

Chapter 1

Risk: Life's Question Mark

We also believe in taking risks, because that's how you move things along . . .

—Melinda Gates

Risk. The buzzword of our time. Myriad advances in medical science and modern technology might make you think our world is safer, more ordered, and more predictable than ever before in history, and we would be hearing less about risk. It's true that people are living longer, more productive lives. Being in one's seventies or even eighties is no longer looked upon as being in a time of looming death. Members of this demographic are going into space, flying at Mach 2 in jet fighters, and starring in new sitcoms. Yet along with all of the good brought about by technology has come the awareness that our universe remains a very unpredictable place.

We can and do change the future, but there's always a price, with both societal and individual costs in the equation. Technology has given us the ability to measure the intimate building blocks of life, to routinely visit the sanctity of space above our planet, and to control our lives in countless ways. But somehow, on the great scale of existence, along with all of these wonderful things has come the ability to see the dark as well as the light. The double-edged sword of technology that enables us comes with its price, albeit directly or indirectly.

Our ability to document and measure the frequency and severity of human tragedies and the bad things that happen generally exceeds our ability to know what to do about them. Changing regulations and laws will continue to be a mechanism by which we can prevent accidents involving the public. Still, somewhere in the process a decision always must be made on how much safety, security, or predictability is enough. There is always a cost involved. In a world where our abilities to see, communicate, and measure situations usually exceed the resources required to control the possible outcomes, we need a rationale to balance what we can do against what we can afford. This is the process of risk management.

What is risk? In simple, concise terms, *risk is the future's uncertainty*. It is a characteristic of life that everyone has in common. One might argue that other forms

of life perceive the future and therefore they too must experience risk. While it's true, for example, that as the weather begins to change, some animals start storing food and others migrate, this is more instinct than decision-making. The concept of risk appears to be unique to humans. What separates us from the rest of the animal kingdom is precisely the characteristic that enables us to recognize the concept of risk: It is our ability to exercise rational thought. You might argue about the degree of rational thought possessed by some people, but as a group, this is what separates us from all other life forms. Our unique mental capabilities enable us to apply information from the past, react to the present, and plan for the future.

Yet the more we learn about our world, the more we learn about the plethora of ways we can be harmed by it.

Some of the things we fear and risk are of our own making, such as chemicals, cars, and planes. Other risks are from natural causes. The picture is blurred even further when we factor in the reporting of such events. Between the volume of information available and the style and motivations of today's media, we hear, see, and read only a small subset of what actually happens each day. There is no absolute scale to measure tragedy to determine what news gets reported and what news remains quiet. Reporters today can stream content of their choice to our TVs, computers, and web-enabled cellphones from around the world. What the media chooses to show us does have an effect on us. Research has shown that the more we're exposed to sensational and shocking content relative to our experience, the greater our perception that the world is a hazardous place.

Here's an example. In the early 1990s there was general perception that violent crime was a widespread national problem in the United States even though the reported crime statistics actually indicated a decreasing trend. When this issue was studied by social scientists, they found a correlation between people who believed crime was on the rise and the amount of violent and dramatic programming they viewed on TV. The 5-year study showed that over a large segment of the population, with varying crime rates, watching television news was correlated with increased fear of and concern about crime [1]. Also fueling the misperception was the amount of dramatic and violent prime-time TV programming watched per week. Even though the shows were fictional, their realism in part triggered the same, if not a stronger, reaction than did the actual news.

The media's influence on our perception and judgment is pervasive and subtle. Another study indicated that TV viewers watching medical dramas and news which had medical content responded with a loss of wellbeing and increased fears for personal health and for the health of those around them [2].

