions, thoughts, and reactions to newly developed messages and materials will help ensure that the materials speak effectively to the target audiences, evoke the intended response, avoid the greater costs of ineffective materials, and reflect a participatory approach to message and material development.

*Develop methodology for impact evaluation.* To measure the impact of the VICP communication strategy on the intended audiences and to help inform subsequent stages of VICP messaging, an evaluation framework should be established prior to the communication launch. A first step in this process is to select the most appropriate research design to evaluate the impact of the communication strategy, such as a pre-post design with sample surveys of the intended audience before and after the material dissemination or an interrupted time-series design that measures behavior change at multiple intervals over an extended period of time using service statistics.

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## 8. Appendices

### Review of the VICP Literature

1. Vaccine Injury Table and Qualification and Aids to Interpretation
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3. Vaccination Laws, Requirements, and Recommendations
4. Research Report Search Terms
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6. What You Need to Know About the National Vaccine Injury Compensation Program (VICP) booklet
7. National Vaccine Injury Compensation Program (VICP) Web site homepage
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  - b. Parents & Parents-to-be
  - c. Older Adults
16. Focus Group Participant Demographics

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<sup>27</sup> A human papillomavirus (Gardasil) VIS is included. Vaccine Information Statements currently exist for 20 vaccines, including a "Multiple Vaccine" VIS (as per [www.cdc.gov/vaccines/pubs/vis](http://www.cdc.gov/vaccines/pubs/vis), April 26, 2010).

<sup>28</sup> Examples for Chicago, IL focus groups are included. Charlotte, NC guides are identical except for facility information and group times.

<sup>29</sup> Discussion guides as originally submitted to and approved by the Division of Vaccine Injury Compensation (DVIC) are included. Several revisions to questions and/or follow-ups were made on site at focus groups with the DVIC Project Officer present.

## Review of the VICP Literature

APPENDIX 1.

Vaccine Injury Table and Qualifications and Aids to Interpretation<sup>a</sup>

Vaccine	Adverse Event	Time Interval
<b>I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)</b>	A. Anaphylaxis or anaphylactic shock <sup>1</sup>	0-4 hours
	B. Brachial neuritis <sup>6</sup>	2-28 days
	C. Any acute complication or sequela (including death) of above events <sup>4</sup>	Not applicable
<b>II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib)</b>	A. Anaphylaxis or anaphylactic shock <sup>1</sup>	0-4 hours
	B. Encephalopathy (or encephalitis) <sup>2</sup>	0-72 hours
	C. Any acute complication or sequela (including death) of above events <sup>4</sup>	Not applicable
<b>III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)</b>	A. Anaphylaxis or anaphylactic shock <sup>1</sup>	0-4 hours
	B. Encephalopathy (or encephalitis) <sup>2</sup>	5-15 days
	C. Any acute complication or sequela (including death) of above events <sup>4</sup>	Not applicable
<b>IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)</b>	A. Chronic arthritis <sup>5</sup>	7-42 days
	B. Any acute complication or sequela (including death) of above event <sup>4</sup>	Not applicable
<b>V. Measles virus-containing vaccines (e.g., MMR, MR, M)</b>	A. Thrombocytopenic purpura <sup>7</sup>	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient <sup>8</sup>	0-6 months
	C. Any acute complication or sequela (including death) of above events <sup>4</sup>	Not applicable
<b>VI. Polio live virus-containing vaccines (OPV)</b>	A. Paralytic polio	
	• in a non-immunodeficient recipient	0-30 days
	• in an immunodeficient recipient	0-6 months
	• in a vaccine associated community case	Not applicable

Vaccine	Adverse Event	Time Interval
	B. Vaccine-strain polio viral infection <sup>9</sup>	
	• in a non-immunodeficient recipient	0-30 days
	• in an immunodeficient recipient	0-6 months
	• in a vaccine associated community case	Not applicable
	C. Any acute complication or sequela (including death) of above events <sup>4</sup>	Not applicable
<b>VII. Polio inactivated-virus containing vaccines (e.g., IPV)</b>	A. Anaphylaxis or anaphylactic shock <sup>1</sup>	0-4 hours
	B. Any acute complication or sequela (including death) of above event <sup>4</sup>	Not applicable
<b>VIII. Hepatitis B antigen-containing vaccines</b>	A. Anaphylaxis or anaphylactic shock <sup>1</sup>	0-4 hours
	B. Any acute complication or sequela (including death) of above event <sup>4</sup>	Not applicable
<b>IX. Hemophilus influenzae (type b polysaccharide conjugate vaccines)</b>	A. No condition specified for compensation	Not applicable
<b>X. Varicella vaccine</b>	A. No condition specified for compensation	Not applicable
<b>XI. Rotavirus vaccine</b>	A. No condition specified for compensation	Not applicable
<b>XII. Pneumococcal conjugate vaccines</b>	A. No condition specified for compensation	Not applicable
<b>XIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage <sup>b c</sup></b>	A. No condition specified for compensation	Not applicable

<sup>a</sup>Effective date: November 10, 2008

<sup>b</sup>As of **December 1, 2004**, hepatitis A vaccines have been added to the Vaccine Injury Table (Table) under this Category. As of **July 1, 2005**, *trivalent* influenza vaccines have been added to the Table under this Category. Trivalent influenza vaccines are given annually during the flu season either by needle and syringe or in a nasal spray. All influenza vaccines routinely administered in the U.S. are trivalent vaccines covered under this Category. See [Federal Register Notice: April 12, 2005](#)

<sup>c</sup>As of February 1, 2007, [meningococcal \(conjugate and polysaccharide\)](#) and [human papillomavirus \(HPV\)](#) vaccines have been added to the Table under this Category.

## Qualifications and Aids to Interpretation

(1) **Anaphylaxis and anaphylactic shock** mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) **Encephalopathy.** For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a “significantly decreased level of consciousness” (see “D” below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older**, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

- (1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;
- (2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and
- (3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(1)(A) and (2)(1)(B) of this section for applicable timeframes):

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon



family members or other individuals); or  
(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) **Seizure and convulsion.** For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) **Sequela.** The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(5) **Chronic Arthritis.** For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination;

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile

rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) **Brachial neuritis** is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

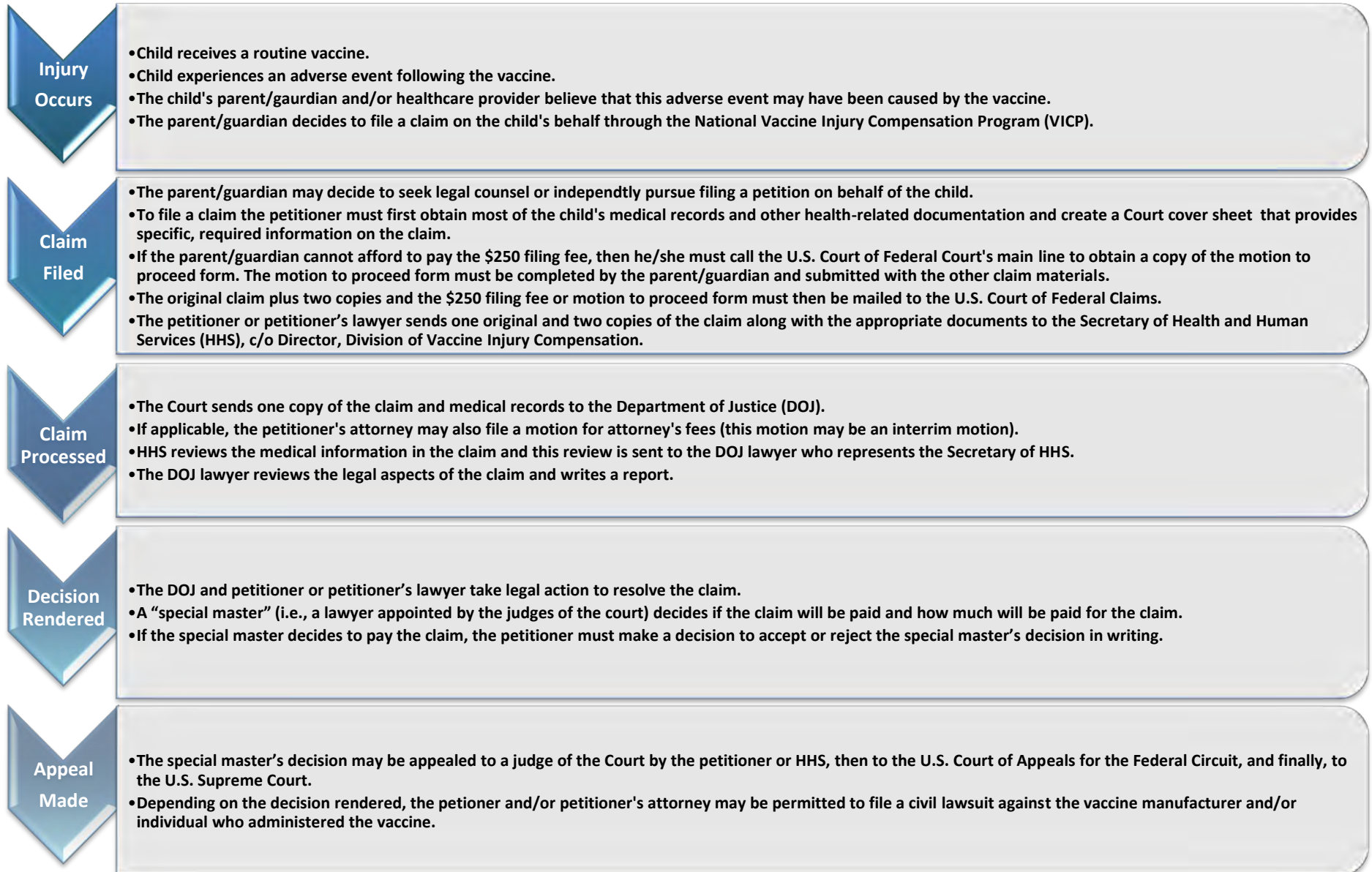
(7) **Thrombocytopenic purpura** is defined by a serum platelet count less than 50,000/mm<sup>3</sup>. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) **Vaccine-strain measles viral infection** is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9) **Vaccine-strain polio viral infection** is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

## APPENDIX 2.

### Process to File Claims With the VICP



## APPENDIX 3.

### *Vaccination Laws, Requirements, and Recommendations*

In 1809, Massachusetts was the first State to enact legislation that required smallpox vaccination (Colgrove & Bayer, 2005; Omer et al., 2009). Other States followed suit; however, which vaccines were required and how related legislation was enforced varied between States. During the seminal *Jacobsen v. Massachusetts* (1905) case, in which the defendant refused to be vaccinated against smallpox on the basis of limited scientific evidence regarding the vaccine's risks and benefits, the U.S. Supreme Court upheld the State's compulsory smallpox vaccine law. From then on, the Court has generally supported State-level passage and enforcement of compulsory vaccine laws to maintain and promote the public's health.

Nevertheless, the precedent that State governments should honor their constituents' constitutional rights related to their individual freedoms remains integral to this Federal support. Therefore, most State vaccination laws include provisions for certain exemptions. Medical exemptions are permitted in all 50 States. Forty-eight States, all except Mississippi and West Virginia, also allow exemptions for religious beliefs that prohibit the use of immunizations. In addition, 21 States allow personal belief or philosophical exemptions, including Arkansas, Arizona,<sup>30</sup> California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Vermont, Washington, and Wisconsin (Institute for Vaccine Safety, 2009).

Parallel to compulsory vaccination laws, immunization requirements for school entrance (i.e., school immunization laws) and employment are State-based (Omer et al., 2009). State immunization requirements have been federally supported since 1922, when the Supreme Court ruled that Texas' school entrance immunization requirements were constitutional. The *Zucht v. King* (1922) case was filed on behalf of a girl who was excluded from both public and private schools in San Antonio for not adhering to the State's immunization requirements.

Although variations in childhood immunization requirements between States are well established, differences in how these requirements are interpreted and implemented at the local level have only recently been studied (National Vaccine Program Office, 2010; Orenstein & Hinman, 1999). Furthermore, these local-level differences may have broader implications for States in terms of their vaccine exemption rates.

Most State vaccination laws and immunization requirements correspond to the childhood immunization schedule annually recommended by the Advisory Council on Immunization Practices (ACIP).<sup>31</sup> The schedule includes recommendations for currently licensed vaccines for children aged 18 years and younger (National Center for Immunization and Respiratory Diseases, 2010). The ACIP additionally reviews the Centers for Disease Control and Prevention (CDC) Adult Immunization Schedule and publishes annual recommendations in the *Morbidity and Mortality Weekly Report*.

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<sup>30</sup> Arizona offers a personal belief exemption for school but not day care.

<sup>31</sup> According to the National Center for Immunization and Respiratory Diseases (NCIRD) (2010), "the ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. In addition to the 15 voting members, ACIP includes 8 *ex officio* members who represent other federal agencies with responsibility for immunization programs in the U.S., and 26 non-voting representatives of liaison organizations that bring related immunization expertise."

The table below provides a summary of the immunizations recommended by the ACIP for children, adolescents, and adults in the United States as of January 2010. Of the recommended vaccines listed, all except the Herpes zoster (shingles) vaccine are covered by the Vaccine Injury Compensation Program (NCIRD, 2010). More detailed information regarding the immunization schedules can be found on the NCIRD Web page.<sup>32</sup>

**ACIP Recommendations for Children, Adolescents, and Adults in the United States**

Recommended Vaccinations by Age Group (NCIRD, 2010)		
Children (aged zero to six)	Children/Adolescents (aged seven to 18)	Adults (18 years and older)
<ul style="list-style-type: none"> <li>• Hepatitis B (HepB)</li> <li>• Rotavirus (RV)</li> <li>• Diphtheria and tetanus toxoids and acellular pertussis (DTaP)</li> <li>• <i>Haemophilus influenzae</i> type b (Hib)</li> <li>• Pneumococcal conjugate (PCV)</li> <li>• Inactivated poliovirus (IPV)</li> <li>• Influenza (seasonal)</li> <li>• Measles, mumps, and rubella (MMR)</li> <li>• Varicella</li> <li>• Hepatitis A (HepA)</li> <li>• Meningococcal conjugate (MCV4)</li> </ul>	<ul style="list-style-type: none"> <li>• Tetanus and diphtheria toxoids and acellular pertussis (Tdap)</li> <li>• Human papillomavirus (HPV)</li> <li>• Meningococcal conjugate (MCV4)</li> <li>• Influenza (seasonal)</li> <li>• Pneumococcal polysaccharide (PPSV)</li> <li>• Hepatitis A (HepA)</li> <li>• Hepatitis B (HepB)</li> <li>• Inactivated poliovirus (IPV)</li> <li>• Measles, mumps, and rubella (MMR)</li> <li>• Varicella</li> </ul>	<ul style="list-style-type: none"> <li>• Tetanus, diphtheria, and acellular pertussis (Td/Tdap)</li> <li>• Human papillomavirus (HPV)</li> <li>• Varicella</li> <li>• Herpes zoster</li> <li>• Measles, mumps, and rubella (MMR)</li> <li>• Influenza (seasonal)*</li> <li>• Pneumococcal polysaccharide* (PPSV)</li> <li>• Hepatitis A (HepA)*</li> <li>• Hepatitis B (HepB)*</li> <li>• Meningococcal*</li> </ul>

\* Recommended only if another risk factor is present.

<sup>32</sup> URL: <http://www.cdc.gov/vaccines/default.htm>

## APPENDIX 4.

Research Report Search Terms <sup>33</sup>
Adult vaccine injury
Childhood vaccine injury
Division of Vaccine Injury Compensation (DVIC), HRSA
Effective communication strategies to reach health care providers
Effective communication strategies to reach parents
Federal and State vaccine exemptions
Federal vaccine rules and regulations
Media coverage of vaccination
Media coverage of vaccine injury
Perceptions of the VICP
Perceptions of vaccine risk
State vaccine rules and regulations
Vaccination decisionmaking
Vaccine campaigns
Vaccine enforcement
Vaccine injury
Vaccine injury compensation
Vaccine Injury Compensation Program (VICP)
Vaccine risk

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<sup>33</sup>Various portions and combinations of these search terms were used.

## APPENDIX 5

The National Vaccine Injury Compensation Program (VICP) brochure

records and/or other appropriate documents, the U.S. Court of Federal Claims' cover sheet, and \$250.00 filing fee with the claim. If you are unable to pay the \$250.00 filing fee, would like to obtain a cover sheet, or need a sample claim, please call the Court at (202) 357-6400.

