BAYER CORPORATION'S PETITION FOR RECONSIDERATION OF DETERMINATION THAT 1984 EPA REPORT FORMALLY IDENTIFIED ALL "MERCURY AND MERCURY COMPOUNDS" AS REPRODUCTIVE TOXINS AND FOR CLARIFICATION OF LISTING

I.

INTRODUCTION

On July 1, 1990, the Health & Welfare Agency added "mercury and mercury compounds" to the list of chemicals known to the state of California to cause reproductive toxicity. This authoritative body listing was predicated on a formal identification contained in a 1984 EPA report entitled *Mercury Health Effects Update, Health Issue Assessment*; EPA-600/8 – 84-019F ("1984 EPA Report").[1] Notice of Intent to List Chemicals, 90 Cal. Reg. Notice Reg. No. 17-2 (April 27, 1990) [attached hereto as Exhibit B].

A "formal identification" of a chemical under Proposition 65 ("Prop. 65")[2] means a statement in a final authoritative body document that "specifically and accurately identifies the chemical" and concludes either (1) that human studies indicate the chemical causes reproductive toxicity or (2) that sufficient data from reliable experimental animal studies indicates that "an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." 22 Cal. Code of Regs. § 12306(a), (d) & (g).

Bayer Corporation ("Bayer") does not dispute that the 1984 EPA Report formally identifies elemental mercury, methylmercury and metallic mercury vapor as reproductive toxins within the meaning of 22 Cal. Code of Regs. section 12306(g). However, the 1984 EPA Report does **not** formally identify either thimerosal or phenylmercuric acetate ("PMA") as a reproductive toxin. Indeed, as the Alameda County Superior Court recently noted, "[t]he 1984 EPA report never mentions Thimerosal" and explicitly concludes that PMA's prenatal effects in humans are "'not known.'"[3]

Bayer files this reconsideration petition pursuant to Title 22, California Code of Regulations, section 12306 to discern whether OEHHA interprets the "mercury and mercury compounds" listing to encompass thimerosal and PMA.

If OEHHA interprets the "mercury and mercury compounds" listing to encompass thimerosal or PMA, Bayer respectfully requests reconsideration of the listing since the EPA does not now – and has not ever – formally identified either thimerosal or PMA as a reproductive toxin. To the extent OEHHA interprets the authoritative body listing to include chemicals not

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1 A copy of the 1984 EPA Report is attached hereto as Exhibit A. Throughout this petition, all reference to the EPA are references to the United States Environmental Protection Agency.

2 Proposition 65 is the short-hand name for the "Safe Drinking Water and Toxic Enforcement Act of 1986." Cal. Health & Safety Code sections 25249.5 et seq.

3 *See People of the State of California ex rel. Bill Lockyer v. Altaire Pharmaceuticals, et al.*, No. 2001-016727 (September 8th order re motion for summary judgment) ("Alameda County Summary Judgment Order") (noting also that "even after a full briefing of the issue[,] there is nowhere in the current record any ... study ... by any scientist that PMA or Thimerosal are known to cause harm"), p. 1.

formally identified in the cited authoritative body source, Bayer's reconsideration petition must be granted.

If OEHHA does not interpret the "mercury and mercury compounds" listing to encompass thimerosal and PMA, Bayer respectfully requests clarification of the listing to so state. It does not "further consumer protection, legitimate business needs, or respect for the law" to compel publication of Prop. 65 warnings for chemicals that are not known to the state of California to cause reproductive harm. Alameda County Summary Judgment Order (Exhibit C) at 2.

II.

ANALYSIS

A. OEHHA Has The Power And Responsibility To Reconsider And Clarify The Authoritative Body Listing For "Mercury And Mercury Compounds."

Pursuant to Title 22, California Code of Regulations section 12306(j), any interested party may request that OEHHA reconsider its "determination that a chemical has been formally identified as causing cancer or reproductive harm." 22 Cal. Code of Regs. § 12306(j).

