

Facility Automation Management Engineering (F.A.M.E.) Systems

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Sunday, 27 August 2006

To Whom It May Concern:

The review that follows this introductory letter is a critical assessment of the article, "**Act could turn the tide on common birth defect**" by Peter Hotez and Rosalynn Carter from the McClatchy-Tribune News Service as published on the Register-Guard website at:

<http://www.registerguard.com/news/2006/08/18/ed.col.autism.0818.p1.php?section=opinion>

that I downloaded as a part of my research in this area on Friday 18 August 2006 when I visited that webpage.

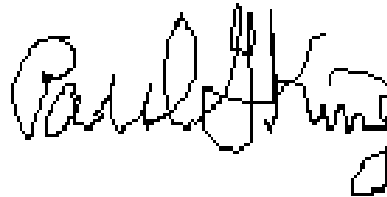
In general, to clearly differentiate between my assessment comments and those of the article, the article's printed statements are quoted in an *italicized "Times New Roman"* font followed by this reviewer's remarks in indented text written in a "**News Gothic MT**" font, the font used in this cover letter.

Quotes from general reference articles and documents will be presented in an "**Arial**" font; federal laws and statutes will be quoted in a "**Lydian**" font; and, *in rare instances*, a "**Perpetua**" font will be used to condense a quoted article.

For those who have access to a color printer, this reviewer's comments are made in a **blue** color with existing text corrections, if any, in **orange**.

Should anyone find any factual misrepresentations in this reviewer's remarks, then this reviewer requests that you send 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,

A handwritten signature in black ink that reads "Paul G. King". The signature is written in a cursive style with a large, prominent "P" and "K".

Paul G. King, PhD, MS, BA
Founder,

F.A.M.E. Systems

An In-depth Assessment of:

“Act could turn the tide on common birth defect”

A McClatchy-Tribune News Service article written by Peter Hotez and Rosalynn Carter

First, this article’s authors begins with a misleading title because:

- a. The “**Act**” being discussed is the “Combating Autism Act” and
- b. There is no proof that autism is a “*common birth defect*” or, *for that matter*, even a “*birth defect*” *per se*.

“A bill that marshals an army of new research dollars to strike a forceful blow against autism deserves - and we hope will get - full consideration from the House of Representatives when it returns in September.”

Factually, *as written*, the House version of the Combating Autism Act, H.R. 2421, provides only a few million dollars a year with most of those dollars apparently directed toward:

- “Educating” the healthcare providers and the public,
- Finding “genes” linked to autism, and
- The tracking of the cases,

and *not* to finding and eliminating the known environmental causative factors, including eliminating the Thimerosal *currently* allowed to be used in the manufacture of some vaccines and other drug products without proof of safety.

That there are these environmental causative factors has been proven to be the case because the incidence of autism in identical twins where one is diagnosed with autism is significantly less than the 100% it would be if the cause were *solely* genetic.

If these authors, or the readers of this review, are interested in learning more about this, this reviewer recommends Richard Lathe’s recent book, “**Autism, Brain, and Environment**,” published by Jessica Kingsley Publishers [2006] and printed and bound in the United States by Thomson-Shore, Inc. ISBN-13: 978-1-84310-438-4 and ISBN-10: 1-84310-438-5. [**Note:** This recent informative tome is strongly recommended on its jacket by Simon Baron-Cohen, Professor of Developmental Psychopathology at Cambridge University and Director of the Autism Research Centre, Cambridge and Boyd Haley, Professor and now-past Chair, Department of Chemistry, University of Kentucky, who are often on opposite sides in the autism debate.]

Since there are proven environmental factors, again “autism” *cannot* be purely a “birth defect”.

Thus, not only is the authors’ title knowingly deceptive but their characterization of the proposed funding is, *at best*, also disingenuous – the “*blow against autism*” embodied in the legislation is:

- *Not “forceful”* and,
- *For the most part*, misdirected.

In addition, *if Thimerosal is not a factor*, this reviewer asks that these authors to explain the following realities:

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- The reality that in informal surveys conducted by Dan Olmsted, a Senior Editor for UPI (United Press International) seeking autism cases among the Pennsylvania Amish on 2005 failed to find but one case of autism in an Amish child who had an unknown vaccination status but did find two other cases in which the Amish child with autism had been vaccinated with Thimerosal-containing vaccines.
[\http://www.washtimes.com/upi-breaking/20050321-115921-9566r.htm, “The Age of Autism: The Amish anomaly” and <http://washingtontimes.com/upi-breaking/20050417-052541-5549r.htm>, “The Age of Autism: Julia”]

- The reality that, *as again reported by Dan Olmsted*, that a large (practice cares for more than a 1,000 children a year) Chicago, Illinois pediatric practice, “Homefirst Health Services,” also reports no cases of autism among the 15,000 babies they have delivered that were *not* vaccinated, and, *even more telling*, Dan Olmsted reported:

“Schattauer” (“Dr. Paul Schattauer, who has been with Homefirst for 20 years and treats ‘at least’ 100 children a week”) “said Homefirst’s patients also have significantly less childhood asthma and juvenile diabetes compared to national rates. An office manager who has been with Homefirst for 17 years said she is aware of only one case of severe asthma in an unvaccinated child.

‘Sometimes you feel frustrated because you feel like you’ve got a pretty big secret,’ Schattauer said. He argues for more research on all those disorders, independent of political or business pressures.

The asthma rate among Homefirst patients is so low it was noticed by the Blue Cross group with which Homefirst is affiliated, according to Eisenstein.” [“Dr. Mayer Eisenstein, Homefirst’s medical director who founded the practice in 1973.”]

‘In the alternative-medicine network which Homefirst is part of, there are virtually no cases of childhood asthma, in contrast to the overall Blue Cross rate of childhood asthma which is approximately 10 percent,’ he said. ‘At first I thought it was because they (Homefirst’s children) were breast-fed, but even among the breast-fed we’ve had asthma. We have virtually no asthma if you’re breast-fed and not vaccinated.’

Because the diagnosis of asthma is based on emergency-room visits and hospital admissions, Eisenstein said, Homefirst’s low rate is hard to dispute. ‘It’s quantifiable – the definition is not reliant on the doctor’s perception of asthma.’”

[\http://www.washingtontimes.com/upi/20051204-060313-6829r.htm, “The Age of Autism: ‘A pretty big secret’” by Dan Olmsted, UPI Senior Editor, Dec. 7, 2005 at 2:08PM]

Either the authors must “admit”:

- a. All vaccines can cause autism, *a position that even this reviewer finds extreme, or, failing that,*
- b. Thimerosal-preserved vaccines and, *in some cases*, the live-virus vaccines (*i.e.*, the live-virus MMR, MMRV, varicella, and influenza vaccines) can “cause” the “regressive” form of autism in which, at some time after birth, the child’s development begins to regress¹

because the realities are:

¹ “Regressive” autism is the predominate form of autism today. Moreover, though, in most cases, the regression occurs before the child is three years of age, neurodevelopmental regression into “autism” has been reported to occur in much older children.

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- a. *In the genetically diverse population of Homefirst Health Services' Chicago, Illinois pediatric practice, there is no evidence of autism among those who are not vaccinated and*
- b. *In a more genetically homogeneous population, the Pennsylvania Amish, autism is reported as rare (less than 1 in 10,000) and almost all of the autism cases are children who have been vaccinated.*

Based in these realities, either:

- a. All vaccines cause autism or
- b. The Thimerosal-containing vaccines and, perhaps, some of the live virus vaccines are major causative factors in autism.

This is the case because:

- Those who are *not* vaccinated are rarely (less than 1 in 10,000) diagnosed with autism
- While the rate for autism in the population of children where the vaccination rate exceeds 85% is, *according to the latest government survey, greater than 50 in 10,000.*

When it comes to asthma, these authors' dilemma is even worse.

Here, Homefirst Health Services reports, "virtually no asthma if you're breast-fed and not vaccinated," which easily translates to a less than 1 in 10,000 rate for asthma in children who are *not* vaccinated (since the practice has cared for more than ten thousand such children in the past 17 years) in an area, Chicago, Illinois, where the reported asthma rate in the general population of children, *who are mostly vaccinated*, is 10 % (1,000 in 10,000) – a 1,000-plus-fold higher rate.

Again, *since it is clear that something about the vaccines is clearly a causative factor for asthma*, these authors must either blame:

- a. All vaccines as causative factors or,
- b. *Based on the scientific toxicological evidence*, accept that Thimerosal-containing vaccines are the causative factors.

Hopefully, the reader will have an easier time accepting the reality of the adverse effects of Thimerosal-preserved vaccines and the sub-acute mercury poisoning they cause in all injected with them than these authors who, *when faced with the preceding realities in 2005*, continue to claim that Thimerosal is *not* a causative factor in autism.

If they truly believe their own rhetoric, then they must admit that all vaccines are causative factors.

There are no other science-based choices.

Thus, this reviewer challenges them to choose their "poison" – either:

- a. Accept that Thimerosal-preserved biological products, including vaccines, are a major causative factor in autism based on the ever-growing body of evidence of Thimerosal toxicity at levels below 0.05 ppm, or,

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- b. Continue to ignore the toxicological evidence of clinical harm and claim that all vaccines are a causative factor.

“Passed unanimously by the Senate on Aug. 3, the Combating Autism Act will increase research funds for autism and offers new hope that a cure can be found for the nation’s most common genetic disorder.”

Again the authors make a knowingly misleading statement here because “*autism*” has been proven to be a condition that clearly has environmental causative factors and it has been proven *not* to be a single “*genetic disorder*.”

Since it is *not* a single “*genetic disorder*” and there is proof of environmental causative factors, “*autism*” cannot be “*the nation’s most common genetic disorder*.”

“The bipartisan act would bolster an already strong base of existing science about the origins of autism. Medical researchers believe it could lead to breakthroughs that might eventually help cure a disease that affects a growing number of children and their families.”

Given the claimed nature of “*autism*” – a causeless disorder with complex genetic and environmental causative factors and the fact that the bulk of the money will be spent in other than “causative” research activities, the best that the act will do for the majority of those diagnosed with “*autism*” is better define and track the number of cases.

The current best evidence is that “*autism*” and all of the associated clinical neurodevelopmental disorders and disease conditions are triggered by one or more environmental factors.

Thus, the best that could be hoped for would be a preventive regimen for future children coupled with appropriate mitigation therapy regimens for those who have already been damaged.

Thus, the authors’ use of the word “*cure*” is either a failure of the authors to understand the nature of autism and other related neurodevelopmental disorders or a knowingly craven attempt by the authors to mislead the public.

“Equally important, the bill could finally lay to rest an unfounded theory propounded by a small group of physicians and parents, who claim a link between autism and the thimerosal preservative contained in many vaccines.”

