INFORMED CONSENT AND CAUTION IN RISK ASSESSMENT: TWO KEY ELEMENTS IN THE PROTECTION OF PUBLIC HEALTH

-A commentary on the Air Toxics "Hot Spots" Information and Assessment Act (AB 2588)

By Dr. Jorge R. Mancillas
Assistant Professor of Anatomy and Cell Biology
UCLA School of Medicine
Los Angeles, California
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Four years ago, as I considered job offers from several academic institutions, one factor that influenced my decision to join the faculty of the UCLA school of Medicine was the leadership of its Dean, Dr. Ken Shine, who is now President of the National Institute of Medicine. In particular, I was inspired by his identification of ethical considerations as one of two key issues central to medical education and research. Considering the ethical implications of technological advances, and exercising ethical behavior in the practice of medicine are amongst the cornerstones of the education our medical students receive at UCLA. One of the central tenets of ethical behavior in medical practice is that of informed consent: even when dealing with a person's exposure to a medication or medical procedures intended to benefit them, patients must be fully informed of any risks involved and give their expressed consent.

If in their attempts to alleviate human suffering, medical professionals and institutions must actively involve the beneficiaries by informing them and getting their consent, the least that those exposed to environmentally released substances with toxic potential deserve, is to be informed of the risks associated with that exposure.

Informed consent in professional, business or political practices is at the core of ethical behavior. Short of active participation in public affairs, informed consent is the minimal requirement for the operation of a truly democratic society.

The Air Toxics "Hot Spots" Information and Assessment Act (AB 2588) represents a significant step towards broadening discussions of environmental policy and towards the creation of a climate in which, through the involvement of communities affected by toxic emissions, delineation of policy will be less vulnerable to the influence of small and unrepresentative but powerful pressure groups.

I would like to voice my strong support for AB2588, and present evidence in favor of setting lower notification trigger levels than currently contemplated. This is necessary because the risk assessment process on which determination of significant risk levels is based, often leads to the underestimation of risk.

In fact, previous experience shows that, as the resolution of our technology improves and analysis of health risk expands to consider a broader category of illnesses, acceptable levels are revised downwards. This was certainly the case in determining acceptable levels of exposure to lead. Analysis of the levels of lead in children's blood considered acceptable over the years, shown in figure 1 (attached), illustrates a common trend in the setting of acceptable levels. In the case of lead, they were adjusted downward 4 times in a period of 11 years. Figure 2 (attached) illustrates that the adverse health effects of lead, which has well-documented neurotoxic effects, are not restricted to the nervous system. As we evaluate its effects on other organ systems, it is likely that acceptable blood levels will be further revised downwards, as indicated by the question marks at the bottom of each column.

Even current levels may underestimate the health risks involved. Recent studies show that children with lead exposure levels below the 15 mg/dl considered to be a hazard do not display measurable neurotoxic effects. Yet, they score 8% lower than non-exposed children at age 2 on a standard mental development index. (Trends in pharmacological sciences 9:59-62, 1988)

There are several reasons why risk is often underestimated as a result of the current design of the risk assessment process. Analysis of the magnitude of a risk should require consideration in a three dimensional matrix of probability, potency and scope. Thus, risk assessment should include consideration of: 1) the likelihood of exposure and the levels of such exposure over time; 2) the potency of the substance to cause (multiple) adverse effects, how that potency is affected by interactions with other agents, and by the stage of development and state of health of those exposed, and 3) the size of the population exposed.

The table below lists 4 considerations which illustrate flaws in the way we currently consider the 3 basic components of health risk evaluation: the toxic substance, the population at risk and the measurement of adverse health effects.

TABLE 1:
RISK ASSESSMENT: WHY RISK IS OFTEN UNDERESTIMATED

1.- The effects of toxic substances are tested in isolation. They do not include consideration of combinatory, cumulative or synergistic effects.

SUBSTANCE TESTED + ***OTHER SUBSTANCES*** **-> RECEPTOR -> HEALTH EFFECTS**

2.- Health risks levels usually refer to average healthy individuals and may not apply to sensitive groups or periods of vulnerability in normal individuals.

TOXIC SUBSTANCE -> RECEPTOR ***- CHILDREN - AGED - SENSITIVE POPULATIONS - RECENT HEALTH HISTORY*** **-> HEALTH EFFECTS**

3.- Assays of adverse health effects are narrow: one or a few health parameters are used as indicators

TOXIC SUBSTANCE -> RECEPTOR -> HEALTH EFFECTS ***-CANCER OR TERATOGENICITY RISK EVALUATED -NEUROTOXICITY INADEQUATELY ASSESSED***

4.- Adverse health effects may not be detected in individuals, but have significant social impact.

TOXIC SUBSTANCE -> RECEPTOR -> HEALTH EFFECTS ***- ASSAYED AS INDIVIDUAL EFFECTS***

Because of the time constraints for this testimony, I will limit myself to considerations of point number 3, but I would like to emphasize that even the simple table above does not provide a comprehensive enough matrix for risk assessment.

