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THE GREATER GOOD MOVIE

A Production of BNP Pictures, 2011 | 84 minutes

A FILM BY LESLIE MANOOKIAN, KENDALL NELSON AND CHRIS PILARO

THE GREATER GOOD DISCUSSION GUIDE

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Section 1 – GUIDELINES FOR THE FACILITATOR

In recent years, the vaccination of children has been a topic of growing concern, one that often generates strong feelings. THE GREATER GOOD may produce an emotional response among viewers as it challenges many of our accepted ideas regarding vaccines. The Facilitator should be aware of these flashpoints and be prepared to manage the discussion, allowing various points of view to be expressed while maintaining a calm atmosphere of civil discourse.

The purpose of the film is to help viewers understand that the vaccine issue is not black and white, as many have been led to believe, and that there are various personal and public policy aspects that deserve in-depth examination and discussion. The overall goal of THE GREATER GOOD is to educate parents, caregivers, healthcare professionals and policy makers about issues surrounding childhood vaccination.

Objectives of the Film:

- To provide a tool for conducting an open and rational conversation about vaccine issues
- To show that the vaccine issue is not as black and white as viewers may have believed
- To explore concerns surrounding childhood vaccination
- To examine the roles of government, the pharmaceutical industry and the medical profession regarding vaccination
- To address the issue of parental informed consent and to educate parents and caregivers of their rights related to vaccinating their children
- To highlight the gaps in the science around vaccination
- To reframe the debate from doctors vs. parents to one of scientific debate
- To reframe vaccine safety concerns from only autism to the epidemic of chronic illness US children face today where 1 in 5 are developmentally disabled, 1 in 8 have allergies and 1 in 9 have asthma

Ideas and Themes in the Film:

Among the topics for discussion that the film raises are:

- Inadequate research into vaccine safety and effectiveness
- Conflicts of interest on the part of both medical professionals and government regulators
- Parental rights over their children's medical care
- Harm caused by vaccines
- The power and influence of the pharmaceutical industry

In addition, THE GREATER GOOD can be used to start a discussion centered on any of the following topics:

- Medical ethics
- Public health laws
- Parental rights / Informed consent
- Drug advertising & marketing, especially on television
- Government regulation of health industry & medical practices
- Legal liability
- Vaccine courts

Planning Ahead

The guidelines below offer ways the facilitator can help the audience engage with the film and explore its themes through meaningful and productive discussion.

1. ***Identify your audience.*** The film can be used with a wide range of audiences. Decide if the screening and discussion will be for a special audience or for the general community. Among the groups that would have an interest in the film are:

- Educators
- Parents and families
- Grandparents
- Healthcare professionals, including medical doctors, nurses and holistic health practitioners, such as naturopaths, acupuncturists, chiropractors, etc.
- Public health workers
- Natural birthing communities, including midwives and doulas
- Liability attorneys
- Parents' rights advocates
- School administrators
- Local and state legislators

If the screening is for a general community audience, consider inviting representatives of the groups listed above to participate as audience members or as commentators or discussants. If you are showing the film to the general community, learn who is in the audience through a show of hands before the screening starts. Knowing who is in attendance will help you manage the discussion afterward and facilitate the conversation, particularly if the audience includes an outspoken individual.

2. ***Decide on a format.*** There are several ways to structure a screening event, depending on your goals. Here are two suggestions:

- a screening and discussion led by you or another expert facilitator, followed by audience Q & A
- a screening followed by small group discussions of specified topics, with experts in the audience to help lead the small groups

Be sure the schedule allows time (20-30 minutes) for the audience to brainstorm and discuss actions they might take as a result of seeing the film.

3. ***Tailor your discussion.*** To some extent, this will depend on who is in the audience. In the unlikely event that audience members are reticent about expressing themselves, you may try suggesting a topic. For example if you have a group of parents, you might want to focus on informed consent. The discussion, however, should be allowed to develop organically according to the concerns and interests of the audience.

4. ***Become familiar with the issues.*** Watch the film ahead of time and visit THE GREATER GOOD web site for more information on the experts in the film and issues surrounding vaccines, vaccine safety, and state regulations concerning vaccines. Learn about the main arguments in support of, and the cautions about, vaccination. *It is especially important to be aware of some areas of sensitivity, such as informed consent and current policies and exemptions allowed in your state.*

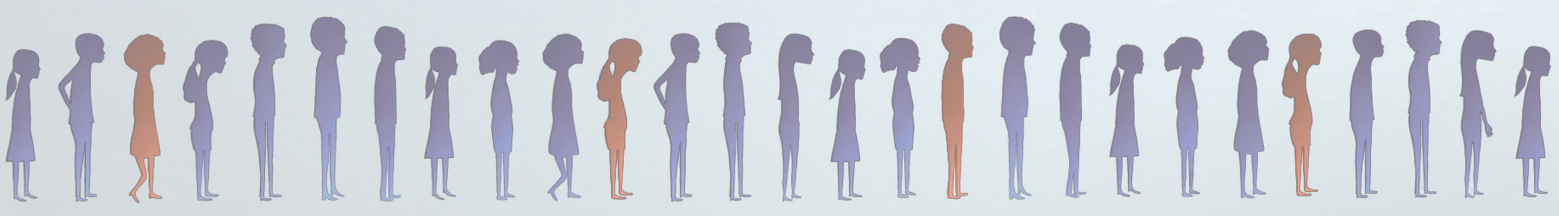
Be sure to read the Vaccine Fast Facts and FAQs so that you are well-informed before the screening and discussion. http://www.greatergoodmovie.org/resources