Here the authors make an apparently knowingly disingenuous statement.

This is the case because this act provides for no dedicated funding to prove:

- The level of Thimerosal that is safe (with a 100-fold safety factor) to be in a drug formulation administered to humans.
- The level of Thimerosal that presents no risk to the developing fetus for:

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- a. Mercury poisoning and/or
- b. An induced mutation and/or
- c. Fetal teratogenicity when his or her mother is injected with the maximum amount of each drug formulation that contains the highest permissible level of Thimerosal.
- That more than 75% of those diagnosed with “*autism*” are *not* poisoned by mercury from injected Thimerosal-containing vaccines and/or by Thimerosal-derived mercury along with mercury and other heavy metals from other sources.

Until and unless the scientifically sound studies required to prove the preceding are conducted and the safe level of Thimerosal on biological products is found to be 10,000 ppm (1% by weight) or higher, the safety of the use of 0.01% Thimerosal in the majority of vaccine formulations using this level of Thimerosal as a preservative *cannot* be established.

However, obtaining the requisite scientifically sound proof is a scientific impossibility because:

- Infant mortality has been observed in children treated with small amounts of 0.1% Thimerosal in Merthiolate formulations (Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR. Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic,” ***Archives of Disease in Childhood***. 1977; **52**: 962-964) and
- The FDA’s 1998 ban on topical over-the-counter products containing 0.1% Thimerosal was based on proven tissue toxicity and a proven lack of effectiveness.

Moreover, toxicological proof of a link between 0.01% Thimerosal in biological drug formulations and the clinical sub-acute mercury-poisoning symptoms, which are used to diagnose “*autism*,” by that injected Thimerosal has *repeatedly* been established.

Furthermore, there is an ever-growing body of evidence that clearly establishes the validity of the “*theory propounded by a small group of physicians and parents, who claim a link between autism and the thimerosal preservative contained in many vaccines*”²

“Recently, five recent major studies examining the health records of hundreds of thousands of children in the United States, Britain, Denmark, Sweden and Canada found no link between autism and vaccines or thimerosal.”

Factually, the recent study in Canada (Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. ***Pediatrics***. 2006 Jul; **118**(1): e139-e150):

- a. Did *not* examine the “*health records of hundreds of thousands of children*” [it only examined the diagnosis and age of 180 PDD cases of the

² The readers can consult the applicable references in **Appendix A** if they wish to confirm this reviewer’s assertions here.

approximately 190 PDD cases found in a single English-speaking school district of “27749” registered students in Montreal, Quebec – a predominantly French-speaking province] and

- b. *Based on this reviewer’s assessment of the study*, the study actually does provide evidence of a link between the maximum level of Thimerosal exposure and the incidence of what the Canadians and British have labeled pervasive developmental disorders (PDD), which include “autism” and which the American medical establishment has labeled autistic spectrum disorders (ASDs).

Moreover, the initial United States’ epidemiological study results by the CDC’s group headed by Dr. Verstraeten, who did examine the computerized summaries of the medical records of “hundreds of thousands of children in the United States,” found strong evidence of a link between the Thimerosal exposure and the risk of being diagnosed with neurodevelopmental disorders, including the “autism” disorder.³

The British, Danish and Swedish epidemiological studies to which the authors seem to be alluding have been proven to be:

- Poorly designed and/or executed,
- Fatally flawed,
- Conducted by researchers with clear conflicts of interest, and
- Supported by undisclosed CDC funding in some instances

by independent researchers who reviewed them (see, for example:

1. Bernard S. Analysis of the Danish Autism Registry database in response to Hviid *et al.* paper on thimerosal in JAMA. (October, 2003). Available at: http://www.safeminds.org/research/docs/Hviid_et_alJAMASafeMindsAnalysis.pdf and last accessed February 2, 2006, and
2. Blaxill M. Danish-autism study in Pediatrics: Misleading and uninformative on autism-mercury link. Sept. 2, 2003; **E-pub at www.SafeMinds.com**: 1-4).

As of August 2006, no vaccine apologist or vaccine proponent has as yet published any peer-reviewed rebuttal to the assessment of those independent reviewers that has factually disputed the independent reviewers’ assessments that these studies were and are poorly designed and/or executed, fatally flawed, biased by the studies’ conflicted authors, and underwritten by the CDC.

Further, this reviewer notes that the authors failed to mention, much less address, the current 9 independent epidemiological studies (references:

1. Geier DA, Geier MR. Thimerosal in childhood vaccines, neurodevelopmental disorders, and heart disease in the United States. *J Am Phys Surg*. 2003; **8**: 6–11.
2. Geier DA, Geier MR. An assessment of the impact of thimerosal on childhood neurodevelopmental disorders. *Pediatr Rehabil*. 2003; **6**: 97–102.
3. Geier MR, Geier DA. Neurodevelopmental disorders after thimerosal-containing vaccines: a brief communication. *Exp Biol Med (Maywood)*. 2003 Jun; **228**(6): 660-664.

³ See: <http://www.safeminds.org/research/library/GenerationZeroNotes.pdf>.

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4. Geier DA, Geier MR. An assessment of the impact of thimerosal on childhood neurodevelopmental disorders. *Pediatr Rehabil.* 2003 Apr-Jun; **6**(2): 97-102.
5. Geier DA, Geier MR. A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism. *Med Sci Monit.* 2004 Mar; **10**(3): P133-139.
6. Geier DA, Geier MR. An evaluation of serious neurological disorders following immunization: a comparison of whole-cell pertussis and acellular pertussis vaccines. *Brain Dev.* 2004 Aug; **26**(5): 296-300.
7. Geier DA, Geier MR. Neurodevelopmental disorders following thimerosal-containing childhood immunizations: a follow-up analysis. *Int J Toxicol.* 2004 Nov-Dec; **23**(6): 369-376.
8. Geier DA, Geier MR. A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up analysis. *Med Sci Monit.* 2005 Apr; **11**(4): CR160-CR170.
9. Geier DA, Geier MR. An Evaluation of the Effects of Thimerosal on Neurodevelopmental Disorders Reported Following DTP and Hib Vaccines in Comparison to DTPH Vaccine in the United States. *J Toxicol Environ Health A.* 2006 Aug; **69**(15): 1481-1495.)

that have:

- Established a link between Thimerosal (49.55% mercury by weight) and various neurodevelopmental disorders, including autism, and
- Been published in peer-reviewed journals.

Moreover, *except for the first two of these nine studies*, the healthcare establishment has *not* even bothered to try attacking the validity of these studies or their findings of a link between:

- a. The level of Thimerosal exposure or the differential level of Thimerosal exposure and
- b. the risk of neurodevelopmental disorders including, *in some cases*, autism.

In addition, the attacks on the first two papers were *not* accompanied by substantive evidence supporting the problems alleged.

In addition, the results in the later studies in the “same” Vaccine Safety Data link (VSD) database used by the CDC in its published epidemiological studies (initially conducted in the late 1990s by a CDC group nominally headed by Dr. Verstraeten) confirmed the validity of the findings of the “link supportive” authors in one of the papers that the medical establishment tried to attack with unsupported innuendo and anonymous slanders against those authors, which were posted on the Internet by the American Association Of Pediatrics.

“The peer-reviewed studies - published in prestigious medical journals - show that the rates of autism either remained the same or increased after mercury-containing thimerosal was removed from childhood vaccines.”

Factually, the published “*peer-reviewed studies*” to which the authors of this article are referring were, *as this reviewer has reported*, found to be fatally flawed by independent researchers whose published assessments have *not*

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been factually refuted by either the authors of these published “*peer-reviewed studies*” or other vaccine proponents or apologists.

Thus, like the published “*peer-reviewed studies*” on Vioxx, also “*published in prestigious medical journals,*” the dismissive studies to which the authors of this article seemingly refer have been shown to be knowing manipulations of the actual data to misrepresent factual reality.

Given the proven flaws and biases in the dismissive studies to which these authors are referring, the conclusions reached by said dismissive studies are obviously *not* valid — regardless of where they were published.

“Unfortunately, misplaced media attention to this nonexistent link obscures the very real issues surrounding autism and shifts attention away from what is genuinely needed: federal funding for increased research into the disorder, advanced training for medical professionals, increased early diagnosis and improved services for autistic children and their parents.”

Here, the authors begin by making knowingly misleading and unsupported assertions (about an alleged “*nonexistent link*” and claimed “*misplaced media attention*”).

These assertions ignore the factual reality that the link between Thimerosal and the resultant mercury poisoning that produces clinical mercury-poisoning symptoms (including the set of symptoms that are used to diagnose “*autism*”) has been established by many studies.

In addition, this reviewer notes that the mainstream media has given the “Thimerosal causes mercury poisoning that is diagnosed as ‘*autism*’” issue little “*media attention.*”

Moreover, as this article clearly shows, the “*media attention*” appears to be predominantly focused on publishing the misinformation and propaganda promulgated by the mainstream healthcare establishment and vaccine apologists, like the authors of this editorial appear to be.

Furthermore, contrary to the authors’ views, the “*what is genuinely needed*” is precisely what this act is designed *not* to do:

- Establish what is the safe level for Thimerosal in a given drug product formulation for the highest, most frequent dosing and least body mass (with a safety factor of at least 100).
- Prove that Thimerosal-preserved drugs can be injected into pregnant women with no adverse risk to the fetus at Thimerosal levels 100 times higher than the maximum amount of Thimerosal injected in the worst-case scenario.
- Prove that none of those diagnosed with autism and any other autistic spectrum disorder have been mercury poisoned.
- Prove that chelation to remove poisonous levels of mercury and other heavy metals does *not* improve the functioning of most of the children diagnosed with both an autistic spectrum disorder and poisoning by mercury and/or other heavy metals.
- Prove that the use of Lupron to lower the androgen levels in children

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- who are diagnosed with both an autistic spectrum disorder and hyperandrogeny or precocious puberty does *not* improve the functioning of most of the children so diagnosed.

Instead of focusing on establishing the validity of the mitigatory therapy regimens that seem to be improving the health of most of the children diagnosed with autism, the act would, as *these authors admit here*, would authorize, but not provide federal funds for:

- “increased research into the disorder” with an apparent focus on genetics,
- “advanced training for medical professionals,”
- “increased early diagnosis and,” though *not* mentioned,
- federal medical tracking of the number of autistic spectrum cases,

but *not* really, as *the authors claim*,

“improved services for autistic children and their parents”

because it would take tens of billions of dollars annually to *effectively* improve the services for all the current million plus “*autistic children and their parents.*”

“Given that autistic spectrum disorders are among the most common genetic conditions - occurring in one of every 166 live births - we should not waste any more time pursuing what amounts to a dead-end speculation.”