The reliance on one type of adverse health effect as an index of the toxicity of a substance or of the health risk it poses, can be tremendously misleading. Substances, because of their chemical nature and the variety of their cellular and sub-cellular targets, vary in their ability to disrupt different biological processes, tissue types or organ systems. As indicated in a report by a panel of 15 distinguished neuroscientists and neurotoxicologists:

"Concerns about carcinogenicity have dominated discussion about the risks posed by toxic substances. However, other adverse health effects on organs and organs systems, particularly the nervous system, may pose an equal or greater threat to public health. Consequently, it is important to devise risk assessment strategies to address non cancer health risks."

("Neurotoxicity: identifying and controlling poisons of the nervous system." page 15
New developments in neuroscience, office of technology assessment, U.S. Congress, April 1992)

The risk of neurotoxicity is not a minor concern in considerations of airborne toxic substances. As illustrated in figure 3, of the Toxic Release Inventory's top 25 chemicals emitted into the air in 1987, 19 were neurotoxic substances.

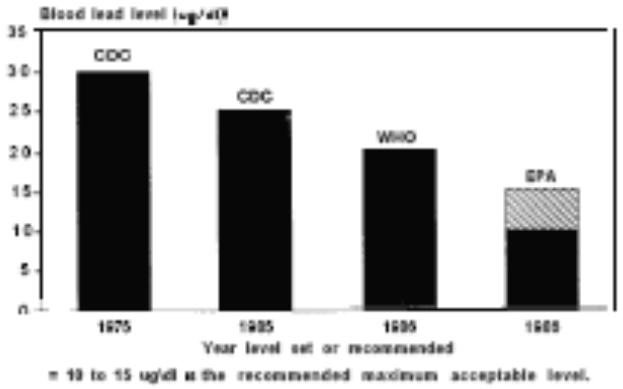
Since cost-benefit analysis seems to be a prime consideration these days, it is important to mention that the OTA's 1990 Report on Neurotoxicity estimates the annual health costs of neurotoxicity due to preventable exposure to environmental agents to be $ 0.5 to 1.5 billion dollars ("Neurotoxicity: identifying and controlling poisons of the nervous system." page 229). The health benefits of reducing the neurotoxic effects of just one substance, lead, is estimated to involve savings of $ 416 million currently spent on medical care and compensatory education.

As a biomedical researcher, I feel privileged that in my daily activities not only do I have access to a wealth of information that helps me better assess the health risk posed by environmental agents. In addition, literally just a few steps down the hall from my laboratory, are the hospital facilities of the UCLA Medical Center. It is the human suffering that occurs there daily, the constant struggle between life and death, that helps me keep in perspective what the acquisition of knowledge, the application of biomedical technology and the seemingly academic discussions about environmental health risks, are all about. Personally, I am tired of using public funds to contribute to the development of medical technology, seeing my colleagues work tirelessly to treat patients, and collectively trying to halt the advance of disease, only to be defeated by further assaults to human health by the preventable exposure to environmental toxins.

Considering the economic costs and the costs in human suffering, I urge the SCAQMD Board and its staff to take a conservative approach to protecting human health and adopt the lowest notification trigger levels based on the most stringent evaluation of risk levels currently available.

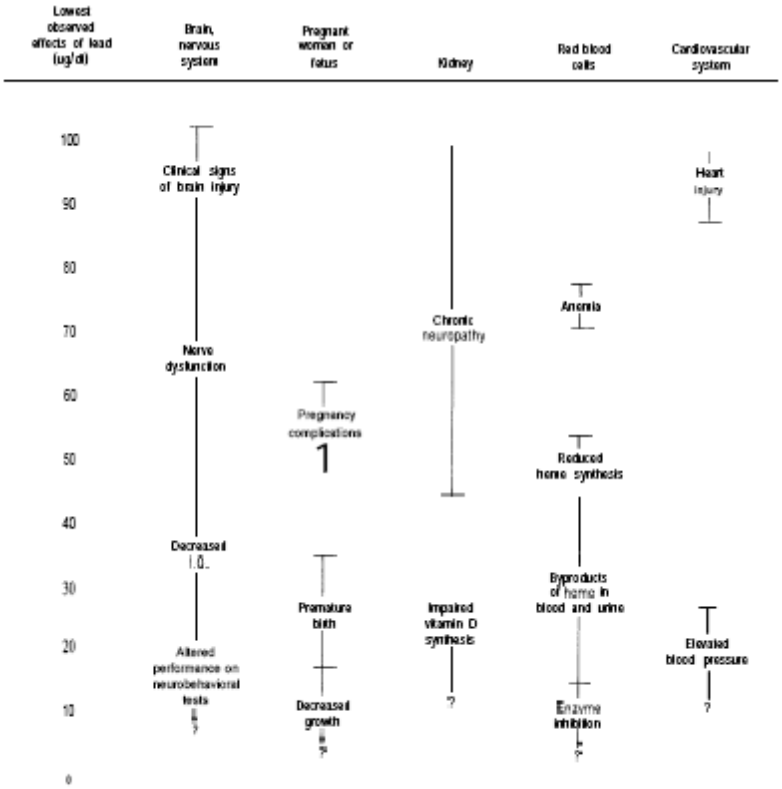
FIGURES

Figure 1.- Children's blood lead levels considered acceptable by various agencies



SOURCE: Office of Technology Assessment, 1990.

Figure 2.- Adverse health effects of Lead



SOURCE: U.S. Environmental Protection Agency, "Drinking Water Regulations; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper; Proposed Rules" (53 FR 31565), 1988.