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11
12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA

14 ALEXANDER REDFOOT, a Minor, by and Through)
15 his Guardian ad Litem, MICHELL REDFOOT;)
MICHELL REDFOOT)

16 Plaintiffs,)

17 v.)

18 B.F. ASCHER & COMPANY, INC. AND)
19 KOLMAR LABORATORIES, INC.; and DOES 1)
through 10, inclusive,)

20 Defendants.)
21

Case No. C05-02045 PJH

**DEFENDANTS'
MEMORANDUM OF POINTS
AND AUTHORITIES IN
SUPPORT OF SUMMARY
JUDGMENT, OR IN THE
ALTERNATIVE, MOTION FOR
SUMMARY ADJUDICATION
CLAIMS**

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

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1 Defendants B.F. ASCHER & COMPANY, INC. and KOLMAR LABORATORIES, INC. submit
2 the following memorandum of points and authorities in support of their motion for summary judgment, or in the
3 alternative, motion for summary adjudication of claims, pursuant to Federal Rule of Civil Procedure 56 as to
4 the entire First Amended Complaint for Damages filed by plaintiffs ALEXANDER REDFOOT and MICHELL
5 REDFOOT. Defendants are concurrently filing a motion to preclude the proposed testimony of plaintiffs'
6 experts, a "*Daubert* Motion." Defendants incorporate by reference the arguments set forth in the related
7 *Daubert* Motion.

8 **I. INTRODUCTION**

9 Plaintiffs have filed a products liability action against the manufacturer and distributor of a product called
10 Ayr Saline Nasal Mist. Plaintiffs allege that the thimerosal-containing nasal spray caused plaintiff
11 ALEXANDER REDFOOT's autism. Pursuant to this motion, defendants request that summary judgment be
12 entered in their favor based on plaintiffs' inability to produce reliable and sufficient evidence of general or
13 specific causation. Specifically, plaintiffs have no reliable, statistically significant evidence to support their
14 allegation that the Ayr Saline Nasal Mist utilized by plaintiffs is capable of causing autism in the general
15 population, or that the product caused ALEXANDER REDFOOT's autism. As explained in defendants'
16 contemporaneously filed *Daubert* Motion, the scientific evidence offered by plaintiffs is fundamentally flawed,
17 inherently unreliable, and entirely inadmissible. Moreover, the scientific evidence to date which examines the
18 possibility of a causal relationship between thimerosal containing products and autism has concluded that the
19 evidence favors a *rejection* of a causal relationship. Based on plaintiffs' inability to produce sufficient evidence
20 of causation, defendants are entitled to a judgment as a matter of law.

21 Plaintiff's negligence per se claim must fail based on the fact that the cited regulation simply does not
22 apply to the product at issue in this case. Plaintiffs claim that defendants negligently and/or intentionally
23 concealed and made misrepresentations regarding the hazards associated with the thimerosal-containing nasal
24 spray also must fail based on the fact that there is no reliable scientific evidence that the nasal spray was harmful
25 to the health of humans. Therefore, plaintiffs cannot establish that defendants were aware of any probable
26 dangerous consequences associated with the product or that defendants willfully and deliberately failed to avoid
27 such consequences. Based on the inability to prove any conduct upon which to base an award of punitive
28 damages, defendants are entitled to an order denying plaintiffs' claim for punitive damages.

1 **II. FACTUAL AND PROCEDURAL BACKGROUND**

2 **A. Plaintiffs' Claims**

3 Plaintiff MICHELL REDFOOT claims she administered an over-the-counter nasal spray called Ayr
4 Saline Nasal Mist to her minor son plaintiff ALEXANDER REDFOOT for several years for the child's
5 recurring nasal congestion. The Ayr Saline Nasal Mist used by plaintiffs was distributed by B.F. ASCHER &
6 COMPANY, INC. and was manufactured by KOLMAR LABORATORIES, INC. The Nasal Mist
7 contained thimerosal. Plaintiffs contend that as a result of ALEXANDER's chronic exposure to the thimerosal
8 preservative contained in the Nasal Mist, he was exposed to toxic levels of mercury and that said exposure
9 directly and proximately caused him to suffer from autism.¹

10 On April 1, 2005, plaintiffs filed a complaint for damages against B.F. ASCHER in Contra Costa
11 Superior Court. The case was removed to the Northern District Court in May of 2005. A First Amended
12 Complaint which added KOLMAR LABORATORIES as a defendant was filed on June 19, 2006. The
13 Complaint alleges that the nasal spray was defective in design and failed to contain adequate warnings to
14 plaintiffs concerning the mercury content and the neurological dangers associated with mercury and thimerosal.