The authors again mistakenly assert that “*autistic spectrum disorders*” are “*genetic conditions*” even though the scientific evidence has only established that genetics affects susceptibility in most cases and *not* incidence *per se* because the rate of “*autistic spectrum disorders*” in identical twins is less than 100% for the other twin when one twin is diagnosed with autism.⁴

Further, the ever-growing body of scientifically sound genetic and toxicological evidence *clearly* supports environmental issues as major factors in the majority of the autistic-spectrum-disorder cases.

Thus, contrary to the authors’ views, “*we*” most certainly should continue to seek to find, define, and, *to the extent possible*, eliminate these environmental causative factors.

“The Combating Autism Act would, among other things:

- Double the amount that the National Institutes of Health spends on autism research.”

The authors are almost correct here.

Factually, this act would only authorize the spending of more money; it would *not* appropriate that money.⁵

⁴ See, for example, Bailey A, Le Couteur A, Gottesman U, Bolton P, Simonoff E, Yuzda E, Rutter M. Autism as a strongly genetic disorder: Evidence from a British twin study. *Psychol Med.* 1995; **25**: 63-67. “In the combined sample 60% of monozygotic (MZ) pairs were concordant for autism versus no dizygotic (DZ) pairs; ...”

⁵ If a bill appropriates money it must originate in and first be passed by the House before going to the Senate. Since this proposed House act was first passed by the Senate, it *cannot* legally

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- “• Create a screening program in all 50 states for the early identification of children with autism.”

Here this reviewer notes that this act would effectively create another unfunded liability for the States and, *in this reviewer's view*, provide insufficient funds over too short a period for an effective program

- “• Fund the efforts of the Autism Treatment Network to identify the best medical practices in the treatment of autistic kids.”

Here, this reviewer understands that this proposed funding is *not* in the best interests of those with autism and their parents because the “*efforts of the Autism Treatment Network*” would continue to be directed:

- Toward “educational” interventions, including various forms of aversion therapy, and the use of psychotropic drugs to control objectionable behaviors (which would profit the pharmaceutical industry), and
- Away from complete differential analysis to establish the underlying causes that led to a diagnosis of autism coupled with appropriate dietary interventions and, *for those proven to have been poisoned by mercury and other heavy metals*, the mitigative use of appropriate chelation therapy to reduce their levels of mercury and other heavy metals coupled with appropriate multivitamin/multi-mineral supplements as well as, *for those also diagnosed with hyperandrogeny or precocious puberty*, the appropriate corrective use of Lupron, which would help heal the disease underlying the symptoms exhibited by those who have been poisoned mercury and/or other heavy metals.

Furthermore, *while this reviewer is not opposed to “educational” interventions*, he does have reservations about the use (often misuse) of aversion therapy and is strongly opposed to the use of psychotropic drugs in children who are already neurologically impaired.

This reviewer’s opposition to psychotropic drugs is based on the scientifically sound evidence that the use of such drugs adversely affects brain function, and induces addiction and, *in some cases*, suicidality in those children given many of these drugs.

- “• Continue funding of the epidemiological and public education programs on autism at the Centers for Disease Control and Prevention.”

Thus, this reviewer finds that the “*funding of the epidemiological and public education programs on autism at the Centers for Disease Control and Prevention*” would be a inappropriate because:

appropriate any money for any purpose. Factually, this act only authorizes spending maximums over the specified period – it does *not* appropriate any funds.

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- By losing the datasets used in their previous VSD study, continuing to severely restrict independent researchers' access to the VSD database and transferring the VSD database data 2000 into the control of a private firm – effectively placing that data off limits to independent study, the “Centers for Disease Control and Prevention” (CDC) has proven that the CDC should *not* be funded for any more epidemiological programs – these studies, *if necessary*, should be transferred to a non-conflicted agency within the Department of Health and Human Services (DHHS) – and the CDC's programs and funding should be restricted to disease control and prevention function.
- In addition, since CDC officials have repeatedly testified and/or admitted that they are justified in knowingly misrepresenting the safety of vaccines and their adverse effects to advance vaccine uptake – effectively claiming the end (improving vaccine uptake) justifies the means (misrepresenting the safety [by knowingly understating the risks of harm and the severity of those risks of harm] and overstating the effectiveness of vaccines [by hyping {inflating} their effectiveness and/or the duration of their effectiveness]), they should *not* receive any additional funds for “*public education programs on autism*” until and unless the CDC stops these less-than-ethical practices.

The current reality is that the CDC's “*public education programs on autism*” are, *as this article*, disinformation and propaganda programs designed to mislead the public about the claimed safety of Thimerosal-containing vaccines without providing any scientifically sound substantive toxicological evidence to prove, with a 100-fold safety margin, what the safe level is for injected Thimerosal.

“The bill, which would authorize nearly \$1 billion over the next five years to conduct a variety of activities to fight the disease, is long overdue and deserves swift passage.”

Contrary to the views of these authors, this reviewer finds that this bill should *not* be passed in its present form because it does *not* require the DHHS and its subsidiary agencies to find and eliminate the root causes of autism and all of the related diseases⁶ whose epidemic incidence rate increases seem to track the increase in the amount of Thimerosal injected into pregnant women, babies, children, adolescents, young adults, adults, and the elderly without proof of safety as required by law since 1973.

“At present, research about autism is limited.”

In general, this reviewer agrees with the authors here.

However, given the wording of this act, including the omission of:

⁶ The other disease conditions showing a correlated epidemic increase include, but are *not* limited to, asthma, autoimmune dysfunction, chronic debilitating skin disorders, diabetes (both type I and type II), food allergies, general immune-system dysfunction, gut absorption disorders, idiopathic dilated cardiomyopathy (IDCM), inflammatory bowel disease (IBD), multiple sclerosis, leukemias and other cancers, and obesity.]

- The words, “Thimerosal” and “mercury,” and
- Phrases, “clinical toxicology,” “reproductive toxicity,” “long-term low-dose toxicology,” “long-term teratogenicity, mutagenicity, and carcinogenicity studies,” and “mercury poisoning,”

this reviewer realizes that one of the true purposes of this act is to fund research that covers up the clear link between injected Thimerosal and sub-acute mercury poisoning, including the subset of mercury-poisoning symptoms that are used to diagnose “autism” and the other recognized neurodevelopmental disorders.

“We do know it is a genetic disorder associated with structural changes in the brain that begin prior to birth.”

Here again, the authors are simply wrong.

First, there is no proof that autism is:

- Purely “a genetic disorder” or
- Solely “associated with structural changes in the brain that begin prior to birth.”

Second, *in most cases*, the body of scientific evidence points to:

- Environmental factors,
- Environmentally induced changes in the brain that occur both before and after birth, and
- A complex set of genetic influences that are contributing factors to the person’s susceptibility (risk) to being harmed.

Third, injected Thimerosal has been proven to be a significant factor in animal studies and humans susceptible to sub-acute mercury poisoning.

Moreover, for sub-acute doses, the resultant mercury poisoning in susceptible study subjects has been shown to produce clinical symptoms including the set of symptoms used to diagnose autism and other neurodevelopmental disorders.

Finally, the scientifically sound genetic evidence has clearly established that “autism,” the authors’ “*it*,” is not a single “genetic disorder.”⁷

⁷ Recent case studies that included complete genetic evaluation have found that two defined genetic conditions, Rhett and Fragile X, and genetic abnormalities in another region have collectively been found to be major causative factors in less than 5% of the cases who have a confirmed diagnoses of “autism.” Moreover, though Fragile X is a known risk factor for autism spectrum disorders, only one in 5 boys with Fragile X are diagnosed with ASD [Brown WT, Jenkins EC, Cohen IL, Fisch GS, Wolf-Schein EG, Gross A, Waterhouse L, Fein D, Mason-Brothers A, Ritvo E, *et al.* Fragile X and autism: A multicenter survey. *Am J Med Genet.* 1986; **23**: 341-352. Abstract: “We screened 183 autistic males for the fra(X) and found 24 (13.1%) to be positive. Adding the subjects of this study to those of 11 other surveys, of which 6 were positive and 5 were negative, a total of 614 autistic males have been screened. Overall 47 (7.7%) were positive. Based on this estimate and the prevalence of autism and fra(X), we estimate that 12.3% of fra(X) males are autistic. We have found that 17.3% of our fra(X) males were autistic and overall a 21.2% frequency has been reported, these higher figures are most likely due to biases in age and ascertainment. With an overall 7.7% frequency of fra(X) among autistic males and an estimated 12.3% of autism among fra(X) males, we conclude there is likely to be a significant association of fra(X) with autism. Because fra(X) appears to be the single most common cause of the condition, chromosomal testing is recommended for any autistic person with undiagnosed etiology.”

“We also know that autism genes produce effects that lead to an excessive increase in head size at about one month of age, well before a baby receives its first set of pediatric vaccines.”

Again the authors begin by making a less than factual statement.

Factually, head-size studies have produced conflicting results about the asserted “*excessive increase in head size at about one month of age,*” and the authors here have conveniently forgotten to mention that fact or the fact that Thimerosal is indirectly or directly injected into the child by:

- One, or more, pre-birth injections of a significant percentage of U.S. mothers with a Thimerosal-preserved biological product (formerly [until 2005 in some cases], a Thimerosal-preserved Rho(D) product in up to 15 percent of U.S. mothers [Rh-negative mothers who have a possible Rh incompatibility with their fetus] and, currently, the Thimerosal-preserved inactivated influenza vaccine estimated to be given to >20% of pregnant women).
- The “day one” injection of newborns with a Thimerosal-preserved (up to the end of 2005 in some cases) Hepatitis B vaccine or, on an ongoing basis, a Thimerosal-containing Hepatitis B vaccine.

Thus, the authors’ “*well before a baby receives its first set of pediatric vaccines*” statement seems to be, at best, knowingly designed to mislead the reader about the possibility of a Thimerosal link to the “*excessive increase in head size at about one month of age*” reported in one head-size study.

Moreover, the recent systematic review by Redcay and Courchesne (Redcay E, Courchesne. When is the brain enlarged in autism? A meta-analysis of all brain size reports. *Biol Psychiatry*. 2005; **58**: 1-9.) concluded, *for those having an autistic spectrum diagnosis (ASD), that, on average, their brain size is somewhat reduced at birth, increases substantially during the first year of life but plateaus so that, in adults, their head sizes in ASD adults are not distinguishable from those of the “normal” adults.*

“And we know heredity is the most important risk factor for these structural changes in autistic brains.”

Here the authors again misstate the facts.

