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LATHAM & WATKINS LLP

July 22, 2011

Cheryl A. Falvey, General Counsel
Michael Babich, CHAP Project Manager
US Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

RE: Chronic Hazard Advisory Panel (CHAP) for Phthalates

Dear Ms. Falvey and Dr. Babich:

This letter is submitted on behalf of ExxonMobil Chemical Company (ExxonMobil) to express concerns and offer comments concerning the deliberative process of the Chronic Hazard Advisory Panel (CHAP) on Phthalates and Phthalate Substitutes. These comments are based on our observations of the first four CHAP meetings and our review of Section 108 of the Consumer Product Safety Improvement Act (CPSIA). This letter amplifies and supports several points made in a letter submitted by the Phthalate Esters Panel of the American Chemistry Council (ACC) on June 9, 2011, and provides additional perspective on several issues of particular relevance to the two high molecular weight phthalates that ExxonMobil produces.

The purpose of the CHAP is to provide scientific advice and recommendations to the Consumer Product Safety Commission (Commission), as it determines what actions, if any, should be taken with respect to use of phthalates and phthalate alternatives in consumer products intended for children. The process employed by the CHAP will determine to a large degree the utility of the final report to the Commission. We appreciate the significant efforts already expended by the CHAP members to meet their charge and recognize that considerable work remains to be done. The comments in this letter on the CHAP deliberative process are intended to help CPSC and the CHAP to achieve the objectives set forth in the CPSIA.

ExxonMobil is committed to conducting business in a manner that protects human health and the environment and is an active supporter and participant in numerous initiatives to ensure responsible product stewardship. ExxonMobil supports agency evaluations of the safety of its products that are based on a careful and objective evaluation of all relevant data, employing sound principles of hazard, exposure and risk assessment. ExxonMobil has participated in all meetings of the CHAP on Phthalates and Phthalate Substitutes, and will continue to do so with the goal of supporting a rigorous and objective scientific assessment of phthalates and phthalate substitutes.

Preliminary Comment about DINP and DIDP

ExxonMobil has a particular interest in two high molecular weight (HMW) phthalates – diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP).[1] The circumstances pertaining to these two compounds underscore the importance of the concerns raised in this letter. Each has been extensively tested, and neither has been classified as a carcinogen, mutagen or reproductive toxin (CMR). Neither is listed as a "substance of very high concern" (SVHC) under REACH, and neither historically has been individually regulated as a hazardous or toxic chemical. This is in contrast to low molecular weight (LMW) phthalates, several of which are classified as CMRs, are listed under REACH as SVHCs, and appear on various regulatory lists.[2]

Human biomonitoring data gathered by the Centers for Disease Control and Prevention (CDC) show that exposures to DINP and DIDP from *all sources* are well below relevant health benchmarks derived from animal studies. Exposures from use of either phthalate in any consumer products, including children's products, similarly would be expected to be far below relevant health benchmarks, and the prior assessments of DINP in toys by the Commission and a prior CHAP support that conclusion.

Moreover, Danish EPA official Frank Jensen recently identified DINP as a high quality and cost effective *substitute* for low molecular weight phthalates, thus recognizing that a high molecular weight phthalate can be both a phthalate *and* a phthalate substitute.[3]

ExxonMobil believes each phthalate must be evaluated separately and judged on its individual merit, and that the assessments by the CHAP should address not only hazard but also *exposure and risk.* Only by considering all available hazard, exposure and risk information for each phthalate and each phthalate substitute can the CHAP and the Commission meet their statutory obligations set forth in the CPSIA.

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1 HMW phthalates are those with alkyl side chains whose alcohol carbon backbones are C7 or greater. Members of this group include DINP, DIDP and di-(2-propylheptyl) phthalate (DPHP).

2 LMW phthalates are those with alkyl side chains whose alcohol carbon backbones range from C3 to C6. Members of this group include di(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), di-isobutyl phthalate (DIBP), dipentyl phthalate (DPP) and diisoheptyl phthalate (DIHP). These LMW phthalates are classified as reproductive and developmental toxins (Category 1B under the UN Globally Harmonized System and the European Union (EU) Classification, Labeling and Packaging Regulation) due to effects observed in rodent studies.