### What is Vaccine Adverse Event Reporting System (VAERS)?

VAERS is a Federal program used to report injuries or illnesses that occur after a vaccine is given. Filing a VAERS report is not the same as filing a claim with the VICP. For more information about VAERS, call 1-800-822-7967 or visit [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

### How do you obtain more information?

For further information and to obtain a copy of "What You Need to Know about the National Vaccine Injury Compensation Program (VICP)," you may contact the VICP at:

National Vaccine Injury  
Compensation Program  
5600 Fishers Lane, Room 11C-26  
Rockville, MD 20857  
1-800-338-2382  
[www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)

For information about Rules of the Court, including requirements for filing a claim, and/or a list of lawyers who file and handle VICP claims, you may contact:

Clerk  
U.S. Court of Federal Claims  
717 Madison Place, N.W.  
Washington, DC 20005  
(202) 357-6400  
[www.uscfc.uscourts.gov/osmpage.htm](http://www.uscfc.uscourts.gov/osmpage.htm)

For additional information about lawyers, you may contact your State or local bar association.



U.S. Department of Health and Human Services  
Health Resources and Services Administration  
Healthcare Systems Bureau  
Division of Vaccine Injury Compensation  
[www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)  
1-800-338-2382

February 2006

## THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP)



U.S. Department of Health and Human Services  
**HRSA**  
Health Resources and Services Administration



## What is the National Vaccine Injury Compensation Program (VICP)?

Vaccines save lives by preventing disease in the people who receive them. Most people who get vaccines have no serious problems. However, vaccines, like any medicines, can rarely cause serious problems, such as severe allergic reactions. In those rare cases, the VICP, which is a Federal program, provides compensation to people who are found to be injured by certain vaccines.

## What vaccines are covered by the VICP?

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Influenza [given each year during flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Pneumococcal conjugate (PCV)
- Polio (OPV or IPV)
- Rotavirus (RV)
- Varicella (VZV)
- Any combination of the vaccines listed above
- Additional vaccines may be added in the future

For information about these vaccines, contact the Centers for Disease Control and Prevention's National Immunization Information Hotline at 1-800-232-2522 or visit their Web site at [www.cdc.gov/nip](http://www.cdc.gov/nip).

## Who may file a claim?

- You may file a claim if you received a vaccine covered by the VICP and believe that you have been injured by this vaccine.
- You may file a claim if you are the parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP, and believe that the person who received it was injured by this vaccine.
- You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person's death resulted from the vaccine injury.
- You may file a claim if you are not a United States citizen.
- Some people who receive vaccines outside of the U.S. may be eligible for compensation, but must meet other criteria. For more information on these criteria, call 1-800-338-2382 or visit the VICP Web site at: [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

In addition, to be eligible to file a claim, the effects of the person's injury must have: 1) lasted for more than 6 months after the vaccine was given; or 2) resulted in a hospital stay **and** surgery; or 3) resulted in death.

## Do you need a lawyer to file a claim?

You do not need a lawyer to file a claim. However, since this is a legal process, most people use a lawyer. If certain minimal requirements are met, the VICP will pay your lawyer's fees and other legal costs related to your claim, whether or not you are paid for the vaccine injury or death. The VICP will not pay

the fees of petitioners representing themselves, but will pay their legal costs, whether or not the claim is paid, as long as certain minimal requirements are met.

## What are the deadlines to file a claim?

The general filing deadlines are:

- For an **injury**, your claim must be filed within 3 years after the first symptom of the vaccine injury.
- For a **death**, a claim must be filed within 2 years of the death and 4 years after the start of the first symptom of the vaccine-related injury from which the death occurred.

When a **new vaccine** is covered by the VICP, or when a **new injury/condition** is added to the Vaccine Injury Table (Table), claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change. The Table lists and explains injuries that are presumed to be caused by vaccines. For more details about the Table, visit [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

For example, the hepatitis A vaccine was covered by the VICP as of December 1, 2004. Under the general filing deadline for an injury, the claim must be filed within 3 years after the first symptom of the vaccine injury. However, claims that do not meet the general filing deadline must be filed by December 1, 2006 for injuries or deaths that occurred on or after December 1, 1996.

## What do you need to file a claim?

The claim is not filed using a specific form. However, you must include your medical

## APPENDIX 6

What You Need to Know About the National Vaccine Injury Compensation Program (VICP) booklet

# What You Need to Know About the National Vaccine Injury Compensation Program (VICP)



February 2006



**NOTE:**

*What You Need to Know About the National Vaccine Injury Compensation Program (VICP)* is not a legal document. The official provisions are contained in the relevant laws, regulations and Court decisions. Because this provides only general information, you may wish to consult a lawyer.

**What You Need to Know  
About the  
National Vaccine  
Injury Compensation  
Program (VICP)**

February 2006



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## List of Acronyms and Terms

- Aids      Qualifications and Aids to Interpretation
- DOJ      U.S. Department of Justice
- HHS      U.S. Department of Health and Human Services
- HRSA     Health Resources and Services Administration
- VAERS    Vaccine Adverse Event Reporting System
- VICP     National Vaccine Injury Compensation Program
- Court     U.S. Court of Federal Claims
- Table     Vaccine Injury Table



## What is the National Vaccine Injury Compensation Program (VICP)?

Vaccines save lives by preventing disease in the people who receive them. Most people who get vaccines have no serious problems. However, vaccines, like any medicines, can rarely cause serious problems, such as severe allergic reactions. In those rare cases, the VICP, which is a Federal program, provides compensation to people found to be injured by certain vaccines. The U.S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court).

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

## Why and when was the VICP created?

In the early 1980s, news reports of serious side effects from the DTP (diphtheria, tetanus, pertussis) vaccine caused some to question the safety of the vaccine. Parents began filing many lawsuits against vaccine companies, doctors, and nurses. Some vaccine companies decided to stop making vaccines, which created vaccine shortages and threatened the Nation's health.

All of these problems led a group of doctors, public health organizations, vaccine companies and private citizens to encourage Congress to enact a new law to compensate those found to be injured by childhood vaccines. The National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the VICP, which began on October 1, 1988.

## What vaccines are covered by the VICP?

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Influenza [given each year during the flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Polio (OPV or IPV)

- Pneumococcal conjugate (PCV)
- Rotavirus (RV)
- Varicella (VZV)
- Any combination of the vaccines above
- Additional vaccines may be added in the future

For a description of the diseases prevented by these vaccines, see page 15 in the Appendix.

## How does the VICP work?

First, a claim must be filed by or on the behalf of the individual thought to be injured by a vaccine covered by the VICP. A claim is started by filing a legal document called a petition that is prepared by you or your lawyer to request compensation under the VICP. Anyone who files a claim is called a petitioner. The only form required is the Court's cover sheet for the claim. You may obtain a copy of the cover sheet and a sample claim by calling (202) 357-6400. Your claim should address the following information:

- who was injured by the vaccine;
- which vaccine caused the injury;
- when the vaccine was given;
- the city and State or country where the vaccine was given;
- the type of injury;
- when the first symptom of the injury appeared; and
- how long the effects of the injury lasted.

Your claim should also include your medical records and/or other appropriate documents, the Court's cover sheet, and the \$250.00 filing fee. If you are unable to pay this fee, call (202) 357-6400 for assistance. The original claim and two copies plus a \$250.00 filing fee should be sent to:

Clerk  
U.S. Court of Federal Claims  
717 Madison Place, N.W.  
Washington, D.C. 20005

One copy should be sent to:

Director, Division of Vaccine Injury Compensation  
HRSA, Healthcare Systems Bureau  
Parklawn Building, Room 11C-26  
5600 Fishers Lane  
Rockville, Maryland 20857

## Who may file a claim?

- You may file a claim if you received a vaccine covered by the VICP and believe that you have been injured by this vaccine.
- You may also file a claim if you are a parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP and believe that the person was injured by this vaccine.
- You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person's death resulted from the vaccine injury.
- You may file a claim if you are **not** a United States citizen.
- Some people who receive vaccines outside of the U.S. may be eligible for compensation. The vaccines must have been covered by the VICP and given in the following circumstances:
  - the injured person must have received a vaccine in the U.S. trust territories; or
  - if the vaccine was administered outside of the U.S. or its trust territories: 1) the injured person must have been a U.S. citizen serving in the military or a U.S. government employee, or have been a dependent of such a citizen; or 2) the injured person must have received a vaccine manufactured by a vaccine company located in the U.S. and returned to the U.S. within 6 months after the date of vaccination.

In addition, to be eligible to file a claim, the effects of the person's injury must have: 1) lasted for more than 6 months after the vaccine was given; or 2) resulted in a hospital stay **and** surgery; or 3) resulted in death.

## **What medical records and other documents are requested to ensure a timely review of my claim?**

You must include certain medical records and/or other appropriate documents with the claim. If some medical records are unavailable, you must identify those records and explain why they are unavailable. The medical review and processing of the claim may be delayed if you do not include the appropriate medical records and other documents with the claim.

In order to ensure that your claim is processed in a timely manner, the VICP suggests that you include the following medical records and other documents when filing your claim with the Court and the Secretary of Health and Human Services, c/o Director, Division of Vaccine Injury Compensation.

### ***Medical Records***

#### **1.\* Prenatal and Birth Records**

- Mother’s prenatal record
- Delivery record
- Birth Certificate
- Newborn hospital record including doctors’/nurses’ notes, and radiology/lab results
- Any hospitalization face sheet with final diagnosis

#### **2. Medical Records Prior to Vaccination**

- Clinic notes (such as Well Baby visits)
- Private doctor visits
- Growth charts/lab/radiology results
- Consultation reports and evaluations
- Developmental charts

#### **3. Vaccination Record (if available)**

- Lot number
- Manufacturer

#### **4. Post-Injury Hospital/Emergency Treatment Records**

- Admission/discharge summaries
- History and physical records
- Progress notes (including doctors’/nurses’ notes)
- Medication records
- Lab/radiology/EEG results
- Flow sheets (respiratory care/treatments)
- Consultation reports and evaluations

## 5. Post-Injury Outpatient Records

- History and physical records
- Progress notes (including doctors'/nurses' notes)
- Medication records
- Lab/radiology/EEG results
- Clinic notes
- All evaluations



## 6. Vaccine Adverse Event Reporting System (VAERS) form (if submitted)

## 7. Long Term Records (that apply to your injury)

- School records
- Consultation reports and evaluations
- Educational testing records
- Psychological testing records
- Police/ambulance records

## 8. Death Records (if applicable)

- Death Certificate
- Autopsy report (if done)
- Autopsy slides

\*Note: Number 1 may be omitted if the injured person is an adult.

## Do I need a lawyer to file a claim?

You do not need a lawyer to file a claim. However, since this is a legal process, most people use a lawyer. If certain minimal requirements are met, the VICP will pay your lawyer's fees and other legal costs related to your claim, whether or not you are paid for a vaccine injury or death. The VICP will not pay the fees of petitioners representing themselves, but will pay their other legal costs, whether or not the claim is paid as long as certain minimal requirements are met.

## What are the deadlines to file a claim?

The general filing deadlines are:

- For an ***injury***, your claim must be filed within 3 years after the first symptom of the vaccine injury.
- For a ***death***, your claim must be filed within 2 years of the death and 4 years after the start of first symptom of the vaccine-related injury from which the death occurred.

When a ***new vaccine*** is covered by the VICP or when a ***new injury/condition*** is added to the Vaccine Injury Table (Table), claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change. The Table lists and explains injuries that are presumed to be caused by vaccines. For more details about the Table, visit [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

For example, the hepatitis A vaccine was covered by the VICP as of December 1, 2004. Under the general filing deadline for an injury, the claim must be filed within 3 years after the first symptom of the vaccine injury. However, claims that do not meet the general filing deadlines must be filed by December 1, 2006 for injuries or deaths that occurred on or after December 1, 1996.

## What is the process for filing a claim?

A summary of the claims process is provided below. The Court has documents which explain the process in more detail. To obtain these documents, you may visit the Court's Web site at [www.uscfc.uscourts.gov/osmpage.htm](http://www.uscfc.uscourts.gov/osmpage.htm) or call (202) 357-6400. Most petitioners use a lawyer since this is a legal process, and the Rules of the Court are very specific and must be followed.

The process for filing a claim is:

1. the petitioner or petitioner's lawyer sends one original and two copies of the claim along with the medical records, other appropriate documents and a \$250.00 filing fee to the Court;
2. the petitioner or petitioner's lawyer sends one copy of the claim including the medical records and other appropriate documents to the Secretary of Health and Human Services, c/o Director, Division of Vaccine Injury Compensation;
3. the Court sends one copy of the claim and medical records to the DOJ;
4. HHS reviews the medical information in the claim and this review is sent to the DOJ lawyer who represents the Secretary of Health and Human Services;
5. the DOJ lawyer reviews the legal aspects of the claim and writes a report;

6. the HHS and DOJ reviews are combined into one report that is sent to the Court and petitioner or petitioner's lawyer;
7. the DOJ and petitioner or petitioner's lawyer take legal action to resolve the claim;
8. a "special master" (a lawyer appointed by the judges of the Court) decides if the claim will be paid and how much will be paid for the claim;
9. if the special master decides to pay the claim, the petitioner must make a decision to accept or reject the special master's decision in writing; and
10. the special master's decision may be appealed to a judge of the Court by the petitioner or HHS, then to the U.S. Court of Appeals for the Federal Circuit and, finally, to the U.S. Supreme Court.

### **What must be proved in order to be paid?**

You must prove that:

- the injured person received a vaccine listed on the Table; and
- the first symptom of the injury/condition on the Table as defined in the Qualifications and Aids to Interpretation (Aids)\* occurred within the time period listed on the Table; or
- the vaccine caused the injury; or
- the vaccine caused an existing illness to get worse (significantly aggravated).

In addition, the Court must determine that the injury or death did not result from any other possible causes.

### **What is the Vaccine Injury Table?**

The Table makes it easier for some people to get compensation. The Table lists and explains injuries/conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries/conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occur within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found. For example, if you received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) within 4 hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury if no other cause is found.

If your injury/condition is not on the Table or if your injury/condition did not occur within the time period on the Table, you must prove that the vaccine caused the injury/condition. Such proof must be based on medical records or opinion, which may include expert witness testimony.

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\*The Aids define some of the injuries/conditions listed on the Table.

The Table and Aids change sometimes. To obtain a copy of the latest Table and Aids, visit the VICP Website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation), or call 1-800-338-2382.

The following is a list of the vaccines covered by the VICP. These vaccines can be given alone or combined with other vaccines. The listing also includes the injuries/conditions associated with these vaccines and the time period in which the first symptom of these injuries/conditions must occur in order for the VICP to presume that the vaccine was the cause. For a description of the diseases prevented by these vaccines, see page 15 in the Appendix.

**Important: This is only a summary of the Table. [The definitions of these injuries/conditions are in the Aids.]**

<b><i>Vaccine</i></b>	<b><i>Injuries/Conditions</i></b>	<b><i>Time Period</i></b>
DIPHTHERIA	See pertussis and tetanus.	
<i>HAEMOPHILUS INFLUENZAE</i> TYPE b (Hib)	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
HEPATITIS A (HAV)	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
HEPATITIS B (HBV)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) <sup>2</sup>	0-4 hours
INFLUENZA	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
MEASLES, MUMPS, RUBELLA (MMR, MR, M, R)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) <sup>2</sup>	0-4 hours
	Disorder of the brain (Encephalopathy) <sup>2</sup>	5-15 days
MEASLES (MMR, MR, M)	A decrease in the number of platelets in the blood (Thrombocytopenic Purpura) <sup>2</sup>	7-30 days
	Measles virus infection in an immunodeficient person <sup>2</sup>	0-6 months
PERTUSSIS (DTaP, Tdap, DTP, P, DTP-Hib)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) <sup>2</sup>	0-4 hours
	Disorder of the brain (Encephalopathy) <sup>2</sup>	0-72 hours
PNEUMOCOCCAL CONJUGATE (PCV)	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
POLIO		
INACTIVATED POLIO (IPV)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) <sup>2</sup>	0-4 hours
ORAL POLIO (OPV) <sup>3</sup>	1) Paralysis from the polio virus in the person who: <ul style="list-style-type: none"> <li>– received the vaccine<sup>2</sup></li> <li>– received the vaccine and is unable to have a normal immune response to this vaccine (immunodeficient)<sup>2</sup></li> <li>– came in contact with a person who recently received the vaccine<sup>2</sup></li> </ul>	0-30 days 0-6 months no time limit



<b><i>Vaccine</i></b>	<b><i>Adverse Event (Serious Side Effects)</i></b>	<b><i>Time Period</i></b>
POLIO ( <i>continued</i> )		
ORAL POLIO (OPV) <sup>3</sup>	2) Vaccine-strain polio infection in the person who: <ul style="list-style-type: none"> <li>– received the vaccine<sup>2</sup></li> <li>– received the vaccine and is unable to have a normal immune response to this vaccine (immunodeficient)<sup>2</sup></li> <li>– came in contact with a person who recently received the vaccine<sup>2</sup></li> </ul>	0-30 days 0-6 months  no time limit
ROTAVIRUS		
LIVE, ORAL, RHESUS-BASED (RV) <sup>3</sup>	The intestine or bowel folds into itself (Intussusception) <sup>2</sup>	0-30 days
OTHER ROTAVIRUS (RV)	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
RUBELLA (MMR, MR, R)	A persistent swelling of the joints (Chronic Arthritis) <sup>2</sup>	7-42 days
TETANUS (DTaP, Tdap, DTP-Hib, DT,Td or TT)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) <sup>2</sup>	0-4 hours
	Damage to a nerve or group of nerves in the under arm (Brachial Neuritis) <sup>2</sup>	2-28 days
VARICELLA (VZV)	There are no Table injuries for this vaccine. <sup>1</sup>	Not applicable
ADDITIONAL VACCINES MAY BE ADDED IN THE FUTURE.		