There is no doubt that communication media of all forms influences our perceptions of reality. But is the world more dangerous today than it was in the past? You might think so based on what we hear, see, and read. But that's not the case. Actually, we are safer today than at any other time in recorded history. In 1850 the life expectancy in the United States was 38.3 years, in 2010 it was 78.2 years: about a 40-year increase in 160 years. The risks presented by disease, transportation, and even crime have shown decreasing trends over the same time interval. Then how can we think that today's life has more hazards than ever before? Primarily it's because the news

media has learned that fear sells more than safety, or to put it another way, harm sells more than good. Executives at the broadcast companies just didn't dream up this idea. These companies stay sensitive to public opinion through consulting firms that conduct surveys and perform market research to determine what viewers want to see, hear, and read. After all, stations with the highest ratings can demand the highest advertising prices and revenue generation is the ultimate motivator.

It's easy to point fingers at the journalistic and media press and blame them for our apparent misperceptions. But our world contains a diversity of cultures, technological sophistication, and infrastructure-related services that deliver different standards of care to their constituents. Consequently what's sensational or shocking for someone living in a country or region with high service levels may be interpreted as "nomal" or "routine" for someone viewing the events in a part of the world with lower standards of care. The tremendous diversity in safety, health, and crime risk levels can be seen in life expectancy differences shown in Figure 1.1 [3]. Monaco is apparently the safest, or lowest risk country, with a life expectancy of about 89.8 years. The country in the list with the highest risk is Angola, having a life expectancy of 38.5 years—just slightly higher than the United States in 1850.

So how are we supposed to know what to believe, when to be skeptical, when to discard information, and then what to do? Of course there is no "one size fits all" answer. Everyone's manner in dealing with life's uncertainties is different. Each of us makes choices in daily life according to countless different factors. Yet regardless

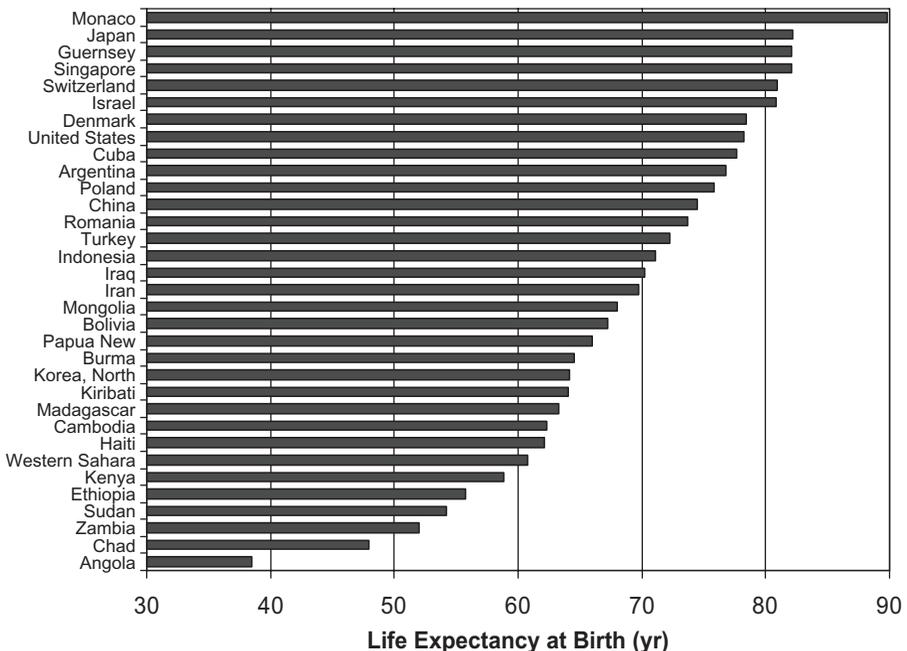


Figure 1.1 Life expectancy by country, 2010.

of the details, we all have in common the fact that there are limits: finite resources we can apply to make our futures more secure. Perhaps quality is free, but risk reduction isn't and sooner or later, like it or not, in one form or another, risk remains.

