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The Non-cost-effective Vaccination Program for *Neisseria Meningitidis,* and Other Vaccination-Program Concerns and Suggestions

Introduction

In determining whether a given vaccination program can be cost-effective, the factors that need to be considered are**: a)** all of the costs of the vaccination program, **b)** the estimated number of disease cases prevented, and **c)** the estimated number of deaths from the disease for which the vaccine is claimed to be somewhat protective for some period of time.

In general, for a preventive (prophylactic) vaccination to be cost-effective**: a)** the disease itself must be common (endemic) and have a significant (>10%) mortality rate in those with a clinical case of the disease (e.g., measles in children), **b)** the vaccine must be highly effective (providing true disease protection to more than 90% of those who are inoculated for their "lifetime"), **c)** the vaccine, its administration costs, and its adverse-event costs must be sufficiently low so that the projected average cost savings from vaccination are significantly more than the average disease-case-associated costs, and **d)** the serious adverse reactions (death, permanent disability and life-threatening events) caused by the vaccine must be significantly rarer than those caused by the disease before the vaccine approval and the other vaccination-associated costs (e.g., emergency room visits, hospitalizations and extended hospitalizations) must be sufficiently low so that their population costs are some small fraction of the population administration costs and, collectively, are much less than the costs associated with the disease in the absence of any effective vaccine.

Unfortunately, the requirement that a vaccination program must be truly cost-effective when all of the preceding costs are considered is consistently ignored.

In the current vaccine approval process, the submitter of the application is allowed to**: a)** make unsubstantiated claims of vaccine effectiveness based on anti-body titer, **b)** ignore the costs of the adverse events associated with vaccination, **c)** make unproven claims as to the level of disease protection provided and the duration of the protection provided by the vaccination series proposed and **d)**, using all of the preceding devices, define the cost of any vaccination program in a manner that justifies the list price proposed by the manufacturer for the vaccine.

The Advisory Committee on Immunization Practice (ACIP) to the Centers for Disease Control and Protection (CDC), apparently acting as a rubber stamp for the vaccine makers, simply presumes that the projections offered by the approved vaccine's manufacturer or the researchers whom they have given grants or have otherwise hired are valid and, before (in the case of the now-withdrawn Wyeth RotaShield® rotavirus vaccine), or soon after, approval (in the case of the meningococcal meningitis vaccines (Sanofi's Menomune® and Menactra®, and Novartis' MenVeo®) and the HPV vaccines (Merck's Gardasil® and GlaxoSmithKline's Cervarix®) simply adds the vaccines to the recommended vaccination schedule without any long-term study of**: a)** the in-use performance of the vaccine and **b)** the delayed-adverse-reaction profile for the vaccine.

Then, when the vaccine fails to meet its claimed protection period or protection level, rather than removing the vaccine from the recommended national vaccination program as it should, the CDC, through its ACIP, simply adds one or more booster doses without regard for the reality that, even if the initial vaccination program were cost-effective, the addition of any booster clearly renders it much less cost-effective or, more often, non-cost-effective.

With the preceding realities in mind, let us consider the cost-effectiveness of the original "one dose" meningococcal meningitis vaccination program for children ages 11- or 12- years old, or 13 to 18 years of age if they missed the vaccination at age 11 or 12, and a second dose to college freshman living in dormitories, with the understanding that the ACIP has just recommended a second dose to all children at age 16 because the claimed but unsubstantiated 10-year protection interval used to get the vaccines approved has been found to be overly optimistic and a equally unsubstantiated 5-year period of protection is now being claimed.

The Realities Concerning the Current Meningococcal Meningitis Vaccination Program

Given: **a)** an administered per-dose average cost of US$ 150.00[1]; **b)** an annual US-population segment needing vaccination of about 4,000,000 individuals in the year the vaccine was approved (January 2005); **c)** a maximum vaccine in-use effectiveness of "85%" for the diphtheria-toxoid-(Menactra) and Diphtheria-CRM_{197} (MenVeo)- conjugated oligosaccharide antigens for the "A", "C", "Y" and "W-135" strains in the current recommended vaccines; and **d)** an average *maximum* disease 0.67 strain-prevalence fraction for the covered strains, this mass vaccination program: **1)** with "100 %" coverage, would prevent less than 57% of the disease cases observed annually and **2)** would have an annual cost of in excess of US$ 600 million per fully dosed population segment.

Since this cost estimate does not include the second doses for the college students living in dormitories, it obviously underestimates the maximum costs but it certainly can be used to project an annual cost of about US$ 1 billion for the ACIP's recent 2nd-dose recommendation.

