A License to Kill? Part 3: After Gardasil's Launch, More Victims, More Bad Safety Analysis and a Revolving Door Culture

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In parts 1 (HERE) and 2 (HERE) of this series, Age of Autism identified a disturbing pattern of conflicts within the Department of Health and Human Services (DHHS) regarding Merck's Gardasil vaccine. In an unprecedented "public-private partnership," researchers at the National Institutes of Health (NIH) patented the technology for the "virus-like particles" (VLPs) that provoke Gardasil's immune response to the human papillomavirus (HPV) and licensed their VLP technology to Merck. The terms of the patent license effectively made DHHS Merck's financial partner on Gardasil, giving DHHS a clear conflict of interest on decisions regarding Gardasil.

This partnership gave Gardasil favorable treatment at key decision points, treatment that was financially rewarding to both parties. While the NIH Director celebrated his researchers' "heroic" achievement and the researchers received numerous awards, including "Federal Employees of the Year," officials at NIH's sister agency, the Center for Biologic Research and Evaluation (CBER) of the Food and Drug Administration (FDA), stood watch over the Gardasil clinical trials. CBER's review failed to hold Gardasil to a high standard of safety. Instead of comparing Gardasil to an inert placebo, as they should have, CBER based its entire safety assessment on a comparison of Gardasil's adverse event profile with the adverse events associated with a "placebo" that was actually an immunologically active aluminum-based adjuvant. Despite the fact that an alternative comparison, pitting Gardasil against a relatively inert "carrier solution," should have warned them of clear evidence of harm to Gardasil recipients, CBER approved Merck's Gardasil Biologics License Application (BLA) anyway. In the meantime, following CBER's approval of Merck's BLA a key committee at the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), put Gardasil on a fast track and immediately recommended three doses of the Gardasil vaccine to all American women between nine and twenty-six years of age. In a matter of days, Merck was guaranteed a blockbuster launch for Gardasil and within months Gardasil had reached annual revenue levels of well over $1 billion. Soon, Gardasil would become the #1 royalty generator for NIH's technology licensing group, completing the partnership circle.

As a result of this favorable treatment at the hands of it regulatory partners at DHHS, by late 2006, Merck's Gardasil was reaching a mass market of young American women. FDA had downplayed the fatalities associated with Gardasil in the clinical trials, but in a population of less than 12,000 young people, three sudden deaths following Gardasil and ten deaths within a year were a clear cause for concern. And as Gardasil's reach was extending to a population numbering in the millions, the body count would soon rise. At this point in the process, the locus of DHHS conflict of interest would shift from agencies responsible for prelicensing activities such as clinical trial review and public health policy assessments to the agencies responsible for what insiders call "postlicensure surveillance" activities. The events the follow Gardasil's launch is where part 3 of this series begins.

The body count rises

On July 20, 2008, the New York Post reported the vivid account of a mother who claimed her daughter was killed by Gardasil. In a story titled "My Girl Died As 'Guinea Pig' For Gardasil," Lisa Ericzon's description of her daughter's tragic death was both detailed and disturbing. As told by the Post's reporter, the story began like this:

Jessica's Gravestone "She loved SpaghettiO's, pepperoni, lilies, listening to her iPod and making her pals laugh. In her senior

yearbook, she wrote, "The best things in life aren't things, they're friends." Now that's the quote chiseled into her gravestone.

Jessica Ericzon, 17, was "an all-American teenager," as described by one of her upstate LaFargeville teachers. Last February, she was working on her softball pitches, getting ready for a class trip to Universal Studios in Florida and hitting the slopes to snowboard with her older brother. Then one day, the blond, blue-eyed honors student collapsed dead in her bathroom. It started with a pain in the back of her head.

On the advice of her family doctor, Jessie had taken a series of three Gardasil shots.

Sadly, Jessica Ericzon's death was not an isolated incident. Since Gardasil's launch in late 2006, a rising number of parents have stepped forward to report the deaths of their daughters at the hands of the vaccine. Gardasil has now become a global product, so these reports have come from around the world; but the United States is by far Merck's largest market, so most of the reported fatalities have come from closer to home. Jessica Ericzon came from upstate New York, about a mile south of the Canadian border, and her parents were among the first to go public about Gardasil. But they haven't been the last. There are at least ten public reports of young women allegedly killed by Gardasil in the months since FDA approved Merck's BLA on June 8, 2006. Many more have been reported privately to the CDC.

