



How an HPV Industry was established; by deception, role confusion, abrogation of responsibilities and an apparent focus on profit before people.

1983	Dr. zur Hausen discovers HPV16 DNA in invasive cervical cancer cells
1984	Dr. zur Hausen discovers HPV18 DNA in invasive cervical cancer cells
1991-1993	Three universities and the NCI ¹ file patents on various aspects enabling production of HPV L1-VLP-based prophylactic vaccines
2001	Dr. Mark Schiffman is a senior investigator with NCI's Division of Cancer Epidemiology and Genetics (DCEG) ² In 2001 Dr Schiffman states "Cervical cancer should be a vaccine-preventable disease." (This despite the fact any technology that could be used to produce such a vaccine is currently tied up in multiple patent

¹ The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH), which is one of 11 agencies that compose the Department of Health and Human Services (HHS), **another being the FDA** (the regulator that approves new vaccines and drugs). The NCI, established under the National Cancer Institute Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates **as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice.**

The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

The conflicts that exist in the NCI are well documented in article attached as appendix 1.

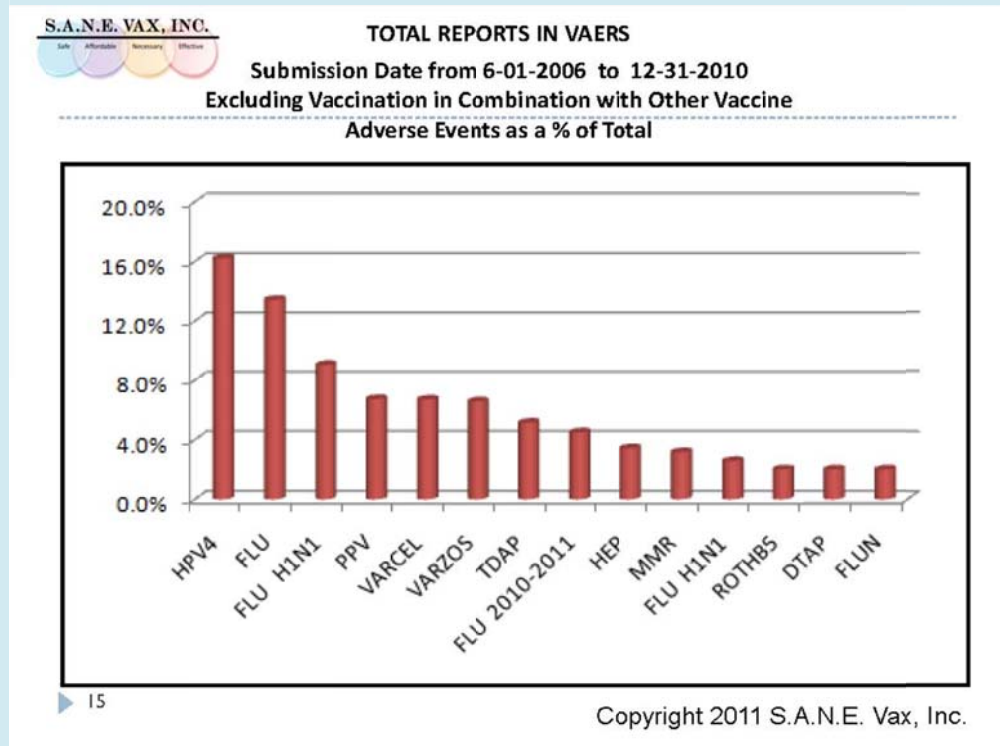
² Dr Mark Schiffman is a Senior Investigator at the NCI's Division of Cancer Epidemiology and Genetics (DCEG) is the world's largest and leading cancer epidemiology research group. With its cadre of renowned epidemiologists, geneticists, and biostatisticians, DCEG conducts population and multidisciplinary research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention. The Division's research impacts public health policy in the United States and around the world. Through its programs in cancer epidemiology, genetics, statistics, and related areas, the Division:

1. Conducts broad-based, **high quality, high impact** research;
2. Maintains a national and international perspective, giving priority to emergent issues identified through clinical, laboratory, and epidemiologic observations, as well as to public health concerns identified by the Institute, Congress, regulatory agencies, and other appropriate bodies;
3. Develops infrastructures, resources, and strategic partnerships in molecular epidemiology across NCI, NIH, and the extramural community; and
4. Trains the next generation of scientists in cancer epidemiology and related fields.