Given that the number of clinical cases reported in 2004, the year before Menactra's approval and the CDC's recommendation to add it to the national vaccination recommendations, were about 1,360 and the cases in 2008, when the claimed uptake was 41.8% of the children between 13 and 18 years of age (5 years and 0.418 x ~ 20 million eligible children ≈ 8.36 million children inoculated) were about 1,170, it would appear that the vaccination program "saved" *no more than* 190 cases (see the cases data in ***Table 1***) at an overall 2008 cost of about US$ 260 million or about US$ 1.4 million dollars per case prevented.

Since about 10% of those diagnosed with a clinical case of N. meningitidis succumb (die), the cost per death prevented for the "19" deaths saved would be about US$ 14 million[2].

The Dissonance between 2010 Realities and Mainstream Media Hype

Late in 2010, prior to the CDC/ACIP recommendation for another dose of vaccine, the mainstream media made much of an apparent outbreak in a Colorado college town.

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[1] The cost estimate is derived from a presumed US$ 50.00 cost for the administration and records keeping associated with each dose and the CDC price list for vaccines found at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm when visited on 3 January 2011, where the CDC per-dose prices for Sanofi's Menactra and Novartis' MenVeo were both US$ 79.75 and the wholesale prices to the market were US$ 106.49 and US$ 103.41 respectively (after Sanofi just raised its wholesale price from $103.41). At retail, per-dose prices of US$140.00 have been reported and the overhead cost in many physicians' offices exceeds US$50.00. Overall, the estimated average per-dose cost of US$ 150.00 probably underestimates the true per-dose costs.

[2] Factually, in 2010, the CDC only claimed a saving of 9 lives annually (see: http://www.fiercepharma.com/story/cdc-panel-backs-additional-vax-doses/2010-10-28?utm_medium=nl&utm_source=internal) (or ~ 90 cases) for the one-dose program, which could increase the overall cost for each death saved in 2008 to about US$ 30 million.

To hear the media tell it, the outbreak could be attributed to the lack of vaccination and everyone, including those who had already been vaccinated, was encouraged to be vaccinated.

Mass vaccination clinics were held at the university and thousands were vaccinated.

However, though the CDC's numbers for disease cases in 2010 are tentative and the number of "meningococcal meningitis"-associated deaths are not available, the current count on notified cases is the lowest that has been reported in the last 67 years (see **Table 2**'s "**Notified Cases**" column 1).

How, except to enrich the vaccines' makers and the healthcare establishment, does this reality justify adding another dose of vaccine?

Obviously, outside of the media's hype and the CDC/ACIP recommendations, there is no medical cost-effectiveness justification for including another dose of any vaccine for meningococcal meningitis in the US recommended vaccination[3] program

Program Realities and Recommended Actions

Clearly, this vaccination program is not a cost-effective use of the American public's healthcare dollars.

Thus, this vaccine should:

a. Never have been added to the US CDC's national vaccination recommendations[4] and

b. Be immediately deleted from all US mass vaccination programs.

Further, given the "deaths" data for the period from 2000 through 2009, it is not clear that the vaccination program has resulted in any significant reduction in deaths for a disease that, in the USA is rare (≤ 1.5 in 100,000 individuals annually) and has generally been below this level since 1970 and was trending below 1 in 100,000 individuals annually since 1999 – 6 years before the first conjugated, general-use vaccine was approved in 2005.

Thus, this vaccine is but another example of a vaccine that was introduced for an already rare disease that was naturally waning in the USA apparently so that, ignoring the vaccination-related deaths and permanent disabilities, any further reductions in disease cases could be attributed to the vaccination program.

Since the CDC's ACIP has just recommended another mass dosing of a meningococcal meningitis vaccine for this rare disease at "16" years of age, the non-cost-effectiveness of this vaccination program is even clearer[5].

Factually, the vaccines for *N. meningitidis* are but further examples of out-of-control vaccination policies where no real regard is given for vaccination-program cost-effectiveness other than the profits that will accrue to the vaccine maker and the healthcare establishment.

From the CDC's own data, it is clear that:

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[3] This writer rejects the use of the term "immunization" as it applies to any vaccination program that does not confer lifetime immunity to the diseases for which the vaccine is supposed to provide protection, where, the term "lifetime", means the protection provided by inoculation with the vaccine that has been proven to last *not less than* 50 years after the administration of one-dose of the vaccine in at least 95% of those vaccinated.

[4] Based on a preliminary assessment, since 1985, the CDC has also wrongly added the vaccines for hepatitis B, Hib, chickenpox, influenza, rotavirus, and human papilloma virus (HPV) to the vaccination programs for children even though none of the recommended vaccination programs using these vaccines is currently medically cost-effective.

