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11
12 IN THE UNITED STATES DISTRICT COURT
13 FOR THE NORTHERN DISTRICT OF CALIFORNIA

14 ALEXANDER REDFOOT, a minor by and)
15 through his Guardian Ad Litem, MICHELL)
16 REDFOOT)

17 Plaintiff,

18 vs.

19 B.F. ASCHER & COMPANY; and DOES 1
20 through 10, inclusive,

21 Defendants.

) Case No. C05-02045 PJH

)
) PLAINTIFF'S MEMORANDUM IN
) OPPOSITION TO DEFENDANTS' MOTION
) FOR SUMMARY JUDGMENT, OR IN THE
) ALTERNATIVE, MOTION FOR
) SUMMARY ADJUDICATION OF CLAIMS

) Date: April 4, 2007
) Time: 9:00 a.m.
) Ctrm: 3

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Kennedy v. Collagen Corp., 161 F.3d 1226 (9th Cir. 1998) 2

1 Plaintiff respectfully requests that this Honorable Court deny the Defendants' Motion to
2 for Summary Judgment, or in the Alternative, Motion for Summary Adjudication of Claims. For
3 the reasons set forth in the Plaintiff's response to the Defendants' *Daubert* motion which is being
4 filed concurrently and which Plaintiff incorporates by reference, the causation opinion testimony
5 of her retained expert witness, Dr. Mark Geier, as well as the testimony of her non-retained
6 witnesses, Dr. James Bradstreet, Dr. George Lucier, Dr. Boyd Haley and Dr. Arthur Krigsman, is
7 valid, relevant, satisfies the requirements set forth in *Daubert v. Merrell Dow Pharm.*, 509 U.S.
8 579 (1993) and the Federal Rules of Evidence 401, 702 and 703, and is sufficient to raise a jury
9 issue regarding both the general causation issue of whether exposure to thimerosal can cause
10 autism in susceptible individuals and the specific causation question of whether Alexander
11 Redfoot is one of those susceptible individuals whose autism was caused, at least in substantial
12 part, by his exposure to thimerosal from his daily exposure to Ayr Saline Nasal Mist during the
13 first several years of his life.
14
15

16
17 1. INTRODUCTION

18 Multiple, consistent, valid and reliable epidemiologic studies demonstrate that increasing
19 doses of ethylmercury from thimerosal results in greater risks of developing autism. This finding
20 is confirmed by *in vitro*, *in vivo* and animal experiments and the toxicological and biologic
21 effects of mercury. Although there have been some published epidemiologic studies by
22 researchers with ties to the pharmaceutical companies who manufacture vaccines that purport to
23 refute the association between thimerosal and autism, those studies suffer from significant
24 methodological flaws that impact the validity of their conclusions. When the totality of evidence
25 is considered, it is clear that Plaintiff's experts have appropriately concluded that exposure to
26 thimerosal from the B.F. Ascher/Kolmar product can, and did, contribute to cause Alexander
27 Redfoot's autism.
28

1 **2. PLAINTIFF HAS PRESENTED SUFFICIENT RELIABLE AND VALID EVIDENCE**
 2 **OF BOTH GENERAL AND SPECIFIC CAUSATION TO PERMIT JURY**
 3 **CONSIDERATION**

- 4 **a. Multiple peer-reviewed epidemiologic studies have demonstrated a dose-**
 5 **response relationship between thimerosal and autism and that, even at low**
 6 **levels, exposure to thimerosal increases the risk of developing autism.**

7 Dr. Geier has published more than ten papers in the peer-reviewed literature involving
 8 epidemiologic evaluations of exposure to thimerosal and the risk of autism. These studies
 9 demonstrate a statistically significant risk of autism that increases as exposure to thimerosal
 10 increases. While there may be some flaws in some of Dr. Geier's papers, those imperfections are
 11 not enough to render his work invalid as a matter of law. As the court in *In re*
 12 *Phenylpropanolamine (PPA) Products Liability Litigation*¹ aptly stated:

13 Scientific studies almost invariably contain flaws. *See* Federal
 14 Judicial Center, *Reference Manual on Scientific Evidence* 337 (2d
 15 ed.2000). . .("It is important to recognize that most studies have
 16 flaws. Some flaws are inevitable given the limits of technology and
 17 resources.") *See also In re Orthopedic Bone Screw Prods. Liab.*
 18 *Litig.*, MDL No. 1014, 1997 WL 230818, at *8-9 (E.D. Pa. May 5,
 19 1997) ("[T]here is no such thing as a perfect epidemiological
 20 study."; despite weaknesses, court found study sufficiently reliable
 21 to be admissible). When faced with epidemiological evidence, the
 22 court must determine whether the flaws compromise the study's
 23 findings. . . . [as long as the methodology is scientifically sound]
 24 any flaws that might exist go to the weight afforded the HSP, not
 25 its admissibility. *See Kennedy [v. Collagen Corp.]*, 161 F.3d (so
 26 long as the court finds the expert's reasoning scientific and useful
 27 to the jury, opposing opinions and evidence go to the weight
 28 afforded an expert's opinion, not to admissibility). *See also*
Hemmings v. Tidyman's Inc., 285 F.3d 1174, 1188 (9th Cir.
 2002)("[I]n most cases, objections to the inadequacies of a study
 are more appropriately considered an objection going to the weight
 of the evidence rather than its admissibility. Vigorous cross-
 examination of a study's inadequacies allows the jury to
 appropriately weigh the alleged defects and reduces the possibility
 of prejudice.")

¹ 289 F.Supp.2d 1230, 1240-41 (W.D. WA 2003)

1 **b. Competent, consistent peer-reviewed published clinical, biological and**
2 **genomic evidence supports the causal relationship between thimerosal and**
3 **autism.**

4 In 2001, the Immunization Safety Review Committee of the IOM investigating
5 thimerosal-containing vaccines and neurodevelopmental disorders, including autism, concluded
6 that:

7 although the hypothesis that exposure to thimerosal-containing
8 vaccines could be associated with neurodevelopmental disorders is
9 not established and rests on indirect and incomplete information . .
 the hypothesis is biologically plausible.²

10 Without any published epidemiologic studies, however, the committee concluded that
11 “the evidence is inadequate to accept or reject a causal relationship between exposure to
12 thimerosal from vaccines and the neurodevelopmental disorders of autism, ADHD, and speech or
13 language delay.”³ To address this evidentiary limitation, the IOM made a series of
14 recommendations. One of these recommendations involved clinical studies:

15 [v]ery little is known about the pharmacokinetics of ethylmercury
16 exposure in humans. Better understanding of these mechanisms
17 would have greatly facilitated the risk assessment of thimerosal in
18 vaccines. The committee recommends research on how children,
19 including those diagnosed with neurodevelopmental disorders,
20 metabolize and excrete metals – particularly mercury.⁴

21 In response to that request, Dr. Burbacher conducted pharmacokinetic studies on
22 primates and found that when thimerosal is introduced into the body, the ethylmercury
23 component rapidly dissipates throughout the body and preferentially accumulates in the brain,
24 kidney and liver. Once inside the brain, many of the ethylmercury molecules break down into
25 their separate components – organic (ethyl) and inorganic (mercury). While the blood-brain
26

27
28 ² Immunization Safety Review, Thimerosal-Containing Vaccines and Neurodevelopmental Disorder, IOM 2001 at p. 4 of the Executive Summary (Exhibit 1)

³ *Id.* at p. 6.