	<p>interference declarations; despite the fact cervical cancer rates in the United States were at an all-time low due to increased pap screening levels.). Why? Of importance is the fact that the NCI/FDA also recommends the use of Digene Corp's HC2 testing technology despite recognizing that PCR technology is a much more sensitive test. It is also worth pointing out that Dr Schiffman and Digene Corp's CEO De Lorincz co-author 34 articles on HPV and related issues.</p>
2001-Nov	<p>The FDA decides to allow Merck to use CIN2/3 or worse by histology – with virology to determine the associated HPV type as the primary endpoint in the evaluation of a vaccine to prevent cervical cancer – even though those lesions frequently reverse on their own. The old truism that rubbish in equals rubbish out remains unchallenged.</p>
2002	<p>Merck granted fast track designation for the development of Gardasil a vaccine to prevent cervical cancer, despite the fact Gardasil met neither of the two FDA qualifying criteria for such a designation, lets repeat that again <i>despite the fact Gardasil met neither of the two FDA qualifying criteria for such a designation</i>. Interestingly it appears that the NCI conducted much of the supporting research (for the FDA) for the fast track approval, a clear conflict of interest as the NCI later becomes a partner with Merck to introduce the very same vaccine.</p>
2001-2005	<p>Merck conducts clinical trials with their proprietary adjuvant as a control solution (placebo) potentially masking adverse events, no DNA sequencing to verify HPV genotypes involved in any abnormal cervical cells observed, and not one case of cervical cancer in any of the study populations. By not using the same adjuvant as used in the vaccine in the placebo – it is impossible to determine if there were any adverse events! Whatever happened to comparing apples with apples, particularly when it comes to injecting a vaccine into tens of millions of people?</p>
2005-Feb	<p>Merck and GSK enter cross-license agreement for HPV patents. Merck, make Gardasil, GSK make Cervarix, both use the same patent protected VLP technology both have increased adverse events post vaccination. Anyone seeing a glimmer of a link here?</p>
2005-May	<p>NCI's nonexclusive license converted to co-exclusive licenses to Merck and GSK, making the US government partners with pharmaceutical companies for HPV vaccine production. A reasonable person might believe that there is a possible conflict of interest here</p>
2006-June	<p>Despite the fact there is no scientific evidence that HPV alone causes cancer, despite the fact cancer is not a contagious disease, despite the fact that cervical cancer has become rare in the US, the FDA granted approval for Gardasil as a cervical cancer preventative. No safety concerns were raised about this being the first vaccine to use genetically engineered virus-like particles. An eminent vaccine scientist employed by Merck Dr M Hilleman wrote a paper in 1990 http://www.ncbi.nlm.nih.gov/pubmed/2198327 that expressed concern over the implications of DNA not discovered in vaccines as outlined in the following quote</p>

	<p>“There is also concern for use of plasmid vectors employing promoter elements from oncogenic viruses. The principal concern for safety lies with retention of residual DNA in the vaccine, especially since induction of cancer is a single-cell phenomenon, and a single functional unit of foreign DNA integrated into the host cell genome might serve to induce cell transformation as a single event or part of a series of multifactorial events. Current proposed standards for vaccines would permit contamination with up to 100 pg of heterologous DNA per dose. This is equivalent to about 10(8) "functional lengths" of DNA. Total safety would seem to require complete absence of DNA from the product”. (Emphasis added).</p>
2008-June	<p>FDA requires Merck add arthralgia, myalgia, asthenia, fatigue, and malaise to the potential adverse events section of the Gardasil package insert. With the significant increase in adverse events showing up in VAERS it is disappointing that the FDA has to instruct Merck to add these, rather than Merck add them willingly.</p>
2008-Sept	<p>FDA grants expanded approval for Gardasil to include vulvar and vaginal cancer prevention.</p>
2007-2010	<p>Merck applies four times to get approval for Gardasil use in older women – FDA declines.</p>
2010-Dec	<p>FDA grants extended approval for Gardasil use in the prevention of anal cancer in males and females. So now Merck turns its attention to men.</p> <p>What’s worse is that in an article published on the infectious news website http://www.infectiousdiseaseneews.com/article/86993.aspx that was based on research published in the Lancet in August 2011. In the article, infectious news reports that the research demonstrates that Gardasil resolves anal cancer. The article is inaccurate and misleading, no it’s very misleading as only an efficacy against the composite endpoint of AIN2 and AIN3 associated with HPV 6, 11, 16, and 18 was established, with most of the efficacy seen for HPV 6-related AIN1. What the report did was to add two words that completely changed the context of the research. Those words were “anal cancers”. Surely Pharma and researchers charged with ensuring accuracy would demand that this type of misleading reporting is immediately corrected, yet all too often it does not, what then follows is that the two words get repeated by others and picked up elsewhere so that fiction replaces fact and a vaccine against a virus becomes a cure for a cancer – just like that.</p>
2010	<p>India calls a halt to HPV vaccine trials under allegations of ethical violations and safety risks.</p>
2010	<p>The government of France refuses to allow HPV vaccines to be marketed as cancer preventatives. France becomes the first Western government to recognize that HPV vaccines are NOT a cancer cure!</p>
2011	<p>VAERS data suggests that HPV4 (Gardasil) is the most frequently reported vaccine</p>