Where, as here, the chemicals under scrutiny have never been formally identified as reproductive toxins by an authoritative body – and thus are "no longer identified as causing . . . reproductive toxicity" within section 12306(j)'s parlance – it is incumbent upon OEHHA to undertake the requested reconsideration. *Id.* (stating that the agency "shall" reconsider under these circumstances). Unless OEHHA clarifies that the present "mercury and mercury compounds" listing does not encompass thimerosal and PMA, OEHHA is obliged to refer the chemicals to the Developmental and Reproductive Toxicant Identification Committee ("DART Committee") for its recommendation concerning whether these chemicals have been "clearly shown through scientifically valid testing according to generally accepted principles" to cause reproductive toxicity. 22 Cal. Code of Regs. §§ 12306(j), 12305(a)(1).

Of course, if OEHHA does not interpret the "mercury and mercury compounds" listing to encompass thimerosal or PMA, full reconsideration is not necessary. Under these circumstances, a scope clarification akin to that which OEHHA issued on June 6, 2003 for the "nickel and certain nickel compounds listing" will suffice.

B. OEHHA Must Reconsider And Clarify The Mercury And Mercury Compounds Listing Because The 1984 EPA Report Did Not Formally Identify Thimerosal Or PMA As A Reproductive Toxin.

Although section 12306(j) speaks of reconsidering authoritative body listings when the chemical is "no longer identified" as causing reproductive toxicity, 22 Cal. Code of Regs. §12306(j)(1), it applies with even greater force where, as here, the chemical was not formally identified as a reproductive toxin in the authoritative body document upon which the listing was originally based. In short, section 12306(j) is intended to facilitate reconsideration "where the Agency has listed a chemical in error." Health & Welfare Agency, Final Statement of Reasons

for 22 California Code of Regulations, Division 2, Section 12306 – Chemicals Formally Identified By Authoritative Bodies [attached hereto as Exhibit E].

1. **A "Formal Identification" Requires An Authoritative Body Statement That Specifically And Accurately Identifies The Chemical And Concludes That (1) Human Studies Indicate That Chemical Causes Reproductive Toxicity, Or (2) That Reliable Experimental Animal Studies Indicate Human Reproductive Toxicity Is Biologically Plausible.**

To determine whether the 1984 EPA Report formally identifies thimerosal or PMA as a reproductive toxin, one must first understand what "formal identification" means within the context of Prop. 65. The starting point for this analysis is the statute, California Health & Safety Code section 25249.8(b), which provides as follows in pertinent part:

> A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter . . . if a body considered to be authoritative by [the Scientific Advisory Panel] has formally identified it as causing cancer or reproductive toxicity . . . .

Cal. Health & Safety Code § 25249.8(b).

In April 1989, the Scientific Advisory Panel ("SAP" or "Panel") met to consider whether the EPA was a "body considered to be authoritative" within the meaning of section 25249.8(b). Panel members agreed that it was, but were preoccupied with "issues of process." Transcript of Scientific and Advisory Panel Meeting of April 14, 1989 ("SAP Transcript") [attached hereto as Exhibit F] at 102. Specifically, Panel members did not want the authoritative body listing process to be "compromise[d] or degrade[d]" by reliance upon unofficial, stray statements by EPA officials or by reliance upon ambiguous references to classes of chemicals. *Id.* Panel Member North was emphatic on this latter point. He pointed out, for example, that the Panel had just been discussing PCBs, "a class of substances in which there is ambiguity, once it is realized that **there are lots of members of that chemical class and the available evidence may apply to some of those members of the class, but not to others**." SAP Transcript (Exhibit F) at 106 (emphasis added). Obviously, the State's panel of experts did not envisage basing formal identifications on vague references to classes of chemicals like "mercury compounds."

