Facility Automation Management Engineering (FAME) Systems
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Wednesday, 9 November 2005

To Whom It May Concern:

The review that follows this introductory letter is a critical assessment of the opinions expressed by Dr Michael Fitzpatrick, which were electronically published at http://www.spiked-online.com/Articles/0000000CAE25.htm, apparently a web site based in England, which I visited as a part of my research in this area on 5 November 2005.

In general, to clearly differentiate between my assessment comments and those of the author, the author's printed statements are quoted in a "Times New Roman" font followed by this reviewer's remarks in an indented "**Nimrod**" font.

In cases where there is an important spelling or grammatical error, that error is noted by using a parenthesized "sic; *correction*" text "(sic; *xxxxx*)" insertion inserted immediately after the error.

Quotes from general reference articles and documents will be presented in an "Arial" font and federal laws and statutes will be quoted in a "Lydian" font.

For those who have access to a color printer, this reviewer's comments are made in a blue color with text needing correction in **red**.

A draft of the reviewer's was submitted to the writer on 5 October 2005, who responded to this reviewer on 7 October 2005 (**see Appendix A**); and the one issue, the degree to which the National Autistic Society receives pharmaceutical industry support, which the writer of the original raised, was addressed by deleting that phrase from the draft.

Should anyone find any factual misrepresentations in this reviewer's remarks, then this reviewer requests that the factual error along with the scientifically sound and appropriate documents that prove your point to this reviewer so that this reviewer can learn from you, incorporate that new knowledge into his understanding, and, where indicated, appropriately correct this document.

Respectfully,

Paul G. King, PhD, MS, BA
Founder, **F.A.M.E. Systems**

An In-depth Review of "When quakery kills …"

"When quackery kills

The tragic death of a five-year-old autistic boy in the USA following treatment with mercury chelation reveals the dangers of alternative therapies.

by Dr Michael Fitzpatrick"

"The tragic death of a five-year-old autistic boy in the USA this summer following mercury chelation - a treatment now being promoted by groups of parent activists on both sides of the Atlantic - reveals the dangers of alternative therapies."

First, the writer is partially correct.

A five-year-old boy, Abubakar Nadama, tragically died while he was being administered an EDTA chelating agent.

However, the doctor is incorrect in that the chelating agent used, some form of EDTA, is *not* recognized as an effective chelating agent for mercury.

Intravenous EDTA chelation is *generally* recognized as a treatment for removing other metal ions (e.g., lead, arsenic, and aluminum from those diagnosed as being poisoned by said metal ions.

Thus, the writer's "with mercury chelation**" is, at best a misnomer.**

Furthermore, chelation is a medically recognized therapy (and *not*, as the writer's rhetoric, "dangers of alternative therapies**," suggests, *an* "*alternative therapy*") for the detoxification of those who have been proven to be intoxicated (poisoned) by some metal or metal compound to which they have been exposed through ingestion, inhalation, and/or injection.**

In addition, the therapy being used in this case was *not* a treatment "being promoted by groups of parent activists on both sides of the Atlantic**."**

Factually, the EDTA chelation therapy being used was a treatment *prescribed* by a licensed medical doctor.

"Abubakar Tariq Nadama lived with his family - of Nigerian origin - in Batheaston in Devon, England, until his mother took him to Portersville, Pennsylvania, where the Advanced Integrative Medicine Center offers to eliminate mercury from the body through the intravenous injection of the chelating agent EDTA (1)."

As this reviewer has previously stated, the treatment purportedly offered "to eliminate mercury from the body through the intravenous injection of the chelating agent EDTA**" is *not* generally recognized as an appropriate treatment for the chelation of bound mercury in the body so that the chelated mercury may be eliminated excreted).**

"A growing number of campaigners believe that autism is the result of mercury toxicity, caused, at least in part, by the mercury-based preservative thiomersal (thimerosal in the USA) formerly used in childhood vaccines."

The writer's statement seems to be factually incorrect here because:

1. **Many of the "**campaigners**" know that the Thimerosal (Thiomersal in the UK) causes mercury poisoning at levels below 20 nanograms of Thimerosal (10 nanograms of mercury) per gram of tissue.**
2. **As of 6 September 2005, CDER Vaccine Thimerosal web page[1] shows that the vaccine manufacturers are *now* shipping 7 "Thimerosal preserved" vaccines:**

[1] http://www.fda.gov/cber/vaccine/thimerosal.htm

- **All of the multi-dose vials of Aventis Pasteur, Incorporated's "Meningococcal" vaccine, Menomune®,**
- **Aventis Pasteur, Limited's multi-dose "DT" vaccine,**
- **Mass Public Health's "Td" vaccine**
- **Aventis Pasteur, Incorporated's "TT" vaccine,**
- **Most lots of Aventis Pasteur, Incorporated's "Influenza" vaccine, Fluzone,**
- **Most lots of Chiron/Evans' "Influenza" vaccine, Fluvirin, and**
- **BIKEN's, "Japanese Encephalitis" vaccine, JE-VAX, which is distributed by Aventis Pasteur, Incorporated,**

along with 9 "Trace Thimerosal" or "Near-Trace Thimerosal" vaccine products:

- **Aventis Pasteur, Incorporated's "DTaP" vaccine, Tripedia,**
- **Aventis Pasteur, Incorporated's "DTaP-Hib" vaccine, Trihibit,**
- **GlaxoSmithKline's "DTaP-HepB-IPV" vaccine, Pediarix,**
- **Aventis Pasteur, Incorporated's single-dose "DT" vaccine,**
- **Aventis Pasteur, Incorporated's "Td" vaccine, Decavac,**
- **GlaxoSmithKline's "Hepatitis B" vaccine, Engerix-B,**
- **GlaxoSmithKline's "HepA/HepB" vaccine, Twinrix,**
- **GlaxoSmithKline's "Near Trace[2] Thimerosal/mercury" influenza vaccine, Fluarix, and**
- **The "Preservative Free" lots of Chiron/Evans' "Influenza" vaccine, Fluvirin.**

Thus, including other vaccines containing Thimerosal (which are still in-date though not currently being released into the US market), today there are at least 18 in-date vaccine products in commerce that contain some level of Thimerosal with half of these vaccine drug products containing a preservative level of Thimerosal.