The very low molecular weight (VLMW) phthalates dimethyl phthalate (DMP) and diethyl phthalate (DEP) are used in cosmetics and toiletries and are not classified for reproductive effects.

3 Danes cite combined exposure in REACH phthalates proposals, ChemicalWatch (Apr. 21, 2011). *See also* L Høibye, J Maag, E Hansen (2011). Background data for Annex XV dossier - DEHP, BBP, DBP and DIBP. Miljøprojekt Nr. 1362 2011, Danish Environmental Protection Agency, http://www2.mst.dk/udgiv/publications/2011/04/978-87-92708-97-7.pdf ("Costs of substitution differ depending on product group and vary from marginal price increases to significant increases. The least expensive option appears to be substitution to non-classified phthalates as DINP and DIDP.").

These and additional comments on the CHAP deliberative process are set forth in greater detail below. We thank you for considering these comments.

Comments on Process for CHAP Deliberations

I. The CPSIA Requires that the CHAP Deliberations be Based on Reasonable Estimates of Risk, not on Hazard Alone.

At the March 2011 CHAP meeting, there was some suggestion that the CHAP determinations could be based purely on hazard, without regard to whether reasonably anticipated exposures to a given phthalate or phthalate substitute might pose a risk. Reference was made to classification and labeling in Europe, which is hazard-based, but chemical regulation in Europe remains risk-based.[4] Regardless, the CPSIA requires that assessments and recommendations by the CHAP be based on risk, and that any subsequent actions by the Commission also be based on risk, not hazard alone.

Indeed, risk principles permeate Section 108(b)(2).[5] Every reference to "exposure" incorporates the concept of risk. The reference to a "level at which there is a reasonable certainty of no harm" is clearly risk-based.[6] Further, the CHAP is required to make recommendations concerning substances it believes should be declared "banned hazardous substances," which is defined in the Federal Hazardous Substances Act (FHSA) in terms of *risk*. Under the FHSA, a substance may be declared "toxic" based on hazard alone, but to be a "hazardous substance" it must be capable of causing injury or illness "during or as a proximate result of any customary or reasonably foreseeable handling or use."[7] The criteria for declaring a substance a "banned hazardous substance" are described further below, but the term unquestionably calls for a determination of potential risk. Accordingly, the CHAP deliberations and recommendations must consider not only the health effects produced by phthalates and phthalate alternatives, but also potential children's exposure to such substances from use of toys and child care articles.

The CHAP should not base its risk determinations on unrealistic estimates of exposure, but rather those from foreseeable and normal use. The CPSIA charges the CHAP to "examine

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4 While the European Union (EU) considers only hazard with respect to classification and labeling of chemical substances, EU regulatory assessments clearly are risk-based. Under Regulation (EC) No. 1907/2006 (REACH), recommendations for chemical management given in the extended safety data sheet (SDS) are to be risk based. REACH Articles 14(4) & 31(7) and Annex I. Even for chemicals subject to the new authorization procedures, the determination of whether a use will be authorized is to be risk-based. REACH Articles 62 & 63.

5 *See especially* CPSIA § 108(b)(2)(B)(iii), (iv), (v) & (vii), 15 U.S.C. § 2057c(b)(2)(B)((iii), (iv), (v) & (vii).

6 CPSIA § 102(b)(2)(B)(vii), 15 U.S.C. § 2057c(b)(2)(B)(vii). For comparison, see FDA's regulation applying a "reasonable certainty of no harm" standard to food contact materials, found at 21 C.F.R. § 170(3)(i), which clearly contemplates assessments of hazard, exposure and risk.