⁴ *Id.* at p. 80.

1 barrier does not prevent ethylmercury from easily crossing and entering the brain, it does not
2 permit inorganic mercury to pass through as easily. The inorganic mercury deposited in the
3 brain in this manner is trapped because it cannot easily cross back through the blood-brain
4 barrier resulting in an accumulation of inorganic mercury in the brain.⁵

6 Dr. Burbacher was able to determine the half-life for the inorganic mercury deposited in
7 the brain of the primates as a result of the breakdown of the ethylmercury introduced when
8 thimerosal was injected in doses and times comparable to the US vaccination schedule. He
9 calculated the half-life of the inorganic mercury to be more than 120 days.⁶

11 From this data, Dr. Burbacher concluded that the total mercury in the blood is a poor
12 predictor of brain levels particularly because the diffusion of mercury from the blood to target
13 organs is a dynamic process. The rapid uptake of mercury out of the blood and to the brain
14 means that for any given ethylmercury exposure, the ethylmercury is in the brain soon after it is
15 introduced into the body. A significant portion of the ethylmercury enters the brain, breaks down
16 and deposits inorganic mercury that will remain long after any remaining intact ethylmercury has
17 been removed from the brain.⁷ For his thimerosal-exposed monkeys, Burbacher also found an
18 average concentration of inorganic mercury of 16 parts per billion representing between 21 to
19 86% of the total mercury in the brain.⁸

22 Assuming the half-life for inorganic mercury is a minimum of 120 days and that it takes 5
23 half-lives to eliminate most of the mercury from the brain, any inorganic mercury produced as a
24 result of a single introduction of thimerosal by vaccination or inhalation would remain in the
25

26 ⁵ Burbacher, et al., "Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines
27 containing Thimerosal", ENRIVON HEALTH PERSP, 113:1015-21 (2005)(Exhibit 2); see Geier Report, p. 5, Defendant Exhibit A-2.

28 ⁶ *Id.* This was an estimate because the level of inorganic mercury in the brains of the thimerosal exposed primates never actually
went down during the course of the study.

⁷ There is no valid reason to assume that ethylmercury entering the blood stream through the nasal passages after a treatment with
a thimerosal-containing nasal spray would act any differently.

⁸ Geier Report at p. 5, Defendant Exhibit A-2.

1 brain for more than two years. The above calculation does not include the portion of
2 ethylmercury that is not broken-down to its constituent components.

3
4 Researchers at the Department of Physiology and Biophysics at the University of Calgary
5 discovered that mercury ions (inorganic mercury) markedly disrupted the brain cell membrane
6 structure of growth cones of neurites by interfering with their microtubule assembly.⁹ Brain
7 neurons require intact microtubules for axonal transport, membrane structure and normal neurite
8 outgrowth. To determine whether this phenomena was specific for mercury, four other heavy
9 metals were tested with no observable effect. The authors concluded that their experiment “may
10 implicate mercury as a potential etiological factor in neurodegeneration that could ultimately be
11 observed as altered neurobehavior.”

12
13 Many researchers took up the 2001 IOM committee’s recommendation to research how
14 children, including those diagnosed with neurodevelopmental disorders, metabolize and excrete
15 metals – particularly mercury. For example, Vargas demonstrated and defined an ongoing innate
16 immune activation occurring within the microglia and astroglial populations of the cerebellum of
17 autistic children.¹⁰ While Vargas was unable to discern the exact starting point of this process,
18 the following passage from his paper refutes the notion that autism is a disease of prenatal origin
19 as is advocated by the Defendants’ experts:
20

21
22 Based on our observations, a selective process of neuronal
23 degeneration and neuroglial activation appear to occur
24 predominantly in the PCL [Purkinje cell layer] and GCL [granular
25 cell layer] of cerebellum in autistic subjects, findings that are
26 consistent with an active and ongoing *postnatal* process of
neurodegeneration and neuroinflammation. These observations do
not support the previously proposed hypothesis that the changes in
the cerebellum in autism result solely from developmental

27
28 ⁹ Leong, “Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury”, NEUROREPORT 12:733-737 (2001)(Exhibit 3)

¹⁰ Vargas, “Neuroglial Activation and Neuroinflammation in the Brain of Patients with Autism”, ANN NEUROL 2005 (Exhibit 4)

1 abnormalities in olivary-cerebellar circuits and a reduced number
 2 of Purkinje cells. Instead, our observations suggest that the
 3 pathological changes observed in the cerebellum in autistic patients
 4 do not occur exclusively during prenatal development but appear
 5 to involve an ongoing chronic neuroinflammatory process that
 6 involves both microglia and astroglia. Furthermore, this process
continues beyond early neurodevelopment and is present even at
very late stages in the life of patients with autism (emphasis
 added).

7 Purkinje cells are exceptionally large inhibitory neurons in the cerebellum that form one
 8 of the most powerful connections in the nervous system.¹¹ Purkinje cells have been shown to be
 9 reduced in children with autism¹² and are known to be vulnerable to mercury¹³ and oxidative
 10 stress. Recent studies have shown that oxidative stress is increased in autism and that
 11 glutathione deficiencies result in oxidative stress and increased vulnerability of neurons (like
 12 Purkinje cells) to mercury.¹⁴ They have also shown that a key cellular defense mechanism
 13 against mercury is the up-regulation of glutathione, and cysteine.¹⁵ Dr. Jill James, a former
 14 senior FDA researcher, found that low cysteine/low glutathione is a nearly ubiquitous finding in
 15 autism.¹⁶

16
 17
 18 *In vitro* and *in vivo* experimental evidence is useful for determining or at least giving
 19 insight into the biological mechanism of injury or disease. In certain instances, experimental
 20
 21
 22

23 ¹¹ Ghez, The cerebellum. In *Principles of Neural Science* 3rd ed., Kandel, Schwartz and Jessell, eds., pp. 626-646. Norwalk,
 Connecticut: Appleton and Lange.

