XC: Board Members 06-1-4
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AIR RESOURCES BOARD
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VIA DHL

January 23, 2006

Clerk of the Board
Air Resources Board
1001 I street, 23rd Floor
Sacramento, CA 95814

Re: Comments to be considered by the Air Resources Board (ARB) during its January 26, 2006 "Hearing To Identify Environmental Tobacco Smoke As A Toxic Air Contaminant"

To the Clerk of the Air Resources Board:

On January 26, 2006, the ARB will be tasked with evaluating an ARB Staff Report ("Report") on Environmental Tobacco Smoke ("ETS") and determining whether that Report justifies designating ETS as a Toxic Air Contaminant ("TAC") pursuant to Sections 39650-39674 of the California Health & Safety Code. In addition to evaluating the body of this Report, the ARB must, as a matter of law, also take a close look at the procedures under which this Report has been developed.

Over the course of the ARB's consideration of this issue, the R. J. Reynolds Tobacco Company ("RJRT") and others have provided comments to the ARB and its Scientific Review Panel ("SRP") regarding scientific and legal/procedural deficiencies in the ARB's analysis of this issue. Many of the deficiencies identified by RJRT and others have been either inadequately addressed or outright ignored by the SRP or the ARB.

Rather than simply re-iterating RJRT's prior comments in this letter, I would like to highlight some of the key points previously raised by RJRT and address, where appropriate, the inadequate responses to these comments previously provided by the ARB staff and/or the SRP.[1]

[1] In order to make a complete record before the ARB, I also am attaching RJRT's previously submitted comments along with this letter. The 2003 comments are attached as "Attachment 1" and the 2004 comments are attached as "Attachment 2."

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I also will set forth some additional evidence in support of RJRT's comments not addressed in previous submissions.

RJRT's 2003 Comments to the ARB

In 2003, RJRT's comments to the ARB focused on two fundamental deficiencies with the ARB's analysis of ETS. First, RJRT explained the failure of the ARB Report to appropriately conduct a California-specific risk assessment as required by Section 39660 of the California Health & Safety Code. In this discussion, the comments focused on the Report's flawed use of attributable risk calculations.[2] Second, RJRT's 2003 comments to the ARB focused on the Report's conclusions regarding ETS and breast cancer.[3]

With respect to the ARB's failure to conduct a California-specific risk assessment, the ARB/OEHHA Staff responded to RJRT's comments as follows:

> *OEHHA and ARB are advised by their respective legal counsels that the actions taken and proposed are appropriate. The intended purpose of the public comment period for the public health effects document is to identify scientific issues in the report that may need further attention, rather than to debate legal issues.*
>
> *One issue, which OEHHA can address, is the comment that the attributable risk calculations are irrelevant for California. The comment fails to recognize that the lower smoking rates in California are factored into the calculations of attributable risk. There is no reason to believe that Californians would, in fact, not respond to ETS like other people, given the broad diversity of people present in California in terms of genetic, lifestyle, diet, and so forth.*

Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant, *Part C: Public Comments and ARB/OEHHA Staff* Responses (June 24, 2005), p. 161.

This response simply glossed over the issues raised by RJRT and then demonstrated a complete lack of understanding regarding the concept of attributable risk. While it is correct that

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[2] See Attachment 1, pp. 1-5.

[3] See Attachment 1, pp 5-14. Additionally, RJRT was not alone in its criticism of the Report's conclusions regarding breast cancer. See, e.g., Comments of Michael Thun, American Cancer Society ("Attachment 3"). While RJRT does not necessarily endorse all of Dr. Thun's comments, they provide an excellent example of the disagreement in the scientific community with the conclusions reached in the ARB Report regarding ETS and breast cancer. After reviewing the entire record, RJRT continues to disagree with the Report's conclusions regarding ETS and breast cancer and does not believe that the Report's conclusions regarding breast cancer are justified by the available scientific evidence.

the attributable risk calculations utilized by the ARB took into account "the lower smoking rates in California," these calculations did not -- and indeed could not – take into account the fact that exposures in California are substantially lower and occur in different venues than the exposures and corresponding venues of exposure identified in the epidemiology studies utilized in the attributable risk calculations.

The simplistic use of attributable risk calculations, regardless of the quality of those calculations, is not appropriate for meeting the requirements set forth in Section 39660(c)(2) of the California Health and Safety Code.[4] Pursuant to Section 39660(c)(2), the relevant issue is whether current exposures in California warrant designation of ETS as a Toxic Air Contaminant and, if so, what are "the levels of exposure that may cause or contribute to adverse health effects [in California]." Yet, the ARB's attributable risk calculations completely bypass this issue because they are based on epidemiology studies conducted outside of California that evaluated exposures that either practically no longer exist in California (indoor occupational exposures) or exposures in environments that the ARB does not have authority to regulate (indoor occupational exposures and residential exposures). The glaring differences in exposure that studies have found in the context of indoor environments versus the extremely low and artificially determined outdoor point source emissions relied on in the Report, magnifies the problems with utilizing these epidemiology studies to purportedly calculate an attributable risk for Californians exposed to ETS in environments potentially subject to ARB regulation.