Because of members' collective concern that designating the EPA as an authoritative body would induce agency reliance upon any and all statements attributable to the EPA, regardless of whether such statements were final and official and specifically and unambiguously addressed the chemical in question, the Panel declined to designate the EPA as an authoritative body at the April 1989 meeting. Instead, the Panel presented and discussed a motion which was intended to preserve the "integrity of the [listing] process." SAP Transcript (Exhibit F) at 102. The most notable feature of the Panel's motion was that it designated the EPA as an authoritative body only for those chemicals for which the "EPA's designation addresse[d] **specifically and unambiguously the chemical formula**, the valence state, the routes of exposure and **the identity of members within a class of chemical for which designation as a carcinogen or**

reproductive toxicant is warranted by the scientific information available." SAP Transcript (Exhibit F) at 103 (emphasis added).

Ultimately, the Panel decided not to vote on the integrity-preserving motion concerning requisites for formal identification at the April 1989 meeting. Instead, the Panel opted to avail itself of the Health & Welfare Agency's regulatory expertise. SAP Transcript (Exhibit F) at 138. The Agency then took the formal identification criteria which the Panel had drafted specifically to govern formal identifications extracted from EPA documents and devised a "generic" regulation that could be used to govern formal identifications regardless of their authoritative body source. Final Statement of Reasons (Exhibit E) at 12, 13 (noting that section 12306(g)'s "requirements for formality are based on limitations suggested by the Panel at its April 14, 1989 meeting"). The result became section 12306(d) of Title 22 of California Code of Regulations, which provides as follows:

> For the purposes of this section a chemical is "formally identified" by an authoritative body when the lead agency determines that:
>
> (1) the chemical has been included on a list of chemicals causing cancer or reproductive toxicity by the authoritative body; or is the subject of a report which is published by the authoritative body **and which concludes that the chemical causes cancer or reproductive toxicity**; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action; and
>
> (2) the list, report, or document **specifically and accurately identifies the chemical**, and has been:
>
> (A) Reviewed by an advisory committee in a public meeting, if a public meeting is required, or
>
> (B) Made subject to public review and comment prior to its issuance, or
>
> (C) Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or
>
> (D) Signed, where required, by the chief administrative officer of the authoritative body or a designee, or
>
> (E) Adopted as a final rule by the authoritative body, or
>
> (F) Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

22 Cal. Code of Regs. §12306(d) (emphases added).

As the foregoing makes clear, for the purposes of Prop. 65, not every mention of or allusion to a chemical found in an authoritative body document constitutes a "formal identification" sufficient to justify a listing. Here, the listing is explicitly based on an EPA report rather than a list or document indicative of final action. Within this context, OEHHA can satisfy the criteria of a "formal identification" if, and only if:

- **thimerosal and PMA are the subject of a report which is published by the authoritative body**
- **that "specifically and accurately" identifies a chemical and**
- **concludes either (1) that human studies indicate the chemical causes reproductive toxicity or (2) that sufficient data from reliable experimental animal studies indicates that "an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible."**

22 Cal. Code of Regs. § 12306(a), (d) & (g).

As OEHHA's recent past practice makes clear, these statutory and regulatory requirements for formal identification mean that there is much more to making authoritative body listings than simply copying and pasting from authoritative body documents. OEHHA is obliged to "review the bases for these [possible] chemical additions in the context of the regulatory criteria governing Proposition 65 listing via the authoritative bodies mechanism," and to reject any potential listings that fail to satisfy them.[4] In other words, OEHHA must ensure that the cited authoritative document specifically and accurately identifies the chemical and concludes that it causes "reproductive toxicity" within the meaning of section 12306(g).

Applying these two criteria, within the last four years, OEHHA has declined to list at least nine chemicals proposed as reproductive toxins under the authoritative body mechanism, even though each of these chemicals was specifically listed either on the EPA's Toxic Release Inventory or in National Toxicology Program reports.[5] Because the voters, the Panel, and the Agency were just as concerned with the quality of authoritative body listings as with the quantity, not everything passes muster under section 12306(g)'s formal identification requirements.