24 ¹² Bailey, "A clinicopathological study of autism," *BRAIN*, 121:889-905 (1998)

25 ¹³ Sorenson, "Neuron loss in cerebellar cortex of rats exposed to mercury vapor: a stereological study," *ACTA NEUROPATHOL.*,
 100:95-100 (2000); Warfvinge, "Mercury distribution in the neonatal and adult cerebellum after mercury vapor exposure of
 pregnant squirrel monkeys," *ENVIRONMENTAL RES* 83:93-101 (2000)

26 ¹⁴ Chauhan, "Oxidative stress in autism," *PATHOPHYSIOLOGY*, 13:171-81 (2006)(Exhibit 5)

27 ¹⁵ James, "Thimerosal neurotoxicity is Associated with glutathione depletion: protection with glutathione precursors",
NEUROTOXICOLOGY 26:1-8 (2005)(Exhibit 6), *see also* Makani, "Biochemical and molecular basis of thimerosal-induced
 apoptosis in T cells: a major role of mitochondrial pathway", *GENES AND IMMUNITY* 3:270-278 (2002) (Exhibit 7); Westphal,
 "Homozygous gene deletions of the glutathione S-transferases M1 and T1 are associated with thimerosal sensitization", *INT ARCH*
 28 *OCCUP ENVIRON HEALTH* 73:384-388 (2000) (Exhibit 8)

¹⁶ James, "Metabolic biomarkers of increased oxidative stress and impaired methylation capacity in children with autism," *AM J*
CLIN NUTR 80:1611-7 (2004)(Exhibit 9)

1 evidence of this nature can, by itself, establish a cause and effect relationship.¹⁷ At a minimum,
 2 the understanding obtained from this evidence assists in the determination of whether the
 3 putative causal relationship is biologically plausible and coherent with, and not in conflict, the
 4 generally known facts of the biology of the disease.
 5

6 Multiple *in vitro* experiments with cells from the brains of animals have showed that
 7 thimerosal is a microtubule poison which inhibits microtubule assembly.¹⁸ An *in vivo*
 8 experiment with human cerebral cortical neurons showed that, at micromolar concentrations,
 9 thimerosal causes membrane damage and cell death.¹⁹ Researchers have also shown that
 10 thimerosal has an adverse impact on calcium in cells which can lead to cell death or disruption of
 11 proper cell function.²⁰
 12

13 As these studies show, thimerosal, at least at an experimental level, is capable of causing
 14 harm to brain cells that are important to neuronal development. While not definitive proof of
 15 causation, they do offer evidence of how damage can occur that strengthens the hypothesis that
 16 he thimerosal could cause neurological injuries.
 17

18 In 2004, the Interagency Vaccine Group (IAVG), whose members represent several units
 19 of the Department of Health and Human Services; the CDC's Vaccine Program Office; the
 20 NIH's National Institute of Allergy and Infectious Diseases; the FDA; the NVICP; and the
 21

22
 23 ¹⁷ According to Sir Bradford Hill, the noted epidemiologist whose nine considerations for determining causation have widely
 24 been accepted in courts throughout the United States, "such laboratory evidence can enormously strengthen the hypothesis and,
 indeed, may determine the actual causative agent." Hill, President's Address, "The Environment and Disease: Association or
 Causation?", PRO R SOC MED 58:295-300 (1965) at p. 298 (Exhibit 10)

25 ¹⁸ Brunner, "Effects of 10 known or suspected spindle poisons in the *in vitro* porcine brain tubulin assembly assay" MUTAGENESIS
 6(1):65-70 (1991)(Exhibit 11); see also Alexandre, "Effect of taxol and okadaic on microtubule dynamics in thimerosal-arrested
 primary mouse oocytes: a confocal study", BIOLOGY OF THE CELL 95:407-414 (2003)(Exhibit 12)(thimerosal induces an
 26 instantaneous, complete and long-lasting microtubule network disassembly).

27 ¹⁹ Baskin, "Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human
 Neurons and Fibroblasts, Toxicological Sciences" 74(2):361-8 (2003)(Defendant Exhibit D-1). Defendants complain about this
 study because the experiment was performed at doses higher than what is postulated is in the brains of children after exposure to
 thimerosal. Such observations go to the weight of the evidence, not its admissibility.

28 ²⁰ See Splawski, "Ca_v1.2 Calcium Channel Dysfunction Causes a Multisystem Disorder Including Arrhythmia and Autism",
 CELL 119:19-31 (2004) (Exhibit 13); Ueha-Ishibashi. "Effect of thimerosal, a preservative in vaccines, on intracellular Ca²⁺
 concentration of rat cerebellar neurons" TOXICOLOGY, 195(1):77-84 (2004) (Exhibit 14).

1 Centers for Medicare & Medicaid Services, asked the IOM Immunization Safety Review
2 Committee to revisit the hypothesized causal association between vaccines and neurological
3 injury in order to update its conclusions and recommendations based on the significant number
4 of studies performed since its last meeting in 2001.²¹ As detailed above, most of the non-
5 epidemiologic studies conducted in the intervening three years provided substantial direct
6 evidence that thimerosal has the capacity to cause neurodevelopmental disorders and explained
7 the biologic mechanisms of how this would happen. Given the position of the IOM in 2001,
8 surely these studies would provide sufficient evidence to make the causal connection. After all,
9 courts have found biological plausibility to be a scientifically reliable methodology supporting
10 experts' opinions regarding general causation, particularly where it is consistent with other
11 available data. *See In re Phenylpropanolamine (PPA) Litigation*, 289 F.Supp. 2d at 1246
12 (neurologist expert's testimony that PPA could cause ischemic strokes was admissible based on
13 biological plausibility and other non-epidemiological sources); *Ambrosini v. Labarraque*, 101
14 F.3d 129, 136 (D.C. Cir. 1996) (epidemiologist's reliance on biologic plausibility and other
15 consistent lines of evidence held to be scientifically reliable); *Becker v. National Health Prods.*
16 *Inc.*, 896 F. Supp.100, 101 (N.D.N.Y. 1995)(expert's testimony was admissible based in part on
17 the known pharmacologic actions of active ingredients of dietary supplement).

