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Exposure assessment at a crossroads: The risk of success†

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Introduction

I am honored to have the opportunity to speak to you today — as a fellow scientist, a fellow advocate of exposure assessment, and as a friend. By the end of my remarks, I hope you will understand why I am deeply concerned about the future of exposure assessment. This new profession, which has contributed so much to risk analysis and offers such great potential for vast new insights, is itself at risk of being marginalized by external forces that do not have the best interests of exposure assessment at heart. Some of these forces were set in motion awhile ago; others by September 11th.

I too am an exposure assessor. In economics, the Law of Demand states that the quantity demanded of a thing declines as its price increases. We estimate the responsiveness of individuals and markets — that is, populations — based on small changes at the margin. You can think of price as equivalent to "dose" and changes in quantity demanded as "responses." Economists analyze how individuals and populations respond to small changes in their level of exposure to prices. The Law of Demand is the world's first dose–response function.

In my previous life at the U.S. Office of Management and Budget (OMB), I was a tireless advocate of greater funding for and reliance upon exposure assessment. In the three years since I left OMB, my respect for exposure assessment has not flagged.

Among other duties at OMB, I reviewed many epidemiological surveys and exposure assessment projects, including NHEXAS. OMB must approve such surveys pursuant to its authority under the Paperwork Reduction Act if they involve collecting the same information from 10 or more persons. One of the first lessons I learned after arriving at OMB was that every federal agency thought that the optimal sample size for a survey was nine.

An iconoclastic history of exposure assessment

I now want to paint an iconoclastic picture of the past, present and future of exposure assessment from the peculiar vantage point of an interloper economist. The future I will set forth is one that I hope you strive to avoid.

Past: The Cinderella Years

Exposure assessment was long the neglected stepchild in the risk assessment family. Health risk assessment struggled under the Wicked Hegemony of Toxicology. The evildoers poisoned rats and mice and read their entrails to predict what would happen to humans exposed to doses quite likely hundreds or thousands of times lower. In lieu of empirical data, the toxicologists relied on conservative default assumptions about exposure. These assumptions were close enough for government work.

Many of you broke into exposure assessment during what I call its *Cinderella* Years. The wicked stepmother toxicologists abused you mercilessly. You said risk assessment suffered from huge data gaps because the toxicologists were indifferent to exposure. They said, "Take a hike, but first clean out the sludge from our slimy vats and kettles." You said that real-world exposure data were needed to make informed estimates about risk. They said, "Get back to work, slaves, and fetch us more water to boil our Fisher 344 rats." You said that risk assessment required exposure assessment as well as hazard assessment. They said, "Exposure doesn't matter as long as hazard is enough to determine public policy." And you were both right.

Present: The Fat and Happy Years

Over time this criticism took its toll on the Wicked Hegemony of Toxicology. The risk assessment tent grew to include exposure assessment as almost an equal player.

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A number of great new projects were devised, coalitions were built to nurture them, and arguments were developed to market them. In every case I know, exposure was described as a significant data gap in the risk assessment paradigm.

NHEXAS marked the end of the *Cinderella* Years and the onset of the Fat and Happy Years. Exposure assessment met the Prince and learned that the glass slippers fit. The years since then have been filled with wedded bliss, progeny, and maybe a bit less attention to fitness. The Prince's hairline is receding, he now has a paunch, and he prefers to watch polo matches from the comfort of his Barcalounger. As for *Cinderella*, she has lost some of her girlish figure. The demands of chauffeuring her new charges around to soccer practice, ballet classes and the ubiquitous hazardous waste dump have taken their toll. She has put her glass slippers away on the top shelf of the closet in favor of a more sensible pair of flats.

The "Demand Side" of Exposure Assessment: Federal Agencies I am an economist so I think in terms of demand and supply. Funders, including federal agencies as well as corporations, have distinct interests that have to be accommodated. These interests are not necessarily consistent with filling data gaps in the risk assessment paradigm.

