Exhibit 4 –November 2, 2010

A Comparison:

Probable 2009-A-H1N1-Flu-shot-related Fetal Losses and Maternal Deaths in Pregnant Women Attributed to Unverified H1N1-infection-related Complications

—

an Upside-down Risk-Benefit Reality

Prepared by Eileen Dannemann, Paul G. King, PhD, and Gary S. Goldman, PhD
from reports to the VAERS database and reports gathered by CoMeD member Eileen Danneman,
Director of the National Coalition of Organized Women (NCOW) –
as reported on August 11, 2010 & corrected on November 2, 2010

2009-A-H1N1-Flu-shot-related Fetal Losses Compared to Maternal Deaths in Pregnant Women Attributed to H1N1-infection-related Complications

Summary Statement

Based on analysis of data from two different sources, the 2009-A-H1N1 inactivated-influenza vaccination program contributed to an estimated 1,588 miscarriages and stillbirths among women 17 to 45 years of age.

Estimated 2009-A-H1N1-flu-shot-related Miscarriages and Stillbirths

The National Coalition of Organized Women (NCOW) collected data on miscarriages and stillbirths in pregnant women (aged 17 to 45) that occurred after they were administered a 2009 A-H1N1 flu vaccine.

Using the VAERS database (including updates through July 11, 2010) as a second ascertainment source, capture-recapture statistical methods were used to estimate the true number of miscarriages and stillbirths following A-H1N1 flu vaccination in the U.S.

Typically, even so-called "complete" studies conducted by the CDC have been shown to miss from 10% to 90% of the actual cases because of under-reporting.[1]

The capture-recapture estimate, while not 100% accurate, is nonetheless a very cost effective and quick way of attempting to get a complete count of all cases when two or more ascertainment sources (VAERS and the NCOW survey) have failed to collect all the existing cases.[2]

Overall, this approach shows that approximately 15% of the occurrences of a miscarriage or stillbirth were actually reported.

The ascertainment-corrected estimate for the total number of 2009-A-H1N1-flu-shot-associated miscarriages and stillbirths during the 2009-2010 flu season is 1,588 (95% goodness-of-fit confidence interval, 946 to 3587).

---

[1] Hook EB, Regal RR. Capture-recapture methods (Letter). ***The Lancet*** 1992: **339**; 742. Hook EB, Regal RR. The value of capture-recapture methods even for apparent exhaustive surveys; the need for adjustment for source of ascertainment intersection in attempted complete prevalence studies. ***American Journal of Epidemiology*** 1992; **135**:1060-1067.

[2] Goldman GS. Using capture-recapture methods to assess varicella incidence in a community under active surveillance. ***Vaccine*** 2003; **21**: 4250-4255.

The formula and calculations used were based on a "numerically unbiased estimate" for *d* (of the 2x2 matrix cell) given by Hook and Regal. The *b* and *c* terms of the matrix each contain the number of cases that are not duplicates, therefore 248 total cases (178 VAERS/70 other-source) minus 7 duplicate cases. Thus, *a*=7, *b*=171 VAERS cases, and *c*=63 NCOW other-source cases.

Using these figures and the formula for the missed cases: $D_{nue} = (bc)/(a+1)$, yields 1347 (95% C.I., 705 to 3346).[3]

Based on these data, the 241 total cases reported represent about 15.1 % of the capture-recapture estimate of the total number of instances, with the 178 VAERS reports amounting to approximately 11.2 % of this estimated total. Interestingly, since other CDC studies have reported that VAERS typically captures from 1% to 10% of the actual cases (typically the reporting of minor adverse reactions are reported at the lower percentage; while the reporting of more significant or major adverse events occurs at the higher percentage). Thus, the estimate of the true number of 1,588 total cases of miscarriages and stillbirths appears reasonably consistent with these findings.

A Crude Risk-Benefit Assessment for Vaccinating Pregnant Women with Flu Shots Containing an Inactivated A-2009-H1N1 Strain of Influenza

The US Centers for Disease Control and Prevention (CDC) has stated that 56 pregnant women died (it is unknown whether their fetuses died with them in all instances) from complications related to having the H1N1 influenza pandemic virus in 2009.

Unfortunately, the CDC, despite Freedom of Information Act (FOIA) requests, has not been forthcoming with the surveillance data on these cases.

