EPA AT 40: REFLECTIONS ON THE OFFICE OF RESEARCH AND DEVELOPMENT

BERNARD D. GOLDSTEIN, MD*

The fortieth anniversary of EPA is an opportunity to congratulate the Agency on how far it has come and to consider the challenges of the future. It is a time to reminisce, to be nostalgic, and to reflect on the applicability to the future of the lessons of the past. In this idiosyncratic review of EPA's science and technology, I will begin by considering whether EPA should have an Office of Research and Development (ORD), and, if so, how should it be organized. This commentary will focus on the principals guiding the organization of research and development within EPA. It will explore the increasing importance of systems approaches, including the role of public health and sustainability, to provide EPA with the credible base for achieving its goals of protecting health and the environment. Every EPA administrator has affirmed the centrality of science and technology to accomplishing EPA's mission of protecting health and the environment and has projected the importance of science and technology to EPA's own staff and to the external community. Yet, in considering the role of science at EPA, one needs to go beyond the words to look at deeds, including budgetary support.[1] One example supporting cynicism is provided by a quote from Administrator Ann Gorsuch Burford, President Reagan's initial appointee as EPA administrator. In a book she wrote after being forced out of her role as administrator due to the perception that she was unwilling to address the nation's environmental concerns, Burford said, "When I entered EPA, zealotry poisoned every aspect of environmental protection and made intelligent judgment of the issues nearly impossible. We brought science and scientists into EPA to a greater degree than ever before, but we did not get credit for it."[2]

---

* Professor, Department of Environmental and Occupational Health, University of Pittsburgh Graduate School of Public Health.

1. Put another way, "Most administrators of the Environmental Protection Agency . . . pay lip service to science, particularly at their confirmation hearings." E. Donald Elliott, *Strengthening Science's Voice at EPA*, 66 LAW & CONTEMP. PROBS. 45, 45 (2003).

2. ANNE BURFORD WITH JOHN GREENYA, ARE YOU TOUGH ENOUGH? 275 (1986).

Yet one of the major criticisms during her tenure was that she had distorted the science to support her pro-industry position.[3] The blow to the reputation of EPA's science and technology efforts left scars that have not fully disappeared. A recent publication by Herman Miller of the Hoover Institute based a large part of its argument for the dissolution of EPA on its perceived scientific ineptitude.[4]

The impact of Administrator Burford on ORD is not one of the happiest recollections of the past, but the lesson is clear. Every EPA administrator will always proclaim that EPA's actions are based on the best possible science; no administrator will ever admit to ignoring or distorting science to achieve policy goals. EPA's leadership cannot be judged on what it says about science, but only on its actions.

When one looks beyond EPA's own statements, the Agency's actions indicate that science and technology are of less concern than programmatic activities. An example is the relative slowness at which the Assistant Administrator for Research and Development has been chosen by incoming administrations, whether Republican or Democratic. In virtually every new administration, the Assistant

---

3. In the same book she describes a budgetary battle with OMB because of her wanting a larger Superfund budget in which the compromise was to cut money from the R&D budget. *Id.* at 77. She also quotes Ed Meese as saying, "If we give you all that research money, all you'll do is go out and find more problems that need to be solved." *Id*. at 80. For further description of the troubled period, see Daniel Benjamin, *Mutually Assured Corruption; The Justice Department and Anne Burford's EPA*, WASH. MONTHLY, Jan. 1986, *available at* Academic OneFile, Doc. No. A4080006.