Federal agency support depends primarily on programmatic relevance and only secondarily on scientific merit. Programmatic relevance, in turn, is determined by the practical utility of exposure information toward meeting a regulatory or bureaucratic purpose.

Not all elements of an agency's agenda benefit equally from investments in exposure assessment. Economic theory predicts that agencies' interest in such investments rises with the size of the potentially exposed population and falls with the magnitude of hazard to the individual. For a chemical risk whose hazard is calculated to be large, investments in exposure data are not cost-effective because regulatory action can be taken without them. For a chemical risk whose hazard is estimated to be small, evidence of widespread exposure may be necessary to generate a sufficiently high degree of concern. Rarely will a regulatory agency say that anything within its jurisdiction is not a significant risk. Claims of programmatic success always must be tempered by caveats that the problem is much, much worse than we thought it was.

In recent years we have all heard about "stakeholders." That's a lovely, seemingly neutral term, but for what? — people and organizations who have a strong financial, organizational, political, or bureaucratic interest in the outcome. We talk about "round tables" and the need for stakeholder groups to be broadly representative. This is all foolishness. Some stakeholders have a great deal of power and influence, including in many cases, veto power. Other stakeholders participate as window dressing. Their presence merely confers legitimacy on the power brokers amongst them (Belzer, 1998). I have heard it said that a stakeholder is anyone with the means, motive and opportunity to participate. If that description sounds both accurate and indistinguishable from that of a criminal suspect, the parallel was neither accidental nor unintended.

Stakeholders have become a critical part of the "demand side" for federally funded research. Stakeholders provide the political muscle that is necessary to get Congress to authorize action and appropriate funds. A proposed federal research project that lacks stakeholder support is going nowhere. The converse, of course, also is true: a major federal research project that *is* going somewhere is probably going where the principal stakeholders want it to go — that is, toward their financial, organizational, political, or bureaucratic interests in the outcome.

The "Supply Side" of Exposure Assessment: Exposure Assessors Researchers desire sustained funding for their efforts because, like everyone else, they want to make a living and they dislike financial uncertainty. In some cases, they may desire more than that, such as the establishment or perpetuation of a research empire, or maybe great public accolades. Scientists who publish suffer a special set of perverse incentives. This begins with an inclination to look for things that interest them, and an occasionally consuming desire to find what they are looking for. Negative results are much less frequently published and carry little or no prestige, unless of course they prove a hated intellectual competitor to be dead wrong. That delightful and deeply rewarding special case aside, the worst possible outcome after a career in research is to have discovered nothing new, special, novel or revolutionary.

Researchers who need government funding supply services to meet the demands set forth by stakeholder alliances. We do so with vigor when we like what these alliances like, and we do so holding our noses if we are just trying to make a living. Some of us are privileged to work in areas that we find financially, intellectually and spiritually rewarding. We who love our work are especially prone to let our work fog our minds with self-importance, sometimes even a crusader's zeal and self-righteousness. Just ask our wives, increasingly our husbands, and especially our children. Oh, how they have suffered.

NHEXAS as an Example When it was first submitted to OMB for review under the Paperwork Reduction Act, NHEXAS was marketed as a three-part solution to all those pesky data gaps (Sexton et al., 1995). Phase I was going to prove the concept using a few relatively small, geographically distinct samples. In Phase II the show was headed for Broadway to great acclaim, including a national probability sample, a tighter focus and much lower costs per respondent. Then we were going to take on Phase III and get valid and

reliable exposure data for a host of subpopulations of special concern.[1] Phase I is largely completed, but little is heard any more about Phases II and III.

The original supporting statement for NHEXAS implied that it would provide reliable estimates of the upper tail of an n-dimensional joint probability distribution of persons highly exposed across multiple chemicals and multiple pathways.[2] Needless to say, the sample sizes necessary to obtain reliable estimates of this are much greater than the numbers that were proposed. Equally important, at OMB we were skeptical of the practical utility of obtaining the upper bound of an n-dimensional joint probability distribution when the broad middle of each individual exposure distribution had yet to be characterized.