[5] See **Table 3**'s footnote 3 .

a. This current vaccination program for preventing *N. meningitidis* infections is not cost-effective even when the costs of the harms[6] caused to some of those vaccinated are not considered, and

b. Any mass vaccination program for *N. meningitidis* using the current vaccines is an obvious waste of our healthcare dollars.

Therefore, the CDC should immediately stop recommending any preventive mass vaccination program for *N. meningitidis*.

In addition, *recognizing that this mass vaccination program is an obvious waste of precious healthcare dollars*, all of the affected States should immediately suspend all recommendations or mandates for the preventive vaccination against *N. meningitidis*.

Then, each of the States should sue the vaccine makers on the behalf of their residents to recover the costs of the vaccination program and the injuries it caused from the vaccine makers, who obtained approvals for, sought inclusion in the US recommended vaccination program, and supplied 'preventive' vaccines for four of the common invasive types of *N. meningitidis*, when they knew, should have known, and were responsible for knowing, that their approved vaccines were not-at-all cost-effective in significantly reducing each State's residents' long-term risk of infection by, or death from an infection by, any one of the nine types (serogroups) of *Neisseria meningitidis*, which are known to cause invasive disease (A, B, C, D, X, Y, Z, 29E and W-135) in the USA, including the diphtheria-toxoid- or Diphtheria-CRM_{197}- linked antigens for the A, C, Y and W-135 types in the current diphtheria-toxin-conjugated vaccines.

Independent Review of All CDC-recommended Preventive Vaccination Programs

Finally, given the reality that the vaccines for *N. meningitidis* are not cost-effective, independent review should be made of all of the other vaccination programs.

Those vaccines for which the overall costs, including the costs of the harm done to some and the costs associated with the vaccine-injuries and the vaccine-related deaths, indicate that a given prophylactic/preventive vaccine is not *medically* cost-effective under the current CDC/ACIP recommendations should either be removed from the national vaccination recommendations or, *if truly cost-effective for all of is components at a reduced number of doses*, the national vaccination recommendations should be scaled back to the point where the use of the vaccine is truly medically cost effective for all of its components.

In instances, like, for example, the vaccine for measles, mumps, and rubella or the vaccines for diphtheria, tetanus and pertussis, where the vaccination program is not cost-effective for one or more components, the vaccine makers should be required to reformulate the vaccine to remove the component or components for which there is no true medical cost-effectiveness.

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[6] For example, in the period from January 2005 through 2010, VAERS added about 7,095 adverse events for children in the age range where the vaccines for *N. meningitidis* were listed, with reports of 20 deaths, 98 life-threatening adverse events, 49 instances of permanent disability, 3007 hospitalizations, 19 extended hospitalizations and 2,412 emergency-room visits. Given a VAERS reporting history of *less than* 10 percent, multiplying the reported instances by 10 would still probably underestimate the real instances. On this basis, to save less than 130 *N. meningitidis* infections and the CDC's about "9" deaths *annually*, the current 'one dose' vaccination program at an uptake level of about 70 % probably *annually* causes in excess of 66 deaths, 161 permanent disabilities, 312 life threatening events, 1,006 hospitalizations, 63 extended hospitalizations and 7,900 emergency room visits (see **Table 3**). Clearly, the risks associated with the current 'one dose' vaccination program outweigh the claimed benefits.

Moreover, the CDC should immediately remove the "Meningoccocal"[7] and other non-cost-effective vaccines from its vaccination recommendations and use other public health strategies to address the rare cases of *N. meningitidis* occurring each year in the USA.

Longer-term Corrective Actions

Pre-approval Corrective Actions

Unlike other types of drugs, the US Food and Drug Administration (FDA) approves vaccines without: **a)** any proof of in-use effectiveness for the claimed protection interval, **b)** mandating that the vaccine formulation does not produce any significant increase in adverse effects in a population of not less than 50,000 healthy individuals than those caused by a true placebo (i.e., a pH 7.4, isotonic saline solution containing glucose at the level of the vaccine components), **c)** demanding that the risk of serious vaccination-associated adverse events be at least 10 times less than the risk of serious adverse events associated with the disease itself, and **d)** requiring the prospective manufacturer of the vaccine to prove that adding the "new" vaccine to the vaccination schedule will not *adversely* impact the long-term health of the actual population who will be vaccinated.

The FDA should be compelled to *immediately* revise its current shoddy vaccine-approval process to require approval standards that are as high as, or higher than, those which are currently required for any other class of drug given as a disease preventive to healthy individuals where the drug can potentially cause both short-term and long-term harm.