Factually, “*heredity*” has *not* been proven to be “*the most important risk factor for these structural changes in autistic brains.*”

Based on the animal studies by Hornig *et al.* (Hornig M, Chian D, Lipkin WI, **IMMEDIATE COMMUNICATION**, “Neurotoxic effects of postnatal thimerosal are mouse strain dependent,” *Molecular Psychiatry*. Jun 8, 2004: 1-13. In print: *Mol Psychiatry*. 2004 Sep; **9**(9): 833-45) and others (see, for example:

1. Clarkson, T. The toxicology of mercury. *Crit Rev Clin Lab Sci*. 1997; **34**(3): 369-403.
2. Clarkson TW. Mercury: Major issues in environmental health. *Environ Health Perspect*. 1992; **100**: 31-38.
3. Davis LE, Kornfeld M, Mooney HS, Fiedler KJ, Haaland KY, Orrison WW, Cernichiari E, Clarkson TW. Methylmercury poisoning: Long term clinical,

- radiological, toxicological, and pathological studies of an affected family. *Ann Neurol*. 1994; **35**(6): 680-688.
4. Matheson DS, Clarkson TW, Gelfand EW: Mercury toxicity (acrodynia) induced by long-term injection of gammaglobulin. *J. Pediatr*. 1980; **97**(1): 153-155. [Also in the 2001 FDA TOX REPORT.]
 5. Amin-Zaki L, Majeed MA, Elhassani SB, Clarkson TW, Greenwood MR, Doherty RA. Prenatal methyl mercury poisoning. *Am J Disabled Child*. 1979; **133**: 172-177.
 6. Amin-Zaki L, Majeed MA, Clarkson TW, Greenwood MR. Methylmercury poisoning in Iraqi children: Clinical observations over two years. *British Medical Journal*. 1978 March 1: 613-616.
 7. Amin-Zaki, L., Elhassani S, Majeed MA, Clarkson TW, Doherty RA, Greenwood M. Intra-uterine methyl mercury poisoning in Iraq. *Pediatrics*. 1974; **54**(5) 587-595.
 8. Suzuki T., Takemoto T. I., Kashiwazaki H., Miyama T., Metabolic fate of ethyl mercury salts in man and animal. **Mercury, Mercurials, and Mercaptans**, Chapter 12; 209-233. Miller M. W., Clarkson T. W., eds. (Springfield: Charles C. Thomas, 1973), p. 209-40.
 9. Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. Comparison of blood and brain mercury levels in infant monkeys exposed to methyl mercury or vaccines containing Thimerosal. *Environ Health Perspec*. 2005; **113**: 1015-1021.
 10. Bakir F, Damluji SF, Amin-Zaki L, Murradha M, Khaladi A, Alrawi NY, Tikriti S, Dhahir HI, Clarkson TW, Smith JC, Doherty RA. Methyl mercury poisoning in Iraq. An inter-university report. *Science*. 1973; **181**: 230-241.)

as well as autopsy studies on deceased humans (again, **see**: Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR. Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic," *Archives of Disease in Childhood*. 1977; **52**: 962-964).

Thimerosal exposure and, *to a lesser extent*, exposure to elemental mercury and other mercury compounds are also important risk factors for the structural changes observed in the brains of those diagnosed with autism or other neurodevelopmental disorders.

“A stepped-up effort to fund such research could lead to the development of new treatments, genetic screening tools and an evidence-based program of genetic counseling.”

Contrary to the authors’ assertions, the current act, if passed with the language in the submitted House bill and the approved Senate bill, S. 843, the stepped efforts to fund the proposed research will lead to:

1. The development and use of more psychotropic drugs to control behavior rather than finding and removing the causative environmental agents, developing effective mitigatory therapies for those diagnosed with autism, and
2. The development of “*genetic screening tools and an evidence-based program of genetic counseling*” designed to kill off any fetus that has a genetic susceptibility to clinical levels of mercury poisoning by Thimerosal that would lead to a diagnosis of autism so that Thimerosal may

continue to be used to sub-acutely mercury poison “resistant” fetuses and babies to preserve most of the epidemic increases in the other childhood disease conditions on which the healthcare establishment seems to currently rely for a significant percentage of its revenues.

Thus, the current provisions of the obviously healthcare-establishment-crafted “Combating Autism Act” are seemingly intended to support the craven creation of a “more-resistant” captive population [by killing off those carrying genes that make them more “susceptible”] so that the current level of the milking of the American public “herd” by the healthcare establishment can be maintained and, in time, enhanced by the continued knowing unnecessary mercury poisoning of us all starting when we are fetuses.

In this reviewer’s analysis, the language in this act has been designed to support the knowing creation of a “healthcare-establishment optimized ‘herd’” that the healthcare establishment can continue to abuse for its profit and the cover up of the nature and the magnitude of the insidious sub-acute mercury poisoning effects from the repeated knowing injection of poisonous levels of Thimerosal into pregnant women, newborns, fetuses, babies, children, adolescents, and adults.

Hopefully, the American public will wake up, recognize that the healthcare establishment’s apparent on-going 80-year knowing mercury-poisoning of fetuses, babies, children and other Americans is a criminal racket, and demand:

- The government stop serving the healthcare establishment,
- Serve the interests of the American public, and,
- *Like the tobacco establishment*, the government prosecute all the involved healthcare-establishment sectors, along with all of the accountable individuals in those sectors, to the full extent of the law under the criminal sections of the RICO statutes for their concerted knowing unnecessary⁸ mercury-poisoning of the American public by the highly toxic mercury-poison, Thimerosal.

[Note: Thimerosal is *unnecessarily* used as a process sterilant or preservative in biological medicines, including vaccines and serums, by those who know, should know, or are responsible for knowing the resultant mercury-containing drugs mercury poison those who receive them to some degree and thereby increase the risk and/or susceptibility to various diseases in those who were injected with these mercury-containing drugs.]

“The Combating Autism Act is, indeed, an act of enlightenment.”

Factually, this reviewer finds that, as drafted in the House and passed by the Senate, the “*Combating Autism Act*” is a healthcare-establishment rewarding piece of legislation that will do little to find the true root causes of autism and the other neurodevelopmental disorders, including Thimerosal-related encephalopathies as well as vaccine-induced

⁸ Factually, there are other safer, non-mercury-containing compounds that can be, have been, and are being used as process sterilants and preservatives in the manufacture of biological drug products.

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encephalitis events that seems to be predominantly triggered by live-virus vaccines.

Instead it appears to be designed to fund the healthcare establishment's ongoing efforts in:

- Healthcare provider indoctrination disguised as medical training,
- The brainwashing of the American public with vaccine propaganda disguised as "*public education programs*," and
- Convincing the American public that the root cause of autism (and the other neurodevelopmental disorders as well as the other diseases whose epidemic rise has been shown to be related to the subacute mercury poisoning via Thimerosal-containing vaccines and other medicines) is, *contrary to the proven scientific realities*,
 - Strictly "*genetic*" or, *as the Orwellian doublespeak written by these authors suggests*,
 - A "*common birth defect*"

Never mind that "*autism*," the authors' alleged "*common birth defect*" is so "*common*" that it was rare (1- to 5- cases in 10,000 live births) about 20 years ago but is *presently* a "50- to 60- cases in 10,000 live births" occurrence and the observed epidemic rise in autism (and the long list of other diseases that this reviewer has listed) is concomitant with the growth in the use of Thimerosal as a process sterilant and preservative in biological medicines, including, but *not* limited to, vaccines, sera, and monoclonal antibody drugs.

These authors need to look into the mirror and ask themselves:

- "Why, in the admitted absence of any proven safe level for Thimerosal, haven't all uses of Thimerosal been stopped and all Thimerosal-containing medicines been recalled and destroyed?"
- "Why, after all parties (governmental, industry and medical) promised in 1999 to remove Thimerosal from all childhood vaccines, has this promise been deliberately broken?"
- "Why, other than to mercury-poison the recipients, have the parties allowed a Thimerosal-preserved inactivated influenza vaccine (that has been proven to be ineffective in: **a**) preventing the spread of flu and **b**) protecting young children from getting the flu) to be added to the vaccines given to pregnant women and children as young as six months of age?"
- "Why, other than to mercury-poison the recipients, have the parties allowed an ineffective Thimerosal-preserved inactivated influenza vaccine to be administered to pregnant women when: **a**) Thimerosal is a proven human teratogen, mutagen, and cancer-inducing agent at Thimerosal levels below 1 ppm and **b**) the requisite scientifically sound multi-generational reproductive toxicity studies have *not* been conducted in to establish, *with a safety factor of at least 100*, the maximum safe level of Thimerosal that can be injected into a pregnant woman at any point in her pregnancy with no (less than a projected 1 in 10,000,000) risk of harm to the unborn fetus?"

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- “Why, other than to mercury-poison the recipients, have the parties, *who promised to remove Thimerosal from all childhood vaccines in 1999*, “allowed” the maximum total dose of Thimerosal to return to more than half⁹ the pre-1999 nominal 200-µg levels of Thimerosal-derived mercury for a 5-year-old?

This reviewer has repeatedly asked these questions.

However, *to date*, this reviewer has received no cogent responses to these questions from those, *who, like these authors*, are obvious vaccine apologists.

Perhaps these authors will be the first to provide cogent answers to these questions, but this reviewer doubts that they will respond, much less respond in a fact-based manner.

“In addition to helping us to understand the root causes of autism, it should undercut those who inaccurately blame lifesaving vaccines for the disorder.”

First, since the act fails to even mention much less address, the known environmental factors, *including injected Thimerosal*, which have been proven to be part of the root causes of at least 85% of the diagnosed autism cases, this reviewer fails to see how this act can help the American people “*to understand the root causes of autism.*”

Second, this reviewer finds that the “*Combating Autism Act*,” as it now stands, will do nothing to undercut those who accurately blame the increase in the level of sub-acute mercury poisoning delivered by the Thimerosal contained in injected biological medicines, including vaccines, for the epidemic rise in autism, other developmental disorders and host of other diseases that this reviewer finds to have a seemingly similar correlated rapid increases that roughly parallel the rise in the maximum average levels of Thimerosal to which fetuses, newborns, babies, toddlers, children, adolescents, young adults, adults and the elderly have been and are being exposed without proof of safety, including the minimum legal proofs required by 21 CFR Sec. 610.15(a) (**see Appendix A, Section G. 8. g**) for each formulation submitted for U.S.-licensing by any manufacturer of any biological drug product.