As a result of OMB review, the project's objectives were scaled back to comport with its marketing literature. The revised objective was to (a) develop probability-based estimates of central tendency and the likely shape of exposure distributions for each chemical of interest; (b) uncover the most important exposure pathways and cull remote, speculative ones; and (c) develop improved methods that could be used for nationwide probability samples of vastly greater ambition and complexity (Phases II and III).

I should say at this point that no one at OMB ever checked to verify that Phase I was implemented according to research protocols used to support it. OMB acts like a protective father who does full FBI checks on all the gentlemen who come calling to court his daughters, but doesn't bother to verify that the girls ever came home, much less before midnight with their honor intact.

This may change, by the way. Preliminary research I have done based on a small convenience sample suggests that material noncompliance with published research protocols is widespread. This is a serious data quality problem, and it could lead to an expanded public disclosure requirement in which agencies must document *actual* compliance with their own research protocols whenever they use or disseminate data collected pursuant to an approved data collection. Such a disclosure requirement would certainly be a reasonable effort to enhance transparency and improve public accountability. For those of you who have research programs whose surveys were subject to OMB review, it would be a good idea to review these protocols occasionally — just to ensure that you are actually abiding by them, of course. Some departures from protocol could be deeply embarrassing.

NHEXAS was a product of the same demand and supply factors for federally funded research that I described earlier. Its design was neither an accident nor the optimal use of resources to address the most important environmental health problems in the US.

Consider the environmental pollutants and contaminants of interest when NHEXAS was designed. Listing them more or less in their order of priority, they were:

> Pesticides, pesticides, metals, pesticides, VOCs, pesticides, and of course, pesticides.

The really big environmental health issues of the day — fine particulate matter and mercury — were missing.

Fine PM was a huge scientific and policy issue at the time. It had been the subject of several large-scale epidemiology projects that associated premature mortality with short- and long-term ambient outdoor pollutant concentrations. The interpretation of these studies remains controversial; remember that the association between PM and mortality in one critical study was about as strong as the association between mortality and hard water (Krewski et al., 2000). Although weak, the observed associations extended over a huge population. The assumption of causality became the difference between thousands of premature deaths each year, and zero (Lutter and Belzer, 2000). One would think that an aggressive effort to collect indoor and personal exposure data for fine PM would illuminate both the nature of this risk and the available policy alternatives. In NHEXAS, however, fine PM was not a pollutant of concern.[3] Why?

Exposure to certain metals, especially from air pollution and food, also received considerable regulatory interest at this time. EPA was then engaged in a huge project required by the 1990 Clean Air Act Amendments to look at the entire array of hazardous air pollutants (HAPs) emitted by fossil fuel-fired power plants and to determine whether these emissions warranted regulation under Title III. Mercury was the HAP of greatest concern. There were no good data on mercury exposure in the general population, and different NHEXAS projects examined between 4 and 10 different metals. But not mercury. Why?

What was included in NHEXAS and what fell through the cracks were consistent with the predictions of the economic model I mentioned earlier. Concern in the

[1] EPA obtained specific legislative authorization for NHEXAS through similar representations. Then-Deputy Administrator Bob Sussman testified in 1994 that "ORD has now committed to complete the pilot phase of this program for the general population, and, in the future, to conduct special studies to examine subpopulations who may be more highly exposed" (Sussman, 1994).

[2] The Baltimore project had a different objective — determining whether short-term data could be extrapolated to estimate long-term exposure.

