

# United States Senate

WASHINGTON, DC 20510

November 29, 2011

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Sebelius,

We are writing to express our concerns regarding the National Toxicology Program's (NTP) 12<sup>th</sup> Report on Carcinogens. Questions remain regarding the process involved in making these recommendations. It is crucial that the federal agencies charged with protecting human health make consistent, coordinated public health decisions, and we are concerned this is not the case. Therefore, we request that the Department of Health and Human Services have an independent agency, such as the National Academy of Sciences – the organization originally chartered to resolve scientific disputes within the federal government – conduct a review of the NTP's 12<sup>th</sup> Report on Carcinogens. This review should include a causal determination of potential carcinogenicity based on best available science, a weight-of-evidence approach, and a clear analysis of scientific uncertainty. Further, this report should include information on how the NTP process can be reformed to enhance transparency and efficiency to ensure external scientific and public involvement in future Reports on Carcinogens.

The National Toxicology Program, Environmental Protection Agency, National Institute for Occupational Safety and Health, Food and Drug Administration, and Agency for Toxic Substances and Disease Registry all use different criteria, scientific procedures, and descriptors for carcinogenicity classification. The fact that different federal agencies have issued contradictory reports on carcinogens raises significant doubts about the validity of any of these reports and questions the use of their data in forming federal regulations.

The NTP Report listed styrene as a “reasonably anticipated” carcinogen. This is contrary to two recent weight-of-the-evidence assessments that concluded styrene is not likely to cause cancer in humans. One report was conducted by the European Union and the other by a “blue ribbon” panel of epidemiologists whose findings were published in the November 2009 issue of the Journal of Occupational and Environmental Medicine. Both studies' findings were dismissed by the NTP and not fully considered.

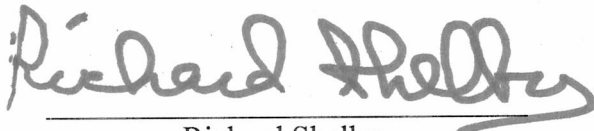
Further, in April 2011, the nonpartisan, nonprofit National Academy of Sciences released a report that questions the federal process used to determine the classification on formaldehyde. The NTP Report used the Environmental Protection Agency's draft Integrated Risk Information System (IRIS) Assessment of Formaldehyde as a main factor in its decision. However, after reviewing the Environmental Protection Agency's recommendations on formaldehyde, the

National Academy of Sciences stated: *“Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies.”* The National Academy of Sciences review raises serious questions about the NTP assessment of formaldehyde. We find it deeply concerning that the NTP Report would disregard current scientific studies and use a flawed system to review data – evident in both these cases.

The Report on Carcinogens is used as justification for regulations across our government. In fact, workplace warnings are automatically required under Occupational Safety and Health Administration regulations following a listing in the Report even though the NTP admits that it does not determine if workers actually are at risk. Both styrene and formaldehyde are important for thousands of smaller manufacturers located in cities, towns, and rural areas all across America. NTP's action put these companies at risk of unwarranted lawsuits and increased costs for liability insurance, and places small business owners in the position of having to explain that NTP has not actually determined that their workers, plant neighbors, and customers are really at risk. Once an agent is listed, there is no administrative appeal from the NTP. Therefore, it is critical that the Report encompass the entire breadth of current scientific data to ensure that any regulations implemented will protect worker safety and public health.

We share your commitment to protecting public health and look forward to working with you to ensure our American workforce is protected by evaluating and improving the current NTP process.

Sincerely,




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Richard Shelby



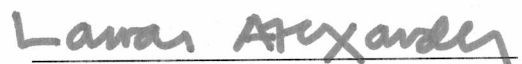
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Mark Warner



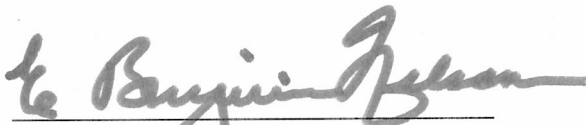
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Thad Cochran



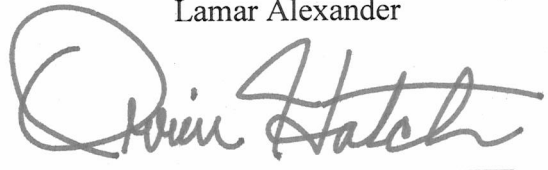
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Lamar Alexander



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Ben Nelson



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Orrin Hatch



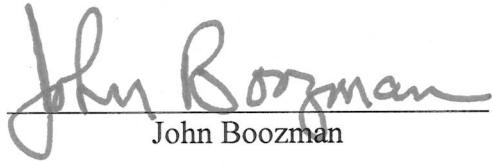
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Jeff Sessions



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Roger Wicker

  
John Boozman

  
John Hoeven