Post-approval Corrective Actions

For all "new"[8] vaccines, the FDA should require a minimum 50-year follow up on the health of all those involved in any Phase 3 clinical trial used to obtain approval as well as a minimum 10-year follow-up on the first 1,000,000 individuals inoculated with the vaccine after its approval (an extended Phase 4 trial).

During the 10 years following approval of any new vaccine, the CDC should be prohibited from recommending that it be included in any government-recommended vaccination program.

In addition, the government should be prevented from adding the new vaccine to the National Vaccine Injury Compensation Program's (NVICP's) list of covered vaccines.

Furthermore, the CDC should be prevented from recommending the addition of any "booster" or additional dose of a vaccine to an existing vaccination program unless independent analysis of

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[7] For example, the current CDC recommendations for "Meningococcal Vaccine" read:

"**3. Meningococcal conjugate vaccine (MCV4).**

- Administer at age 11 or 12 years, or at age 13 through 18 years if not previously vaccinated.
- Administer to previously unvaccinated college freshmen living in a dormitory.
- Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, or certain other conditions placing them at high risk.
- Administer to children previously vaccinated with MCV4 or MPSV4 who remain at increased risk after 3 years (if first dose administered at age 2 through 6 years) or after 5 years (if first dose administered at age 7 years or older). Persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose. See *MMWR* 2009;58:1042–3."

[8] For the purpose of this discussion, any change in formulation with respect to any antibody component in an existing approved vaccine would render that vaccine a new vaccine and remove it from the NVICP's list for 10 years. Thus, of necessity, the NVICP would not cover the current ineffective influenza vaccines, which change antigens annually. Similarly, the new Pfizer/Wyeth Prevnar® 13 vaccine would not be covered by the NVICP until some time in 2020 at the earliest.

the data, including the direct and indirect costs associated with the harm from adverse reactions, clearly establishes that the additional dose is *medically* cost-effective.

Moreover, whenever an additional dose of an FDA-approved, NVICP-covered vaccine is added to the US vaccination recommendations, it should be excluded from being covered by the NVICP for a period of not less than 10 years from the date the government recommends that dose.

For all of the existing vaccine formulations approved for less than 5 years:

1. The formulation should be removed from the current US-recommended vaccination program unless: **a)** its current vaccination program were *independently* proven to be *medically* cost-effective and **b)** its risk of serious adverse reactions were *independently* proven to be 10 times or more less than the rate of serious adverse reactions associated with the disease at the disease's pre-vaccine-approval rate of clinical cases.
2. For all vaccines removed from the US recommended vaccination program based on criterion "1", the vaccines should be removed from the NVICP's list of covered vaccines and the removal should be retroactive to the vaccine's approval date.

For all existing vaccine formulations approved for more than 5 years:

1. For vaccines that are given in multiple doses beyond an initial series of no more than 3 doses when they were originally approved, each additional dose should be removed from the US-recommended vaccination program unless: **a)** the current vaccination program, including the last recommended dose were *independently* proven to be *medically* cost effective and **b)** its risk of serious adverse reactions were *independently* proven to be 10 times, or more, less than the rate of serious adverse reactions associated with the disease at the disease's pre-vaccine-approval rate of clinical cases.
2. For vaccines in the US-recommended vaccination program for which the initial vaccination or vaccination series cannot be *independently* proven to be *medically* cost-effective when all costs, including those associated with vaccine-associated adverse events, are considered, the vaccine should be removed from the US-recommended vaccination program.
3. For booster doses or initial series that are independently determined not to be cost-effective in a mass vaccination program, the dose or doses that are not *medically* cost-effective should be removed from the NVICP program beginning on: **a)** the date the additional dose was recommended or **b)**, for non-cost-effective initial doses, the date the initial series was added to the recommended schedule.

Finally, recognizing that the governmental agencies and the vaccine makers have knowingly failed to live up to their commitments to safen vaccines as set forth in the NVICP, except for the tax on each vaccine dose[9], the NVICP should be terminated by act of Congress in 2011.

When vaccines are approved and regulated in the same manner as other types of drugs and the vaccine makers are subject to the same legal liabilities that the makers of other types of drugs bear, then the marketplace may again 'incentivize' the vaccine makers to make safer vaccines.

If vaccines truly are, *as they are continually advertised*, "the safest of medicines", then, the vaccine makers have little to fear from the civil court system.

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[9] The tax will need to continue to provide the funds the "vaccine court" needs to address the thousands of cases remaining in its backlog and to pay the compensation for those claimants, who have won or will win their case.