Hosting an Event

Please see our guide on how to host a screening. This document has additional details on how to prepare, including the timing involved with preparing for your event. http://www.greatergoodmovie.org/resources

Choose a venue that is accessible to various kinds of transportation, accommodates wheelchairs and strollers, and has a room with good sight lines so everyone can see the screen. Spend a few minutes before the screening to *introduce any special guests or speakers* and to acknowledge the groups that are represented.

As the facilitator, give everyone an opportunity to be heard. Encourage participants to speak succinctly, and be consistent about interrupting those who you feel are going on too long or are derailing the conversation. Plan a strategy for preventing one or two people from dominating the discussion. For example, one way to bring the discussion back on track is to say, "Thank you for your contribution to the discussion. Given that we have a limited time together and that others want to speak, is there a specific point you want to raise?"



Explain the ground rules for discussion. After you screen the film, prepare the attendees for how to have dialogue. The issues presented in THE GREATER GOOD can engender strong feelings, so be prepared to remind the audience of this; ask them to follow a few basic rules:

- Listen actively, with an open heart and without interrupting each other.
- Avoid use of inflammatory language, and speak in the first person (e.g., "I think….", "My experience has been…").
- Try to understand each other, and practice compassionate listening.
- We are encouraging dialogue, not debate; share your experience without trying to convince others that you are right.
- Remember that everyone sees through the lens of his or her own experience. Audience members may have different views about the content and meaning of the film, and providing stories on which they've based their opinions will help others understand their perspective.
- Keep in mind that most of what we believe we know about vaccines may not necessarily be accurate. This may be uncomfortable for some to accept but our purpose is to try to separate fact from fiction in order to ensure the safest vaccine program possible and to enable everyone to exercise their right to informed consent.

Creating a Sense of Closure

The information presented in the film and discussion may be new to some people, and they may find it unsettling. Identify what the needs are for your audience. Based on the action plans, do they want to continue meeting? Are they looking for more information? Be sure to have materials available; you may want to print the Resources section of this guide to hand out.
For ideas and guidance in planning future discussions about the topic of vaccines, check the resources listed on the web site of the National Coalition for Dialogue & Deliberation (http://ncdd.org/). NCDD promotes the use of dialogue, deliberation, and other innovative group processes to help people come together across differences to tackle our most challenging problems. The Beginner's Guide (http://ncdd.org/rc/beginners-guide) offers helpful information on getting started.

Section 2 – THE FILM

THE GREATER GOOD is a character-driven documentary film that explores the issues of vaccine safety, informed consent, government mandates, and the politics surrounding the development and marketing of vaccines. Through the experiences of three families whose children were harmed by vaccines, the film raises ethical questions about modern medical practice and public health policies. Mixing verité footage, intimate interviews, 1950s-era government-produced movies and recent TV news reporting, THE GREATER GOOD looks behind the fear, hype and politics that have polarized the vaccine debate in America today. Featuring experts with a wide range of opinions, the film underscores the complexity of the issue. By putting vaccines in a wider context, THE GREATER GOOD offers the opportunity for a rational and scientific discussion on how to create a safer and more effective vaccine program.

Featured Families

The Schrag-Swanks, Wichita, Kansas – Gabi Swank, age 15, and her mother, Shannon Schrag, are a middle-American family caught in the controversy over Gardasil, the HPV vaccine developed by Merck and promoted heavily on MTV. Soon after receiving the vaccine, Gabi started to experience neurological and other physical symptoms that include strokes, seizures, muscle weakness and other symptoms.

The Kings, Portland, Oregon – Jordan, age 12, was a normal baby, but as a toddler he began to exhibit unusual behavior that included walking on tiptoe and flapping his hands. His parents, Fred and MyLinda, took him to their pediatrician who diagnosed Jordan with autism. Dr. John Green identified the cause as the mercury in the vaccines Jordan had received as an infant.

The Christners, Tulsa, Oklahoma – Dr. Stephanie Christner's infant daughter, Victoria, had a delayed reaction which took the form of chronic inflammation brought on by routine vaccinations she received at two and four months. Victoria died at the age of five months. Devastated, Dr. Christner began researching vaccine safety—something that she never questioned in medical school—and found numerous studies going back decades that documented vaccine injuries and death.

