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OUR UNSCIENTIFIC REGULATORY WAR ON “CARCINOGENS”: TIME FOR AN ARMISTICE

by

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America’s limited health resources are being squandered in a vain attempt to squash public health ants, while diverting energies away from rampaging public health elephants. Two recent news items are illustrative: The National Toxicology Program (NTP), a division of the Department of Health and Human Services (HHS), released its 11th biennial edition of the “Report on Carcinogens;” and the President sent his budget to Congress, containing significant cuts in a variety of domestic programs.

For almost fifty years, the American consumer has been told that there is a “cancer epidemic” and that trace levels of synthetic chemicals in their food and water are the main culprits. They have been told that cancer is a modern disease, linked to a small number of synthetic chemicals which can be identified using high-dose animal tests, and that removing these substances from our food supply, air and water will vastly reduce cancer rates.

None of these notions are true—yet our entire regulatory apparatus related to chemicals in the environment is based on these pillars of salt. The NTP, its directorate at the National Institute of Environmental Health Sciences (NIEHS), the Environmental Protection Agency (EPA), and other regulatory bodies devote the bulk of their multi-billion dollar budgets to reducing, eradicating, and measuring trace levels of synthetic chemicals in environmental media and food. Why? The only conceivable justification for such massive expenditures is to improve our health and increase longevity by preventing cancers which have their origin in exposure to chemicals.

Yet it is a fact that trace amounts of synthetic chemicals do not promote adverse health events, specifically cancer, in Americans.¹ The “rodent-is-a-little-man” hypothesis of carcinogen testing has spawned unprecedented increases in environmental regulation and has contributed

¹This is the conclusion of a recently published book, *America’s War on “Carcinogens”: Reassessing the Use of Animal Tests to Predict Human Cancer Risk* (The American Council on Science and Health, New York, 2005). http://www.acsh.org/publications/pubID.990/pub_detail.asp.

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substantially to the cost of many consumer goods and services, insurance premiums, legal fees, and taxes at every level, while reducing job opportunities (except for regulators and lawyers) and incentives for innovation. The thicket of federal and state laws and regulations—including “Superfund,” Proposition 65 in California, federal regulation of pesticides and food additives—all assume that whatever causes cancer in a rodent, at whatever dosage/exposure, will probably cause human cancer. These laws disrupt commerce and productivity, adversely impact our food supply and consumer choice, and, perhaps worst of all, distract attention and resources from the actual, preventable causes of cancer in Americans.

The genesis of the hugely expensive, distracting regulatory approach to “carcinogens” was the so-called Delaney Clause of the Food Drug and Cosmetic Act of 1958, which mandated the proscription of any synthetic food additive found to be an animal carcinogen, regardless at what dose the toxic effect occurred, regardless of the infinitesimal exposure to humans, and regardless of the potential benefit of the substance banned. “Chemophobia” reigned at that time; the situation was only partially ameliorated in 1996 with the passage of the Food Quality Protection Act, which exempted certain pesticide residues. The fear of chemicals has become entrenched in our society and in our regulatory culture with essentially no scientific support, but also without organized scientific protest—until now.²

This situation grew only worse as the years passed, with Rachel Carson’s book *Silent Spring*, the thalidomide disaster, worsening air and water pollution, and the resulting establishment of the EPA in 1972. Indeed, one of the first notable EPA actions was possibly the single worst decision in regulatory history in terms of its anti-science and anti-human ramifications: the banning of DDT, the most effective protector against malaria ever known. The human toll of this ban is counted in the hundreds of millions over the past 35 years. No thought was given then, or now, to the well-known toxicological precept that anything is toxic in sufficient dose: “the dose makes the poison”—but not for the NTP or the EPA. No thought was given, then or now, to the availability, or lack thereof, of alternatives to banned “carcinogens.” Thus, millions have to die without any effective DDT alternative.

In fact, while some of the rules promulgated at EPA and its daughter regulatory bodies have been effective at reducing the worst of the pollutants’ ravages, especially in air quality, the effects of the persistent assault against trace levels of synthetic chemicals has been an unmitigated failure, a complete waste of efforts and money, and a major distraction from addressing the real causes of cancer in America.

Further, this misdirected war on “carcinogens” accounts for the frequent health scares popping up on the news and in full-page ads in newspapers, calling for consumers to avoid various foods and products, often naming children as the most vulnerable to these alleged toxins. Activist groups, often in consort with media acolytes looking for viewers, politicians seeking easy sound bites, and plaintiffs’ lawyers looking for their next litigation opportunity, propagate these alarms. All of these scares—examples of which include cyclamates in 1969, saccharin in 1977, Alar in 1989, and PCBs in salmon in 2004—are the direct result of the inappropriate extrapolation of high-dose animal cancer tests to predict human cancer risk.³

²*See id.*

³*Facts versus Fears* (The American Council on Science and Health, New York, 4th Edition, 2004). http://www.acsh.org/publications/pubID.154/pub_detail.asp.

Several points illustrate the fallacy of trying to predict human cancer risk from rodent tests. First of all, toxicologists know that high-dose rat carcinogen tests cannot accurately predict mouse cancer risk—much less predict human cancer risk.