<sup>1</sup> When no injury is identified with this vaccine, the petitioner must prove that the injury was caused by the vaccine.

<sup>2</sup> In addition, any serious problems resulting from this injury/condition, including death.

<sup>3</sup> This vaccine is no longer given in the U.S.

## What are the types of payments?

For an *injury*, you may be paid:

- a reasonable amount for past and future nonreimbursable medical, custodial care, and rehabilitation costs, and related expenses (There is no limit on the amount a person with an injury may be paid for these types of expenses. Payments are based on your vaccine injury needs.);
- up to \$250,000 for actual and projected pain and suffering;
- lost earnings; and/or
- reasonable lawyers' fees and other legal costs or *legal costs, not fees, of petitioners representing themselves*, if your claim was filed on a reasonable basis and in good faith.

For a **death**, you may be paid:

- up to \$250,000 as a death benefit for the estate of the deceased; and
- reasonable lawyers' fees and other legal costs or *legal costs, not fees, of petitioners representing themselves*, if your claim was filed on a reasonable basis and in good faith.

## Can I file a lawsuit outside the VICP?

Most of the time, you must **first** file and have your claim processed with the VICP before a civil lawsuit can be filed against the vaccine company or the person who gave the vaccine. If you would like to file a civil lawsuit outside of the VICP, contact a lawyer for advice.

## What is the Vaccine Adverse Event Reporting System (VAERS)?

VAERS is a Federal program used to report injuries or illnesses that occur after a vaccine is given. Filing a VAERS report is not the same as filing a claim with the VICP. VAERS and the VICP are different programs. For more information about VAERS, call 1-800-822-7967 or visit their Web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

## How do I obtain more information about the VICP?

National Vaccine Injury Compensation Program  
Parklawn Building, Room 11C-26  
5600 Fishers Lane  
Rockville, Maryland 20857; or  
1-800-338-2382  
[www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)

## How do I obtain more information about filing a claim?

Clerk  
U.S. Court of Federal Claims  
717 Madison Place, N.W.  
Washington, D.C. 20005  
(202) 357-6400  
[www.uscfc.uscourts.gov/osmpage.htm](http://www.uscfc.uscourts.gov/osmpage.htm)

## How do I obtain a list of lawyers?

Clerk

U.S. Court of Federal Claims

717 Madison Place, N.W.

Washington, DC 20005

(202) 357-6400; or

Your State or local bar association



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# Appendix

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# Description of Diseases Prevented by VICP Covered Vaccines

## ***Vaccines***

## ***Description of Diseases Prevented by Covered Vaccines***

### **DIPHTHERIA**

A bacterial disease which can cause a thick covering in the back of the throat, and can lead to breathing problems, paralysis, heart failure, and even death.

### ***HAEMOPHILUS INFLUENZAE TYPE B***

A bacterial disease which can cause meningitis, pneumonia, severe swelling in the throat (making it hard to breathe), infections of the blood, joints, bones, and covering of the heart, and death. Meningitis is an infection of the covering of the brain.

### **HEPATITIS A**

Hepatitis A virus can cause mild “flu-like” illness, jaundice, severe stomach pains and diarrhea, and can lead to a serious liver disease.

### **HEPATITIS B**

Hepatitis B virus can cause short-term (acute) illness, and can lead to loss of appetite, diarrhea and vomiting, tiredness, jaundice (yellow skin or eyes), and pain in muscles, joints, and stomach. It can also cause long-term (chronic) illness which can lead to liver damage (cirrhosis), liver cancer and/or death.

### **INFLUENZA**

Influenza virus can cause fever, sore throat, chills, fatigue, cough, headache, and muscle aches. It is a very contagious disease which spreads from infected persons to the nose or throat of others.

### **MEASLES**

Measles virus can cause rash, cough, runny nose, eye irritation which can lead to ear infection, pneumonia, seizures (jerking and staring spells), brain damage, and death.

### **MUMPS**

Mumps virus can cause fever, headache, and swollen glands, and can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

*(Continued)*

## ***Vaccines***

## ***Description of Diseases Prevented by Covered Vaccines***

### **PERTUSSIS (WHOOPIING COUGH)**

A bacterial disease which can cause coughing spells so bad that it is hard to eat, drink, or breathe, and can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death. It is also called Whooping Cough.

### **PNEUMOCOCCAL CONJUGATE**

A bacterial infection which can lead to serious illness and death, and is the leading cause of bacterial meningitis in the United States.

### **POLIO**

Polio virus can cause paralysis (can't move arm or leg) or death by paralyzing the muscles that help people breathe.

### **ROTAVIRUS**

Rotavirus can cause diarrhea which can lead to dehydration and other problems in children.

### **RUBELLA**

Rubella virus can cause rash, mild fever, and arthritis (mostly in women). It is also called German Measles.

### **TETANUS**

A bacterial disease which can cause painful tightening of the muscles, usually all over the body, and can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus enters the body through cuts or wounds. It is also called Lockjaw.

### **VARICELLA (CHICKENPOX)**

Varicella virus can cause a rash, itching, fever, and tiredness, and can lead to severe skin infection, scars, pneumonia, brain damage, or death. It is also called Chickenpox. The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.







**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Health Resources and Services Administration**  
**Healthcare Systems Bureau**  
**Division of Vaccine Injury Compensation**  
**<http://www.hrsa.gov/vaccinecompensation>**  
**1-800-338-2382**

## **APPENDIX 7**

National Vaccine Injury Compensation Program (VICP) Web site homepage



**HRSA** U.S. Department of Health and Human Services  
Health Resources and Services Administration

Home  
Questions?  
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## National Vaccine Injury Compensation Program (VICP)

- [Home](#)
- [Omnibus Autism Proceeding](#)
- [Covered Vaccines](#)
- [Persons Eligible to File a Claim](#)
- [Filing a Claim with the VICP](#)
- [Filing Deadlines](#)
- [Vaccine Injury Table list of vaccines and associated injuries covered under the program](#)
- [Frequently Asked Questions](#)
- [Statistics Reports](#)
- [Strategic Plan](#)
- [Advisory Commission on Childhood Vaccines \(ACCV\)](#)
- [Contact Information](#)
- [Vaccine Injury Compensation Trust Fund](#)
- [Review of Adverse Effects of Vaccines](#)
- [Media Inquiries](#)
- [VICP Authorizing Legislation \(PDF - 497 KB\)](#)

The 2009 pandemic H1N1 influenza vaccine (swine flu vaccine) is not covered under the VICP. If you received the 2009 pandemic H1N1 influenza vaccine (swine flu vaccine) or drugs to treat or prevent H1N1 influenza such as Tamiflu, Relenza or Peramivir and think that you have been seriously injured by this vaccine or these drugs, see the [Countermeasures Injury Compensation Program](#).

### About VICP

On October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Injury Compensation Program (VICP). The VICP was established to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court).

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

### Additional HHS Vaccine Information

- [Countermeasures Injury Compensation](#)
- [Childhood Immunization Information for Consumers](#) (National Library of Medicine MEDLINEPlus)
- [National Center for Immunization and Respiratory Diseases](#) (Centers for Disease Control and Prevention)
- [2008 Draft Strategic National Vaccine Plan](#) (National Vaccine Program Office)

*This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving claims for compensation under the VICP.*

### News

[VICP Authorizing Legislation](#) (PDF - 497 KB) (January 13, 2010)

[Review of Adverse Effects of Vaccines Committee Membership](#) Comment on provisional appointments by April 9

**Order Free VICP Brochures and Booklets in English and Spanish**

**Call 1-800-338-2382 or Order on Line**

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- [Booklet in English](#)
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**APPENDIX 8.**

Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS)

# HPV (HUMAN PAPILLOMAVIRUS) VACCINE

Gardasil®

## WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

### 1 What is HPV?

**Genital human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

### 2 HPV vaccine - Why get vaccinated?

HPV vaccine is important because **it can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of **two vaccines that can be given to prevent HPV**. It may be given to both males and females. In addition to preventing cervical cancer, it can also prevent **vaginal and vulvar cancer** in females, and **genital warts** in both males and females.

The other vaccine is given to females only, and only for prevention of cervical cancer.

### 3 Who should get this HPV vaccine and when?

#### Females: *Routine Vaccination*

- HPV vaccine is recommended for girls **11 or 12 years of age**. It may be given to girls starting at age 9.

#### Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact – because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

#### Females: *Catch-Up Vaccination*

- The vaccine is also recommended for girls and women **13 through 26 years of age** who did not get all 3 doses when they were younger.

#### Males

Males **9 through 26 years** of age may get HPV vaccine to prevent genital warts. As with females, it is best to be vaccinated before the first sexual contact.

#### HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

### 4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.

- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's **HPV in pregnancy registry** at 800-986-8999. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a **moderate or severe illness** should wait until they are better.

## 5 What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
  - Pain (about 8 people in 10)
  - Redness or swelling (about 1 person in 4)
- Fever:
  - Mild (100° F) (about 1 person in 10)
  - Moderate (102° F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)
  - Fainting. Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

## 6 What if there is a severe reaction?

### What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

### What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

*VAERS does not provide medical advice.*

## 7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling 1-800-338-2382 or visiting their website at <http://www.hrsa.gov/vaccinecompensation>.

## 8 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at <http://www.cdc.gov/hpv> and <http://www.cdc.gov/vaccines>



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)  
Human Papillomavirus (HPV) *Gardasil* 3/30/2010

## Scan of the Field: VICP Players, Media, and the Online Environment



APPENDIX 9.

Select Sources of Vaccine & VICP-Related Information				
Name & URL	Organization/ Agency type	Leadership	Brief description	Select connection to VICP or VICP-related information, if any
<p><b>American Academy of Family Physicians (AAFP)</b></p> <p><a href="http://www.aafp.org">www.aafp.org</a>  <a href="http://www.familydoctor.org">www.familydoctor.org</a></p>	Professional association	Executive Vice President & Chief Executive Officer, Douglas E. Henley, MD, FAAFP; Board President, Lori J. Heim, MD, FAAFP	AAFP is the national association of family doctors. Founded to promote and maintain high quality standards for family doctors who are providing continuing comprehensive health care to the public. It is one of the largest national medical organizations, with more than 94,600 members in 50 States, District of Columbia, Puerto Rico, the Virgin Islands, and Guam. The Scientific Assembly is the Academy's largest meeting for continuing education, drawing more than 17,000 physicians and visitors.	Web site houses some editorials mentioning VICP. Web site houses some journal articles mentioning VICP. Web site houses some Centers for Disease Control and Prevention (CDC) documents mentioning VICP, including immunization schedules, etc. AAFP hosts <a href="http://www.familydoctor.org">www.familydoctor.org</a> site with extensive vaccine information, including <i>Healthy Living</i> section on <i>Vaccines ("shots")</i> .
<p><b>American Academy of Pediatrics (AAP)</b></p> <p><a href="http://www.aap.org">www.aap.org</a></p>	Professional association	Executive Director, Errol R. Alden, MD; Board President, Judith S. Palfrey, MD, FAAP	TAAP and its member pediatricians dedicate their efforts and resources to the health, safety and well-being of infants, children, adolescents and young adults. AAP has approximately 60,000 members in the United States, Canada, Mexico, and many other countries. Members include pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. The mission of AAP is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults.	Web site includes an external link to VICP Web site. Web site houses some documents mentioning VICP, including immunization schedules, etc. Web site houses information on immunizations/vaccines in <i>Children's Health Topics</i> section.

Name & URL	Organization/ Agency type	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>American Academy of Physician Assistants (AAPA)</b></p> <p><a href="http://www.aapa.org">www.aapa.org</a></p>	Professional association	Chief Executive Officer, William (Bill) Leinweber, MBA; Board President, Stephen H. Hanson, MPA, PA-C	AAPA is the only national professional association that represents all PAs across all medical and surgical specialties in all 50 States, D.C., Guam, the armed forces, and the Federal services. AAPA provides comprehensive support and advocacy for PAs so that they may, in turn, provide patients with increased access to quality, cost-effective health care. Founded in 1968 to support the growing PA profession, AAPA works to increase the professional and personal growth of the more than 73,000 PAs in practice today through a range of information, advocacy and services.	Web site includes an external link to VICP Web site and includes AAPA policy on vaccinations.
<p><b>American Medical Association (AMA)</b></p> <p><a href="http://www.ama-assn.org/ama/no-index/physician-resources/1797.shtml">http://www.ama-assn.org/ama/no-index/physician-resources/1797.shtml</a></p>	Professional association	Executive Vice President & Chief Executive Officer, Michael D. Maves, MD, MBA; Board Chair, Joseph M. Heyman, MD	AMA helps doctors help patients by uniting physicians nationwide to work on the most important professional and public health issues. The mission is to promote the art and science of medicine and the betterment of public health. AMA policy on issues in medicine and public health is decided through its democratic policy-making process, in the AMA House of Delegates.	Web site houses some journal articles referencing VICP. Web site houses some external links to news articles referencing VICP.
<p><b>American Nurses Association (ANA)</b></p> <p><a href="http://www.nursingworld.org/">http://www.nursingworld.org/</a></p>	Professional association	President, Rebecca M. Patton, MSN, RN, CNOR	ANA is the only full-service professional organization representing the interests of the U.S.' 3.1 million registered nurses through its constituent member nurses associations, its organizational affiliates, and its workforce advocacy affiliate, the Center for American Nurses. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.	Web site houses external links to immunizations/vaccine resources such as CDC immunization schedules.

Name & URL	Organization/ Agency type	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>Autism Speaks</b></p> <p><a href="http://www.autismspeaks.org/">http://www.autismspeaks.org/</a></p>	<p>Advocacy organization; Nonprofit</p>	<p>President, Mark Roithmayr</p>	<p>Autism Speaks was founded in February 2005 by Bob and Suzanne Wright, grandparents of a child with autism. Since then, Autism Speaks has grown into the nation's largest autism science and advocacy organization, dedicated to funding research into the causes, prevention, treatments and a cure for autism; increasing awareness of autism spectrum disorders; and advocating for the needs of individuals with autism and their families.</p>	<p>N/A</p>
<p><b>CDC Advisory Committee on Immunization Practices (ACIP)</b></p> <p><a href="http://www.cdc.gov/vaccines/racs/acip/">http://www.cdc.gov/vaccines/racs/acip/</a></p>	<p>Government agency <i>advisory committee</i></p>	<p>Chair, Carol J. Baker, MD</p>	<p>ACIP consists of 15 experts in fields associated with immunization, who have been selected by the Secretary of the Department of Health and Human Services (HHS) to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. The <b>role</b> of ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the U.S., and an increase in the safe use of vaccines and related biological products. The Committee <b>develops written recommendations</b> for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. ACIP is the only entity in the Federal government that makes such recommendations.</p>	<p>Web site houses immunization schedules and committee recommendations.</p>

Name & URL	Organization/ Agency type	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>CDC National Center for Immunization and Respiratory Diseases (NCIRD) &amp; National Immunization Program (NIP)</b></p> <p><a href="http://www.cdc.gov/ncird/index.html">http://www.cdc.gov/ncird/index.html</a></p> <p><a href="http://www.cdc.gov/vaccines/">http://www.cdc.gov/vaccines/</a></p>	Government agency	NCIRD Director, Anne Schuchat, MD, RADM; NCIRD Associate Director for Communication Science, Kristine Sheedy, PhD	The mission of NCIRD is the prevention of disease, disability, and death through immunization and by control of respiratory and related diseases. Their challenge is to effectively balance our efforts in the domestic and global arenas as well as accommodate the specific needs of all populations at risk of vaccine preventable diseases from children to older adults.	<p>NCIRD Web site houses documents related to vaccine safety and vaccine information.</p> <p>CDC <a href="http://cdc.gov/vaccines">cdc.gov/vaccines</a> Web site houses information on VICP in multiple formats including immunization schedules, statistics, requirements/laws, new articles, reports to Congress, etc. Web site also houses the <i>Epidemiology and Prevention of Vaccine-Preventable Diseases "Pink Book"</i> publication, Vaccine Adverse Event Reporting System (VAERS), and Vaccine Information Statements (VISs).</p>
<p><b>The Children's Hospital of Philadelphia (CHOP), Vaccine Education Center</b></p> <p><a href="http://www.chop.edu/service/vaccine-education-center/home.html">http://www.chop.edu/service/vaccine-education-center/home.html</a></p>	Hospital-based nonprofit	Director, Paul A. Offit, MD	The CHOP Vaccine Education Center provides complete, up-to-date and reliable information about vaccines to parents and healthcare professionals. The Center provides videos, informational tear sheets, and information on every vaccine. Resources explain how vaccines work, how they are made, who recommends vaccines, when they should be given, if they are still necessary, and, most importantly, if they are safe.	Web site houses educational materials and information on vaccines for parents and health care professionals. Information is in the form of tear sheets, booklets, newsletters, VHS/DVD, etc.