7 15 U.S.C. § 1261(f)(1)(A).

the likely levels of children's, pregnant women's, and others' exposure to phthalates, *based on a reasonable estimation of normal and foreseeable use and abuse of such products."*[8] While exposure from abuse is to be considered, that abuse also must be foreseeable and normal – not a purely speculative or unrealistic scenario. The CPSIA clearly was following the approach set forth in the FHSA, which also requires consideration of "customary or reasonably foreseeable handling or use,"[9] and thus the clear intent is that phthalates and phthalate substitutes be judged by the same standards being used to judge other materials. If the CHAP were to employ excessively conservative assumptions, it would produce exposure estimates that are not realistic, and not "reasonably foreseeable." To avoid that result, assumptions employed in any exposure estimates must be reasonable individually *and in the aggregate.*

For phthalates, the CHAP has the advantage of biomonitoring data, and the very comprehensive review of published monitoring data by Dr. Kathleen Clark,[10] which can provide a reality check of any exposure estimates produced by the CHAP. The CHAP also can take advantage of prior exposure assessment work conducted by the Commission[11] and the prior phthalate CHAP,[12] which focused on exposure to DINP from children's products, and included migration and child observation studies.

II. The CHAP Deliberations Should Be Based on the Legal Criteria for Declaring a Substance to be a Banned Hazardous Substance.

Given that the charge to the CHAP is to make recommendations for "banned hazardous substances," it is important that the CHAP understand and follow the statutory definition of "banned hazardous substance." The FHSA provides that a substance may be declared a "banned hazardous substance" only if the following criteria are met:

1) it has the capacity to produce personal injury or illness to humans through ingestion, inhalation, or dermal absorption; and

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8 CPSIA 108(b)(2)(B)(iii), 15 U.S.C. § 2057c(b)(2)(B)(iii) (emphasis added).

9 15 U.S.C. § 1261(f)(1)(A).

10 Dr. Clark's report, "Human Exposure to Phthalates Esters," is available on the Commission's website at http://www.cpsc.gov/about/cpsia/chap0710.html. The analysis will be published in an upcoming issue of the peer reviewed journal *Human and Ecological Risk Assessment*. Dr. Clark's Database for DINP and DIDP was submitted in July 2010 with comments from ExxonMobil Chemical Company and is available on the Commission's website at http://www.cpsc.gov/about/cpsia/chap/exxonDINPDIDPdb.pdf. Dr. Clark's Concentration Databases for DEHP and other PEs are available on the Commission's website at http://www.cpsc.gov/about/cpsia/chapmain.html.

11 CPSC (2002). Response to Petition Requesting Ban of Use of PVC in Products (HP 99-1). US Consumer Products Safety Commission, Bethesda, MD, available at http://www.cpsc.gov/library/foia/foia02/brief/briefing.html (first seven links).

12 CHAP (2001). Report to the US Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP), June 2001, available at http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf .

2) it may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children; and
3) it is contained in a toy or other article intended for use by children "in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted," or it is intended or packaged for household use and "the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce."[13]

Any recommendation by the CHAP that is not based on these criteria would be inherently flawed, and of no utility to the Commission. However, it is not apparent from the CHAP deliberations that the CHAP members are familiar with these criteria.

III. The CPSIA Directs the CHAP to Focus on Potential Risks from Children's Toys and Child Care Articles.

As discussed in the ACC letter, the CPSIA directed the Commission to appoint a CHAP "to study the effects on children's health of all phthalates and phthalate alternatives *as used in children's toys and child care articles.*"[14] The ultimate use of the CHAP report is by the Commission in determining whether to "declare any children's product" containing any phthalates to be a banned hazardous product.[15]

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[13] The term "banned hazardous substance" is defined under the FHSA to mean, in relevant part, "(A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as a 'banned hazardous substance' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this chapter for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce." 15 U.S.C. § 1261(q)(1).

In turn, in pertinent part, a "hazardous substance" is "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substances or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. § 1261(f)(1)(A).

"The term 'toxic' shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. § 1261(g).

[14] CPSIA § 108(b)(2)(A), 15 U.S.C. § 2057c(b)(2)(A) (emphasis added).

[15] CPSIA § 108(b)(3), 15 U.S.C. § 2057c(b)(3).

