CRE RESPONSE TO ATRAZINE PORTION OF JAMA ARTICLE

Dr. Rosenstock's article in JAMA[1] attacks Data Quality Act ("DQA ") Petitions that the Center for Regulatory Effectiveness ("CRE") filed with two federal agencies: the National Toxicology Program ("NTP") and the Environmental Protection Agency ("EPA"). These DQA Petitions requested that the agencies correct information they disseminated about the herbicide atrazine. Dr. Rosenstock's discussion of our DQA Petitions contains many material factual errors.

For example, she incorrectly states in her article that "[a]trazine is already classified as an established animal carcinogen and hence a possible human carcinogen by the International Agency for Research on Cancer."

In fact, IARC classifies atrazine as "not classifiable as to carcinogenicity in humans."[2] The IARC Monograph on atrazine also explains that with regard to animal tests, "[T]here is strong evidence that the mechanism by which atrazine increases the incidence of mammary gland tumors in Sprague-Dawley rats is not relevant to humans."[3] The IARC Monograph concludes, "There is inadequate evidence in humans for the carcinogenicity in humans of atrazine."[4]

The IARC Monograph on atrazine provides the primary basis for our DQA Petition to the NTP. Like Dr. Rosenstock, the NTP misstated the IARC findings in the NTP's public announcement that it might review atrazine in NTP's Report on Carcinogens ("RoC"). CRE's DQA Petition sought correction of these misstatements. We do not understand how Dr. Rosenstock could have repeated the NTP's misstatements if she had actually read our DQA Petition.

Dr. Rosenstock's attack on our DQA Petition to EPA is also based on misstatements of fact. For example, Dr. Rosenstock states in her article:

> "*Atrazine...has been repeatedly demonstrated to be a potent endocrine disruptor, causing among other changes gonadal abnormalities in frogs. [footnotes omitted]. For these reasons, atrazine will be phased out of use by 2007 in the European Union.*"

The two omitted footnotes in the above quotation cite two articles by Dr. Tyrone Hayes. Dr. Rosenstock incorrectly states that the EU ban on atrazine is based on these two Hayes articles. In fact, the EU ban on atrazine is based on an arbitrary 0.1 ppb groundwater standard that the EU

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[1] JAMA, May 24, 2006; 295(20): 2407 - 2410, http://jama.ama-assn.org/cgi/content/extract/295/20/2407

[2] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, "Some Chemicals that Cause Tumors of the Kidney or Urinary Bladder in Rodents and Some Other Substances," Vol. 73, p. 94 (1999)("IARC Monograph").

[3] *Id.*

[4] *Id.*

applies to all pesticides. This standard has nothing to do with the Hayes articles. The EU standard is instead based on a purely "political" decision, as the EU's own Scientific Steering Committee admits:

> "*In the 70s, a political decision was taken to reduce to 'zero' the presence of pesticides, independent of their toxicity. However, a "zero level" is neither achievable and cannot be assessed [sic]. As a consequence the "zero level" was transformed in an analytical level of 0.1 ug/L, which was considered to be the limit of detection for the techniques used at that time*."[5]

The EU ban on atrazine ignores the EU's own Scientific Steering Committee's atrazine review, which concluded, "It is expected that the use of atrazine, crop protection practice, will not have have any harmful effects on human or animal health or any on the environment."

If Dr. Rosenstock is looking for a government where regulation is based on politics, not science, then she should look toward Europe, not the United States.

Dr. Rosenstock's statement that "[at]trazine ...has been repeatedly demonstrated to be a potent endocrine disruptor, causing among other changes gonadal abnormalities in frogs" is also incorrect. Her sole support for this statement is the two Hayes articles which discuss his atrazine tests on frogs. Dr. Rosenstock does not mention that Dr. Hayes's frog tests flunked peer review conducted by objective, outside experts in the field..

During its registration review of atrazine, EPA convened a Scientific Advisory Panel ("SAP") to review Dr. Hayes's tests and all other available tests of atrazine frog effects. The other available tests included industry-funded tests. The SAP's extensive unbiased expert review included three days of public hearings. Dr. Hayes spent almost an entire day of these hearings trying to defend his tests. At the conclusion of its Peer Review, the SAP agreed with EPA that none of the frog tests, including Dr. Hayes' tests, were reliable. In the SAP's own words:

> "*There is not sufficient evidence to indicate that atrazine consistently produces effects across the range of amphibian species examined.*"
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> "*There were deficiencies and uncertainties with respect to the methods, conduct, and results of the studies submitted.....given these deficiencies and limitations, the panel concluded that the current data would not be suitable for ecological risk assessment.*"
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[5] *Official Journal of the European Union, Commission Decision of 10 March 2004 concerning the non-inclusion of atrazine in Annex I to Council directive 91/414/EEC and the withdrawal of authorization for plant protection products containing this active substance (notified under document number C(2004) 731), at Section 6.1*

> "*The panel concluded that although they agreed that a causal relationship can be hypothesized between atrazine and effects on gonadal development, the uncertainties and deficiencies in existing studies precluded acceptance of the hypothesis....*"[6]

The SAP's findings are consistent with our DQA Petition to EPA. We argued in that Petition that neither Dr. Hayes' tests nor the industry-funded tests had been demonstrated to be reliable. Dr. Rosenstock is, therefore, factually incorrect when she states that we were "relying on its [presumably CRE] own industry-funded studies" in our EPA Petition. Quite the contrary, our DQA petition argued that none of the available tests were reliable. We do not understand how Dr. Rosenstock could have read our Petition and misunderstood our argument.

Our DQA Petitions, and the agencies' responses to them, are now and always have been public information, just like all other DQA Petitions.[7]

Finally, we ask whether JAMA peer reviewed Dr. Rosenstock's article before publishing it. Competent, unbiased peer review would have discovered the many errors identified above.

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[6] Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 17-20, 2003, at page 25, available online at http: www.epa.gov/scipoly/sap/2003/june/junemeetingreport.pdf.

[7] For the NTP Petition see http://aspe.hhs.gov/infoquality/requests.shtml. For the EPA Petition, see http://www.epa.gov/quality/informationguidelines/iqg-list.html.