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The Coalition for Mercury-free Drugs (CoMeD) Soundly Refutes World Health Organization's Arguments for Using Thimerosal in Vaccines

The World Health Organization (WHO) has presented arguments as to why developing countries should keep accepting the use of Thimerosal[1] (about 50% mercury by weight) as a preservative in their multi-dose vaccines. However, as CoMeD's rebuttals will establish, the WHO's "arguments" are misleading, fatally flawed and/or invalid.

WHO argument 1: No alternative to Thimerosal has been evaluated and shown to be safe and effective as a preservative in vaccines.

CoMeD rebuttal 1: Safe and effective alternative preservatives are available. For example, 2-phenoxyethanol (2-PE) has been successfully used as a preservative in vaccines for decades. Specifically, 2-PE has been used as a preservative in now Sanofi-Pasteur's IPOL®, an inactivated, multiple-type poliovirus vaccine administered to millions of children in the USA after the US Food and Drug Administration (FDA) approved it in 1989[2]. Additionally, 2-PE was also used as a preservative by GlaxoSmithKline in several other FDA-approved vaccines marketed in the USA in the late 1990s and early 2000s, including GlaxoSmithKline's Infanrix® DTaP vaccine, Havrix® Hepatitis A vaccine, and Twinrix® Hepatitis A/Hepatitis B vaccine[3] before the US formulations were switched to today's single-dose, no-preservative formulations.

In addition, a 2-PE-preserved vaccine formulation was recently shown to be more in-use effective as a preservative during a 30-month period for a multi-dose Pifzer Prevenar 13™ formulation than the corresponding Thimerosal-preserved Prevenar 13 formulation, which failed the European Pharmacopeia's "antimicrobial effectiveness acceptance criteria"[4].

Finally, at times, Thimerosal-preserved vaccines have failed to prevent microbial growth[5] or to maintain sterility[6].

Thus, "**WHO argument 1**" is clearly unfounded.

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1 Thimerosal, Thiomersal, Timerosal, and Merthiolate are the most common trade names for sodium ethylmercuri-thiosalicylate. In the USA, all trade names are capitalized.

2 http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM218597.pdf, last visited on 5 July 2012. Document label is Summary for Basis of Approval - IPOL (PDF - 333KB) on FDA web page located at, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm180053.htm, which is titled, "**IPOL - Poliovirus Vaccine Inactivated (Monkey Kidney Cell)**".

3 http://mercury-freedrugs.org/docs/20110105_CoMeD_onepager_Preservatives_rb.pdf.

4 Khandke L, Yang C, Krylova K, Jansen KU, Rashidbaig A. Preservative of choice for Prev(e)nar 13™ in a multi-dose formulation. ***Vaccine*** 2011 Sep 22; **29**(41): 7144–7153.

5 Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. ***Pediatrics*** 1985; **75**: 299-303

6 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146700.htm.

WHO argument 2: Adequate supplies of vaccines without Thimerosal cannot be made available in sufficient quantities; therefore, some children would not be vaccinated in a timely manner; and this lack of vaccination would have a negative impact on those children's health.

CoMeD rebuttal 2: Many countries have effectively banned the use of Thimerosal-preserved vaccines (e.g., the Union of Soviet Socialist Republics [now, Russia, in the 1980s]; Denmark, Norway and Finland [in the early 1990s]; and the United Kingdom [in 2004]). Though there is no national ban on Thimerosal-preserved vaccines in the United States of America (USA), several states (e.g., California, Delaware, Illinois, Iowa, New York, and Missouri) currently have laws restricting their use in pregnant women and young children.

In no instance has there been a critical 21st-century shortage of any preserved vaccine product in the USA, including one caused by Thimerosal-preserved vaccine-lot sterility failure (see footnote "**6**"), which could not be managed to ensure the most vulnerable were vaccinated in a timely manner.