The "mercury and mercury compounds" listing was among the very first authoritative body listings. To the extent the Agency interprets it to encompass elemental mercury, methyl-mercury and vapor of metallic mercury, it is sound. Beyond that, however, it manifestly is not. As explained below, there can be no doubt that the 1984 EPA Report utterly fails to specifically and accurately identify thimerosal and PMA conclude that these chemicals cause reproductive toxicity.

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4 OEHHA, Candidates for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet The Scientific Criteria (22 CCR 12306(g))(March 19, 1999) [attached hereto at Exhibit G].

5 *See* OEHHA, Candidates for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet The Scientific Criteria (22 CCR 12306(g))(March 19, 1999) (rejecting proposed authoritative body listings for nine chemicals because "the overall amount of evidence on developmental toxicity [was] insufficient relative to the listing criteria specified in 22 CCR 12306(g)) (Exhibit G at 2); *see also* OEHHA Notice of Interested Parties, March 7, 2003, Decision Not To Proceed With Listing of Diethanolamine Via the Authoritative Bodies Listing Mechanism (March 7, 2003) (noticing intent not to list diethanolamine via the authoritative bodies mechanism because "it is not clear that the scientific criteria for listing under the authoritative bodies mechanism have been met") [attached hereto as Exhibit H, pp. 1-2].]

2. The 1984 EPA Report Does Not Specifically And Accurately Identify Thimerosal, Much Less Conclude That It Causes Reproductive Toxicity.

The 1984 EPA Report does not contain even a single mention of thimerosal.[6] That fact alone should put an end to any debate concerning whether the Report "formally identifies" thimerosal as a reproductive toxin, especially in light of section 12306(d)'s specific and accurate identification requirement. It strains credulity (and does violence to the EPA-specific criteria the Panel suggested in 1989) to suggest that an EPA document that never even mentions thimerosal "specifically and accurately" identifies it as a reproductive toxin.

Even if there were a mention of thimerosal in the 1984 EPA Report – which there indisputably is not – such mention would still not suffice to comprise a formal identification sufficient to support a listing. As OEHHA itself has repeatedly recognized, any specific and accurate identification of thimerosal by the EPA must also be accompanied by a **conclusion** that thimerosal causes reproductive toxicity.

The 1984 EPA Report is utterly devoid of any such conclusion. It is important to understand that the 1984 EPA Report was "not intended to be an exhaustive review of all the mercury literature." 1984 EPA Report (Exhibit A) at G-14. Instead, the Report was intended to inform the anticipated revision of the 1973 mercury emission standard. *Id.* It is thus unsurprising that the 1984 EPA Report addressed only four types of mercury (vapor of metallic mercury, inorganic divalent mercury, methylmercury and phenylmercury), and primarily emphasized the delineation of the health effects of airborne mercury. *Id.*

Given the 1984 EPA Report's stated parameters and objectives, it is not surprising that the Attorney General could find but one statement within it that remotely relates to a class of chemicals containing thimerosal. That statement, which appears on page 6-5 of the 1984 EPA Report, is as follows:

> Methyl mercury and other short-chain alkyl mercurials primarily damage the central nervous system.

By no stretch of the imagination can this oblique reference to "other short-chain alkyl mercurials" be construed as an EPA conclusion that **thimerosal** causes **reproductive toxicity**. First of all, **thimerosal is not a short-chain alkyl mercurial.**[7] The only possible relevance is the fact that one of the metabolites of thimerosal is a short-chain alkylmercurial. Second, a statement that short-chain alkyl mercurials damage the **adult central nervous system** simply does not satisfy section 12306(g), which defines chemicals **"causing reproductive toxicity"** as those for which:

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[6] *See* Declaration of F. Jay Murray, Ph.D., In Support of Defendant Bayer Corporation's Motion for Summary Judgment Or, Alternatively, Summary Adjudication [attached hereto as Exhibit I] at ¶ 22; Supplemental Declaration of F. Jay Murray, Ph.D., In Support of the Court's Motion for Stay [attached hereto as Exhibit J] at ¶ 11; Alameda County Summary Judgment Order (Exhibit C) at 1.