About the writer, Paul G. King, PhD

Paul G. King, PhD Analytical Chemist, is a scientist who has:

- *Intensively studied:*
  - *the use of mercury compounds in medicine,*
  - *vaccines and*
  - *vaccination programs*

  for more than a decade,
- *Expressed his concerns to the FDA about the approval of Sanofi's Menactra in the review meeting held immediately before the FDA made its decision to approve this vaccine,*
- *Established that he supports mass vaccination programs only when the vaccine has been proven to be reasonably safe, in-use effective, and clearly medically cost effective in the USA or other nation where medical cost-effectiveness[A] has been clearly established when all of the costs, including the costs of all of the vaccination-associated adverse events, have been properly considered.*
- *Sorted out the underlying science to the extent that he could find such from all of the published information available from those with differing views about the vaccines currently recommended by the CDC as a prophylactic health measure for meningococcal meningitis and the 2005 – 2010 and proposed 2011 vaccination programs using those vaccines (Sanofi's Menactra® and Novartis' MenVeo®[B]).*

If any, after reading this article, the cited documents, or any other article published by this reviewer, you find any significant error for which there is unbiased science that clearly supports your alternative view, then, by all means, send your alternative view and the supporting t documentation to me through dr-king@gti.net and, if your studies are truly unbiased, this author will be glad to: ***a)*** *modify his views accordingly and* ***b)*** *publish an updated article reflecting his modified views and crediting you and the unbiased supporting documents you submit.*

If you find areas where the text in this review has grammatical, spelling or word-usage errors, please let the author know so that he may appropriately correct them and publish an appropriately revised version of this article.

For additional information about Dr. King, his interests and his writings, the reader can visit the Internet web site, http://www.dr-king.com/.

A. *In general, Dr. King has come to oppose approval of any mass vaccination program on a "societal cost" basis because such predeterminations have been repeatedly shown to overestimate the cost savings from the vaccination program.*

B *Currently, Dr. King is pursuing a complete listing of the undisclosed ingredients in the MenVeo formulation, which, contrary to the clear labeling requirements set forth in* ***21 CFR § 201.100*** *for parenteral (injected and infused) drugs (see* ***§201.100(b)(5)(iii)****), was approved by the US FDA without the disclosure of the chemical name and, except for buffering agents and isotonic strength adjusters, the amount of each component in the vaccine on a per-dose basis.*

