Cost of Vaccines from Birth to Eighteen

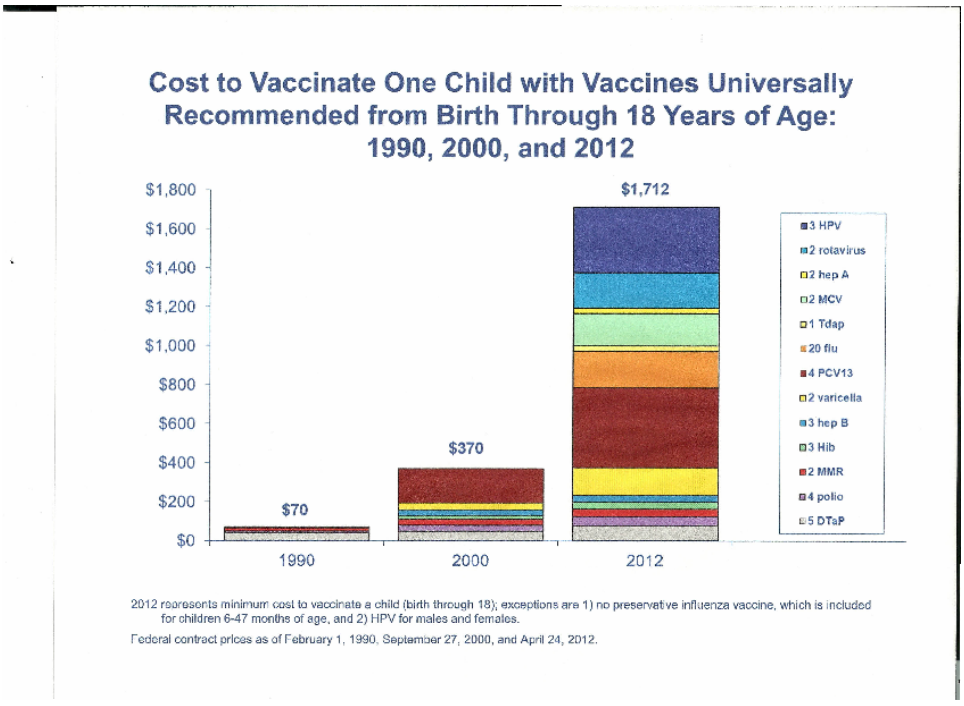
The US National Vaccine Advisory Committee met on June 6, 2012.

Anne Schuchat, MD (RADM, USPHS), Assistant Surgeon General, United States Public Health Service (USPHS) and Director, National Center for Immunization and Respiratory Diseases addressed the Committee with a very well prepared presentation simply titled "Vaccine Management".
http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/shuchat_062912.pdf

Dr. Schuchat who was formerly the Director of the CDC's National Immunization Program (NIP) is a knowledgeable expert in the field of vaccinations. It is pretty safe to state therefore that all the scientific and financial information she provided to the Committee was reliable and accurate, not withstanding the CDC disclaimer on the last page that *"The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention."* The presentation is definitely well worth seeing in its entirety.

Slide 4 of Dr. Schuchat's presentation titled "Selected Recent US Immunization Policy Decisions (2005-2011)" listed the latest vaccine additions and changes and the years they were approved by the ACIP [4 in 2005, 6 in 2006, 1 in 2008, 2 in 2010 and 1 in 2011, the HPV vaccination of adolescent males.]

As noteworthy was Slide 16 listing the cost of the recommended vaccines from Birth to Eighteen over the years and specifically in 1990, 2000 and 2012.