Featured experts

Dr. Norman W. Baylor – Director, Office of Vaccines Research and Review, FDA; FDA liaison to CDC's Advisory Committee on Immunization Practices

Kevin Conway, Esq. – lawyer who represents persons in the Federal Vaccine Compensation Program

Mark B. Feinberg, MD, Ph.D. – Vice President, Medical Affairs and Policy, Merck & Co.; 20 years experience in both academia and government, doing research, patient care and health care policy

Barbara Loe Fisher – Co-founder and President, National Vaccine Information Center; author of *DPT: A Shot in the Dark*

John Green, MD – long-time practitioner in emergency, family practice, environmental and holistic medicine and allergies

Diane Harper, MD, MPA, MS – lead researcher, Gardasil; professor, Dept. of Obstetrics/Gynecology, University of Missouri, Kansas City

Dr. Paul Offitt, MD – Chief, Division of Infectious Diseases, Children's Hospital of Philadelphia; Merck consultant and vaccine developer

Walter Orenstein, MD – former director, National Immunization Program, CDC; currently on staff at the Bill and Melinda Gates Foundation

Lawrence B. Palevsky, MD – pediatrician who uses a holistic approach to children's wellness and illness; co-founder and President of the Holistic Pediatric Association

Stanley Plotkin, MD – helped discover vaccine against rubella and co-developed other vaccines; author of standard reference book, *Vaccines*

Robert W. Sears, MD – pediatrician and author, *The Vaccine Book;* practices pediatrics with a combination of alternative and traditional medical care

Christopher Shaw, Ph.D. – neuroscientist and professor in the Dept. of Ophthalmology and Visual Sciences at the University of British Columbia; research includes studies of aluminum adjuvant-induced neuropathology

Cliff Shoemaker, JD. – vaccine injury lawyer; argued the 2008 Hannah Poling case in which the government conceded a connection between Hannah's autism and the vaccines she received

Melinda Wharton, MD – Deputy Director, National Center for Immunization and Respiratory Diseases, CDC

Renee Gentry, Esq. – lawyer who represents persons in the Federal Vaccine Compensation Program

Section 3 – BACKGROUND INFORMATION

Brief History of Vaccines and the Controversies Surrounding Them

For centuries, smallpox was the scourge of humankind in countries throughout the world and efforts were focused on controlling and curing this virulent disease. In 1794, British doctor Edward Jenner used the common cowpox virus to vaccinate a boy against smallpox. He repeated his experiment successfully on several other people and his advance was hailed around the world.

By the mid 1850s, the smallpox vaccine was mandated in Britain. Public support for the vaccine, however, was falling, as many people were still succumbing to smallpox despite mandatory vaccination. Many were also developing complications such as encephalitis (brain inflammation), and eczema vaccinatum (a severe skin condition), both of which could be fatal.

The following points are key to examining the role the small pox vaccine played in the development of vaccines.

While the vaccine was touted as responsible for the decline in the incidence of smallpox in Britain, the use of the vaccine was plummeting as the public rioted against forced vaccination.[1] This naturally raised the question: was the vaccine actually responsible for the decline in disease incidence, given that the use of the vaccine was also in steep decline?[2] Moreover, even countries that did not vaccinate widely for smallpox witnessed smallpox incidence rates decrease anyway.[3]

Throughout the 19th century European scientists worked to find the underlying causes of diseases such as cholera, rabies, pneumonia, meningitis, tuberculosis, rubella and diphtheria. Interestingly, some of the diseases for which there were no vaccines were also declining, underscoring the importance of public health measures in the reduction of infectious diseases. In Leicester, England, for example, quarantining was used to control smallpox, leading to the development of the *Leicester Protocol*, which was mostly forgotten in the enthusiasm for vaccination.[4]

Despite the scant evidence that the smallpox vaccine was solely responsible for the decline in incidence of the disease, enthusiasm for vaccines grew. Vaccines were developed – mainly in the years following World War II – for many other diseases, from pertussis and tetanus, to measles and rubella. However, sentiment against vaccinations has never gone away. The earliest objections to vaccination were for personal or religious convictions by people who felt vaccinations to be useless or harmful. The concerns of early activists were similar to arguments put forth today. These include: vaccines can cause harm; compulsory vaccination infringes individual liberty**;** and, improvements in sanitation, hygiene and nutrition are just as, or more, effective in preventing disease.

Although official histories of infectious diseases attribute their broad decline to vaccination, government statistics show that declines in infectious diseases, and the mortality from them, began long before the advent of vaccines or the widespread use of antibiotics.[5,6,7] This is not to say that vaccines had no role in the reduction of infectious diseases; rather, other factors were also responsible and the story is not nearly as black and white as is widely believed. While the history of vaccines is often presented as straightforward, the smallpox example has been repeated numerous times with other vaccines and infectious diseases. This results in public perception attributing the decline of infectious disease and disease mortality exclusively to vaccination, though facts and data do not support this conclusion.