Name & URL	Organization/ Agency type\	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>HHS National Vaccine Program Office (NVPO)</b></p> <p><a href="http://www.hhs.gov/nvpo/">http://www.hhs.gov/nvpo/</a></p>	Government agency	Director, Bruce Gellin, MD, MPH	<p>NVPO is responsible for coordinating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities. NVPO provides leadership and coordination among Federal agencies as they work together to carry out the goals of the National Vaccine Plan. The National Vaccine Plan provides a framework, including goals, objectives, and strategies, for pursuing the prevention of infectious diseases through immunizations. NVPO is responsible for coordinating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities. NVPO is located in the Office of Public Health and Science (OPHS), HHS.</p>	<p>Web site houses information on National Vaccine Advisory Committee—who recommends ways to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to prevent adverse reactions to vaccines—membership, meetings, working groups, and recommendations, and information on 1994 National Vaccine Plan, including updated 2008 Draft Strategic National Vaccine Plan.</p>
<p><b>Department of Justice (DOJ)</b></p> <p><a href="http://www.justice.gov/civil/torts/const/vicp/index.htm">http://www.justice.gov/civil/torts/const/vicp/index.htm</a></p>	Government agency	Attorney General, Eric H. Holder, Jr., JD	<p>The VICP is a program designed to encourage childhood vaccination by providing a streamlined system for compensation in rare instances where an injury results from vaccination. Individuals who believe they have been injured by a covered vaccine can file a claim against HHS in the US Court of Federal Claims seeking compensation from the Vaccine Trust Fund. DOJ, which represents HHS, consistently works to ensure that fair compensation is awarded in every case that meets the eligibility criteria. If found eligible, claimants can recover compensation for related medical and rehabilitative expenses, and in certain cases, may be awarded funds for pain and suffering and future lost earnings.</p>	<p>Web site houses history and mission of VICP.</p>

Name & URL	Organization/ Agency type\	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>Every Child By Two (ECBT)</b></p> <p><a href="http://www.ecbt.org/">http://www.ecbt.org/</a></p>	<p>Independent vaccination campaign; Nonprofit</p>	<p>Co-founder and Director, Rosalynn Carter</p>	<p>The goals of ECBT are to raise awareness of the critical need for timely immunizations and to foster a systematic way to immunize all of America's children by age two. To forward its agenda, ECBT enlists the support of elected officials and their spouses, concerned community leaders, and representatives of many national organizations. ECBT works with immunization partners nationwide to educate those who effect policy decisions regarding immunizations and to seek funding for state immunization programs who are responsible for the delivery of vaccines to the uninsured and underinsured children of this nation.</p>	<p>Web site houses external link to VICP.</p>
<p><b>Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER)</b></p> <p><a href="http://www.fda.gov/BiologicsBloodVaccines/default.htm">http://www.fda.gov/BiologicsBloodVaccines/default.htm</a></p>	<p>Government agency</p>	<p>Commissioner, Margaret Hamburg, MD</p>	<p>FDA consists of six product centers, one research center, and two offices. FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation.</p>	<p>Web site houses documents mentioning VICP including information on vaccine regulation and licensing, vaccine safety, and VAERS.</p>

Name & URL	Organization/ Agency type\	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<b>Immunization Action Coalition (IAC)</b>  <a href="http://www.immunize.org/">http://www.immunize.org/</a>	Nonprofit	Executive Director, Deborah L. Wexler, MD	IAC works to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. The Coalition also facilitates communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, health care organizations, and government health agencies. For more than a decade, CDC has worked in concert with and provided financial support to IAC for the purpose of educating health professionals about U.S. vaccine recommendations.	Web site houses newsletters mentioning VICP as well as links to government agency programs also mentioning VICP.
<b>The Johns Hopkins University, Institute for Vaccine Safety (IVS)</b>  <a href="http://www.vaccinesafety.edu/">http://www.vaccinesafety.edu/</a>	Educational institution	Director, Neal A. Halsey, MD	The purpose of IVS is to obtain and disseminate objective information on the safety of recommended immunizations. The Institute provides a forum for dissemination of data regarding specific issues concerning the safety of immunizations; investigates safety questions where insufficient data are available to provide definitive conclusions; conducts methodological and empirical research on post-licensure vaccine safety evaluation; and undertakes individual research projects to obtain specific information regarding vaccine safety when existing information about the safety of a specific vaccine is insufficient or flawed.	Web site houses links to VAERS and VISs, which mention VICP.

Name & URL	Organization/ Agency type\	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<b>National Foundation for Infectious Diseases (NFID)</b>  <a href="http://www.nfid.org/">http://www.nfid.org/</a>	Nonprofit	Executive Director, Leonard Novick; Board President, George C. Hill, PhD	NFID is a non-profit organization founded in 1973 and dedicated to educating the public and health care professionals about the causes, treatment and prevention of infectious diseases.	Web site houses general publications and fact sheets on vaccines.
<b>National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NAID)</b>  <a href="http://www3.niaid.nih.gov/">http://www3.niaid.nih.gov/</a>	Government agency	Director, Anthony S. Fauci, MD	NIAID is one of the 27 Institutes and Centers of NIH. NIH is the primary Federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 60 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the U.S. and around the world.	Web site houses information on vaccine research and development.
<b>National Network for Immunization Information (NNii)</b>  <a href="http://www.immunizationinfo.org/">http://www.immunizationinfo.org/</a>	Nonprofit service	Executive Director & Editor-in-Chief, Martin G. Myers, MD; Steering Committee Co-Chairs, Samuel Katz, MD & Louis Sullivan, MD	NNii's mission is to provide the public, health professionals, policy makers, and the media with up-to-date, scientifically valid information related to immunization to help them understand the issues and to make informed decisions. NNii is an affiliation of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, AAP, ANA, AAFP, the National Association of Pediatric Nurse Practitioners, the American College of Obstetricians and Gynecologists, the University of Texas Medical Branch, the Society for Adolescent medicine and the American Medical Association. NNii is a service provided by Immunizations for Public Health, a non-profit dedicated to making immunization information available to those who need it.	Web site has a section dedicated to VICP: <a href="http://www.immunizationinfo.org/issues/immunization-policy/national-vaccine-injury-compensation-program-vicp">http://www.immunizationinfo.org/issues/immunization-policy/national-vaccine-injury-compensation-program-vicp</a>



Name & URL	Organization/ Agency type	Leadership	Brief description	Select connection to VICP or VICP- related information, if any
<p><b>National Vaccine Information Center (NVIC)</b></p> <p><a href="http://www.nvic.org/">http://www.nvic.org/</a></p>	<p>Advocacy organization; Nonprofit</p>	<p>Co-founder and President, Barbara Loe Fisher</p>	<p>NVIC is a national, non-profit educational organization founded in 1982. The oldest and largest consumer organization advocating the institution of vaccine safety and informed consent protections in the mass vaccination system, NVIC is responsible for launching the vaccine safety and informed consent movement in America in the early 1980's. NVIC provides assistance to those who have suffered vaccine reactions; promotes research to evaluate vaccine safety and effectiveness, as well as to identify factors which place individuals at high risk for suffering vaccine reactions; and monitors vaccine research, development, regulation, policy-making and legislation. NVIC works to protect the right of citizens to exercise the human right to informed consent to medical interventions which carry a risk of injury or death for themselves or their children, including vaccination.</p>	<p>Web site houses external link to VICP Web site in <i>Federal Resources</i> section. Other Federal Resources include the FDA, CDC, Morbidity &amp; Mortality Weekly Report (MMWR), and VAERS. Web site also houses a number of publications and/or opinion pieces on vaccine injury compensation, vaccine laws, and informed consent.</p>

APPENDIX 10.

Major Magazines and Newspapers Searched <sup>34</sup>	
Magazines	Newspapers
<i>Reader's Digest</i>	<i>Wall Street Journal</i> (New York)
<i>Better Homes and Gardens</i>	<i>USA Today</i> (Virginia)
<i>National Geographic</i>	<i>New York Times</i> (New York)
<i>Good Housekeeping</i>	<i>Los Angeles Times</i> (California)
<i>Woman's Day</i>	<i>Washington Post</i> (District of Columbia)
<i>Family Circle</i>	<i>New York Daily News</i> (New York)
<i>Ladies' Home Journal</i>	<i>Chicago Tribune</i> (Illinois)
<i>People Magazine</i>	<i>Newsday</i> (New York)
<i>Game Informer</i>	<i>Houston Chronicle</i> (Texas)
<i>Time Magazine</i>	<i>Dallas Morning News</i> (Texas)
<i>Prevention</i>	<i>Chicago Sun Times</i> (Illinois)
<i>Taste of Home</i>	<i>Boston Globe</i> (Massachusetts)
<i>Sports Illustrated</i>	<i>San Francisco Chronicle</i> (California)
<i>TV Guide</i>	<i>New York Post</i> (New York)
<i>Cosmopolitan</i>	<i>Arizona Republic</i> (Arizona)
<i>Southern Living</i>	<i>Newark Star Ledger</i> (New Jersey)
<i>Newsweek</i>	<i>Philadelphia Inquirer</i> (Pennsylvania)
<i>O, The Oprah Magazine</i>	<i>Rocky Mountain News</i> (Colorado)
<i>Glamour</i>	<i>Cleveland Plain Dealer</i> (Ohio)
<i>Redbook</i>	<i>San Diego Union Tribune</i> (California)
<i>Parenting</i>	<i>Denver Post</i> (Colorado)
<i>Family Fun</i>	<i>Minneapolis Star Tribune</i> (Minnesota)
<i>Seventeen</i>	<i>Detroit Free Press</i> (Michigan)
	<i>Orange County Register</i> (California)
	<i>Oregonian, The</i> (Oregon)

<sup>34</sup> Top magazines and newspapers based on subscriptions/circulation as found on [www.magazinecost.com](http://www.magazinecost.com) and [www.newspapers.com](http://www.newspapers.com), most recently accessed April 26, 2010. *Maxim* and *Playboy* were also listed on [www.magazinecost.com](http://www.magazinecost.com), but research excluded these publications.

## APPENDIX 11.

### Supporting Online Environmental Scan Documentation

Select Sources for Online Environmental Scan	
Source	URL
Age of Autism	<a href="http://www.ageofautism.com">www.ageofautism.com</a>
Autism Speaks	<a href="http://www.autismspeaks.org">www.autismspeaks.org</a>
Cafe Mom	<a href="http://www.cafemom.com">www.cafemom.com</a>
Centers for Disease Control and Prevention	<a href="http://www.cdc.gov">www.cdc.gov</a>
Discover Magazine Blog	<a href="http://blogs.discovermagazine.com">blogs.discovermagazine.com</a>
Facebook	<a href="http://www.facebook.com">www.facebook.com</a>
Health Resources and Services Administration	<a href="http://www.hrsa.gov">www.hrsa.gov</a>
MySpace	<a href="http://www.myspace.com">www.myspace.com</a>
National Vaccine Information Center	<a href="http://www.nvic.org">www.nvic.org</a>
Twitter	<a href="http://www.twitter.com">www.twitter.com</a>
U.S. Department of Health and Human Services	<a href="http://www.hhs.gov">www.hhs.gov</a>
Vaccination Liberation	<a href="http://www.vaclib.org">www.vaclib.org</a>
Wall Street Journal Blog	<a href="http://blog.wsj.com">blog.wsj.com</a>

### Search Term Analysis

An analysis of Internet search results also offers some insight into what sites are visible and relevant to the public regarding the Vaccine Injury Compensation Program (VICP), vaccine injury, and vaccine risks/benefits.

User-generated social media sites do not appear in the top search results generated on Internet search engines Yahoo!, Google, and Bing for VICP-related terminology, as of January 22, 2010. Currently, if sites relating to the VICP, vaccine injury, and vaccine risks/benefits do appear on the first page of results, none of them are user-generated. A few other outcomes of this research task include:

- When searching for “VICP” using Google, Bing, and Yahoo! search engines, the official VICP Web site ([www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)) is the first result on all three.
- Three out of the top ten search results on Google do not mention or relate to the VICP.
- The official VICP Web site is the top search result on Google and Bing when searching for the keywords “vaccine injury.”

Although most search results are generated according to complicated, proprietary algorithms, authority and popularity carry a great deal of weight when determining search result relevance. Therefore, these results can be considered useful indicators of a site’s relevance and visibility to potential audiences, and can be considered a user-generated product.

Expanded Search Term Analysis "DVIC"			
Search Engine	Google	Yahoo!	Bing
Results	DefenseImagery.mil: <a href="http://www.defenseimagery.mil">www.defenseimagery.mil</a>	Defense Visual Information Center: <a href="http://www.defenseimagery.mil/index.htm">http://www.defenseimagery.mil/index.htm</a>	DefenseImagery.mil: <a href="http://www.defenseimagery.mil/index.htm">http://www.defenseimagery.mil/index.htm</a>
	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/roster.htm">www.hrsa.gov/Vaccinecompensation/roster.htm</a>	DVIC homepage: <a href="http://www.dvic1.org/">http://www.dvic1.org/</a>	DVICE: <a href="http://dvice.com/">http://dvice.com/</a>
	<a href="http://www.bhphotovideo.com/c/product/331637-REG/Sanyo_POA_CA_DVIC_POA_CA_DVIC_Component_to_DVI_A.html">Sanyo   POA-CA-DVIC Component to DVI-A Cable   POA-CA-DVIC   B&amp;H:</a> <a href="http://www.bhphotovideo.com/c/product/331637-REG/Sanyo_POA_CA_DVIC_POA_CA_DVIC_Component_to_DVI_A.html">http://www.bhphotovideo.com/c/product/331637-REG/Sanyo_POA_CA_DVIC_POA_CA_DVIC_Component_to_DVI_A.html</a>	Dvico: <a href="http://www.dvico.de/">http://www.dvico.de/</a>	Thank You for Visiting: <a href="http://dvic.com/">http://dvic.com/</a>
	Defense Visual Info Ctr (DVIC) Photos: <a href="http://www.au.af.mil/au/awc/awcgate/awc-dvic.htm">http://www.au.af.mil/au/awc/awcgate/awc-dvic.htm</a>	DVICE: <a href="http://dvice.com/2.php">http://dvice.com/2.php</a>	DVIC homepage: <a href="http://dvic1.org/">http://dvic1.org/</a>
	Metropolitan Police Department: Domestic Violence Intake Center (DVIC): <a href="http://mpdc.dc.gov/mpdc/cwp/view,a,1232,q,541152,mpdcNav_GID,1557.asp">http://mpdc.dc.gov/mpdc/cwp/view,a,1232,q,541152,mpdcNav_GID,1557.asp</a>	Dvic > Новости компании: <a href="http://www.dvic.ru/news/">http://www.dvic.ru/news/</a>	Defense Visual Info Ctr (DVIC) Photos: <a href="http://www.au.af.mil/au/awc/awcgate/awc-dvic.htm">http://www.au.af.mil/au/awc/awcgate/awc-dvic.htm</a>
	DVIC Advanced Search: <a href="http://www.dodmedia.osd.mil/dvic/srch_template.htm">http://www.dodmedia.osd.mil/dvic/srch_template.htm</a>	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/roster.htm">www.hrsa.gov/Vaccinecompensation/roster.htm</a>	DVIC - What does DVIC stand for? Acronyms and abbreviations by the ...: <a href="http://acronyms.thefreedictionary.com/DVIC">http://acronyms.thefreedictionary.com/DVIC</a>
	DVIC homepage: <a href="http://www.dvic1.org/">http://www.dvic1.org/</a>	DVI-D Cable, 15-feet, Male-to-Male - Model No. CAB-DVIC-15MM ...: <a href="http://www.kvmgalore.com/shopping/product_info.php?products_id=1112&amp;kartSess=9bcfc4e37983b6982a3fd72e2c919ae2">http://www.kvmgalore.com/shopping/product_info.php?products_id=1112&amp;kartSess=9bcfc4e37983b6982a3fd72e2c919ae2</a>	www.dodmedia.osd.mil: <a href="http://www.defenseimagery.mil/index.htm">http://www.defenseimagery.mil/index.htm</a>
	DVIC - What does DVIC stand for? Acronyms and abbreviations by the ...: <a href="http://acronyms.thefreedictionary.com/DVIC">http://acronyms.thefreedictionary.com/DVIC</a>	DVIC Advanced Search: <a href="http://www.dodmedia.osd.mil/dvic/srch_template.htm">http://www.dodmedia.osd.mil/dvic/srch_template.htm</a>	DVIC - Definition by AcronymFinder: <a href="http://www.acronymfinder.com/DVIC.html">http://www.acronymfinder.com/DVIC.html</a>
	Template:PD-USGov-Military-DVIC - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Template:PD-USGov-Military-DVIC">http://en.wikipedia.org/wiki/Template:PD-USGov-Military-DVIC</a>	Gefen CAB-DVIC-DLX-60MM Audio Video Cable - Yahoo! Shopping: <a href="http://shopping.yahoo.com/22830289-gefen-cab-dvic-dlx-60mm-audio-video-cable/">http://shopping.yahoo.com/22830289-gefen-cab-dvic-dlx-60mm-audio-video-cable/</a> Vaccine FAQ - eMedicineHealth - experts in everyday ...	