[7] The chemical structure of thimerosal is $C_9H_9HgNaO_2S$. The presence of nine carbon atoms in the molecule is inconsistent with the term "short-chain." Although one part of the thimerosal molecule has a short-chain alkyl group, another part of the thimerosal molecule is thiosalicylate, an aryl (not alkyl) group.

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity; or

(2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

22 Cal. Code of Regs. § 12306(g).[8]

The conclusion is inescapable that the 1984 EPA Report does not "formally identify" thimerosal as a reproductive toxin. The Report never mentions thimerosal, and thus plainly did not "specifically and accurately" identify it. Furthermore, the 1984 EPA Report is devoid of any conclusion that thimerosal – or even any class of chemicals that includes a metabolite of thimerosal – causes reproductive toxicity. Thus, to the extent OEHHA interprets the "mercury and mercury compounds" listing to include thimerosal, that interpretation is erroneous.

3. Although The 1984 EPA Report Specifically And Accurately Identifies PMA, It Does Not Conclude That PMA Causes Reproductive Toxicity Within The Meaning Of Section 12306(g).

Although the 1984 EPA Report specifically and accurately identifies PMA, it does not formally identify PMA as a reproductive toxin for a very simple reason: the 1984 EPA Report does not conclude that PMA causes reproductive toxicity. *See* Murray Declaration In Support of Bayer Corporation's Motion for Summary Judgment (Exhibit I) at ¶¶ 20, 21; Supplemental Murray Declaration In Support of the Court's Motion for Stay (Exhibit J) at ¶¶ 7-10.

To reiterate, under Prop. 65, a conclusion that a chemical cause[s] reproductive toxicity" necessitates a conclusion that:

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity; or

(2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route or exposure, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

22 Cal. Code of Regs. § 12306(g).

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[8] As explained below, even if the 1984 EPA Report had rendered a relevant conclusion that short-chain alkyl mercurials cause reproductive harm instead of an irrelevant conclusion that short-chain alkyl mercurials cause harm to the adult central nervous system, OEHHA would still have to ensure that this conclusion was based on relevant, sufficient scientific studies.

In the summary of the 1984 EPA Report section entitled "Toxic Effects of Mercury in Man And Animals," the EPA explicitly concludes:

> It is **not known** whether phenylmercury compounds produce prenatal effects in humans.

The EPA Report (Exhibit A) at 5-20 (lamenting also that "[d]espite widespread use of phenylmercury compounds, little is known about their human toxicology").

This explicit conclusion obviously eliminates the possibility that the 1984 EPA Report formally identified PMA as a reproductive toxin by concluding that "[s]tudies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity." 22 Cal. Code of Regs. § 12306(g). Thus, if the 1984 EPA Report formally identified PMA as a reproductive toxin, it must have done so by satisfying section 12306(g)'s second prong. That is, the 1984 EPA Report must have concluded that, taking into account the adequacy of the experimental design and other parameters, "[s]tudies in experimental animals indicate that there are sufficient data indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." 22 Cal. Code of Regs. § 12306(g).

But the 1984 EPA Report did not "conclude" anything of the sort. The sum total of what the 1984 EPA Report had to say about studies of the impact of phenylmercury compounds on experimental animals was the following:

> The only teratogenic information on phenylmercury compounds was reported by Gale and Ferm (1971), in which Syrian golden hamsters were intravenously dosed with 5, 7.5, 8 and 10 mg/kg phenylmercuric acetate on the eighth day of gestation. With the exception of the lowest dose, all other doses induced increased resorption rates and edema along with a few miscellaneous abnormalities, including exencephaly, cleft lip and palate, and rib fusions.

1984 EPA Report (Exhibit A) at 5-17.

As even a cursory review reveals, the above paragraph is not a **conclusion** of any kind. Distilled to its essence, it is simply a statement that

- there is only one experimental animal study for phenylmercury; and
- that one study found that injecting hamsters with high doses of PMA caused resorption and abnormalities.

