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Recently, media attention on Bisphenol A (BPA) has increased. This increase has mainly been triggered by two newly published studies on BPA. Via this statement we would like to put the study results into the context of the existing wealth of scientific data on Bisphenol A: The weight of the scientific evidence shows that there is no basis for health concerns over human exposure to BPA. This has been confirmed by the responsible European authorities.

**Leranth et al.\*:**  
**An exploratory study which is not relevant for human risk assessment**

The Leranth et. al study was published online in PNAS in September 2008. Recent media articles about it contain speculation about health effects for humans that go far beyond the actual findings of the study. The highly exploratory study does not support a conclusion that the reported observations could result in adverse effects on humans.

The authors used an irrelevant route of exposure (subcutaneous), thus by-passing the normal oral exposure by which BPA is rapidly metabolised and excreted. Actual levels of the tested substances in the monkeys' bodies were not measured therefore true exposure levels could not be determined. Only very few parameters were examined for a single bisphenol A dose at only one point in time, with no historical data for comparison. It is therefore very difficult to determine whether observations, if any, were dose dependent, temporary or permanent and/or of biological relevance. Parameters such as behavioural functions, cognitive functions, or signs of toxicity were not examined. Therefore, contrary to the claim made in several media articles, the Leranth et. al study does not support a conclusion that current human exposure to BPA could adversely affect the brain.

**Lang et al.\*\*:** *(embargoed by 16.00 today)*  
**A statistical evaluation of epidemiological data with several limitations**

It is important to understand that the study published today in JAMA measures whether a human has been exposed to a particular compound, but the biomonitoring data by itself does not provide much more information. The study builds on the existing NHANES (US National Health and Nutrition Examination Survey) database by applying statistical models to try to see whether detectable levels of BPA might be statistically correlated to health effects.

While the study authors do conclude that urinary concentrations of BPA were associated with three kinds of health effects, they warn that the study has significant limitations:

- First, as the authors themselves note, they do not conclude that the presence of BPA is causing adverse health effects – they merely noted a statistical association.
- Second, the authors note that the analyses themselves have statistical limitations (they are cross-sectional in nature).
- Third, the authors note that their approach “may have resulted in false-positive associations.”

The authors themselves are careful to caution that their study does not demonstrate that humans are experiencing adverse health effects at the extremely low levels of bisphenol A to

which the general population is exposed, and they conclude that follow up studies must proceed.

Other significant design flaws appear to exist in this study. For example, there are two types of diabetes: type 1, which is the result of genetic factors, and type 2, which develops due to other factors, typically in adults. The JAMA study was based on NHANES data, and the NHANES data does not indicate which participating adults had which kind of diabetes. This makes it impossible to exclude the adults with diabetes due to genetic factors.

The information presented by this study must be placed in context with the large body of existing scientific evidence on bisphenol A, much of which involves actual laboratory testing to observe potential health effects. BPA is one of the most widely studied compounds in the world, and existing scientific evidence from many studies does not “match” the associations found in the JAMA work. For example, there is strong existing evidence from animal studies that BPA does not result in obesity, and obesity is a known risk factor for adult onset diabetes.

While properly designed and executed statistical studies on BPA and other compounds can bring valuable new insights with respect to human health, sometimes they do not, and sometimes they merely claim “false associations” that add little to and even confuse the body of science. We are confident that the authors’ own admonitions about the limitations of this single study will be respected.

### **Bisphenol A is safe in its intended uses**

BPA has been the subject of extensive scientific testing and government reviews worldwide. International responsible authorities such as the European Commission, the European Food Safety Authority (EFSA), the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare have all assessed the comprehensive database on BPA. Based on a weight-of-evidence approach, these assessments have consistently concluded that human exposure levels to BPA are low and within the safe limits set by government authorities. Just recently the EU Commission (June 2008), EFSA (July 2008), and the US FDA (August 2008) re-confirmed their long-standing conclusions that products made from BPA are safe for their intended uses. Over 50 years of research and extensive use throughout the world provide convincing evidence that products made from materials based on BPA are safe for their intended uses.

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*\* Csaba Leranth et. al.: “Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates”. PNAS 105(37): 14187-14191*

*\*\* Iain A. Lang et. al.: “Association of urinary Bisphenol A concentration with medical disorders and abnormalities in adults.” JAMA. 2008;300[11]:1303-1310.*