Expanded Search Term Analysis "VICP"			
Search Engine	Google	Yahoo!	Bing
Results	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/">www.hrsa.gov/Vaccinecompensation/</a>	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/roster.htm">www.hrsa.gov/Vaccinecompensation/roster.htm</a>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>
	What is VICP?: <a href="http://www.wisegeek.com/what-is-vicp.htm">http://www.wisegeek.com/what-is-vicp.htm</a>	vicp.cc - Site Info from Alexa: <a href="http://www.alexa.com/siteinfo/vicp.cc">http://www.alexa.com/siteinfo/vicp.cc</a>	Vaccine court - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_court">http://en.wikipedia.org/wiki/Vaccine_court</a>
	Vaccine Litigation & VICP: <a href="http://www.whale.to/vaccines/court.html">http://www.whale.to/vaccines/court.html</a>	Vaccine Injury Claims under the National Vaccine Injury...: <a href="http://www.anapolschwartz.com/practices/vaccines/nvicp.asp">http://www.anapolschwartz.com/practices/vaccines/nvicp.asp</a>	VICP - What does VICP stand for? Acronyms and abbreviations by the ...: <a href="http://acronyms.thefreedictionary.com/VICP">http://acronyms.thefreedictionary.com/VICP</a>
	Video Imaging Co-Processor (VICP) Signal Processing Library...: <a href="http://focus.ti.com/docs/toolsw/folders/print/sprc831.html">http://focus.ti.com/docs/toolsw/folders/print/sprc831.html</a>	VICP Signal Processing Library: <a href="http://focus.ti.com/docs/toolsw/folders/print/sprc831.html">http://focus.ti.com/docs/toolsw/folders/print/sprc831.html</a>	Vaccine litigation & VICP: <a href="http://www.whale.to/vaccines/court.html">http://www.whale.to/vaccines/court.html</a>
	VICP - What does VICP stand for? Acronyms and abbreviations by the ...: <a href="http://acronyms.thefreedictionary.com/VICP">http://acronyms.thefreedictionary.com/VICP</a>	What is VICP? <a href="http://www.wisegeek.com/what-is-vicp.htm">http://www.wisegeek.com/what-is-vicp.htm</a>	VICP - Definition by AcronymFinder: <a href="http://www.acronymfinder.com/VICP.html">http://www.acronymfinder.com/VICP.html</a>
	VICP, National Vaccine Injury Compensation Program: <a href="http://www.drhull.com/EncyMaster/V/VICP.html">http://www.drhull.com/EncyMaster/V/VICP.html</a>	PDF] National Vaccine Injury Compensation Program	VicP - LivePerson Expert – Cooking: <a href="http://www.liveperson.com/vicp/">http://www.liveperson.com/vicp/</a>
	[PDF] THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP): <a href="ftp://ftp.hrsa.gov/vaccinecompensation/84522_Brochure.pdf">ftp://ftp.hrsa.gov/vaccinecompensation/84522_Brochure.pdf</a>	Newly Licensed Vaccines & VICP Coverage: <a href="http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/std_adp.php?p_faqid=721&amp;p_created=1139350441&amp;p_topview=1">http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/std_adp.php?p_faqid=721&amp;p_created=1139350441&amp;p_topview=1</a>	National Vaccine Injury Compensation Program: <a href="http://www.in.gov/isdh/files/VICP.pdf">http://www.in.gov/isdh/files/VICP.pdf</a>
	DOJ Vaccine Compensation Program – About the Program: <a href="http://www.justice.gov/civil/torts/const/vicp/about.htm">http://www.justice.gov/civil/torts/const/vicp/about.htm</a>	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>
	Category:VICP - Texas Instruments Embedded Processors Wiki: <a href="http://wiki.davincidsp.com/index.php/Category:VICP">http://wiki.davincidsp.com/index.php/Category:VICP</a>		VICP meaning - Acronym Attic: <a href="http://www.acronymattic.com/VICP.html">http://www.acronymattic.com/VICP.html</a>

**Expanded Search Term Analysis  
"Vaccine Injury Compensation Program"**

Search Engine	Google	Yahoo!	Bing
<b>Results</b>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/">http://www.hrsa.gov/Vaccinecompensation/</a>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>
	The Vaccine Injury Compensation Law: <a href="http://www.vaccineinfo.net/yourrights/legalhelp/injurycomplaw.shtml">http://www.vaccineinfo.net/yourrights/legalhelp/injurycomplaw.shtml</a>	Curtis Webb – Vaccine Injury Law and Compensation: <a href="http://www.vaccineinjurycompensation.com/">http://www.vaccineinjurycompensation.com/</a>	Vaccine injury - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_injury">http://en.wikipedia.org/wiki/Vaccine_injury</a>
	DOJ Vaccine Compensation Program - About the Program: <a href="http://www.justice.gov/civil/torts/const/vicp/about.htm">http://www.justice.gov/civil/torts/const/vicp/about.htm</a>	Attorneys at Law - Vaccine Injury Alliance - Specializing in ...: <a href="http://www.vaccineinjury.org/">http://www.vaccineinjury.org/</a>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/table.htm">http://www.hrsa.gov/vaccinecompensation/table.htm</a>
	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>	Vaccine Injury Compensation - Vaccine Lawyer, Attorney: <a href="http://vaccineclaim.com/">http://vaccineclaim.com/</a>
	National Childhood Vaccine Injury Act - Wikipedia, the free ...: <a href="http://en.wikipedia.org/wiki/National_Childhood_Vaccine_Injury_Act">http://en.wikipedia.org/wiki/National_Childhood_Vaccine_Injury_Act</a>	Vaccine injury - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_injury">http://en.wikipedia.org/wiki/Vaccine_injury</a>	Vaccine Compensation Attorney - Randall G. Knutson: <a href="http://www.vaccineclaim.com/vaccine-attorney.html">http://www.vaccineclaim.com/vaccine-attorney.html</a>
	RATIONALIZING VACCINE INJURY COMPENSATION: <a href="http://doi.wiley.com/10.1111/j.1467-8519.2007.00590.x">http://doi.wiley.com/10.1111/j.1467-8519.2007.00590.x</a>	Vaccine Injury Compensation - Vaccine Lawyer, Attorney: <a href="http://www.vaccineclaim.com/">http://www.vaccineclaim.com/</a>	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>
	VACCINE INJURY, criminal ramifications of vaccine injuries: <a href="http://www.shirleys-wellness-cafe.com/vaccines_phillips_criminal.htm">http://www.shirleys-wellness-cafe.com/vaccines_phillips_criminal.htm</a>	Vaccine Injury Compensation	Vaccine court - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/National_Vaccine_Injury_Compensation_Program">http://en.wikipedia.org/wiki/National_Vaccine_Injury_Compensation_Program</a>
	[PDF] Smallpox Vaccine Injury Compensation: <a href="http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL31960.pdf">http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL31960.pdf</a>		DOJ Vaccine Compensation Program - About the Program: <a href="http://www.justice.gov/civil/torts/const/vicp/about.htm">http://www.justice.gov/civil/torts/const/vicp/about.htm</a>
		Vaccine Injury Lawyers: <a href="http://www.mctplaw.com/vaccine-injury/">http://www.mctplaw.com/vaccine-injury/</a>	
		The Vaccine Injury Compensation Law: <a href="http://www.vaccineinfo.net/yourrights/legalhelp/injurycomplaw.shtml">http://www.vaccineinfo.net/yourrights/legalhelp/injurycomplaw.shtml</a>	
		CDC National Vaccine Program Office: Vaccine Fact Sheets	

Expanded Search Term Analysis "Vaccine Court"			
Search Engine	Google	Yahoo!	Bing
Results	Vaccine court - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_court">http://en.wikipedia.org/wiki/Vaccine_court</a>	Vaccine court - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_court">http://en.wikipedia.org/wiki/Vaccine_court</a>	Vaccine court - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_court">http://en.wikipedia.org/wiki/Vaccine_court</a>
	Vaccine Program/Office of Special Masters   US Court of Federal Claims: <a href="http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters">http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters</a>	Vaccine Program/Office of Special Masters   US Court of ...: <a href="http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters">http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters</a>	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>
	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/">http://www.hrsa.gov/Vaccinecompensation/</a>	HRSA - National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>	Vaccine Program/Office of Special Masters   US Court of Federal Claims: <a href="http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters">http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters</a>
	Vaccine Court Rejects Autism Claims: <a href="http://www.webmd.com/brain/autism/news/20090212/vaccine-court-rejects-autism-claims">http://www.webmd.com/brain/autism/news/20090212/vaccine-court-rejects-autism-claims</a>	Autism - Vaccines - Autism and the Vaccine Court: <a href="http://autism.about.com/od/autismandthelaw/a/vaccinecourt.htm">http://autism.about.com/od/autismandthelaw/a/vaccinecourt.htm</a>	Robert F. Kennedy, Jr. and David Kirby: Vaccine Court: Autism Debate ...: <a href="http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html">http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html</a>
	Court Links Hepatitis B Vaccine To A Death - Primary Source - CBS News: <a href="http://www.cbsnews.com/blogs/2009/02/02/primarysource/en-try4770907.shtml">http://www.cbsnews.com/blogs/2009/02/02/primarysource/en-try4770907.shtml</a>	FAQ: Vaccine Court Hears Autism Cases: <a href="http://www.webmd.com/brain/autism/features/faq-vaccine-court-hears-autism-cases">http://www.webmd.com/brain/autism/features/faq-vaccine-court-hears-autism-cases</a>	Autism - Vaccines - Autism and the Vaccine Court: <a href="http://autism.about.com/od/autismandthelaw/a/vaccinecourt.htm">http://autism.about.com/od/autismandthelaw/a/vaccinecourt.htm</a>
	Robert F. Kennedy, Jr. and David Kirby: Vaccine Court: Autism ...: <a href="http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html">http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html</a>	Vaccine Court's Ruling Adds to Confusion Over Autism Link: <a href="http://www.ama-assn.org/amednews/2008/04/07/hlsb0407.htm">http://www.ama-assn.org/amednews/2008/04/07/hlsb0407.htm</a>	David Kirby: The Vaccine-Autism Court Document Every American Should ...: <a href="http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-d_b_88558.html">http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-d_b_88558.html</a>
	Vaccine Court: Hepatitis B Shot Caused MS - AGE OF AUTISM: <a href="http://www.ageofautism.com/2009/02/vaccine-court-hepatitis-b-shot-causes-ms.html">http://www.ageofautism.com/2009/02/vaccine-court-hepatitis-b-shot-causes-ms.html</a>	Inside the "Vaccine Court" " Scienceline: <a href="http://www.scienceline.org/2008/07/25/policy-grant-autismvaccinecourt/">http://www.scienceline.org/2008/07/25/policy-grant-autismvaccinecourt/</a>	Vaccine Court Rejects Autism Claims: <a href="http://www.webmd.com/brain/autism/news/20090212/vaccine-court-rejects-autism-claims?src=RSS_PUBLIC">http://www.webmd.com/brain/autism/news/20090212/vaccine-court-rejects-autism-claims?src=RSS_PUBLIC</a>
	U.S. vaccine court denies autism cases   Reuters: <a href="http://www.reuters.com/article/idU5TRE51B4AN20090212">http://www.reuters.com/article/idU5TRE51B4AN20090212</a>	Robert F. Kennedy, Jr. and David Kirby: Vaccine Court: Autism ...: <a href="http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html?view=print">http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html?view=print</a>	Vaccine Court Cases – Vaccines Can Trigger Autism, 13 Times
	neurodiversity weblog: A Brief Introduction to Vaccine Court: <a href="http://neurodiversity.com/weblog/article/142/">http://neurodiversity.com/weblog/article/142/</a>		Vaccine Court (Yup, Vaccine Court) Rules Boosters Didn't Trigger ...: <a href="http://blogs.wsj.com/law/2009/02/12/vaccine-court-yup-vaccine-court-rules-boosters-didnt-trigger-autism/">http://blogs.wsj.com/law/2009/02/12/vaccine-court-yup-vaccine-court-rules-boosters-didnt-trigger-autism/</a>
	A special court rejects autism-vaccine theories. - By Arthur Allen ...: <a href="http://www.slate.com/id/2211156/">http://www.slate.com/id/2211156/</a>		FAQ: Vaccine Court Hears Autism Cases: <a href="http://www.webmd.com/brain/autism/features/faq-vaccine-court-hears-autism-cases">http://www.webmd.com/brain/autism/features/faq-vaccine-court-hears-autism-cases</a>

Expanded Search Term Analysis "Vaccine Injury"			
Search Engine	Google	Yahoo!	Bing
Results	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/Vaccinecompensation/">http://www.hrsa.gov/Vaccinecompensation/</a>	Vaccine injury - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_injury">http://en.wikipedia.org/wiki/Vaccine_injury</a>	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>
	Vaccine injury - Wikipedia, the free encyclopedia: <a href="http://en.wikipedia.org/wiki/Vaccine_injury">http://en.wikipedia.org/wiki/Vaccine_injury</a>	Attorneys at Law – Vaccine Injury Alliance – Specializing in...: <a href="http://www.vaccineinjury.org/">http://www.vaccineinjury.org/</a>	Vaccine injury - Wikipedia, the free encyclopedia
	Attorneys at Law - Vaccine Injury Alliance - Specializing in ...: <a href="http://www.vaccineinjury.org/">http://www.vaccineinjury.org/</a>	HRSA – National Vaccine Injury Compensation Program: <a href="http://www.hrsa.gov/vaccinecompensation/">http://www.hrsa.gov/vaccinecompensation/</a>	Attorneys at Law – Vaccine Injury Alliance – Specializing in...: <a href="http://www.vaccineinjury.org/">http://www.vaccineinjury.org/</a>
	Vaccine Injury Case Offers a Clue to the Causes of Autism ...: <a href="http://www.scientificamerican.com/article.cfm?id=vaccine-injury-case-offer">http://www.scientificamerican.com/article.cfm?id=vaccine-injury-case-offer</a>	Irish Vaccines Injuries Support Group Ireland   Vaccine ...: <a href="http://www.vaccineinjury.ie/index.html">http://www.vaccineinjury.ie/index.html</a>	Vaccines: Vaccine Adverse Events Reporting System Injury Database...: <a href="http://www.healing-arts.org/children/vaccines/vaccines-database.htm">http://www.healing-arts.org/children/vaccines/vaccines-database.htm</a>
	VIAL - Vacinfo.Org - Home Page: <a href="http://www.vacinfo.org/">http://www.vacinfo.org/</a>	Vaccine Injury Help Center   : <a href="http://www.vaccineinjuryhelpcenter.com/">http://www.vaccineinjuryhelpcenter.com/</a>	Victims Of Vaccine Injury and Reactions
	Vaccines: Vaccine Adverse Event Reporting System Injury Database ...: <a href="http://www.healing-arts.org/children/vaccines/vaccines-database.htm">http://www.healing-arts.org/children/vaccines/vaccines-database.htm</a>	National Vaccine Injury Compensation Program	Vaccine court - Wikipedia, the free encyclopedia
	CDC National Vaccine Program Office: Vaccine Fact Sheets	Vaccine Injury Compensation - Vaccine Lawyer, Attorney: <a href="http://www.vaccineclaim.com/">http://www.vaccineclaim.com/</a>	Vaccine Injury Lawyers: <a href="http://www.mctplaw.com/vaccine-injury/">http://www.mctplaw.com/vaccine-injury/</a>
	DOJ Vaccine Compensation Program - About the Program: <a href="http://www.justice.gov/civil/torts/const/vicp/about.htm">http://www.justice.gov/civil/torts/const/vicp/about.htm</a>	The National Vaccine Injury Compensation Program: <a href="http://www.texmed.org/Template.aspx?id=4086">http://www.texmed.org/Template.aspx?id=4086</a>	Vaccine Injury Compensation – National Vaccine Information Center: <a href="http://www.nvic.org/injury-compensation.aspx">http://www.nvic.org/injury-compensation.aspx</a>
	VACCINE INJURY, criminal ramifications of vaccine injuries: <a href="http://www.shirleys-wellness-cafe.com/vaccines_phillips_criminal.htm">http://www.shirleys-wellness-cafe.com/vaccines_phillips_criminal.htm</a>	Vaccine Injury Compensation – National Vaccine Information Center	Vaccine Injury   Potts Sadaka LLC - Personal Injury Lawyers: <a href="http://www.defendingtheconsumer.com/vaccine-injury-lawyer/">http://www.defendingtheconsumer.com/vaccine-injury-lawyer/</a>
Swine Flu, Part 2 – Media's Vaccine Injury Dichotomy - AGE OF AUTISM: <a href="http://www.ageofautism.com/2009/04/swine-flu-part-2-medias-vaccine-injury-dichotomy.html">http://www.ageofautism.com/2009/04/swine-flu-part-2-medias-vaccine-injury-dichotomy.html</a>			