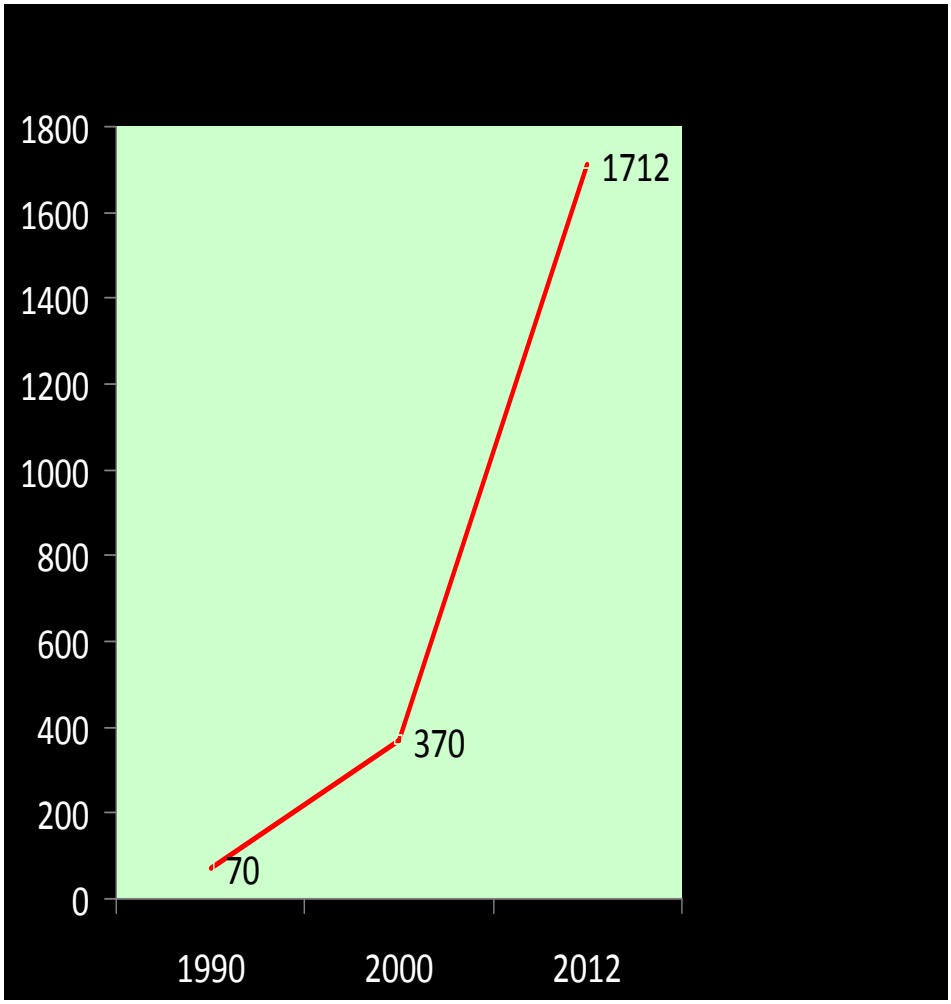
It is not clear what the statement at the bottom of the slide about the HPV vaccine for males and females really means. It is also not clear if the discussed cost is solely related to the Vaccine for Children Program discussed on slide 15 or not.

The colors of the bars and legend are better seen on the slide than on the above-scanned image.

Slide 16 clearly shows that the cost to vaccinate one child with the recommended vaccines from birth through age 18 was $70 in 1990 and that it increased to $ 370 in 2000 and more precipitously to $1,712 in 2012, a staggering 2,346% increase in 22 years.

According to the graph, the PREVNAR-13 (Brown) and the HPV vaccines (Blue) clearly cost remarkably more than other vaccines and indeed possibly as much or more than all other recommended vaccines combined. Also of note is the fact that even in 2000, PREVNAR-7 cost more than all other vaccines combined.

The following simple linear graph of the data on Slide 16 demonstrates even better how much the “Cost to Vaccinate One Child with Vaccines Universally Recommended from Birth Through 18 Years of Age: 1990, 2000, and 2012” has increased.



The most recent CDC Vaccine Price List was reviewed and updated on July 31, 2012.
[http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm]

The list includes the CDC's "discounted" prices and the higher prices that doctors in private practice must pay for their purchased recommended pediatric vaccines.