Reducing future's uncertainty is not something that we can do easily even as a global community. The tradeoff between money and benefits are very real issues. The 6.9 billion people alive today and the approximate 75 million additions every year each want a better place to live and grow. In the United States alone, there is a birth about every 8 seconds and a death every 11 seconds. Reducing uncertainty in our future is not getting any easier, and the challenges facing a growing population on a fixed amount of real estate show we don't have a choice any more. Balancing risk reduction and cost is something we all do, even corporations and governments. No one has what it takes to make the world totally secure and predictable.

Your life is a product of many factors. Some you control, some the government regulates, and some others don't easily fit into a category. The future will always be a question mark. You can't avoid uncertainty as long as you're alive, so it makes sense to figure out a strategy to deal with this variable common to everyone on the planet.

Another fact in the same category is the clear requirement that we make decisions—what to eat, what to wear, where to go, and what to do. And then there are the decisions that we make for others. So here lies the essence: If there is a 20% chance of rain today, do you carry an umbrella? How do you make decisions in the environment of uncertainty? From the context of technical problem calculations by scientists, mathematicians, and engineers, to the decisions made by you and me—we all make decisions about how we will manage the risks in our lives.

Decisionmaking involves analysis of information in some form and a choice selected from two or more alternatives. There are usually other factors to consider, including direct costs, opportunity costs, and related implications. There are also ethical issues to consider that reference the value system of the people involved. Ethical considerations are especially important when decisions are made containing inherent uncertainty in situations where finite resources exist. Risk management is one form of the decisionmaking process within the broader field of ethics. The outcomes vary depending on which philosophy and method you adopt in decisionmaking.

Since this entire book is about risk in decisionmaking, it makes sense to begin with a discussion about some of the ways decisions are made. The following principles can provide a frame of reference when you need to choose a course of action in the environment of finite resources and uncertainty. There are five ethical decision principles [4] discussed here. They are important in understanding risk management decisions in the context of ethics.

1. Utilitarian

The philosophy was developed primarily by Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873). The basic premise of this approach is that

the action selected should provide the greatest good for the greatest number of people, or the least harm for the greatest number of people.

2. Peoples' Rights

This concept, developed by the 18th century thinker Immanuel Kant and his followers, says that a person's right to choose is an essential part of life. The inherent ability to choose freely is unique to humans. Kant believed that people have dignity based on their ability to choose freely and subsequently have the moral right to have these choices respected. It is a violation of human dignity to manipulate people as objects and in other ways in which they are not allowed freedom of choice.

There are other rights also included in Peoples' Rights. For example:

- *The right not to be harmed:* We have the right not to be injured without knowingly doing something to deserve it.
- *The right to personal privacy:* We have the right to maintain unique ownership of information and of our "personal space" unless we choose to share it or our choice does not violate the rights of others.
- *The right to be treated fairly:* We have the right to receive goods and services as specified in a contract or agreement.
- *The right to the truth:* We have a right to be told the truth and to be informed about matters that significantly affect our choices.

In this principle, actions are unethical to the extent they violate the rights of others: the greater the violation of rights, the more serious the unethical action.

3. Fairness or Justice

The basis of this approach is Aristotle's view that "equals should be treated equally and unequals unequally." In other words, people should be treated fairly but people can receive different treatment based on different qualifications. For example, two workers of equal skill and experience should receive the same salary, and workers with less skill and experience should receive lower wages. Fair treatment in employment hiring for example means that "equals" should be interpreted relative to the duties and skills required to perform the work. There are situations where people are treated as "unequals" for good reasons. For example, blind people should not be allowed to drive buses.

Another application of this philosophy is in defining "distributional justice." Two people can be guilty of the same crime but can receive different punishments. Suppose, person #1 is a repeat offender and person #2 is not. Person #1 was the leader in the crime and person #2 played a smaller role. These situations suggest that unequal punishments may be appropriate.