[3] Lioy (1999) dates NHEXAS' design as occurring in 1992, three years before OMB approval was obtained. He says PM2.5 was identified as a "critical need" for exposure analysis in "1995–96." Pursuant to well-known judicial deadlines, EPA's revised PM NAAQS was proposed in 1996 and finalized in 1997. Lioy is too generous; "critical need" for exposure data apparently was discovered only after the proposed PM NAAQS revision generated substantial controversy.

general public about pesticides had been flagging for years, and evidence of widespread exposure to pesticides, especially to children, was surely one way to rekindle it. Pesticides made an excellent candidate for a project like NHEXAS.[4]

Published ecologic studies on PM were judged adequate to tighten the NAAQS without real exposure data. Therefore, exposure data for fine PM were not important. Mercury had been explicitly blacklisted in the 1990 Clean Air Act Amendments. Emissions had to be reduced by at least 90% irrespective of human exposure or control cost.[5] Why does a regulatory agency need exposure information for such pollutants, when they do not matter for decision making?

On two instances at OMB I sought to fill these "data gaps." The first was a matchmaking exercise. During the late-1995 interagency review of EPA's draft report to Congress on mercury, reliable exposure data for the general population were both lacking and essential. EPA had calculated that 50% or more US women of childbearing age who consumed fish or shellfish, and 40% of girls, were exposed above the RfD.[6] Scientists in other government agencies hotly contested these calculations. We had either a serious health crisis on our hands or an impending risk communication disaster. Our review showed that these population risk estimates were extrapolated from exposure modeling based on short-term fish consumption surveys — not actual human exposure. According to these models, one swordfish meal was enough to ruin the fortunes of any children you were so brazen to conceive.

I nosed around and found out that the investigators performing the Region V component of NHEXAS had cleverly collected hair samples as a sort of a speculative investment in future research opportunities. I put them in touch with other federal agencies willing to fund mercury analysis, and the result was an excellent example of exposure assessment filling an important data gap that a critical stakeholder didn't want filled. Based on actual exposure data, CDC reported last March that one tenth of the population is exposed within an order of magnitude of the lower-bound of the benchmark dose (U.S. Centers for Disease Control and Prevention, 2001). Needless to say, this is a very different risk message. For now, at least, canned tuna is "safe."

The second instance was a highly expedited expansion of the Arizona component of NHEXAS to cover what was actually a major, freestanding exposure project in the border area. At the time, EPA was proposing to base the revised PM NAAQS for PM2.5 based on an assumed, linear and fixed relationship with PM10. So I conditioned my quick approval of the Arizona Border Extension Survey on an agreement with the principal investigators to simultaneously collect exposure data on both PM10 and PM2.5. While I haven't seen published research on these associations, many are looking forward to seeing them before the next NAAQS review. The results could significantly illuminate future decision making.

The invasion of the mission-creep body snatchers

The invasion of the mission-creep body snatchers occurred after NHEXAS was well underway. Suddenly, the range of problems for which it became the perfect solution began to grow like Topsy. I have counted more than a dozen significant grant applications claiming that vast secrets of the universe could be found in the NHEXAS database, if only the applicants' work were funded. In congressional testimony delivered in 1997, Bill Farland acknowledged that NHEXAS was "designed to provide baseline data," which is a fair enough characterization of its stated purpose. But he added that NHEXAS "also can be used to assess cumulative total exposure and risks [from][7] multiple environmental agents through multiple pathways" (Farland, 1997). This language sounds a lot like the plan submitted to OMB in which NHEXAS presumably would find the upper tail of an n-dimensional joint probability exposure distribution. As for *cumulative* exposure, this became a serious issue only after passage of the Food Quality Protection Act in 1996. That makes the design of NHEXAS a half-decade earlier a truly remarkable act of scientific prophecy.

To reinforce this point, I do not know anyone who believes that Congress had the remotest idea of what it was doing when it approved FQPA in the Senate by a voice vote (142 Congressional Record S8738) and in the House by 417-0 (142 Congressional Record H8148). Such votes typically are reserved for things like commemorations of Irritable Bowel Syndrome Awareness Month and the naming of rural post offices. The word

[4] Suggestions to the contrary notwithstanding, the passage of the Food Quality Protection Act in 1996 did not reflect any widespread public concern about pesticides. The action-forcing event was a strict judicial interpretation of the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, which threatened to eliminate the use of many pesticides for which benefits dramatically exceeded risks. FQPA then became the vehicle whereby numerous interest groups loaded up the measure with a host of pet projects and issues, including the evisceration of the historic practice of regulating pesticides based on balancing risks and benefits.