15 The First Amended Complaint asserts the following causes of action: 1) Strict Products Liability: Failure
16 to Warn; 2) Negligence: Failure to Warn; 3) Intentional and/or Reckless Concealment and/or Non-Disclosure
17 of Known Defective and/or Dangerous Conditions Associated with Use of Ayr Saline Nasal Mist; 4)
18 Negligence Per Se; and 5) Allegations Against Doe Manufacturer/Distributor/Supplier Defendants, including
19 allegations of misrepresentations. The Complaint includes a request for punitive damages based on the
20 allegation that defendants had specific prior knowledge that there was an unacceptable risk of injury resulting
21 from the use of the nasal spray and that the defendants intentionally failed to reveal their knowledge of the
22 hazards of the product and concealed and suppressed that knowledge from those who used the product.

23 **B. The Critical Role Epidemiology Plays in Ascertaining Causation**

24 Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it.
25 To define that relationship, the epidemiologist examines the general population, comparing the incidents of the
26

27
28 ¹Autism, autism spectrum disorder ("ASD") and pervasive developmental disorder ("PDD") are terms
sometimes used synonymously to describe a range of related conditions.

1 disease among those people exposed to the factor in question to those not exposed. The epidemiologist then
2 uses statistical methods and reasoning to allow him or her to draw a biological inference between the factor
3 being studied and the disease's etiology. *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *as*
4 *modified on rehearing*, 884 F.2d 166 (5th Cir. 1989).

5 The Agent Orange and Bendectin litigation helped to increase the judicial recognition and acceptance of
6 the critical role that epidemiology plays in establishing causation. In the Agent Orange litigation, Judge
7 Weinstein recognized that in a mass tort case, "epidemiological studies on causation assume a role of critical
8 importance." *In Re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223, 1239 (E.D.N.Y. 1985), *aff'd* 818
9 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988). A number of courts have agreed with Judge
10 Weinstein. For example, in *Brock*, the Court reversed the trial court's denial of a judgment notwithstanding the
11 verdict and held that "the most useful and conclusive type of evidence in a case such as this is epidemiological
12 studies." *Id.* at 311.

13 **C. Epidemiological Studies and Scientific Evidence Regarding the Association Between**
14 **Thimerosal and Autism**

15 Plaintiffs have not cited any reliable, peer-reviewed epidemiological studies purporting to establish a
16 causal link between the administration of thimerosal-containing nose spray and the onset of autistic disorder.
17 As stated in the related *Daubert* Motion, there is no reliable scientific evidence that thimerosal is toxic to
18 humans at the incremental doses delivered by nasal sprays or that thimerosal can cause neurological damage
19 that manifests as autism.

20 The only expert report regarding causation offered by plaintiffs was prepared by Dr. Mark Geier, a
21 geneticist. Dr. Geier is not board certified in pediatrics or pediatric neurology, nor is he certified as an
22 epidemiologist or a biostatistician. He is not a toxicologist. Dr. Geier has published four studies concluding that
23 there is a statistically significant increased relative risk of autism among children given thimerosal-containing
24 vaccines. Defendants have challenged the reliability of those studies, as well as the qualifications of Dr. Geier
25 and plaintiff's other non-retained experts pursuant to their *Daubert* Motion.

26 As stated in the *Daubert* Motion, the Centers for Disease Control and Prevention and the National
27 Institutes of Health requested that the Institute of Medicine, a division of the National Academy of Sciences,
28 undertake an independent scientific review of existing and emerging vaccine-safety concerns, including the

1 general causation issues, i.e., thimerosal causing autism. That function was performed by a group of prominent
2 scientists who were selected to serve on the IOM's Immunization Safety Review Committee. In May 2004,
3 after reviewing the available evidence on both sides of the debate, including presentation and submissions by
4 some of plaintiffs' experts, the IOM Immunization Safety Review Committee concluded that "the evidence
5 favors rejection of a causal relationship between thimerosal-containing vaccines and autism." Exhibits to
6 Defendants' *Daubert* Motion and Summary Judgment Motions, Exhibit C-4 and C-5.

7 Given the lack of direct evidence for a biological mechanism and that fact that
8 all well-designed epidemiological studies prove evidence of no association
9 between thimerosal and autism, the Committee recommends that cost-benefit
10 assessments regarding the use of thimerosal-containing versus thimerosal-free
11 vaccines and other biological or pharmaceutical products, whether in the United
12 States of other countries, should not include autism as a potential risk.