Table 1 ***N. Meningitidis*** **Disease Information from MMWR and CDC Reports**

Year	**2004**	**2005** [vaccine apprv'd]	**2006**	**2007**	**2008** [41.8% cvg 13-17]	**2009**	**2010**	**2011**	**2012**	**2013**
U.S. total resident population (in 1000s)	293,123	295,734	300,151	302,200	304,500	307,006	308,745			
Disease cases	**1,361**	**1,245**	**1,194**	**1,077**	**1,172**	'**980**'	"749"			
Incidence per 100K population	**0.464** 2005 Report	**0.421**	**0.398**	**0.357**	**0.385**	'**0.319**'	"0.243"			
Deaths	**138** [2006 Report]	**123** [2008 Report]	**105** 2008 Report]	"140" [CDC ABC 2007 Report]	"130" [CDC ABC 2008 Report]	"110" [CDC ABC 2009 Report]				
Deaths as % of Cases	*10.1*	*9.88*	*8.79*	*"13.0"*	*"11.1"*	*"11.2"*				
Deaths per million population	**0.471**	**0.416**	**0.350**	"0.463"	"0.427"	"0.358"				
Year	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**
U.S. total resident population (in 1000s)	260,289	262,765	265,190	267,743	270,298	272,691	281,482	285,312	287,422	290,810
Disease cases	**2,886**	**3,243**	**3,437**	**3,308**	**2,725**	**2,501**	**2,256**	**2,333**	**1,814**	**1,756**
Incidence per 100K population	**1.109** [1997 Report]	**1.234** [1997 Report]	**1.296** [1997 Report]	**1.236**	**1.008**	**0.917**	**0.801**	**0.818**	**0.631** [2003 Report]	**0.604**
Deaths	**276** [1999 Report]	**273** [1999 Report]	290 [1999 Report] **286** {2001 Report}	309 [1999 Report] **305** {2001 Report}	234 [1999 Report] **231** {2001 Report}	**227** [2001 Report]	**211** [2002 Report]	**199** [2003 Report]	**161** [2005 Report]	**161** [2005 Report]
Deaths as % of Cases	*9.56*	*8.42*	*[8.44] { 8.32}*	*[9.34] { 9.22}*	*[8.59] {8.48}*	*9.08*	*9.35*	*8.53*	*8.88*	*9.17*
Deaths per million population	**1.060**	**1.040**	[1.10] { **1.078**}	[1.16] { **1.139**}	[0.87] **{0.855}**	**0.832**	**0.750**	**0.697**	**0.560**	**0.555**
Year	**1984**	**1985**	**1986**	**1987**	**1988**	**1989**	**1990**	**1991**	**1992**	**1993**
U.S. total resident population (in 1000s)*	236,158	238,740	241,078	243,400	245,807	247,239	248,710	252,177	255,082	257,908
Disease cases	**2,746**	**2,479**	**2,594**	**2,930**	**2,964**	**2,727**	**2,451**	**2,130**	**2,134**	**2,637**
Incidence per 100K population	**1.163**	**1.038**	**1.076**	**1.204**	**1.206**	**1.103**	**0.985**	**0.845**	**0.836**	**1.022**
Deaths	**300**	**257**	**286**	**258**	**278**	**273**	**215**	**198**	**201** [1997 Report]	**260** [1997 Report]
Deaths as % of Cases	*10.9*	*10.4*	*11.0*	*8.80*	*9.38*	*10.0*	*8.77*	*9.30*	*9.42*	*9.86*
Deaths per million population	**1.270**	**1.076**	**1.186**	**1.060**	**1.131**	**1.104**	**0.864**	**0.785**	**0.788**	**1.008**
Year	**1974**	**1975**	**1976**	**1977**	**1978**	**1979**	**1980**	**1981**	**1982**	**1983**
U.S. total resident population (in 1000s)	211,390	213,121	214,659	216,332	218,059	220,099	226,505	229,307	231,534	233,981
Disease cases	**1,346**	**1,478**	**1,605**	**1,828**	**2,505**	**2,724**	**2,840**	**3,525**	**3,056**	**2,736**
Incidence per 100K population	**0.637**	**0.694**	**0.748**	**0.845**	**1.149**	**1.238**	**1.254**	**1.537**	**1.320**	**1.169**
Deaths									**364**	**299**
Deaths as % of Cases									*11.9*	*10.9*
Deaths per million population									**1.572**	**1.278**
Year	**1964**	**1965**	**1966**	**1967**	**1968**	**1969**	**1970**	**1971**	**1972**	**1973**
U.S. total resident population (in 1000s)	191,141	193,526	195,576	197,457	199,399	201,385	203,805	206,256	208,232	209,851
Disease cases	**2,826**	**3,040**	**3,381**	**2,161**	**2,623**	**2,951**	**2,505**	**2,262**	**1,323**	**1,378**
Incidence per 100K population	**1.478**	**1.571**	**1.729**	**1.094**	**1.315**	**1.465**	**1.229**	**1.097**	**0.635**	**0.657**
Year	**1954**	**1955**	**1956**	**1957**	**1958**	**1959**	**1960**	**1961**	**1962**	**1963**
U.S. total resident population (in 1000s)	161,164	164,308	167,306	170,371	173,320	176,513	179,979	182,992	185,771	188,483
Disease cases	**4,436**	**3,455**	**2,735**	**2,691**	**2,581**	**2,180**	**2,259**	**2,232**	**2,150**	**2,470**
Incidence per 100K population	**2.752**	**2.103**	**1.634**	**1.579**	**1.489**	**1.235**	**1.255**	**1.220**	**1.157**	**1.310**
Year	**1944**	**1945**	**1946**	**1947**	**1948**	**1949**	**1950**	**1951**	**1952**	**1953**
U.S. total resident population (in 1000s)	132,885	132,481	140,054	143,446	146,093	148,665	151,235	153,310	155,687	158,242
Disease cases	**16,312**	**8,208**	**5,693**	**3,420**	**3,376**	**3,519**	**3,788**	**4,164**	**4,884**	**5,077**
Incidence per 100K population	**12.275**	**6.196**	**4.065**	**2.384**	**2.311**	**2.367**	**2.505**	**2.716**	**3.137**	**3.208**