However, Dr. Alicia Siston (of the CDC) did acknowledge that the maternal deaths were mostly unconfirmed H1N1-virus related deaths.

The CDC reported that two (2) actually pregnant women died, obviously along with their fetuses, in their first trimester from H1N1 virus “complications” but their vaccination status is unclear.

By comparison, from the data available as of July 11, 2010, there were 126

---

[3] The Confidence Interval (abbreviated C.I.) provides a lower and an upper range of the actual number of miscarriages. Confidence Intervals are large when the sample size is small and they usually narrow as the sample size increases. As noted, though the estimated number of influenza-vaccination-associated miscarriages and stillbirths is 1620, the actual number of influenza-vaccine-associated miscarriages and stillbirths could be higher than 3,600 and was certainly more than 900.

identifiable first-trimester[4] reports of fetal miscarriage after H1N1 vaccination.

Based on this data, presuming: **a)** the women who died were not vaccinated since they allegedly came down with the 2009-A-H1N1 flu that led to their deaths, **b)** there were about 4 million who were pregnant during the flu season, **c)** the pregnancies were single, and **d)** about 25% of pregnant women were vaccinated with an H1N1 flu shot[5], this means that the risk of fetal death in the unvaccinated mothers who died from H1N1 complications was about 1 in 1,500,000 (1.5 million); while the risk of fetal death in the first trimester was about 1 in 8,000 (126 in 1 million).

Simplistically, based on the results from this analysis, not vaccinating could have been up to about 187.5 times safer for the fetus than vaccinating with the 2009-A-H1N1 flu shot was.

Further, the CDC has reported that, in 2009, 56 pregnant women died in all trimesters from, mostly unconfirmed, A-2009-H1N1-related complications (1 in 53,570).

In comparison, from the data available as of July 11, 2010, there were 241 reports of miscarriage or stillbirth (the 178 reports to VAERS plus the 70 Other-source reports minus the 7 in common to both datasets) in all trimesters after 2009-A-H1N1 vaccination of a pregnant woman.

Here, presuming (worse case) that all of the women who died were not vaccinated and all of their fetuses died, the risk of a fetal death in the unvaccinated pregnant women was about 1 in 53,570.

Based on 1,000,000 vaccinated women and the estimated average of 1,588[6] developing babies who are likely to have died, the fetal-death-risk for the mothers who were vaccinated with the inactivated 2009-A-H1N1 flu shot was 1 in 630.

Simplistically, not vaccinating appears to have been about 85 (95% C.I. = 65-111) times safer for the fetus and may have been as much as 192 (95% C.I. = 148 – 250) times safer for the fetus than vaccinating the pregnant mother with an inactivated 2009-A-H1N1 flu shot.

---

4 Since the trimester data was lacking in many instances, this "126" number is a minimum number.

5 The 25% presumption is based on the emphasis on pregnant women's getting the 2009-A-H1N1 and the previous year's experience balanced by the overall reluctance (as evidenced by the lower utilization of doses of the 2009_A-H1N1 flu vaccine [about 90 million doses] than the seasonal flu [about 114 million doses] in the civilian population) in spite of pressure from healthcare providers, the media, and the CDC to vaccinate.

6 Using a simple capture-recapture evaluation based on the data available as of July 11, 2010, the reporting completeness estimate is 15.0% and the estimated total of A-H1N1 miscarriages and stillbirths is 1,588 (with a 95% C.I. range of 946 to 3587 A-H1N1-associated miscarriages and stillbirths).

Thus, from the viewpoint of the children developing in utero, it would have been far safer for their mothers not to be vaccinated while pregnant.

Moreover, based on the reality that 178 reports in VAERS, the 71 Internet reports, and the 7 identified reports that appear in both datasets as of July 11, 2010 do not extend beyond April 24, 2010, and the fact that vaccinating with the H1N1 flu shots did not stop until the end of June, the estimate for the number of influenza-vaccine-associated miscarriages and stillbirths for the 2009-2010 flu season is likely to be greater than 1588[7].

Why Perpetuate Increased Risk to the Child Developing In Utero?

According to the FDA indications and the manufacturers' package inserts for the 2009-2010 inactivated-influenza vaccines, which carried "Pregnancy Category C" teratogenicity warnings, the flu shot should not be administered to pregnant women unless "clearly needed".

