A License to Kill? Part 2: Who Guards Gardasil's Guardians?

Blaxill 2 photo (Read Parts 1 HERE and 3 HERE of this series.)

By Mark Blaxill

In the first part of this report (HERE), Age of Autism identified a pattern of conflict of interest at the Department of Health and Human Services (DHHS) involving Merck's Gardasil vaccine. Researchers at the National Cancer Institute (NCI) invented critical technology for the "virus-like particles" (or VLPs) that were used in the Gardasil vaccine. As the invention reached the commercial marketplace, these researchers' bosses at the National Institutes for Health (NIH) celebrated their work as "heroic" and "a journey we can learn from." Meanwhile, officials in the NIH Office for Technology Transfer (OTT) filed for patents on the VLP technology invented at NCI, licensed those patent rights to vaccine manufacturers and eventually received royalties from Merck, Gardasil's manufacturer, and GlaxoSmithKline (GSK).

In the second part of the series, Age of Autism will follow the Merck-DHHS "public-private partnership" as it moved beyond NIH to its sister agencies. In a subsequent process at the Food and Drug Administration (FDA), officials in the Center for Biologics Evaluation and Research (CBER) supervised the clinical trials and granted Merck the first "Biologics License Application" (BLA) for a human papillomavirus (HPV) vaccine. Three weeks later, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended universal HPV vaccination for women from nine to twenty-six years of age, guaranteeing in one series of votes that Gardasil would reach blockbuster status for Merck: annual revenues of well over $1 billion. Subsequently, agencies within FDA and CDC have been responsible for monitoring Gardasil's safety in the field, as officials within the Health Resources Services Administration (HRSA) brace themselves to sit in judgment over a new wave of vaccine injury claims. As we pointed out in the first part of this series, this conflict of interest is both extraordinary in scope and poorly understood by the general public.

At the same time, simply observing the possibility of conflict between the commercial activities of NIH and the regulatory roles of other agencies doesn't necessarily mean that there will be bias, negligence or lack of diligence on the part of DHHS regulators. Nevertheless, the proclamation of great victory for a vaccine against cervical cancer—one that prompted the NIH Director to single out the invention for praise to both Congress and the President and won its inventors recognition as Federal Employees of the Year—could certainly have created pressure to usher Gardasil through the BLA approval and ACIP recommendation processes with special attention and unusual dispatch. As a result, one might argue that the *potential* for bias on the part of CBER and ACIP regulators--regulators who would have had a dangerous temptation to relax their required skepticism and hold the favored new product to lower standards of safety—gave them a responsibility for unusual diligence and extra care. But what does the evidence really say about their *actual* level of diligence? Did CBER and ACIP officials betray their eagerness to enable the celebration of a new "anti-cancer vaccine" or did they hold Gardasil to even more exacting standards of safety? Let's take a closer look at how FDA and CDC approached their respective responsibilities for Gardasil.

How stringent was FDA's safety review for Gardasil?

When the FDA issued its approval of Merck's BLA for Gardasil on June 8, 2006, its decision was based on a review of Merck's data from five separate clinical trials, each of which included efficacy and safety assessments for Gardasil. Four of the five trials approached their efficacy and safety studies in similar fashion, comparing Gardasil against a "placebo" that contained an active

ingredient, with one trial comparing Gardasil against what the CBER reviewers described as a "saline placebo." All together, these five trials examined a total of close 12,000 subjects who received at least one dose of Gardasil and compared their outcomes to roughly 10,000 subjects who received up to three injections of what Merck and CBER officials agreed to describe as a "placebo."

But what is a placebo, really? One definition describes a placebo as "an innocuous or inert medication; given as a pacifier or to the control group in experiments on the efficacy of a drug." The operative term here is the word *inert*. But in four of the five trials, Gardasil placebos contained a substance called an *adjuvant*, "a substance which enhances the body's immune response to an antigen." According to one of the trial publications, most of the Gardasil trial placebos actually contained an *"amorphous aluminium hydroxyphosphate sulfate adjuvant… and was visually indistinguishable from vaccine."* So although the majority of the placebo treatments in the Gardasil trials did not include Gardasil VLPs, they were by no means inert. In control populations representing nearly 95% of all "placebo" recipients, the study subjects received a formulation that actually included an immunologically active (and potentially harmful) aluminum adjuvant.