Table 2 ***N. Meningitidis*** **Disease Information from MMWR and CDC Reports**

Year	Notified Cases		Incidence per 100K people	□ Incidence* Rate x 100% [* =yr –yr+1/yr]	Deaths		Deaths per 1,000 K people	□ Death* Rate x 100% [* =yr –yr+1/yr]
2010 [CDC Recommends 2nd dose at "16" yrs]	"749"		"0.24"	"– 24.8"	N/A		N/A	N/A
2009	'980'	2,152	'0.319'	'– 17.14'	'110'	'240'	'0.358'	'– 16.16'
2008 [41.8% uptake in 13-18 yr-olds]	**1,172**		**0.385**	+ 7.84	**130**		0.427	– 7.78
2007	**1,077**	2,271	**0.357**	– 10.30	**140**	245	0.463	+ 32.29
2006	**1,194**		**0.398**	– 5.46	**105**		0.350	– 15.86
2005 [General-use Vaccine approved Jan. 2005]	**1,245**	2,606	**0.421**	– 9.27	**123**	261	0.416	– 11.68
2004	**1,361**		**0.464**	–23.18	**138**		0.471	– 15.14
2003	**1,756**	3,570	**0.604**	– 4.28	**161**	322	0.555	– 0.89
2002	**1,814**		**0.631**	– 22.86	**161**		0.560	– 19.66
2001	**2,333**	4,589	**0.818**	+ 2.12	**199**	310	0.697	– 7.07
2000	**2,256**		**0.801**	– 12.65	**211**		0.750	– 9.86
1999	**2,501**	5,226	**0.917**	– 9.03	**227**	458	0.832	– 2.69
1998	**2,725**		**1.008**	– 18.45	**231** [2001 report]		0.855	– 24.93
1997	**3,308**	6,745	**1.236**	– 4.63	**305** [2001 report]	591	1.139	+ 5.66
1996	**3,437**		**1.296**	+ 5.02	**286** [2001 report]		1.078	+ 3.65
1995	**3,243**	6,129	**1.234**	+ 11.27	**273**	549	1.040	– 1.87
1994	**2,886**		**1.109**	+ 8.51	**276**		1.060	+ 5.16
1993	**2,637**	4,771	**1.022**	+ 22.10	**260**	461	1.008	+ 27.92
1992	**2,134**		**0.837**	– 0.95	**201**		0.788	+ 0.38
1991	**2,130**	4,581	**0.845**	– 14.21	**198**	413	0.785	– 9.14
1990	**2,451**		**0.985**	– 10.70	**215**		0.864	– 21.74
1989	**2,727**	5,691	**1.103**	– 8.54	**273**	551	1.104	– 2.39
1988	**2,964**		**1.206**	+ 0.17	**278**		1.131	+ 6.70
1987	**2,930**	5,524	**1.204**	+ 11.90	**258**	544	1.060	– 10.62
1986	**2,594**		**1.076**	+ 3.66	**286**		1.186	+ 10.22
1985	**2,479**	5,225	**1.038**	– 10.75	**257**	557	1.076	– 15.28
1984	**2,746**		**1.163**	– 5.13	**300**		1.270	– 0.63
1983	**2,736**	5,792	**1.169**	– 11.44	**299**	663	1.278	– 18.70
1982	**3,056**		**1.320**	– 14.12	**364**		1.572	---
1981	**3,525**	6,365	**1.537**	+ 22.57	N/A	N/A	N/A	N/A
1980	**2,840**		**1.254**	+ 1.29	N/A		N/A	N/A
1979	**2,724**	5,229	**1.238**	+ 7.75	N/A	N/A	N/A	N/A
1978	**2,505**		**1.149**	+ 35.98	N/A		N/A	N/A
1977	**1,828**	3,433	**0.845**	+ 12.97	N/A	N/A	N/A	N/A
1976	**1,605**		**0.748**	+ 7.78	N/A		N/A	N/A
1975	**1,478**	2,824	**0.694**	+ 8.95	N/A	N/A	N/A	N/A
1974	**1,346**		**0.637**	– 3.04	N/A		N/A	N/A
1973	**1,378**	2,701	**0.657**	+ 3.46	N/A	N/A	N/A	N/A
1972	**1,323**		**0.635**	– 42.11	N/A		N/A	N/A
1971	**2,262**	4,767	**1.097**	– 10.74	N/A	N/A	N/A	N/A
1970	**2,505**		**1.229**	– 16.11	N/A		N/A	N/A
1969	**2,951**	5,574	**1.465**	+ 11.41	N/A	N/A	N/A	N/A
1968	**2,623**		**1.315**	+ 20.20	N/A		N/A	N/A
1967	**2,161**	5,542	**1.094**	– 36.73	N/A	N/A	N/A	N/A
1966	**3,381**		**1.729**	+ 10.06	N/A		N/A	N/A
1965	**3,040**	5,866	**1.571**	+ 6.29	N/A	N/A	N/A	N/A
1964	**2,826**		**1.478**	+ 12.82	N/A		N/A	N/A
1963	**2,470**	4,620	**1.310**	+ 13.22	N/A	N/A	N/A	N/A
1962	**2,150**		**1.157**	– 5.16	N/A		N/A	N/A
1961	**2,232**	4,491	**1.220**	– 2.79	N/A	N/A	N/A	N/A
1960	**2,259**		**1.255**	+ 1.62	N/A		N/A	N/A
1959	**2,180**	4,761	**1.235**	– 17.06	N/A	N/A	N/A	N/A
1958	**2,581**		**1.489**	– 5.70	N/A		N/A	N/A
1957	**2,691**	5,426	**1.579**	– 3.43	N/A	N/A	N/A	N/A
1956	**2,735**		**1.635**	– 22.25	N/A		N/A	N/A
1955	**3,455**	7,891	**2.103**	– 23.58	N/A	N/A	N/A	N/A
1954	**4,436**		**2.752**	– 14.21	N/A		N/A	N/A
1953	**5,077**	9,961	**3.208**	+ 2.26	N/A	N/A	N/A	N/A
1952	**4,884**		**3.137**	+ 15.50	N/A		N/A	N/A
1951	**4,164**	7,952	**2.716**	+ 8.42	N/A	N/A	N/A	N/A
1950[1]	**3,788**		**2.505**	+ 5.83	N/A		N/A	N/A