Of these, currently *only* JE-VAX, "Td" and "TT" vaccines are *not* routinely administered to children 18 and under.

The Menomune vaccine is given to high schoolers entering the military or headed to colleges.

Though *not* routinely administered, JE-VAX is administered to American children who will be traveling in the Far East where Japanese Encephalitis is endemic.

3. **As was the case with the previous mercury poisoning (by the addition of Calomel [84.98% mercury; very sparingly soluble mercury (I) chloride] to teething powders in the late 1800s to 1940 in the US, which the medical profession diagnosed/labeled as the causeless "Pink Disease" and "Acrodynia" instead of diagnosing the harm observed as the mercury poisoning as they should have), the current medical profession is knowingly using a variety of causeless diagnoses/labels, including "autism," to hide the mercury poisoning caused by the injection of Thimerosal-containing vaccines into babies, children, adolescents, adults, and the elderly, where Thimerosal is known to be highly toxic at levels below 20 ppb (20 ng of Thimerosal per gram [or mL] of material) as well as a systemic and persistent accumulative poison through its initial metabolite, ethylmercurihydroxide, and its final metabolite, "bound inorganic mercury," which, *based on large-mammal studies*, has a half-life of decades.**

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[2] A "Near-Trace Thimerosal" vaccine is any vaccine that nominally contains **not** more than 1.25 µg/0.5-mL dose.

"Many parent activists claim that chelation therapy has produced dramatic improvements in their children."

Factually, the doctors treating children having confirmed diagnoses of either mercury poisoning or heavy metal poisoning, have established that, *in a holistic treatment regimen*, the careful use of chelation (using DMSA, DMPS and/or some dietary supplement chelating agents) has been shown to produce significant long-term improvement in those children who have been chelated until the majority of the mercury in their bodies has been removed provided the supportive dietary and other measures (medicines, diet, and education) are maintained.

"Shortly after his third course of treatment, Abubakar sustained a cardiac arrest and died."

Factually, "Abubakar sustained a cardiac arrest and died**" during "**his third course of treatment**" – *not* after it.**

"In 2004, the US Institute of Medicine systematically examined - and rejected - claims that vaccines (MMR as well as those containing mercury) may cause autism (2)."

Factually, the IOM report's summary reported (bolding added for emphasis):
"This eighth and final report of the Immunization Safety Review Committee examines the hypothesis that vaccines, specifically the measles-mumps-rubella (MMR) vaccine and thimerosal-containing vaccines, are causally associated with autism. The committee reviewed the extant published and unpublished epidemiological studies regarding causality and studies of potential biologic mechanisms by which these immunizations might cause autism. **The committee concludes that the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism**. **The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism**. The committee further finds that potential biological mechanisms for vaccine-induced autism that have been generated to date are theoretical only."

Thus, the IOM did not reject either hypothesis but, as the bolded passages clearly state, found that the epidemiological evidence the committee reviewed favored "rejection of a causal relationship between**" the MMR vaccine and Thimerosal-containing vaccines and the causeless neurodevelopmental disorder "**autism."

The preceding is problematic for two reasons:

- **The summary clearly indicates that the findings of the IOM discounted or did *not* consider the applicable in vitro and in vivo research and case studies, which: a) dated from the 1930s through early 2004 and b) clearly established that injecting Thimerosal into living systems mercury poisons them, and**
- **The epidemiological evidence was *not* sufficient to reject either of the two hypotheses *nor*, because of the nature of the epidemiological studies considered, was the hypothesis of a link between total Thimerosal exposure and the risk of autism properly evaluated. [Because more than 80% of those diagnosed with "autism" are males and this diagnosis *cannot* be truly confirmed until the children are 5 years of age, the most applicable epidemiological studies (those involving US children) should have excluded all females and all males under 5 years of age, but they did *not*.)**

Based on the preceding facts, the writer's statement is *not* supported by either the facts stated in the IOM report *nor*, worse, by the findings from the sound scientific research and case studies, which were either ignored or discounted.

"The US drug regulatory agency, the FDA, approves chelation therapy only for acute mercury poisoning: there is no scientific evidence of its benefits in autism - or any other condition - and little information about its risks (3)."

The writer's statement is misleading and the referenced document is *neither* a peer-reviewed publication *nor* from applicable sound governmental publications.

Factually, medicine approves the use of chelation to treat anyone that has been proven to be poisoned by mercury, lead, arsenic, copper, aluminum, iron or any other metal, for which it has been established that a metal excess is poisoning the a person, whenever a medically approved treatment regimen exists, as it did here.