[5] The Dirty (Half) Dozen are listed at 42 USC 7412(c)(5): alkylated lead compounds, polycyclic organic matter, hexachlorobenzene, mercury, PCBs, and 2,3,7,8 TCDF and TCDD. Regulations achieving 90% emission reductions were required by November 15, 2000.

[6] See EPA (1995b), Figures 4-15 to 4-19 (women) and 4-20 to 4-29 (children).

[7] In original, "to."

"cumulative" appears just three times amidst approximately 21,000 words, and the contexts in which it was used do not suggest that anything revolutionary was intended.[8] Meanwhile, the scientific basis for the section on so-called "endocrine disruptors" was a single, high-profile article that appeared in *Science* in June 1996, two months before FQPA was enacted (Arnold et al., 1996). As you all know, that paper was formally withdrawn in 1997.[9] On October 12, 2001, the principal author was debarred for scientific misconduct, having manufactured the data for the article in a way that was apparently undetectable to his five coauthors.[10]

Over the past several years, the idea that exposure assessment was needed to "fill data gaps" has slowly given way to a dramatically different and, in my view, fundamentally inconsistent and dangerous alternative vision. Slowly but surely, exposure assessment is shifting away from concern about data gaps in risk assessment to a new focus on the body burden of chemicals. The word "burden" is key here, because it has a quintessentially negative connotation. Body burdens are always bad. No one talks about caviar and body burden in the same sentence.

To its credit, CDC did not use this term in its March 2001 *National Report on Human Exposure to Environmental Chemicals* (U.S. Centers for Disease Control and Prevention, 2001). Press releases are notorious for cutting corners on science, but the one that accompanied this study clearly stated that "[t]he presence of a chemical in blood or urine does not necessarily indicate that the chemical will cause disease."[11] This message vanished almost immediately, no doubt in large part because of Bill Moyers' public broadcasting expose *Trade Secrets* (Moyers and Jones, 2001). Predictably, media coverage of the CDC's report and Moyers' expose merged into one amorphous, murky and wholly nonscientific message that body burden is equivalent to risk.

This evolution has serious negative implications for exposure assessment. First, it says that all those pesky data gaps in the risk assessment paradigm weren't really as important as we said they were. The collection of exposure data — that is, data above the limit of detection — is an end in itself.

Second, supplanting exposure assessment with body burden abandons the risk assessment paradigm in favor of a quantity paradigm analogous to the Toxic Release Inventory (TRI). For whatever sins the Wicked Hegemony of Toxicology wrought because it ignored exposure, the TRI paradigm is worse because it ignores hazard, too.[12] This has become almost comical, as nontoxic substances such as chlorofluorocarbons — chemicals that are so benign that they are used as propellants in children's asthma inhalers — have been added to the TRI list of "toxic chemicals."

Third, body burdens are always with us, especially as the technology for detecting ever-smaller quantities improves. Mere detection could become the only measure of exposure that matters. If this occurs, there will be no market for your services beyond demonstrating the presence of one or more molecules. As evidence for this phenomenon I call your attention to one of the scientists favored by Bill Moyers in *Trade Secrets*, who was quoted in *JAMA* after the release of CDC's exposure report last March, saying with regard to phthalates:

> We know enough already. We should get it off the market. There's no reason in the world to put chemicals into human bodies that we know produce harmful effects in animals (Vastag, 2001).

[8] §408(b)(2)(C)(i)(III) (EPA must assess risk based on "available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity"); §408(b)(2)(D)(v) (EPA "shall consider, among other relevant factors," "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity"); and §408(p)(3)(B) (EPA "may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance," in the context of testing for endocrine effects).