One of the five trials, however, was different. In this trial, the only one that examined a younger population of nine-to-fifteen year olds, the placebo recipients did not receive an aluminum adjuvant. By contrast, and according to most of the FDA documentation, the nearly 600 control subjects in this trial received a formulation most commonly described as either a "non-alum placebo" or a "saline placebo." The safety results of this trial deserve special notice, since it's the only trial that compared Gardasil to a solution that could reasonably be described as "inert."

But even that assumption would overstate the case. Although the "saline placebo" did contain water and sodium chloride (ordinary table salt), the FDA was incorrect to suggest that there were no other active ingredients. According to the published description of this trial's methods, *"The placebo used in this study contained identical components to those in the vaccine, with the exception of HPV L1 VLPs and aluminum adjuvant, in a total carrier volume of 0.5 mL."* Formulations like this, which are made up of everything in the vaccine except its immunologically active components, are sometimes called a "carrier solution." The correct description of the placebo as a "carrier solution" rather than a "saline placebo" was provided only once in the CBER review, buried in a table on page 301. Nowhere in either the CBER review or the published account of the trial can one find any description of this placebo's ingredients.

It is possible, however, to infer the composition of the carrier solution from Merck's Gardasil package insert, which lists the vaccine's immunologically inactive ingredients. These include: "yeast protein, sodium chloride [table salt], L-histidine [an amino acid], polysorbate 80 [an emulsifier], sodium borate, and water for injection." At least one of these chemicals, sodium borate, is a chemically reactive toxin, one that has many industrial uses as an active ingredient. These include applications as: a replacement for mercury in gold mining; an insecticide and fungicide; and a food additive that is now banned in the United States.

Is there any defense for the FDA to allow this approach to placebo selection in the Gardasil trials? From an efficacy standpoint, one can reasonably argue that yes, using an adjuvant in a placebo makes sense, since it will provide the most rigorous test of the value of the active ingredient under review, in this case the VLPs invented at NCI. And in fact, the returns from all five clinical trials provided convincing evidence that when the VLPs were added to a vaccine formulation containing the aluminum adjuvant, a strong immune response resulted. CBER therefore drew the reasonable conclusion that Gardasil works, at least against the endpoints it was able to measure.

But is it safe? When it comes to the accurate measurement of adverse effects of Gardasil, there is little justification for reliance on a placebo with ingredients that are not inert. There is some limited value, perhaps, in comparing adverse events that are introduced solely by the addition of VLPs to the vaccine solution. But a truly rigorous safety assessment would investigate the full safety profile of the VLPs *in combination with* the aluminum adjuvant and compare that profile to the profile of an inert solution. After all, the adjuvant is present precisely because it is not inert.

If the FDA trial standards were truly to enforce a high standard of safety, they would require the comparison of Gardasil's safety profile to a true saline placebo. But Merck performed no such analysis and CBER permitted them to apply a lesser safety standard of safety analysis. As a result, CBER issued its BLA approval without any idea whatsoever of the true risks of Gardasil. Not surprisingly, most of the comparisons between adverse outcomes for those receiving doses of Gardasil and those exposed to an aluminum adjuvant "placebo" showed little evidence of injury risk from Gardasil.

Unfortunately, the conclusion that Gardasil was therefore safe was horribly wrong.

A different view of the Gardasil trial data

Based on the data provided in CBER's review of the Gardasil trials, it is possible to piece together an alternative view of Gardasil's adverse event profile by examining three separate populations: 1) the subjects who received actual doses of Gardasil (over 96% got all three doses); 2) the subjects who received a "placebo" containing an aluminum adjuvant (over 98% got 225 micrograms of amorphous aluminum hydroxide sulfate) formulated in a carrier solution that made it visually indistinguishable from the full vaccine; and 3) the subjects who received only doses of a carrier solution. For the Gardasil and aluminum adjuvant groups, safety results were collected in two ways: a smaller set of reported outcomes was measured for the entire trial group (the "general safety population") and a smaller group (the "detailed safety population"), including the entire carrier solution group, followed a more detailed protocol. The respective sizes of these safety assessment groups are shown below. Unfortunately, the small relative size and somewhat unmatched profile of the carrier solution group reduces the statistical power of a comparative analysis across the three groups: the age profile of this carrier solution trial was younger (9-15 years of age) than the other four trials (10-26 years of age, with the bulk falling between 16-23 years old); and less female (54%) than the Gardasil recipients (over 90%) and the aluminum adjuvant recipients (100% female). Nevertheless, the results of this three way comparison are the closest thing we have to a valid, non-passive safety analysis; and they show striking differences in safety profiles, none of which can be attributed to sample bias.