18
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20
21
22 Unfortunately, the IOM simply ducked the issue. For reasons never explained in its 199
23 page review (2004), rather than deal with the broad category of neurological development
24 disorders, as they had originally, the IOM chose to focus solely on autism, a small subset.²² Not
25 satisfied with that manipulative move, the IOM went one better, and retracted its finding of
26

27
28 ²¹Immunization Safety Review, Vaccines and Autism, Institute of Medicine (2004) at p. 2 (Exhibit 15)

²²Immunization Safety Review, Vaccines and Autism, Institute of Medicine (2004) at p. 7 (Exhibit 15)(“the conclusion in the 2001 report pertained to a broader set of Neurological Developmental Disorders, this report’s conclusion applies *only* to autism)(emphasis in the original)

1 biological plausibility by simply abandoning the term altogether. Three years after the fact, after
2 hundreds of articles detailing how and why thimerosal in vaccines causes neurological damage,
3 the IOM committee simply stated that it now “reviews evidence regarding ‘biological
4 *mechanisms*” that might be consistent with the proposed relationship between immunization and
5 a given adverse event.”²³

7 Notwithstanding the IOM’s deliberate avoidance of the issue, this Court should find that
8 the evidence concerning the relationship between thimerosal and the broad category of
9 neurological developmental disorders is reliable, valid and sufficient for a jury to assess.

11 **c. The epidemiologic studies used support a refutation of the causal nexus
12 between thimerosal and autism were performed by researchers with conflicts
of interest and are fraught with methodological flaws.**

13 In June of 1999, it was publicly recognized for the first time that mercury in vaccines
14 exceeded by many times the level thought to be safe. In a July 7, 1999 statement, the U.S. Public
15 Health Service formally requested that the manufacturers make a clear commitment and a plan to
16 eliminate or reduce as expeditiously as possible the mercury content of their vaccines

18 Some time between June of 2000 and January of 2001, the CDC retained the Institute of
19 Medicine at the National Academies of Science to study the issue of whether mercury in
20 vaccines could cause or contribute to neurodevelopmental injuries. In a December 18, 2000
21 letter, the president of the National Vaccine Information Center, Barbara Loe Fisher, wrote to the
22 senior program office at the Institute of Medicine, Kathleen Stratton. She expressed her
23 significant concern that the IOM committee would be working in close collaboration with the
24 CDC, and would be funded by the CDC:

27 In this respect, the circumstances under which IOM is assembling
28 a physician committee to analyze the scientific data to determine

²³ *Id.* at 3.

1 whether a reported adverse event or serious chronic illness is
2 causally related to vaccinations, is quite different from the
3 circumstances under which IOM assembled three physician
4 committees in 1991 and 1994 to analyze the scientific data to
5 determine causation.²⁴

6 Fisher went on to note that the CDC “which makes national policy for and promotes use of
7 vaccines on a mass basis, has a long history of maintaining that vaccines do not cause injury or
8 death.” Fisher expressed concern that many of the members of the proposed committee were
9 “employed by universities or associated with organizations that receive significant NIH, CDC
10 and vaccine industry research grants to develop new vaccines or promote CDC mass vaccination
11 policies.”²⁵ Fisher concluded:

12 The concern is that the committee as an aggregate may be
13 ideologically reluctant to depart from the CDC’s position on
14 vaccine risks and national vaccine policies while evaluating the
15 scientific evidence (or lack of scientific evidence) regarding
16 causality (and other factors). . .²⁶

17 Fisher’s concerns were well founded.

18 The text of the transcript of National Academy of Sciences, Institute of Medicine,
19 Organizational Meeting of the Immunization Safety Review Committee reveals just the type of
20 bias that the National Vaccine Information Center was concerned about:

21 Dr. Goodman: “Just the phrase favours, is again, open to
22 misinterpretation the same way association is. Then we have to
23 discuss do we want to use the word established, which is a very
24 high bar.” (underscore added)

25 Dr. Stratton: “We will never have it here. I think that actually you
26 don’t have to agonize over it. Not to prejudge your decision over
27

28 ²⁴ Letter from Barbara Loe Fisher, President & Co-Founder to Kathleen Stratton, December 18, 2000(Exhibit 16)

²⁵ *Id.* at 5.

²⁶ *Id.* at 5.

1 the next 3 years, but I will bet you 100 bucks you will never come
2 up with a category 5. It won't even cross your mind."²⁷

3 The text makes clear that the CDC, who was paying the bills, was also driving the train.

4 Dr. McCormick, for example, in speaking of the CDC, noted that the agency "wants us to
5 declare, well, these things are pretty safe on a population basis."²⁸ The committee members
6 recognized that "the issue that is driving CDC is their perception and probably knowledge of
7 utilization of immunization. . . ; is that correct?" Dr. Stratton responded:

8
9 In general, of course they have a worry if there is a big safety
10 concern that then people won't get immunized when they should.
11 Of course, they (the CDC) are worried about immunization
12 coverage rates and whether they are going to go up or down.²⁹

13 The committee's bias and predetermination of the causality issues presented were
14 reconfirmed by Dr. Stratton:

15 We said this before you got here, and I think we said this
16 yesterday, the point of no return, the line we will not cross in
17 public policy is to pull the vaccine, change the schedule. We
18 would say it is under revisit, but we would never recommend that
19 level. We wouldn't say compensate, we wouldn't say pull the
20 vaccine, we wouldn't say stop the program.³⁰

21 Stratton agreed that the probable conclusion was going to be that the evidence was "inadequate
22 to accept or reject a causal relation."³¹

23 In notes taken by the various committee members at the January 12 meeting and during
24 several meetings in March, 2001, it is apparent that the committee was predisposed to rejecting

25 ²⁷ National Academy of Sciences, Institute of Medicine, Organizational Meeting of: Immunization Safety Review Committee,
26 Closed Session, January 12, 2001 at p. 130. (Exhibit 17)

²⁸ *Id.* at 33.

²⁹ *Id.* at 52-53.

³⁰ *Id.* at 74. McCormick, the committee head, also confirmed Stratton's comments in discussing whether autism could be
27 associated with vaccines, noting that "we are not ever going to come down that it is a true side effect," despite the fact that the
28 Committee had not yet considered any evidence on the issue. *Id.* at 97.