**The National Vaccine Injury Compensation Program:** Awareness, Perception, and Communication Considerations  
*Developing a Comprehensive National Vaccine Injury Compensation Program Research Report*



Despite the lack of visibility of user-generated sites when searching key terms, a wide range of organizations and writers do address vaccines, the VICP, and vaccine risks/benefits within the user-generated space. Participants in these conversations include people who identify themselves as parents, relatives of children, and individuals believed to have been vaccine injured, as well as health care professionals, attorneys, and advocates.

Based on online scan findings, the link between vaccines, vaccine injury, VICP, and vaccine risks/benefits in this discussion is discussed related to autism. The following conversation is representative of this observation:

*“Hey all you ‘concerned’ people...SOME KIDS ARE IMPACTED BY VACCINES, HENCE THE VACCINE INJURY FUND! Not all kids with autism have adverse reactions, but some do. Some are born with autism, other regress and develop it later. The genetic ‘science’ is weak at best. The genes in question were found in less than 5% of those with autism. The studies touted to vindicate vaccines are retrospective. There have been ZERO double blind randomized clinical trials on the impact of 35 injections, many containing more than one virus. Stop villifying [sic] those who believe their child was harmed.”<sup>35</sup>*

Emotion and anecdote also enter into related discussions. Relative to these discussions, the Division of Vaccine Injury Compensation (DVIC) or the VICP, or even a “vaccine injury fund”, is not highly visible. When tracking the course of a conversation within the user-generated space, when the VICP or “vaccine injury court” was brought up by an individual, there was little subsequent conversation after its mention.

The following excerpt comes from the *Wall Street Journal* Law Blog, and illustrates how the awareness and discussion of the VICP is not robust. A description of the VICP is offered in the body of the blog post:

*“And so what of the vaccine court? According to the Court of Federal Claims’ Web site, the National Childhood Vaccine Injury Act of 1986 set up a compensation scheme whereby those ‘allegedly suffering injury or death as a result of the administration of certain compulsory childhood vaccines may petition the federal government for monetary damages.’ The court, established to bypass the ‘often costly and lengthy civil arena of traditional tort litigation,’ is run by the congressionally-created Office of Special Masters...”<sup>36</sup>*

The ensuing conversation in the comments section of this blog focused briefly on the post’s focus, the VICP, but moves quickly into a debate about the alleged link between vaccines and autism, the preservatives used in vaccinations, and other related topics that do not directly relate to the VICP.

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<sup>35</sup> Discover Magazine Blog. (2009, April 4). *Jenny McCarthy counts for something*. Retrieved January, 14, 2010, from <http://blogs.discovermagazine.com/badastronomy/2009/04/02/jenny-mccarthy-counts-for-something/>.

<sup>36</sup> Wall Street Journal Blog. (2009, February 12). Vaccine court (yup, vaccine court) rules boosters didn’t trigger autism. Retrieved January 20, 2010 from <http://blogs.wsj.com.law/2009/02/12/vaccine-court-yup-vaccine-court-rules-boosters-didnt-trigger-autism/tab/article/>.

## Conversations with Subject Matter Experts

## APPENDIX 12.

### *Developing a Comprehensive National Vaccine Injury Compensation Program*

#### **Semi-Structured Subject Matter Expert Discussion Guide**

##### **I. Background**

Thank you for agreeing to participate in this discussion and assisting us in our research to develop an outreach and marketing strategy for the National Vaccine Injury Compensation Program (VICP). My name is \_\_\_\_\_ and I will be conducting the interview with my colleague \_\_\_\_\_. We work for Altarum Institute based in Washington, DC. Altarum, in partnership with Banyan Communications, is conducting discussions with several Subject Matter Experts in the field of vaccine risk/benefit communication on behalf of HRSA's Division of Vaccine Injury Compensation (DVIC) to inform the development of an outreach and marketing plan for the VICP.

Before we begin, I would like to review a few more details about our discussion:

- The discussion will last approximately one hour. If you need to discontinue before the end of the hour, please let us know.
- The information you share is confidential. As previously mentioned, after we conduct all of the Subject Matter Expert discussions, the information we collect will be combined with information obtained through a literature review, environmental scans, discussion with DVIC's advisory commission (ACCV), and focus groups with target audiences to develop a research report, which will be submitted to DVIC. Your name will not appear anywhere in the report and what you say today will not be attached to your name at any point.
- Altarum is an independent contractor and doesn't have a vested interest in anything that is said during the interview other than obtaining your perspective about how best to communicate about the VICP to the public.

Do you have any questions before we proceed?

##### **II. Introduction**

I would like to start by asking you some questions about your current position and role.

1. Please tell me your job title and how long you have served in this role.
2. How would you describe your current position and work?
3. Please briefly describe your experience with vaccine risk/benefit communication research and/or practice.

**III. Knowledge of the VICP**

4. How familiar are you with the VICP? When and how did you become aware of this program? *(Gauge general level of knowledge.)*
5. Which organizations or agencies are sources of information about the VICP?
6. How do these organizations/agencies communicate information about the VICP? *(Media formats, target audiences?)*
7. Where else do you think the public gets information about the VICP?
8. To what extent is the public aware of the VICP? *(Ask to specify by audience, if they are knowledgeable.)*
9. What do you think the public's perception of the VICP is? *(Ask to specify by audience, if they are knowledgeable.)*

**IV. Communicating About the VICP** *(Ask for specific examples from their experience, if they have any.)*

10. What do you see as the key issues to consider when developing an outreach and marketing strategy for the VICP?
11. Based on your experience, what do you think is the best way(s) to increase knowledge about the VICP, without advocating for or discouraging vaccination? *(Ask to specify by audience, if knowledgeable, and probe for any differences they see in strategies by audience.)*

Follow-up:

- Which audience segments, if any, should be the focus of any outreach efforts?
  - What are the optimal communication channels? *(Media format, setting, timing)*
  - What information should be conveyed?
  - What tone should the messaging take to best resonate?
  - What types of images (if any) should be used?
12. What factors might influence an individual's perception and understanding of the VICP? How can those factors be addressed?
  13. What factors might assist DVIC in communicating with target audiences about the VICP?

14. What barriers might DVIC face in communicating with target audiences? How can those barriers be addressed?
15. What stakeholders and events do you know of that might impact an outreach and marketing strategy undertaken by the VICP? How might they affect and/or receive an outreach and marketing strategy for the VICP?
16. Before we end today, is there anything I have not asked that you feel is important to keep in mind when developing an outreach and marketing strategy for the VICP?

Thank you again for your time and insights.

## Target Audience Focus Groups

**APPENDIX 13.**

***Developing a Comprehensive National Vaccine Injury Compensation Program:  
Focus Group Target Audiences and Locations***

**Proposed Target Audiences:**

Based on our review of peer-reviewed literature within the past 10 years on vaccine risk/benefit communication as it relates to the VICP, we have found a dearth of information regarding the level of knowledge or communication about VICP and therefore, have not identified any specific audience segments to target DVIC’s outreach efforts. It is evident from the literature, however, that parents are a primary target audience for messaging about vaccine risks/benefits and that primary care health professionals are the main sources of information about vaccines and main distributors of Vaccine Information Statements (VIS). Given these findings and DVIC’s mandate to inform the “public” of the VICP, we recommend targeting those audiences that are the focus of vaccine outreach efforts:

- **Parents & parents-to-be:** Parents/caretakers of vaccine-age children & pregnant women
- **Health care professionals:** Primary care pediatricians/physicians, nurses, & front-line staff (private, community health center, school-based)
- **Older adults:** People 50 years of age and older

We find these target audiences to be very appropriate as they closely align with the CDC’s recommended populations for a number of vaccinations.

**Proposed Locations:**

In order to reach a broad population base, we recommend conducting focus groups in two types of locations-- a large, diverse urban center and a less populated location with a significant rural influence. Chicago, IL and Charlotte, NC meet these criteria, respectively. We plan to conduct one focus group for each of the target audiences outlined above in both locations for a total of 3 groups each. A profile of each location is provided below.

**Chicago, IL:** Chicago, IL is -and has consistently been- ranked one of the nation’s top three largest cities; currently behind NY (#1) and LA (#2). As shown in the table below, Chicago is a very diverse city and attractive as a focus group location in terms of the cost (less expensive than NY) and distance (closer in distance than LA).

Population*	Percent change 2000 to 2006	White persons	Black persons	American Indian & Alaska Native persons	Asian persons	Persons of Hispanic or Latino origin	Estimated vaccination rate**
2,833,321	-2.2%	42.0%	36.8%	0.4%	4.3%	26.0%	87.8%

**Charlotte, NC:** The 7<sup>th</sup> fastest growing city in the US outside of NY, LA, and several cities in AZ & TX, Charlotte, NC has a diverse population with a significant rural and agricultural influence. Other cities considered “fastest growing” are located in the Southwest and have disproportionately large Latino populations and therefore, do not represent ideal locations for our data collection.

Population*	Percent change 2000 to 2006	White persons	Black persons	American Indian & Alaska Native persons	Asian persons	Persons of Hispanic or Latino origin	Estimated vaccination rate**
630,478	11.2%	58.3%	32.7%	0.3%	3.4%	7.4%	92.0%

\*All stats through ‘estimated vaccination rate’, 2006 Census estimates

(<http://quickfacts.census.gov/qfd/index.html>)

\*\*For state; children aged 19-35 mos; average of DTaP, MMR, VAR rates (CDC National Immunization Survey [NIS] 2007 - <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5735a1.htm#tab2>)



## APPENDIX 14a.

### Altarum Institute & Banyan Communications *Developing a Comprehensive National Vaccine Injury Compensation Program*

#### Focus Group Screening Guide: Health Care Professionals

Hello, my name is \_\_\_\_\_ and I am calling from Survey Center Focus, a research consulting company, on behalf of the US Department of Health and Human Services, Division of Vaccine Injury Compensation. The Department has contracted with Banyan Communications - in conjunction with Altarum Institute, a research and consulting organization - to develop a communications plan to increase the general public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program, also known as the VICP. As a part of the plan, the Banyan/Altarum team is conducting focus groups with select target audiences. One of the audiences is primary care physicians and health care professionals. We are interested in learning about physicians' and health care professionals' familiarity with the Vaccine Injury Compensation Program and their opinions on effective program messaging and communication strategies.

**Would you be interested in participating in a focus group?**

- Yes
- No (*Thank and terminate call*)

**Great, I would like to ask you some questions to determine which, if any, focus group you could participate in. These questions will only take a few minutes of your time.**

---

**Do you or your health care facility (e.g., private practice, hospital) administer vaccines to patients?**

- Yes
- No (*Thank and terminate call*)

**To which age groups do you or your health care facility administer vaccines?**

- Infants & Children
- Adolescents
- Adults
- Older adults (50+)
- No majority, a combination of all of the above

**What is your position within your health care facility?**

- Physician/Pediatrician
- Physician's Assistant (PA)
- Nurse
- Other (specify) \_\_\_\_\_

**How many years of experience do you have in your position (overall, not just at your current facility)?**

- Under 3 years
- 3-5 years
- 5-10 years
- Over 10 years

**How would you best describe the health care facility in which you work?**

- Private practice
- Community health center
- School
- Hospital
- Assisted living facility/nursing home
- Other (specify) \_\_\_\_\_

**What is your race?**

- White or Caucasian
- Black or African American
- American Indian or Alaska Native
- Asian or Pacific Islander
- Multiple races
- Other (specify) \_\_\_\_\_

**Are you of Latino origin or descent?**

- Yes
- No

**What is your gender?**

- Male
- Female

---

*We would like the indicated combination of the above positions, races/ethnicities, and genders; as well as a well-distributed combination of the above experiences and types of facilities/settings. If the person **does not qualify** for the focus group:*

**Based on the answers you gave me, I can see the focus group you would fit into is already full. Thank you for your time.**

*If the person **does qualify** for the focus group:*

**Based on your responses, we would like to invite you to participate in one of our focus groups. First, I would like to tell you a little more about the group:**

---

**The National Vaccine Injury Compensation Program: Awareness, Perception, and Communication Considerations**  
*Developing a Comprehensive National Vaccine Injury Compensation Program Research Report*

It will last no longer than 1 hour and you will be asked some questions about your familiarity with the Vaccine Injury Compensation Program and your opinion on VICP messaging and communication strategies that would resonate with you. Your comments will be confidential. Your name will not be attached to anything you say in the group.

The focus group will consist of a minimum of 7 and a maximum of 9 other physicians and health care professionals and a facilitator. There will be light refreshments and we will provide you \$150 cash for your time.

The group will take place on April 12, 2010 at 5:00pm at Survey Center Focus, 153 West Ohio Street, 4<sup>th</sup> Floor, Chicago, IL.

Now that you know more about the focus group, will you be able to attend?

- Yes  
 No *(Thank and terminate call)*

*(Inform them of public transportation options)*

---

Thank you for answering my questions. So that we can start on time, please arrive at 4:45pm. We will not be able to let people in after the group has started. People who come late will not receive the \$150.

The focus group is for invited participants and is not open to the public. You cannot send someone else in your place.

We are counting on your help, so please call us well in advance of the group if something comes up and you are no longer able to attend. You can call \_\_\_\_\_ *(give appropriate Survey Center Focus phone number/office hours)*. We will also send you a confirmation with information about the focus group. This confirmation will include a telephone number as well.

Before we hang up, I would like to get the correct spelling of your name, your email address *(mailing address or other alternate contact info, if no email)*, and your phone number, so that I can send you a confirmation with the date, time, and location of the focus group. Also, someone will call you the day before the group to remind you.

What is your name, email address *(or other)*, and phone number?

\_\_\_\_\_

Do you have any questions you would like to ask me?

Thank you again for your time. We look forward to seeing you at the focus group.

APPENDIX 14b.

Altarum Institute & Banyan Communications  
*Developing a Comprehensive National Vaccine Injury Compensation Program*

Focus Group Screening Guide: Parents & Parents-to-be

Hello, my name is \_\_\_\_\_ and I am calling from Survey Center Focus, a research consulting company, on behalf of the Federal government's Department of Health and Human Services, Division of Vaccine Injury Compensation. The Department has asked Banyan Communications - in conjunction with Altarum Institute, a research and consulting organization - to develop a plan to help increase the public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program, also known as the VICP. As a part of the plan, the Banyan/Altarum team is conducting group discussions with select target audiences. One of the audiences is parents and expecting parents. We are interested in learning about what parents and expecting parents know about the Vaccine Injury Compensation Program and their opinions on good ways to educate the public about the program's existence.