Sources:

[1] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1082657/?page=16

[2] http://web.mac.com/richardhalvorsen1/smallpox.html - see chart

[3] Dick G. Smallpox: A Reconsideration of Public Health Policies. Progress in Medical Virology 1966: 8: 1-29

[4] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1082657/?page=1

[5] Neil Miller, Vaccines: Are They Safe and Effective? p.18-0

[6] http://w.whale.to/vaccine/mckinlay.pdf, p.413

[7] Historical Statistics of the United States, Colonial Times to 1970, Page 77. US Department of Commerce, Bureau of the Census.

Genesis of the Current Vaccine Concerns

Today's vaccine concerns spring from incidents that took place in the 1970s and 1980s. The DPT (Diphtheria Tetanus and Pertussis) vaccine, as originally constituted, sometimes produced reactions in children who received it, including fever, seizures, irritability, and episodes of unresponsiveness. Because of the frightening nature of some of these reactions, many people began to believe that the vaccine was responsible for brain injury and even death. Concerns about vaccines were further aroused by a 1982 TV documentary, "DPT: Vaccine Roulette", which raised awareness of the purported dangers of the vaccine. Anxieties about DPT spread and resulted in a host of lawsuits against vaccine manufacturers, who paid tens of millions of dollars to settle the claims. Investigations by both British and American medical authorities found that the DPT shot was in fact causing death and permanent brain damage in some children. [1]

In 1998, a report by British doctor Andrew Wakefield and a group of his medical colleagues identified bowel disease in children with regressive autism. The discovery of this new condition was based on a study of 12 children with autism spectrum disorders many with onset soon after receiving the MMR (Measles, Mumps, and Rubella) vaccine according to parental reports. (It is worthy to note 9 of the 12 injuries were initially reported by parents).[2] The study caused a great furor and Dr. Wakefield became the subject of an investigation by the General Medical Council, the medical licensing body in Britain, after a freelance journalist filed a complaint. It was alleged that Dr. Wakefield committed gross misconduct, and although he was never tried in a court of law, the British medical journal *The Lancet* retracted the paper it published about Dr. Wakefield's study. Additionally, Dr. Wakefield was struck off the Medical Register, which meant he could no longer practice medicine in Britain. Esteemed pediatric gastroenterologist Professor John Walker Smith (Dr. Wakefield's supervisor and co-author) was also investigated and charged by the General Medical Council but was eventually fully exonerated by the British High Court. The Court reprimanded the General Medical

Council for their mishandling of the case. Dr. Wakefield, who lives in the U.S., currently has a defamation suit pending in a Texas court.

A major result of this episode was to undermine public trust in vaccines and vaccine safety. There is conflicting scientific evidence about the connection between the MMR vaccine and autism, but many parents and doctors connect their children's autism to the vaccine. As awareness about vaccine safety and potential side effects has grown, more parents have become wary of vaccination and have begun to question the safety of vaccines, their ingredients and even whether they are necessary to protect their children's health. As research studies continue to uncover harmful effects of vaccines, organizations such as the National Vaccine Information Center are educating the public about these harmful effects and advocating for changes in the vaccination program for children. It is noted that there is a link between the timing of the increases in the vaccine schedule in the late 1980's and early 1990's and the epidemic of chronic diseases we see today: allergies, asthma, autoimmune diseases, learning disabilities, behavioral problems, developmental disabilities, diabetes, obesity, and autism; there are many studies that link many chronic illnesses to vaccines or their ingredients (see FAQ sheet for more detailed information).

Sources:
[1] http://www.ncbi.nlm.nih.gov/pubmed/6786580 and http://www.nap.edu/openbook.php?record_id=9814&page=2
[2] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/fulltext

The Current State of Vaccine Science

How Vaccines Work

In principle, vaccines are supposed to confer immunity to a disease in the same way that the actual disease does. When a person is sick, the body produces infection-fighting antibodies. After the person recovers, these antibodies remain in the body. If the person is exposed to that disease again, the antibodies quickly signal the body to start making more antibodies to fight the infection. The person is considered to be immune from the disease and may not even know that he or she was exposed to it again. One difference between a vaccine and actually getting a disease is that in most cases, the vaccine produces immunity without causing the illness. Another, more important difference, is that the immunity from a vaccine is often temporary, while the immunity gained from contracting the disease is usually permanent.

…. And Some Evidence That They Don't

It is well-understood in the scientific community that vaccines do not always work. Sometimes, after being vaccinated, a person fails to produce antibodies (commonly known as "primary vaccine failure"), and sometimes a person's antibodies decline at a faster rate than normally expected (commonly known as "secondary vaccine failure"). Additionally, recent studies have shown that the presence of antibodies—the traditional measure of a vaccine's effectiveness—does not necessarily equal immunity.

Sources:
http://www.vaccines.me/articles/uifpi-what-is-vaccine-failure.cfm
http://www.vaccines.me/articles/cgezx-antibody-response-to-vaccine-does-not-equal-immunity-or-protection.cfm
http://www.vaccinationnews.com/scandals/2003/jan_31/primary_vaccine_failure.htm

The Steps in Vaccine Development

The development of a new vaccine is a multi-year process that begins with researchers studying the virus or bacteria in question to learn how it causes disease. The researchers then examine the best ways to protect people from the disease, determining the quantity of the virus to use and the number of doses to give. Much of this early work is done in academic research laboratories with funding from foundations or the government.
Testing of the vaccine goes through three phases, and *these studies, costing hundreds of millions of dollars, are done by pharmaceutical companies:*

Phase I – A small number of participants (less than 100) is tested to see if the vaccine is safe and if it causes an immune response.