Moreover, since any instrument (treaty) that would ban the use of Thimerosal in the manufacture of preserved vaccines and other drugs would have a significant transition period, the vaccine makers would have more than adequate time to establish their stocks of preserved vaccines made without the use of Thimerosal and/or no-Thimerosal single-dose vaccines while they phased out the production of their Thimerosal-preserved vaccines.

Therefore, adequate levels of vaccines would be maintained so that all those parents who wanted their children vaccinated would be able to have them vaccinated in a timely manner barring critical worldwide vaccine-manufacturing failures.

Finally, since there has been no study comparing the long-term health of the initially healthy never-vaccinated children to the long-term health of the matched initially healthy, fully vaccinated children, there is no scientifically sound proof that the lack of vaccination truly would negatively impact the overall long-term health of the never-vaccinated children.

Thus, the facts do not support any part of the WHO's compound "**argument 2**".

WHO argument 3: The benefit of vaccines outweighs the theoretical risk of using Thimerosal.

CoMeD rebuttal 3: This WHO argument is fatally flawed. First, in the balancing of "benefits" and "risks", the "weighing" of both must be examined from the viewpoint of the individual being vaccinated. However, since vaccination does not protect all of those who have been inoculated and, *absent exposure to the disease*, there is no benefit to those who have been vaccinated, the benefits for each person are, *at the times of inoculation*, clearly theoretical.

Moreover, since there have been no disease-challenge studies for many vaccines, there is no proof that these vaccines actually will protect anyone inoculated with them from contracting the "covered" diseases, *often misleadingly referred to as "vaccine-preventable diseases"*, when the persons vaccinated are subsequently exposed to any of those "vaccine covered" diseases.

However, though the probability that any given individual will have a serious adverse reaction is not defined, all who are vaccinated do have some real risk of having a serious reaction to the vaccine. Further, these serious adverse reactions may permanently injure, maim, or kill each of those who are inoculated with a given vaccine and have such serious adverse reactions following that vaccination. Finally, many of these serious vaccine risks are clearly documented in the each of the vaccines' package insert.

Thus, *for prophylactic vaccines given to "healthy" individuals*, the benefits are theoretical, while the risks to a given individual may be unknown before the inoculation, but these risks are not theoretical.

In addition, Thimerosal is a mercury-bioaccumulative human carcinogen, mutagen, reproductive toxin, teratogen, and immune-system disruptor at body concentrations below 0.05 part-per-million (ppm) of mercury [below 50 microgram (µg) of mercury per kilogram (kg) of tissue]. Further, Thimerosal's general toxicity "risk" can be defined by how far away the amount of Thimerosal-derived mercury in each vaccine dose is from the average concentration of Thimerosal in the critical tissues (e.g., the brain) of the person inoculated that is a "safe" level for the Thimerosal-derived vaccine mercury (in µg of mercury per kg of body weight). The "safe" body level, for a bioaccumulative mercury-based poison like Thimerosal, is that concentration in any organ in the body that produces no observed adverse effect (NOAE) based on an appropriate extrapolation from a suitable injected-Thimerosal chronic toxicity animal study's established NOEA level (commonly referred to as the NOAEL[7]) for injected Thimerosal in the study animal.

For example, for one FDA-recognized chronic toxicity study in rats[8], the NOAEL $_{\text{Injected Thimerosal, rat}}$ can be used to define the critical NOAEL for both the developing child and the human adult. Further, for rats and central nervous system toxicity, all that is needed to convert a valid general NOAEL $_{\text{Injected Thimerosal, rat}}$ (based on a chronic rat toxicity study) into a NOAEL $_{\text{Injected Thimerosal, adult}}$ is to divide the rat value by 100. Similarly, *for the developing child*, the rat NOAEL should be divided by 1,000[9]

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[7] http://medical-dictionary.thefreedictionary.com/NOAEL, last visited on 6 July 2012: "NOAEL, *n* 'no-observed-adverse-effect-level,' the maximum concentration of a substance that is found to have no adverse effects upon the test subject. Jonas: Mosby's Dictionary of Complementary and Alternative Medicine. (c) 2005, Elsevier".