In addition, a simple search of the FDA website with the key terms "chelation"
and "mercury" found the following entries:

IMPORT ALERT IA6641
... 05% Betamethasone dipropionate 64L--06/53LC Mercury Top Gel .05% Fluocinonide 64L--28 ... 3/26/04
A product used for chelation therapy is represented to be useful ...
www.fda.gov/ora/fiars/ora_import_ia6641.html - 11-02-2005 - Cached

Chapter 5: Center of Veterinary Medicine
... to assure proper daily intake. Chelation is the pharmaceutical process of bonding ... veterinary drug products that contain mercury as an active ingredient, and ...
www.fda.gov/ora/about/enf_story/archive/2002/ch5/cvm1.htm - 08-22-2005 - Cached

2005 FDA Science Forum - Abstracts by Title and Category
... rats were injected with a single NOAEL or LOAEL dose of chromium (sc), mercury (iv) or lithium (ip) salts, metals which typically exert effects on proximal ...
www.cfsan.fda.gov/~frf/forum05/abs05ct.html - Large File: 101k - 06-09-2005 - Cached

Internal Radioactive Contamination--Development of Decorporation ...
... II. background. Internal radioactive ... investigational purposes. A. Radiation Contamination Scenarios. ...
www.fda.gov/cder/guidance/6394dft.htm - Large File: 101k - 02-14-2005 - Cached

[PDF] **Guidance for Industry**
Page 1. Guidance for Industry Internal Radioactive Contamination ... 2/8/2005
Page 2. Guidance for Industry ...
www.fda.gov/cder/guidance/6394dft.pdf - 02-14-2005 - Text Version
[More results from www.fda.gov/cder/guidance/]

[PDF] **Volume IV, Section 6**
... 64, No. 144, 40875. 21. (1994, September). Mercury in Fish: Cause for Concern? FDA Consumer ... lead is in the metallic state, (2) chelation of the Pb by the food ...
www.fda.gov/ora/science_ref/lm/vol4/section/06.pdf - 12-08-2004 - Text Version
www.fda.gov/ohrms/dockets/dailys/04/sep04/092304/04P-0349-ec12.htm

... to show high levels of mercury ? chelation studies show that children with autism
excrete high levels of mercury compared to normal controls, suggesting that ...
www.fda.gov/ohrms/dockets/dailys/04/sep04/092304/04P-0349-ec12.htm - 10-13-2004 - Cached

FR Doc 03-23489
... The Chelation of Heavy Metals, Alexander Catsch (Oxford: Pergammon Press, 1979), 171-183. 17. Chen, WY, YC Wang, and MS Kuo, ``Determination of Total Mercury ...
www.fda.gov/ohrms/dockets/98fr/FR%20Doc%2003-23489.htm - 09-15-2003 - Cached

[PDF] **Federal Register / Vol. 68, No. 178 / Monday, September 15 ...**
... The Chelation of Heavy Metals, Alexander Catsch (Oxford: Pergammon Press, 1979), 171-183. 17. Chen, WY, YC Wang, and MS Kuo, ``Determination of Total Mercury ...
www.fda.gov/ohrms/dockets/98fr/03-23489.pdf - 09-15-2003 - Text Version
[More results from www.fda.gov/ohrms/dockets/98fr/]

www.fda.gov/ohrms/dockets/dailys/03/Jun03/061603/03N-0169-EC18.html
... 99 ppb mercury, averaging 35 ppb (expected range < 2 ppb; atomic fluorescence spectrometry). High readings may be related with chelation therapy. Current IQ ...
www.fda.gov/ohrms/dockets/dailys/03/Jun03/061603/03N-0169-EC18.html - 08-04-2003 - Cached

[TEXT] **www.fda.gov/ohrms/dockets/dailys/02/Sep02/091702/80029638.txt**
... to pay out of pocket for testing or chelation therapy and Medicaid doesn't cover it. They can't even request mercury-free fillings in order to avoid further ...
www.fda.gov/ohrms/dockets/dailys/02/Sep02/091702/80029638.txt - 10-17-2002 - Cached

[MS WORD] **ATDEPARTMENT OF HEALTH AND HUMAN SERVICES**
... to avoid eating four kinds of fish with the highest levels of mercury, namely, shark, swordfish, king mackerel, and tilefish, avoid these completely if you are ...
www.fda.gov/OHRMS/DOCKETS/ac/02/transcripts/3872t1.doc - 09-19-2002 - Text Version

ATDEPARTMENT OF HEALTH AND HUMAN SERVICES
ATDEPARTMENT OF HEALTH AND HUMAN SERVICES. FOOD AND DRUG ADMINISTRATION. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION. ...
www.fda.gov/OHRMS/DOCKETS/ac/02/transcripts/3872t1.htm - Large File: 101k - 09-19-2002 - Cached
[More results from www.fda.gov/OHRMS/DOCKETS/ac/02/transcripts/]

Thimerosal FAQs
CBER - Thimerosal FAQs
www.fda.gov/cber/vaccine/thimfaq.htm - Posted: 12-13-2001 - Cached

[TEXT] **www.fda.gov/ohrms/dockets/dailys/01/Jan01/011201/emc000010.txt**
... supplements and chelation fail to produce a return to good health, we find that individualized Chinese herbal prescriptions can address mercury induced ...
www.fda.gov/ohrms/dockets/dailys/01/Jan01/011201/emc000010.txt - 03-27-2001 - Cached

[TEXT] www.fda.gov/ohrms/dockets/dailys/01/Jan01/011201/emc000007.txt
... toxic with mercury and other harmful metals such as aluminium, arsenic and cadmium.
It was recommended that I be treated with intravenous DMPS chelation by a ...
www.fda.gov/ohrms/dockets/dailys/01/Jan01/011201/emc000007.txt - 03-27-2001 - Cached

Different chelating agents are recognized as being appropriate for different metals depending upon whether they have a high affinity for sulfur-, oxygen-, or nitrogen- containing chelating agents. Generally, mercury has a higher affinity for sulfur-containing chelating agents, and these chelating agents are the one that should be used for chelating mercury out of the human body. The two medically recognized most appropriate chemical chelating agents for mercury are DMSA (meso-2,3-dimercaptosuccinic acid) and DMPS (sodium 2,3-dimercaptopropane-1-sulfonate), where the chemical term "mercapto" denotes an "S–H" (a sulphur [or sulfur] hydrogen group).

Factually, the use of intravenous EDTA for mercury chelation is not generally recommended medical practice for mercury detoxification.

