

Gardasil and Cervarix: Vaccination insanity

In my memoirs of deaning [<http://henrybauer.homestead.com/files/TRAPFULL.pdf>], I had written,

“I would find myself thinking, Now I’ve seen everything; nothing can surprise me anymore, only to experience a novel surprise the next day or the next week”.

HIV/AIDS matters are like that too, only more so, and increasingly other “medical-science” “news”. The absurdities, the self-contradictions in the mainstream portfolio of shibboleths is an endless source of wonderment. Plain common sense is notable by its absence. But still, used as I am to this by now, periodically my jaw still drops as the level of absurdity reaches a new nadir. So it was when I saw the headline,

FDA panel urges HPV vaccine be given to boys

http://www.cnn.com/2009/HEALTH/09/09/fda.gardasil.males/index.html?eref=igoogle_cnn

Gardasil is a very expensive vaccine against human papilloma virus (HPV), some but not all of whose strains seem to be significantly *correlated* with genital warts or cervical cancers. As everyone should know, as all students of Statistics 101 are taught, correlation doesn’t signify causation. Therefore, it’s no surprise that the rate at which HPV-infected women actually develop an “HPV-associated” cancer is about 1 in 300 [“CDC mongers fear and hawks deadly vaccine”, 13 March 2008] <http://wp.me/p8Qhq-1V> or perhaps even lower, say 1.2 per 1000 (see below). By what stretch of the imagination could HPV then be indicated as the *CAUSE* of those cancers? What’s worse, Gardasil is responsible for some severe “side” effects including deaths.

So my jaw did drop at the suggestion that this drugmakers’ boondoggle should now be foisted on males as well as females

[“http://www.cnn.com/2009/HEALTH/09/09/fda.gardasil.males/index.html?eref=igoogle_cnn](http://www.cnn.com/2009/HEALTH/09/09/fda.gardasil.males/index.html?eref=igoogle_cnn)

Committee says shots could prevent genital warts in males 9 to 26

Vaccine's maker claims studies show 90 percent less HPV-caused disease

HPV common in both sexes, CDC says, but men develop fewer problems

Committee also favors Cervarix, new vaccine from GlaxoSmithKline

WASHINGTON (CNN) -- Boys may soon be able to get Gardasil”

“May soon be able to get” sounds as though something highly desirable is at last being shared with a group previously discriminated against. Yet there’s no earthly reason why boys should be inoculated with a vaccine that has potentially serious “side” effects, is very expensive, and supposedly protects --- though imperfectly --- against what is experienced by only a very small proportion of those who harbor a virus that in rare instance supposedly causes things that are no serious threat to health.

“A Food and Drug Administration advisory committee voted Wednesday to recommend that the vaccine be made available to boys and young men aged 9 to 26 for protection against genital warts caused by HPV. The vaccine protects against four types of HPV, and two of those are believed to be responsible for 70 percent of cervical and anal cancers, and HPV-associated penile and throat-and-neck cancers. The other two cause 90 percent of genital warts cases, researchers say. At Wednesday’s advisory committee meeting, pharmaceutical giant Merck & Co., maker of Gardasil, presented data from three clinical trials that the company claims supports broadening the distribution of the vaccine to include males. The trials included more than 5,400 boys and men from six continents and 23 countries. According to Anna Giuliano, an independent scientist

at Moffitt Cancer Center in Tampa, Florida, and the trials' principal investigator, 'The data clearly demonstrates that there was a benefit to men in receiving Gardasil. Overall, we saw a 90 percent reduction in disease --- genital warts and pre-cancerous lesions --- caused by HPV in men and an 89 percent reduction in genital warts incidence'. . . . Giuliano said there were no serious adverse events related to the vaccine. There were some minor side effects such as pain at the injection site and low-grade fever."