[8] Mason MM, Cate CC, Baker J. Toxicology and Carcinogenesis of Various Chemicals Used in the Preparation of Vaccines. ***Clin Toxicol***, 1971; **4**(2): 185-204.

[9] The factors in this statement are based on dividing the rat value by 10 to convert from the adult rat studied to adult human and dividing by another factor of 10 to address variability in the human population to get the "divide by 100"

Regrettably, there are no applicable governmental, vaccine-manufacturer, or science-based NOAEL values in a recognized peer-reviewed journal for injected Thimerosal. Factually, since 2004, CoMeD (in citizen petitions and civil law suits in federal court) has repeatedly asked the most responsible US federal officials and their subordinates to provide the requisite NOAELs and the studies from which they were derived. However, neither the US Secretary of the Department of Health and Human Services (Secretary DHHS), nor the Secretary's key subordinate in charge of making certain that the Thimerosal is "safe", the Commissioner of the FDA, nor any FDA official have, *as of 5 July 2012*, been able to provide even the requisite NOAEL values for injected Thimerosal-derived mercury studies using animal-equivalent chronic dosing[10].

Absent these NOAEL values, there is no scientifically sound way to establish how "safe" or "unsafe" injecting a Thimerosal-preserved vaccine may be.

Thus, there is no peer-reviewed, journal-published, scientifically sound basis upon which to weigh the theoretical benefits of a given Thimerosal-preserved vaccine against its toxicological risks.

To partially address this gap in published NOAEL values, CoMeD's Science Advisor has[11], based on one FDA-recognized chronic toxicity study for injected-Thimerosal in rats, estimated the injected-Thimerosal NOAEL values in terms of the bioaccumulative mercury (Hg) contained in the Thimerosal injected. The resulting estimated NOAELs for injected Thimerosal in humans are "0.002" µg of Hg per kg for the developing child and "0.02" µg of Hg per kg for the adult[12].

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value for adult humans. Then, the toxicologist simply divides the adult human value by another factor of 10 to get the "divide by 1,000" value for developing children.

10 Since a pH-balanced, isotonic solution of Thimerosal at its nominal preservative concentration of 100 parts-per-million (ppm) [0.01%] is the level in humans and the dosings are: **a)** a 0.5-milliliter (ml) dose for adults, the children developing in utero, and children 3 years of age and older, and **b)** a 0.25-ml dose for babies under 3 years of age.

11 http://mercury-freedrugs.org/docs/20120514_The_AnythingButMercury_Realities_b.pdf

12 Because the end metabolite of the Thimerosal injected is bioaccumulative mercury that in the human brain, has a half-life of between 18 and 20 years (or, presuming a 80-year life span, between 22.5% and 25% of the human life span in Japan) [Sugita M. The biological half-time of heavy metals. The existence of a third, "slowest" component. ***Int Arch Occup Environ Health*** 1978; **41**(1): 25-40], there is little change in the daily level of "inorganic mercury" that bioaccumulates in the brain. Thus, it is not appropriate to average the dose over any short-term time period. In such instances, the general NOAEL expression in terms of mass of toxicant per kg of body weight per day is not appropriate and the appropriate NOAEL expression reduces to mass of toxicant per kg of body weight. In addition, in a study [Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-Dependent Distribution of ^{203}Hg-Mercury Compounds in Rat and Monkey as studied by Whole Body Autoradiography. ***J Hygenic Chem*** 1971; **17**(2): 93-107] using ^{203}Hg radiolabeled ethylmercury chloride, though the level of mercury in the blood fell rapidly to a level well below the level injected initially in terms of µg of Hg per kg of animal weight, the level in the brain increased in the brain of the short-lived monkeys studied to the point that, *8 days after a single near-vaccine-level dose*, the level of Hg in the brain tissue significantly exceeded (was about 120% of) the initial level dosed in terms of µg of Hg per kg of wet monkey brain tissue. Since humans are continually exposed to low doses of mercury from the food they eat, the water they drink, the air they breathe, and, for breastfed babies, the breast milk they consume, the small daily losses of "inorganic mercury" are probably mostly offset by a percentage of mercury from the low daily doses of mercury from other sources that bioaccumulates in the brain's tissues.