Would you be interested in participating in a group discussion?

- Yes *(Continue)*
- No *(Thank and terminate call)*

Great, I would like to ask you some questions to determine which, if any, focus group you could participate in. These questions will only take a few minutes of your time.

---

1. How many children do you have?

- None *(Skip to Question 3)*
- 1
- 2
- 3
- 4 or more

2. How old is/are your child(ren)? *(If 18+, thank and terminate call)*

\_\_\_\_\_

3. Are you expecting/pregnant?

- Yes
- No

**4. Have your children received vaccinations or are you planning to have them vaccinated?**

- Yes
- No
- Partially (explain) \_\_\_\_\_

**5. What is your gender?**

- Male
- Female

**6. Are you employed?**

- Yes
- No

**If yes, what is your job/position?**

\_\_\_\_\_

**7. What is the highest level of education you have completed?**

- Did not complete high school
- High school
- Associate's
- Bachelor's
- Master's/Doctorate
- Other (specify) \_\_\_\_\_

**8. What is your race?**

- White or Caucasian
- Black or African American
- American Indian or Alaska Native
- Asian or Pacific Islander
- Multiple races
- Other (specify) \_\_\_\_\_

9. Are you of Latino origin or descent?

- Yes  
 No

---

*We would like the indicated combination of the above genders, expecting parents, and races/ethnicities; as well as a well-distributed combination of the above education/employment statuses. If the person **does not qualify** for the focus group:*

Based on the answers you gave me, I can see the group meeting you would fit into is already full. Thank you for your time.

*If the person **does qualify** for the focus group:*

Based on your responses, we would like to invite you to participate in one of our group meetings. First, I would like to tell you a little more about the meeting:

It will last no longer than 1 hour and you will be asked some questions about your familiarity with the Vaccine Injury Compensation Program and your opinion on VICP messaging and communication strategies that you would respond well to. Your comments will be confidential. Your name will not be attached to anything you say in the group.

The focus group will consist of a minimum of 7 and a maximum of 9 other parents and expecting parents. There will be light refreshments and we will provide you \$75 cash for your time.

The group will take place on April 13, 2010 at 10:00am at Survey Center Focus, 153 West Ohio Street, 4<sup>th</sup> Floor, Chicago, IL.

Now that you know more about the group meeting, will you be able to attend?

- Yes  
 No (*Thank and terminate call*)

*(Inform them of public transportation options)*

---

Thank you for answering my questions. So that we can start on time, please arrive at 9:45am. We will not be able to let people in after the meeting has started. People who come late will not receive the \$85.

The group meeting is for invited participants and is not open to the public. You cannot send someone else in your place.

We are counting on your help, so please call us well in advance of the meeting if something comes up and you are no longer able to attend. You can call \_\_\_\_\_ (*give appropriate Survey Center Focus phone number/office hours*). We will also send you a confirmation with information about the group meeting. This confirmation will include a telephone number as well.

Before we hang up, I would like to get the correct spelling of your name, your email address (*mailing address or other alternate contact info, if no email*), and your phone number, so that I can send you a confirmation with the date, time, and location of the group meeting. Also, someone will call you the day before the meeting to remind you.

What is your name, email address (*or other*), and phone number?

\_\_\_\_\_

Do you have any questions you would like to ask me?

Thank you again for your time. We look forward to seeing you at the group meeting.

APPENDIX 14c.

**Altarum Institute & Banyan Communications**  
***Developing a Comprehensive National Vaccine Injury Compensation Program***

**Focus Group Screening Guide: Older Adults**

Hello, my name is \_\_\_\_\_ and I am calling from Survey Center Focus, a research consulting company, on behalf of the Federal government's Department of Health and Human Services, Division of Vaccine Injury Compensation. The Department has asked Banyan Communications - in conjunction with Altarum Institute, a research and consulting organization - to develop a plan to help increase the public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program, also known as the VICP. As a part of the plan, the Banyan/Altarum team is conducting group discussions with select target audiences. One of the audiences is adults 50 years old and older. We are interested in learning about what this age group knows about the Vaccine Injury Compensation Program and their opinions on good ways to educate the public about the program's existence.

**Would you be interested in participating in a group discussion?**

- Yes *(Continue)*
- No *(Thank and terminate call)*

**Great, I would like to ask you some questions to determine which, if any, focus group you could participate in. These questions will only take a few minutes of your time.**

---

**What is your age?**

- Under 50 years *(Thank and terminate call)*
- 50 – 59 years
- 60 – 69 years
- 70 – 79 years
- 80+ years

**Have you ever received a vaccination as an adult over the age of 50?**

- Yes
- No
- Partially (explain) \_\_\_\_\_

**What is your gender?**

- Male
- Female



**Are you employed?**

- Yes
- No

**If yes, what is your job/position?**

\_\_\_\_\_

**What is the highest level of education you have completed?**

- Did not complete high school
- High school
- Associate's
- Bachelor's
- Master's/Doctorate
- Other (specify) \_\_\_\_\_

**What is your race?**

- White or Caucasian
- Black or African American
- American Indian or Alaska Native
- Asian or Pacific Islander
- Multiple races
- Other (specify) \_\_\_\_\_

**Are you of Latino origin or descent?**

- Yes
- No

**In what environment do you live?**

- Home, independently
- Home, with family
- Assisted living/Older adult community
- Nursing home
- Other (specify) \_\_\_\_\_

---

*We would like the indicated combination of the above genders and races/ethnicities; as well as a well-distributed combination of the above ages and education/employment statuses. If the person **does not qualify** for the focus group:*

**Based on the answers you gave me, I can see the group meeting you would fit into is already full.  
Thank you for your time.**

If the person does qualify for the focus group:

Based on your responses, we would like to invite you to participate in one of our group meetings. First, I would like to tell you a little more about the meeting:

It will last no longer than 1 hour and you will be asked some questions about your familiarity with the Vaccine Injury Compensation Program and your opinion on VICP messaging and communication strategies that you would respond well to. Your comments will be confidential. Your name will not be attached to anything you say in the group.

The focus group will consist of a minimum of 7 and a maximum of 9 other parents and expecting parents. There will be light refreshments and we will provide you \$85 cash for your time.

The group will take place on April 13, 2010 at 1:00pm at Survey Center Focus, 153 West Ohio Street, 4<sup>th</sup> Floor, Chicago, IL.

Now that you know more about the group meeting, will you be able to attend?

- Yes
- No *(Thank and terminate call)*

*(Inform them of public transportation options)*

---

Thank you for answering my questions. So that we can start on time, please arrive at 12:45pm. We will not be able to let people in after the meeting has started. People who come late will not receive the \$85.

The group meeting is for invited participants and is not open to the public. You cannot send someone else in your place.

We are counting on your help, so please call us well in advance of the meeting if something comes up and you are no longer able to attend. You can call \_\_\_\_\_ *(give appropriate Survey Center Focus phone number/office hours)*. We will also send you a confirmation with information about the group meeting. This confirmation will include a telephone number as well.

Before we hang up, I would like to get the correct spelling of your name, your email address *(mailing address or other alternate contact info, if no email)*, and your phone number, so that I can send you a confirmation with the date, time, and location of the group meeting. Also, someone will call you the day before the meeting to remind you.

What is your name, email address *(or other)*, and phone number?

\_\_\_\_\_

Do you have any questions you would like to ask me?

**Thank you again for your time. We look forward to seeing you at the group meeting.**

## **APPENDIX 15a.**

### ***Developing a Comprehensive National Vaccine Injury Compensation Program***

#### **Focus Group Discussion Guide: Health Care Professionals**

##### **V. Background**

Welcome and thank you for being here today. My name is \_\_\_\_\_ and I will be leading this focus group with you. I work for Altarum Institute, a research and consulting organization, based in Washington, DC. Altarum, in partnership with Banyan Communications, is helping the US Department of Health and Human Services, Division of Vaccine Injury Compensation, also known as DVIC, to research the development of a communications plan to increase the general public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program (or, VICP). As a part of this research, we are conducting focus groups with select target audiences. One of these audiences is primary care physicians and health care professionals like you. In this focus group, we are interested in learning about your familiarity with the Vaccine Injury Compensation Program and your opinions on effective VICP messaging and communication strategies.

The purpose of focus groups is to get the honest opinions of small groups of people about a specific topic. Again, we want to hear what you know about the VICP and your opinions on how you think DVIC should communicate about the program. Your comments will be used to inform DVIC's outreach and communication efforts.

Before we begin, I would like to review a few more details about our discussion:

- Altarum is an independent contractor. I don't work for HRSA or DVIC, so please feel free to share your thoughts, whether they are positive or negative.
- It is ok to disagree with one another. I want to hear everyone's point of view. If you disagree, please do so respectfully.
- Only one person should talk at a time. We are tape recording this session so that we don't miss anything important. I may remind you of this during the group.
- I would like everyone to participate. But, you each don't have to answer every question. You don't have to raise your hand either. If, however, I really want to know what you think about a particular question, I may call on you.
- I have a lot that I want to talk about today. So, don't be surprised if at some point I interrupt the discussion and move to another topic. But, don't let me cut you off. If there is something important you want to say, let me know and you can add your thoughts before we change subjects.

- We will be using first names only today. Everything you say is confidential. After we conduct several more of these focus groups, we will write a report for DVIC. Your name will not appear anywhere in the report and what you say today will not be attached to your name at any point. We also ask that you don't tell other people what was said by anyone during the group.

The group will last approximately one hour. We will finish by \_\_\_\_\_. If you need the leave for a restroom break, the bathrooms are \_\_\_\_\_.

Do you have any questions before we start?

#### **VI. Introductions**

I would like to start by going around the room and having each of you tell us a little about yourself. Please share your first name and your favorite vacation destination. I'll start.

4. My name is \_\_\_\_\_.
5. My favorite vacation destination is \_\_\_\_\_.

#### **VII. General Practice and Vaccination Information**

6. In what setting/type of health care facility do you work? (e.g. private practice, community health center, etc.)
7. What is your position/role at your health care facility? (e.g. pediatrician/physician, physician's assistant [PA], nurse)
8. How often does your health care facility provide vaccinations to patients? (Frequently? Infrequently?)
9. Who does your health care facility primarily vaccinate? (e.g. children/adolescents, adults/pregnant women, older adults, travelers)

#### **VIII. Knowledge and Perception of the VICP**

10. Are you familiar with the VICP? (*Facilitator: If "no" for a significant amount of participants, provide introductory VICP information.*)
  - a. If so, how familiar? (Do you know the process/requirements for investigating compensation?)

- b. If so, when and how did you become aware of this program?
11. Are you familiar with the Division of Vaccine Injury Compensation?
- a. If so, how familiar?
12. In your opinion, are your patients familiar with the VICP?
13. What perception/opinion do you have of the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*

Follow-up:

- Easy or difficult to access
- Clear or confusing process
- Fair or unfair system

#### **IX. *Trusted Sources of Information***

14. Where do you get your information about the risks and benefits of vaccines?
- a. Which organizations or agencies are your trusted sources of information for this? And why?
- b. How do these organizations/agencies communicate with you about the risks and benefits of vaccines? How do you access the information?
15. Where do you get your information about the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*
- a. Which organizations or agencies are your trusted sources of information for this? And why?
- b. How do these organizations/agencies communicate with you about the VICP? How do you access the information?
16. If/when you seek out information about the risks and benefits of vaccines and/or the VICP,
- a. Do you access the Internet for this information? Are there particular Web sites and/or search engines you access? Which one(s)?
- b. Do you read certain magazines, newsletters, newspapers? Which one(s)?
- c. Do you listen to talk shows, radio stations? Which one(s)?
17. Do (or would) messages from the US Department of Health and Human Services regarding vaccinations evoke trust and confidence?

- a. If yes, why?
  - b. If no, why?
18. Which other government agencies' (Federal or local) vaccine-related messages (would) evoke trust and confidence, if any? And why?
19. Which public health and medical organizations' vaccine-related messages (would) evoke trust and confidence, if any? And why?
- X. *Communicating About the VICP: Actual***
20. What information on the risks and benefits of vaccines do you provide to your patients, if any?
- a. In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - b. Do you feel you have sufficient information?
  - c. If you do not provide any information, why?
21. What information on the VICP do you provide to your patients, if any?
- a. In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - b. Do you feel you have sufficient information?
  - c. If you do not provide any information, why?
22. When do you provide vaccine risk/benefit and/or VICP information to your patients?
- a. Do you feel you have sufficient time to review this information with your patients?
23. Who in your health care facility provides vaccine risk/benefit and/or VICP information to your patients?
- XI. *Communicating About the VICP: Future considerations***
24. Are you familiar with DVIC's materials and information about the VICP?
- a. *The National Vaccine Injury Compensation Program (VICP) brochure?*
  - b. *What You Need to Know About the National Vaccine Injury Compensation Program (VICP) booklet?*
  - c. *National Vaccine Injury Compensation Program (VICP) Web page?*  
[\(http://www.hrsa.gov/vaccinecompensation/\)](http://www.hrsa.gov/vaccinecompensation/)

- d. If so, how do you access these materials and information?
25. What is your reaction to DVIC's materials regarding the VICP? (*Facilitator: Share materials.*)
- The brochure?
  - The booklet?
  - Web page?

Follow-up:

- Readability/User-friendliness
- Tone
- Images
- Detail
- Layout/Links

26. What (additional) information about the VICP would you like to know, if any?
- What level of detail?
  - In what format? (e.g. verbal/training, print, online, video/tv, mobile communication, etc.)
27. When communicating about the VICP, what recommendations do you have about the type of messaging that is used?

Follow-up:

- Specific terminology to use or avoid
- Images to use or avoid
- Tone to use or avoid

28. What (additional) information about the VICP would you like to provide to your patients, if any?
- What level of detail?
  - In what format? (e.g. verbal, print, online, video, mobile communication, etc.)
29. Before we end today, is there anything I have not asked that you feel is important to keep in mind when communicating about the Vaccine Injury Compensation Program? Do you have any final questions?

Thank you again for your time and insights.

## APPENDIX 15b.

### *Developing a Comprehensive National Vaccine Injury Compensation Program*

#### **Focus Group Discussion Guide: Parents & Parents-to-be**

#### **XII. Background**

Welcome and thank you for being here today. My name is \_\_\_\_\_ and I will be leading this group discussion with you. I work for Altarum Institute, a research and consulting organization, based in Washington, DC. Altarum, in partnership with Banyan Communications, is helping the Federal government's Department of Health and Human Services, Division of Vaccine Injury Compensation, also known as DVIC, to research the development of plan to increase the public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program, also known as the VICP. As a part of this research, we are conducting discussions with select target audiences. One of these audiences is parents and expecting parents like you. In this discussion, we are interested in learning what you know about the Vaccine Injury Compensation Program and your opinions on good ways to educate the public about the program's existence.

This discussion is called a "focus group". The purpose of focus groups is to get the honest opinions of small groups of people about a specific topic. Again, we want to hear what you know about the VICP and how you think DVIC should communicate about the program. Your comments will be used to inform DVIC's outreach and communication efforts.

Before we begin, I would like to review a few more details about our discussion:

- Altarum is an independent contractor. I don't work for the Federal government or DVIC, so please feel free to share your thoughts, whether they are positive or negative.
- It is ok to disagree with one another. I want to hear everyone's point of view. If you disagree, please do so respectfully.
- Only one person should talk at a time. We are tape recording this session so that we don't miss anything important. I may remind you of this during the group.
- I would like everyone to participate. But, you each don't have to answer every question. You don't have to raise your hand either. If, however, I really want to know what you think about a particular question, I may call on you.
- I have a lot that I want to talk about today. So, don't be surprised if at some point I interrupt the discussion and move to another topic. But, don't let me cut you off. If there is something important you want to say, let me know and you can add your thoughts before we change subjects.
- We will be using first names only today. Everything you say is confidential. After we conduct several more of these focus groups, we will write a report for DVIC. Your name will not appear



anywhere in the report and what you say today will not be attached to your name at any point. We also ask that you don't tell other people what was said by anyone during the group.

The group will last approximately one hour. We will finish by \_\_\_\_\_. If you need the leave for a restroom break, the bathrooms are \_\_\_\_\_.

Do you have any questions before we start?

### **XIII. Introductions**

I would like to start by going around the room and having each of you tell us a little about yourself. Please share your first name and your favorite vacation destination. I'll start.