when it comes to adverse events.



2011-May

VAERS registers 22,194 adverse events reports after HPV vaccinations, including 378 abnormal pap smears, 41 cases of cervical cancer, and 97 deaths. Interestingly adverse events following Gardasil vaccination are higher than any other vaccine in the VAERS database.

(Note: VAERS is a voluntary system – there are no penalties for failure to report adverse events, indeed many do not even know it exists. Given this, is it a surprise that it is estimated that only 1-10% of adverse events are actually reported. Making it even more damning is that adverse events in the US are compared to doses distributed, not doses administered, therefore expressed as a percentage of actual administered doses, adverse events could be significantly higher as no one knows how many doses are in storage.)

Present

Even though post-licensure monitoring for safety and efficacy is required for fast-tracked drugs, **there is currently no accurate system in place to monitor HPV vaccine efficacy or safety** (Emphasis added). HPV tests currently available to medical consumers use a more than 20 year old, analytically inaccurate and unreliable technology developed before PCR technology was introduced into clinical labs. There is no DNA sequencing involved, despite the fact that DNA sequencing is the recognized 'gold standard' for HPV testing. Why? Surely the FDA would insist that efficacy and content testing is maintained at the highest possible level. The NCI's own mission statement includes this statement ...(NCI) conducts broad-based, high quality, high impact research. One wonders if they meant high impact in the

way it appears to be impacting so many of those that have received Gardasil. Remember this is a vaccine in which the NCI are a beneficiary by virtue of their commercial relationship with Merck.

Merck continues to seek additional expansions to the approved uses of Gardasil.

No one will know for 20 years or more whether the vaccine will have any impact on cervical cancer. But we do know two things; a high proportion of women do not have their 2nd or 3rd dose. Is this because their experience with the first or second dose may well have influenced this decision? As well and potentially far worse is that as Gardasil has been misleadingly promoted as a cancer vaccine – no one knows how many women will no longer continue with pap smears which could lead to a rapid increase in cervical cancer in the years ahead.

No one knows whether suppressing HPV 16 and 18 will cause other genotypes to become more virulent.

No one knows what impact genetically engineered virus-like particles may have on the human body. That is until now.

On August 29th 2011, SANEvax wrote to the FDA to advise them that it has tested 13 separate lots of Gardasil sourced worldwide from a variety of production batches and 100% of them were contaminated with recombinant HPV DNA. It tested this using technology available to the FDA. Of even greater concern is that the DNA was found to be tightly bound to the adjuvant (aluminium hydroxyphosphate), is this the reason why so many young women have faced so many severe adverse events. Interestingly Merck, its partners (CSL in Australia) and others including co-inventor Prof Ian Frazer have categorically stated that Gardasil contains no DNA. This is underscored here

<http://www.medicines.org.uk/emc/document.aspx?documentid=19016> which in part contains the statement " Gardasil is an adjuvanted non-infectious recombinant quadrivalent vaccine prepared from the **highly purified virus-like particles (VLPs)** of the major capsid **L1 protein** of HPV types 6, 11, 16 and 18. **The VLPs contain no viral DNA**, they cannot infect cells, reproduce or cause disease". (Emphasis added). This is further supported by the FDA here <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM231522.pdf> which states "**GARDASIL® is not a live virus vaccine; it contains no viral DNA, and is therefore incapable of causing infection**". (Emphasis added.)