As to side effects, other sources paint a very different picture indeed:

Gardasil side effects prompt CDC study (August 13, 2008 by Christe Bruderlin-Nelson)

<http://www.fiercepharma.com/story/gardasil-side-effects-prompt-cdc-study/2008-08-13-0>

"Merck is likely quite displeased with the barrage of negative press about its cervical cancer vaccine's side effects, especially after a public interest group, Judicial Watch, released a report at the end of last month saying there were 9,749 adverse reactions and 21 reported deaths related to Gardasil in the last two years. According to the report, there have been 78 severe outbreaks of genital warts, six cases of Guillain-Barré syndrome and at least 10 miscarriages reported to the Vaccine Adverse Event Reporting System (VAERS) since the approval of Gardasil. However, a study in the New England Journal of Medicine found that **clinicians, patients and drug companies report only about 10 percent of side effects to VAERS, so the actual number of Gardasil side effects could be much higher**" [emphasis added].

A law firm is preparing a suit for damages: <http://www.schmidtandclark.com/gardasil>

"As of June 1, 2009, more than 25 million doses of Gardasil were distributed in the United States and there have been 14,072 reports of adverse events following Gardasil vaccination in the United States. Of these reports, 93% were reports of events considered to be non-serious, and 7% were reports of events considered to be serious. As of June 2009, there have been 43 U.S. reports of death among females who have received the Gardasil vaccine! . . . Among the fatalities reported to government officials were a 17-year-old girl in New York who collapsed and died of a suspected heart problem two days after getting the last in the series of three Gardasil injections. An 11-year-old girl suffered a heart attack three days after a Gardasil shot. And a 12-year-old girl with no prior medical problems died in her sleep three weeks after a Gardasil shot."

Gardasil Side Effects: Should Women Get It? (19 August 2009)

<http://www.nowpublic.com/world/gardasil-side-effects-should-women-get-it>

"Published in today's edition of the Journal of the American Medical Association, a study shows that of the 23 million doses of Gardasil administered to young women since it came on the market on June 1, 2006 to December 31, 2008, 12,424 adverse reactions have been reported. The data also show that 6.2%, or 772 of the young women, experienced serious side effects after taking the Gardasil vaccine, including anaphylaxis, a lethal allergic reaction, blood clots, pancreatic failure, and otor neuron disease. There have also been 32 reports of death, and only 20 of the deaths could be verified, as the others were either provided by Merck & Co. without further information or unverifiable secondhand reports.

Despite the figures, the tone of the study was reassuring.

'We feel confident recommending people get the vaccine; the benefits still outweigh the risks,' said Dr. Barbara A. Slade, the study's first author and medical officer with the Centers for Disease Control and Prevention, which did the study together with the Food and Drug Administration."

Infatuation is less evident in Europe with this expensive intervention, which carries serious risks, to ward off a very rare threat that can be avoided readily and with less risk:

"Now there is another side of the controversy: when inoculating a healthy population against a disease that can be prevented through screening, is any level of risk acceptable?"

‘There are not a huge number of side effects here, that’s fairly certain,’ said the editorial writer, Dr. Charlotte Haug, an infectious disease expert from Norway, about the vaccine. ‘But you are giving this to perfectly healthy young girls, so even a rare thing may be too much of a risk. I wouldn’t accept much risk of side effects at all in an 11-year-old girl, because if she gets screened when she’s older, she’ll never get cervical cancer,’ Dr. Haug said in an interview.”

Deborah Kotz, blogging “On Women”, points to the difficulty of learning about cases of side effects: [http://health.usnews.com/blogs/on-women/2009/04/01/gardasil-side-effects-parents-seek-answers.html](http://health.usnews.com/blogs/on-women/2009/04/01/gardasil-side-effects-parents-<u>seek-answers.html</u>)

“Gardasil Side Effects? Parents Seek Answers

. . .