On the preceding basis, even if the young developing child under 3 years of age weighs 25 kg (about 55 pounds), each 12.5 µg of Hg is 0.5 µg of Hg per kg of the child's weight or about 250 times the "safe" level of "0.002" µg of Hg per kg.

For adults weighing 136 kg (about 300 pounds), each 25 µg of Hg injected is about 0.694 µg of Hg per kg of the adult's weight or about 34.7 times the "safe" level of "0.02" µg of Hg per kg.

Based on the preceding values, because, *even for overweight children and adults*, the exposure levels exceed the "safe" levels by large factors, Thimerosal-preserved vaccines are not even toxicologically "safe" as required in the USA by **42 U.S.C. § 262(a)(2)(C)(i)(I)** for administration to either developing children or adults.

Because these vaccines are not toxicologically "safe", the theoretical benefits of Thimerosal-preserved vaccines cannot exceed their toxicological risks because vaccines are "drugs" and, *in the USA*, any drug that is not "safe" is deemed to be an adulterated drug under **21 U.S.C. 351(a)(2)(B)**.

Further, *as outlined in the vaccines' package insert*, Thimerosal-preserved vaccines may cause other serious acute adverse effects, including immediate lifetime disability and death as well as, *in the longer term*, elevated vaccine-associated risks for a variety of serious chronic medical conditions (e.g., asthma, arthritis, cardiovascular disease, diabetes, liver disease, multiple sclerosis, and obesity).

Given the "established" lack of "safety" as well as the serious adverse events associated with inoculation with a given Thimerosal-preserved vaccine, clearly the, *at best*, theoretical benefits of inoculation with a given Thimerosal-preserved vaccine cannot "out weigh" the established "safety" and adverse-reaction risks.

Hence, the theoretical "benefit of vaccines" does not outweigh the established "risk of using Thimerosal" as a preservative in said vaccines' formulations.

Therefore, "**WHO argument 3**" is clearly specious.

WHO argument 4: The cost of switching to alternative preservative vaccines would be too much.

CoMeD rebuttal 4: The cost of switching to an alternative preservative is estimated by the World Health Organization to be $1 million per vaccine globally[13]. So, if there were 30 vaccines that required this switch, the cost would be about $30 million to switch all vaccines to a Thimerosal-(mercury)-free formulation. The estimated lifetime cost of caring for a US child with a serious neurodevelopmental disorder is conservatively estimated "to be more than $2.3 million for a person with an autism spectrum disorder (ASD) and intellectual disability and $1.4 million for a person with ASD and no intellectual disability"[14]. Thus,

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[13] As reported during the UNEP INC4 meeting 27 March – 2 April 2012 in Punta del Este, Uruguay.

[14] http://www.autismspeaks.org/science/science-news/autism%E2%80%99s-costs-nation-reach-126-billion-year, second paragraph. However, other articles from 2004 and 2006 cite higher costs (for

even if this cost were $30 million, saving 15 to 20 children from an ASD diagnosis in the USA would more than offset this cost.

Currently, in the USA, *after correcting for the most recent increase in the CDC's estimated incidence for an ASD diagnosis from 1 child in every 110 children to 1 child in every 88 children*[15], the annual estimated costs, *based on research reported in March of 2012*, have increased to the point that the costs currently exceed $157.5 billion per year"[16] to care for children with a diagnosis in the autism spectrum *without correcting for the underreporting inherent in the CDC's reported survey numbers for individuals with an ASD diagnosis*.