It appears that physicians maintain the latitude to decide on an individual case-by-case basis, whether a patient is at personal high risk and that, in his/her opinion a flu shot is needed despite the lack of safety testing by the manufacture on issues such as fetal harm.

Based on the aforementioned outcomes showing an increased risk of miscarriage and stillbirth in the pregnant women who received this vaccine and the clear lack of "confirmed" A-2009-H1N1-caused maternal deaths, it appears that the 2009-A-H1N1 flu shot vaccination was "clearly needed" in the 2009-2010 flu season solely if the intention of the United States government and its pharmaceutical partners was to test the new clinically untested vaccine on an unsuspecting pregnant population. Another possible reality is the unthinkable — "population-control experimentation".

In spite of the 178 VAERS fetal-death-associated influenza vaccine reports, the FDA has approved seasonal flu vaccines for the 2010-2011 flu season that, in addition to another "A" strain and a "B" strain of influenza, contain the "same" level of the "same" 2009-A-H1N1 viruses that were present in the 2009-2010 pandemic "swine flu" vaccines and has again approved several Thimerosal-preserved flu-shot formulation that may be given to pregnant women without a prominent "Warning: Contains Mercury" caution on the vial.

Furthermore, the CDC is again strongly recommending that pregnant women get these 2009-A-H1N1-containing flu shots (without recommending that those shots must not contain Thimerosal) in spite of the observed 20-plus-fold increase (to 178 plus) in reporting of A-2009-H1N1-associated miscarriages and stillbirths to VAERS as compared to the about seven (7) flu-vaccine-associated miscarriages and stillbirth reported to VAERS in each of the 2007-2008 and 2008-2009 flu seasons.

Without evidence of safety, in 2009, the CDC commenced an inordinately broad public propaganda campaign for the "pandemic" (2009-A-H1N1) flu shot aimed at pregnant women.

This propaganda program included videos, posters, advertisements, chain store and pharmacy involvement and strident "standard of care" recommendations to physicians and vaccine providers knowing that it and all facets of this "pandemic" flu program were protected by federal legislation that held them harmless in case of vaccine injury.

It is to be noted that all these "real" women who had miscarriages and stillbirths in the 2009-2010 2009-A-H1N1 instances reported have no recourse to legal redress, only empty wombs and feelings of disempowerment.

Moreover, though there is a supposed administrative program to provide compensation for such "pandemic"-related vaccine injuries, it has not yet been fully implemented and no funds have been appropriated for the compensation of the vaccine-related injuries to these women.

More egregiously, the campaign to push these untested and novel "Pandemic" 2009-A-H1N1 (Swine Flu) inactivated-influenza vaccine shots on pregnant women included pressuring these pregnant women by repeated warnings that they were putting themselves and their babies in mortal danger if they did not get a 2009-A-H1N1 flu shot.

These warning of impending death were based on mostly "unconfirmed" reports of 2009-A-H1N1-ifluenza-related maternal deaths, despite the availability of reliable testing methods to identify the 2009-A-H1N1 virus.

The following questions need to be asked of our public health officials and the CDC and their answers critically reviewed before any more pregnant women are offered or talked into getting another flu shot during pregnancy:

- Why did the Department of Health and Human Services (DHHS) and the CDC not clearly disclose that the 56 maternal flu-related deaths from the "H1N1" virus were unconfirmed 2009-A-H1N1 deaths and may not all even have been flu-related deaths?