Phase II – If the vaccine passes the Phase I study, a larger study (with several hundred participants) is done, looking at the same questions of safety and immune response.

Phase III – This phase involves thousands of participants over a wide geographic area to determine that the vaccine works in people with different backgrounds and lifestyles. The data are checked by the U.S. Food and Drug Administration for proper procedure and consistent results. The information is then reviewed by the CDC's (Centers for Disease Control and Prevention) Advisory Committee on Immunization Practices, which determines whether to add the new vaccine to the CDC's recommended vaccine schedule. Individual states may then mandate the vaccine.

After the vaccine is licensed for use, it is monitored by the CDC through the Vaccine Adverse Events Reporting System to detect any side effects that may not have shown up during Phase III studies. If adverse effects are found, the vaccine may be withdrawn and/or modified.

Adapted from http://www.chop.edu/service/vaccine-education-center/

Problems with Vaccine Development

While the vaccine development process detailed above gives an overview of how a new vaccine reaches the public, there are areas of concern that deserve closer scrutiny.

Gaps in the Science

- There have been no large, controlled studies comparing vaccinated to unvaccinated populations, so we have no information on the actual long-term outcomes for each group.
- Vaccine safety trials allow the use of an active placebo such as mercury, aluminum, or another vaccine, rather than something neutral and harmless such as water or saline. Therefore, the true side effects of the vaccine are masked and unknown.
- Vaccines are given in combination with other vaccines (ex. Rotavirus, Hib, Pneumococcus, Polio, and Diphtheria,Tetanus, and attenuated Pertussis at 2 months); yet, they are studied individually. So the effects of the combined administration of vaccines are not known.
- The ever-growing vaccine schedule in the U.S. has never been studied to ascertain safety. The schedule grew from 11 doses of four vaccines during the first year of life in 1982, to 26 doses of nine vaccines during the first year of life in 2012. However, the safety of the cumulative effects of this change has never been studied.

Conflicts of Interest

A conflict of interest occurs when an individual or organization is involved in multiple interests, one of which could possibly corrupt the motivation for an act in the other. In 2009, Congress authorized the U.S. Food and Drug Administration (FDA) when reviewing the safety and effectiveness of new vaccines, to grant waivers to special and regular government employees who have financial conflicts, when it is determined that the FDA's need for a particular individual's service outweighs his or her potential financial conflict of interest. Congress also authorized the FDA to grant waivers to special and regular government employees with potential financial conflicts when necessary to afford the Biological Products Advisory Committee their essential expertise.* Consequently, individuals serving on FDA advisory committees, who may stand to gain financially from a positive review of a new vaccine, are allowed to participate in the committee's discussion and to vote for the approval of a new vaccine. As such, employees of and consultants to pharmaceutical companies can be directly involved with policy and recommendation of vaccines. In addition, critics refer to a "revolving door" between the pharmaceutical industry and Federal agencies through which employees are "exchanged". This situation was starkly illustrated when former CDC Director Dr. Julie Gerberding became President of Merck's global vaccine division after the requisite one year grace period and the former head of the National Institute of Health became Sanofi-Aventis' head of research and development.

*(From transcript of FDA's Vaccine and Related Biological Products Advisory Committee meeting, Nov. 18, 2009
Sources:
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM197910.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=names%20of%20fast%20track%20vaccines&utm_content=4)

Fast Tracking

Under the FDA Modernization Act of 1997, Fast Track regulations "facilitate the development of products that treat serious diseases where an unmet medical need exists." Fast Track regulations are also designed to expedite the review process for new drugs, including the potential for companies to ask for priority review. A priority review reduces the time it takes the FDA to review a new drug application. Serious problems can result even though early results show a vaccine to be effective. Studies are often halted when the vaccine is approved, as happened with Gardasil (human papillomavirus (HPV)). Such early termination limits the study to a relatively small population and provides no information on long-term effects of the vaccine. Over the past decade, numerous vaccines have been fast-tracked, even in the absence of a public health threat. Among those vaccines are several for inoculating against biologic threats such as anthrax; some for treating certain cancers; a booster vaccine for bacterial meningitis; and one to stop nicotine addiction.

Problems with VAERS

The Vaccine Adverse Events Reporting System (VAERS) grew out of the 1986 National Childhood Vaccine Injury Act (NCVIA). Managed jointly by the FDA and the CDC, VAERS is meant to collect information about possible side effects after the administration of an approved vaccine. Under VAERS, healthcare providers are required to report any specific adverse events that might indicate a need for further study of the vaccine. However, this provision is not enforced. Moreover, VAERS is a passive system, dependent on healthcare providers filling out long, onerous reports. The system has been faulted for being unreliable, in particular for underreporting (only between one and ten percent of vaccine events get reported), inconsistent data quality, and an absence of an unvaccinated control group.