Thus, the overriding focus of the CHAP's deliberations and report should be on the potential health consequences for children from phthalates and phthalate substitutes as those plasticizers are used in toys and child care articles. The CHAP deliberations, however, have not always had such a focus. For example, CHAP members have several times referred to potential effects of diethyl phthalate (DEP), which is not used to plasticize vinyl and for which production volume is far less than that of phthalates that are used as vinyl plasticizers. Further, the results of animals testing, discussed further in the ACC letter, show the toxicity of DEP to be very low. Thus, while the CPSIA includes reference to consideration of exposures to phthalates from other sources, expenditure of CHAP or Commission staff resources on DEP, which has low toxicity and is not used in products that the CPSC regulates, would seem to be of little benefit for the purposes of the CHAP.[16]

Given the purpose for convening the CHAP set forth in the statute, the complexity of the task before the CHAP, and the practical reality that the Commission has authority to regulate only those consumer products that are within its jurisdiction, we urge that you emphasize to the CHAP that it should give its primary attention to the study of the health effects of phthalates and phthalate plasticizers as used in children's toys and child care articles.

IV. The CPSIA does not Require the CHAP to Determine Whether the Interim Ban of DnOP, DINP and DIDP Should be Made Permanent.

CHAP members have several times spoken of the CHAP making a recommendation whether the Section 108(b)(1) interim prohibition on use of DNOP, DINP or DIDP in children's toys or child care articles should be extended. While the CHAP is charged with making certain recommendations, the CHAP is not charged specifically with determining whether to continue the prohibition on DINP, DIDP and DnOP. Rather, the CPSIA expressly directs the Commission to make that determination.[17]

The charge given to the CHAP is to "make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in subsection (a) [DEHP, DBP and BBP] or phthalate alternatives that the panel determines should be declared banned hazardous substances."[18] This is separate and apart from the determination

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16 As discussed above, the focus of the CPSIA phthalates provisions is on children's toys and child care articles. A "child care article" is "a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." CPSIA § 108(e)(1)(C), 15 U.S.C. § 2057c(e)(1)(C). The definition of "consumer product" excludes cosmetics as defined by Federal Food, Drug and Cosmetics Act 201(i), 21 U.S.C. § 321(i) ("(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap").

17 CPSIA § 108(b)(3), 15 U.S.C. § 2057c(b)(3) ("Not later than 180 days after receiving the report of the [CHAP] ..., the Commission shall ... promulgate a final rule to—(A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1) ....").

18 CPSIA § 108(b)(2)(C), 15 U.S.C. § 2057c(b)(2)(C).

the Commission must make concerning whether to declare "any children's product containing any phthalates to be a banned hazardous product."[19]

Section 108(d) of the CPSIA provides that that any ban promulgated by the Commission pursuant to 108(b)(3) would be a product safety standard under the Consumer Product Safety Act (CPSA), which provides for "banned hazardous products." A "banned hazardous substance" – the focus of the CHAP recommendations – is defined by the FHSA, whereas "banned hazardous product" is an element of the CPSA.

This distinction reflects a proper understanding of the CHAP's role as a deliberative scientific body and the Commission's role as a regulatory body.[20] Despite the name, a declaration that a substance is a "banned hazardous substance" does not mean that the substance necessarily must be prohibited from use in all consumer or children's products. The Commission might approve a voluntary standard or promulgate regulations that require specific labeling or limit some uses but not others, or set concentration limits for certain uses.[21] Thus, by staying within its charge, the CHAP would not encroach on the Commission's role, which is to determine the extent to which any products covered by the interim ban should be banned permanently. The CHAP is not charged with that determination, nor with any other *risk management* function, but rather is charged with considering hazard and exposure information, and reaching science-based determinations about potential risks, that might then inform the *Commission's* risk management decisions.[22]

V. The CHAP is not Required to Undertake a *Quantitative* Cumulative Risk Assessment.

The charge to the CHAP is to "complete an examination of the full range of phthalates that are used in products for children."[23] As one element of that examination, the CHAP is to "consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products."[24] The CHAP should understand that the terms "examine" and "consider" do not require undertaking a *quantitative* cumulative risk

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[19] CPSIA § 108(b)(3)(B), 15 U.S.C. § 2057c(b)(3)(B).