In response to my recent post about the government deciding to take a closer look at cases of paralysis that occurred after Gardasil vaccination, I received comments and E-mails from several devastated mothers whose daughters became ill for no apparent reason in the days and weeks after getting the vaccine

Here's a sample:

‘My 21-year-old daughter, Chris, got her third shot of Gardasil on June 3, 2008,’ Emily Tarsell wrote me last week in an E-mail. ‘She was found dead in bed 18 days later. She was a healthy, bright, talented young lady who played on the tennis team at Bard College where she would have graduated with honors this year.’

‘My daughter developed epilepsy since being vaccinated, and when I share her experience with people, most doubt the connection,’ Nina Kenney wrote in an E-mail.

‘My daughter, in the middle of her series of injections of Gardasil, had a bout of Bell's palsy that paralyzed the right side of her face,’ Della Smith wrote in this blog comment. ‘Two months after that, she was diagnosed with Graves's disease. The doctor says an immune reaction to something he can't determine is most likely responsible.’

No one knows if these girls were injured by Gardasil or just coincidentally got sick after the vaccination, but certainly their cases need to be thoroughly investigated. And after hearing the stories of several parents who contacted me, I find that one thing is glaringly clear: There is nowhere for them to turn for help besides one another. . . .

Some doctors refuse to file VAERS reports at all, and sometimes the reports contain incomplete or ambiguous information. Tarsell says she's heard from a few parents via her website who said their doctors don't believe Gardasil could have caused their daughters' medical problems. In Tarsell's case, the physician who filed the VAERS report wrote that the autopsy report found that her daughter died of an inflammation of the spleen caused by a life-threatening virus. While the autopsy did find some minor inflammation of the spleen, the report concluded that the death was due to ‘cardiac arrest, cause undetermined.’”

Other anecdotes came from Australia:

<http://au.todaytonight.yahoo.com/article/43654/health/gardasil-effects-controversy>

”Allie Harvey lined up along with 2.2 million other Australian women to be administered with Gardasil, the cervical cancer vaccine developed by former Australian of the Year Professor Ian Frazer. ‘I had a headache, I was dizzy, I was nauseous, my right side was weak, my right fist was clenched and I was hallucinating,’ Allie said. ‘It was absolutely terrifying because I didn’t know why it was happening. I felt absolutely terrified.’ . . . Far more frightening for the year 12 student --- who received the first of three injections for the vaccine at school courtesy of a government sponsored initiative --- was the response she received from the health professionals around her. ‘The nurses that had come in from the government told me that I didn't have a rash, that it wasn't a reaction to the immunisation, that I was pretty much making things up,’ Allie said. But Allie wasn't alone. Jade Foreman, 15, is another of the 496 young women who have reported having adverse reactions to the vaccine. ‘I woke up one morning and tried to stand up and I couldn't put

pressure on my legs, I had funny feelings in my legs,' Jade said. Since receiving the life saving injection at her school in June this year, Jade has been under intense physio to enable her to walk again. She is only able to cope with two hours of school per day. 'I now have no social life,' Jade said. 'The pain is ruling my life. Apart from the lower back pain and the neck and the middle back pain, I'm having trouble with my arms dropping things and funny sensations in my arms. It's just ruining my life.'

Scientist and health researcher Bronwyn Hancock believes the mass-distribution of Gardasil is simply unsafe. 'The Gardasil vaccine has never been shown to be safe or effective in preventing cervical cancer,' Bronwyn said. 'There are so many limitations with the testing that they've done.' As a member of the Vaccination Information Service, an anti-immunisation group, Bronwyn says the research behind Gardasil is too flimsy and that the 18 million women worldwide who've already had the vaccine could be setting themselves up for broader health and fertility issues. 'They themselves admit they haven't tested it to show that it doesn't cause infertility or cancer,' she said."

