ARSENIC IN DRINKING WATER AND CANCER:
A COMMENTARY FOR THE 2005 JOINT SAB/SAP ARSENIC REVIEW†

Gary Kayajanian, Ph. D., J.D.
Lake Worth, FL 33467
[561] 649-6629

USEPA Administrator Browner charged Agency staff, the SAB and the National Academy of Science with helping her answer the question, "Should EPA maintain the Arsenic in Drinking Water standard at 50 µg/L or should EPA lower the standard?" Relying on a faulty model-driven analysis that fooled both expert panels, the EPA Offices of Water and ORD claimed that lower bladder cancer mortality rates were associated with arsenic levels below 50 µg/L – at 20, 10, 5 and 3 µg/L. [The USEPA opted to lower the standard to 10 µg/L -- the lowest standard it could justify using a stilted economic analysis.]

What was faulty in the bladder cancer analysis EPA performed? EPA associated bladder cancer death mortality rates in 42 Taiwan villages with drinking-water levels ranging from 10 to 934 µg/L. EPA grouped the villages into four exposure categories – 0-100, >100-300, >300-600, and >600 µg/L – and extrapolated the bladder cancer mortality rate from the highest to the lowest exposure grouping in each sex. There was never a need for EPA to extrapolate data, because five of the villages had arsenic exposures "around 50 µg/L" [between 42 and 60 µg/L] and five had lower arsenic levels [between 10-32 µg/L]. How do the real bladder cancer data relate to arsenic exposure? Three-to-four times higher bladder cancer mortality rates are associated with 10-32 µg/L compared to "around 50 µg/L" – values significant in both males and females [$p < .03$ and $< .01$, respectively]. (See Table 1, below.)

Table 1 Arsenic level	Bladder cancer deaths per 1000-person years: Males	Bladder cancer deaths per thousand-person years: Females
10-32 µg/L	11/23.616 = 0.4658	14/21.523 = 0.6505
42-60 µg/L	5/41.181 = 0.1214	6/37.256 = 0.1610

[Data source: NAS 1999 Report "Arsenic in Drinking Water," pp. 308-309.]

Lung and liver – the other cancer endpoints in the Taiwan data set -- each shows a benefit attached to "around 50 µg/L" compared to the lower exposure. Taken together, in Table 2 below, the lung plus liver plus bladder cancer mortality rate is highly significant [$p < .001$ in each sex.]

Table 2 Arsenic level	Lung + Liver + Bladder cancer deaths per 1000-person years: Males	Lung + Liver + Bladder cancer deaths per 1000-person years: Females
10-32 µg/L	39/23.616 = 1.65	35/21.523 = 1.62
42-60 µg/L	22/41.181 = 0.53	19/37.256 = 0.51

[Data source: NAS 1999 Report "Arsenic in Drinking Water," pp. 308-309.]

In developing its arsenic-in-drinking-water risk analysis, EPA could have relied on other data sets, including the epidemiology study by Agency scientists on the population of Millard County, Utah. The average daily arsenic in drinking water dose for each subject, as calculated by EPA scientists, ranged from 0 to less than 175 µg/L. Both total cancer and heart disease mortality rates are reduced at arsenic levels 25-<75 µg/L [the surrogate for 50 µg/L] compared to levels 0-<25 µg/L [the surrogate for 10 µg/L]. The cancer observations, in Table 3 below, are highly significant in women [$p < .000001$]; the heart disease deaths, in Table 4 below, are significant in men [$p < .03$].

Table 3 Arsenic level	Total cancer deaths per 100 surviving men	Total cancer deaths per 100 surviving women
0-<25 µg/L	8.047	9.189
25-<75 µg/L	7.220	2.784

Table 4 Arsenic level	Total heart disease deaths per 100 surviving men	Total heart disease deaths per 100 surviving women
0-<25 µg/L	42.34	27.36
25-<75 µg/L	31.66	22.92

Why is my analysis of arsenic data presented above superior to the EPA and NAS analyses, agreed to by the SAB? (1) As a fundamental principle of science, whenever modeled data, such as the extrapolated estimates developed by EPA and the NAS, are contradicted by the data themselves, the model, and claims based on it, must be rejected. (2) The response pattern of cancer mortality to arsenic levels in each study reinforces the other's pattern.

ASSESSMENT OF BENEFITS ASSOCIATED WITH ARSENIC IN DRINKING WATER LEVELS NEAR 50 µg/L.

* If current cancer incidence and mortality levels were associated with all drinking water sources providing arsenic at 50 µg/L, then reducing the arsenic level to 10 µg/L would result in 2,979 extra cancers per day in women, of which 1301 would be extra cancer deaths per day.

* In the alternative, if current cancer incidence and mortality levels were associated with all drinking water sources providing arsenic at 10 µg/L, then increasing the arsenic level to 50 µg/L would avoid 1024 cancers per day in women, of which 447 would be cancer deaths.

* If current heart disease death levels were associated with all drinking water sources providing arsenic at 50 µg/L, then reducing the arsenic level to 10 µg/L would result in 288 extra heard disease deaths per day in men.

* In the alternative, if current heart disease deaths were associated with all drinking water sources providing arsenic at 10 µg/L, then increasing the arsenic level to 50 µg/L would avoid 215 heart disease deaths per day.

* To reiterate, these are per day benefit calculations, which differ from the life-time risk calculations EPA traditionally offers by a factor of 25,550. These cancer and heart disease benefits, based on straightforward calculations from real epidemiology data, serve as an imposing health counterweight to any <u>other</u> imagined or modeled adverse health claims EPA conjures. Of course, my analysis virtually precludes any cancer claim EPA might offer.

† Patent Pending

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