Third, *in general*, those who blame Thimerosal do *not* blame the vaccine *per se* for autism or any other of the childhood or adult diseases whose

⁹ The preceding is the reality when a child’s mother is vaccinated with an *ineffective* Thimerosal-preserved influenza vaccine during pregnancy (effectively delivering as much, if *not* more, Thimerosal [49.55% mercury by weight] to the fetus [about 20 µg] as RhoGAM used to provide to only those mothers who are Rh negative) and, *after birth*, the child initially receives two *ineffective* Thimerosal-preserved flu shot (one each at about 6 and 7 months of age [50 µg of Thimerosal]) and, *when an ineffective Thimerosal-preserved flu-vaccine is administered each year thereafter*, 25 µg of Thimerosal for two years (50 µg of Thimerosal) followed by 50 µg of Thimerosal a year for two more years (100 more µg of Thimerosal) and up 6 µg of Thimerosal in the other childhood vaccines that contain “trace” levels of Thimerosal for a grand total of 226 µg of Thimerosal (nominally equivalent to 112 µg of mercury.)

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epidemic rise parallels the rise in the maximum level of Thimerosal administered, they accurately blame the Thimerosal.

Since any and all vaccines can be formulated without the need to use Thimerosal or any other mercury compound as a process sterilant or preservative, why has the healthcare establishment reneged on its promise to remove Thimerosal from vaccines?

Why has it added Thimerosal-preserved vaccines back to the childhood schedule by permitting Thimerosal-preserved inactivated-influenza vaccines to be given to pregnant women and annually to children starting when they are 6-months old?

Why has this establishment fought the State legislatures who have enacted or tried to enact State laws prohibiting, or restricting, the use of Thimerosal-preserved vaccines and other mercury-containing medicines, so that, *in most cases*, Thimerosal-preserved vaccines and other medicines *cannot* legally be given to pregnant women and young children vaccines except in an emergency situation?

Finally, it would seem that those who repeatedly state “*those who inaccurately blame lifesaving vaccines for the disorder*” are vaccine proponents and vaccine apologists such as these authors and *not* those who blame the Thimerosal in some vaccines for the autism “*disorder*”!

“That mistaken belief, if perpetuated, could create a public health crisis that will make urgently needed vaccines unavailable to our children.”

Factually, by

- *Falsely claiming to have removed Thimerosal,*
- *Refusing to remove all Thimerosal, a highly poisonous and unnecessary component, from all medicines, and*
- *Fighting State legislation to restrict or ban all uses of Thimerosal or any other mercury-containing compound in vaccines or, in some cases, in all medicines,*

the healthcare establishment, including the manufacturers who continue to make vaccines that contain Thimerosal and their lobbyists are fueling the artificial “*health crisis*” of which these authors speak that could allegedly make a few vaccines “*unavailable to our children*” (and *not* those who know Thimerosal is a highly toxic mercury compound for which the safe level for human exposure has never been proven for the American public).

However, *because the only truly “needed vaccines” for the national immunization program that will truly be unavailable are the ineffective Thimerosal-preserved inactivated-flu-virus vaccines*, this reviewer sees no real impending “*public health crisis*.”

What this reviewer does see is the authors using fear mongering to stir up the American public to behave in the illogical manner that the authors are suggesting they should.

“Already, there have been widespread demands by state legislatures to limit the use of vaccines in children or to change their mode of production.”

Here the authors again begin with a misstatement of the facts.

Factually, “*there have been widespread demands by state legislatures to limit the use of vaccines in children*” that contain, in most cases, more than a trace of Thimerosal or, *in some cases*, any level of added mercury.

Since the medicine manufacturers, federal government and the healthcare professionals pledged to remove Thimerosal from ALL childhood vaccines in 1999, this reviewer sees no problem with the “*state legislatures*” passing laws to ensure that the promises made are kept.

Since:

- The manufacturers asserted that that could remove Thimerosal from all processes used to make childhood vaccines,
- *With a few exceptions*, the manufacturers have not only removed Thimerosal from the processes used to make childhood vaccines but also from the processes used for all their U.S.-licensed vaccines,
- Most of the formulations for vaccines licensed in the U.S. in 2005 and 2006 (e.g., Adacel®, Boostrix®, Gardasil®, Havrix®, Menactra®, ProQuad®, RotaTek®, and Vaqta®, to name a few), have used 2-phenoxyethanol, a long-recognized safer and equally effective alternative to mercury-containing compounds [though a higher concentration is needed] or other FDA-recognized compounds, as a process sterilant and, *where required*, a vaccine preservative.

this reviewer sees no rational reason that any State should *not* act to support the positive changes being made by the vaccine manufacturers who had already changed “*their mode of production*” to keep the promise they voluntarily made to the American public in 1999.¹⁰

IF these authors have:

- a.** Any valid scientific reason that proves that Thimerosal is the only compound that can be used, which they have *not* shared **and**
- b.** Scientifically sound toxicology studies that prove that Thimerosal at the current maximum permitted preservative level (0.01% Thimerosal) is safe for all fetuses, children and adults,

THEN this reviewer invites these writers to share these with the American public.

Absent the preceding, this reviewer simply suggests that these authors’ fear mongering should simply be ignored.

¹⁰ Since it takes several years to develop a new vaccine’s formulation, conduct the required safety and effectiveness studies, and file the appropriate supporting documentation, and the first State laws were *not* enacted until 2005, this reviewer finds it odd that these authors would even raise this issue at this time unless, *as it appears to this reviewer and some other scientists*, they are desperate to keep unnecessarily mercury-poisoning some portion of the American public to sustain their current income levels.

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“In California, for instance, soon children will no longer be allowed to receive the influenza vaccine - a ban that could trigger an epidemic in the nation’s most populous state.”

Yet again, the authors begin by making a knowingly false statement.

The truth is that, *except in a declared emergency*, healthcare providers will no longer be able to give young children (3 and under) and pregnant women a Thimerosal-preserved influenza vaccine dose.

However, since there is a U.S.-licensed “no Thimerosal” inactivated-influenza vaccine that is approved for children as young as 6 months of age, young children and pregnant women can be given this “no Thimerosal” vaccine.

In addition, since there is also “trace Thimerosal” influenza vaccine, physicians may, under the California law, legally elect to give that vaccine to pregnant women.

Further, since the current inactivated-influenza vaccines have been shown *not* to be effective in protecting young children from getting the flu or, *for that matter*, preventing the spread of influenza in the population, California’s restrictions (they did *not* pass any absolute ban) on the use of Thimerosal-preserved inactivated-influenza vaccines *simply cannot* “*trigger an epidemic in the nation’s most populous state.*”

Because there are U.S.-licensed versions of all of the other childhood vaccines for diseases (for which there are disease-controlling vaccines) endemic in the United States that truly can cause a true “epidemic” that do *not* contain Thimerosal or contain a permissible (under California law) “trace Thimerosal” level, this reviewer is at a loss as to the disease about which these authors are talking.

In this regard, this reviewer respectfully requests these authors to list the known human diseases and vaccines of which they are speaking.

“Reduced immunization rates will substantially reverse public health gains made over the last four decades and lead to unnecessary childhood deaths.”

Presuming the authors are still speaking about California and the influenza vaccine, there should be no “*(r)educed immunization rates*” because a “no Thimerosal” inactivated-influenza vaccine is available for those in the covered groups who themselves, *in the case of pregnant women*, or whose parents, *for young children*, elect to have them receive a “flu” shot as well as a U.S.-licensed “trace Thimerosal” influenza vaccine approved for use in adults that a physician may administer to pregnant women.

Moreover, if anything, since Californians will be reassured about vaccination because they will see that their government is moving to protect them and their children from the risk of being poisoned by Thimerosal-preserved vaccines, the influenza vaccine uptake rates may even increase although these inactivated-influenza vaccines have been shown to be ineffective in: **a)**

protecting the person vaccinated from getting the flu or **b)** stopping the spread of influenza.

Furthermore, since these inactivated-influenza vaccines have been shown to be no more effective than a placebo injection in children 2 years of age and under, there is virtually no risk that any change (increase or decrease) in the level of uptake for the inactivated-influenza vaccine could “*lead to unnecessary childhood deaths*”.

“In the meantime, it is important to remember that today’s vaccines save lives.”

This reviewer must first note that the authors’ assertion here is, *at best*, a partial truth.

Factually, the data indicate that, *in those nations having high standards for hygiene and water*, some vaccines do save more lives than they take and the protection they provide outweighs the harm done and the vaccine’s costs.

However, some of today’s vaccines are neither cost-effective nor are so safe that the protection they provide outweighs the harm that they inflict on some.

Moreover, the body of scientific evidence suggests that some of the newer vaccines are being knowingly misrepresented to the American public as life savers when they are neither cost-effective nor disease-prevention-effective for use in a national immunization program.

Effectively all that these vaccines do is line the pockets of the healthcare providers who administer the vaccines, the healthcare providers who treat those who suffer the adverse side-effects of these vaccines, and the vaccine manufacturers who profit from every dose.

Moreover, *because they are, in general, immune from being sued for even the knowing harm that their vaccines may cause*, these manufacturers *obviously* have little incentive to truthfully market their vaccine products.

“Some estimates indicate that the global use of childhood vaccines for diphtheria, pertussis, tetanus, measles, mumps, rubella, Haemophilus influenzae meningitis and polio have saved 160 million lives over the last 25 years. That number is equivalent to all of the lives lost in all world wars during the 20th century.”

Since those who make these estimates are the producers, purveyors, and supporters of childhood vaccines, thus reviewer cautions the reader that the authors’ claims should be take with a large “grain of salt.”

Moreover, while the global figures are impressive, this reviewer must note that the authors fail to tell the American public the truth about:

- The lives saved in America that were truly attributable to the aforesaid list of vaccines and, *more importantly*,
- The “*per-person-saved*” costs,
- The number of children who have been killed by the vaccination programs, and

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- The number of children who been irreparably harmed by the aforesaid list of vaccines.

over that self-same 25-year period for each of the vaccines in the authors' list.

Until the American public is told the truth, the whole truth, and nothing but the truth about all vaccines so that they can make a decision that is truly based on informed consent, the ongoing misrepresentations, *such as many of the statements by these authors*, about vaccines will continue to undermine the American public's confidence in the U.S.-licensed vaccines and the national vaccination programs.

Moreover, until the true net cost-effectiveness of each vaccine is assessed and reported, America will continue to waste precious healthcare dollars on vaccines and vaccination programs that are not cost effective – vaccines and vaccination programs that benefit the healthcare establishment but do *not* benefit the American public.

Though we spend the most on healthcare for our children, even Cuba, a nation that spends more than an order of magnitude less *per capita* on healthcare than the United States (U.S.), has a lower infant mortality (6.22 deaths per 1,000 live births) than the U.S. does (6.42 deaths per 1,000 live births).

In addition, Japan, a country that has a more modest national vaccination program with no mandatory school or job restrictions has an infant mortality of 3.24 deaths per 1,000 live births and Sweden, a nation that totally banned the use of Thimerosal in vaccines in the early 1990s, recalled all Thimerosal-containing vaccines, and has an even more modest vaccination program than Japan, has a 2006 infant mortality rate of 2.76 deaths per 1,000 live births – a rate less than half the mortality rate in the United States.¹¹

Based on the preceding realities, the authors should seriously reconsider their unsupportable defense of the use of Thimerosal in medicine.