Both the FDA and Merck are equally accountable for releasing a product that fails to meet its specifications. Both the FDA and Merck realise the need for VLP protein purification to remove all recombinant HPV DNA from the vaccine. Otherwise, they would have to perform additional clinical safety trials to prove that such residual

recombinant HPV DNA is totally harmless. Consumers do not have to prove that the DNA bound to aluminum adjuvant is harmful. It is the FDA/Merck's responsibility to show that the latter compound is harmless if present in the vaccine. It is very clear that they did not do that. Given this it is essential that the contaminated product is recalled until the side effects of the HPV DNA in the vaccine are properly evaluated or until the contaminant is totally removed from the vaccine. No one can argue that this is other than a very reasonable demand.

Conclusion.

A vaccine for cancer has been created and distributed to millions of people around the world – yet vaccines don't cure cancer and Gardasil is vaccine for a virus and perhaps a vaccine that doesn't even address the issues that it was in fact created for.

HPV is a naturally occurring phenomenon and in the vast majority of cases it cures itself, Pap smears have had an amazing and beneficial influence in managing cervical cancer over many years. They are also a lot less expensive than Gardasil.

In 2004 VIOXX (a Merck drug) was withdrawn from the market. Vioxx provided Merck revenues of \$2.5B in 2003.

In 2005 the NCI (a US government agency that falls under the Department of Health which also administers the FDA) in effect partners with Merck in the development and distribution of Gardasil. Several NCI scientists have publically stated that they assisted the FDA in steering the approval through!

In 2006 Gardasil obtains FDA approval and Merck's sales guys hit the streets and by 2008 it's approved for use in over 80 countries. In many of these countries, Merck is either in partnership with Government or protected by vaccine legislation. In effect Merck can corporatise profits but institutionalise risk.

In 2007 significant levels of adverse reactions post Gardasil start getting reported and this increases both in volume and type – and there seems to a common link – most are associated with triggering an Auto Immune disorder and the list of these is long and getting longer. As well the first deaths post Gardasil are reported.

In 2008 Merck estimated Gardasil revenue of between \$1.4b and \$1.6b.

In 2009 the clamor that there are issues with Gardasil rise, there are increasing media reports of these but Merck continues to sell and works with FDA and others to expand the use of Gardasil into a range of new markets, older, younger, male, and female – all become target markets for Gardasil.

In 2011 SANEvax advise the FDA that Gardasil is contaminated with recombinant HPV DNA.

In 2012 we hope that we can add the next paragraph.

The FDA and other regulators today announced that Gardasil is to be withdrawn from the market. Further that transparent and independent inquiries are established to determine:

- 1.** How this occurred
- 2.** Who is at fault
- 3.** What penalties are to be imposed and most importantly
- 4.** How to right the terrible wrong that has been imposed on so many young women around the world because of the introduction of a vaccine that served no good purpose other than to line the pockets of Merck and others.

All information in this timetable can be verified either in the attached document, "Creating an HPV Industry," or on the FDA Website. This document prepared by Norma Erickson, President of SaneVax Inc with the assistance of Stephen Tunley.

NIH and conflicts of interest in vaccine development and regulation

As the world's largest single sponsor of biological research, NIH frequently funds research with commercially valuable outcomes. When that R&D generates potentially valuable inventions, NIH submits patent applications to the U.S. Patent and Trademark Office (USPTO) and actively pursues the approval of those patents, which when granted become valuable commercial property for DHHS, the patents' owner. Since NIH has neither the authority nor the capability to pursue product commercialization efforts, in order to encourage private companies to invest in conducting the necessary clinical trials, NIH's Office of Technology Transfer (OTT) was created to grant commercial licenses for such DHHS patents to commercial partners, including vaccine manufacturers. When new products invented at NIH clear the requisite regulatory hurdles at the Food and Drug Administration (FDA) and reach the market, OTT then shares in the profits. They also distribute the rewards back to the scientific teams whose products have succeeded in reaching the commercial stage: when license fees flow into OTT's coffers, the Federal employees who invented the technology are entitled by NIH policy to a share of the royalties.

From a technology development standpoint, such commercial arrangements are the result of an intentional public policy; in fact they resulted from an Act of Congress. The Bayh-Dole Act of 1980 was written with the express purpose of making it easier for federally-funded academic research to receive patent protection that would allow the ready licensing of the fruits of commercially valuable R&D to private businesses. At the time, the concern of Congress was that federally funded inventions too often languished within the academy because businesses had insufficient incentive to invest in clinical trials, since these inventions were often unsupported by the powerful competitive protection afforded by an exclusive patent license.