³¹ *Id.* at 123. She stated that "chances are, when all is said and done we are still going to be in this category. It is just a general
feeling that we probably still are not going to be able to make a statement." *Id.*

1 the hypothesis of thimerosal causing autism.³² One committee member noted that “CDC needs
 2 Marie (McCormick) here for response,” i.e. a causation finding of “insufficient or inadequate.”³³
 3

4 Other entries in the notes are consistent with Plaintiff’s theory that the CDC set up the
 5 IOM and provided it with epidemiological studies from other countries that would facilitate the
 6 ultimate conclusion that causation either cannot be established or should be refuted. For
 7 example, at page 01848, we find the notation:

8 “What we care most about” → Consistent body of epi evid that
 9 consist shows no assoc.³⁴

10 Another committee member took note of the CDC’s plan to use epidemiology from
 11 Europe to disprove causation, writing that “other countries – looked at issue b/c of nature of
 12 other countries? CDC-project w/Denmark on autism.”³⁵
 13

14 After the 2001 IOM report, in accordance with the CDC’s plan, epidemiologic articles
 15 studying autism and thimerosal in Denmark and Sweden, and finding no evidence to support a
 16 link between the two, began appearing in the medical literature.³⁶ Many of those articles were
 17 written by authors, or published in journals, that had direct links and relationships with the
 18 vaccine manufacturers and could be expected to support their interests. Many of those conflicts
 19 of interest were not properly presented to the public and scientific community, leading many to
 20 question the nature of the research and its conclusions. For example, the lead author of
 21 “Association Between Thimerosal-Containing Vaccine and Autism,” JAMA, 290(13):1763-66
 22
 23
 24

25 ³² Handwritten notes from IOM Committee meetings (Exhibit 18)

26 ³³ *Id.* at 01876.

27 ³⁴ *Id.* at 01848.

28 ³⁵ *Id.* at 01905.

³⁶ In 2003, three such studies were published: Hviid, “Association Between Thimerosal-Containing Vaccine and Autism,” JAMA, 290(13):1763-66 (2003)(Defendant Exhibit D-12)(Denmark); Stehr-Green, “Autism and Thimerosal-Containing Vaccines: Lack of Consistent Evidence of an Association,” AM J PREV MED, 25(2):101-106 (2003)(Defendant Exhibit D-17)(Denmark and Sweden); and Madsen, “Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data,” PEDIATRICS, 112:604-606 (2003)(Defendant Exhibit D-16)(Denmark).

1 (2003), Anders Hviid, failed to disclose that he was an employee of the Staten Serum Institute, a
2 European vaccine manufacturer.³⁷

3
4 The specific details of the flaws in the methodology and data collection inherent to the
5 studies of the Swedish and Danish populations by Hviid, Stehr-Green and Madsen are
6 extensively reviewed in Plaintiff's response to Defendants' *Daubert* motion³⁸ and will not be
7 recounted in detail here. Suffice it to say that the supposed rise in autism rates after thimerosal
8 was removed from vaccines could easily have been accounted for by the fact that, after the date
9 thimerosal was removed, the Danish registry: (1) began counting out-patient cases of autism in
10 addition to the hospitalized patients they had counted previously; (2) added a large clinic that
11 accounted for 20% of the autism caseload; and (3) changed from the restrictive definition of
12 autism contained in ICD-8 to the more expansive definition in ICD-10. Moreover, the low rate
13 of autism during the use of thimerosal-containing vaccines could be related to the fact that
14 Danish children received a fraction of the dose of thimerosal as their American counter-parts.
15
16

17 In addition to the Madsen study of Danish children, "Thimerosal and the Occurrence of
18 Autism: Negative Ecological Evidence From Danish Population-Based Data," *PEDIATRICS*,
19 112:604-606 (2003), the periodical *PEDIATRICS* published two other epidemiologic studies of
20 thimerosal use that purported to refute the association of thimerosal to autism: Verstraeten,
21 Davis, et al., "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized
22 Health Maintenance Organization Databases", *PEDIATRICS* 112(5):1039-1048 (Nov. 2003) and
23 Andrews, Miller et al., "Thimerosal Exposure in Infants and Developmental Disorders: A
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28 ³⁷ Transcript of February 9, 2004 IOM Committee meeting (Exhibit 19)

³⁸ See Plaintiff's Response to Defendants' Motion to Preclude the Proposed Testimony of Plaintiff's Expert Witnesses Pursuant to FRE 401, 702, 703 and *Daubert*, at pp. 19-23.

1 Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association”,
2 PEDIATRICS, 114(3):584-591(2004).³⁹

3
4 In 1999, Thomas Verstraeten began working on what ultimately became his published
5 study on an examination of the VSD (Vaccine Safety Database) to determine whether there may
6 have been an association between the mercury in vaccines and the significant increase in cases of
7 neurological injuries. Soon after he started the work, Verstraeten communicated in various e-
8 mails with his eventual co-author, Robert Davis, a noted vaccine industry consultant, about
9 efforts necessary to reduce or eliminate the significant risk found to be associated with the
10 mercury. These efforts included “running, re-thinking, re-running, re-thinking. . .” the data sets
11 and numbers in an effort to reduce the association effect.⁴⁰ Verstraeten titled a December 17,
12 1999 memo “It just won’t go away.”⁴¹ and sent another e-mail to Davis (January 4, 2000)
13 entitled “Thimerosal analyses, it all came back. . .”⁴² Verstraeten also expressed concern “we
14 should use sound scientific argumentations and not let our standards be distorted by our desire to
15 disprove an unpleasant theory”⁴³ Despite obvious efforts to manipulate the data to reduce the
16 effect, Verstraeten’s confidential report of February, 2000⁴⁴ concluded that there was an
17 increased risk of neurodevelopmental problems, resulting from the mercury in the vaccines.
18
19

20
21 By June of 2000, Verstraeten had prepared a final report, suitable for publication, with an
22 abstract confirming the nature of his findings.⁴⁵ This study was never published. On June 7-8,
23 2000 a meeting was convened by the CDC at the Simpsonwood Retreat Center near Atlanta,
24

25
26 ³⁹ Defendant Exhibit D-13 and D-14, respectively.

⁴⁰ Verstraeten e-mail to Davis, November 29, 1999 (Exhibit 20) at p.

⁴¹ Verstraeten e-mail to Davis, December 17, 1999 (Exhibit 21) at p. 1

⁴² Verstraeten e-mail to Destefano, January 4, 2000 (Exhibit 22).