In general, DMSA and DMPS are the two chemicals recommended for chelating mercury to facilitate its elimination from the body.

For these two chemical agents, most physicians who treat mercury-poisoned children use and/or prescribe lotion formulations and oral dosing, the safer nodes of administration, followed by intramuscular injections and, *to the extent possible*, avoid intravenous infusion of these mercury-complexing agents.

EDTA in its calcium disodium form (calcium disodium edentate) is the recommended form for medical use, because it protects the patient from EDTA-induced calcium depletion and the most appropriate heavy metal target is lead and other heavy metals that prefer to complex with oxygen-based chelating agents, like EDTA, – not mercury, because mercury has a stronger affinity for sulfur-based chelating agents, like DMSA and DMPS, than for oxygen-based chelating agents.

Further, the fact and cause of this child's death does *not* call the use of chelation into question; it only calls that particular doctor's decisions and practices into question.

In that regard, Dr. Fitzpatrick needs to take the proverbial "beam" (the deaths and horrible injuries and surgeries endured by the many children from medical procedures gone bad) out of his own "eye" before attempting to address the "mote"(a tragic *isolated* death of an innocent child in this case) in the "eye" of another.

"Yet, despite the categorical dismissal of the mercury-autism theory by medical and scientific authorities, the anti-mercury campaign has continued to gather momentum."

Contrary to the writer's non-scientific views, "the anti-mercury campaign has continued to gather momentum**" because the review of the existing body of applicable scientifically sound evidence and the applicable peer-reviewed published investigations by independent scientists have clearly established that injecting Thimerosal-containing vaccine solutions into humans mercury poisons:**

- **All of the humans injected to some degree,**
- **Some of them to the degree that they exhibit one or more of the symptoms of clinical mercury poisoning (according to the 2004 CDC/AAP "Autism A.L.A.R.M.," 1 child in 6),**
- **A few to the degree that they are "diagnosed with an autism-spectrum disorder" (as per the 2004 CDC/AAP "Autism A.L.A.R.M., 1 child in 166), and,**
- **A very few to death.**

"Earlier this year, David Kirby, a New York journalist, published Evidence of Harm, a book promoting the anti-mercury cause, which has received widespread publicity (4)."

This reviewer finds that the writer's view of the book, Evidence of Harm, overreaching because the author presents the evidence on both sides of the issue in a fairly balanced manner.

"Defeat Autism Now! - a US-based network of parents and doctors who offer a range of unorthodox treatments (including mercury chelation) - staged a conference in Scotland in October."

First, this reviewer notes that the "treatments" are:

1. **Prescribed by the DAN doctors,**
2. ***For the most part*, are recognized medical (western, eastern and/or homeopathic) practices, and**
3. ***While some of these therapies may be "alternative medicine*,**
   - **They generally are *not* "**unorthodox treatments,**" and**
   - **The preferred chelation therapies for mercury detoxification typically involve the topical, oral, intramuscular and/or intravenous dispensing of appropriately formulated solutions or suspensions of the chelating agents DMSA and/or DMPS.**

Otherwise, the writer's basic statement, "Defeat Autism Now… staged a conference in Scotland in October**" of 2005, seems to be factually correct.**

"Later this month, a conference in Birmingham, England, features a presentation on 'the risks and benefits of chelation' by the Dublin-based chelation therapist Dr Gabriel Stewart. This conference is organised by Desumo, one of the companies that profited from the MMR scare by providing single vaccines (though this is not the firm whose proprietor, Dr David Pugh, was subsequently jailed for fraud). (The conference also features a rare UK appearance by Dr Andrew Wakefield, the leading promoter of the MMR-autism link, who now works in private practice in Texas.) It is not clear whether Desumo is planning to diversify into the lucrative chelation business, now that the single vaccine market is shrinking, or is merely providing a platform from which Dr Stewart can advertise his Dublin clinic."

Other than the off-topic, speculative and intentional prejudicial parenthetical remarks, "(though this is not the firm whose proprietor, Dr David Pugh, was subsequently jailed for fraud)**" and "**(The conference also features a rare UK appearance by Dr Andrew Wakefield, the leading promoter of the MMR-autism link, who now works in private practice in Texas.)**," and the speculative and inflammatory, "**It is not clear whether Desumo is planning to diversify into the lucrative chelation business, now that the single vaccine market is shrinking, or is merely providing a platform from which Dr Stewart can advertise his Dublin clinic**" or the simply inflammatory, "**one of the companies that profited from the MMR scare by providing single vaccines**," this reviewer does *not* understand the value of these remarks with respect to the issue of the validity, or lack thereof, of using**

medically recognized chelation therapies to reduce the level of any metal ion whose excess has been proven to be present at levels poisonous to the body.

"According to his own website, Dr Stewart trained in chelation therapy in Los Angeles, after qualifying as a doctor from University College Galway and working as a GP in Canada for 20 years (5). He returned to set up his 'Chelation Ireland Clinic' in November 2000 and he claims 'huge success with heart disease' (he believes that 95 per cent of bypass surgery is unnecessary) (6). He is also 'seeing the effects of the therapy on other diseases' such as Alzheimer's, Parkinson's, multiple sclerosis and diabetes."

This reviewer sees no point to the writer's including information on what Dr. Stewart claims or the diseases for which Dr. Stewart[3] has seen, apparently positive, effects when chelation us used (heart disease, Alzheimer's, Parkinson's, multiple sclerosis and diabetes), unless the writer has proof that mercury poisoning is *not* a factor in the causation of these diseases.

Based on the science of which this reviewer is aware, mercury has definitely been shown to be a factor[4] in some heart disease and Alzheimer's and Thimerosal has been implicated[5,6] in multiple sclerosis (MS) and diabetes because it has been shown to be a strong autoimmune triggering agent, and both MS and pancreatic diabetes are considered to be autoimmune diseases.

