Risk Assessment Reform is for Real

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Dr. Gori seems opposed to anything he cannot observe and count. His notions about scientific theories are hard to understand in a trained scientist. He states "Predictive knowledge—not guesses—is what sends men to the moon, builds skyscrapers, flies airliners, runs computers, provides effective medicines and all technological improvements that enrich our lives."

Does he actually believe that scientific knowledge showed people how to build the first skyscrapers, aircraft, etc.? Does he think there is no "art" in the design and operation of space craft and computers? Does he think that all or even most medicines are designed from scientific knowledge rather than trial and error?

All of these human achievements depend on risk analysis. Drugs are toxic, the Food and Drug Administration and the individual physician must balance the potential harm against benefits. The moon landings required a careful risk analysis of which challenges were likely to arise during the mission, and what backup and other systems should be provided to decrease the risks of death. Human activity, from driving your car to deciding what to eat, depends on risk analysis.

Dr. Gori focuses his comments on health risk assessments, particularly carcinogenic risk analyses. His criticism of giving animals the maximum tolerated dose will not come as news to Bruce Ames. His reservations about interspecies extrapolation are well known to biologists (Lave et al., 1988). Scientists have been addressing these criticisms, seeking knowledge about mechanisms that would permit better interpretation of high dose or animal data. The work on d-limonene exemplifies what is possible.

He states "Epidemiologic meaning is conjured out of speculative reports that are often weaker than background noise. Such imaginary data are then manipulated in a framework of arbitrary guesses—the official default assumptions—and the outcomes are improperly styled as scientific and objective when, in reality, they are neither."

If the charge is that bad risk analysis is being done, I agree. So there is bad engineering, bad cooking, bad piloting, and bad commentary on risk analysis. Risk analysts need to work harder at making uncertainties explicit and exposing the foolishness of some assertions—both those that underestimate risk and those that overstate risk.

Risk analysis is important because we have adopted a preventive approach. Rather than counting the cancers, crash victims, and other casualties, we have decided to try to prevent disease and trauma. This is a fateful decision, since it is much easier to discover human carcinogens by counting the bodies. In the bad old days, we welcomed a new chemical, drug, process, or product as a social benefit—until the bodies piled up. It is no mystery to me that every one of the rich nations has adopted a preventive approach.

All public health officials know they are making a decision when they wait for more data before declaring a chemical to be a carcinogen, a process, or product to be unsafe. Is the public interest served by waiting until there is a scientific consensus that a chemical is a human carcinogen or that passive smoking causes lung disease? I would not ban asbestos at the first hint of danger, but I wouldn’t wait until scientists were unanimous that current exposure levels cause massive increases in lung cancer.

Along with 19 other former presidents and fellows of the Society for Risk Analysis, I testified in favor of requiring risk analysis and of pushing scientists to estimate the most likely values using the best available scientific data and theories. The current practice of risk analysis by the Environmental Protection Agency and Food and Drug Administration tends to use too many default assumptions, be too slow to recognize new science, and to favor arbitrarily conservative assumptions. The regulatory reform legislation addresses all three of these problems. In my judgment, it will do much to give the public and our leaders better information to manage risks and will speed progress in the science of risk analysis.

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