Vaccine Watch: Gardasil Side-Effects? (8 July 2008; Sharyl Attkisson is an investigative correspondent for CBS News)

<http://www.cbsnews.com/blogs/2008/07/08/couricandco/entry4240888.shtml>

"Yesterday I spoke to the families of young women who believe the Gardasil HPV vaccine may have --- or did in fact --- cause their child's serious illness. One of the cases involves a now 18-year old young woman named Amanda. Amanda's parents say she developed a serious reaction to Gardasil after her first dose last summer. It began with soreness where she received the injection. The soreness eventually travelled down her arm, her legs, and led to a horrible autoimmune myofasciitis that is so painful Amanda had to go on morphine for the pain. She was transformed, through the illness, from a high school varsity sport athlete to a chronically ill person who takes a handful of pills a day just to keep her illness tolerable. When she goes off the medicine, the excruciating pain and other debilitating symptoms return. One thing that's different about Amanda's case than some of the others is that both of her parents [are] medical doctors who didn't think twice about having their daughter get the shot --- but are now second-guessing themselves. They call their daughter's illness after Gardasil 'a very sobering experience.' Amanda's dad says, 'as the father of three girls, I've had to ask myself why I let my eldest one get an unproven vaccine against a few strains of a nonlethal virus that can be dealt with in many more effective ways. It's not like they are at high risk. It was the regrettable acceptance of the vaccine party line that [mis]led me.'"

That last sad story illustrates the dilemma in which physicians find themselves when official sources combine with drug companies to tout interventions whose benefits are anything but obvious and which have been insufficiently tested, let alone proven.

So, let's by all means now extend the "benefits" of these injections to boys:

"The vaccine would be administered in boys and young men exactly as it's been given to girls and young women: three doses over a period of six months. Merck spokeswoman Pam Eisele said the cost will be \$130 per dose."

Here are the risks being guarded against:

"According to the Centers for Disease Control and Prevention, about 20 million Americans are infected with HPV. There are 6.2 million new infections each year. The CDC says that at least 50 percent of sexually active men and women get an HPV infection at some time in their life. The American Social Health Association says HPV is the most common sexually transmitted virus and puts that number at 75 percent or more."

Yet while these “infections” are so common as to be virtually routine, almost no one contracts the diseases that these infections supposedly cause:

“The CDC says that although HPV is very common in both sexes, most men won't develop symptoms or serious health problems, and there is no test to detect the virus in men. The only approved HPV test on the market is for women, for use in cervical-cancer screening.”

By far the most serious claimed consequence of HPV is cervical cancer; but this is a very rare condition, and the incidence has in any case been declining for a couple of decades:

“in the past 40 years, the number of cases of cervical cancer and the number of deaths from cervical cancer have decreased significantly. This decline largely is the result of many women getting regular Pap tests, which can find cervical precancer before it turns into cancer.¹ In 2005,* 11,999 women in the U.S. were told that they had cervical cancer, and 3,924 women died from the disease.²” (Centers for Disease Control and Prevention).

<http://www.cdc.gov/cancer/cervical/statistics/>

Let's say half the infected are men and half women. So the incidence of cervical cancer was about 12,000 among 10 million, or 1.2 per thousand; and the death rate was one third of that and could be decreased to essentially none by better screening. **It seems that the serious “side” effects of the vaccine are about as common as what the vaccination is supposed to protect against.**

Nevertheless:

“The advisory committee also voted that Cervarix, a new HPV vaccine made by GlaxoSmithKline, appeared to be safe and effective for girls and young women 10 to 25 years of age. Cervarix has been approved in Europe. ‘This is an important step in cancer prevention for the millions of girls and young women at risk for cervical cancer,’ said Barbara Howe, vice president and director of North American vaccine development for GlaxoSmithKline.”

--- not to speak of an important step toward greater profits for GlaxoSmithKline. And, of course, there are those unfortunate “side” effects:

“Still, the panel recommended that Glaxo do more studies that would monitor miscarriages and other problems ***reported by patients***” [emphasis added].

Categories: clinical trials, experts, Legal aspects, uncritical media, vaccines

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