Furthermore, the actual name of Dr. Stewart's clinic is the "Chelation-Ireland Clinic" – as noted in the reference but not the text.

"Dr Stewart recommends chelation for 'stress and fatigue' and claims that it is 'the most effective anti-ageing treatment'. Though the title of his Birmingham talk seems to acknowledge that chelation carries risks, these are not specified on his website - unlike the claimed benefits. While Dr Stewart does not indicate what qualifications he has in relation to children or autism, his website declares that he 'also treats autistic children'."

This reviewer finds the writer's statements are problematic because, under "Expertise," Dr. Stewart's website, http://www.chelation-oreland.com, states:

"Does this treatment have side effects?

Reaction to EDTA (or vitamins), which rarely occurs, is minimal. It can be avoided by giving smaller doses and building up to the desired level. ***Inflammation*** at the site of IV may occur and is treated with compresses. Diabetics and patients suffering from heart failure and kidney disease are carefully monitored and dosages may be adjusted according to their condition.

Is Chelation Therapy Safe?

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3 According to http://www.chelation-ireland.com/aboutus.htm, "Dr T. E. Gabriel Stewart M.B.B.CH. B.A.O. M.I.C.G.P. A.P.C.T. qualified as a medical doctor at University College Galway. He spent twenty years working as a GP in Canada where he first came across Chelation therapy. A number of heart patients at his practice experienced dramatic results after travelling to the United States for Chelation therapy. Dr Stewart was impressed and determined to investigate the treatment for the benefit of his other patients. He visited the US clinic and discovered qualified doctors with thousands of well documented case histories of dramatic improvement. In Los Angeles Dr Stewart completed a series of specialized courses in Chelation therapy. He passed the examinations set by the American College for Advancement in Medicine (ACAM) and became an accredited member of that organisation. ACAM is a US medical association which has established a protocol to maintain high standards of practice for Chelation therapy. Physicians are certified only after they have taken training courses, passed written and oral examinations and had supervised experience."

4 http://www.mercury-freedrugs.org/docs/

5 Vojdani A, Pangborn JB, Vojdani E, Cooper EL. Infections, toxic chemicals and dietary peptides binding to lymphocyte receptors and tissue enzymes are major instigators of autoimmunity in autism. Int J Immunopathol Pharmacol. 2003 Sep-Dec;16(3):189-99. DG-IV-1

6 Havarinasab S, Haggqvist B, Bjorn E, Pollard KM, Hultman P. Immunosuppressive and autoimmune effects of thimerosal in mice. Toxicol Appl Pharmacol. 2005 Apr 15;204(2):109-21.

> Over one million persons worldwide have been chelated, with no significant adverse effects or reported ***deaths*** in the last twenty years *following the protocol laid down by A.C.A.M (The American College for Advancement in Medicine)* of which Dr Stewart is a member**,"**

***three risks* for the Dr. Stewart's EDTA chelation protocol are *clearly* mentioned, *reaction*, *inflammation*, and *death*.**

Thus, the writer's "Though the title of his Birmingham talk seems to acknowledge that chelation carries risks*, these are not specified on his website* - unlike the claimed benefits**," seems to be at odds with the information provided on Dr. Stewart's website.**

Moreover, based on Dr. Stewart's statement on "Is Chelation Therapy Safe?" it would seem that the death of Abubakar Nadama was, at least in part, caused by the failure of the treating physician or some other healthcare provider in the clinic to *rigorously* follow the recognized A.C.A.M. protocol for the use of intravenous EDTA chelation.

"Though the death of Abubakar Nadama has caused widespread shock throughout the world of autism, it seems not to have deterred the anti-mercury campaigners. In the same angry tones in which campaigners blame the medical establishment for poisoning their children with vaccines, they repudiate their critics in the US media: 'We are not desperate parents willing to try anything. We are educated, caring parents who have done thousands of hours of research and administered dozens of medical tests on our children under the care of knowledgeable physicians.' (7)"

Given the facts of the Abubakar Nadama case, the death of this child, while tragic, has *not*, as the writer states, "caused widespread shock throughout the world of autism**."**

Moreover, the writer's phrasing, "(i)n the same angry tones ...**" is a blatant attempt to:**

- **Disparage the response by a single person speaking for a single organization, Generation Rescue, and**
- **Portray that response as the response of all those who had problems with the misinformation published in the US media.**

Factually, the US media, like this British writer, attempted to discredit recognized medical therapies that use mercury-appropriate chelating agents, DMSA and DMPS, to treat people with diagnosed mercury poisoning by using a tragic death of a single child being treated with a different, non-mercury-specific chelating agent, EDTA.

For those readers who would like to read an in-depth rational rebuttal to one of the inflammatory articles, which were published in the US media on this tragic incident, they can read this reviewer's rebuttal[7] to Dr. Paul A. Offit's article addressing this tragic chelation incident, "Conventional wisdom must conquer medical sensationalism," which was published on 19 September 2005 in the electronic version of the San Gabriel Valley Tribune.

"Parent activists challenge mainstream scientific expertise with the evidence of their own experience and with the results of their own painstaking researches."

This reviewer finds the writer's statement seems to be more "spin" than substance here.

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7 http://www.mercury-freedrugs.org/docs/051101_Thimerosal(49_55_%20mercury)CausesMercuryPoisoningII--RebuttalToDr_Offit'sViews.pdf

Since this reviewer is a research scientist with no damaged child, who writes from the basis of his studies of the scientifically sound, peer-reviewed published literature on the ongoing mercury poisoning of American babies:

- **By various mercury compounds, principally Calomel (84.98% mercury by weight) and Thimerosal (49.55% mercury),**
- **During two time periods, late 1800s to 1940 for Calomel and 1930s to date for Thimerosal,**

this reviewer is more than qualified to challenge the less-than-scientifically-sound pronouncements of the "mainstream scientific expertise**" (the writer's and the Establishment's published apologistic views) because this reviewer has shown that, among other things, the Establishment's pronouncements have been, and are, *knowingly* ignoring the scientifically sound research findings on the toxicity of Thimerosal and its metabolites that date back to the 1930s.**

"But both these sources of knowledge may be misleading and relying on them may have damaging consequences for children with autism and their families."