- Why were these maternal deaths not confirmed when reliable testing methods were available in every state?
- Why did the CDC/DHHS and the states' departments of "public health" stop identifying/confirming 2009-A-H1N1 virus as distinct from the seasonal influenza and other circulating influenza type "A" viruses early on in the declared pandemic season?
- Was it grossly negligent on the part of healthcare providers providing obstetrical care not to check the Vaccine Adverse Events Reporting System (VAERS) on their own as the data became available before they continued to give these vaccines to their pregnant patients?
- Why did the CDC fail to warn those who provide healthcare to pregnant women of the increased risk of "miscarriage" associated with the 2009-A-H1N1 vaccines when the reports to VAERS exceeded 5 times the previous years' maximum numbers?
- Why is the CDC knowingly encouraging non-compliance with the statute requiring the basic information about all vaccinations (date of administration, the vaccine manufacturer and lot number of the vaccine, the name and address and, if appropriate, the title of the healthcare provider administering the vaccine, and any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of DHHS) be recorded in each patient's permanent medical records (see 42 U.S.C. § 300aa-25(a)) by allowing and promoting a "kiosk stop and shot" mentality where the public is offered vaccination at unlikely locations (e.g., airports, chain stores, schools, and offices), where it is highly unlikely that requisite information will be recorded in the manner required by law?
- Was this "dire" circumstances charade (orchestrated to increase the vaccine uptake in pregnant women) simply a premeditated, willful "population control" initiative aimed at this population segment?
- Considering the preceding unanswered questions, the emerging data on fetal demise following the mother's vaccination, the FDA-approved manufacturer's warning not to give the flu shot to pregnant women unless "clearly needed" due to a lack of clinical trials for fetal demise and other reasons; the upcoming untested co mingled virus; and the continued use of the neurotoxin, Thimerosal, why would the DHHS, CDC, ACIP, Public Health Service continue to recommend the flu to pregnant women yet another season?

- Can it be argued that it was beyond gross negligence but, in fact, willful misconduct on the part of CDC/DHHS and others to aggressively push this pandemic flu shot on pregnant women based on a few[8] unconfirmed, purportedly 2009-A-H1N1-related, maternal deaths during pregnancy?
- Can it be argued, that, in willfully disregarding the recent VAERS and survey reports of suspected fetal harm, the CDC is wrong to continue its recommendation of the seasonal flu shots containing the inactivated 2009-A-H1N1 virus and, for most doses produced, a preservative level of Thimerosal for pregnant women in 2010-2011 flu season?
- Can it be argued that it is an act of willful misconduct that the CDC does not even provide the VAERS data for the first half of the 2009-2010 flu season for the reported 2009-A-H1N1-vaccine-related adverse event reports of fetal harm in their risk-to-benefit Vaccine Information Statements (VIS) for the coming season's flu shots?

Stark Realities and Odd Public Health Choices

Further, since one of the vaccine manufacturers of a no-Thimerosal seasonal vaccine formulation (see GlaxoSmithKline's Fluarix®) has obtained a "Pregnancy Category B" rating[9,10], why has the CDC failed to recommend that, where possible[11],

---

[8] To put this into perspective, 56 deaths in a population of about 4,000,000 pregnant women is about 1.4 deaths per 100,000 or less than 0.0014 % of the population. This means that more than 99.9986 percent of the pregnant women did not die from 2009-A-H1N1-related causes.

[9] This rating was obtained based on a rat study that gave female rats a vaccine dose that, on a weight basis, was 52 times the level given to pregnant women and found that no adverse effects on the female rats' subsequently conceiving, carry, and delivering normal litters of healthy pups that developed normally [http://us.gsk.com/products/assets/us_fluarix.pdf, last visited on 8 August 2010]. An apparent indication that the 2009-2010 miscarriages and stillbirths in pregnant women were most likely related to the highly toxic Thimerosal component that the Fluarix vaccine tested did not contain. The probability that the miscarriages and stillbirths were induced by he Thimerosal contained in these vaccines is supported by the study published in 1971 by GA Goncharuk [Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. Hyg Sanit. 1971; 36: 40-43], as reported in pages P-31 and P-32 of a citizen petition (see the docket FDA-2007-P-0001; originally filed as 2007-P-0232):

> " By 1971, researchers had become more sophisticated and started evaluating the effects of ethylmercury on several successive generations of offspring.
>
> Goncharuk administered an ethylmercury compound to albino rats, and subsequently, these animals were mated.
>
> Investigations were made of the sexual cycle, and the viability, physical development and fertility of the progeny of the first and second generations.

pregnant women should only be given this flu vaccine, or, when Fluarix cannot be given, a similarly formulated (no Thimerosal[12]) flu shot?

Or is the federal healthcare bureaucracy content to risk another flu season in which potentially hundreds of pregnant women may miscarry or have a stillborn child shortly after they get their Thimerosal-preserved 2010-2011 trivalent inactivated-influenza vaccines that will contain an inactivated-2009-A-H1N1 component[13] because the US National Vaccine Injury Compensation Program, enacted in 1986, generally protects this bureaucracy, the vaccine makers, and the healthcare providers from being held liable for the harm caused to pregnant women who "miscarry" after a flu shot?