[20] That the distinction was intentional on the part of Congress is shown by reference elsewhere in the CPSIA to "a banned hazardous product or substance" and other references to "banned hazardous substance" under the FHSA. *E.g.*, CPSIA §§ 101(a)(1) & 102(b)"(f)(1)", 15 U.S.C. § 1278a(a)(1) & 15 U.S.C. § 2063(f)(1).

[21] *See* 16 C.F.R. § 1500.17.

[22] The CHAP also need not concern itself with whether the ban on DEHP, DBP and BBP should be retained. That risk management decision has been made by Congress and can be changed only by Congress. Thus, to the extent the CHAP attempts to consider cumulative exposures, discussed later in this letter, it need not consider potential exposures to these phthalates from children's products, as there will be no such exposures unless the statutory ban is removed.

[23] CPSIA 102(b)(2), 15 U.S.C. § 2057c(b)(2).

[24] CPSIA 102(b)(2)(iv), 15 U.S.C. § 2057c(b)(2)(iv).

assessment. In fact, the CPSIA does not mandate a cumulative risk assessment at all; it requires only that the CHAP "consider the cumulative effect of total exposure to phthalates." The statutory language allows for a qualitative approach to the issue of cumulative effects.

This distinction is important, because science pertaining to cumulative risk assessment is still evolving, with many questioning the ability to produce a meaningful quantitative cumulative risk assessment at this time.[25] However, one can use the existing data to make qualitative judgments. The CHAP's charge to "consider" cumulative effects could encompass such outcomes as a qualitative judgment that cumulative effects are not likely to occur due to differences in toxicological outcomes, that exposures are so low that cumulative effects are not a concern, that science is not at a point to allow for a cumulative risk assessment, and/or that cumulative effects are accounted for by use of uncertainty factors.

Quantitative calculations conducted as an initial screening exercise, such as those already published, can help to inform a qualitative judgment, but the CHAP should not take such calculations beyond the limits of the current science. Further, the CHAP should verify that each phthalate included in any qualitative or screening-level quantitative cumulative assessment in fact shares the toxicological outcome that is the basis for the cumulative assessment. As discussed in the ACC letter, a given phthalate should not be included simply because exposure data are available or because it is a phthalate. And of course the selected endpoint must be relevant to humans.[26]

We further note that the cumulative exposure to which the CPSIA refers encompasses only phthalates.[27] The CHAP should not include other substances in any cumulative assessment it undertakes.

VI. The CHAP is not Bound by but is Directed to Consider the Prior CHAP and Commission Studies.

Commission staff have provided the CHAP members with the report of the prior DINP CHAP, the Commission's exposure-related studies (including studies of the migration of DINP from vinyl toys when mouthed, and time spent mouthing by children) and the Commission's conclusions concerning potential risks posed by DINP in children's toys. As discussed in the ACC letter, the CPSIA directs the current CHAP to conduct a *de novo* review, but also directs that "[the findings and conclusions of any previous Chronic Hazard Advisory Panel on this issue

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[25] *E.g.*, Testimony given to US Senate Committee on Environment and Public Works Subcommittee on Superfund, Toxics and Environmental Health hearing on Current Science on Public Exposures to Toxic Chemicals,. February 4th, 2010 (minute 56.10 of archived flash video at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Choose&Hearing_id=8a722315-802a-23ad-4e9a-b8477139e63f).

[26] ExxonMobil believes that there is no toxicological endpoint shared by all phthalates that is relevant to humans. Most phthalates induce some degree of peroxisome proliferation in rodents, but numerous studies demonstrate that that effect is not relevant to human risk assessment. Male reproductive toxicity is seen in several LMW phthalates, not in DINP and DIDP.

[27] CPSIA 108(b)(2)(B)(iii), 15 U.S.C. § 2057c(b)(2)(B)(iii).

and other studies conducted by the Commission shall be reviewed by the panel."[28] Those previous findings and conclusions are not determinative, but they represent extensive work by a prior panel of independent experts as well as substantial work by the Commission staff. It is important, therefore, that the CHAP members have sufficient time to review and consider that material. We urge that a systematic effort be made to take advantage of relevant prior work product including the prior migration and exposure studies.