The key word in Aristotle's statement is "equals." The approach is not a justification for favoritism or discrimination. To examine the degree in which this philosophy is being applied to a particular situation, test the notion

that the groups are indeed equal in the relevant characteristics. This will tell you if the principle is being correctly applied.

4. Common Good

This principle has its origins in the early Greek philosophers, and presents a socialcentric ethical view. What is good for the community trumps the good of individuals. The community is composed of individuals who believe that their own wellbeing is closely connected to the wellbeing of the entire community. All members share this common belief. In short, the principle states: "What is ethical is what advances the common good."

The community could be a nation, a town, or a company. Situations where this approach is applied are military service, affordable healthcare, effective law enforcement, and low environmental emissions. This principle challenges us to think of ourselves as individuals who choose to work together for the purpose of achieving common goals that we could not accomplish as individuals.

5. Virtue

All ethics relate behavior to a set of standards, but this approach recognizes that even though humans are imperfect, we should strive to achieve certain ideals. It represents a moral compass to help improve behavior in a way that will achieve the fullest development of humanity. Virtues are attitudes and behaviors like honesty, courage, compassion, and integrity. In dealing with an ethical problem using the virtue principle, a relevant question is: What will promote my personal and also community character development?

These five principles are not mutually exclusive. They are references by which to compare your decision alternatives and to measure the nature of your actions. Basically, the ethical tenets can be tested by asking five questions:

1. Which alternative will do the most good for the most people?
2. Which alternative will respect the rights of the most people?
3. Which alternative has the least discrimination or favoritism and treats people equally?
4. Which alternative is the best to advance the common good?
5. Which alternative will promote and develop moral virtues?

Now let's consider some examples and see how to apply these ethical principles to test the efficacy of certain decisions.

Suppose you are a medical professional. You could be a licensed physician or just someone who has medical art skills that are not common to the population. You are walking down the street and the person in front of you suddenly collapses to the ground. By instinct, you rush over to the individual now lying unconscious on the ground and observe the symptoms of a heart attack. Someone in the gathering group calls for emergency services and the police. The person making the call tells everyone that an ambulance will be here within 5 minutes. You notice the person's breathing is subsiding and then stops. The faint siren of an ambulance can be heard in the

distance. What should you do? There are several options but let's evaluate the two basic alternatives:

Option 1: Walk away to avoid any involvement in the situation eliminating the potential for liability from the person or person's family for damages allegedly incurred from your assistance.

Option 2: Start CPR immediately, giving orders to other persons to help in the procedure.

Now let's apply the five principles by asking the five questions.

1. *Which alternative will do the most good for the most people?* Option 1.

Emergency services have liability protection and will arrive shortly. You, on the other hand, could suffer extremely high court costs and subsequent financial penalties from civil litigation. These costs do more harm by adding the high costs of malpractice insurance and by choosing not to lend aid, you help to keep these insurance costs down for the medical professional community.

2. *Which alternative will respect the rights of the most people?* Option 2.

Each individual has the right not to be injured and the right to be treated fairly. You need to take action because you possess the skills that can aid the victim with care to help him mitigate harm.

3. *Which alternative has the least discrimination or favoritism and treats people equally?* Option 2.

By not exercising your skills you are discriminating against the victim and favoring yourself. As part of your normal work duties, you would provide these services without question to the best of your ability. By choosing not to provide the same level of care, you are discriminating for your personal gain. This is unfair.

4. *Which alternative is the best to advance the common good?* Option 2.

Which option would be good for the community? The fact that a passerby could (and would) save the life of a stranger is certainly the type of behavior that promotes strong community identification. Even if the victim died, the fact that a stranger courageously tried to help is a powerful message of the common goal of community safety and caring.

5. *Which alternative will promote and develop moral virtues?* Option 2.

Answering this question is the easiest one of the five in this example. Providing needed assistance to a stranger, whether it's for a medical condition, a flat tire, or some change for a parking meter is emblematic of the virtue communicated in the Golden Rule: "Do unto others as you would have them do unto you."