While the writer's "both these sources of knowledge may be misleading**" is true, it is just as true that relying on the Establishments pronouncements may be misleading.**

To the extent that one is relying on any misleading information, one's reliance on such may have "damaging consequences**."**

However, since this reviewer's body of evidence includes the key research studies on the toxicity of Thimerosal and its metabolites that the Establishment's pronouncements *knowingly* ignore, the probability is high that relying on the information provided by this independent scientific reviewer and others like him is much less likely to mislead than relying on those sources that knowingly ignore these research studies.

For those readers who are interested, the documents posted on the web page, http://www.mercury-freedrugs.org/docs/, contain the information and references upon which this reviewer relies when addressing the reality that injecting Thimerosal (49.55% mercury) into humans mercury poisons all of them to varying degrees – just as rubbing Calomel-laced (where Calomel is 84.98% by weight mercury) teething powders (where these powders were up to 26% by weight Calomel) on the gums of babies mercury poisoned them in the period from the late 1800s to 1940 in the US.

"The experience of having a child with autism - as I have - qualifies you to speak authoritatively on your experience as a parent of a child with autism: it does not give you any particular insights into the science of autism. Indeed, one of the problems of being the parent of a child with autism is that it gives you little time or energy to study the wider aspects of the subject. In recent years, however, some parents have devoted much time to reading scientific papers on autism. But, when such parents demand to be heard - and are heard - in scientific controversies it is important that the limitations of parental experience and study are recognised."

First, this reviewer completely agrees with the writer's statements here.

Second, based on the writer's statements, it seems clear to this reviewer that the writer has *not*, for whatever reasons, "devoted much time to reading scientific papers on autism**" much less to studying the toxicology literature on mercury, Calomel, and Thimerosal (Thiomersal in the UK).**

Third, since some of the parents speaking out are medical doctors, recognized academic research scientists, and, yes, even biometricians and epidemiologists, who have studied and are qualified to speak on these issues, this reviewer finds it

odd that the writer has apparently not listened to these doctors and research scientists, whether they be parents or simply, as this reviewer, scientists who have been and are studying the body of knowledge on mercury poisoning that includes information on the scientifically controlled detoxification of those who are mercury poisoned in a holistic controlled environment.

"Modern scientific knowledge in any discipline is complex and highly specialised. The professional understanding of research scientists and clinicians is the product of a long process of study, training and experience."

While this reviewer agrees with the writer that <u>understanding</u> of any scientific discipline is "the product of a long process of study, training and experience,**" this reviewer does *not* agree that all "(m)**odern scientific knowledge is complex and highly specialized**," as the writer asserts.**

Based on the writer's phrasing, it seems that the writer has confused the requirements for the understanding of a scientific discipline with those for the understanding of the facts about some topic addressed by that discipline.

For example, it is modern scientific knowledge that water has a nominal formula weight of 18.02 grams per mole — this knowledge is *neither* complex *nor* highly specialized, and most interested persons can learn and understand this information by simply querying the Internet about the composition of water.

Moreover, the chelation of mercury to remove it from someone who has been proven to be mercury poisoned is not a scientific discipline but rather a scientific topic that is amenable to study and understanding by any person who: a) has average or above average intelligence and an understanding of the scientific method, b) a desire to understand the topic, and c) studies that topic intensively.

"Such knowledge and expertise cannot be acquired through reading journals, downloading information from the internet and attending occasional conferences."

Based on the preceding realities established by this reviewer, this reviewer must respectfully disagree with the writer here because the issue at hand is a topic and clearly not a discipline.

"At best, parents can acquire a 'narrow-band competence' that may allow them to select information supporting some pre-conceived conviction, and presenting this may be effective for campaigning purposes."

Since some of the parents of which the writer speaks are trained in the very discipline that deals with the topic at hand, *chelation to remove mercury from mercury-poisoned humans*, it seems obvious that the writer's remarks are, at best, misplaced.

"But a narrow and selective approach can lead to the sort of dogmatic outlook expressed by the anti-vaccine campaigners, which is inimical to scientific inquiry and discussion."

Ironically, this reviewer agrees with the writer for the most part, but notes that the same criticism applies to pro-vaccine "campaigners,**" such as the writer, who not only obviously express a "**dogmatic outlook**" that "**is inimical to scientific inquiry and discussion**" but also dogmatically mischaracterizes those opposed to:**

a) **the mercury poisoning of their children and themselves by Thimerosal in <u>some</u> vaccines and/or**
b) **use of the combined MMR vaccine instead of a separate vaccine for each virus component (measles, mumps, and rubella),**

as "anti-vaccine campaigners**."**

"The closer relationship between parents' groups and scientific research into autism may give rise to a number of problems."

This reviewer only notes that the close relations between: a) the pharmaceutical and medical establishments and b) scientific research has given rise to a much larger number of problems than the possible problems alluded to by this writer.

"One is that, under pressure from parents desperate for rapid results, scientists may circumvent the procedures that have been established to ensure adequate standards and to safeguard the public."

While this reviewer finds the writer's remarks condescending, this reviewer must note that the pharmaceutical and medical establishments have had more than half a century to do the scientific research necessary to determine and publish the definitive toxicological research required to establish the modes of toxicological action for Thimerosal and its metabolites, ethylmercurihydroxide and "bound inorganic mercury," but has steadfastly refused to do the requisite in-depth toxicological studies.