Simply put, to the extent that one of the purposes of designating a substance as a Toxic Air Contaminant is to determine if regulation of that substance is warranted, the ARB Report has done absolutely nothing to address that issue. Unless the ARB plans to attempt regulation of indoor occupational exposures or residential exposures to ETS (something that it is clearly not authorized to do), the ARB's efforts to comply with the requirements set forth in Section 39660(c)(2) of the California Health and Safety Code should be premised on the risk the ARB believes to be present in the environments over which the ARB has authority to regulate. The ARB clearly has made no such attempt and thus the Report on ETS does not comply with the statutory requirements set forth in Section 39660(c)(2).

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[4] First and foremost, the use of attributable risk calculations requires the underlying epidemiology to be scientifically accurate. For the reasons set forth in RJRT's prior submissions to Cal/EPA, RJRT submits that the underlying epidemiology suffers from substantial scientific inaccuracies which only magnify the inappropriateness of using these studies for attributable risk calculations. However, RJRT also recognizes that the ARB takes a different view regarding the strength of the epidemiology and its support for the ARB's conclusions regarding ETS and disease. Thus, rather than debate whether the epidemiology actually supports the ARB's general conclusions regarding ETS and disease – conclusions with which RJRT disagrees – these comments will focus on the Report's inappropriate use of the epidemiology for developing California-specific attributable risk calculations.

RJRT's 2004 Comments to the SRP

In 2004, RJRT provided additional comments to the ARB and the SRP that focused specifically on legal matters pertaining to the membership of the SRP.

First, RJRT did not - and still does not - believe that the make-up of the SRP that reviewed the ETS Report meets the statutory requirements set forth in California Health and Safety Code § 39670(b)(1) mandating that one of the SRP members is to "be qualified as a pathologist," and one of the members is "to be qualified as an oncologist."[5]

Second, RJRT believes that at least two SRP members (Dr. Stanton Glantz and Dr. Katherine Hammond) have engaged in activities that give an appearance of having a conflict of interest that should have disqualified them from participating on the SRP that reviewed this Report. I will not re-visit the reasons set forth in RJRT's 2004 Comments other than to state our belief that these reasons continue to remain valid and they speak for themselves.[6] I do, however, want to add some additional points in support of this belief that were not raised in RJRT's 2004 comments.

With respect to both Drs. Hammond and Glantz, it became evident during the course of the SRP's consideration of the ETS Report that neither panel member was shy about citing to and discussing their own publications on ETS. However, their willingness to cite to their own work seemed to be limited to those publications that they believed supported the Report's conclusions. Neither Drs. Hammond nor Glantz ever informed the SRP that each of them had co-authored publications that predicted threshold exposure levels for ETS below which regulation would not be necessary.[7]

Interestingly, in each of these publications, Drs. Glantz and Hammond calculated ETS exposure threshold levels that were at or above the levels that the ARB Report predicted for outdoor ETS exposures in California. Yet, both panel members chose, for whatever reason, to ignore their own data during the SRP panel discussions. Indeed, in Dr. Glantz' publication, he analyzes what he claims is unpublished data from Philip Morris and specifically criticizes Philip Morris for not sharing their data with the Cal/EPA. Yet, as a member of the SRP, he never shared this data with Cal/EPA either.

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[5] See Attachment 2, p. 2.
[6] See Attachment 2, pp. 2-3.
[7] See Attachment 4 (Glantz 2005 publication in which he analyzes purportedly unpublished data from Philip Morris and calculates an "acute reference exposure level" for ETS pursuant to Cal/EPA guidelines) and Attachment 5 (1998 Hammond publication where she predicts a level of exposure to ETS that she characterizes as "De minimis" and defines as "a level at or beneath which involuntary risk is generally of no regulatory concern.")

While RJRT admittedly does not endorse these Glantz or Hammond publications and their analyses, RJRT cites these publications to the ARB as further evidence that Drs. Glantz and Hammond have engaged in behavior that gives an appearance of having a conflict of interest that should disqualify them from participating on an SRP that reviewed the ARB's Report on ETS. Both Drs. Glantz and Hammond participated in the drafting and/or editing of the ARB Report and on the SRP panel evaluating the Report. Yet, neither of their own published calculations of an ETS exposure threshold appear anywhere in the ARB Report or the SRP transcripts discussing the Report.

Additionally, with respect to Dr. Glantz, RJRT is not alone in its concerns. Drs. James Enstrom and Geoffrey Kabat submitted extensive comments regarding Dr. Glantz to the ARB in June 2005. For the convenience of the Board, I am attaching a copy of their comments to this letter as Attachment 6. While RJRT does not necessarily endorse all of the allegations contained in Attachment 6, RJRT feels that the Board needs to consider these allegations in determining whether Dr. Glantz has engaged in behavior that gives an appearance of having a conflict of interest.

Before concluding my comments on the conflict of interest issue, I feel it important to reiterate what I said in my 2004 letter to the ARB regarding this issue. I want the Board to understand that RJRT is not accusing either Dr. Glantz or Dr. Hammond of impropriety. Rather, RJRT believes that their activities related to the tobacco industry, generally and ETS, specifically, call into question their objectivity to the point that there is an appearance of conflict. Based on this appearance, RJRT does not believe that either Dr. Glantz or Dr. Hammond should have participated in the SRP Review of the ETS Report.

In sum, RJRT has several concerns regarding the ARB's Report on ETS and the process under which it was evaluated by the SRP. RJRT does not believe that the Report is scientifically sufficient or that the entire process was legally sufficient to designate ETS as a toxic air contaminant.

Sincerely,

Mitchell A. Neuhauser
Senior Counsel – Regulatory Affairs
R. J. Reynolds Tobacco Company

Attachments 1-6