Vaccine Court

"Vaccine court" is a term referring to the Office of Special Masters of the U.S. Court of Federal Claims. The purpose of this federal court is to administer a no-fault system for litigating vaccine injury claims. Vaccine court, however, is not a real court of law. Rather, it is a parallel system in which there is no judge or jury and no normal process of discovery, due process or precedent. The program is run by Federal appointees defending a Federally administered and Federally funded vaccine program. The appointees, the "Special Masters", are often affiliated with the vaccine industry. Most importantly, this court, established by the National Childhood Vaccine Injury Act (NCVIA) in 1986, is the only court in the U.S. where claims against vaccine manufacturers can be heard. It is funded by patients, who pay a 75 cent Federal excise tax on every purchased dose of vaccine. To win an award, a claimant must show a causal connection between a vaccine and injury, that is, provide proof that a child presents one of several listed adverse effects soon after receiving a vaccination. Since the court was established, the list of compensable events has been restricted, and only about 20 percent of cases receive awards. In February of 2011, the US Supreme Court ruled that applicants to the Federal vaccine court can no longer sue in civil court, even if the vaccine maker could have made a safer vaccine.

Influence of the Pharmaceutical Industry

Pharmaceutical Research and Manufacturers of America (PhRMA) is the biggest single lobby in Washington DC. In 2007, the industry fielded more than 1,100 lobbyists, or about two for every member of Congress. That same year, the industry's lobbying expenditures rose 30 percent from the year before, to a record $189 million. Typically, PhRMA employs former federal officials—FDA regulators, Congressional staffers and members of Congress—to do the work of lobbying. As a result of its multi-faceted influence, the pharmaceutical industry has been able to create an industry-friendly atmosphere at the FDA and CDC, prevent Medicare from negotiating lower prescription drug prices, and support the lack of limits on advertising of prescription drugs directly to consumers.

Sources:
http://www.iwatchnews.org/2005/07/07/5786/drug-lobby-second-none
http://www.iwatchnews.org/2009/03/24/2917/commentary-changing-washington-hard-p

Ethical Considerations

In addition to the science, there are ethical questions associated with vaccination. The key ethical debates are related to vaccine regulation, development, and use. They generally fall into four main areas:

1. Mandates. In the U.S., state policies mandate certain vaccines, especially for school entry. Some citizens disagree with these mandates, feeling that they infringe on individual autonomy or liberty**.** Some people are concerned that the research to assess long-term effects of vaccines is incomplete, and some individuals have religious or philosophical beliefs that conflict with vaccination.

2. Research and testing. Ethical issues in this area revolve around vaccine safety and the conflicting priorities of the various stakeholders involved in vaccine development, including experts in public health, epidemiology, and immunology as well as pharmaceutical companies. Some people question the adequacy of research underlying vaccines, which is overwhelmingly funded by pharmaceutical companies that have much to gain by having a new vaccine on the market and keeping existing vaccines on the market. Doctors who serve on panels such as the *Advisory Committee on Immunization Practices* (*ACIP*), which reviews vaccine studies and makes recommendations regarding their use, may have a financial stake in the approval of a new vaccine. Political considerations may create pressures on public health and research professionals to rush a vaccine to market without adequately testing for safety or possible side effects.

Questions for Parents

To help ensure that parents are well-informed, here are some questions they might ask their pediatrician when weighing decisions about vaccinating their children:

1. Can you please show me the studies that evaluate the saety of the CDC's recommended vaccine schedule.
2. What vaccinations are recommended immediately after birth, and why? What if I postpone these until my child is a little older?
3. Is there information about the effects of vaccinating on a more gradual schedule, such as that suggested by Dr. Robert Sears?
4. What are the ingredients of the routine vaccinations given during the first year of life? In addition to the bacteria or virus, what else do the vaccines contain, including metals, salts, preservatives, stabilizers, antibiotics, or other ingredients?
5. Are there any tests that can be done to determine my child's sensitivities to a particular vaccine or to vaccine ingredients?
6. In addition to vaccines, are there guidelines you can offer about other things that can affect my child's health and well-being, such as infant formula and baby food, or screen time (that is, time spent watching TV or using a computer)?
7. Based on my research I haven't come across any studies that evaluate the safety of the CDC's recommended vaccine schedule. How do you make your decisions re: what is safe for your patients? Can you point me to the studies that evaluate the schedule? Do you follow up with your patients to see if they are having side affects or reactions? What vaccine reactions did you learn about in medical school and which, if any have you seen in your practice?

3. Parental informed consent. The argument can be made that, given the gaps in the science, it is not possible to provide truly informed consent, but the National Childhood Vaccine Injury Act of 1986 requires doctors to give vaccine recipients, or their parents or guardians, a Vaccine Information Sheet with basic information about vaccine risks and benefits. Some lawmakers and patient rights advocates believe that consent is vital, given that vaccines are a medical procedure which can injure and kill some individuals. Opponents fear that consent may make parents unnecessarily concerned and fearful about the vaccination process. Especially troubling is that some states (e.g., California) have disregarded parents' rights by allowing children to be vaccinated at school without parental notification.