Okay. Now that you have some experience with these ethical principles, let's apply them to a much larger and difficult scenario.

You are the risk manager of a small town of 10,000 people that is located just below a large dam. The winter brought above-average snowfall to the northern

mountains and now that spring has arrived, the combination of melting snow and heavy rain is causing excessive stress on the dam structure. Late at night in the middle of a heavy rainstorm, you receive a call from the dam manager that the dam is going to fail within the hour. As a prudent risk manager you have emergency evacuation plans already in place and you proceed to quickly activate the emergency evacuation teams. Just before you make the first call to the teams, the dam manager calls you to let you know that one of the two roads out of town is blocked by a large mudslide. You re-evaluate your evacuation strategy and determine that you are completely sure you can safely evacuate about half of the town's population. This is Option 1. Another strategy, Option 2, indicates there is the possibility of saving everyone but also a possibility that everyone would perish. The odds are about 50:50 for saving or killing everyone. Time is growing short. There is no time to do any additional data collection and analysis. You need to make a decision, now! The longer you wait the more likely the dam will break and everyone will perish. Which option are you going to choose? Let's go through the questions and examine the ethics of the two options.

1. *Which alternative will do the most good for the most people?* Option 1.
At least with this choice you are sure half of the town's population will survive.
2. *Which alternative will respect the rights of the most people?* Option 1.
This moral action treats everyone the same. The fact that a single person died in the flood from the failed dam is random. You did not preselect him or her for death. You treated everyone equally.
3. *Which alternative has the least discrimination or favoritism and treats people?* Option 1.
Apply Aristotle's statement, "Equals should be treated as equals and unequals unequally," to this situation. All 10,000 people equally share in the hazard. There is no special group that is exposed to a lower- or higher-hazard environment. By selecting Option 1, you have treated everyone the same and have saved 5,000 people. Of course, Option 1 also ensures 5,000 deaths.
4. *Which alternative is the best to advance the common good?* Option 2.
As members of the same community, you believe that it is better to try to save everyone than it is to only save half of the town's people. You want to give everyone a chance to live.
5. *Which alternative will promote and develop moral virtues?* Option 2.
All life is sacred and you believe it is immoral to commit half of the town to certain death. It is this ethic that you employ when you select Option 2, in which you have a chance of saving everyone.

I suspect that you probably disagree with some of my choices in these examples. Each person can look at a situation differently relative to his or her personal values so that there is no "right" or "wrong" response to the aforementioned situations. People respond to events based on their values and this is why risk management decisions for the same set of circumstances can be radically different. The five

principles give you a structure by which to test the ethical quality of decisions in your value system. The decisions can be yours or others' who make decisions that influence your life. Ethical considerations are integral to decisionmaking, for no other purpose than to help you examine the moral quality of the decisions we make in our lives.

Notice that up to this point there is one blatant omission in this discussion: the law. None of the five principles refer to obeying the law as a tenet of ethical behavior. The ethical principles are much more insightful and broadly applicable than simple laws. And it's worth noting that ethical behavior may, depending on your value system, involve violating the law. Don't quote this book at your court trial. The legal system, established for the common good, does have a process by which to change laws. If you believe, for example, that a certain law is unethical, you can ask your congressional representatives to write a law to change it or you can get convicted of its violation and pursue your case through the legal system, perhaps all the way to the Supreme Court, to have it altered. The processes to change laws has also been established for the common good and it can work.