[1] **1949**: 3,519 cases, 2.367; **1948**: 3,376 cases, 2.311; **1947**: 3,420 cases, 2.384; **1946**: 5,693 cases, 4.065; **1945**: 8,208 cases, 6.196; and **1944**: 16,312 cases, 12.28. **1948–49**: 6,895 cases. **1946–47**: 9,113 cases.

Table 3 VAERS Adverse-Event Reports from January 2005 to 31 December 2010 for Sanofi's Menactra® for the A, C, Y and W-135 Strains of *N. Meningitidis*

Age Range (in years)	Deaths	Permanent Disability	Life Threatening	Not Serious	Hospitalized	Extended Hospitalization	Emergency Room Visit	Age Range Total
9-12	2	4	12	,976	32	3	462	1,491
12-17	8	32	53	2,041	143	8	1,213	3,498
17-44	10	13	33	1,173	132	8	737	2,106
Totals	20	49	98	4,190	307	19	2,412	7,095
Estimated Raw Totals	"200"	"490"	"980"	"41,900"	"3,070"	"190"	"24,120"	"70,950"
Projected ~ Avg. Annual Adverse Events for ~1 dose of vaccine[1] [at ≈ 80% uptake]	"75"[2,3]	"184"	"357"	---	"1,150"	"71"	"9,033"	----

[1] Based on average uptakes of: "6"% (estimated) for 2005, 11.7% for 2006, 32.4 % for 2007, 41.8 % for 2008, 53.6 % for 2009, and "68.0" (projected from 2008/2009 trend), the average uptake in this period was about "35.6" %. To estimate for 80% uptake, multiplied "Estimated Raw Total" by 2.247 to correct for an average uptake of 80%, divided by 6 to concert to an annualized basis & rounded the result to the to nearest integer to get the "Projected ~ Avg. Annual Adverse Events" in each category.

[2] Based on the CDC's reported claims (see: http://www.fiercepharma.com/story/cdc-panel-backs-additional-vax-doses/2010-10-28?utm_medium=nl&utm_source=internal), the one-dose program is currently, in 2010 with a reviewer-projected 68% uptake in 2010, saves 9 lives from the disease or about 90 clinical cases of meningococcal meningitis at a cost of up to 64 meningococcal-vaccine-associated deaths from severe adverse reactions of which only 6, or fewer, are actually reported to VAERS. Even were there 100% reporting in VAERS, the CDC's reported 9 lives saved from the disease must be offset by 7-8 vaccination-associated deaths, the 18-19 cases of permanent disability, and the 35-36 life-threatening reactions and the costs associated therewith.

[3] Under a two-vaccination scenario, the CDC's reported saving of 24 lives annually (or about 240 cases), an increase of 15 lives saved (or about 150 cases prevented), must be offset by at least double the number of serious adverse events if not more. Thus, at best, the CDC has simply moved the deaths from the disease to deaths from the vaccination; and, at worst, multiplied the overall deaths (disease-associated and vaccination associated) by about a factor of 8. Moreover, the annual vaccination program costs (at 90% average uptake for the first dose and 60 % average uptake for the second dose) will exceed US$ 960 million presuming there are no more price increases. If this scenario does save the CDC's reported 24 deaths, the cost to do so, excluding the vaccination-associated deaths, permanent disabilities and other adverse-event costs from the vaccination program, will still exceed US$ 40 million per life saved annually. Finally, when the vaccine-associated deaths are included, the costs per death prevented will soar. Finally, *if as projected*, vaccination injuries cause more deaths than the disease-related deaths prevented, this vaccination program will join the hepatitis B program for young children as a program that clearly causes much more harm that it protects the health of those vaccinated with the vaccine.