Such a passing reference to the fact that there is but one study that even pertains to phenylmercury compounds fails to satisfy section 12306(g)'s second prong. There is no indication whatsoever in the 1984 EPA Report that the EPA believed that, "taking into account the adequacy of the experimental design and other parameters," the Gale and Ferm study yielded "sufficient data" to "indicat[e] that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." 22 Cal. Code of Regs. § 12306(g).

Even if the EPA had not just mentioned the 1971 hamster study as a passing bibliographical reference, but had actually concluded based upon it that PMA causes reproductive harm, that conclusion would not necessarily constitute a formal identification. Rather, it would still be incumbent upon OEHHA to ascertain whether, in forming its conclusion, the EPA "relied upon scientific data in an amount sufficient to conclude that the chemical causes reproductive toxicity." Final Statement of Reasons (Exhibit E) at 22. As noted above, within just the past four years, OEHHA inquiries into the amount of data upon which putative listings are based have resulted in the rejection of at least nine chemicals proposed for listing as reproductive toxins pursuant to the authoritative body mechanism. *See* Exhibit G. Because the 1984 EPA Report cites just one phenylmercury study, the requirement that a formal identification be based upon a sufficient amount of scientific data would not be fulfilled in this case either.

In summary, the 1984 EPA Report cannot possibly support an authoritative body listing of "mercury and mercury compounds" that encompasses PMA, because the Report does not conclude that PMA causes reproductive harm. On the contrary, the only Report conclusion pertinent to PMA is that "[i]t is not known whether phenylmercury compounds causes prenatal effects in humans." 1984 EPA Report (Exhibit A) at 5-20. This statement could not be further from the "formal identification" contemplated and defined by 22 Cal. Code of Regs. § 12306(d) and (g).

C. If OEHHA Believes Other Authoritative Body Documents Formally Identify Thimerosal And PMA As Reproductive Toxins And Wishes To Expand The "Mercury And Mercury Compounds" Listing To Encompass Them, OEHHA Must Formally Propose Expansion Of The Listing.

Bayer's review of the existing scientific literature on thimerosal and PMA has not uncovered any authoritative body document that formally identifies either thimerosal or PMA as a reproductive toxin within the meaning of section 12306(g). If, however, OEHHA is of the opinion that authoritative body documents exist which (1) "specifically and accurately" identify these chemicals and (2) conclude that human or experimental animal studies indicate they cause reproductive harm, OEHHA must initiate the proper administrative process to revise the authoritative basis and amend the listing accordingly.

OEHHA's analogous effort to expand the "nickel and certain nickel compounds" listing demonstrates exactly how this is done. Like "mercury and mercury compounds," "nickel and certain nickel compounds" was a borrowed listing.[9] Specifically, the nickel listing was based on the National Toxicology Program's *First Annual Report on Carcinogens*, which explicitly concluded that "nickel and certain nickel compounds" were reasonably anticipated to cause

[9] Notice of Interested Parties re: 1) Clarification of Chemical Listing of Nickel and Certain Nickel Compounds and 2) Report For Consent On Proposed Listing of Nickel Compounds As Known To Cause Cancer, June 6, 2003 (hereinafter "Notice to Interested Parties re Nickel") [attached hereto as Exhibit M].

cancer.[10] *Id.*; *see also* National Toxicology Program, U.S. Public Health Service, *First Annual Report on Carcinogens*, Vol. 1 (July 1980) [relevant pages attached hereto as Exhibit K].