Slide2
There are several ways in which the CBER trial review permits a comparative safety analysis across all three groups. The first is by comparing immediate adverse events at the injection site: events such as pain, swelling, "erythema" (redness of the skin), hemorrhage and pruritis (itching). These events are highly specific and show up in the first few days; they can, however, vary quite a bit in terms of severity. The Gardasil trials reported their results for these injection site adverse events in the "detailed study population" within five days after any vaccination visit. The comparison of these outcomes is shown below (using a scale that keeps the ratios between the rates of the adverse events constant).

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As the chart shows, the vast majority of the Gardasil (81%) and aluminum adjuvant (75%) groups reported some kind of adverse event, most of which involved some kind of pain. By contrast, less than half of the carrier solution group (45%) reported an adverse event. This pattern continues in almost all of the individual categories, with the Gardasil group showing the largest rate of local reactions, followed closely by the aluminum adjuvant group and then with a clear drop off in the frequency of adverse events in the carrier solution group. On a retrospective basis, all but one of the reduced risks for the carrier solution group were statistically significant.

The most striking difference between the three groups is in the area of "serious adverse events." Although less frequent than minor instances of pain or swelling at the injection site, these serious events were disturbingly common in the groups exposed to active substances. Nearly 5% of the Gardasil recipients had a serious adverse event, well over six times the rate of the carrier solution group. And more than 2% of the aluminum "placebo" recipients had severe reactions, more than three times the rate of adverse events in the carrier solution group. Based on this finding alone, it's hard to defend the choice to classify Merck's adjuvant as an "inert" placebo.

A second approach to comparative safety analysis involves examining the adverse events that caused the participants to withdraw from the trial in a two week period after any vaccine visit. These withdrawals included a range of adverse reactions, only a small fraction of which the investigators designated as “severe.” But sudden deaths (which need not be specific to the vaccine) were also included. The comparison of the discontinuation rates in the three groups is shown below.

Slide4
Overall, the rate of discontinuation was low, at less than half a percent. But in the carrier solution group not a single recipient chose to drop out of the trial. In addition, there were three discontinuations after two weeks due to deaths in the Gardasil group and one such death in the aluminum adjuvant groups, whereas there were zero deaths at any point in the carrier solution group. Seven discontinuations (four in the Gardasil group and three in the aluminum adjuvant group) were due to other severe adverse events. These are obviously small numbers, and the deaths were dismissed by the reviewers as unrelated to vaccination. And in fact, the rate of discontinuation in the Gardasil and aluminum adjuvant groups was nearly identical. As a result of this similarity on outcomes, the CBER reviewers dismissed any effect of vaccination on withdrawal decisions, in all likelihood because the vast majority of the officially designated “placebo” group was exposed to the aluminum adjuvant.

A third approach to a comparative safety analysis takes a longer view of adverse events, using data for serious adverse events over a twelve month period after the beginning of the trial. The FDA review includes voluminous data on these events, but one of the easiest to measure is simply the overall rate of serious adverse events. The trial data show rates for such serious events that were similar between the Gardasil and placebo group. Indeed the rate of serious adverse events in the Gardasil group (1%) was actually lower than the placebo group as a whole (1.1%). Not surprisingly, however, this result was driven entirely by a high rate of serious adverse events in the aluminum adjuvant group. When one examines the rate of serious adverse events in two distinct placebo groups, the rate of serious adverse events in the aluminum adjuvant group rises even higher, to 1.27%, while the rate in the carrier solution group comes out at zero. This comparison is shown below.

Slide5
A final approach to safety assessment takes the extensive twelve-month data on the medical conditions in all trial subjects and examines the longer term adverse events in specific categories of interest. Several such categories show disturbing patterns. Autoimmune conditions like arthritis, lupus and thyroiditis were sharply higher in the Gardasil group when compared to the overall “placebo” group and were even noted by the FDA reviewer as a source of concern. These occurred at a rate of over 1 in 1000 in the Gardasil group; there were, however, zero reported cases of autoimmune disorders in the carrier solution group. As in the two week analysis, death rates over twelve months were higher in the Gardasil and aluminum groups. By contrast, the carrier solution group had no deaths in the longer period. The chart below shows the results for the twelve month analysis.