[9] *Science* 277:462 (July 25, 1997).

[10] See 66 Fed. Reg. 52137: "Steven F. Arnold, PhD, Tulane University: Based on the report of an investigation conducted by Tulane University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Arnold, former Research Assistant Professor at the Center for Bioenvironmental Research at Tulane University Medical Center, engaged in scientific misconduct. Dr. Arnold committed scientific misconduct by intentionally falsifying the research results reported in Table 3 of a paper published in the journal *Science* and by providing falsified and fabricated materials to investigating officials at Tulane University in response to a request for original data to support the research results and conclusions reported in the *Science* paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the *Science* paper as a whole."

[11] Even CDC could not resist offering this project up to those whose sole interest seems to be finding the worst case. The press release also says "CDC will expand the Report to include exposure data from studies of people exposed from localized or point-source exposures (e.g., data on levels of mercury in people who eat mercury-contaminated fish from a polluted river)." See http://www.cdc.gov/nceh/dls/report/media/pressrelease321.htm.

[12] "TRI data alone cannot indicate the risk that chemical releases pose to human health and the environment... A determination of risk depends on many factors, including the toxicity of the chemical, the extent of exposure, the type of release, and the conditions of the environment. For example, small releases of highly toxic chemicals may present a greater risk than large releases of less toxic chemicals." See U.S. Environmental Protection Agency, 1995.

I noticed that all of you abided by this advice at last night's dinner at the Aquarium, and I fully expect that you will do so again at tomorrow night's oyster roast.

The National Children's Study nee Longitudinal Cohort Study: Permanent Employment for Exposure Assessors or Permanent Exile?

Children have become a fixation in environmental health for the better part of the last decade, and the seeds for this fixation were sown long before that. In 1993, a panel of the National Research Council reported the obvious facts that (a) children are not little adults, and that (b) they *might* face greater risks than adults because we really didn't know much about how their risks differ. I am summarizing, of course, because the NRC panel devoted hundreds of pages toward documenting these obvious facts, plus many more obvious facts that I won't mention in the interest of brevity.

I call these obvious facts because they were like dog-bites-man news stories. I do not recall anyone seriously claiming that children were little adults. Our lack of toxicological data on children reflected nothing more that a strong reticence about using them as laboratory guinea pigs. Our lack of exposure data could be remedied, but it was the same data gap that we had for adults.

Activists then spun these obvious facts into breathless prose alleging that chemicals *generally* pose greater hazards to children; that children are *consistently* exposed more than adults to these hazards; and that therefore they experience *unambiguously greater* risks. And the spin quickly overtook the science and found a home in public policy. Instead of uncertainty about *whether* children face greater risks than adults, it has now become a conventional wisdom that these risks are genuine. Said the Task Force on Children's Health Risks and Safety Risks in the opening sentence of its status report in July 2000, "[c]ompared to adults, children are at increased risk from environmental influences because of vulnerable developing systems and enhanced exposure" (President's Task Force on Environmental Health Risks and Safety Risks to Children, 2000). Well, maybe, though it looks to me like the marketing is getting ahead of the science. And empirical evidence contradicting the party line on these issues will most definitely be unwelcome.

The nascent National Children's Study (NCS) has similarly disturbing aspects. Children's health is the inverse of body burden, for as bad as anything with a body burden must be, there seems to be nothing that can't be marketed as long as children are clothed in it.

Last October, Congress enacted the Children's Health Act of 2000, which authorized this massive study. It was the culmination of years of stakeholder lobbying. According to the law, the purpose of this study is "to evaluate the effects of both chronic and intermittent exposures on child health and human development," while investigating "basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes."[13] The study also must "incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological and psychosocial environmental influences on children's well-being[.]"[14] Understanding these cosmic mysteries for most children isn't enough, because the study must "gather data on environmental influences and outcomes on diverse populations of children" and "consider health disparities among children," both of which "may include the consideration of prenatal exposures."[15]

To paraphrase an old saying, we could devote the efforts of an infinite number of PhDs to this assignment and never yield a result.

