

KAYAJANIAN'S COMMENTARY ON THE 12/27/05 SAB DRAFT ON ARSENIC

These comments pertain only to the inorganic arsenic portion of the SAB/SAP (Panel) Review, specifically on the shape of the cancer dose response curve from 0 to 100 ppb. The Panel concludes on page 33, lines 23-25, "there is no clear indication of what shape a non-linear dose-response would take for application to human cancer risks at low exposures (<50 or 100ppb)." The panel is wrong. In the Taiwan data set EPA endorsed in 2001 by its use to justify lowering the drinking water standard from 50 to 10 ppb and in the Millard data set EPA scientists published on, there is an abundance of relevant and material data showing a significantly elevated cancer and other mortality rate "below 50 ppb" compared to "around 50 ppb," which the Agency and the SAB have otherwise ignored: (1) In the Taiwan data set, a significant three-to four fold increase in the bladder cancer death rate and the lung + liver + bladder cancer death rate associated with 10-32 ppb compared to 42-60 ppb arsenic in drinking water; (2) In the Millard County, Utah data set, a significant three fold increase in total cancer mortality in women and a significant 33% increase in the heart disease mortality data associated with 0-<25 ppb compared to 25-<75 ppb arsenic in drinking water. The shape similarity of the dose response curves for different cancer endpoints within and between these studies strengthens the conclusion drawn with respect to each endpoint and each study.

A number of questions were raised by panelists in the September 12-13, 2005 Meeting to denigrate the data in these studies, so that EPA regulators in the Offices of Water and Research and Development could employ a default linear extrapolation (page 33, lines 31-33). I offered post-meeting written responses to these questions which should have resolved them. Dr. Cantor guessed some misclassification of data had occurred in the Millard County data set. The Panel is correct (page 24, lines 22-24) that such misclassification could profoundly depress the magnitude of the observed risk. But since the total cancer mortality rate in women (whether misclassified or not) is so significantly greater ($p < .000001$) in the 0-<25 ppb grouping than in the 25-<75 ppb category, Dr. Cantor's "guess" becomes irrelevant. In Taiwan, if you exclude the one village in five with multiple wells not within the 10-32 or 42-60 ranges, the comparisons made still remain significant, for bladder cancer and the three-cancer mortality rate. [Further, any misclassification of exposure occurring as a result of multiple wells in a village likely means the significant findings observed are truly even more significant.]

The studies most relevant to human health are the epidemiology studies Agency Offices and some panelists want to ignore. There is no reason for panelists additionally to require knowledge of "complex properties and MOA's of iAs and its metabolites" to justify the conspicuous findings of the Taiwan and Utah data sets. These studies significantly show the clear benefits (a reduction in cancer and heart disease deaths) associated with arsenic levels around 50 ppb in water. Asking members of the public, directly or indirectly, to cover the capital and maintenance costs of compliance with EPA arsenic regulations that lower this level (and then have to dispose of the hazardous arsenic waste product removal creates) is asking the public to pay for increasing their cancer incidence and heart disease mortality rates – just the opposite of the stated intent of EPA's arsenic regulations.