⁴³ Verstraeten e-mail to Grandjean, July 14, 2000 (Exhibit 23)

⁴⁴ Thimerosal VSD Study, Phase I, Update 2/29/00, Confidential (Exhibit 24)

⁴⁵ Draft, Verstraeten, “Risk of neurologic and renal impairment associated with thimerosal-containing vaccines,” 6/01/00 (Exhibit 25)

1 Georgia.⁴⁶ Attendees included CDC representatives, vaccine industry consultants, and
2 representatives of GSK, Merck, Wyeth, and Aventis.⁴⁷ In the transcript, Verstraeten detailed at
3 some length his conclusion that there was a positive signal regarding causation and that there
4 were statistically significant relationships between the exposures and the entire category of
5 neurodevelopmental delays.⁴⁸ The only criticism that Verstraeten accepted as significant from
6 the assembled scientists was that this study **under-represented the actual risk**, because so
7 many of the children were only 1 or 2 years old:
8

9
10 The one thing that is for sure, there is certainly an under-
11 ascertainment of all these because some of the children are just not
12 old enough to be diagnosed. So the crude incidence rates are
13 probably much lower than you expect because the cohort is still
14 very young.⁴⁹

15 Reactions to Verstraeten's conclusions were mixed, but several present expressed concern that
16 the information could be inflammatory and harmful to vaccine interests. Dr. Bernier, of the
17 CDC, ordered that the information be maintained as confidential and discussed using "the
18 machinery that we have in place" to "consider" the data.⁵⁰

19 Concern was also expressed that the findings would support lawsuits against the
20 industry.⁵¹ Dr. Brent went on to note that "you will not find a scientist with any integrity who
21 would say the reverse with the data available, i.e. thimerosal doesn't cause injury." He went on
22 to state that "we are in a bad position from the standpoint of defending any lawsuits if they are
23 initiated and I am concerned."⁵²
24

25
26 ⁴⁶ Transcript, Scientific Review of Vaccine Safety Datalink Information, June 7-8, 2000, Simpsonwood Retreat Center, Norcross,
27 Georgia (Exhibit 26).

⁴⁷ *Id.* at 5-7.

⁴⁸ *Id.*, at 40-41.

⁴⁹ *Id.* at 42.

⁵⁰ *Id.* at 113.

⁵¹ *Id.* at 195.

⁵² *Id.* at 233.

1 Dr. Clements expressed concern that “perhaps the study shouldn’t have been done at all,
2 because the outcome could have, to some extent, been predicted. . .” Clements went on to state
3 that “my mandate as I sit here in this group is to make sure that at the end of the day that a
4 hundred million are immunized with DTP, Hepatitis B and if possible HIB, this year, next year
5 and for many years to come. . .”⁵³

7 Dr. Brent encouraged the CDC to get other populations to study “because of the fact that
8 I do not think that reanalysis of this data is going to be as helpful as we had hoped.”⁵⁴ Dr. Stehr-
9 Green, the principal author of “Autism and Thimerosal-Containing Vaccines: Lack of Consistent
10 Evidence of an Association,” AM J PREV MED, 25(2):101-106 (2003) that was published three
11 years after this meeting, commented: “You may not want to do this study because the results are
12 not likely to be useful for resolving this issue and in fact may raise concerns and havoc in
13 locations in which we cannot deal based on this study.”

16 A little more than a year after the Simpsonwood meeting, in July of 2001, Verstraeten
17 presented his findings to the IOM committee. In the transcript of that meeting, Verstraeten
18 advised that he had (as of 8:00 a.m. that morning) been hired to work for a vaccine company
19 (GlaxoSmithKline).⁵⁵ He then proceeded to present his “latest” data with further reduced
20 relative risks, concluding that he could neither support nor refute the idea that mercury in
21 vaccines could cause neurological injury, the ultimate conclusion of his published study.

27
28 ⁵³ *Id.* at 251.

⁵⁴ *Id.* at 253.

⁵⁵ Transcript, National Academy of Science, IOM Immunization Safety Review Committee, Thimerosal-Containing Vaccines and Neurodevelopmental Outcomes Public Meeting, July 16, 2001 (Exhibit 27)

1 Co-author Davis also had clear conflicts of interest. At a February 9, 2004 meeting of the
 2 IOM, Davis admitted for the first time that he had previously been funded by Merck,
 3 GlaxoSmithKline, and Wyeth, manufacturers of thimerosal-containing vaccines.⁵⁶
 4

5 Interestingly, in their article regarding the VSD study that was published in
 6 PEDIATRICS, neither Verstraeten nor Davis referenced any conflicts, and Verstraeten is
 7 incorrectly identified to be a CDC employee.⁵⁷ This is despite the fact that PEDIATRICS
 8 requires that the type of conflicts identified by Davis be listed.⁵⁸ Davis, as a more senior
 9 scientist, spent significant time working with Verstraeten to “rerun” data, add population groups,
 10 etc. during the time frame from the fall of 1999 through the summer of 2001. One consistent
 11 effect of his involvement was the continuing reduction of the risk found to be associated with
 12 thimerosal in vaccines.
 13

14 One wonders why Robert Davis, a well known vaccine consultant with lengthy and
 15 significant ties to the industry, was permitted to be involved with the project, much less to
 16 influence the younger and less experienced Verstraeten, a CDC employee until July of 2001.
 17 Perhaps this process was part of the “partnership” between CDC and industry⁵⁹, but in any event
 18 it is apparent that Davis’ input significantly influenced the ultimate results.
 19

20 Elizabeth Miller has also published and presented her results to the IOM in February of
 21 2004. At the time of her presentation to the IOM, Miller admitted that “my department does, on
 22

23 ⁵⁶ Transcript of February 9, 2004 IOM Committee meeting (Exhibit 19)

24 ⁵⁷ He had not worked for the CDC for two years.

25 ⁵⁸ (Exhibit 28)

26 ⁵⁹ The CDC ranks its priorities as follows:

- 27 1. Disease prevention
- 28 2. Immunization coverage
3. **Partnerships**
4. Science
5. Systems
6. **Vaccine safety**
7. NIP work environment.

See *National Immunization Program: A Blueprint for Sustained Success, A Strategic Plan, 2000-2005*. (Exhibit 29) (Emphasis added). It seems odd that “partnerships” with industry should take significant precedence over vaccine safety.