Finally, if the 2009-A-H1N1 inactivated-influenza vaccination program most likely contributed to about 1588 miscarriages and stillbirths in women aged 17 to 45 years and about 1,000,000 women received the vaccine, how many of those at least 996,000-plus surviving fetuses suffered lesser levels of lesser harms that have led, or

---

His 1971 paper reported that females that had been previously exposed to the ethylmercury compound became pregnant only on the 4th or 5th occasion when they were placed with males when in estrus, whereas non-exposed control females became impregnated on the 1st or 2nd mating.

The number of offspring per litter was significantly smaller in the animals treated with the ethylmercury compound than in controls.

Moreover, young rats from mothers that had been previously exposed to the ethylmercury compound died significantly more frequently than the controls.

Observations of the first-generation progeny revealed a lag in weight growth in comparison to controls, especially during the 1st and 2nd months of extrauterine life.

In addition, the first-generation progeny had birth weights that exceeded those of the control group, and studies of skeletal ossification in the young rats found a number of cases with retardation of the appearance and development of ossification centers in the bones of the fore and hind paws.

Studies of the organs and the tissues of the first generation progeny revealed mercury in the stomach and intestine at birth and in the first week of life, apparently through the entry of mercury: a) across the placental barrier, and b) by way of their mother's milk, respectively.

Subsequently, the paper noted that the first generation progeny of mothers that had been previously exposed to the ethylmercury compound had significantly reduced fertility in comparison to the controls.

The second-generation progeny also had low viability, lagged in their weight growth, and were retarded with respect to ossification in several cases.

Finally, the researcher reported, when mating the second-generation progeny, that there was a significant decrease in fertility in comparison to the control group".

[10] For more information on the 2010-2011 Fluarix formulation see: http://us.gsk.com/products/assets/us_fluarix.pdf, last visited on 8 August 2010.

[11] Fluarix is only approved for those 18 years of age and older.

[12] The no Thimerosal single-dose formulations of Afluria®, Fluvirin®, and Fluzone® are approved for use in individuals who are under the age of 18 years.

[13] Since some vendors are already shipping vaccines that can be given to pregnant women, this year's flu season, if it is anything like last year's season, will start in early October 2010 at the latest and end in June of 2011 – 9 months later. Since a pregnancy nominally lasts 9 months, it should be obvious that almost all women who conceived in 2010 and at least half who conceive in 2011 will be eligible for a 2010-2011 flu shot.

will lead, to developmental, neurodevelopmental, cardiovascular, gastrointestinal, hormonal and/or behavioral disorders or chronic childhood diseases like childhood asthma, COPD, Crohn's, diabetes, IDCM, MS and leukemia, to name a few?

Given these findings, public health officials **should**:

1. Cease and desist from recommending that pregnant women get flu shots containing an 2009-A-H1N1 influenza viral component (with or without Thimerosal) during their pregnancies, **and**
2. Identify the common component in the 2009-A-H1N1 inactivated-influenza vaccines that caused this surge in miscarriages and stillbirths, which seems to be either the inactivated 2009-A-H1N1 influenza virus or, *more probably*[14], the Thimerosal, the current US trade name for sodium ethylmercurithiosalicylate, used as a preservative or in-process sterilant in the manufacture of most of the doses of 2009-A-H1N1 inactivated-influenza vaccines available to pregnant women, and remove it from all inactivated-influenza vaccine doses that can be given to pregnant women.

End of Exhibit 4 – rev. August 11, 2010

[14] That Thimerosal "more probably" is the cause of the "miscarriage" problem is based on:

- The fact that many of these pregnant women received two doses of Thimerosal-preserved vaccine (one "seasonal" and one "pandemic") and
- The huge differences in the two rat studies discussed in this article [i.e., a Fluarix vaccine formulation containing no added ethylmercury compound with all "normal" outcomes and a multigenerational rat study where chronic-toxicity-level doses of an ethylmercury compound were given to the test rats and no facet of the outcomes monitored {fertilization, carriage to term, litter size, pup morphology, early death, and development into adulthood and reproducing} was "normal" when compared to outcomes observed in the unexposed control rats]