Even the federal government has, to date, failed to conduct the requisite studies though a project to do the requisite studies was generated in 1999[8]

Given the preceding realities, this reviewer would ask the writer to explain these failures.

"These procedures require that scientific work is reviewed by peers before publication, that provisional results are confirmed or replicated before claims of significant findings are made, that therapies are subjected to rigorous trials before they are recommended for public consumption."

Since the chelation procedure, intravenous EDTA chelation, (which is associated with the tragic death the writer has used as his reason for this article) has been the subject of all of the preceding studies and even has a medical certification program governed by A.C.A.M (The American College for Advancement in Medicine), this reviewer finds that the EDTA chelation meets all of the aforementioned criteria and yet the patient died.

"It is unfortunate that in the network of parents promoting chelation and other unorthodox therapies, it has become commonplace for all these safeguards to be violated."

This reviewer finds the writer's statement seems *not* to be supported by any factual evidence that establishes the validity of the writer's assertions.

In addition, this reviewer notes the requirement "that therapies are subjected to rigorous trials before they are recommended for public consumption**," is continually being violated by the pharmaceutical industry, who has repeatedly been found to conduct less than sufficiently rigorous and, in some cases, problematic trials and/or trial-data manipulations leading to a subsequent withdrawal of the drugs or treatments after they had killed hundreds and maimed thousands – for example, the now-withdrawn painkiller, Vioxx, which has been estimated by the FDA to have caused up to 50,000 deaths from the increased risk for heart attack and strokes to long-term users, and more than three times that number of severe injuries.**

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[8] According to the web page http://cerhr.niehs.nih.gov/CERHR chems/index.html, of mid-September 2005, containing Thimerosal, CAS 54-64-8, was not nominated by the FDA to have its toxicity appropriately studied until "11/99." However, that proposed study's status was changed to "Nomination Deferred" in "7/00" because there were "Chemicals with higher priorities" for, given the studies (*like one for a soy extract*) that were allowed to proceed, no scientifically sound reason.

Factually, the need for rigorous trials for therapies that remove mercury from mercury-poisoned individuals can be overcome by a sufficiently large body of case studies that show that the therapy removes mercury, provided, *under the care of a knowledgeable physician or other qualified healthcare provider*, the side effects of the therapy are minimal.

Moreover, the "Defeat-Autism-Now!" (DAN) doctors and scientists belong to a group scientists committed to finding therapies that improve the quality of life for their patients who: a) have been given causeless "autism" diagnoses by the medical establishment and b) have been proven to be mercury poisoned and/or poisoned by mercury and other heavy metals (e.g., lead, arsenic, antimony, and bismuth).

All of their therapies are peer reviewed by the group before any change is made to the published DAN protocols.

In addition, as the writer notes, "provisional results are confirmed or replicated before claims of significant findings are made**" within or outside of the group.**

Finally, independently funded clinical trials are currently underway in Arizona to quantitate the magnitude of the improvements documented in the case studies.

However, as with a rigorous clinical trial where the initial findings clearly indicate that a "test therapy" is clearly superior to the "control therapy," that trial is planned to appropriately treat all those in the "control arm" of the study as soon as the "test therapy" arm provides sufficient data to establish the superiority of the "test therapy."

"Scientists who identify with this approach release unpublished data and make claims of unconfirmed findings at public conferences.

First, this reviewer notes that making non-specific and general statements, as the writer does here, is of little real value in any rational discussion.

Second the writer seems to be confused because scientists often present "unpublished data" at scientific conferences that are open to the public to establish their being first to: a) make a given discovery, b) prove some proposition, or c) find a "better" therapy.

Since these are firsts, it should be obvious to all, that their claims/findings are "unconfirmed findings**."**

"Parents seize upon provisional reports that appear to confirm some aspect of the unorthodox approach or to validate some therapeutic intervention."

While this reviewer cannot disagree with the writer's general statement, he does *not* understand what it has to do with the use of DMSA and DMPS for the chelation treatment of people who have been proven to be mercury poisoned since these drugs and this therapy has been used for decades.

"There are clear dangers that such prematurely released results are unlikely to be confirmed and that therapies promoted in this way will turn out to be ineffective or to have harmful side-effects, or both."

While the writer's generalizations here may be true, this reviewer again asks what has this statement to do with chelation therapies for treating mercury poisoning that have been recognized as sound medical practice and used in the treatment of the mercury poisoned for decades?

"When scientists appeal over the heads of their peers directly to a public lacking in scientific expertise there are dangers of manipulation."

While the writer's statement is true, again what has this to do with the use of a medically proven therapy (chelation with DMSA and DMPS) for treating the mercury poisoned?

In addition, this reviewer also notes that the tactic of manipulation, mentioned by the writer, seems to be the second-most-often used tactic by the medical, pharmaceutical, and governmental establishments to speak to the American public — right behind the tactic of fear mongering – warning about some dire outcome that may never happen in order to "coerce" the public into following a suggested course of action that is only guaranteed to benefit one (the pharmaceutical industry) or more of the industries (pharmaceutical, medical, hospital, insurance, nursing home, habilitation, rehabilitation, and eldercare industries) that make up the "healthcare establishment."

"I have attended conferences at which speakers have addressed parents in scientific jargon so dense as to be incomprehensible. Though the object of this exercise appears to be to demonstrate the intellectual authority of the speaker, it means using science to impress rather than to explain and it often leaves parents bewildered and confused."

Again, this reviewer asks, what has this to do with the use of a medically proven therapy (chelation with DMSA and DMPS) for treating the mercury poisoned?