“By passing the Combating Autism Act this year, Congress can help millions of American families - both those who are affected by autism and those who will continue to have access to vaccines that protect their children from many other preventable diseases.”

Again, this reviewer finds that, as written, the “*Combating Autism Act*” will provide very little in the way of help to most “*American families*.”

Moreover, contrary to these authors' rhetoric, “*those who will continue to have access to vaccines that protect their children from many other preventable diseases*,”

¹¹ The source for the posted Infant mortality data is:
<https://www.cia.gov/search?NS-search-page=document&NS-rel-doc-name=/cia/publications/factbook/rankorder/2091rank.html&NS-query=infant+mortality&NS-search-type=NS-boolean-query&NS-collection=World%20Factbook&NS-docs-found=481&NS-doc-number=2>
(this page was last updated on 8 August, 2006 when this reviewer visited it on 19 August 2006).

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ignores the reality that this act does *not* address vaccine access and, in this act, *in and of itself*, will do little to affect the American families' "*access to vaccines.*"

Factually, this act is a creature of the healthcare establishment that is designed to authorize funding to support that establishment's agendas and *not* to help the American public.

That this reviewer's assessment is "on point" is confirmed by the fast-tracking by the healthcare-industry-influenced Senate HELP committee, the unanimous approval of the Senate version of the act, and the failure of the act to mention, much less specifically address,

- Thimerosal,
- Mercury poisoning, and
- The toxicological assessment of the link between Thimerosal exposure level and the set of mercury poisoning symptoms used to diagnose autism, or any of the other debilitating childhood and adult diseases whose epidemic increase over the past two plus decades parallels the years of increase in the maximum level of Thimerosal exposure (and decrease in the short period of decreasing Thimerosal exposure from 1999 to 2002).¹²

"Dr. Peter Hotez heads the Department of Microbiology, Immunology and Tropical Medicine at George Washington University in Washington, D.C. Former first lady Rosalynn Carter is co-founder of Every Child by Two, the Carter/Bumpers Campaign for Early Childhood Immunization. Readers may write them in care of Peter Hotez, 2300 I St. N.W., Ross Hall 736, Washington, DC 20032."

[**Note:** Dr. Peter Hotez, M.D. (Cornell), Ph.D. (Rockefeller) has "background and interests" that read as follows:

"Discovery and development of appropriate technology for neglected tropical diseases. Vaccine discovery, development and testing for human hookworm infection

Description of research:

My research interest is in the discovery, development and evaluation of appropriate technology, e.g., vaccines, diagnostics and drugs, for the neglected tropical diseases. The neglected tropical diseases are a group of conditions that occur almost exclusively in rural areas of poverty in the developing world. I currently serve as the Principal Scientist of the Human Hookworm Vaccine Initiative (HHVI), a public private partnership sponsored by the Sabin Vaccine Institute with major funding from the Bill and Melinda Gates Foundation. The four-fold mission of the HHVI is:

- Research & Development : To develop a safe, efficacious, and low-cost vaccine in order to reduce the burden of disease caused by human hookworm infection
- Dissemination : To ensure that the Human Hookworm Vaccine is made available to impoverished people living in Africa , Asia , and the Americas
- Innovation : To conduct basic and applied research that will facilitate the development of new tools for hookworm control

¹² A period that was retarded by *not* recalling and destroying all vials of in-date lots of Thimerosal-preserved vaccines as well as by: **a)** unofficially recommending Thimerosal-preserved inactivated-influenza vaccines be administered to pregnant women and young children in 2002, **b)** the CDC's officially adding it to its list of suggested vaccinations for pregnant women and young children [6 months to 35 months of age] in Dec. 2003, and **c)** the CDC's increasing the age range for young children to 6 months to 59 months of age in 2006 – all without proving what the safe level was for any of these groups and with total disregard for these vaccines' proven ineffectiveness in children.

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- Advocacy : To make the scientific and lay communities aware of the importance of human hookworm infection and related neglected diseases as public health threats

In addition to my research interests, I have an educational and advocacy interest to promote training in appropriate technology for research institutes and schools in developing countries and curricula of U.S. medical and public health schools.”

Based in the preceding it is clear to this reviewer that this author has an inherent conflict of interest that he knowingly failed to disclose.

Further, it seems clear that this author was the principal writer of this article.]

About Dr. Paul G. King, this article’s reviewer:

- Dr. King is a PhD Analytical Chemist, an MS Inorganic Chemist, and the founder of Facility Automation Management Engineering (F.A.M.E.) Systems, a CONFIDENTIAL consultancy in chemistry and pharmaceuticals as well as in compliance with CGMP (current good manufacturing practice).
- He can be reached by mail at 33 Hoffman Avenue, Lake Hiawatha, New Jersey 07034-1922-33, USA and by e-mail through his website, <http://www.dr-king.com> or directly at drking@gti.net.
- Dr. King currently receives no compensation from any party of interest on either side of the issue of the sub-acute mercury poisoning of humans from the fetal stage onward by Thimerosal-containing biological products.

[**Note:** Based on:

- More than a decade of research into the published literature surrounding the use of any form of mercury in medicine,
- The lack of any of the published definitive studies required to satisfy the legal requirement set forth in 21 CFR Sec. 610.15(a) and
- The repeated Congressional testimony by U.S. Food and Drug Administration (FDA) officials that admit the requisite studies have *not* been conducted and, in spite of this knowing violation of the statutes and laws governing drugs (e.g., 21 U.S.C. 351(a)(2)(B), 21 CFR Parts 210 and 211, and 21 CFR Sec. 610.15(a)) by the manufacturers, the FDA has, since 1973, knowingly licensed adulterated drugs and, since 1988, “thumbed their noses” at the unanimous Supreme Court decision (Berkovitz v. US) that such actions by a government violate the law. [**See Appendix A, Section G** for the text to the cited statutes, laws, and the Supreme Court decision.]

the current toxicological evidence has convinced Dr. King that, *in the absence of scientifically sound proof of long-term safety, the safe (with the 100-fold safety margin appropriate for highly poisonous compounds whose use is not absolutely necessary) individual dose for Thimerosal in a vaccine that is administered to children infrequently (once or twice in a decade) is less than 0.03 microgram (µg). Similarly, for biological products given more frequently (e.g., a vaccine administered annually, like the influenza vaccines) or to a pregnant woman, that safe level per dose for Thimerosal may be less than 0.006 µg. Likewise, for drugs given as frequently as biweekly (e.g., some of the monoclonal antibody drugs, like Humira®), there can be no justification for the use of Thimerosal in the production of such drugs.]*

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- "The seasoned conclusion Wigzell gives is, 'Our opinion, however, is that the problems associated with the spread of mercury via vaccination are so minor that there is no reason to push a hastened solution.'"
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 - t. Mader R, Narendran A, Lewtas J, et al. Systemic vasculitis following influenza vaccination—report of 3 cases and literature review. *J Rheumatol*. 1993; **20**: 1429-1431.
 - u. Blumberg S, Bienfang D, Kantrowitz FG. A possible association between influenza vaccination and small-vessel vasculitis. *Arch Intern Med*. 1980; **140**: 847-848.
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- 137. THIMEROSAL-RELATED PATENTS:**
- a. Kharasch, U.S. patent 1,672,615 (1928). [Morris Selig Kharasch of College Park Maryland, Applied for Patent for "Alkyl Mercuric Sulphur Compound and Process for Producing it" on 29 June 1927, Serial No. 2002,468. Patent 1,672,615 was issued on 5 June 1928];
 - b. Kharasch, U.S. patent 1,862,896 (1932) [Morris S. Kharasch of Chicago, Illinois, Applied for Patent for "Stabilized Bactericide and

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Process of Stabilizing it" on 22 August 1931, Serial No. 558,830. Patent 1,862,896 was issued on 14 June 1932];

- c. Kharasch, U.S. patent 2,012,820 (1935) [Morris S. Kharasch of Chicago, Illinois, assigner to Eli Lilly and Company, Indianapolis, Indiana, a Cooperation of Indiana, Applied for Patent for "Stabilized Organo-Mercuri-Sulphur Compounds" on 17 February 1934, Serial No. 711-822. Patent 2,012,820 was issued on 27 August 1935]; and
- d. Davidson, U.S. patent 2,864,844 (1958).

F. Pertinent Epidemiological MMR-Study-Review References:

1. Goldman GS, Yazbak, FE. An investigation of the association between MMR vaccination and autism in Denmark. *J Am Phys Surg*. 2004 Fall; **9**(3): 70-75. [EPIDEMIOLOGY – evidence of a link between autism & MMR vaccine.]
2. Stott C, Blaxill M, Wakefield AJ. MMR and autism in perspective: The Denmark story. *J Am Phys Surg*. 2004 Fall; **9**(3): 89-91. [EPIDEMIOLOGY – evidence of a link between autism & MMR vaccine.]

G. Key Federal Statutes, Regulations, and Judicial Decisions:

1. **21 CFR Section 610.15(a)**. Thimerosal has been illegally used as a preservative since 1973 when the FDA enacted regulations requiring a compound to be proven safe before use as a preservative. (See: 21 CFR 610.15(a):

“TITLE 21--FOOD AND DRUGS.

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS

Subpart B--General Provisions

Sec. 610.15 Constituent materials.

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. ...”

[**Note:** The crude toxicity studies done under contract to the FDA, in the 1960s, did *not* establish a safe level for exposure in humans. In addition, it did *not* even study: **a**) the effects of long-term intermittent dosing at drug levels, **b**) the dosing in pregnancy (including multi-generation reproduction studies), **c**) dosing in developing infants, children and adolescents, or **d**) dosing in the elderly. The animal studies that were conducted only looked for gross changes in one animal species (the rat) without any proof of comparable toxicity in humans. Since other studies had been published that had established Thimerosal is a teratogen and mutagen as well as causes multigenerational genetic effects, the failure to do these studies *cannot* be justified. Finally, the FDA's 2001 literature studies failed to find many important references including those published by governmental agencies including the FDA.]

2. **21 U.S.C. Section 351(a)(2)(B)**. Title 21 of the United States Code (21 U.S.C. Section 351(a)(2)(B): Oct. 10, 1962, Pub. L. 87-781, title I, Sec. 101, 76 Stat. 780, added:

“(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;”

after the existing 21 U.S.C. Section 351(2), which was redesignated as 21 U.S.C. Section 351(2)(A).