4. Access disparities. In the U.S., access to vaccination depends to some extent on socioeconomic and racial or ethnic minority status. This raises the question of whether or not all lives are of equal value and deserving of opportunities to be protected by vaccination. At times of vaccine shortage, as occurred several instances in the past decade, healthcare providers must make decisions about who should receive a vaccine and who must be left vulnerable to disease**.** An underlying consideration, of course, is whether there is a need to vaccinate in the first place.

Excerpted from: http://www.historyofvaccines.org/content/articles/ethical-issues-and-vaccines.

Section 4 – DISCUSSION QUESTIONS

We have provided a range of questions to encourage a dynamic dialogue with your audience. We suggest you pick 4-6 of the following questions to use at your event.

1. All medical procedures, including vaccination, carry some risk. How much risk do you feel is acceptable? Should that risk be balanced between the individual and the general public, or is it more important to protect one over the other? What risks are you willing to take—or not take—when it comes to vaccinating your child?

2. What is an appropriate response from a parent when a child expresses strong interest in an advertised drug or vaccine, as Gabi did after seeing Gardasil's "Be one less" commercial? How should a school respond when it hears about this kind of marketing from students who have seen the commercials?

3. Critics argue that shortening, or fast-tracking, the Gardasil clinical trials did not allow for possible side effects to be studied. Is it ever a good idea to fast-track approval of a vaccine? What type of situation might justify fast-tracking?

Vaccine Fast Facts

- The CDC recommends 26 doses of nine vaccines by the first birthday, 48 doses of 14 vaccines by age six, and 70 doses of 16 vaccines by age 18.
- Vaccines can contain aluminum and other toxins. Recent research on aluminum found in vaccines has demonstrated significant neurological and autoimmune damage in humans.
- Vaccine ingredients have not been tested for safety in doses given to human infants either singularly or in combination for co-toxicity.
- The same federal health agencies responsible for developing, regulating and making vaccine policy are also in charge of monitoring vaccine safety.

Find more Fast Facts at http://www.greatergoodmovie.org/resources.

4. Who should decide what we put, or inject, in our bodies? At what point should the government have input?

5. What is the state's interest in mandating vaccines? What is its responsibility to inform and educate the public about the necessity of a vaccine as well as possible adverse effects that might result?

6. What is the responsibility of doctors when it comes to informing their patients about the ingredients in vaccines and possible adverse reactions? How would you go about determining if your doctor has all of the data to provide you with the information you need?

7. Dr. Offitt also says that parents are not necessarily the best judges of their children's needs. Do you agree? Why or why not?

8. What was your reaction to Dr. Green's conclusion that Jordan's autism was caused by heavy metals, particularly the mercury in vaccines?

9. Does advertising of pharmaceutical products on television help or harm the public?

10.Where should we start to change our current system of vaccine development and vaccine mandates? Should it begin with government, with the medical profession, or somewhere else?

11. After watching this film do you feel motivated to share it with others? What strategies would you use to begin a conversation with someone who thinks differently from you on this topic?

12. Should vaccines or any other medical treatment be required for admission to school or in exchange for any other publicly available service?

Section 5 – ACTION ITEMS

With other audience members, brainstorm actions that you might take as an individual and that people might do as a group. Here are some ideas to get you started:

1. Share THE GREATER GOOD with five friends. Copies of the film are available from http://www.greatergoodmovie.org/ as well as the movie trailer.

2. Continue the conversation in your community. For ideas and guidance in planning future discussions about the topic of vaccines, check the resources listed on the web site of the National Coalition for Dialogue & Deliberation (http://ncdd.org/). Their Beginner's Guide (http://ncdd.org/rc/beginners-guide) offers helpful information on getting started.

3. Get involved with local and national policy: There are three different types of exemptions from vaccination that parents can seek, religious, medical and philosophical.

Learn the laws in your state regarding vaccine mandates and exemptions. ***Each state varies as to which of the three they allow, and changes in policies are constantly being suggested.*** You can find this information on the National Vaccine Information Center's (NVIC) interactive map (http://www.nvic.org/Vaccine-Laws/state-vaccine-requirements.aspx) or at http://www.greatergoodmovie.org/. If your state does not allow for a philosophical exemption, consider petitioning your state legislature to establish one

On the national level Congress is charged with overseeing the National Childhood Vaccine Injury Act and all its provisions, however Congress is not fulfilling its responsibilities (as explained by Barbara Loe- Fisher in The Greater Good).

4. Help to expand vaccine exemptions and to protect the right to informed consent. Join the NVIC Advocacy Team to support efforts to shape vaccine policies at the state and national level. For more information visit http://nvicadvocacy.org/members/Home.aspx.