13 Institute of Medicine of the National Academy of Sciences, Immunization Safety Review: Vaccines and
14 Autism, p. 13 (2004).

15 On September 26, 2006, the Food and Drug Administration, Department of Health & Human
16 Services, prepared a written response to a citizen petition which asked the Secretary of Health and Human
17 Services or the Commissioner of the Food and Drug Administration to take numerous actions pertaining to
18 vaccines and other mercury-based preservatives. The petition was denied based on the FDA's conclusion that
19 the products were safe. The FDA's Response discussed the basis of the FDA's decision that the products are
20 safe and explained why the studies on which the citizen petition relied did not support the contention that the
21 licensed and approved products containing thimerosal were unsafe. See, *Daubert* Motion, Index C, FDA
22 Response to Citizen Petition, Exhibit C-2. The Response stated:

23 [W]e believe the use of thimerosal in nasal products does not pose a threat to
24 human health. . .

25 We decline your request for those actions and remedies on the substantive
26 grounds that the few vaccines and other legally marketed products that contain
27 thimerosal are safe and that no action against those products based on their
28 thimerosal content is appropriate. . .

 [S]tudies and other evidence support FDA's determination that vaccines and
 other FDA-approved products containing thimerosal are safe. The evidence on
 which your petition relies either does not support your requests, or is too
 flawed to be considered valid scientific evidence. Therefore, FDA has no
 grounds to revoke the licenses and withdraw the approvals of thimerosal-
 containing products, or to take any other action. . .

 [T]he available evidence supports FDA's conclusion that all currently licensed

1 vaccines and other pharmaceutical drug products containing thimerosal are safe.

2 (Response, pages 11, 22-23.)

3 In addition, the World Health Organization; the United States Centers for Disease Control and
4 Prevention; the American Academy of Pediatrics; the U.K. Committee on the Safety of Medicines; and the
5 European Agency for the Evaluation of Medicinal Products have all concluded that no credible evidence exists
6 to support the suggestion of causal relationship between thimerosal and autism.²

7 **III. ARGUMENT**

8 **A. Plaintiffs must Prove General and Specific Causation Within a Reasonable Medical**
9 **Probability Based upon Competent Expert Testimony**

10 California law is well settled that in a personal injury action causation must be proven within a
11 reasonable medical probability based upon competent expert testimony. *Jones v. Ortho Pharmaceutical*
12 *Corp.* (1985) 163 Cal.App.3d 396, 402, cited with approval in *Kennedy v. Southern California Edison*
13 *Co.*, 268 F.3d 763, 768 (9th Cir. 2001). Mere possibility alone is insufficient to establish a prima facie case.

14 That there is a distinction between a reasonable medical “probability” and a
15 medical “possibility” needs little discussion. There can be many possible
16 “causes,” indeed, an infinite number of circumstances which can produce an
17 injury or disease. A possible cause only becomes “probable” when, in the
18 absence of other reasonable causal explanations, it becomes more likely than
19 not that the injury was a result of its action. This is the outer limit of inference
20 upon which an issue may be submitted to the jury.

21 *Id.* at 403.

22 The fact that a determination of causation is difficult to establish cannot provide a plaintiff with an
23 excuse to dispense with the introduction of some reasonably reliable evidence proving causation. Although
24 juries are normally permitted to decide issues of causation without guidance of experts, if the cause of the
25 disease/injury is beyond the experience of laymen, it can only be explained through expert testimony. Such
26 testimony, however, can enable a plaintiff’s action to go to the jury only if it establishes a reasonably probable
27 causal connection between an act and a present injury. *Id.*

28 Causation in toxic tort cases is typically discussed in terms of generic and specific causation. *In re*

²See Exhibits to Defendants’ *Daubert* and Summary Judgment Motions, Exhibits C-1, C-3, C-6, C-7 and C-9.

1 *Hanford Nuclear Reservation Litigation*, 292 F.3d 1124, 1133 (9th Cir. 2002). General, or “generic”
 2 causation has been defined by courts to mean whether the substance at issue had the capacity to cause the
 3 harm alleged, while specific or “individual causation” refers to whether a particular individual suffers from a
 4 particular ailment as a result of exposure to a substance. *Id.* In order to prevail on their claims, plaintiffs must
 5 establish both generic and individual causation. *Id.* at 1134. This means that plaintiffs must establish not only
 6 that the thimerosal-containing nasal spray was capable of causing autism, but in addition, that the nasal spray
 7 was the cause-in-fact of the ALEXANDER REDFOOT’s autism.