1. My name is \_\_\_\_\_.
2. My favorite vacation destination is \_\_\_\_\_.

### **XIV. General Family & Vaccine Information**

3. Are you familiar with any local, State or Federal vaccine requirements and recommendations for children and/or adults?
4. Have your children received vaccinations or are you planning to have them vaccinated?
  - a. If yes, why? (e.g. school requirements, CDC/gov't recommendations, etc.)
  - b. If no, why?
  - c. If partially, why?
5. Have any of your children experienced a negative effect that was determined to be the result of a vaccine? Do you know anyone with children who have experienced a negative effect that was determined to be the result of a vaccine?
  - a. If so, please explain. (Do you know if this was documented in the Vaccine Adverse Event Reporting System [VAERS]? Investigated with the VICP?)

### **XV. Knowledge and Perception of the VICP**

6. Are you familiar with the VICP? *(Facilitator: If "no" for a significant amount of participants, provide introductory VICP information.)*
  - a. If so, when and how did you become aware of this program?

7. Are you familiar with the Division of Vaccine Injury Compensation?
  - a. If so, how did you learn about DVIC?
8. What perception/opinion do you have of the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*

Follow-up:

- Easy or difficult to access
- Clear or confusing process
- Fair or unfair system

#### **XVI. Trusted Sources of Information**

9. Where do you seek information about the risks and benefits of vaccines, if any?
  - a. What people or organizations or agencies do you trust for this information? And why?
  - b. How do these people or organizations/agencies communicate with you about the risks and benefits of vaccines?
10. Where do you seek information about the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*
  - a. What people or organizations or agencies do you trust for this information? And why?
  - b. How do these people or organizations/agencies communicate with you about the VICP?
11. If/when you seek out information about the risks and benefits of vaccines and/or the VICP,
  - a. Do you access the Internet for this information? Are there particular Web sites and/or search engines you access? Which one(s)?
  - b. Do you read certain magazines, newsletters, newspapers? Which ones?
  - c. Do you listen to talk shows, radio stations? Which one(s)?
12. Do (or would) you trust and have confidence in messages from the US Department of Health and Human Services regarding vaccinations?
  - a. If yes, why?
  - b. If no, why?
13. Which other government agencies' (Federal or local) vaccine-related messages do (or would) you trust, if any? And why?

14. Which public health and medical organizations' vaccine-related messages do (or would) you trust, if any? And why?

**XVII. Communication About the VICP: Actual**

15. What information on the risks and benefits of vaccines, if any, is provided to you by your pediatrician's office and/or other health care setting(s) you visit?
- In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - Do you feel the information is helpful?
16. What information on the VICP, if any, is provided to you by your pediatrician's office and/or other health care setting(s) you visit?
- In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - Do you feel the information is helpful?
17. When and where are you provided information on the risks and benefits of vaccines and/or the VICP by your health care provider?

Follow-up:

- In person before a vaccination
  - In person after a vaccination
  - In the mail before or after a vaccination
- Do you feel it is an appropriate setting?
  - Do you feel it is an appropriate time?
18. Who in your pediatrician's office or other health care setting(s) provide(s) you information on the risks and benefits of vaccines and/or the VICP?
19. Do you receive information on the risks and benefits of vaccines or the VICP anywhere else?
- If so, where/from whom?

**XVIII. Communicating About the VICP: Future considerations**

20. Are you familiar with DVIC's materials and information about the VICP?
- The National Vaccine Injury Compensation Program (VICP) brochure?*
  - What You Need to Know About the National Vaccine Injury Compensation Program (VICP) booklet?*
  - National Vaccine Injury Compensation Program (VICP) Web page?*  
(<http://www.hrsa.gov/vaccinecompensation/>)
  - If so, how do you access these materials and information?
21. What is your reaction to DVIC's materials regarding the VICP? (*Facilitator: Share materials.*)
- The brochure?
  - The booklet?
  - Web page?

Follow-up:

- Readability/User-friendliness
- Tone
- Images
- Detail
- Layout/Links

22. What (additional) information about the VICP would you like to know, if any?
- What level of detail?
  - In what format? (e.g. verbal/training, print, online, video/tv, mobile communication, etc.)
23. When communicating about the VICP, what messages would you respond to?

Follow-up:

- Terminology
- Images
- Tone

24. Who would you like to deliver this message?

Sample responses:

- Health care provider
- Local/State health department
- Federal government/agency

25. When and where would you like this message delivered?

Sample responses:

- By mail before vaccination
- In person at the doctor's office well before vaccination
- In person at the doctor's appointment immediately before vaccination

26. Before we end today, is there anything I have not asked that you feel is important to keep in mind when communicating about the Vaccine Injury Compensation Program? Do you have any final questions?

Thank you again for your time and insights.

## APPENDIX 15c.

### *Developing a Comprehensive National Vaccine Injury Compensation Program*

#### **Focus Group Discussion Guide: Older Adults**

#### **XIX. Background**

Welcome and thank you for being here today. My name is \_\_\_\_\_ and I will be leading this group discussion with you. I work for Altarum Institute, a research and consulting organization, based in Washington, DC. Altarum, in partnership with Banyan Communications, is helping the Federal government's Department of Health and Human Services, Division of Vaccine Injury Compensation, also known as DVIC, to research the development of plan to increase the public's awareness of an existing Federal program that provides compensation to people in the case they are found to be injured by certain vaccines. This Federal program is called the National Vaccine Injury Compensation Program, also known as the VICP. As a part of this research, we are conducting discussions with select target audiences. One of these audiences is adults 50 years old and older like you. In this discussion, we are interested in learning what you know about the Vaccine Injury Compensation Program and your opinions on good ways to educate the public about the program's existence.

This discussion is called a "focus group". The purpose of focus groups is to get the honest opinions of small groups of people about a specific topic. Again, we want to hear what you know about the VICP and how you think DVIC should communicate about the program. Your comments will be used to inform DVIC's outreach and communication efforts.

Before we begin, I would like to review a few more details about our discussion:

- Altarum is an independent contractor. I don't work for HRSA or DVIC, so please feel free to share your thoughts, whether they are positive or negative.
- It is ok to disagree with one another. I want to hear everyone's point of view. If you disagree, please do so respectfully.
- Only one person should talk at a time. We are tape recording this session so that we don't miss anything important. I may remind you of this during the group.
- I would like everyone to participate. But, you each don't have to answer every question. You don't have to raise your hand either. If, however, I really want to know what you think about a particular question, I may call on you.
- I have a lot that I want to talk about today. So, don't be surprised if at some point I interrupt the discussion and move to another topic. But, don't let me cut you off. If there is something important you want to say, let me know and you can add your thoughts before we change subjects.
- We will be using first names only today. Everything you say is confidential. After we conduct several more of these focus groups, we will write a report for DVIC. Your name will not appear

anywhere in the report and what you say today will not be attached to your name at any point. We also ask that you don't tell other people what was said by anyone during the group.

The group will last approximately one hour. We will finish by \_\_\_\_\_. If you need the leave for a restroom break, the bathrooms are \_\_\_\_\_.

Do you have any questions before we start?

## **XX. Introductions**

I would like to start by going around the room and having each of you tell us a little about yourself. Please share your first name and your favorite vacation destination. I'll start.

1. My name is \_\_\_\_\_.
2. My favorite vacation destination is \_\_\_\_\_.

## **XXI. General Vaccine Information**

3. Are you familiar with any local, State or Federal vaccine requirements and recommendations for children and/or adults?
4. Do you receive recommended vaccinations for adults over 50?
  - a. If yes, why?
  - b. If no, why?
  - c. If partially, why?
5. Have you ever experienced a negative effect that was determined to be the result of a vaccine? Do you know anyone who has experienced a negative effect that was determined to be the result of a vaccine?
  - a. If so, please explain. (Do you know if this was documented in the Vaccine Adverse Event Reporting System [VAERS]? Investigated with the VICP?)

## **XXII. Knowledge and Perception of the VICP**

6. Are you familiar with the VICP? *(Facilitator: If "no" for a significant amount of participants, provide introductory VICP information.)*
  - a. If so, when and how did you become aware of this program?

7. Are you familiar with the Division of Vaccine Injury Compensation?
  - a. If so, how did you learn about DVIC?
8. What perception/opinion do you have of the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*

Follow-up:

- Easy or difficult to access
- Clear or confusing process
- Fair or unfair system

### **XXIII. Trusted Sources of Information**

9. Where do you seek information about the risks and benefits of vaccines, if any?
  - a. What people or organizations or agencies do you trust for this information? And why?
  - b. How do these people or organizations/agencies communicate with you about the risks and benefits of vaccines?
10. Where do you seek information about the VICP, if any? *(Facilitator: Do not ask question if no participants have heard of the VICP.)*
  - a. What people or organizations or agencies do you trust for this information? And why?
  - b. How do these people or organizations/agencies communicate with you about the VICP?
11. If/when you seek out information about the risks and benefits of vaccines and/or the VICP,
  - a. Do you access the Internet for this information? Are there particular Web sites and/or search engines you access? Which one(s)?
  - b. Do you read certain magazines, newsletters, newspapers? Which ones?
  - c. Do you listen to talk shows, radio stations? Which one(s)?
12. Do (or would) you trust and have confidence in messages from the US Department of Health and Human Services regarding vaccinations?
  - a. If yes, why?
  - b. If no, why?
13. Which other government agencies' (Federal or local) vaccine-related messages do (or would) you trust, if any? And why?



14. Which public health and medical organizations' vaccine-related messages do (or would) you trust, if any? And why?

**XXIV. Communication About the VICP: Actual**

15. What information on the risks and benefits of vaccines, if any, is provided to you by your physician's office and/or other health care setting(s) you visit or in which you live?
- In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - Do you feel the information is helpful?
16. What information on the VICP, if any, is provided to you by your physician's office and/or other health care setting(s) you visit or in which you live?
- In what format is this information? (e.g. verbal, print, online, video, mobile communication, etc.)
  - Do you feel the information is helpful?
17. When and where are you provided information on the risks and benefits of vaccines and/or the VICP by your health care provider?

Follow-up:

- In person before a vaccination
  - In person after a vaccination
  - In the mail before or after a vaccination
- Do you feel it is an appropriate setting?
  - Do you feel it is an appropriate time?
18. Who in your physician's office or other health care setting(s) provide(s) you information on the risks and benefits of vaccines and/or the VICP?
19. Do you receive information on the risks and benefits of vaccines or the VICP anywhere else?
- If so, where/from whom?

**XXV. Communicating About the VICP: Future considerations**

20. Are you familiar with DVIC's materials and information about the VICP?
- The National Vaccine Injury Compensation Program (VICP) brochure?*
  - What You Need to Know About the National Vaccine Injury Compensation Program (VICP) booklet?*
  - National Vaccine Injury Compensation Program (VICP) Web page?*  
(<http://www.hrsa.gov/vaccinecompensation/>)
  - If so, how do you access these materials and information?
21. What is your reaction to DVIC's materials about the VICP? (*Facilitator: Share materials.*)
- The brochure?
  - The booklet?
  - Web page?

Follow-up:

- Readability/User-friendliness
- Tone
- Images
- Detail
- Layout/Links

22. What (additional) information about the VICP would you like to know, if any?
- What level of detail?
  - In what format? (e.g. verbal/training, print, online, video/tv, mobile communication, etc.)
23. When communicating about the VICP, what types of messages would you respond to?

Follow-up:

- Terminology
- Images
- Tone

24. Who would you like to deliver this message?

Sample responses:

- Health care provider

- Local/State health department
- Federal government/agency

25. When and where would you like this message delivered?

Sample responses:

- By mail before vaccination
- In person at the doctor's office well before vaccination
- In person at the doctor's appointment immediately before vaccination

26. Before we end today, is there anything I have not asked that you feel is important to keep in mind when communicating about the Vaccine Injury Compensation Program? Do you have any final questions?

Thank you again for your time and insights.

**APPENDIX 16.**

***Developing a Comprehensive National Vaccine Injury Compensation Program  
Focus Group Participant Demographics***

***Charlotte: Health Care Professionals***

<b>Age group(s) to which administer vaccines</b>	<b>Position</b>	<b>Type of health care facility</b>	<b>Ethnicity</b>	<b>Gender</b>
No majority	Nurse	Hospital	Caucasian	Female
No majority	Physician Assistant (PA)	Private Practice	Caucasian	Female
Adolescents; Adults	Physician	Private Practice	Caucasian	Female
Infants/Children; Adolescents	Nurse	School	Caucasian	Female
No majority	Nurse	Hospital	Caucasian	Female
No majority	Physician	Private Practice	Caucasian	Male
Infants/Children; Adults; Older Adults	Nurse	Hospital	Caucasian	Female
Infants/Children; Adolescents	Physician	Private Practice	African American	Female

***Chicago: Health Care Professionals***

<b>Age group(s) to which administer vaccines</b>	<b>Position</b>	<b>Years of experience</b>	<b>Type of health care facility</b>	<b>Ethnicity</b>	<b>Gender</b>
Infants/Children; Adolescents; Adults; Older Adults (OA)	Nurse	10+	Hospital	Latina	Female
Adults; OA	PA	3	Private Practice	African American	Female
Adults; OA	PA	10+	Hospital	Latina	Female
Infants/Children; Adolescents	Nurse	10+	Private Practice	Caucasian	Female
Infants/Children; Adolescents	Pediatrician	5	Community Health Center (CHC)	Caucasian	Female
Infants/Children; Adolescents	Pediatrician	6	CHC	Asian American	Female
Infants/Children; Adolescents; Adults; OA	Physician & Chief Medical Quality Officer	10+	Hospital/Medical Group	Caucasian	Male
Adults; Older Adults	PA	18	School	Caucasian	Male
Adults; Older Adults	PA	3-5	Hospital	Caucasian	Male

### Charlotte: Parents & Parents-to-be

Number of children or expecting	Children rec'd or planning to receive vaccinations	Gender	Employed	Education	Race/Ethnicity
1: 11	Yes	Female	Yes	Associates	Caucasian
1: 9	Yes	Female	Yes	Masters/Doctorate	Latina
4: 13, 8, 6, 4	Yes	Female	Yes	Bachelors	Caucasian
3: 11, 7, 6	Yes	Female	No	Associates	African American
2: 2, 11wks	Yes	Female	Yes	Bachelors	African American
2: 11, 6	Yes	Female	Yes	Bachelors	Latina
2: 14, 13	Yes	Male	Yes	Bachelors	African American
Expecting	Yes	Female	Yes	Bachelors	Caucasian
2: 2, 1	Yes	Female	Yes	Bachelors	Caucasian

### Chicago: Parents & Parents-to-be

Age	Number of children or expecting	Children rec'd or planning to receive vaccinations	Gender	Employment	Education	Ethnicity
21	Expecting	Yes	Female	Administrative Assistant	Some College	Caucasian
33	1 girl: 14	Yes	Female	Special Education	Bachelors	African American
24	1 girl: 9	No	Female	Customer Service	Some College	African American
35	1 girl: 1.5 1 boy: 3.5	Yes	Female	Homemaker	Bachelors	Latina
32	1 boy: 2	Yes	Female	Staffing Manager	Associates	Caucasian
35	3: 10, 12, 14	Yes	Male	Sales Associate, Banking	Associates	Latino
22	1 girl: 4	Yes	Male	School Gym	High School	Asian American
33	Expecting	Yes	Male	Senior Systems Administrator	Bachelors	Caucasian
30	1 boy: 1 Expecting	Yes	Female	Accountant	Bachelors	Caucasian

### Charlotte: Older Adults

Age	Received vaccinations over 50	Gender	Employment	Education	Ethnicity
70-79	Yes	Female	N/A	High School	Caucasian
50-59	No	Female	Home Health Care	Some College	African American
50-59	No	Female	Walmart Sales	Some High School	African American
60-69	Yes	Male	N/A	Bachelors	African American
60-69	Yes	Male	Real Estate	Masters/Doctorate	Asian/Pacific Islander
50-59	No	Male	Internet Sales	Bachelors	African American
50-59	Yes	Female	N/A	High School	Caucasian
50-59	No	Female	N/A	High School	Latina
50-59	Yes	Male	IT	Bachelors	Latino

### Chicago: Older Adults

Name	Age	Received vaccinations over 50	Gender	Employment	Education	Ethnicity
Roger	67	No	Male	Self employed: Consultant	Masters/Doctorate	Caucasian
Donna	74	Yes	Female	Retired: Judicial secretary	Bachelors	Caucasian
Tina	61	Yes	Female	Retired: Event coordinator	High School	Asian
Josephine	71	Yes	Female	Retired: Telecommunications	Bachelors	African American
George	57	Yes	Male	Plumber	Associates	Latino
Connie	61	No	Female	Retired: Secretary/Housekeeper	High School	Caucasian
Miguel	50	No	Male	Construction	Some College	Latino
Jeff	53	Yes	Male	Self employed: General contracting	Associates	African American
Larry	66	No	Male	Retired: Executive recruiting	Bachelors	Caucasian