VII. Use of Best Available Science and Importance of Transparency of Data and Deliberations.

The CHAP Report will be an important document. To be of maximum benefit to the Commission, it is important that the report reflect the latest and most relevant science. This poses a challenge, as research pertaining to phthalates is always ongoing. In this case, two robust reproduction studies of DINP conducted in rodents by the Hamner Institute and designed specifically to address many of the male reproductive tract endpoints of interest to the CHAP are soon to be released. It is very important that these studies be included in the CHAP deliberations. Toward that end, we have previously requested that an opportunity be provided to present the results of those studies at the July 25 CHAP meeting.[29]

We understand the Commission does not intend to provide a general opportunity for public comment at the July 25 CHAP meeting.[30] However, we believe the CHAP should invite *scientific* presentations by researchers or other parties that have significant new data to present. A presentation affords the CHAP members an opportunity to understand and appreciate the data, and, importantly, an opportunity to ask questions and clarify points, as necessary. The Hamner Institute has worked hard to be in a position to present their research results on July 25. Any information they present could be placed immediately in the public docket. These studies' manuscripts will be provided to the CHAP as soon as they have been accepted for publication, which is anticipated to be late September. Given the importance of this information and its imminent public release, we believe the CHAP members should be able to take this scientific information into account during its deliberations at the July meeting.

It is equally important that the CHAP deliberations be conducted in a transparent manner, and that all information used by the CHAP in its deliberations, including raw data, be made available to stakeholders for review and comment. In this regard, it is not sufficient if a *summary* of information considered by the CHAP is available in the docket or the published literature – any raw data provided to the CHAP must be made available in the public docket. Nor, in our judgment, is it sufficient if the data is made publicly available at the time the CHAP's final report is released, as that approach does not give stakeholders an opportunity to review the data and provide comment to the CHAP during the period critical to its evaluations. We applaud the CHAP for requesting raw data from investigators where access to raw data would better

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[28] CPSIA 108(b)(2)(B), 15 U.S.C. § 2057c(b)(2)(B).

[29] The ACC also has previously requested that an opportunity be provided to present new data, and first made this request by telephone call on May 9, 2011.

[30] *See* Notice of Meeting, 76 Fed. Reg. 38116 (June 29, 2011).

inform the CHAP's deliberations. However, it is not appropriate for the CHAP to consider and rely on information that is not made public. If raw data are important enough to be requested and considered by the CHAP, then the data should be made publicly available at the same time it is being considered.

If access to raw data is deemed necessary by the CHAP for its deliberations, but the raw data are not made available by the investigators, we believe the CHAP should disregard the study or studies for which the raw data is withheld. The same approach should be taken if raw data is provided on terms that do not allow it to be shared with the public -- the CHAP should not use or rely on that raw data or the study itself in its deliberations. The same approach should be taken with all studies, without regard to where a study is conducted or the source of funding.

Transparency is an essential element in sound scientific evaluations, and this Administration has issued several pronouncements to highlight the importance of transparency and require it in agency assessments and deliberations. These include Executive Order 13563,[31] the Presidential Memorandum on Transparency and Open Government issued at the beginning of President Obama's administration,[32] and memoranda issued by OMB Director Cass Sunstein.[33]

We urge the Commission to require the greatest degree of transparency possible in the CHAP deliberations, including access to all studies, reports, raw data and other information considered by the CHAP.

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[31] 76 Fed. Reg. at 3822.

[32] B. Obama, Memorandum of January 21, 2009 re: Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 26, 2009) ("My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.").

[33] *See, e.g.*, C. Sunstein, Open Government is Analytic Government (and Vice-Versa), Remarks on the Occasion of the 30th Anniversary of the Regulatory Flexibility Act (Sept. 21, 2010). ("There is a close connection, even an inextricable relationship, between analytic government and open government.").

Conclusion

We appreciate your consideration of this letter. We respectfully ask that you share this letter with the CHAP members, and urge that the Commission work with the CHAP to address these points.

Sincerely yours,

William K. Rawson
Ann Claassen
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