8 **B. Defendants Can Meet Their Burden under Frcep 56(c) by Showing an Absence of**
 9 **General or Specific Causation**

10 The Supreme Court held in *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986), that Federal Rule of
 11 Civil Procedure 56 contains no express or implied requirement that the moving party “support its motion with
 12 affidavits or other similar materials negating the opponent’s claim.” Where the plaintiff bears the ultimate burden
 13 of proof on causation, the defendant need only to point to the absence of a genuine issue of material fact; it is
 14 not required to produce any evidence at all. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311,
 15 1315 (9th Cir.), *cert. denied*, 526 U.S. 869 (1995). Therefore, defendants in this case will have satisfied their
 16 initial burden of proof if the Court determines that plaintiffs’ causation evidence is inadmissible. *Lust v. Merrell*
 17 *Dow Pharmaceuticals, Inc.* 89 F.3d 594, 598 (9th Cir. 1996).

18 **C. Plaintiffs Have Failed to Produce Reliable Scientific Evidence Which Establishes That**
 19 **Ayr Saline Nasal Mist Had the Capacity to Cause Autism**

20 In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995), minors sued a
 21 drug manufacturer for products liability alleging that their mothers’ ingestion of morning sickness pills
 22 manufactured by the defendant caused the plaintiffs’ limb reduction birth defects. The Court stated that
 23 California tort law required the plaintiffs to show not merely that the product increased the likelihood of injury,
 24 but that it more likely than not caused their injuries. *Id.* at 1320.

25 In terms of statistical proof, this means that plaintiffs must establish not just that
 26 their mothers’ ingestion of Bendectin increased somewhat the likelihood of birth
 27 defects, but that it more than doubled it - only then can it be said that Bendectin
 28 is more likely than not the source of their injury. . .

None of plaintiffs’ epidemiological experts claim that ingestion of Bendectin
 during pregnancy more than doubles the risk of birth defects. . .

1 While plaintiffs epidemiologists make vague assertions that there is a statistically
 2 significant relationship between Bendectin and birth defects, none state that the
 3 relative risk is greater than two. Theses studies thus would not be helpful, and
 indeed would only serve to confuse the jury, if offered to prove rather than
 refute causation.

4 *Id.* at 1321.

5 Absent epidemiological proof to meet the “more likely than not” burden of proof requiring statistics to
 6 reflect a relative risk factor of 2.0, plaintiffs cannot recover. *See, also, Brock v. Merrell Dow*
 7 *Pharmaceuticals, Inc.* 874 F.2d 307, *as modified on rehearing*, 884 F.2d 166 (5th Cir. 1989) and
 8 *Richardson v. Richardson-Merrell* 857 F.2d 823, 829 (D.C. Cir. 1988).³

9 As indicated above and as set forth in defendants’s *Daubert* Motion, not only is there a lack of
 10 sufficiently reliable epidemiological proof to establish causation, there is epidemiological evidence that there is
 11 *no* causal connection. Therefore, plaintiffs’ experts’ reliance on case reports and other data are not sufficient to
 12 show that the thimerosal-containing nasal spray was capable of causing the minor plaintiff’s autism. *Meister v.*
 13 *Medical Engineering Corp.* 267 F.3d 1123, 1130-1132 (C.A.D.C. 2001).

14 **D. Plaintiffs Cannot Rule out Other Possible Causes of Plaintiff’s Autism and Therefore**
 15 **Cannot Establish Specific Causation**

16 Plaintiffs must provide reliable evidence of specific causation, that is, evidence that the Ayr Saline Nasal
 17 Mist specifically caused ALEXANDER REDFOOT’s autism. In order to prove specific causation, plaintiffs’
 18 expert must rule out other possible causes of the minor plaintiff’s autism.

19 In *Claar v. Burlington Northern R. Co.*, 29 F.3d 499 (9th Cir. 1994), the Court granted summary
 20 judgment in favor of a railroad in a case filed by former employees who alleged they suffered from a variety of
 21 ailments stemming from exposure to chemicals while working at the railroad’s facility. In addition to refusing to
 22 admit expert declarations which failed to explain the basis for their conclusions, the Court noted that none of the
 23 experts made any effort to rule out other possible causes for plaintiffs’ alleged injuries. *Id.* at 502. In,
 24 *Daubert II*, the Court noted that the plaintiffs’ specific cause expert offered no tested or testable theory to
 25 explain how, from his review of the plaintiffs’ medical records, he was able to eliminate all other potential
 26

27 ³Both cases were used as a basis for the Court’s decision in the Southern California District Court
 28 opinion in *Daubert v. Merrill Dow Pharm, Inc.* located at 727 F. Supp. 570 (S.D. Cal. 1989).

