The Honorable Secretary Kathleen Sebelius  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Sebelius,

As you know, significant questions have been raised about the scientific integrity, credibility and relevance of the National Toxicology Program's (NTP) Report on Carcinogens (RoC). Reports like the NTP's RoC send strong signals to the American people and the marketplace and can create economic consequences, confusion and unwarranted fear when the science does not support the conclusions.

This concern was reflected by bipartisan Congressional action in the Consolidated Appropriations Act of 2012 requiring the Department of Health and Human Services (HHS) to contract with the National Academy of Sciences (NAS) to conduct a scientific peer review of the 12th RoC determinations related to formaldehyde and styrene. While the Congressional intent and directive to evaluate the RoC were clear, it has now been five months since the law was passed and yet no contract has been executed. Moreover, Dr. Linda Birnbaum recently stated that the contract may not be finalized until the end of FY 2012. I am therefore writing to urge you to expedite this matter so the NAS can begin its important peer review of the formaldehyde and styrene sections of the RoC without further delay.

The NAS review of styrene and formaldehyde will necessitate examination by the NAS panel of the underlying scientific evaluation policies and practices employed by NTP for data evaluation, for integrating studies to weigh the overall evidence for determining cause and effect, and the RoC listing criteria for determining the potential for carcinogenic hazards to humans at environmentally relevant levels of exposures.

The findings and recommendations of this NAS review will be informative not only for styrene and formaldehyde, but importantly, for future RoC listing substances. Flawed assessments create public confusion, unwarranted alarm, unnecessary product de-selection and litigation, all of which can put jobs at risk without sound scientific basis. Moreover, these shortcomings may have significant unwarranted economic impacts, because risk management decisions throughout the federal government, as well as state governments, routinely draw upon determinations reached in the RoC.
We are also concerned that unless fundamental and permanent improvements are made, the 13th RoC will suffer from the very same shortcomings that plagued the 12th RoC. In this regard, I urge you to suspend the development of the 13th RoC until the NAS completes its review and the NAS recommendations are fully considered and incorporated into the RoC evaluation methods and review processes. Moving forward with developing the 13th RoC before the NAS completes its review is counterproductive because this will perpetuate long standing deficiencies in the scientific rigor of the RoC evaluation methods and review processes.

Improving the RoC is also warranted to assure its compliance with HHS’s Policies and Principles for Assuring Scientific Integrity¹, which specifies that “HHS shall convey scientific and technological information to the public such that the presentation is accurate, transparent, and informative. To do so, HHS shall communicate scientific and technological findings by including a clear explication of underlying assumptions and, where appropriate, an accurate contextualization of uncertainties and a description of the probabilities associated with both optimistic and pessimistic projections.”

Thank you for your attention to these important matters and your continued leadership on the many challenges your Department faces. If you have any questions or comments, please do not hesitate to contact me.

Sincerely,

Cal Dooley