In contrast to Jessica's sudden death, and just a few weeks before the New York Post headline and article, another family went public with their daughter's plight, in a blog named "Jenny's Journey." In their introductory blog post, Jennifer Tetlock's parents relayed an urgent request. Their daughter wasn't dead, but she was dying from what Jenny's doctors had theorized was a rare degenerative neurological condition, an unusual form of early onset amyotrophic lateral sclerosis (or ALS, popularly known as Lou Gehrig's disease). The bloggers, Barbara Mellers, Philip Tetlock, and Barbara Shapiro, were in no sense activists, and weren't eager to join what they later termed the "anti-Gardasil movement." What they wanted most of all was to find a way to save their daughter's life. "One of the major things that would help her doctors figure out what to do", they wrote on June 6, 2008, "is to find other people like Jenny (called "comparables")--people that share her medical condition and perhaps have had luck with certain treatments."

The list of Gardasil victims who have gone public--parents of young women like Jessica Ericzon and Jennifer Tetlock--provides only a fragmentary view of the death toll associated with Gardasil. Many more deaths have been reported to the Vaccine Adverse Events Reporting System (VAERS) in cases where the family has chosen not to go public with their tragic loss. Among the short list of publicized cases, most simply dropped dead like Jessica Ericzon within days of receiving a dose of the vaccine; these cases most closely resembled the three cases of sudden death from Gardasil reported during the clinical trials. Cases of clear "comparables" to Jenny Tetlock, young women who could satisfy Jenny's parents' quest, were less common. Nevertheless, there were a number of these publicly reported cases in which a Gardasil shot seemed to trigger a downward spiral of ill health-- encompassing a diverse range of symptoms--that would culminate in death (many of which came on suddenly as well).

The table below summarizes the connection between Gardasil and ten deaths that have been publicly associated with the vaccine. All of these stories have been reported elsewhere, most of them assembled in a memorial web-site called "The Truth About Gardasil." You can find go to this web-site to read more about the stories of many of these young women (see HERE).

	Name	Date of First Vaccine	Date of Death	Reported Cause, Complications and Timing of Death
1	Santana Valdez	Dec, 2006?	Aug 31, 2007	Sudden death, with airway papillomatosis, less than 4 months after 3rd dose
2	Jenny Tetlock	Mar, 2007	Mar 15, 2009	Juvenile amyotrophic lateral sclerosis with onset after 1st dose

3	Brooke Petkevicius	Mar, 2007	Mar 26, 2007	Sudden death, with seizure and pulmonary embolism, 2 weeks after 1st dose
4	Jessica Ericzon	Jul, 2007	Feb 12, 2008	Sudden death, 1 day after 3rd dose after neurological symptoms
5	Jasmin Soriat	Sep, 2007	Oct 12, 2007	Sudden death, with "respiratory paralysis," less than 1 month after 1st dose
6	Amber Kaufman	Mar, 2008	Apr 7, 2008	Sudden death, with seizure, "cardiac disturbance of undetermined etiology," 1 week after 2nd dose
7	Christina Tarsell	Jun, 2008	Jun 23, 2008	Sudden death, 2 weeks after 3rd dose after symptoms of dizziness and fatigue
8	Moshella Roberts	Apr, 2008	Apr 5, 2008	Sudden death, 4 days after 1st dose
9	Megan Hild	May/Jun, 2008?	Nov 15, 2008	Sudden death, 2 months after 2nd dose after "severe headaches" and "severe stomach pain"
10	Jasmine Renata	Sept, 2008	Sept 21, 2009	Sudden death 6 months after 3rd dose after increasing cardiac and neurological symptoms

These public reports provide varying degrees of detail regarding cause of death. In one case (one where substantial detail has been reported), a young woman named Brooke Petkevicius who died suddenly after her first dose of Gardasil showed symptoms remarkably similar to a case report detailed in CBER's clinical trial review. The February 6, 2008 edition of East Bay Express (see HERE), a San Francisco Bay Area newspaper, provided the following account.

