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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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July 6, 2007

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James L. Pirkle, M.D., Ph.D.
Deputy Director for Science
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National Center for Environmental Health
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4770 Buford Highway, NE
Atlanta, GA 30341-3724

Dear Dr. Pirkle:

Thank you for appearing before the Subcommittee on Environment and Hazardous Materials on Wednesday, April 25, 2007, at the hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure." We appreciate the time and effort you gave as a witness before the subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

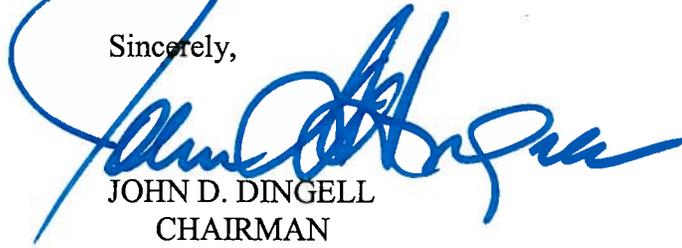
To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business on **Friday, July 20, 2007**. Your written responses should be delivered to **2125 Rayburn House Office Building** and faxed to **(202) 225-2899** to the attention of Rachel Bleshman. An electronic version of your response should also be sent by e-mail to Ms. Bleshman at rachel.bleshman@mail.house.gov. Please send your response in a single Word or WordPerfect formatted document.

James L. Pirkle, M.D., Ph.D.

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Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Rachel Bleshman at (202) 225-2927.

Sincerely,



JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Albert Wynn, Chairman
Subcommittee on Environment and Hazardous Materials

The Honorable John Shimkus, Ranking Member
Subcommittee on Environment and Hazardous Materials

The Honorable Joe Barton and the Honorable John Shimkus

1. From what I know of the CDC/Blount study, your findings were much different than what was found in previous animal studies used by EPA and human data evaluated by NAS. In the conclusion of your study -- as well as in your testimony -- you claim that subsequent, confirmatory analysis is necessary to verify the findings of your study. What things do you believe need to be followed up on? Have you begun this process? How long do you expect this process to take? Can you be absolutely certain that further information gaps will not emerge when you conduct these studies?
2. Some witnesses claim that your study is definitive and that further study of this issue is not required. Yet, your study was unique in that the results that you observed were unexpected and different from everything else that previous studies have found. Do you believe it is a good scientific principle to do more study if the results from an existing study are new?
3. You said in your testimony that the CDC/Blount study showed an "association" between urinary perchlorate and increased TSH and decreased total T4 in women 12 and older, who had urine iodine levels < 100 µg/L. It is possible people might assume then that perchlorate actually "caused" the thyroid changes. Was the CDC/Blount study designed to evaluate whether there is a causal relationship between low levels of perchlorate exposure and thyroid function? Can you please clarify the difference between "an association" and "causation?"
4. Did the CDC/Blount study show other known thyroid iodine uptake inhibiting agents as not having any effect or actually in one case showing a reverse effect from the recognized biological normal ranges? How can this be explained?
5. In the CDC/Blount study, were fluctuations in thyroid hormones among women with low iodine outside normal ranges?
6. Do you believe that the CDC/Blount's thyroid study is sufficiently definitive for EPA Headquarters to rely on in moving forward with a regulatory determination on perchlorate as well as use by EPA Regions in developing site-specific risk assessments and cleanups?
7. In commenting on the CDC/Blount study, which you spoke of in your testimony, the American Thyroid Association (ATA) states that "[t]hese findings are intriguing, although several features of the study may limit the immediate application to guidelines for perchlorate exposure standards." The ATA also states that "further laboratory information is necessary before the implications of the findings can be understood." The Blount study itself says "further research is recommended to affirm these findings." Would you agree with the ATA and the Blount study in this regard, specifically that more study is needed and this study alone is not sufficient for setting a regulatory standard, and could you please explain your answer?

The Honorable Joe Barton and the Honorable John Shimkus (continued)

8. Many of your studies look at the health effects of various things on people of differing socio-economic backgrounds. Did your recent perchlorate study extrapolate that information?

9. Do you agree with Dr. Utiger that people with hypothyroidism should compensate for potential perchlorate exposures through greater dietary intake of iodine rich foods and vitamins?

The Honorable Albert Wynn

1. Are calculations for median estimated dose of perchlorate for adults about 1/10 of EPA's reference dose of 24.5 ppb.?
2. Is it true that the 2006 NHANES study found measurable amount of urine in all 2,820 survey participants and that the levels of perchlorate found in children were 65 percent higher than those found in adults?
3. The CDC 2006 NHANES study was peer reviewed and tested multiple times and CDC testified that it has a high level of confidence in its findings. Does CDC agree that this study is based on the best available, high quality, peer reviewed science and that the data was collected by accepted methods?
4. CDC's second study examined the relationship between urine perchlorate levels and thyroid hormone level, 12 years old and up using perchlorate levels common in the US populations that are much lower than those used therapeutically. This study was also peer reviewed. Is CDC planning a second study to affirm these findings and expand on the study?
5. Is it true that CDC NHANES was peer reviewed and is in compliance with the Information Quality Act, Pub. L. NO. 106-544?
6. Various studies have shown that nursing and bottled fed infants could receive doses of perchlorate from breast milk above EPA's RfD of 24 ug/L. Recent studies have determined the existence of perchlorate doses that were above EPA's RfD of 24 ug/L for infants drinking reconstituted formula made with water containing perchlorate (Baier-Anderson et al. 2006)(Kirk et al. 2005) and have also estimated that nursing infants could receive doses above the RfD even without considering the added exposure associated with EPA's preliminary remedial goal of 24 ug/L (Pearce et al. 2007 and Kirk et al. 2007). Please describe whether the Agency is considering the impact of perchlorate on nursing and bottle-fed infants and/or whether the Agency intends to utilize the above referenced studies or conduct its own studies on the impact of perchlorate on nursing and bottle-fed infants.