Even if stopping all the remaining usages of the remaining Thimerosal-preserved vaccine formulations marketed in the USA only reduced the rate for an autism diagnosis by 50% (from the estimated "1 child in 88"[17] to "1 child in 176" – not the "1 child in 1272" seen in Denmark[18]) and the average lifetime for these children was only "70" years, the yearly increase in costs in the USA, ignoring inflation, would decrease by about $0.6 billion and, *instead of spending about $158.7 billion*, the US would only need to spend about $158.1 billion in the near term without any switching costs since there are no-Thimerosal versions for all the US FDA-approved Thimerosal-preserved vaccines still being marketed in the USA.

If, as in Denmark, the rate for autism fell to "1 in 1272", then, ignoring inflation, the yearly cost increases in the USA would decrease by more than $1.1 billion so that, *in the near term*, the yearly cost would only increase to about $157.6 billion and, if the "1 in 1272" autism rate and near-zero inflation in medical costs were to hold, should start to decrease in a few years.

Since:

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example, http://www.apa.org/monitor/dec04/autism.aspx, which cites a $6 million cost of care for each "untreated" child with autism to age 50; and http://www.hsph.harvard.edu/news/press-releases/2006-releases/press04252006.html, which states, "It can cost about $3.2 million to take care of an autistic person over his or her lifetime"). Even using the 2006 article's $3.2 million and allowing for an inflation in costs of care of only 10% per year through 2011, the 2012 per capita costs for lifetime care would be about $5.7 million. Based on this estimate, the cited current average lifetime cost of about $1.76 million is probably low by a factor of 3.

15 http://www.autismspeaks.org/science/science-news/autism-prevalence-rises-1-88

16 http://www.autismspeaks.org/science/science-news/autism%E2%80%99s-costs-nation-reach-126-billion-year. The first paragraph reported, "New research estimates that autism's costs to the nation have reached $126 billion per year. The figure expands on previous estimates by including indirect costs such as lost family income and productivity in addition to the direct costs of autism-associated care" However, the fourth paragraph reports, "Drs. Knapp and Mandell calculated autism associated costs using the CDC's 2009 ASD prevalence figures of 1 in 110. This past Thursday, the CDC significantly increased their prevalence figure to 1 in 88". Correcting for the increased case rate by multiplying the reported value by [110/88] increases that amount to at least 157.5 billion per year.

17 http://www.cdc.gov/media/releases/2012/p0329_autism_disorder.html, "**CDC estimates 1 in 88 children in United States has been identified as having an autism spectrum disorder**".

18 A 2010 value derived from data in a US Associated Press (AP) release on a study of the possible link between jaundice and autism in Danish children that were born between 1994 and 2004, the "autism" rate was about 1 in 1272 [577/733,826] (http://lubbockonline.com/health/2010-10-11/danish-study-jaundice-autism-newborns-raises-unanswered-questions

a. Most vaccines recommended for children were never Thimerosal-preserved (e.g., all of the childhood live-virus vaccines [the measles, mumps, rubella, varicella, poliovirus, and rotavirus vaccines] and the Sanofi inactivated polio vaccine);

b. There were FDA-approved multiple-dose formulations using 2-PE as the preservative that were manufactured by GlaxoSmithKline for the US market in the late 1990s and early 2000s for DTaP, Hepatitis B, and Hepatitis A; and

c. Pfizer has a developed, 2-PE-preserved multi-dose Prevenar 13 formulation,

all that is required for a complete set of multi-dose childhood vaccines without using Thimerosal as that preservative in those vaccines requiring a post-dose-removal preservative is the development of suitable alternate-preservative multi-dose formulations for: **a)** the BCG vaccines, **b)** the *Haemophylis infuenzae* type B vaccines, and **c)** the appropriate multi-dose meningococcal meningitis (*Neisseria meningitidis*) vaccines.

Hence, the actual developmental costs for "new" vaccines would, presuming the WHO's developmental costs of $1 million is valid, should be significantly less than $10 million provided the existing preservative technologies were shared with all the recognized vaccine makers.