DISCUSSION QUESTIONS

1. After you read this book, you will possess knowledge not common to the general population. This knowledge gives you ethical duties and responsibilities. This is similar to the situation, for example, of a physician's responsibilities. In this case, medical emergencies on airplanes are a classic example where a physician's skills can influence a sick person's wellbeing. As an informed risk manager, you will observe certain behaviors, attitudes, and situations that can produce accidents, disease, and death. Ethically, do you have the moral responsibility to inform people of their increased risks?
2. Give an example of an ethical decision that requires you to violate criminal law. In your example, do you think the jury would find you innocent based on your values and ethics? Are there any well-known people who have done this?
3. Develop your own scenarios and decisions and defend your choices based on the five ethical principles discussed in the chapter.
4. From Figure 1.1, choose two countries and list 10 characteristics for each that are life-expectancy risk factors. Rank the factors from the highest to lowest risk and then estimate the percentage increase in life expectancy you might obtain if the top two factors were mitigated. How would you defend your estimates?

Case Study: Vaccines

The needs of the many outweigh the needs of the few.

Star Trek II: The Wrath of Khan, paraphrased from:

John 11:49–50

Aristotle, The Aim of Man

Without a doubt, vaccines are one of the greatest achievements of the human race. The first vaccine was for smallpox, an infectious disease that has been tracked back to 10,000 B.C. in Northeastern Africa [5–6]. There is evidence that this killer was even well-known by the ancient Egyptian Dynasties (1570–1085 B.C.), and in China at the same time, through Indian Sanskrit texts [7]. The disease traveled to Europe and greatly influenced the development of western civilization through large-scale epidemics accounting for millions of deaths and countless millions more disfigured with lesion scars. The disease followed the spread of civilization to North America with similar devastating epidemics.

Then in 1774, Benjamin Jesty, a successful farmer in Downshay, England, noticed that milkmaids infected with cowpox, a less serious disease related to smallpox, were immune to subsequent outbreaks of smallpox that periodically swept through the area. He inoculated his wife and two young sons with pus from cowpox sores and observed their apparent immunization over time [8]. But Jesty's discovery was not communicated to the world.

Twenty-two years later in 1796, Edward Jenner, a country doctor from Gloucestershire, England, hypothesized the same connection between cowpox and smallpox immunity. Dr. Jenner performed several human inoculations using pus from cowpox sores and observed the same results as did Jesty. After a series of similar highly structured experiments, he published a book called *Inquiry into the Causes and Effects of the Variolae Vaccinae*. His assertion “that the cowpox protects the human constitution from the infection of smallpox” laid the foundation for modern vaccinology [9]. After this information became communicated around the world, smallpox became a preventable disease. Jesty and Jenner probably did not know each other even though they were contemporaries but regardless, they are responsible for saving lives of countless millions of people in the future. The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977 [10]. Smallpox has been eradicated from our planet, and this was just the beginning.

Today there are safe and effective vaccines routinely manufactured and delivered to doctors and healthcare centers, available for the following twelve infectious diseases:

Diphtheria, tetanus, pertussis (DTP)	Measles, mumps, rubella (MMR)
Haemophilus influenzae type b (Hib)	Meningococcal (MCV4, MPSV4)
Hepatitis A (HAV)	Polio (OPV or IPV)
Hepatitis B (HBV)	Pneumococcal conjugate (PCV)
Human papillomavirus (HPV)	Rotavirus (RV)
Influenza—each year at flu season	Varicella (VZV)

Additional vaccines, such as those for HIV, malaria, HPV, and others, are in various phases of testing.

From a societal perspective, immunizing the population, or the majority of the population, from these serious, debilitating, and potentially fatal diseases reduces pain, suffering, and healthcare costs for everyone. And the evidence of their effectiveness is irrefutable [11]. Here are the facts:

- Before 1985, Haemophilus Influenzae type b (Hib) caused serious infections in 20,000 children each year, including meningitis (12,000 cases) and pneumonia

(7,500 cases) [12]. Between 2002 and 2009, there were approximately 35 cases of Hib reported per year.