Second, testing chemicals that occur naturally in the food we eat for “carcinogenic” potential in rodents leads to the same results as testing synthetic chemicals. The effect of the resulting regulation is bizarre and inconsistent: older, more toxic substances are allowed, at acceptable levels—while newer chemicals are banned due to rodent assays, stifling innovation. Furthermore, the rate of cancer in the U.S. is declining despite the introduction of thousands of newly-synthesized chemicals since the introduction of the Delaney Clause.

Finally, in 1958 scientists looking for toxins could only detect them at levels in the parts-per-million or greater range; today, scientists can detect contaminants at parts-per-quintillion levels—equivalent to a drop of water in the ocean, or less. What do such levels mean to human health? Nothing at all.

The NTP’s “Report on Carcinogens” (ROC) puts this issue into stark perspective. <http://ntp.niehs.nih.gov/index.cfm?objectid=72016262-BDB7-CEBA-FA60E922B18C2540>. It lists 58 substances and agents “known” to be human carcinogens, and 188 others “reasonably anticipated” to be so. The problem: mixed in among the few well-characterized human cancer-causing agents (X-rays, human papillomavirus and hepatitis B virus, sunlight) are dozens of polysyllabic chemicals, whose sole transgression is that, at massive doses—orders of magnitude greater than any human exposure—they cause cancer in rodents (likely secondary to near-lethal tissue damage from the chemical tested). This list takes no account of the risk-benefit ratio, cost of regulation, or exposure level required to spur cancer. It takes no note of mechanistic differences in rodent pathophysiology, which often preclude any possibility of extrapolation to human tissues, even from high-dose exposures. And, such listing can trigger regulatory action in and of itself.⁴ The mere listing of a chemical on the ROC publication triggers other agency regulation, and spurs litigation under Proposition 65 in California.

The regulatory science practiced at the EPA/NTP is deficient and based on closely-held beliefs about high-dose animal testing, rather than upon relevant scientific or epidemiological data, and should be reevaluated and modified to conform to generally accepted scientific principles of risk assessment. Rather than relying on a few high-dose rodent tests to label a substance “carcinogenic” (or a “likely carcinogen”), the totality of the data should be considered, including evidence from multiple species and human epidemiology when available. This sort of approach is actually what FDA used for substances “grandfathered” at the time of the Delaney Clause, e.g., aflatoxin, a well-studied and potent human carcinogen, is allowed to be present in foods at minute levels known to be without risk at those levels. This same approach should be applied—based on sound science in risk analysis—to all suspected carcinogens, whether synthetic or natural.

That is not to say, however, that all animal testing as a method of predicting possible risk

⁴Although HHS/NTP denied that this was a likely consequence of its scattershot listings, the United States Court of Appeals for the D.C. Circuit, in *Tozzi v. U.S. Dept of HHS*, 271 F.3d 301 (D.C. Cir. 2001) asserted that such a chemical bull’s-eye was subject to judicial review, if the data upon which a listing was based might be flawed and/or politically-motivated.

from chemicals, pharmaceuticals, etc. is invalid. If a chemical causes cancer in several species, with an observable dose-response effect, such a chemical should be restricted and subject to further extensive testing. But such testing should be based on scientific principles and common sense, and be subject to rigorous analysis, and—the hallmark of the scientific method—be testable from lab to lab, not merely justified by dogma. However, even empiricism cannot support the current methodology, since trace levels of many banned “carcinogens” have never been linked to human cancer under any circumstances.

The “precautionary” approach to trace levels of chemicals federal regulators now adhere to is based on theoretical mechanisms, as well as fear and superstition. It is unscientific and counterproductive to the stated goal of our regulatory apparatus: to protect health and reduce the toll of cancer in America.

Now is the time—indeed, well beyond the time—to return to a sound science, peer-reviewed approach to risk assessment on human cancer risk. This approach is not only in keeping with the scientific method, but is also in keeping with the approach of the federal Office of Management and Budget’s Office of Information and Regulatory Analysis to risk assessment as promulgated in Administrator John Graham’s *Regulatory Review: Principles and Procedures*, Sept. 20, 2001.⁵

This memorandum calls for regulatory agencies to use the best available data and science in formulating regulations, demanding that risk assessments be “objective, realistic and scientifically balanced.” In addition, the regulatory agencies are directed to “select those approaches that maximize net benefits.”

These principles are not being implemented when it comes to assessing the risk of human cancer from synthetic chemicals. The EPA and NTP/NIEHS should take these principles into account when making new regulations about chemicals, and Congress should review any rules which are now clearly unscientific and burdensome to the public. The National Cancer Institute, as the center of the official government scientific outreach on cancer, should re-assert itself into the dialogue on the real causes of human cancer, taking back the ground it has ceded, in its silence, to the toxicologists at NTP/EPA.

The Delaney Clause-based rules add substantially to the cost of consumer products—estimated to be in the many billions of dollars—and have caused (and will continue to cause) the restriction and removal of beneficial products, and impede real progress towards reducing the toll of cancer among Americans—all “at the drop of a rat.”

⁵Graham, John D., MEMORANDUM FOR THE PRESIDENT’S MANAGEMENT COUNCIL: *Presidential Review of Agency Rulemaking by OIRA*. Sept.20, 2001, http://www.whitehouse.gov/omb/infoereg/oira_review-process.html