The NCS has become a stakeholder magnet — the long awaited vehicle for advancing any number of private agendas and political crusades.[16] It is a large positively charged near-earth object that is gathering more and more negatively charged detritus as it hurtles its way toward impact, I think in Atlanta. My concerns have been intensified by certain recent changes. The project's title has been changed from the Longitudinal Cohort Study to the National Children's Study (Scheidt, 2001), which certainly makes the study politically more marketable as its advocates press Congress to actually fund it with new money. But it also increases the study's already phenomenal Stakeholder Infection Quotient.

Already, the direction of the study is evolving in ways that appeal to the dominant stakeholders. Whereas early planning for the study took childhood injuries seriously,[17] the study now focuses on environmental exposures to industrial chemicals such as — surprise! — pesticides and phthalates.[18] There has been a lot of wordsmithing done to create the appearance of interest in socioeconomic factors in children's health, but I fully expect that the ultimate study design will look like these studies always do, with the usual weak boilerplate controls for socioeconomic factors but no serious consideration of their effects on children's health.

Where does exposure assessment fit into this grand plan? Actually, it's not at all clear, and to me it doesn't look good. Each stakeholder has an agenda and a plan for advancing certain interests. You can get a taste for these agendas by examining the hypotheses that planners expect the study to

[13] Section 1004(b)(1)–(2).

[14] Section 1004(c)(1).

[15] Section 1004(c)(2)–(3).

[16] For just one example, see The Partnership for Children's Health and the Environment (2001).

[17] See slide 8 of Scheidt (2001).

[18] See slide 4 in Scheidt (2001).

test. In the grab bag of so-called "operating hypotheses"[19] there are a number that fail the criteria that were set up to guide hypothesis selection.[20] Along the way, more accommodation to stakeholder interests can be expected to occur at the expense of science. The sage who said that the donkey is a horse designed by committee never had to deal with a major scientific survey supervised by stakeholders.

Congress authorized tens of millions of dollars for this project, but as far as I know, no additional funds have actually been appropriated.[21] Its full cost has not been reliably estimated, but it could easily consume the $50 million per year over ten years that I have heard tossed around as plausible figures. Is this something for which the American people want to pay a half billion dollars? I am skeptical that it was ever true, and I am positively disbelieving after September 11th.

Bioterrorism arouses anxieties much deeper and broader than any I have seen about trace levels of industrial chemicals and what the Children's Task Force calls "subtle, but important, effects of low-level environmental exposures" (President's Task Force on Environmental Health Risks and Safety Risks to Children, 2000). I tend to ignore public opinion polls and base my views on the actual behavior of actual people who won't fly, won't drive to the mall, and won't open their mail. I think this will moderate as people become more accustomed to our changed world, but I think it also reflects a fundamental change in public priorities. Some people might worry about pesticides, but more worry more about terrorists spraying them with crop dusters than farmers routinely spraying their fields to kill bugs and weeds. A few people might worry about plasticizers, but many more worry more about plastic explosives in checked airline luggage. Members of Congress who have been petrified of low-dose chemical risks have pleaded with EPA to gas their offices with chlorine dioxide.

Look at what has happened to irradiation. Ten years ago I was at OMB badgering the Food and Drug Administration and the Department of Agriculture to permit food to be irradiated because thousands of people — including a lot of children, by the way — were dying every year from foodborne pathogens. They said that the public wouldn't accept this technology because of its peculiar phobias about nuclear energy. I said the government ought to give consumers the choice and stop perversely cultivating these fears. In the ten years prior to September 11th, the government took baby steps toward permitting irradiation, provided that foods were labeled so as to scare the daylights out of potential buyers. Now, the mail is being irradiated, and soon the public won't buy food any other way.