The policy worked. Within the research universities that receive the vast majority of federal funding, Bayh-Dole has had the desired effect and has enabled university technology transfer offices all over the world to generate billions of dollars of licensing revenue in the last few decades--especially in the life sciences--by licensing patents from federally-funded university research to corporate partners. Bayh-Dole has effectively turned research into big business for many universities and transformed technology transfer offices into important profit centers at academic institutions all over the world.

But when technology licensing takes place *within* federal agencies, Bayh-Dole creates an entirely different problem: an unprecedented web of conflict, one in which the same departments that are tasked with regulating the health and safety of medical products are also profiting from them. **As Lowy and Schiller conceded in their review article disclosure, this conflict of interest came into play directly on Gardasil: both men are named inventors on the technology that makes Gardasil possible;** NIH filed for and received patents on their invention of the VLP technology; DHHS is the owner of the patent family that protects the commercial rights to the invention; in order to bring the product to market, OTT licensed the vaccine technology to Merck; and as Merck has generated billions in Gardasil revenue, OTT has received millions in Gardasil profits.

But DHHS is also responsible for regulating Gardasil in numerous ways. The FDA reviewed the clinical trials in which Gardasil was tested in human populations and passed judgment on Gardasil's safety. An Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and

Prevention (CDC) decided whether or not to recommend Gardasil for young women and children. The FDA and CDC together now conduct the surveillance to decide whether or not Gardasil is proving safe in larger populations. And as some families are now beginning to seek compensation based on claims that Gardasil caused injury in some of its recipients, the division of the Health Resources and Services Administration (HRSA) that oversees the Vaccine Injury Compensation Program (VICP) will soon sit in judgment as to whether, to whom, and how much compensation will be provided to Gardasil's victims.

... all of this activity is supervised in a single department by one Cabinet official, the Secretary of Health and Human Services. The sole non-governmental agency involved in this commercial enterprise is Merck's Vaccine Division. In effect, the Merck-DHHS partnership leaves the business side to Merck while DHHS is solely responsible for

1. Creating the market for Gardasil by funding commercial research, supervising the conduct of clinical trials, judging the outcome of those trials and promoting a policy of universal vaccination;
2. Collecting the license fees that result from Gardasil revenues from Merck and other vaccine manufacturers and then distributing these financial benefits to Federal employees; and
3. Deciding whether or not to protect the policy decisions and profit streams of their sister DHHS agencies through postlicensure safety monitoring and vaccine injury compensation rulings.

Is this good government at work or an example of the medical-industrial complex run amok? In this investigative series, Age of Autism will take a look at how DHHS agencies have managed Gardasil in all three of these sequences. We'll start by taking a closer look at the NIH patent portfolio and the associated license fees that have been flowing into NIH coffers since 2006.

Celebrating the invention of a new market

- Lowy and Schiller are both employed by the National Cancer Institute (NCI). One of the largest of the NIH institutes, NCI was established in 1937 by Franklin Delano Roosevelt. For many decades, NCI has been the agency at the forefront of the so-called "War on Cancer." Perhaps the earliest inspiration for the both the Cancer War and the Gardasil program began during the 1960s, when NCI researchers first began looking in earnest at viruses as a potential cause for cancer. In 1961, NCI leaders created the Laboratory of Viral Oncology to begin the search for cancer-causing viruses; in 1962 the Human Cancer Virus Task Force was first convened; and by the end of the decade, enthusiasm over this research was part of the scientific momentum that persuaded President Richard Nixon to launch the War on Cancer in 1971. Unfortunately for Nixon's legacy, and for most subsequent cancer victims, the War on Cancer has famously failed to find a cure for cancer or to validate theories of viral causation in the vast majority of human cancers.

- But starting in the 1980s, the two exceptions to this litany of failure—hepatitis B virus and the human papillomavirus—led to the launch of two blockbuster new vaccine products. The infant hepatitis B

vaccine was developed in the 1980s and launched in 1991 with an ACIP recommendation that all American infants be vaccinated on the first day of life. And after 1984, when Harald zur Hausen first pinpointed the role of certain strains of human papillomavirus in cervical cancer, the work on another anti-cancer vaccine could begin. By the early 1990s, laboratories all over the world were racing to develop the first HPV vaccine.