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3. **21 U.S.C. Section 321. Definitions; generally.**— Especially:
- a. **Sec. 321(g)(1):** “The term ‘drug’ means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.”
 - b. **Sec. 321(u):** “The term ‘safe’ as used in paragraph(s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.”
 - c. **Sec. 321(bb):** “The term ‘knowingly’ or ‘knew’ means that a person, with respect to information - (1) has actual knowledge of the information, or (2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.”
 - d. **Sec. 321(cc):** “For purposes of section 335a of this title, the term ‘high managerial agent’ - (1) means - (A) an officer or director of a corporation or an association, (B) a partner of a partnership, or (C) any employee or other agent of a corporation, association, or partnership, having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and (2) includes persons having management responsibility for - (A) submissions to the Food and Drug Administration regarding the development or approval of any drug product, (B) production, quality assurance, or quality control of any drug product, or (C) research and development of any drug product.”
 - e. **Sec. 321(dd):** “For purposes of sections 335a and 335b of this title, the term ‘drug product’ means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of title 42.”
4. **21 U.S.C. Section 331. Prohibited acts.** “The following acts and the causing thereof are prohibited:
- (a) **The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated** or misbranded.
 - (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
 - (c) **The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.**
 - (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.
 - (e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 354, 360bbb-3, 373, or 374(a) of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l), or (m), 360e(f), 360i, or 360bbb-3 of this title, or the refusal to permit access to or verification or copying of any such required record.
 - (f) The refusal to permit entry or inspection as authorized by section 374 of this title.
 - (g) **The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.**

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(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; **or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.**

(i)

(j)

(k)

(l) Repealed. Pub. L. 105-115, title IV, Sec. 421, Nov. 21, 1997, 111 Stat. 2380.

(m)

(n)

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p)

(q) (1)

(2)

(r)

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t)

(u)

(v)

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x)

(y) In the case of a drug, device, or food -

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z)

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- (aa)
- (bb)
- (cc)
- (dd)
- (ee)
- (ff)

(gg) The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”

5. 21 U.S.C. Section 333. Penalties.

- “(a) Violation of section 331 of this title; second violation; intent to defraud or mislead
- (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.
 - (2) Notwithstanding the provisions of paragraph (1) of this section, (1) if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.
- (b) Prescription drug marketing violations
- (1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by - (A) knowingly importing a drug in violation of section 381(d)(1) of this title, (B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title, (C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or (D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.
 - (2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties: (A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period. (B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period. For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.
 - (3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than \$100,000.
 - (4) (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or

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offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence -

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation, the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

(6) Notwithstanding subsection (a) of this section, any person who is a manufacturer or importer of a prescription drug under section 384(b) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to

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comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

- (d) Exceptions involving misbranded food
.....
 - (e) Prohibited distribution of human growth hormone
 - (1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.
 - (2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.
 - (3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].
 - (4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.
 - (5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.
 - (f) Redesignated (g)
 - (g) Violations related to devices
 - (1) So in original. Words 'of this section' probably should not appear."
6. **21 CFR PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL.** — Especially:
- a. **“§ 210.1 Status of current good manufacturing practice regulations.**
 - (a) The regulations set forth in this part and in parts 211 through 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.
 - (b) The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.
 - (c) Owners and operators of establishments engaged in the recovery, donor screening, testing (including donor testing), processing, storage, labeling, packaging, or distribution of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in §1271.3(d) of this chapter, that are drugs (subject to review under an application submitted under section 505 of the act or under a biological product

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license application under section 35 I of the Public Health Service Act), are subject to the donor-eligibility and applicable current good tissue practice procedures set forth in part 127 I subparts C and D of this chapter, in addition to the regulations in this part and in parts 21 I through 226 of this chapter. Failure to comply with any applicable regulation set forth in this part, in parts 21 I through 226 of this chapter, in part 127 I subpart C of this chapter, or in part 127 I subpart D of this chapter with respect to the manufacture, processing, packing or holding of a drug, renders an HCT/P adulterated under section 501(a)(2)(B) of the act. Such HCT/P, as well as the person who is responsible for the failure to comply, is subject to regulatory action.”

- b. “§ 210.2 **Applicability of current good manufacturing practice regulations.**
- (a) The regulations in this part and in parts 21 I through 226 of this chapter as they may pertain to a drug; in parts 600 through 680 of this chapter as they may pertain to a biological product for human use; and in part 127 I of this chapter as they are applicable to a human cell, tissue, or cellular or tissue-based product (HCT/P) that is a drug (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 35 I of the Public Health Service Act); shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.
- (b) If a person engages in only some operations subject to the regulations in this part, in parts 21 I through 226 of this chapter, in parts 600 through 680 of this chapter, and in part 127 I of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.”
- c. “§ 210.3 **Definitions.**
- (a) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part and in parts 21 I through 226 of this chapter.
- (b) The following definitions of terms apply to this part and to parts 21 I through 226 of this chapter.
- (1) Act means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).
 - (2) Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
 - (3) Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.
 - (4) Drug product means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.
 - (5) Fiber means any particulate contaminant with a length at least three times greater than its width.
 - (6) Non-fiber-releasing filter means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.
 - (7) Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that

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may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

- (8) Inactive ingredient means any component other than an active ingredient.
- (9) In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product.
- (10) Lot means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.
- (11) Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.
- (12) Manufacture, processing, packing, or holding of a drug product includes packaging and labeling operations, testing, and quality control of drug products.
- (13) The term medicated feed means any Type B or Type C medicated feed as defined in §558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of part 225 of this chapter.
- (14) The term medicated premix means a Type A medicated article as defined in §558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of part 226 of this chapter.
- (15) Quality control unit means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.
- (16) Strength means:
 - (i) The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or
 - (ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).
- (17) Theoretical yield means the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production.
- (18) Actual yield means the quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular drug product.
- (19) Percentage of theoretical yield means the ratio of the actual yield (at any appropriate phase of manufacture, processing, or packing of a particular drug product) to the theoretical yield (at the same phase), stated as a percentage.
- (20) Acceptance criteria means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).
- (21) Representative sample means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

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(22) Gang-printed labeling means labeling derived from a sheet of material on which more than one item of labeling is printed.

7. **21 CFR Part 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS.**— Especially:

a. “Subpart A—General Provisions

§ 211.1 Scope.

- (a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.
- (b) The current good manufacturing practice regulations in this chapter as they pertain to drug products; in parts 600 through 680 of this chapter, as they pertain to drugs that are also biological products for human use; and in part 1271 of this chapter, as they are applicable to drugs that are also human cells, tissues, and cellular and tissue-based products (HCT/Ps) and that are drugs (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act); supplement and do not supersede the regulations in this part unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, or in parts 600 through 680 of this chapter, or in part 1271 of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.
- (c) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this part shall not be enforced for OTC drug products if the products and all their ingredients are ordinarily marketed and consumed as human foods, and which products may also fall within the legal definition of drugs by virtue of their intended use. Therefore, until further notice, regulations under part 110 of this chapter, and where applicable, parts 113 to 129 of this chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

§ 211.3 Definitions.

The definitions set forth in §210.3 of this chapter apply in this part.”

b. “Subpart B—Organization and Personnel

§ 211.22 Responsibilities of quality control unit.

- (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
- (b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.
- (c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.
- (d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

§ 211.25 Personnel qualifications.

- (a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to

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enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

- (b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.
- (c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

§ 211.28 Personnel responsibilities.

- (a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.
- (b) Personnel shall practice good sanitation and health habits.
- (c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.
- (d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

§ 211.34 Consultants.

Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.”

c. “Subpart I—Laboratory Controls

§ 211.160 General requirements.

- (a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.
- (b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

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- (1) Determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.
- (2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.
- (3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.
- (4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 211.165 Testing and release for distribution.

- (a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.
- (b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.
- (c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed.
- (d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.
- (e) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with §211.194(a)(2).
- (f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria.

§ 211.166 Stability testing.

- (a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:
 - (1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;
 - (2) Storage conditions for samples retained for testing;
 - (3) Reliable, meaningful, and specific test methods;

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- (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;
- (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.
- (b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.
- (c) For homeopathic drug products, the requirements of this section are as follows:
 - (1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use.
 - (2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.
- (d) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section.

§ 211.167 Special testing requirements.

- (a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed.
- (b) For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed.
- (c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.

§ 211.170 Reserve samples.

- (a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:
 - (1) For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.
 - (2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:
 - (i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or
 - (ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

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- (3) For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under §211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient.
- (b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows:
- (1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product.
- (2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:
- (i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or
 - (ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days.
- (3) For an OTC drug product that is exempt for bearing an expiration date under §211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed.

§ 211.173 Laboratory animals.

Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use.

§ 211.176 Penicillin contamination.

If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference. Copies are available from the Division of Research and Testing (HFD-470), Center for Drug Evaluation and Research, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.”

8. 21 CFR Part 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

a. “§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each

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applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.”

b. “§ 610.2 Requests for samples and protocols; official release.

- (a) Licensed biological products regulated by CBER. Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Biologics Evaluation and Research (see mailing addresses in §600.2 of this chapter). Upon notification by the Director, Center for Biologics Evaluation and Research, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Center for Biologics Evaluation and Research: Provided, That the Director, Center for Biologics Evaluation and Research, shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.
- (b) Licensed biological products regulated by CDER. Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Drug Evaluation and Research (see mailing addresses in §600.2) for official release. Upon notification by the Director, Center for Drug Evaluation and Research, a manufacturer shall not distribute a lot of a biological product until the lot is released by the Director, Center for Drug Evaluation and Research: Provided, That the Director, Center for Drug Evaluation and Research shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

c. “§ 610.11 General safety.

A general safety test for the detection of extraneous toxic contaminants shall be performed on biological products intended for administration to humans. The general safety test is required in addition to other specific tests prescribed in the additional standards for individual products in this subchapter, except that, the test need not be performed on those products listed in paragraph (g) of this section. The general safety test shall be performed as specified in this section, unless: Modification is prescribed in the additional standards for specific products, or variation is approved as a supplement to the product license under §610.9.