In early 2007, as the pharmaceutical giant Merck began promoting its new vaccine Gardasil as protection against cervical cancer, Brooke Petkevicius was a nineteen-year-old freshman at UC Berkeley. She had seen the ads for the vaccine, and discussed getting it with her mother, whose gynecologist also had recommended it. On March 12, Brooke received the first of three doses. Two weeks later, she dressed to go running with a friend. As they reached the elevator, Brooke suddenly collapsed against the wall and had a seizure.

"She started shaking a lot," recalled the friend, Kristin Bietsch. "And her eyes went glazy a little bit." An ambulance rushed Petkevicius to the hospital, but doctors couldn't save her. Her autopsy indicated that she was killed by a pulmonary embolism, or blood clot, which had blocked the artery between her heart and lungs. "She had a whole bunch of little floating clots in her system," said her mother, Debra Sonner, recalling what doctors told her at the time.

Was Brooke's death just a random coincidence or were there clues from the early safety reviews that anticipated her tragic death? One needn't look far for comparable stories: the following account comes from one of the three sudden deaths after Gardasil reported in the clinical trials.

This 22 year old non-smoking white female subject had symptoms of leg pain prior to the vaccination (11/15/02), and was seeing a masseur for this complaint. She was also on hormonal contraceptives. The subject was vaccinated with her first dose of Gardasil on -------. On --------, Day 19 Postdose 1, the subject experienced suspected deep vein thrombophlebitis (DVT) of the left leg and consulted her own general practitioner. On --------, Day 20 Postdose 1, the subject experienced severe chest pain and was taken to

the emergency room (ER). The subject subsequently experienced a suspected acute massive pulmonary embolism of severe intensity and was admitted to the intensive care unit (ICU). Echocardiography was performed and showed normal aorta and no thrombosis in the vena cava. Abdominal ultrasound was performed with no abnormal findings. On the same day, the subject died of acute massive pulmonary embolism and deep vein thrombosis of the left leg. The autopsy report confirmed the diagnosis of acute massive pulmonary embolism and deep thrombophlebitis of the left leg and also revealed an incidental finding of acute ischemic renal failure.

As this account suggests, the CBER review eventually explained away this death as a coincidence, an unfortunate side effect of taking birth control pills in a situation where the victim suffered from a pre-existing condition. So as soon as reports of similar deaths began entering the VAERS system, the CDC found ways to dismiss comparable cases such as Brooke Petkevicius by pointing a finger at birth-control pills as well. In a June 2007 report on the early deaths from Gardasil that were reported to the Vaccine Adverse Event Reporting System (VAERS), CDC dismissed Brooke's death as yet another coincidence. "Preliminary data indicate that the two women [including Brooke], who died of blood clots were taking birth-control pills, and blood clots are a known risk associated with birth-control pills. All four deaths are being fully investigated but none appear to be caused by vaccination," claimed CDC. With regard to Gardasil, CDC wrote in its defense, "Since more than 5 million doses have been distributed, some deaths will occur coincidentally following vaccination (but not due to vaccination)."

Blaming the victim and citing coincidental death following vaccination are two well-known tactics that long ago became part of the DHHS playbook and CDC is not alone in deploying this tactic. In addition to the pulmonary embolism described above, the CBER review dismissed the two other cases of sudden death following Gardasil. One such case was a 15-year old boy who died of a heart attack less than a month after his first dose of Gardasil; yet CBER reported "the autopsy was inconclusive, but there was a strong family history of arrhythmia." The other case was a 21 year-old woman who died with a convulsion four days after her third Gardasil dose; the CBER review again blamed this victim for her death, reporting that "this subject had a history of seizure disorder and anxiety. She suffered a seizure 4 days after dose 3, and was noted to have cocaine in her urine."