In 2002, the National Toxicology Program ("NTP") published its *Tenth Annual Report on Carcinogens*. In that *Tenth Report*, the NTP explained that only eight specific compounds were encompassed by the reference to "nickel and certain nickel compounds" in the *First Annual Report* upon which the Health and Welfare Agency had relied. National Toxicology Program, U.S. Public Health Service, *Report on Carcinogens, Tenth Edition* (2002) [relevant pages attached as Exhibit L]. In light of this information, in June 2003, OEHHA clarified the scope of the "nickel and certain nickel compounds" listing to reflect the exactitude of the listing's underlying source. *See* Exhibit M. Now it is clear that the "nickel and certain nickel compounds" listing includes eight chemicals formally identified by the foundational NTP report plus one chemical the Scientific Advisory Panel independently identified as a carcinogen. *Id.*

In this respect, the "nickel and certain nickel compounds" listing differs radically from the "mercury and mercury compounds" listing. OEHHA's assertion concerning the scope of the former is rational and supported by the underlying document, while that remains to be seen for the latter. In another respect, however, the evolution of the two listings may have much in common.

The same day that OEHHA announced it was clarifying the existing "nickel and certain nickel compounds" listing to encompass only those compounds contemplated by the 1980 NTP report upon which the listing was originally based, OEHHA also announced that it was proposing a new, broader listing that would supplant the old. *See* Exhibit M. Specifically, OEHHA noted that because, subsequent to the initial listing, NTP had identified *all* nickel compounds as human carcinogens, it was soliciting comment on a proposal to add all nickel compounds to the Prop. 65 list. *Id.* As OEHHA correctly recognized, to expand the nickel listing to include nickel compounds that were not formally identified in the original source, it had to propose a brand new listing. *Id.*

If, through the process of reconsideration, OEHHA were to become convinced that authoritative body documents other than the 1984 EPA Report formally identify thimerosal and PMA as reproductive toxins within the meaning of section 12306(g), OEHHA would have to follow this same process and propose a new, expanded listing. As the law and the nickel example makes clear, if OEHHA ever wants to interpret the "mercury and mercury compounds" listing to include thimerosal and PMA, it must first identify an authoritative body document that it believes specifically and accurately identifies them and concludes that they cause reproductive harm, and then subject that proposed amended listing to public scrutiny. 22 Cal. Code of Regs. § 12306(i).

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[10] Given section 12306(g)'s requirement of a specific and accurate identification, the propriety of the Health & Welfare Agency's original "nickel and certain nickel compounds listing" (and all other vague "and compounds" listings not accompanied by specific CAS numbers) is in serious doubt.

In 1996, Kerr Industries ("Kerr") argued in its own delisting petition that because the 1984 EPA Report only formally identified methylmercury as a reproductive toxin, to the extent OEHHA interpreted the "mercury and mercury compounds" listing to encompass the metallic mercury in dental amalgam, the listing was infirm. In response to Kerr's petition, OEHHA argued that the 1984 EPA Report contains some statements which could conceivably satisfy section 12306's requirements for formal identification. To that point, OEHHA's reconsideration methodology was sound. Thereafter, however, OEHHA opined that reconsideration of the listing was not warranted because authoritative body documents post-dating the listing provided the requisite formal identification. This argument was in error.

Examining post-listing documents is necessary and appropriate to ascertain whether an authoritative body **continues** to identify a chemical as a carcinogen or reproductive toxin that was indisputably formally identified the first time around. But as the California Court of Appeal's decision in *Western Corp. Protection Assn. v. Davis*, 80 Cal. App. 4th 741 (2000), makes clear, where the issue is not whether a chemical continues to be formally identified – but rather whether it was *ever* formally identified – the relevant universe of documents is only those documents upon which the authoritative body relied. *Id.* at 756. OEHHA cannot rely on documents referenced (but not discussed) in the authoritative body document, much less upon documents published years after the fact. *See id.*

As OEHHA's recent formal proposal to expand the "nickel and certain nickel compounds" listing makes clear, neither law nor logic tolerates post-hoc justifications for authoritative body listings. Thus, for the present "mercury and mercury compounds" listing to encompass PMA and thimerosal, OEHHA must do the impossible and locate a formal identification of these chemicals within the confines of the 1984 EPA Report.

III.