- Lowy and Schiller's NCI team were among the four most active research teams in this race, all of whom were aggressively filing patents on their HPV inventions. Along with a third NCI colleague, Reinhard Kirnbauer, Lowy and Schiller filed their first application for a patent entitled "Self-assembling recombinant papillomavirus capsid proteins" on September 3, 1992. Since then--and after splitting the original application into 29 "children" in the form of numerous "divisionals", "continuations" and "continuations-in-part"--nine patents from that family have been granted, as well as four from a branch of the family tree entitled "chimeric papillomavirus-like particles." The ability of the novel "L1 proteins" described in their patent to "self-assemble" into virus-like structures, which when deployed in a vaccine solution could stimulate a protective immune response against HPV, formed the essence of their invention. Although OTT doesn't specify the royalty-bearing patents, the commercially valuable technology that Merck has licensed likely comes from this group of nine "self-assembling recombinant papillomavirus capsid proteins" patents: US5437951, US5709996, US5716620, US5744142, US5756284, US5871998, US5985610, US7220419, and US7361356.

- The NCI team was among the leaders in HPV technology, but the race to make a commercially viable HPV vaccine involved several other research teams from all over the world. Most notable among these were the University of Queensland in Australia, Georgetown University and the University of Rochester. In addition to NCI's filings, each of these university-based research teams filed their own patents; eventually, Merck and GSK got into the act as well. Like many promising areas of technology, the HPV patent landscape became large and crowded in a short period of time.

- Amid this blizzard of activity, the USPTO's Bureau of Patent Appeals and Interferences (BPAI) had to step in to sort out whether these competing patent applications interfered with each other and to distribute the credit, making a series of hotly contested decisions that were ultimately appealed to the Court of Appeals for the Federal Circuit (CAFC), the nation's most powerful patent court. By 2007, all the BPAI and CAFC rulings had come in and the respective contributions of all four groups were conclusively allocated for commercial purposes. The team led by Ian Frazer at the University of Queensland received credit for the being the first to propose the idea of using VLP technology for a vaccine, since their application was filed on July 20, 1992, just six weeks earlier than the NCI team's. But thanks to their unique technology of "self-assembly," most of the invention claims of the NCI patent family remained intact as well; Lowy and Schiller's invention has since been generally accepted as a critical advance in the wave of new technology that made Gardasil possible. In terms of the distribution of financial reward, both Rochester and Queensland have reported receiving royalty income for their HPV inventions (in undisclosed amounts) in addition to the revenues reported by OTT.

- As the technology transfer officials at OTT were paving the way for the financial benefits from Gardasil to flow back to NIH, Lowy and Schiller were benefiting in other ways as well, especially when

it came to scientific credit. Throughout much of 2006 and 2007, they received awards from many quarters for their role in developing Gardasil’s “virus-like particles.” Their joint awards included the *Dorothy P. Landon-AACR Prize for Translational Cancer Research* in April 2007 and the *2007 Novartis Prize for Clinical Immunology*. In addition, Lowy by himself received the *Daniel Nathans Memorial Award* in September 2007 and the American Cancer Society’s *Medal of Honor for Basic Research* in October 2007.

In addition to these awards, on September 19, 2007, Lowy and Schiller received what was perhaps their crowning honor. That’s when the Partnership for Public Service awarded the pair the “*Federal Employees of the Year Service to America Medal*.” According to its sponsors, “*The Service to America Medals* have earned a reputation as one of the most prestigious awards dedicated to celebrating America’s civil servants. Often referred to as the ‘Oscars’ of government service,” they are more commonly known in government circles as the “Sammies.” Upon receiving his crowning honor, Lowy was interviewed for the *NIH Record* and professed the requisite modesty in its October 2007 edition, saying “We are simply symbols of the many people who have made critical contributions to understanding the relationship between papillomavirus infection and cervical cancer.”

If Lowy was modest, the top brass at NIH could barely conceal their pride over their employees’ accomplishments. According to the Partnership for Public Service, “Lowy and Schiller’s 20-year partnership has been a boon to the nation’s health and for the advancement of scientific discovery.”

Collecting the licensing fees

Alongside the science and policy celebrations, the business side of the Merck-NIH partnership proceeded with a bit less fanfare and with a different kind of currency. Once their patent was approved, OTT could then turn to extracting their share of the benefits from their commercial partners’ new products, which in the case of HPV vaccine included sales first from Merck’s Gardasil product and later from GlaxoSmithKline’s Cervarix. Merck reached the market first in 2006, but GSK followed shortly thereafter in 2007. As each company began collecting revenue from their new vaccines, OTT began collecting royalties. The table below shows Age of Autism’s analysis of how Merck and GSK’s revenues may have flowed into OTT’s coffers.