Presently the CDC pays $15 for a dose for DTaP, $ 52.10 for a dose of PEDIARIX, a 5 in 1 combination vaccine, $19.33 for a dose of MMR and $ 72.49 for a dose of VARIVAX, the chickenpox vaccine.

A single dose of PREVNAR-13 costs $ 102.03 and every child needs 4 doses.

A dose of 4-valent HPV vaccine costs the CDC $111.96 and each adolescent, whether male or female, is now supposed to receive 3 doses on a prescribed sequence.

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PREVNAR-13

According to a recent study by Pfizer scientists, "The development, clinical evaluation, and postlicensure impact of the pneumococcal CRM(197) protein conjugate vaccine, PCV13, (Prevnar 13®) builds upon the excellent safety and substantial effectiveness of PCV7 (Prevnar®) in preventing pneumococcal disease in children. PCV13 adds pneumococcal serotypes 1, 3, 5, 6A, 7F, and 19A to serotypes 4, 6B, 9V, 14, 18C, 19F, 23F in PCV7 to provide comprehensive coverage for over 85% of epidemiologically important pneumococcal serotypes in the United States and throughout the world." [PMID: 22830997]

The simple fact is that Pfizer would not have needed to develop and market PREVNAR-13 if PREVNAR, now renamed PREVNAR-7 by necessity, had achieved what it was supposed to do. Studies by reliable independent researchers world-wide have consistently and convincingly documented that changes, often serious, in serotype distribution and antibiotic resistance of Streptococcus pneumoniae isolates occurred in children following the introduction of PREVNAR in 2000.

Possibly the most comprehensive independent vaccine review ever written on the vaccine (or in fact any vaccine) is that by Horwin titled "PREVNAR, A Critical Review of a New Childhood Vaccine" that was published September 19, 2000.
http://www.whale.to/v/prevnar2.html

Every parent and indeed everyone should take the time to read or re-read this outstanding well researched critique.

I quoted Horwin liberally when I reviewed the subject in "Pneumococcus: Penicillin to Prevnar / Performance and Problems" in May 2006.
http://www.vaccinationnews.com/node/19895

Coincidentally, the first reference I listed in my review was by Dr. Schuchat et al

In my summary I stated in part:

"…Increases in the carriage of *non-vaccine serotypes* in major pre-licensure clinical trials of Prevnar in Gambia, Israel and South Africa were not publicized by the CDC nor mentioned by the teams involved in the U.S. trials. They were also never considered by the FDA and the ACIP, when Prevnar was licensed and recommended.

…*New* serotype 19A genotypes have appeared in the past three years making serotype 19A, an increasingly drug resistant strain, the leading cause of invasive pneumococcal disease.

…Although pneumococcal vaccination produces significant antibody titers, it does not seem to affect the course of pediatric recurrent otitis media with effusion, the second target of the Prevnar vaccination program.

…Significant decreases in the incidence of pneumococcal bacteremia caused by vaccine serotypes are accompanied by increased incidence of bacteremia due to penicillin resistant *vaccine-related* serotypes.

…An increase in infections caused by pneumococcal serotypes not included in the vaccine is also becoming obvious."

Some of my conclusions were almost prophetic:

"…A more recent 7-valent conjugate vaccine, PREVNAR, had clear problems during pre-licensure trials elsewhere, but apparently not at home.

-Recently, difficulties related to the use of PREVNAR have surfaced in the U.S. and there is every indication that they will only get worse with time.

-There is always a price to pay when one manipulates nature through vaccination.

-An honest reappraisal of PREVNAR, including its unacceptably high cost, is long overdue.

- A head-in-the-sand attitude will not make bad things go away.