Slide6
How much of the low rate of adverse events in the carrier solution group (officially designated the “018 Protocol”) was due not to real differences in outcome but rather to sample bias, the fact that the population for the 018 Protocol was younger and less purely female than the other four trial populations? The short answer is, not very much. There are several ways to test the effect of sample bias. These include: comparing the adverse event rate in the 018 Gardasil group to the Gardasil groups in the other four protocols (higher adverse events show the 018 population was *more vulnerable*); comparing differences in adverse event rates between boys and girls in the 018 Gardasil group (higher adverse events in boys also show the 018 population was *more vulnerable*); and comparing differences in rates between the 9-12 year olds and the 13-15 year olds in the 018 Gardasil groups (higher adverse events in younger subjects show the 018 group was *more vulnerable*). If anything, most of these comparisons suggest the use of the carrier solution group understates the adverse event rate for Gardasil. For example, the younger subjects in both 018 groups had a higher rate of injection site adverse events and the 018 Gardasil group also had a higher rate of severe adverse events than the other groups. Only the findings on deaths and discontinuations (which were most frequent in the Protocol 018 Gardasil boys and 13-15 year olds)

might have been influenced by sample bias.

The FDA downplayed deaths during the clinical trial

When it came to the most serious adverse event of all, death, the FDA review effectively gave Gardasil a free pass. They failed to mention, of course, that the deaths in their "placebo" group actually received the entirety of the vaccine's contents excepting the VLPs. Nevertheless, they did report briefly on each individual case of death. In cases of death due to traumatic events like motor vehicle accidents, however, no details were reported (could a seizure or heart attack while driving have caused some traumatic events?). In most of the biologically-related deaths, they found reasons not to make any connection to Gardasil or to blame the victims' behavior ("they were on birth control pills") or family history ("the family had a history of arrhythmia"). Here is the FDA reviewer's summary of the deaths in the trial.

There were 10 deaths in the Gardasil recipients (0.8%), and 7 deaths in the placebo group (0.7%). The majority of the deaths were due to trauma in both groups. These deaths did not appear related to vaccine administration.

In each treatment group, there was a death related to a deep vein thrombosis and/or pulmonary embolism, and both subjects were on hormonal contraceptives. The Gardasil recipient with this event had symptoms of leg pain prior to the first vaccination. The other Gardasil recipients who died included one subject with pancreatic cancer 578 days after dose 3, and one young male who died of arrhythmia 27 days after dose 1. This latter subject had a strong family history for arrhythmia. These events did not appear related to administration of the vaccine.

Even if all of these deaths could be explained away one way or another, this certainly sounds like a lot of deaths for such a young, and overwhelmingly female, group (16 of the 17 deaths were in females; one 15 year-old male Gardasil recipient died of a heart attack). What kind of death rate is normal for young women? The trials provide no such reference rate, but such statistics are readily available. Carnegie Mellon has a web-site called "Death Risk Rankings" (see HERE) that provides an interactive tool for calculating death rates within a wide range of demographic categories. For American females in the age range of the Gardasil trials (9-26 years of age), the rates are as follows: 2.75 per 10,000 in 10-19 year olds and 5.03 per 10,000 in 20-29 year olds. [Note: the majority of trial subjects were from the U.S. and Europe. European deaths rates from young women are 30% lower than American death rates, making this a conservative comparison].

Out of 11,778 Gardasil recipients, over 90% of them young women between the ages of 9 and 23, one would expect an annual death rate to be a mix of the rates for the two reference groups, or less than 4 per 10,000 in an entire year. But in the trials, there were three "sudden deaths", i.e. deaths that occurred within just the two weeks of the Gardasil injections, in a review period of less than forty-five days. That's a death rate close to ten times higher than would be expected such a short period. And the overall Gardasil death rate of 8.5 per 10,000 (10 deaths out of 11,778) for the 12 month period of the trial is more than twice what one would expect. The FDA review evinced little concern over this high death rate, preferring instead to compare the deaths in the Gardasil group to that of the "placebo" group. But as one can see from the chart below, the death rate in the aluminum adjuvant group was higher than the reference groups as well.

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In short, the CBER review of Gardasil condoned the use of an immunologically active placebo and not an inert solution. So instead of a adopting an increased measure of diligence in light of the potential for bias due to the DHHS conflict of interest in Gardasil, it appears that FDA permitted Merck to use a lower standard of safety. Only by using the single set of trial data in which the placebo solution was relatively (although not entirely) inert, can one assess the impact of this relaxed standard. Based on an analysis of this data, one is drawn to an inescapable conclusion.

Gardasil was not safe.