Natural skepticism aside, making sense of individual cases like the ten public death reports and the three sudden deaths in the Gardasil trials is tricky business. Without intensive medical investigations one may never find definitive proof of harm from Gardasil. And, of course, the vast majority of Gardasil recipients have survived their vaccination series with no discernible lasting effects. There can be little dispute, however, that Merck has an enormous incentive to downplay obstacles to a profitable new product like Gardasil. And unfortunately, as we've seen in the clinical trial cases, FDA appears to have shared Merck's bias, acting more like an equity participant in a DHHS "public-private partnership" than a conscientious guardian of the public trust; Its CBER reviewers effectively turned a blind eye to troubling signals as they granted Merck its BLA for Gardasil. Inevitably, however, a persuasive critique of vaccine safety monitoring for a blockbuster vaccine like Gardasil needs to move away from the realm of anecdote and into the realm of statistics. As we move beyond the review of individual cases, we'll take a closer look at whether or not DHHS officials displayed notable biases in their analyses of Gardasil's adverse effects in larger populations and how those analyses have been criticized by others.

Lack of diligence in postlicensure safety surveillance

Responsibility for what public health officials call "postlicensure safety surveillance" falls to a small set of DHHS departments. Two of these are the FDA's Vaccine Safety Branch (VSB) and the CDC's Immunization Safety Office (ISO). After CBER approves a vaccine and ACIP recommends it, the baton within DHHS passes next to VSB and ISO. In the passing of this baton, as stipulated previously, the presence of a conflict of interest does not mean that regulatory activity will necessarily reflect bias, negligence or lack of diligence on the part of the next group of regulators: Each department's work deserves to be judged on its own merits. But in light of what appears to be a clear pattern of bias in the prelicensure activities of DHHS, it's reasonable to approach an assessment of

postlicensure activities with some skepticism. What, then, does the public record of postlicensure surveillance activity say about the presence of absence of bias and how VSB and ISO have done their jobs in assessing Gardasil's safety?

The main public output of the FDA and CDC groups' work has so far come in a single report published in the August 19, 2009 issue of the *Journal of the American Medical Association* (JAMA). In that paper, ISO's Barbara Slade and four of her colleagues from CDC joined together with seven FDA colleagues to publish the first-ever analysis of the VAERS data on Gardasil. Not surprisingly, the JAMA paper gave Gardasil a free pass; in the process the authors joined the chorus of DHHS celebration for the breakthrough of its home-grown anti-cancer vaccine. "Vaccination with [Gardasil] has the potential to decrease the global morbidity and mortality of HPV-associated diseases, including cervical cancer. After hepatitis B vaccine, which can prevent liver cancer, [Gardasil] is only the second vaccine licensed with an indication to prevent cancer." And although they acknowledged the possibility of injury due to blood clots like those that killed Brooke Petkevicius, Slade et al argued that the data from VAERS led to the same conclusion as the positive review from their colleagues at CBER. "The postlicensure safety profile presented here is broadly consistent with safety data from prelicensure trials."

As for the specific question of Gardasil deaths, Slade et al acknowledged that there had been deaths associated with Gardasil. But they dismissed the VAERS death reports as not frequent enough to worry about.

*Causes of death included 4 unexplained deaths, 2 cases of diabetic ketoacidosis (**1 complicated by pulmonary embolism**), 1 case related to prescription drug abuse, **1 case of juvenile amyotropic lateral sclerosis**, 1 case of meningoencephalitis (Neisseria meningitidis serogroup B), 1 case of influenza B viral sepsis, **3 cases of pulmonary embolism** (1 associated with hyperviscosity due to diabetic ketoacidosis), 6 cardiac-related deaths (4 arrhythmias and 2 cases of myocarditis), and 2 cases due to idiopathic seizure disorder. The PRR [statistics speak for "proportional reporting ratio", or the VAERS death rate relative to the "background" expected death rate] for deaths in 6- to 17-yearolds was 1.4 (X2=0.42, P=.52). The PRR for deaths in 8- to 29-year-olds was 1.2 (X2=0.01, P=.92). Neither of these met the screening criteria for signal detection. [emphasis added]*