Thus, the overall cost of replacing Thimerosal with a suitable preservative, like 2-PE, are far less than the ongoing costs of caring for a 1-plus % level of children with a diagnosis of "autism" in the USA where the maximum Thimerosal-exposure from the early childhood vaccines has been replaced by more than an equivalent maximum exposure from Thimerosal-preserved flu shots[19], when, based on the "autism" level in Denmark, a country *where no Thimerosal-preserved vaccines haven been used since 1993*, less than 0.078 % of all of the Danish children born between 1994 and 2004 have an "autism" diagnosis[20].

To the extent that stopping the use of Thimerosal-preserved vaccines in Denmark actually reduced the incidence and prevalence rates for diagnosed "autism" cases[21], the

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[19] http://dr-king.com/docs/090813_fnldrft_TheNoThimerosalPreservedVaccineLie_r6b.pdf.

[20] In the previous medical mercury-poisoning epidemic, where the main source of the mercury poison was Calomel, mercurous chloride (about 85% mercury by weight), an inorganic mercury compound, contained in "teething powders" and "worming preparations" and the "disease" was diagnosed as "Pink disease" or "acrodynia", removal of these products from the market caused the peak 1 in 500 cases of "Pink disease/acrodynia" in babies who were exposed to Calomel via teething powders and worming preparations to drop to virtually zero new cases (< 1 new case in every 10,000 children) when all of the Calomel-containing medical products were finally removed from the market. Ironically, some children who are mercury poisoned by their cumulative exposure to Thimerosal-preserved vaccines and other mercury sources also can exhibit the general symptoms that were used to diagnose "Pink disease" (see: http://www.pinkdisease.org/whatisPD.htm). Finally, a recent study (Shandley K, Austin DW. Ancestry of Pink Disease (Infantile Acrodynia) Identified as a Risk Factor for Autism Spectrum Disorders. ***J Toxicol Environ Health, A***, 2011; **74**: 1185-1194) seems to confirm that a person's inherited "genetic susceptibility" to mercury poisoning is a factor in autism spectrum disorders.

[21] http://dr-king.com/docs/20120331_FalsusInUnoFalsusInOmnibusAThimerosalpreservedVaccineConundrum_b.pdf, in the section titled, "**Key Denmark Study's 'Findings' Proven to Differ from the Facts**", beginning on page 1 with the supporting "**Included Redacted Email**" (on page '4'). "Recently revealed documents obtained from the CDC using the U.S. Freedom of Information Act (FOIA) process have uncovered proof that, on, or after, "*Wed 13-11-2002*", some, if not all, of the authors in the key Danish study cited in this discussion and the CDC's liaison person knew that '***the incidence***

healthcare cost savings from stopping the use of Thimerosal-preserved vaccines should more than offset the development costs for multi-dose vials preserved with an alternate preservative such as 2-PE.

Thus, the facts clearly do not support "**WHO argument 4**".

WHO argument 5: We need Thimerosal in vaccines in developing countries because they do not have adequate refrigeration capacity to support the use of single-dose vials.

CoMeD rebuttal 5: If the preservative system is changed to use an alternate, effective, non-bioaccumulative, non-mercury compound or compound mixture as the preservative instead of Thimerosal, this argument, *predicated on the implied necessity of a switch from multi-dose vials to single-dose vials*, vanishes.

Further, accepting that the WHO knows that developing countries have critical refrigeration capacity issues that these countries cannot easily address, the WHO would not have raised this "cold chain" vial-space issue without raising the various cost-issues[22] inextricably linked to the switch from a Thimerosal-preserved multi-dose vaccine to a single-dose vaccine that is neither Thimerosal-preserved nor contains any added Thimerosal.

In addition, according to the preservative effectiveness acceptance criteria in the US Pharmacopeia and the European Pharmacopeia: Thimerosal, *in the actual vaccine formulation at 0.01%*, may be or become ineffective as a preservative well before the expiration date for the Thimerosal-preserved vaccine lot[23]. Moreover, adding Thimerosal (also known as Merthiolate) at a preservative, 0.01%, level to a vaccine formulation has been proven to significantly increase the toxicity of the vaccine[24].