The sheer amount of money that the NCS will cost, combined with the relatively limited installed scientific capacity for exposure assessment, poses special risks to this group. First, as much as some of you might want to get a piece of the action, it would be extremely difficult for *scientific* exposure assessment to get more than a few tempting crumbs. While it could be a full employment program for environmental epidemiologists, exposure assessment per se is likely to be a small part of that. Exposure assessment is expensive compared with epidemiology generally.

Second, should you be successful at commandeering a significant share of this honey pot and the project proceeds according to plan, you will find that the project consumes all of your time and energy for the next 30 years, or until retirement, whichever comes first. You may find yourself in high cotton, or you might just find yourself trapped. How many of you want to collect data for 20 years before publishing significant results? You'll have to do that if the project is seriously intended to be longitudinal. Be my guest if that's what appeals to you, but to me this sounds like the dissertation from hell.

Of course, grandiose projects generally do not proceed according to plan. Has any research program sustained public interest over a full generation? Sometime after you have made an irrevocable commitment to this huge enterprise, funds for it are going to slowly dry up. The public will grow tired of deifying children and will just want them to grow up already. The public will be attracted to other concerns, such as how to detect minute levels of some pathogens that terrorists might sneak into their gazpacho. Chemical and biological terrorism are fundamentally different and more worrisome than run-of-the-mill environmental exposure issues. We are talking about malevolent acts here, not harms resulting from scientific ignorance and the intricacies of random events. Will you be nimble enough to respond to changing circumstances, or will you be too wrapped up in collecting blood and urine from the next generation of unbearable teenagers for a now ancient project whose relevance was long ago forgotten?

If you choose this latter path, I predict that you will become just another stakeholder group devoted to protecting its perks, not protecting public health. We don't know exactly where it is located, but there is a tipping point beyond which so much money gets spent on a public policy issue that the livelihoods of thousands of people depend on its preservation and continued feeding, and sustaining these people becomes more important than the problem we hired them to solve. This has happened many times before. We have seen it in Superfund, nuclear waste cleanups, global climate change, and possibly food safety.

If you become just another interest group, Washington will deal with you the way it deals with other interest groups — that is, it will do the minimum necessary to get you off its back. With the sheer number of interest groups around

[19] See slides 11–12 of Scheidt (2001).
[20] See slide 10 of Scheidt (2001).
[21] The lack of funding is reported most recently in slide 5 of Scheidt (2001): "New money necessary."

today, and the likelihood that each has at least one interest group whose agenda directly conflicts with it, the prospects of successfully competing for resources are not too great. Government will sustain you financially, but at a level that is but a small fraction of the standard to which you would like to become accustomed.

Concluding Remarks

Exposure assessment is at a crossroads. It began as a scientific endeavor to fill data gaps that impeded proper implementation of the risk assessment paradigm. This is an honorable place to be, and it is certainly a large enough challenge. You don't need to look for bigger worlds to conquer.

Meanwhile, the scientific foundation of exposure assessment is besieged — first, by those who would replace the risk assessment paradigm with body burden; and second by those who would subordinate science to the pursuit of varied political objectives under the sentimental guise of children's health.

The National Children's Study could easily foster both ill winds. Their confluence portends synergistic adverse effects on exposure assessment as a scientific profession. Its advocates plan for it to require a huge amount of work over multiple decades. Its purpose, which has always been a little fuzzy around the edges because of the influence of stakeholders with nonscientific agendas, is more dubious than ever after September 11th.

Exposure assessment is the critical link between public concern and actual risk. It doesn't advance the profession if you continue to apply your intellects and extraordinary talents to solving small problems. Nor does it help if you are captured by short cuts like body burden or passing fashions like children's health. Take the opportunity now to devote your energies to the big environmental risk issues facing our world, even if your part in solving these mysteries sometimes appears to be hopelessly small.

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