5. Advocate for more research into vaccine safety. Contact your Congressional representatives with your concerns and specific issues you would like to see addressed. In addition, there are several committees in the U.S. House of Representatives and the U.S. Senate that deal with health issues and regulatory agencies. For specific committee responsibilities, go to www.aha.org/content/00-10/09congresshealthcommittees.pdf or http://www.opencongress.org/wiki/Committees_and_their_jurisdiction.

6. Talk to your doctor about vaccine safety concerns. Ask for information that will help you make informed decisions about your children's health. Consider giving your doctor a copy of THE GREATER GOOD or another resource on vaccine safety. Consider finding a doctor who uses a different vaccine schedule or will vaccinate, or not vaccinate, based on your preference.

7. Learn about other approaches to pediatric health care. One place to start is http://www.mercola.com/, a web site that promotes natural health care. Knowing about different options can help you make informed choices for your children.

Questions for Policy Leaders:

If you choose to advocate with your local and national political leaders, you may want to use some of the following questions to help guide your conversation.

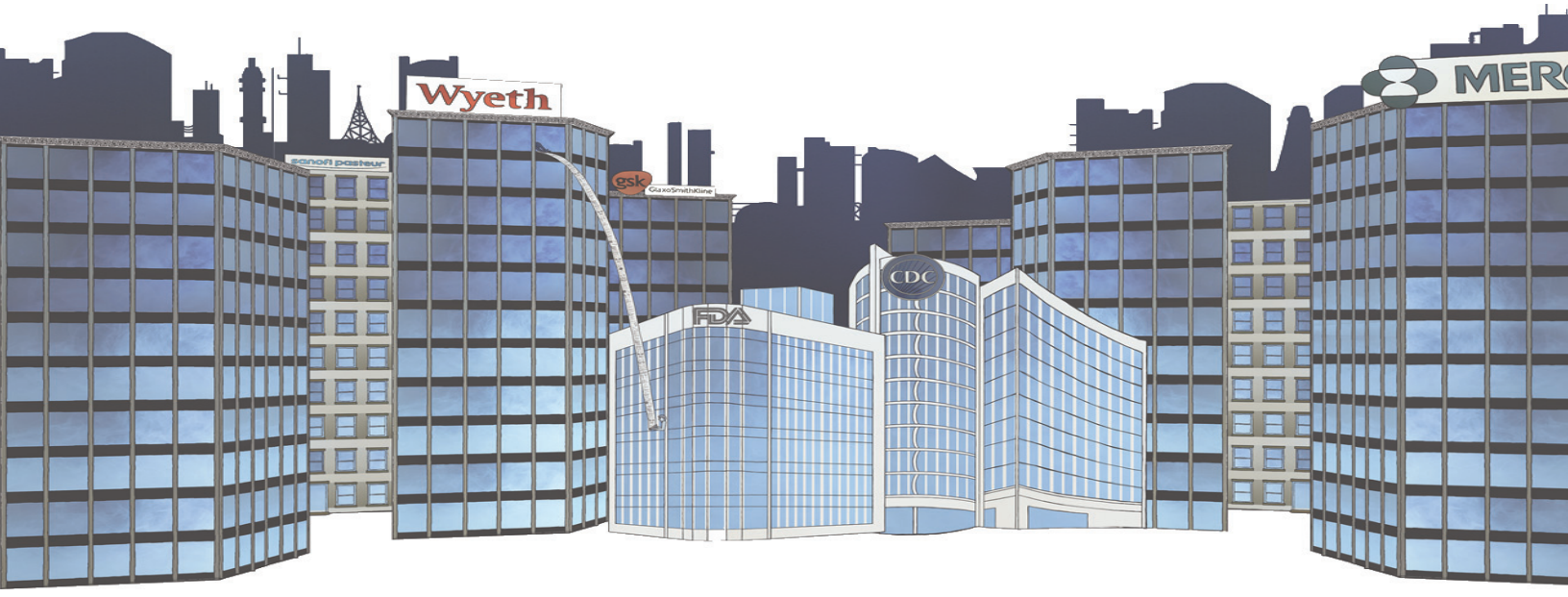
1. Should the manufacturer of any product ever be exempt from liability for its product as is the case with vaccine makers? What incentives do vaccine makers have to produce safer products if they bear no liability?

2. Should every ingredient in a vaccine be studied for safety?

3. Should government ever be in the position of making decisions about what we put into our bodies?

4. Should a member of Federal regulatory agencies ever be allowed on policy making committees if they have conflicts of interest? In what cases, if any, might this be OK?

5. Should we rely on a passive surveillance system like the Vaccine Adverse Events Reporting System to determine the safety of vaccines? What kind of system would be appropriate?



ADDITIONAL RESOURCES

One of the first arguments people make when they are introduced to the idea that vaccines can cause harm is, "Show me the science." We are proud to share that we have an extensive and comprehensive compilation of over 200 resources in the form of research, articles, books, and links to websites.

Please go to our website for the full list and downloadable PDF documents at http://www.greatergoodmovie.org/ and check out the *research* and *learn more* sections.