Criticism of the JAMA analysis came quickly (some preceded the paper's publication) and from several different quarters. One of the most trenchant attacked the relevance of the VAERS case data itself and came from the parents of a Gardasil victim. Like so many parents of vaccine injured children, Jennifer Tetlock's parents had become deeply dissatisfied by the diligence of federal officials in evaluating Gardasil's safety. Jennifer's adverse reaction, as originally diagnosed, was among the least common adverse events; Slade et al reported it as an isolated case. But in April 2009, Jenny's parents publicly voiced their suspicion that their doctor's original diagnosis of juvenile amyotrophic lateral sclerosis may have been misleadingly narrow. They argued that "world-class immunologists suspect that Jenny had a potentially treatable autoimmune disorder mimicking ALS, possibly triggered by the Gardasil vaccination." If true, this interpretation of her reaction placed Jenny's death in a broader category of a severe autoimmune reactions from Gardasil. As reported previously in part 2, this kind of autoimmune reaction was a risk that the clinical trials showed to be quite common.

More broadly, Jenny's parents struck out at CDC's failure of postlicensure diligence.

The CDC does not inspire confidence, so we conducted our own shoestring search to determine whether Jenny was alone. We created a website (jenjensfamilyblogspot.com). Although this website has only drawn 40,000 visitors, it has out-performed the federal government in finding girls ominously similar to Jenny (current score is: Jenny site 2; CDC's VAERS: 0).

One does not need to be a statistician to see how unlikely it is that these two other girls are the only cases out there—or how frightening it is that we already know of three documented cases of girls (those two plus Jenny) who developed ALS within several months after their vaccinations. After all, if the odds of ALS in teenaged girls are 1 in 3 million and we found 3 in only 40,000, it is very possible that many other of the 6 million girls vaccinated have already developed severe neurological collapse, like Jenny.

Jenny's parents may have been uncertain about the proper diagnosis of Jenny's reaction, but they were not alone in their criticism of the statistics underlying the FDA/CDC analysis. In a December 2009 letter to JAMA, Drs. Vicky Debold (Full disclosure: Debold is a director of the Age of Autism sponsor SafeMinds) and Eric Hurwitz criticized the Slade analysis. Debold and Hurwitz identified numerous flaws in the CDC/FDA report, arguing that: a) cases of autoimmune diseases such as Guillain-Barré syndrome were systematically underreported; b) the method for obtaining background rates of disease could include vaccine injury and were thus inappropriate to use in comparisons; and c) the denominator for the case population used to generate the PRRs was grossly overstated. On the last point, Debold and Hurwitz noted that Slade et al had mistakenly used "total vaccine doses distributed" as the denominator for disease rates instead of doses administered (or for that matter the number of women receiving doses), a choice that "systematically inflates the ratio's denominator."

Debold and Hurwitz noted the larger policy problem created by these failures in postlicensure surveillance and by Slade et al's low standard of diligence. "Federal officials have cited this study as evidence that [Gardasil] 'is a safe and effective vaccine,'" they noted. "However, we consider that conclusion to be unwarranted because the study draws inferences from data likely to be systematically biased."

Diane Harper, one of the researchers involved in the Gardasil trials, agreed with Debold and Hurwitz. In an August 2009 interview with CBS News reporter Sharyl Attkisson, she also criticized Slade et al, arguing to Attkisson that "the risks of vaccination are underreported in Slade's article, as they are based on a denominator of doses distributed from Merck's warehouse. Up to a third of those doses may be in refrigerators waiting to be dispensed as the autumn onslaught of vaccine messages is sent home to parents the first day of school. **Should the denominator in Dr. Slade's work be adjusted to account for this, and then divided by three for the number of women who would receive all three doses, the incidence rate of serious adverse events increases up to five fold" [emphasis added].**

Harper also agreed with Jenny Tetlock's parents' suggestion that Slade et al were understating the number of deaths in their risk assessment, the numerator. Harper told Attkisson, "Parents and women must know that deaths occurred. Not all deaths that have been reported were represented in Dr. Slade's work, one-third of the death reports were unavailable to the CDC, leaving the parents of the deceased teenagers in despair that the CDC is ignoring the very rare but real occurrences that need not have happened if parents were given information stating that there are real, but small risks of death surrounding the administration of Gardasil."