Thus, "**WHO argument 5**" here is, at best, misleading because single-dose vials are not needed when, *as has been shown*, an alternate compound, like 2-PE, can be used as the preservative for multi-dose formulations of vaccines that require a preservative.

Finally, in making "**WHO argument 5**", the WHO fails to mention, much less address, the realities that **a)** Thimerosal is not always effective in the vaccine formulation when used as a preservative (see footnote "**19**") and **b)** its use as a preservative significantly increases the toxicity of the vaccine dose (see footnote "**20**").

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and prevalence' [of 'autism'] '***are still decreasing in 2001***'", where the bolded text in a "Times New Roman" font was taken from a key redacted email obtained from the US Centers for Disease control and Prevention (CDC).

22 Since, besides the developmental costs for a single-dose, no-Thimerosal vaccine, which the WHO argument here does not address, there are capital equipment costs to add a new single-dose filling line or retool an existing multi-dose filling line to fill single-dose vials that the WHO argument also ignores, it would appear that "***WHO argument 5***" is an intentionally misleading argument.

23 Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. **Pediatrics** 1985; **75**: 299-303.

24 Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. ***Appl Microbiol***. 1967; **15**: 590-593.

WHO argument 6: The multidose vials with thimerosal are needed because they require less storage space than the single-dose vials.

CoMeD rebuttal 6: Again, the WHO's argument is misleading because it addresses a vial-size issue for which the WHO has provided no foundation (see footnote "**18**"). As it was for "**WHO argument 5**", when an alternate preservative is used, *an argument for which the WHO has addressed the cost aspect*, the same multi-dose vials that are currently being used for the multi-dose vaccines can still be used[25].

Since the argument is again a multi-dose versus single-dose argument, "**WHO argument 6**" is simply expressing another deceptive version of "**WHO argument 5**".

Therefore, in the simple context of replacing the use of Thimerosal as a vaccine preservative with a suitable alternative preservative system, "**WHO argument 6**" is simply another tangential argument.

However, for both "**WHO argument 5**" and "**WHO argument 6**", where the underlying issues go beyond simply the size of the "cold spaces" and "storage spaces" required to address the critical cost issues, the critical cost issue that is ignored is the excess costs from the increased vaccine toxicity that adding a preservative level of Thimerosal to a vaccine formulation has been proven to provide (see footnote "**20**").

While the WHO's position is that Thimerosal-preserved vaccines are "safe", the WHO has no scientifically sound and appropriate toxicity data that clearly shows that:

- **a.** Exposing a developing fetus to some significant portion of the nominally 40 to 62.5 micrograms (µg) of Thimerosal in a Thimerosal-preserved flu shot, or
- **b.** Injecting nominally 20 to 31.2 µg of Thimerosal in a 0.25-mL dose of a Thimerosal-preserved vaccine into a developing child under three years of age, or
- **c.** Injecting nominally 50 to 62.5 µg of Thimerosal in a 0.5-mL dose of a Thimerosal-preserved vaccine into a developing child that is three years of age or older, or
- **d.** Injecting nominally 50 to 62.5 µg of Thimerosal in a 0.5-mL dose of a Thimerosal-preserved vaccine into an individual who is over 18 years of age

does not result, *for the smallest individuals and/or the most mercury-poisoning susceptible individuals in each group*, in a level of Thimerosal-derived mercury in the recipient that exceeds the applicable scientifically sound and appropriate no observed adverse effect level (NOAEL) for the Thimerosal-derived mercury exposure in such persons.

Based on the NOAEL values outlined in "**CoMeD rebuttal 3**", the preceding mercury exposures from a single vaccine dose are neither "safe" nor "nontoxic" for the

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[25] At worst, depending upon the compound or compounds used as a preservative, the elastomeric material facing the vaccine solution in the "stopper" being used to close the vial might need to be changed to a different one if there were stopper/preservative compound compatibility or leaching issues.

persons inoculated with the applicable dose of a Thimerosal-preserved vaccine.