1 occasion, do collaborative work which has commercial sponsorship. . .” and that she was an
 2 expert witness for defendants in the MMR litigation in the U.K.⁶⁰ According to an Internet
 3 publication, these conflicts were not revealed or addressed in three articles related to the MMR
 4 vaccine that supported its safety. “Nowhere on Dr. Miller’s papers does she declare that she is
 5 also an expert witness for the drug companies GlaxoSmithKline, Aventis Pasteur and Merck.”⁶¹
 6 Miller apparently took umbrage at this characterization and wrote a letter to the publication,⁶²
 7 stating:
 8

9 Your insinuation that as a result of acting as an expert witness, and
 10 receiving research funds from commercial sources means I have
 11 become a mouth piece for vaccine manufacturers is wholly
 12 incorrect.⁶³

13 Regardless of her characterization, the bottom line is that Miller has significant conflicts
 14 as a result of her relationship with at least three vaccine Defendants. At a minimum, her
 15 comments to the IOM were less than candid, especially in that she did not acknowledge her
 16 relationship with the three corporatinos. In the published article reporting the results of her
 17 thimerosal work in the journal of PEDIATRICS⁶⁴ no conflicts of interest were acknowledged by
 18 Miller or the other authors despite PEDIATRICS requirements to the contrary.⁶⁵
 19

20 By now, it should be apparent that many of the studies published by pro-industry authors
 21 and relied upon by the IOM were published in the journal of PEDIATRICS. The journal of
 22 PEDIATRICS is a publication of the American Academy of Pediatrics, which is, itself, heavily
 23 conflicted. The AAP has made various statements supportive of the position of vaccine
 24 manufacturers but has not advised its readers that it has received significant funding from the
 25

26 ⁶⁰ Transcript of February 9, 2004 IOM Committee meeting (Exhibit 19) at p. 101.

27 ⁶¹ (Exhibit 30)

28 ⁶² (Exhibit 31)

⁶³ *Id.*

⁶⁴ Andrews, Miller et al., “Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association”, PEDIATRICS, 114(3):584-591(2004) (Defendant Exhibit D-14).

⁶⁵ (Exhibit 32)

1 vaccine companies, including Wyeth, GlaxoSmithKline and Merck.⁶⁶ Additionally,
2 documentation from 1985 demonstrates that the Academy has solicited contributions with a
3 “gentle nudge” from the drug companies for many years.⁶⁷
4

5 In addition to direct relationships between the drug companies and the AAP, it is
6 undisputed that the journal of PEDIATRICS itself receives substantial advertising revenue from
7 these Defendants. This may be why the journal ignored its conflicts and bias policies and did not
8 require Verstraeten, Davis, Miller and others to state their conflicts of interest when publishing
9 on the thimerosal issue.
10

11 In reviewing the epidemiologic studies cited by the Defendants and assessing the
12 conclusions the Institute of Medicine committee drew from them, it is also important to take into
13 consideration the conflicts within the committee itself, as well as the significant conflicts that
14 existed among the scientists that the IOM chose to embrace. The Court should also consider the
15 fact that the IOM committee had abrogated its duty and obligation to seriously consider the
16 issues presented as early as January of 2001.
17

18 3. DR. GEIER HAS PROPERLY RULED OUT OTHER CAUSES OF ALEXANDER’S
19 AUTISM

20 Alexander’s low cysteine, serum creatinine and homocysteine levels, the genomic
21 markers indicating heightened sensitivity to mercury,⁶⁸ coupled with documented elevated fecal
22 and challenged urine mercury levels form an adequate foundation for Dr. Geier’s differential
23 diagnosis of mercury encephalopathy manifested as autism, particularly where he has
24 administered and reviewed test results that eliminated all known causes,
25
26
27

28 ⁶⁶ Lifting the Veil of Secrecy, Corporate Support for Health and Environmental Professional Associations, Charities, and Industry
Front Groups (2003) (Exhibit 33) at p.

⁶⁷ (Exhibit 34).

⁶⁸ MTHFR C677T single mutation – an abnormality affecting the heavy metal detoxification pathway.

1 4. PLAINTIFF HAS PRESENTED SUFFICIENT EVIDENCE TO RAISE AN ISSUE OF
2 FACT REGARDING DEFENDANT'S NEGLIGENCE, NEGLIGENCE PER SE AND
3 INTENTIONAL MISCONDUCT

4 Defendants argue that they are entitled to summary judgment on these three issues.
5 However, there is a substantial amount of evidence that could support a finding of negligence *per*
6 *se*, negligence and punitive damages, and therefore Defendants' summary judgment motion
7 should be denied in all respects.

8 Regarding negligence *per se*, Defendants argue that the thimerosal in their product was
9 not banned by federal authorities in 1998, although they concede that the authorities advised of
10 potential concerns regarding thimerosal. As indicated below, they also admit that they violated
11 California safety regulations (Proposition 65) from 1990 until 2001 due to a failure to warn as
12 required.
13

14 Defendant B.F. Ascher's designated corporate representative, Christopher Ascher,⁶⁹
15 initially testified that he learned of potential hazards of mercury in either 1999 or 2000 although
16 he contends that he did not know prior to that time that thimerosal contained mercury.⁷⁰ In that
17 time frame, he learned that there was a concern that mercury could be a toxic substance at certain
18 levels.⁷¹ This information was received from others within the company.⁷²
19

20 Mr. Ascher conceded that it was the seller's obligation to disclose to the public
21 potentially dangerous ingredients of its products.⁷³ He was aware of no impediment that would
22 have kept B.F. Ascher from telling consumers that their product contained mercury during the
23
24
25

26
27 ⁶⁹ Within the company, Mr. Ascher is the "person most knowledgeable about sales of thimerosal-containing products."
Deposition of Christopher Ascher, May 4, 2006 (Exhibit 35) at p. 35.

28 ⁷⁰ *Id.* at 20-21.

⁷¹ *Id.* at 24.

⁷² *Id.* at 25.

⁷³ *Id.* at 34

1 1990's.⁷⁴ Despite knowledge that mercury could be toxic at some level, B.F. Ascher never
2 changed its label to clarify that the product contained mercury.⁷⁵ In fact, the company apparently
3 never even considered changing the label to advise the public that the product contained
4 mercury.⁷⁶ Ascher agreed that others within the company "had known for some time that
5 thimerosal was a mercury material and that the Ayr product had contained mercury for some
6 time."⁷⁷ Despite this level of knowledge, Ascher testified that the company never did any
7 research and never tested the product to determine whether it might have a neurotoxic effect on
8 humans or on infants (for whom it was marketed).⁷⁸ No efforts were made to test the product,
9 complete research, or provide any warning to consumers at any time until the mercury was
10 removed from the product in September, 2001.⁷⁹

11
12
13 Ascher agreed that toxic substances like mercury are going to have a much more
14 pronounced significant effect on an infant than on an adult.⁸⁰ However, the label was "never
15 changed to tell mothers and fathers that the product [B.F. Ascher was] trying to sell them
16 contained mercury."⁸¹ However, once the product was mercury-free, Ayr promoted it as being
17 "safe," due to the removal of thimerosal.⁸²

18
19 Ascher recognized that there were a significant number of medical and scientific articles
20 discussing the potential hazards of thimerosal. Of particular significance is a 1974 article from
21 the Journal of Toxicology entitled "Tissue Concentrations of Mercury After Chronic Dosing of
22 Squirrel Monkeys with Thimerosal," since the method of exposure was precisely the same as
23
24

25 ⁷⁴ *Id.* at 36.