ACIP's recommendation for universal vaccination of young females

If the FDA was less than diligent in its review of safety profile of the anti-cancer vaccine invented at its sister agency at NIH, how did its counterparts at CDC compare in terms of their own decision processes? Faced with a choice either to take a deliberate course, allowing a period of observation to follow Gardasil's BLA approval, or to rush Gardasil into widespread use, CDC's approach provides another standard of comparison for DHHS's conduct. Would their key decision-making group, the Advisory Committee on Immunization Practices (ACIP) choose the deliberate or the hasty path?

There is very little ambiguity in this answer. ACIP wasted absolutely no time in recommending Gardasil for universal use among young women. Indeed, it would have been hard for them to move any faster. In June 2006, almost immediately after FDA approval, ACIP recommended the HPV vaccination. An account in the March 23, 2007 edition of the CDC publication, *Morbidity and Mortality Weekly Report* (MMWR) showed that ACIP was preparing for near instantaneous approval even before the FDA's final reviews were completed.

The Advisory Committee on Immunization Practices (ACIP) HPV vaccine workgroup first met in February 2004 to begin reviewing data related to the quadrivalent HPV vaccine. The workgroup held monthly teleconferences and meetings three times a year to review published and unpublished data from the HPV vaccine clinical trials, including data on safety, immunogenicity, and efficacy. Data on epidemiology and natural history of HPV, vaccine acceptability, and sexual behavior in the United States also were reviewed. Several economic and cost effectiveness analyses were considered. Presentations on these topics were made to ACIP during meetings in June 2005, October 2005, and February 2006. Recommendation options were developed and discussed by the ACIP HPV vaccine workgroup. When evidence was lacking, the recommendations incorporated expert opinion of the workgroup members. Options being considered by the workgroup were presented to ACIP in February 2006. The final recommendations were presented to ACIP at the June 2006 ACIP meeting. After discussions, minor modifications were made and the recommendations were approved at the June 2006 meeting.

The date of the BLA approval for Gardasil was June 6, 2006. In the June 29 ACIP meeting, just 23 days after the FDA's decision, ACIP gave Gardasil its formal support. The vote was unanimous, with two of the fifteen members abstaining due to their financial involvements with Merck.

But not only was the vote unanimous, the mood in the meeting was celebratory. Numerous vaccine safety advocates attended the June meeting due to their concerns over the influenza vaccines. One attendee recounted the reaction to the Gardasil decision. "After the vote the place erupted in applause. There was hand-shaking and back-slapping. It seemed kind of odd and inappropriate to us." Asked why it seemed inappropriate, the observer explained that the concern arose, "because they were so clearly cheering the recommendation. It was clear and absolutely a celebratory reaction."

The safety discussion was almost exclusively informed, of course, by the FDA's flawed trial data. Not surprisingly, few concerns were raised. Here's what the ACIP minutes had to say about Gardasil's safety profile.

The clinical trial program places strong emphasis on evaluating the safety profile of GARDASIL®. Of ~21,464 subjects, ~11,000 received detailed safety follow-up and the remainder received serious adverse experiences in medical history and pregnancy follow-up. The incidence of overall adverse events (AEs), injection-site AEs, and low-grade fevers >100°F was slightly higher in the GARDASIL® group compared to the placebo group. Systemic AEs were comparable between the two groups. ***Serious AEs and discontinuation due to adverse experiences were extremely rare.*** *[emphasis added]*

As a result of this accelerated process, ACIP made a series of recommendations. The first placed Gardasil on the recommended list of childhood vaccines. "ACIP recommends routine vaccination of females 11-12 years of age, with three doses of the quadrivalent HPV vaccine. The vaccine series can be started as young as nine years of age at the discretion of the provider." In the context of the clinical trials, this was an extremely aggressive recommendation. A scant 85 pre-pubescent girls, nine years of age or younger had received Gardasil in any trial (matched with only 48 controls) and only three percent of the Gardasil trail recipients were in the range of ACIP's target population of 11-12 year olds. Not only was ACIP basing its recommendation on flawed safety analysis, it was extending its recommendations to include groups who lay outside of even this biased assessment.

But ACIP didn't stop there. They also recommended a catch-up vaccine for all young women, even those who would have been sexually active for many years, who had contracted at least one strain of the virus, cleared it, and therefore received diminished benefit from vaccination. "ACIP recommends vaccination for females 13-26 years of age who have not been previously vaccinated. Ideally, vaccine should be administered before onset of sexual activity, but females who are sexually active should still be vaccinated." From a commercial perspective, this recommendation multiplied Gardasil's profit potential for Merck and its NIH partners, creating a near term target market that was seven times larger than just the routine market of 11-12 year- olds.