CONCLUSION

Concerned with the integrity of the authoritative body listing process, the State's panel of experts advised that authoritative body listings extracted from EPA documents should be final and official and should "specifically and unambiguously [address] the chemical formula, the valence state, the routes of exposure and the identity of members within a class of chemical for which designation as a carcinogen or reproductive toxicant is warranted by the scientific information available." Final Statement of Reasons (Exhibit E) at 13; SAP Transcript (Exhibit F) at 103, 106. Ultimately, this formality requirement was generalized. Final Statement of Reasons (Exhibit E) at 12-13. Now, for an EPA document to formally identify a chemical as a reproductive toxin, it must "specifically and accurately" identify the chemical and conclude either (1) that human studies indicate the chemical causes reproductive toxicity or (2) that sufficient data from reliable experimental animal studies indicates that "an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." 22 Cal. Code of Regs. § 12306(g).

With regard to thimerosal and PMA, the 1984 EPA Report does not satisfy these criteria. For this reason, OEHHA must clarify that the "mercury and mercury compounds" listing does not include thimerosal and PMA. If OEHHA believes that subsequent authoritative body documents do formally identify these chemicals as reproductive toxins, it is free to initiate a new listing proposal for prospective application.

Because the Attorney General's enforcement action against Bayer remains pending, Bayer respectfully requests that the reconsideration and clarification of the "mercury and mercury compounds" listing proceed as expeditiously as possible.

INDEX OF EXHIBITS

PETITION FOR RECONSIDERATION OF DETERMINATION THAT 1984 EPA REPORT FORMALLY IDENTIFIED ALL "MERCURY AND MERCURY COMPOUNDS" AS REPRODUCTIVE TOXINS AND FOR CLARIFICATION OF LISTING

Exhibit A: *Mercury Health Effects Update, Health Issue Assessment*; EPA-600/8 – 84-019F ("1984 EPA Report")

Exhibit B: Notice of Intent to List Chemicals, 90 Cal. Reg. Notice Reg. No. 17-2 (April 27, 1990)

Exhibit C: *People of the State of California ex rel. Bill Lockyer v. Altaire Pharmaceuticals, et al.*, No. 2001-016727 (September 8th order re motion for summary judgment)

Exhibit D: *People of the State of California ex rel. Bill Lockyer vs. Altaire Pharmaceuticals, et al.*, No. 2001-016727 (September 25th order granting stay in part)

Exhibit E: Health & Welfare Agency, Final Statement of Reasons for 22 California Code of Regulations, Division 2, Section 12306 – Chemicals Formally Identified By Authoritative Bodies ("Final Statement of Reasons")

Exhibit F: Transcript of Scientific and Advisory Panel Meeting of April 14, 1989 ("SAP Transcript")

Exhibit G: OEHHA, Candidates for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet The Scientific Criteria (22 CCR 12306(g))(March 19, 1999)

Exhibit H: OEHHA Notice of Interested Parties, March 7, 2003, Decision Not To Proceed With Listing of Diethanolamine Via the Authoritative Bodies Listing Mechanism (March 7, 2003)

Exhibit I: Declaration of F. Jay Murray, Ph.D., In Support of Defendant Bayer Corporation's Motion for Summary Judgment or, Alternatively, Summary Adjudication

Exhibit J: Supplemental Declaration of F. Jay Murray, Ph.D., In Support of the Court's Motion for Stay

Exhibit K: National Toxicology Program, U.S. Public Health Service, *First Annual Report on Carcinogens*, Vol. 1 (July 1980) (Relevant Excerpts Only)

Exhibit L: National Toxicology Program, U.S. Public Health Service, *Report on Carcinogens, Tenth Edition* (2002) (Relevant Excerpts Only)

Exhibit M: OEHHA Notice of Interested Parties re: 1) Clarification of Chemical Listing of Nickel and Certain Nickel Compounds and 2) Report For Consent On Proposed Listing of Nickel Compounds As Known To Cause Cancer (hereinafter "Notice to Interested Parties re Nickel"), 23 California Regs. Law Bulletin 298 (June 6, 2003)