1 sources of birth defects, nor did he explain how he alone could state as a fact that the Bendectin caused the
2 plaintiffs' injuries. *Daubert II*, 43 F.3d at 1319.

3 Differential diagnosis, the process of elimination that physicians routinely use to identify the most likely
4 cause of a particular individual's illness, is considered an acceptable source of data on specific causation. By
5 eliminating the patient's symptoms, medical history, diagnostic test results, etc. a doctor can eliminate alternative
6 causes and reach a conclusion about the most likely cause of a particular patient's condition. In the present
7 case, plaintiff's expert Dr. Geier undertook the task of making a differential diagnosis to establish specific
8 causation. Dr. Geier is not a pediatrician or a pediatric neurologist. He is not an expert on autism. Thus, there
9 is a threshold question as to whether Dr. Geier is even qualified to give a causation opinion with respect to the
10 cause of a neurological disorder such as autism in a child.

11 Assuming Dr. Geier would be qualified to render such an opinion, such an opinion would still not be
12 reliable if it failed to acknowledge the one conclusion that is generally accepted in the medical community with
13 respect to the causation of autism, which is, that its cause is unknown. As stated in the FDA's Response to
14 Citizen Petition, the biochemical and molecular pathways and processes relevant to the expressions of autism
15 are currently unknown.⁴ There is currently limited understanding of the etiology of autism. Dr. Geier's failure to
16 take into account the existence of such a strong likelihood of a currently unknown cause of autism serves to
17 negate the reliability of the differential diagnosis he performed.

18 In addition to his failure to consider within his analysis the high probability that an unknown cause
19 cannot be ruled out as the specific cause of the minor plaintiff's autism, Dr. Geier did not rule out all pre-
20 exposure illnesses and conditions. For example, he makes no mention of the fact that the minor plaintiff was
21 macrocephalic at birth, a point which neurologist and pediatrician Paul Fisher, M.D. raises in his report.⁵ Dr.
22 Geier also did not indicate how he excluded a family history of speech and developmental delays which are
23 cited as more likely causes by Dr. Fisher. Dr. Geier has failed to sufficiently rule out alternative causes or pre-
24 existing conditions. As a result, his specific causation opinion should be excluded as unreliable.

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27 ⁴Exhibits to Defendants' *Daubert* and Summary Judgment Motions, Exhibit C-2, page 12 and 14.

28 ⁵Exhibits to Defendants' *Daubert* and Summary Judgment Motions, Exhibit B-5.

1 **E. The Federal Regulation Cited by Plaintiffs in Support of Their Cause of Action for**
 2 **Negligence per Se Does Not Apply to Ayr Saline Nasal Mist**

3 In support of their cause of action for Negligence Per Se, plaintiffs allege that defendants' failure to
 4 warn plaintiffs of the dangers associated with the use of thimerosal and/or thimerosal-containing Ayr Saline
 5 Nasal Mist violates the federal ban on thimerosal products. Plaintiffs refer to 63 Fed. Reg. 19799 (April 22,
 6 1998). However, as set forth in the Expert Witness Opinion of Dr. Rhys Bryant⁶ at paragraphs 52 and 53, the
 7 Federal Regulation referred to, which was part of the FDA's review under the Drug Efficacy Study
 8 Implementation program in which panels of experts reviewed data for over-the-counter drugs on the market,
 9 the FDA took no action to approve or disapprove certain categories of drugs. The Final Rule, amended 21
 10 CFR 310.545, required removal of thimerosal *only when used as an active ingredient in first-aid antiseptic*
 11 *drug products*. The FDA did not put a "federal ban" on thimerosal.