So how should one weigh the net impact of all these claims and criticisms? Certainly, although there are serious health risks, including death, associated with Gardasil, there are also potential benefits, including reduced rates of cervical cancer. Slade's analysis doesn't provide the number of individuals receiving vaccine in the first two years after the Merck vaccine's introduction, but based on the statistics she provides, it's reasonable to assume that something less than 10 million young women received doses of Gardasil (23 million doses distributed with a target of 3 doses per subject). A balanced review of the overall benefits of Gardasil would compare the frequency and consequences of vaccine injury in this population, based on the most objective rate of adverse events, with the vaccine's purported benefits.

If we compare the death rate (these rates were calculated in part 2 of this series) in the Gardasil trial group of 8.5 per 10,000 to an expected death rate in young women of 3.9 per 10,000, we get an extra death risk from Gardasil of roughly 4-5 per 10,000 annually. Applied to a population of 4 million young women per year, that would come to a total of close to 2,000 extra deaths per year that were caused by Gardasil during the period of its launch. This is an extraordinarily high rate and may possibly be explained away by bad luck and coincidences, as the CBER review contended. But it is the only active surveillance analysis ever done on a population exposed to Gardasil. By contrast, the calculated death rate from VAERS reports gives a much lower number, over 100 times lower, a ratio that many consumer advocates (and certainly Jennifer Tetlock's parents) believe reflects more on the poor quality of the VAERS database than the actual risk of death from Gardasil.

But if Gardasil is successful in preventing deaths from cervical cancer, is it possible that society is still coming out ahead overall? The America Cancer Society estimates that there were 4,000 deaths in 2009 from cervical cancer. If Gardasil could prevent a significant number of these deaths in the future, then it's possible that the benefits of the vaccine might exceed the risks. Unfortunately for the vaccine program, the deaths caused by Gardasil are immediate and the preventable deaths from cervical cancer are many years away.

Unfortunately for the public, in assessing the reliability of any estimates of Gardasil's future benefits there are many unknowns: we don't know how long the immunity against HPV will last; we don't know whether costly booster shots and a new round of adverse events will be necessary; and, most important of all, we don't yet have any idea whether or not Gardasil will succeed in preventing a meaningful number of cervical cancer deaths. We know it provides effective immunity against two of the most common cancer-causing strains of HPV. But it's entirely possible that, just as soon Gardasil suppresses these strains of HPV, new cancerous strains will arise to take their place leaving overall cervical cancer rates unchanged. The dirty little secret of the war on cervical cancer is that public health officials have no current way to judge how and whether widespread vaccination with Gardasil will affect the actual rate of cervical cancer and they won't be able to make that judgment for many years.

A similar situation holds in the case of a similarly multi-strain infection and its associated vaccine formulation: in this case the many different strains of *streptococcus pneumoniae*, the bacterial species responsible for invasive pneumoccoal disease (or IPD) and the so-called pneumococcal vaccine. In order to combat IPD, a leading cause of bacterial meningitis, a multi-strain vaccine called Prevnar was introduced by Wyeth in 2000. Prevnar quickly became one of the most commercially successful vaccines of all time, bringing in nearly $3 billion in revenue in 2008. But in asking whether Gardasil will actually work against cervical cancer, it's useful to ask whether a similar vaccine product like Prevnar has been successful in actually preventing IPD?

A recent study from Massachusetts on its effectiveness suggests that Prevnar, contrary to all expectations, did not reduce the incidence of IPD in the state. Instead, although the forms of IPD caused by strains in the vaccine went down after Prevnar's introduction, IPD cases caused by other strains (some of which were even more dangerous than the original strains) rose almost immediately and in opposite proportions, to keep the rate of IPD in Massachusetts constant. In plain language, Prevnar, the most commercially valuable vaccine in history, created no health benefits whatsoever. It just didn't work.

Will this be the case with Gardasil? We will only know with any certainty what Gardasil's benefits will be after many years, even decades of use. Right now, it's too early to tell how many of the 4,000 annual deaths from cervical cancer might be prevented. But several things are clear in the near term: Gardasil has already injured an unknown number of young women, with these injuries likely including deaths that may number in the hundreds, possibly (based on the only data available) as many as 2,000 per year; Gardasil also has left many more young women with crippling chronic conditions like Guillain-Barré syndrome, arthritis and autoimmune thyroid conditions.

