

GARY KAYAJANIAN'S ORAL SAB/SAP COMMENTS ON ARSENIC

Since EPA has confined its examination of arsenic to cancer effects to humans, it should rely on the most relevant data -- namely, (1) significant (2) total cancer data (3) in men and women. In addition, (4) the human data should be real, not modeled or extrapolated. Lesser data can be used to explain "most relevant data," but not supplant it. And when real data contradict modeled or extrapolated data, the model or extrapolation should be junked.

"Most relevant data" exist, in the Millard, Utah health data set Agency scientists collected and published on. Unfortunately, Agency scientists compared the bladder cancer levels in the "exposed" Millard County cohort with "reference" data collected in the rest of the state over a more recent time frame -- leading to criticism of the data set rather than criticism of the USEPA analysis. Within Millard County, the total cancer mortality rate is higher in each sex at arsenic levels in drinking water of 0-<25 µg/L compared to 25-<75 µg/L; in women, the three-fold difference is hugely significant ($p < .000001$).

In 2001, the USEPA relied on extrapolated bladder cancer mortality rates in the Taiwan data set to justify lowering the arsenic in drinking water standard from 50 to 10 µg/L. But the real data "around 50 µg/L" [42-60 µg/L] and "below 50 µg/L" [10-32 µg/L] show the opposite of the extrapolation claim: a significant, three-fold increase in each sex of the bladder cancer mortality rate "below 50 µg/L" compared to "around 50 µg/L." That data set also included lung and liver cancer -- each category shows higher mortality levels "below 50 µg/L" compared to "around 50 µg/L." The mortality rate for all three cancers, taken together is three times higher "below 50 µg/L" than around 50 µg/L" ($p < .001$, in each sex).

In this risk assessment effort, the USEPA models or extrapolates "lesser" data -- toxicological, pharmacological and biochemical data -- to justify or explain cancer claims incorrectly imputed earlier to arsenic at levels below 50 µg/L. I ask this panel to do the obvious: (1) to observe that arsenic "around 50 µg/L" is a potent anti-carcinogen compared to "around 10 µg/L," (2) to reject Agency claims generated from lesser, inconsistent data, and (3) repudiate the previous findings of the Agency's earlier arsenic review.