"There is also a danger that scientists whose work is not of adequate quality to satisfy the standards of mainstream academic institutions may be able to secure recognition - and increasingly funding - from parent groups. The danger of abuse is greatest when there are links among scientists, parent groups and commercial interests, providing diagnostic tests, specialised dietary requirements, food supplements and medications."

Again, this reviewer first asks, what has this to do with the use of a medically proven therapy (chelation with EDTA, DMSA, DMPS, and other chelating agents) for treating those poisoned by some metal ion excess?

In addition, how is the writer's danger of abuse scenario different from, or worse than, the close links among the government regulators, government legislators, academic researchers, parent groups (often "partially" funded by commercial interests), the media (who depend on the commercial interests for a significant portion of their advertising revenues) and commercial interests, which openly exists today in the area of drugs and devices?

Factually, this reviewer's danger of abuse scenario is obviously worse than the writer's scenario.

"The common feature of all these interventions is that they are inordinately expensive and may constitute a substantial financial burden for some families with autistic children, whose resources are already severely stretched."

While this reviewer agrees that some interventions are expensive and they "may constitute a substantial financial burden for some families**," this reviewer notes that some cancer therapies are orders of magnitude more expensive and not only have life-threatening side effects but also only a low success rate, but the writer seems blind to the healthcare establishment's truly "**inordinately expensive**" cancer therapies.**

Again, this reviewer asks the writer, what has this to do with the use of a medically proven therapy (chelation with EDTA, DMSA, DMPS, and other chelating agents) for treating those poisoned by some metal ion excess?

"In response to the death of Abubakar Nadama, the National Autistic Society has taken a welcome stand on chelation therapy. In the current issue of the society magazine, national councillor Mike Stanton writes: 'To subject children to treatment of questionable benefit and unquantifiable risk, because of a hypothetical possibility that their autism might have some connection with a biomedical disorder, is unacceptable. As such, chelation should be roundly condemned as a therapeutic intervention.' (8)"

First, this reviewer notes that the National Autistic Society seems to be heavily invested in promoting its teaching and physical therapy approaches to treating "autistic children."

Second, the "councillor's**" statement, "**To subject children to treatment of questionable benefit and unquantifiable risk, because of a hypothetical possibility that their autism might have some connection with a biomedical disorder, is unacceptable**, is problematic because:**

1. **The "**councillor's**" statement seems untrue on its face since: a) EDTA chelation to reduce heavy-metal toxicity is a medically recognized treatment regimen for any person who has been found to be heavy-metal poisoned, b) metal intoxication was the medical disease for which the boy was being treated, c) EDTA chelation is the recognized first-line treatment for lead poisoning in children, and d) these metal poisonings are medically recognized diseases – not "disorders."**
2. **From the information available, the boy's tragic death was caused by a clinical error in administering the treatment because millions of children have been treated with intravenous EDTA chelation for lead poisoning with no reported deaths when the approved protocols are rigorously adhered to.**

"Dr Michael Fitzpatrick is author of MMR and Autism: What Parents Need to Know (buy this book from Amazon (UK) or Amazon (USA)) and The Tyranny of Health: Doctors and the Regulation of Lifestyle, Routledge, 2000 (buy this book from Amazon UK or Amazon USA). This is an edited version of an article that appears in the current HealthWatch Newsletter (October 2005)".

About the Reviewer

In addition to the information available on his web page[9], this reviewer, Dr. Paul G. King, is the New Jersey Representative for the "Coalition for Mercury-Free Drugs" (CoMeD) [http://www.mercury-freedrugs.org], the current District 33 Democratic Committeeman for Township of Parsippany-Troy Hills, Morris County, NJ, a Taoist philosopher and a servant of Elohim.

As a scientist and student of the federal regulations and statutes governing drugs, Dr. King led CoMeD in the drafting and submission of a Citizen Petition, posted in the FDA Public Docket 2004P-0349 (and on the CoMeD web site), and wrote and submitted CoMeD's response to the FDA's 180-day response letter.

Article's References:

(1) The Times (London), 26 August 2005. (2) Immunisation Safety Review: Vaccines and Autism, Institute of Medicine, 2004

(3) See Chelation therapies: unproven claims and unsound theories, Saul Green, Quackwatch

(4) David Kirby, Evidence of Harm: Mercury in Vaccines and the Autism Epidemic, Medical Controversy, New York: St Martin's Press, 2005. See also Mercury and autism: a damaging delusion by Dr Michael Fitzpatrick

(5) Chelation-Ireland clinic

(6) Heavy heart, Ralph Quinlan Forde, Sunday Herald, 3 April 2005

(7) A statement from Generation Rescue regarding the tragic passing of Abubakar Tariq Nadama

(8) Mike Stanton, 'Biomedical interventions', Communication, 2005; 39: 36 (Autumn)"

[9] http://www.dr-king.com

APPENDIX A

Mike Fitzpatrick's Email of 11/7/05, "Re: Draft of a review of your article 'When Quackery Kills'"

"Delivered-To: drking@gti.net
Date: Mon, 7 Nov 2005 08:01:51 +0000
To: "Paul G. King" <drking@gti.net>
From: Mike Fitzpatrick <fitz@easynet.co.uk>
Subject: Re: Draft of a review of your article 'When Quackery Kills'
X-OriginalArrivalTime: 07 Nov 2005 08:37:44.0880 (UTC)
…

Dear Dr King,

Thanks for your detailed riposte to my article.

I am grateful for your correction regarding the Chelation-Ireland Clinic (which was punctuated correctly in the footnote but not in the text).

Your claim that the National Autistic Society receives a significant proportion of its income from pharmaceutical companies is inaccurate and prejudicial to the reputation of what is by far the most important parent-led organisation working in the sphere of autism in the UK.

Otherwise, I accept your critique as fair comment.

Michael Fitzpatrick
(not to be confused with Fitzgerald, a different tribe)"