- In the 1964–1965 epidemic, there were 12.5 million cases of rubella (German measles). Of the 20,000 infants born with congenital rubella syndrome, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded as a result of the infection [13]. While localized outbreaks occur, especially in children too young to be vaccinated, today there are fewer than 25 cases reported each year [14].
- Before 1963, more than 3 million cases of measles and 500 deaths from measles were reported each year. More than 90% of children had had measles by age 15. In 2008, there were 16 cases [15].
- In 1952, polio paralyzed more than 21,000 people. There have been no reported cases in the United States since at least 2000.
- In the early 1940s, there was an average of 175,000 cases of pertussis (whooping cough) per year, resulting in the deaths of 8,000 children annually. In 2008, 13,278 cases were reported.
- In the 1920s, there were 100,000 to 200,000 cases of diphtheria each year and 13,000 people died from the disease. In the United States there was one reported case in 2000, and none since 2006.

Yet, these health benefits to society are not without human costs. There is another side to these medical success stories that is unsettling for some parents of young children and for some adults. Not everyone reacts favorably to vaccines.

Vaccines are biological agents designed to induce our immune system to produce disease antibodies. This is a delicate task of getting the body to produce a disease's antibodies, without actually giving the donor the full disease. This is done by injecting a weakened form of a particular germ, some kind of inactivated or killed germ, or a germ component. The body then produces antibodies that are designed to kill the germ in the future. Some vaccines require multiple inoculations and even some “booster” shots over time to maintain immunity. But once the body's immune system produces antibodies, it apparently remembers and responds in the future if the germ is detected again. In other words, we become immune to diseases without ever having them. This is what happens most of the time, but there are side effects ranging from minor soreness and rashes to permanent, long-term injuries and death.

How can this happen? Vaccine testing is an extremely detailed process, but not everyone can be tested. Due to an individual's specific genetic makeup and current health conditions, adverse reactions do happen. What I mean by this is there are cases where healthy people are vaccinated with the intent of reducing their disease risk, and instead they die or are permanently injured. There are also cases where people suffering from chronic, long-term health problems react unfavorably to vaccines and get sicker. Vaccine side effects are risks everyone takes when either they or their children receive an immunization.

Vaccines are especially important for schoolchildren where the close contact promotes disease transmission. Consequently, to reduce these risks all 50 U.S. states and Washington, D.C., have school-entry requirements for vaccines. Forty-eight allow exemptions for religious reasons (West Virginia and Mississippi are the only exceptions) and 21 states allow for personal-belief exemptions [16, 17]. Medical exemptions are allowed in all states. Homeschooled children are not subject to state vaccine

requirements. As of 2010, the only exception was North Carolina, which does require vaccinations for homeschooled children [18].

The fraction of the population that suffers injury or death from vaccines is very, very small, yet if you are the victim or, worse yet, if it is one of your children, somehow the law of large numbers and the philosophy exhibited by the quotation cited at the beginning of this case study can be difficult to accept.

The U.S. government has taken action to give victims an opportunity to receive financial compensation for vaccine injury or death through the National Vaccine Injury Compensation Program. It is funded through an excise tax of \$0.75 added to the cost of every administered vaccine dose [19]. The fund is designed as the legal mechanism for victims to receive compensation in order to protect vaccine manufacturers from the financial costs. If victims could sue manufacturers for damages, vaccine costs could be unaffordable for many people. Since it is in society's interest to have as many people as possible receive vaccines, the government is administering injury claims with its own lawyers and processes. Additional information is available at <http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm>.

Between 1998 and January 2011, there were 13,693 cases filed with the Vaccine Injury Compensation Program with over \$2.1 billion paid to 2,569 claimants. Over 40% of the 13,693 cases are related to claimants believing that vaccines caused their children's autism in spite of several scientific studies showing no causal relationship between autism and vaccines. The following legal proceedings describe one family's experience [20].