There was little effective restriction placed on Gardasil's market potential. And only the yeast protein in the carrier solution was cited as a safety concern. "Vaccination should be deferred until after moderate or severe acute illnesses improve," read the ACIP recommendation. "A history of hypersensitivity or severe allergic reaction to yeast or any other vaccine component should be classified as a contraindication. Initiation of the vaccine series should be delayed until after completion of the pregnancy."

The momentum for an aggressive roll-out was strong. Representatives from nine different organizations gave formal statements in support of Gardasil during the public comment period. In the meantime, and with a strong push from Merck, some state officials stood in line to move even faster than ACIP. In February of 2007, Republican Texas Gov. Rick Perry bypassed the legislature and mandated Gardasil for all 11- and 12-year-old girls in the state.

The commercial results were powerful and immediate. Merck reported its first revenues from Gardasil in the second quarter of 2006 (presumably from sales after the June BLA approval), and its revenues began to climb rapidly: $70 million in the third quarter, $155 million in the fourth quarter, all leading to a blockbuster year of 2007 in which Gardasil recorded revenues of $1.5 billion. The financial bonanza had begun in earnest.

A few years later, Merck would attract criticism for its aggressive marketing of Gardasil during this period. Sheila and David Rothman wrote a sharp critique in the *Journal of the American Medical Association* (hardly a radical hotbed of vaccine consumerism) in which they neglected the conflicts described here but noted the extreme measures that Merck adopted.

The marketing of this vaccine broke with traditional practices. Heretofore, vaccines had been identified by the disease they were preventing (measles, mumps) or by their creators (Salk or Sabin). This HPV vaccine followed a different model. It was identified by a trade name, Gardasil, and promoted primarily to "guard" not against HPV viruses or sexually transmitted diseases but against cervical cancer. The marketing campaign that followed, according to Merck's chief executive officer, proceeded "flawlessly." In 2006, Gardasil was named the pharmaceutical "brand of the year" for building "a market out of thin air."

But the Rothmans' critique would do little to delay or disrupt the launch. At the time of the DHHS rush to market there were few dissenting voices and none of them were heard at ACIP.

One lone voice stood out. In March 2007, just as the vaccine was reaching its peak revenue numbers, one of the doctors who had guided the clinical trials voiced an objection. On March 14, 2007, an article in a small newspaper in Fort Wayne, Indiana reported on an interview with one of the scientists involved in the clinical trials. The scientist was named Diane Harper and she expressed dismay

at the ACIP recommendation.

"Giving it to 11-year-olds is a great big public health experiment," said Diane M. Harper, who is a scientist, physician, professor and the director of the Gynecologic Cancer Prevention Research Group at the Norris Cotton Cancer Center at Dartmouth Medical School in New Hampshire.

"It is silly to mandate vaccination of 11- to 12-year-old girls There also is not enough evidence gathered on side effects to know that safety is not an issue."

Harper didn't have much to gain from the commercial success of Gardasil, but she also was taking considerable risks by breaking ranks with her colleagues. One can only imagine how things would have been different if she had been in charge of the review process at FDA rather than running one branch of the clinical trial. In the midst of such a widespread degradation in regulatory ethics and standards, it's interesting to consider why she made that choice.

The Fort Wayne reporter, Cindy Bevington, was frank as to why Harper was telling her story to them rather than a larger media outlet. "For months, Harper said, she's been trying to convince major television and print media to listen to her and tell the facts about the usefulness and effectiveness of this vaccine." Why was an inside critique of the Gardasil promotion campaign not already big news? "No one will print it," Harper said.

Over the coming months, the assessment of adverse effects of Gardasil would be transferred to a different group within DHHS, from CBER and ACIP to the "postlicensure safety surveillance" groups within FDA and CDC. At this point, the deaths and serious adverse events would leave the realm of closely held statistics within a vaccine manufacturer's actively monitored trial sample and into the realm of passive surveillance in the general population; soon watchdog and vaccine safety groups like National Vaccine Information Center and Judicial Watch issued critical analyses, see HERE and HERE. And Harper's concerns over the inadequate safety data would prove prophetic. Why had Harper broken ranks so early? When Bevington asked Harper why she was speaking out despite the momentum to the contrary, her answer was refreshingly simple.

"I want to be able to sleep with myself when I go to bed at night."

(Read Parts 1 HERE and 3 HERE of this series.)


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.