Furthermore, based on the information that is provided in "**CoMeD rebuttal 4**", the removal of Thimerosal-preserved vaccines in Denmark has contributed to the reality that the true incidence and prevalence of "autism" in Denmark is, *for Danish children born in the 1994-2004 timeframe (see footnote "**14**")*, less than 7% of the CDC's most recent guesstimate (see footnote "**13**") for "autism spectrum disorders (ASDs)" in children born in the 1999-2000 timeframe in the USA when Thimerosal-preserved childhood vaccines were used. In addition, though their published paper claimed "autism" increased after the Thimerosal-preserved vaccines were withdrawn in Denmark, some of the publishing authors' internal emails, obtained under the US Freedom of Information Act (see footnote "**17**"), and reviewer observations[26] from a journal that rejected the paper before it was published in ***Pediatrics*** in 2003[27], found that *both the incidence and the prevalence of "autism" actually decreased after Thimerosal-preserved vaccines were removed from the Danish market.*

Given the millions of US dollars that it really costs on average to care for each of these children diagnosed with an ASD, it is clear that the costs of caring for these "mercury-poisoned children" in the cohorts having an ASD diagnosis dwarfs the costs of switching from a Thimerosal-preserved vaccine formulation to a vaccine formula that uses no mercury compound for its preservative system.

Therefore, both "**WHO argument 5**" and "**WHO argument 6**" are also **fatally flawed arguments** that blatantly ignore the staggering costs of the "autism" cases, which to some degree, or percentage, have been shown to be caused or triggered by the mercury-poisoning effects of the Thimerosal-preserved vaccines given to pregnant women and developing children without the requisite proofs of toxicological safety.

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[26] Unpublished documents obtained from the CDC via a Congressional request and shared with a CoMeD member who is currently suing to have his FOIA (Freedom of Information Act) request properly answered (see . 1-2011-cv-01276-ABJ filed in the United States District Court for the District of Columbia).

[27] Kreesten M. Madsen, Marlene B. Lauritsen, Carsten B. Pedersen, Poul Thorsen, Anne-Marie Plesner, Peter H. Andersen and Preben B. Mortensen, "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data", ***Pediatrics*** 2003; **112**: 604-606). The article's abstract contained the following statement (emphasis added), "The discontinuation of thimerosal-containing vaccines in Denmark in 1992 was followed by an increase in the incidence of autism".

Yet, after seeing the claims in this study and other epidemiological studies like it, the Danes did not revert to using Thimerosal-preserved vaccines. Moreover, *based on a 2011 report*, the Danish level of autism dropped to a level of about 1 child in every 1272 Danish children.

In contrast, in the USA: **a)** the early Thimerosal-preserved vaccines did not begin to be phased out until late in 2001; **b)** these vaccines were only slowly phased out with some lots not expiring until some time in 2005; and **c)** starting in 2002, replaced by recommendations that allowed Thimerosal-preserved flu shot to be given to young children so that the maximum cumulative dose of Thimerosal from Thimerosal-preserved flu shots currently exceeds the maximum level from the early childhood vaccines in 2000 by more than 150% as of 2010. Thus, *rather than declining*, the CDC's guesstimated incidence of ASDs in the USA has continued to rise from "1 in 166" in 2004 to "1 in 110" in 2008 (for children born in 1994 and 1996) and to "1 in 88" in 2012(for children born in 1999-2000).

Based on an examination of: **a)** the general reports by the CDC, **b)** the CDC's failure to correct for underreporting in those state locations where such corrections were possible, and **c)** the higher level of incidence in those state locations where their were multiple independent reporting sources, this writer guesstimates that the "true" level for ASDs in the USA today is roughly "1 in 40" (about 2.5%) with an "autistic disorder" level that is roughly "1 in 69" (about 1.4%) using the general diagnostic criteria set forth in DSM IV.