Diane Harper has also argued that assessments of the net benefits of Gardasil have overstated its value. She told Sharyl Attkisson in her interview that, "the risks of serious adverse events including death reported after Gardasil use in the JAMA article by CDC's Dr. Barbara Slade were 3.4/100,000 doses distributed." This rate is substantially lower than our estimates here. Nevertheless, Harper remained concerned that Gardasil's risks outweighed its benefits. "The rate of serious adverse events is on par with the death rate of cervical cancer. Gardasil has been associated with at least as many serious adverse events as there are deaths from cervical cancer developing each year."

In light of the many years required to prevent cases of cervical cancer, it's clear that the current cost of Gardasil outweighs its current benefit. Moreover, it may take many years to realize any net benefit to society from Gardasil; the crossover point where realized benefits exceed the costs incurred is far away and uncertain. At the moment, therefore, there is only one net benefit that is certain: the benefit to Merck's bottom line. And, of course, the bottom line of Merck's business partner at NIH.

Revolving door culture

DHHS has a clear conflict of interest with respect to Gardasil at the institutional level since it shares directly in Gardasil's profits. We've also seen now that this conflict of interest is echoed by (and possibly sustains) a pervasive pattern of regulatory bias in favor of Gardasil during multiple stages of the decision process. But as the Gardasil body count rises, one natural question one might ask is why, at a personal level, more DHHS officials haven't taken the principled stand of Diane Harper, who spoke up against the ACIP Gardasil recommendation because "I want to be able to sleep with myself when I go to bed at night."

In the case of several senior officials involved in overseeing key DHHS decisions during the Gardasil era, some portion of that answer is provided by their subsequent career moves. Indeed, these moves reveal a cultural problem that is in many ways more troubling than the direct Gardasil financial conflicts: a pervasive pattern of senior officials cashing in on their careers in public service in order to obtain lucrative corporate and consulting jobs. The career moves of these senior officials show that a virtual revolving door between regulators and the pharmaceutical, vaccine and biologics companies they are supposed to regulate erodes any meaningful sense in which these officials truly serve consumer interests, especially when it comes to product safety. This revolving door provides the cultural foundation that undergirds some of the more egregious institutional conflicts.

A short account of the recent careers of just a few of the officials involved in regulating Gardasil shows this revolving door in action.

• Mike Leavitt was named on December 13, 2004 as Secretary of DHHS, where he subsequently was responsible most of the critical regulatory decisions involving Gardasil. In January 2009, he left HHS and formed Leavitt Partners, a Washington DC consulting firm that helps its client "enter new markets, enhance the value of their products and navigate dynamic regulatory and reimbursement systems." In his consulting work, Leavitt could certainly teach his clients about Gardasil and how they could follow Merck's example in forging a model "public-private partnership."

• Julie Gerberding was named Director of CDC on July 3, 2002 and served in that role until she resigned on January 29, 2009. Gerberding watched over Gardasil policy at CDC during the period of FDA review in which ACIP put Gardasil on a fast track for approval in June 2006. She also was in charge of the oversight for CDC's postlicensure safety activities during much of the period leading up to Slade et al's JAMA submission when portions of the VAERS analysis were reviewed with ACIP. Less than a year after leaving public service, on December 21, 2009, Merck announced Gerberding's appointment as President of the Merck Vaccine Division, effective January 25, 2010, the minimum interval allowed for a Federal official to assume a position at a company they used to regulate. Gerberding, who once regulated Gardasil, is now directly responsible for its growth and profitability.

• Karen Goldenthal was the Director of the Division of Vaccines and Related Products Applications within CBER, the FDA division responsible for approving Gardasil's BLA in June 2006. In 2007, shortly after Gardasil's approval, Goldenthal left CBER to become Executive Director of PharmaNet Consulting. PharmaNet is "a global, drug development services company, provides a comprehensive range of services to the pharmaceutical, biotechnology, generic drug, and medical device industries." Other FDA executives have taken leadership positions at PharmaNet, including William Egan, former head of Vaccine Research and Review at FDA, now a Vice President in PharmaNet's consulting practice.