- Our new National Immunization Program Director Anne Schuchat is eminently qualified to deal with the situation…"

The amazing story about PREVNAR, now referred to as PREVNAR-7 was that in spite of its problems, it became a spectacular financial success just about everywhere. In a 2007 report by Hedwig Kresse titled "Virile vaccine market sparks growth" the well-known vaccine analyst wrote:

"…Prevnar has become the first blockbuster vaccine, with global sales reaching almost $2 billion in 2006. It has experienced a rapid uptake globally despite its high cost of nearly $320 for the four-dose regimen…" **http://tinyurl.com/bmm9xsl**

Because a more effective pneumococccal pediatric vaccine was needed, Pfizer researchers created a 13-valent product (PREVNAR-13) that included 19A and other emerging strains and the ever-obliging FDA promptly granted a "Priority Status" to the new vaccine's marketing application. **http://tinyurl.com/c3w9ycc**

PREVNAR-13 was licensed on February 24, 2010 to the delight of Pfizer's stockholders. Unfortunately the euphoria was short-lived when to everyone's surprise sales of the new vaccine proved to be not as spectacular as expected. In fact, *sales went down* in 2011. **http://www.drugs.com/stats/prevnar-13**

Pfizer scientists quickly went to work in order to increase the target population and on December 30, 2011, the FDA approved the "pediatric vaccine" for people 50 and older. **http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm285431.htm**

Everyone was happy on New Year's Eve, conveniently forgetting that since 1983 *there already was* an adult 23-valent Pneumococcal vaccine in the United States called PNEUMOVAX-23 that only costs the CDC $22.85.

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The HPV Vaccines

A lot has been written about the HPV vaccines since their introduction and a lot more is certain to be added as experience with those vaccines expands. The vaccines' efficacy in preventing cervical cancer and their reported side-effects are not the subject of this commentary. The financial issues related to GARDASIL, the only vaccine recommended for males, and their similarity to the above-described PREVNAR financial saga are.

Gardasil, licensed in 2006, was vigorously marketed to teen-aged girls and their parents via its "One Less Campaign" and the frequent repetition of the theme song. Unlike commercials for drugs where most of the air time is devoted to the description of every possible side effect, Gardasil commercials only needed to exalt the prevention of cervical cancer.

Strangely, in spite of all the dollars spent on advertising, things did not go exactly the way Merck shareholders had hoped.

On February 4, 2009, in an article titled "Merck Lets Its Gardasil Down" Mike Huckman described how anticipated profits from the sale of the "relatively expensive set of three shots" never materialized and how the sales of Gardasil "fell off a cliff" in Q2 of 2008. **http://seekingalpha.com/article/118340-merck-lets-its-gardasil-down**

This was thought to be due to several causes: The demands for the original target population of 11-18 year-old females being down because many had been vaccinated, the next target of 19-26 year-old females remaining a "marketing challenge" and … the FDA delaying a decision to open up the potential Gardasil market to women as old as 45.

Another "Market" had to be therefore created and launched very promptly.

On May 28, 2010, the CDC used its *Morbidity and Mortality Weekly Report (*MMWR*)* to announce that the FDA had licensed Gardasil for use in males aged 9 to 26. **http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm**

On October 25, 2011, Reuters reported that the Advisory Committee on Immunization Practices, "which advises the U.S. Centers for Disease Control and Prevention", had voted ***to recommend routine use*** of Merck's GARDASIL in 11- and 12-year-old boys.

According to Reuters:

> *"The prior recommendations were based largely on evidence that the vaccine protects boys from genital warts, but the new recommendations reflect several studies showing the vaccine helps prevent cancers in boys as well, Dr. Anne Schuchat, director of the National Center for Immunization and Respiratory Diseases, said in a conference call with reporters.*
>
> *The HPV vaccine offers an opportunity to decrease the burden of HPV in both males and females, Schuchat said.*
>
> *"In addition to providing a direct benefit to boys, there is also the potential that the vaccine will reduce the spread of HPV from males to females," she said.*
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> *Schuchat noted that the HPV vaccine currently is not being as widely used among girls as hoped, and vaccinating boys could help reduce transmission of HPV to girls."* **http://tinyurl.com/66j43pg**

Just six months later, Dr. Schuchat addressed The National Vaccine Advisory Committee to discuss "Vaccine Management" and the rising cost of recommended vaccines from Birth to Eighteen.

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