	<u>Gardasil</u> Revenue (\$M)	<u>Cervarix</u> Revenue (\$M)	<u>NIH Top 20</u> Revenue (\$M)	<u>HPV Rank in NIH</u> Top 20 Revenues (\$M)	<u>HPV</u> Estimated at 1% license fee
<u>2006</u>	<u>235</u>	<u>--</u>	<u>NA</u>	<u>NR</u>	
<u>2007</u>	<u>1,481</u>	<u>20</u>	<u>71 (est)</u>	<u>#4</u>	<u>15</u>
<u>2008</u>	<u>1,403</u>	<u>229</u>	<u>77.4</u>	<u>#2</u>	<u>16</u>
<u>2009</u>	<u>1,108</u>	<u>292</u>	<u>75.7</u>	<u>#1</u>	<u>14</u>

Both Merck and GSK itemize revenue for Gardasil and Cervarix in their quarterly and annual earnings

statements. Their annual results are summarized in the first two columns of the table. **For Merck, Gardasil has been a blockbuster success, yielding a cumulative total of over \$4 billion in revenue through year end 2009.** By contrast, GSK's revenues have been growing more slowly and have not yet reached a cumulative total of half a billion dollars.

- **For their part, OTT does not itemize their HPV license revenues. However, they do report their total royalty revenue as well as the cumulative revenue from their "top 20" technology licenses since 2007. These top 20 licenses have been worth over \$70 million annually in profits for NIH in the last three years, and HPV licenses have soared to the top of those rankings quickly. Last year, OTT reported that HPV licensing was its top revenue generator.** OTT doesn't disclose exactly how much the Gardasil and Cervarix royalties contribute to NIH, but if we make the assumption that their patent licenses entitle them to 1% of the HPV vaccine revenues of their partners (an assumption that appears reasonable based on the available data), then we can safely estimate that OTT has been collecting somewhere in the range of \$15 million per year from Lowy and Schiller's invention.

- In addition to their numerous scientific awards for their discoveries, Lowy and Schiller have received cash distributions from NIH based on their patents. As Federal employees, they are each eligible to receive a share of patent royalties up to \$150,000 per year and Gardasil's success has guaranteed that they would receive the maximum reward. That means that since FDA's approval in 2006, each man has earned roughly a half million dollars in royalty revenue.

- This is the DHHS vision of public private partnership at work. Contrary to the rhetoric, these partnerships aren't simply a high-minded collaboration of scientific visionaries, but rather a large commercial enterprise with extraordinary profits at stake: an enterprise from which NIH receives credit and money and based on which its corporate partners build multi-billion dollar businesses.

- How does such a partnership affect the incentives of regulators whose job it is to make sure the products are safe? It's not obvious that they do. Just because DHHS has a financial stake in Gardasil doesn't necessarily mean that every subsequent decision its employees make is corrupt, part of some nefarious conspiracy to kill young women for money. Indeed, HPV royalty revenues of \$15 million represent just a small fraction of a DHHS budget that rose to well over \$700 billion in 2009. In the larger scheme of things, DHHS revenues on Gardasil are just a small drop in a very large bucket.

- **Far more likely to play a role, however, in public-private partnerships like the Gardasil vaccine are the insidious cultural pressures that emerge in a supremely political organization like DHHS. Can we really expect the Secretary of HHS to take his or her FDA Director to task for implementing lax standards on vaccine approval when the Director of NIH is simultaneously praising the "heroic" researchers who invented the product in the first place? Is it more likely that CDC will apply extra caution in their vaccine policy recommendations when its sister agency is involved or will they be more likely to activate the fast track in their process of making recommendations for Gardasil?** What we have observed so far merely suggests the *potential* for bias in the regulation of products in which DHHS holds a direct stake. In the next part of our series, Age of Autism will investigate the question of whether or not there have been *actual* patterns of bias in the ways in which regulators at FDA and CDC have conducted their duties with respect to Gardasil.

Source Mark Blaxill <http://www.ageofautism.com/2010/05/a-license-to-kill-part-1-how-a-publicprivate-partnership-made-the-government-mercks-gardasil-partner.html>