These departures provide just a few small examples of a pervasive exodus of FDA officials, many of whom leave FDA in order to provide advice to pharmaceutical companies on how to make their way successfully through the pre- and post-licensure processes. And when it comes to vaccines, there is a specific market for former CBER officials to coach vaccine manufacturers on how to get their BLAs approved and their launches more profitable. Like PharmaNet, a consulting company called the Biologics Consulting Group (BCG) shows how active the revolving door between FDA and industry has become. Here's how BCG describes itself.

Biologics Consulting Group, Inc. (BCG) is a team of consultants who provide national and international regulatory and product

development advice on the development and commercial production of biological, drug and device products. Our staff consists of experts in regulatory affairs, product manufacturing and testing, pharmacology/toxicology, facility inspections, statistics, program management, and clinical trial design and evaluation. ***Many of our consultants are former CBER, CDER, and CDRH reviewers. [emphasis added]***

In an environment so stepped in both direct and indirect conflicts of interest, is it any wonder that Gardasil regulators have leaned so steeply in favor of industry while overlooking serious safety concerns?

The early victims of Gardasil look for justice

The final phase of regulatory activities surrounding Gardasil have yet to play themselves out. These involve the process of adjudicating claims of injury and death due to the vaccine. The DHHS agency responsible for this work is the Health Resources Services Agency (HRSA), which houses the Division of Vaccine Injury Compensation, the group responsible for managing the Vaccine Injury Compensation Program (VICP), more commonly known as "vaccine court." In light of the pattern of bias we've observed in the approach other DHHS agencies have taken to Gardasil, one might reasonably question the prospects for fair treatment of Gardasil victims in vaccine court. Can we really expect the director of HRSA to encourage a fair and generous compensation policy on Gardasil when her colleagues over at NIH are profiting from the patent license, CDC is actively promoting its use and her former colleagues at FDA are providing consulting services to companies helping them avoid regulatory pitfalls and keep their profits intact?

As in the case of its sister agencies, the presence of conflict of interest does not necessarily mean that HRSA will demonstrate bias, negligence or failures of diligence in their approach to Gardasil. In advance of any record of decisions, however, it's simply too early to tell how HRSA will respond. In other controversial areas such as the Autism Omnibus Proceeding, petitioners have been deeply disappointed in their treatment at the hands of the vaccine court. And it seems likely that Gardasil families are destined for their own day in vaccine court: HRSA provides "table injuries" that provide compensation for a short list of outcomes on a few vaccines, but there are no table injuries yet specified for Gardasil. (HRSA has commissioned the Institute of Medicine to develop such a list for the entire category of HPV vaccines. A candidate list of injuries can be found in the latest working list from the "Committee to Review Adverse Events of Vaccines", see HERE) So as Gardasil petitioners find their way into the VICP process, HRSA officials will be setting Gardasil injury compensation policy for the first time.

And the Gardasil girls are coming to seek justice. In an early action, on March 13, 2010, the parents of Jennifer Tetlock filed the following petition with the VICP.

The above captioned Petitioners request compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. 300aa-10 et seq. (Supp. 1996), for the death of minor, Jennifer Tetlock who received the third series of the Gardasil vaccination on March 1, 2007 from James Cuthbertson, M.D. in Berkeley, California and thereafter suffered from atypical amyotrophic lateral sclerosis (ALS)-like lower motor neuron disease which was caused in fact by the above stated vaccination.

Will Jennifer Tetlock receive justice? It's hard to imagine how any agency so inextricably linked to the Gardasil program--from invention to approval and recommendation to protection and profit—can possibly be trusted to be a fair arbiter of guilt and innocence.

But one can always hope. After all, the guardians of vaccine safety in DHHS have children themselves. And like Diane Harper, they also need to sleep with themselves when they go to bed at night.

(Read Part 2 HERE and Part 1 HERE.)

Age of Autism CoverMark Blaxill is Editor-At-Large of Age of Autism. His book, The Age of Autism: Mercury, Medicine, and a Manmade Epidemic , co-written with Editor Dan Olmsted, is available now for preorder and debuts in September.