Jane was born on August 30, 1994. The pregnancy and first 15 months of life were normal. Following the standard schedule for infant vaccinations, Jane received the MMR (measles, mumps, rubella) vaccination at 15 months. The vaccines contained the mercury-based preservative called thimerosal. About two weeks later she saw her pediatrician for a fever and rash. The fever initially improved but then rose to a reported 105.7°F with additional symptoms of coughing, gagging, and vomiting. At the pediatrician's office she showed a fever of 100.3°F and had a "purulent postnasal drip." The diagnosis was "sinusitis v. flu" and antibiotics were prescribed. The symptoms subsided and the next visit to the pediatrician was at 18 months for a routine checkup. No significant health issues were observed but the pediatrician did note that Jane was "talking less since ill in January." Three months later the pediatrician noted "developmental delay suspected" and additional testing showed that Jane's brain development was abnormal. At 23 months of age, Jane was diagnosed with "severe autism" and "profound mental retardation." In addition to these neurological problems, she was also diagnosed with chronic constipation, diarrhea, gastro-esophageal reflux disease, erosive esophagitis, and fecal impaction. She has had seizures and displayed symptoms of arthritis and pancreatitis.

Her parents filed a claim with the Vaccine Injury Compensation Program. They claimed that the ethyl mercury in thimerosal used in the MMR vaccines damaged Jane's immune system. As a result, the vaccine-strain measles virus remained in her body, causing her to suffer inflammatory bowel disease and subsequent brain damage.

To obtain compensation under the program, claimants must show "by a preponderance of the evidence," that the vaccine caused the injury. A key piece of evidence would be revealed if the vaccine-strain measles virus could be detected in Jane's body. During a routine gastrointestinal procedure Jane underwent for her medical conditions, a biopsy

was performed and the tissue sample was sent to a testing lab. The results came back positive: the vaccine-strain measles virus was detected. In addition to this “smoking gun” evidence, the parents also engaged six expert witnesses who testified in detail with their endorsement of the vaccine-strain measles causation theory.

The government’s response was to examine the integrity of the testing lab’s results. The lab, which is no longer in business today, was a for-profit, nonaccredited company established to support civil litigation against vaccine manufacturers in the United Kingdom. The government used several expert witness, some hired by vaccine manufacturers, to examine the testing lab’s operational procedures. They concluded the lab’s testing procedures were flawed and the test results were unreliable. In addition, the government witnesses testified to their belief that the vaccine cannot cause autism.

The judge, or “Special Master” in these types of cases, concluded that the evidence did not demonstrate that the MMR vaccine was related to the cause of Jane’s medical conditions. His conclusion was primarily based on three detailed technical facts:

- The testing lab failed to publish the technical sequencing data to confirm the result validity.
- Other labs failed to replicate the results.
- The immunohistochemistry testing results were nonspecific to the measles virus genetic material.

(A complete description of these facts requires knowledge of the detailed microbiology involved in the testing protocol, so no more detail is given here.) The court denied the request for compensation.

The parents filed an appeal in which they supplied an additional witness who testified that the testing laboratory had a good reputation and that its work has been published in peer-reviewed medical journals. He also stated his opinion that the laboratory used proper procedures and took appropriate measures to avoid contamination. The government’s experts, on the other hand, claimed they found a 20% error rate in the lab’s test results, with duplicate samples sometimes even producing opposite results. They claimed the only explanation for the poor testing performance was contamination.

On appeal the court recognized the temporal relationship between the MMR vaccine, fever, and the later emergence of autism, but also said that this relationship is insufficient evidence to show causality and no new evidence was presented that contradicted the Special Master’s initial ruling. The appeal was denied.

There are several scientific articles in published, peer-reviewed journals that essentially support the court’s decision in this case. However, it is also acknowledged that science has not yet determined the cause (or causes) of childhood gastrointestinal disease and autism. This tragic and passionate controversy for many parents will continue until the causality is clearly understood.

Questions

1. If you were the lawyers for Jane, what would you have done differently?
2. Do you think the court ruling is fair? Why? Consider the public implications of your response.
3. Do any other countries have a vaccine compensation program similar to that of the United States?

ENDNOTES

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