12 **F. There Is No Evidence to Support the Intentional Causes of Action or a Claim for**
 13 **Punitive Damages**

14 Plaintiffs assert that defendants were aware of the mercury content and of the dangers to human life
 15 caused by the mercury containing thimerosal and thimerosal-containing Ayr Saline Nasal Mist and that they
 16 failed to warn, recall and/or assure that their defective and unreasonably dangerous product was removed from
 17 the marketplace.⁷ In addition, plaintiffs alleges that KOLMAR LABORATORIES made misrepresentations
 18 regarding the safety of thimerosal to thimerosal-containing product manufacturers and plaintiffs.⁸ In support of
 19 their claim for punitive damages, plaintiffs allege that defendants intentionally failed to reveal their knowledge of
 20 the hazards of the product and fraudulently, consciously and actively concealed and suppressed that knowledge
 21 from those who used the product.⁹

22 In California, an award of punitive damages is controlled by the provisions of Civil Code section 3294,
 23

24 ⁶Exhibits to Defendants' *Daubert* and Summary Judgment Motions, Exhibit B-6.

25 ⁷First Amended Complaint, Third Cause of Action, pages 5-6.

26 ⁸First Amended Complaint, Fifth Cause of Action, pages 7-8.

27 ⁹First Amended Complaint, Punitive Damage Allegations, pages 8-9.

1 which states in pertinent part:

2 (a) In an action for the breach of an obligation not arising from contract, where
3 it is proven by clear and convincing evidence that the defendant has been guilty
4 of oppression, fraud, or malice, the plaintiff, in addition to actual damages, may
5 recover damages for the sake of example and by way of punishing the
6 defendant.

7 The term “oppression” is further defined in Civil Code section 3294(c). “Oppression” means
8 despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person’s
9 rights. “Despicable conduct” is defined as conduct which is so vile, base, or contemptible, that it would be
10 looked down upon and despised by reasonable people. “Fraud” means that defendants intentionally
11 misrepresented or concealed a material fact and did so intending to harm the plaintiff. CACI 3945.

12 Punitive damages may be awarded in a products liability action only if it is shown that the defendant
13 placed a product on the market in conscious disregard of the safety of consumers and others, not if it is merely
14 shown that the defendant acted unreasonably. *Ehrhardt v. Brunswick, Inc.* 186 Cal.App.3d 734, 741-742.
15 The punitive damage standard requires that the defendant have actual knowledge of the risk of harm its creating
16 and, in the face of that knowledge, fail to take steps it knows will reduce or eliminate the risk of harm. In order
17 to justify an award of punitive damages on the basis of conscious disregard of the safety of others, the plaintiff
18 must establish that the defendant was aware of the *probable* dangerous consequences of its conduct and that it
19 willfully and deliberately failed to avoid those consequences. *Id. See, also, Hilliard v. A.H. Robins Co.* 148
20 Cal.App. 3d 374, 395.

21 In the present case, there is no evidence of despicable conduct on the part of any defendant. As
22 discussed *infra*, and in the related *Daubert* Motion, there is no evidence that the amount of thimerosal
23 contained in the Ayr Saline Nasal Mist used by plaintiffs posed a threat to human health. After looking at all the
24 relevant evidence, the FDA specifically concluded that the use of thimerosal in nasal products does not pose a
25 threat to human health. In addition, there is no reliable evidence that the nasal spray caused plaintiff’s autism.
26 Again, the reliable scientific studies reject a causal connection between thimerosal and autism.

27 Plaintiffs cannot present any evidence of actual knowledge or recognition by any responsible employee
28 of defendants of any alleged dangerous properties of the Ayr Saline Nasal Mist in terms of its effect on human
beings as disclosed by *reliable* studies which would have triggered the need for a warning. There is absolutely
no evidence that any vile, base, or contemptible conduct that would be despised by reasonable people was

1 engaged in by defendants or their employees.

2 Based on plaintiffs' inability to produce any evidence that would support the third and fifth causes of
3 action for concealment and/or nondisclosure of known defective and/or dangerous conditions or any award for
4 punitive damages, defendants' request that judgment be entered in their favor on these causes of action.

5 **IV. CONCLUSION**

6 Plaintiffs cannot establish general or specific causation within a reasonable medical probability based on
7 *competent* expert testimony. There is no basis for a negligence per se cause of action as the regulation cited by
8 plaintiffs does not apply to nasal sprays. Any claims for concealment or misrepresentation relating to the
9 alleged hazards associated with the nasal spray cannot be established

10 ///

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16 based on the fact that all reliable scientific evidence indicates the nasal spray did not pose a threat to human
17 health. Based on the above, defendants request that the Court entered a judgment in favor of defendants.

18
19 Dated: February 28, 2007

20 LOW, BALL & LYNCH

21
22 By /s/ Laura S. Flynn
23 MARK F. HAZELWOOD
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