- (a) Product to be tested. The general safety test shall be conducted upon a representative sample of the product in the final container from every final filling of each lot of the product. If any product is processed further after filling, such as by freeze-drying, sterilization, or heat treatment, the test shall be conducted upon a sample from each filling of each drying chamber run, sterilization chamber, or heat treatment bath.
- (b) Test animals. Only overtly healthy guinea pigs weighing less than 400 grams each and mice weighing less than 22 grams each shall be used. The animals shall not have been used previously for any test purpose.
- (c) Procedure. The duration of the general safety test shall be 7 days for both species, except that a longer period may be established for specific products in accordance with §610.9. Once the manufacturer has established a specific duration of the test period for a specific product, it cannot be varied subsequently, except, in accordance with §610.9. Each test animal shall be weighed and the individual weights recorded immediately prior to injection and on the last day of the test. Each animal shall be observed every working day. Any animal response including any which is not specific for or expected from the product and which may indicate a difference in its quality shall be recorded on the day such response is observed. The test product shall be administered as follows:

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- (1) Liquid product or freeze-dried product which has been reconstituted as directed on the label. Inject intraperitoneally 0.5 milliliter of the liquid product or the reconstituted product into each of at least two mice, and 5.0 milliliters of the liquid product or the reconstituted product into each of at least two guinea pigs.
 - (2) Freeze-dried product for which the volume of reconstitution is not indicated on the label. The route of administration, test dose, and diluent shall be as approved in accordance with §610.9. Administer the test product as approved on at least two mice and at least two guinea pigs.
 - (3) Nonliquid products other than freeze-dried product. The route of administration, test dose, and diluent shall be as in accordance with §610.9. Dissolve or grind and suspend the product in the approved diluent. Administer the test product as approved on at least two mice and at least two guinea pigs.
- (d) Test requirements. A safety test is satisfactory if all animals meet all of the following requirements:
- (1) They survive the test period.
 - (2) They do not exhibit any response which is not specific for or expected from the product and which may indicate a difference in its quality.
 - (3) They weigh no less at the end of the test period than at the time of injection.
- (e) Repeat tests—(1) First repeat test. If a filling fails to meet the requirements of paragraph (d) of this section in the initial test, a repeat test may be conducted on the species which failed the initial test, as prescribed in paragraph (c) of this section. The filling is satisfactory only if each retest animal meets the requirements prescribed in paragraph (d) of this section.
- (2) Second repeat test. If a filling fails to meet the requirements of the first repeat test, a second repeat test may be conducted on the species which failed the test: Provided, That 50 percent of the total number of animals in that species has survived the initial and first repeat tests. The second repeat test shall be conducted as prescribed in paragraph (c) of this section, except that the number of animals shall be twice that used in the first repeat test. The filling is satisfactory only if each second repeat test animal meets the requirements prescribed in paragraph (d) of this section.
- (f) [Reserved]
- (g) Exceptions—(1) The test prescribed in this section need not be performed for Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Platelets, Plasma, or Cellular Therapy Products.
- (2) For products other than those identified in paragraph (g)(1) of this section, a manufacturer may request from the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in §600.2 of this chapter), an exemption from the general safety test. The manufacturer must submit information as part of a biologics license application submission or supplement to an approved biologics license application establishing that because of the mode of administration, the method of preparation, or the special nature of the product a test of general safety is unnecessary to assure the safety, purity, and potency of the product or cannot be performed. The request must include alternate procedures, if any, to be performed. The Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, upon finding that the manufacturer's request justifies an exemption, may exempt the product from the general safety test subject to any condition necessary to assure the safety, purity, and potency of the product.”
- d. “§ 610.11a Inactivated influenza vaccine, general safety test.

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For inactivated influenza vaccine, the general safety test shall be conducted in the manner indicated in §610.11 of this chapter except that, with reference to guinea pigs, the test shall be satisfied if the product provides satisfactory results using either the subcutaneous or intraperitoneal injection of 5.0 milliliters of inactivated influenza vaccine into each guinea pig. The requirements for general safety for inactivated influenza vaccine shall not be considered to be satisfied unless each lot of influenza vaccine is assayed for endotoxin in comparison to a reference preparation provided by the Food and Drug Administration, and such lot is found to contain no more endotoxin than the reference preparation.”

e. “§ 610.13 Purity.

Products shall be free of extraneous material except that which is unavoidable in the manufacturing process described in the approved biologics license application. In addition, products shall be tested as provided in paragraphs (a) and (b) of this section.

(a) (1) Test for residual moisture. Each lot of dried product shall be tested for residual moisture and shall meet and not exceed established limits as specified by an approved method on file in the biologics license application. The test for residual moisture may be exempted by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, when deemed not necessary for the continued safety, purity, and potency of the product.

(2) Records. Appropriate records for residual moisture under paragraph (a)(1) of this section shall be prepared and maintained as required by the applicable provisions of §§211.188 and 211.194 of this chapter.

(b) Test for pyrogenic substances. Each lot of final containers of any product intended for use by injection shall be tested for pyrogenic substances by intravenous injection into rabbits as provided in paragraphs (b) (1) and (2) of this section: Provided, That notwithstanding any other provision of Subchapter F of this chapter, the test for pyrogenic substances is not required for the following products: Products containing formed blood elements; Cryoprecipitate; Plasma; Source Plasma; Normal Horse Serum; bacterial, viral, and rickettsial vaccines and antigens; toxoids; toxins; allergenic extracts; venoms; diagnostic substances and trivalent organic arsenicals.

(1) Test dose. The test dose for each rabbit shall be at least 3 milliliters per kilogram of body weight of the rabbit and also shall be at least equivalent proportionately, on a body weight basis, to the maximum single human dose recommended, but need not exceed 10 milliliters per kilogram of body weight of the rabbit, except that: (i) Regardless of the human dose recommended, the test dose per kilogram of body weight of each rabbit shall be at least 1 milliliter for immune globulins derived from human blood; (ii) for Streptokinase, the test dose shall be at least equivalent proportionately, on a body weight basis, to the maximum single human dose recommended.

(2) Test procedure, results, and interpretation; standards to be met. The test for pyrogenic substances shall be performed according to the requirements specified in United States Pharmacopeia XX.

(3) Retest. If the lot fails to meet the test requirements prescribed in paragraph (b)(2) of this section, the test may be repeated once using five other rabbits. The temperature rises recorded for all eight rabbits used in testing shall be included in determining whether the requirements are met. The lot meets the requirements for absence of pyrogens if not more than three of the eight rabbits show individual rises in temperature of 0.6 °C or more, and if the sum of the eight individual maximum temperature rises does not exceed 3.7 °C.”

f. “§ 610.14 Identity.

The contents of a final container of each filling of each lot shall be tested for identity after all labeling operations shall have been completed. The identity test shall be specific for

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each product in a manner that will adequately identify it as the product designated on final container and package labels and circulars, and distinguish it from any other product being processed in the same laboratory. Identity may be established either through the physical or chemical characteristics of the product, inspection by macroscopic or microscopic methods, specific cultural tests, or in vitro or in vivo immunological tests.”

g. “§ 610.15 Constituent materials.

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:

(1) 0.85 milligrams if determined by assay;

(2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or

(3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in §600.2 of this chapter).

(b) Extraneous protein; cell culture produced vaccines. Extraneous protein known to be capable of producing allergenic effects in human subjects shall not be added to a final virus medium of cell culture produced vaccines intended for injection. If serum is used at any stage, its calculated concentration in the final medium shall not exceed 1:1,000,000.

(c) Antibiotics. A minimum concentration of antibiotics, other than penicillin, may be added to the production substrate of viral vaccines.”

h. “§ 610.30 Test for Mycoplasma.

Except as provided otherwise in this subchapter, prior to clarification or filtration in the case of live virus vaccines produced from in vitro living cell cultures, and prior to inactivation in the case of inactivated virus vaccines produced from such living cell cultures, each virus harvest pool and control fluid pool shall be tested for the presence of Mycoplasma, as follows:

Samples of the virus for this test shall be stored either (1) between 2 and 8 °C for no longer than 24 hours, or (2) at 20 °C or lower if stored for longer than 24 hours. The test shall be performed on samples of the viral harvest pool and on control fluid pool obtained at the time of viral harvest, as follows: No less than 2.0 ml. of each sample shall be inoculated in evenly distributed amounts over the surface of no less than 0 plates of at least two agar media.

No less than 1.0 ml. of sample shall be inoculated into each of four tubes containing 10 ml. of a semisolid broth medium.

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The media shall be such as have been shown to be capable of detecting known Mycoplasma and each test shall include control cultures of at least two known strains of Mycoplasma, one of which must be *M. pneumoniae*. One half of the plates and two tubes of broth shall be incubated aerobically at $36\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ and the remaining plates and tubes shall be incubated anaerobically at $36\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ in an environment of 5–10 percent CO₂ in N₂. Aerobic incubation shall be for a period of no less than 14 days and the broth in the two tubes shall be tested after 3 days and 14 days, at which times 0.5 ml. of broth from each of the two tubes shall be combined and subinoculated on to no less than 4 additional plates and incubated aerobically. Anaerobic incubation shall be for no less than 14 days and the broth in the two tubes shall be tested after 3 days and 14 days, at which times 0.5 ml. of broth from each of the two tubes shall be combined and subinoculated onto no less than four additional plates and incubated anaerobically. All inoculated plates shall be incubated for no less than 14 days, at which time observation for growth of Mycoplasma shall be made at a magnification of no less than 300×. If the Dienes Methylene Blue-Azure dye or an equivalent staining procedure is used, no less than a one square cm. plug of the agar shall be excised from the inoculated area and examined for the presence of Mycoplasma. The presence of the Mycoplasma shall be determined by comparison of the growth obtained from the test samples with that of the control cultures, with respect to typical colonial and microscopic morphology.

The virus pool is satisfactory for vaccine manufacture if none of the tests on the samples show evidence of the presence of Mycoplasma.”

9. 42 U.S.C. Sections 300aa-1 through 300aa-34. — Especially:
 - a. “Sec. 300aa-22. Standards of responsibility
 - (a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
 - (b) Unavoidable adverse side effects; warnings
 - (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
 - (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied *in all material respects* with all *requirements* under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows -
 - (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
 - (B) *by clear and convincing evidence* that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).
 - (c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.
 - (d) Construction

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The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part."

b. "Sec. 300aa-23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in -

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible."

c. "Sec. 300aa-25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine -

(1) the date of administration of the vaccine,

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- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
- (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

- (1) Each health care provider and vaccine manufacturer shall report to the Secretary -
 - (A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
 - (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
 - (C) such other matters as the Secretary may by regulation require.Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.
- (2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.
- (3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

- (1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except -
 - (A) the person who received the vaccine, or
 - (B) the legal representative of such person.
- (2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.
- (3) Except as provided in paragraph (1), all information reported under this section shall be available to the public."

d. "Sec. 300aa-27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall -

- (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
- (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction

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reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

- (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
- (2) The Director of the National Institutes of Health shall serve as chairman of the task force.
- (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.”

e. “**Sec. 300aa-3 I. Citizen's actions**

(a) General rule

Except as provided in subsection (b) of this section, any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) of this section before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

10. Kevan BERKOVITZ, a Minor by his Parents and Natural Guardians Arthur BERKOVITZ, et ux., *et al.*, Petitioners, v. UNITED STATES. 108 S.Ct. 1954, 100 L.Ed.2d 531, 56 USL W 4549, (**cite as:** 486 U.S. 531, 108 S.Ct. 1954).