26 ⁷⁵ *Id.* at 42.

27 ⁷⁶ *Id.* at 43.

28 ⁷⁷ *Id.*

⁷⁸ *Id.* at 48-49.

⁷⁹ *Id.* at page 50.

⁸⁰ *Id.* at 52.

⁸¹ *Id.* at 59.

⁸² *Id.* at 59-60.

1 with the B.F. Ascher/Kolmar product.⁸³ The article noted that mercury accumulated in the brain
2 as a result of the nasal exposures:

3
4 However, there was an increase in brain mercury in
5 monkeys which may represent a potential hazard in
6 the chronic use of thimerosal as a preservative in
7 products intended for human use.⁸⁴

8 Ascher confirmed that B.F. Ascher had the ability to go to the library and review information
9 concerning the ingredients of their products. However, he was unaware that they had ever done
10 so.⁸⁵ He generally agreed that a company should research and understand the hazards of the
11 components of its products.⁸⁶ Ascher was also shown an Eli Lilly MSDS (Material Safety Data
12 Sheet) from 1993 that confirmed thimerosal could cause mercury poisoning as well as
13 neurological injury and mild to several mental retardation.⁸⁷ He acknowledged that Lilly had
14 warned thimerosal purchasers (such as Kolmar and B.F. Ascher) that certain individuals were
15 hypersensitive to mercury and more susceptible to injury.⁸⁸ He also recognized that Eli Lilly
16 confirmed the necessity of providing a Prop 65 warning for thimerosal-containing products, but
17 confirmed that B.F. Ascher/Kolmar **never** warned pursuant to the California legal
18 requirements.⁸⁹

19
20 Ascher testified about a pharmaceutical handbook published in 1994 that was found in
21 B.F. Ascher's library.⁹⁰ That publication confirmed that "increasing concerns over its
22 (thimerosal) safety have, however, led some to question its continued use in formulations."⁹¹

23
24
25 ⁸³ *Id.* at 73.

⁸⁴ Blair, "Tissue Concentrations of Mercury After Chronic Dosing of Squirrel Monkeys with Thimerosal," *TOXICOLOGY*, 3:171-176 (1975)) (Exhibit 36).

26 ⁸⁵ *Id.* at 77.

27 ⁸⁶ *Id.* at 78.

⁸⁷ *Id.* at 86-88

⁸⁸ *Id.* at 89.

28 ⁸⁹ *Id.* at 89.

⁹⁰ *Id.* at 91-92.

⁹¹ *Id.* at 92-93.

1 Despite this information, Ascher repeatedly confirmed that he was unaware of any efforts to
2 clarify the nature of the hazard or provide any warnings related to it. The textbook in question
3 also identified six cases of mercury poisoning resulting from thimerosal exposure.⁹²
4

5 After reviewing corporate documents produced in response to a request for production,
6 Ascher recalled that he had been aware, at least by mid-1998, that there was talk about banning
7 thimerosal and that there were concerns within the company about thimerosal hazards.⁹³
8 Despite discussion of the issues, the companies continued to sell the products without labeling
9 them for mercury and without indicating the potential hazards.⁹⁴
10

11 In addition to the evidence presented above, apparently in 1998 the CHPA (Consumer
12 Healthcare Products Association), a trade group/lobbying organization to which B.F. Ascher
13 belonged, advised of its continuing efforts to fight state bans (Connecticut, Maryland, Rhode
14 Island, New York, Massachusetts and others) of mercury-containing products like the
15 Kolmar/B.F. Ascher product at issue in this case.⁹⁵ Ascher conceded that the CHPA was
16 lobbying on B.F. Ascher's behalf to "keep [their] product as something that can be sold."⁹⁶ As
17 late as October 12, 2001, Ascher understood that the CHPA was continuing to fight for B.F.
18 Ascher's right to continue selling mercury products like the one at issue in this case.⁹⁷
19

20 On August 23, 1999, B.F. Ascher received an in-house memo from Parkland Hospital
21 which indicated that the product in question was being used "all day long" on babies. The
22
23
24
25

26
27 ⁹²*Id.* at 93

⁹³*Id.* at 96.

⁹⁴*Id.* at 98.

⁹⁵*Id.* at 103-109.

⁹⁶*Id.* at 107.

⁹⁷*Id.* at 110.

1 doctors were concerned about how much mercury the babies were receiving.⁹⁸ Despite this
2 knowledge, B.F. Ascher/Kolmar did not provide any warnings or information to consumers.

3 After reviewing another B.F. Ascher memo, Mr. Ascher recalled that mercury had
4 become a regulated substance in California as per Proposition 65 on July 1, 1990.⁹⁹ He conceded
5 that the company **never** provided the warning required by the California authorities. *Id.*
6 Ultimately, the state of California sued B.F. Ascher, who paid a \$66,000 fine.¹⁰⁰ Ascher also
7 conceded that at some time during the late 1990's, the company became aware that they had not
8 been following the required California warning. Despite this awareness, they deliberately
9 continued to ignore the requirement and **never** placed the warning on the products.¹⁰¹ This type
10 of conduct clearly demonstrates a "conscious disregard for the safety of consumers and others."
11
12

13 It becomes clear that the level of actual knowledge on the part of these Defendants is
14 more than sufficient to demonstrate that a jury could find negligence, negligence per se and
15 award punitive damages. By at least 1994, B.F. Ascher was aware of potential hazards. Its
16 failure to take any actions thereafter, and its insistence on continuing to sell the product with
17 thimerosal but without any reference to mercury or hazards, clearly rises to the level of a
18 "conscious disregard for the safety of consumers and others." *Ehrhardt v. Brunswick, Inc.*, 186
19 Cal. App. 3d 734, 741-742.
20
21

22 5. CONCLUSION

23 There is more than sufficient evidence for this Court to deny summary judgment as to
24 causation, negligence per se, negligence, and punitive damages. It is noted that Defendants have
25
26

27 ⁹⁸*Id.* at 113

28 ⁹⁹*Id.* at 125.

¹⁰⁰*Id.* at 126.

¹⁰¹*Id.* at 127.

1 **not** sought summary judgment with respect to strict product liability claims. Under the
2 circumstances, Defendants' motion should in all respects be denied.

3 Dated: March 14, 2007

C. Andrew Waters
WATERS & KRAUS, LLC

5 By: /s/ C. Andrew Waters
6 C. Andrew Waters
7 Attorneys for Plaintiff

8 William Levin
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