4. Henry I. Miller, *Happy Birthday EPA?*, REGULATION, Spring 2011, at 4, *available at* Academic OnFile, Doc. No. A253305211. Miller's call for getting rid of EPA is echoed by the American Council of Science and Health with the following quote from Miller: "Notwithstanding Jackson's claims to the contrary, many critics—including this writer—believe that the 40-year experiment with a free-standing EPA has been a failure and that the agency should be abolished and its essential functions reassigned to other, less scientifically challenged government organizations. But that is unlikely to happen because, over the years, the EPA has, in effect, bought the loyalty of a cadre of scientists and advocacy organizations that will defend the agency's precautionary approach and expansionist tendencies. For the foreseeable future, then, American companies and consumers—and our natural environment—will bear the scars of bureaucratic ambition, incompetence, and chicanery." *Id.* at 6. *See also The EPA: More Trouble Than It's Worth and Should Be Abolished, Says Dr. Miller*, AM. COUNCIL ON SCI. & HEALTH (Mar. 29, 2011), http://www.acsh.org/factsfears/newsID.2484/news_detail.asp. Other major recent attacks on EPA have usually fallen short of dismemberment; for example, Newt Gingrich has called for the downsizing of EPA and a change in its name to the Environmental Solutions Agency. *Gingrich Calls for Replacing the EPA*, USA TODAY, Jan. 25, 2011, http://www.usatoday.com/news/washington/environment/2011-01-25-gingrich-epa_N.htm.

Administrator for ORD has been among the last EPA assistant administrators confirmed by the Senate.[5]

I. SHOULD EPA HAVE AN OFFICE OF RESEARCH AND DEVELOPMENT?

EPA's fortieth birthday provides an opportunity to reflect both on the organization of science within EPA as a whole and on the organizational structure within the Office of Research and Development. After forty years it may seem inevitable that there is an organizational structure within EPA, the Office of Research and Development, that has the primary responsibility for science and technology. But other structures are possible. An obvious example for comparison resulted from the almost contemporaneous passage of the Occupational Safety and Health Act which formed the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH).[6] Despite being developed almost simultaneously, and both having mandates to protect against chemical risk, EPA, on the one hand, and OSHA and NIOSH, on the other, embody two very different approaches to the organization of scientific input.

The scientific and technical components of EPA and OSHA are organized very differently. EPA contains its scientific and technical arm, the Office of Research and Development, within its own organizational structure. The Assistant Administrator (AA) for Research and Development, who is the head of ORD, is a political appointee at a level of other AAs heading EPA program offices.[7] In contrast, OSHA and its scientific and technical adviser, NIOSH, are parts of two completely separate Cabinet-level departments, the

5. This is not always because they are the last selected. Bailus Walker, Jr., then Dean of the University of Oklahoma School of Public Health, was chosen relatively early by President Clinton, but the long delay in the appointment process caused him to withdraw from consideration. Similarly, the present AA for ORD, Paul Anastas, was not the last selected by President Obama, but his nomination was held up for many months by Senator Vitter of Louisiana before a compromise was reached on the Senator's demand that EPA's formaldehyde risk assessment be reviewed by the National Academy of Sciences. In both instances one wonders whether the process would have moved more quickly had the individual been nominated as AA of a program office. Joaquin Sapin & ProPublica, *How Senator Vitter Battled the EPA Over Formaldehyde's Link to Cancer*, SCI. AM., Apr. 16, 2011, http://www.scientificamerican.com/article.cfm?id=vitter-formaldehyde-epa; *EPA Nominations Made*, 101 ENVTL. HEALTH PERSP. 469, 469 (1993).

6. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590.

7. *See Environmental Protection Agency*, U.S. GOV'T ACCOUNTABILITY OFFICE, http://www.gao.gov/highrisk/agency/epa/index.php#reports (last visited Nov. 1, 2011).

Department of Labor and the Department of Health and Human Services, respectively. The head of OSHA is an Assistant Secretary of Labor while the Director of NIOSH is further down the Health and Human Services bureaucracy; the Director of NIOSH in fact reports to the head of the Centers for Disease Control—who reports to the Assistant Secretary for Health at Health and Human Services.[8]

Because of these differences in structure, there are major differences in the way ORD and NIOSH are funded and reviewed. At EPA, the AA of ORD must vie *within* the Agency for budgetary support, and the AA can expect that ORD's budget will be subject to review within EPA, by the Office of Management and Budget (OMB), and by Congress, and will be judged by its responsiveness to the needs of the program offices to accomplish the broad strategic goals of EPA. In contrast, OSHA and NIOSH respond not only to different agency heads but also to different intra-OMB and congressional oversight committees—although there are some attempts to coordinate review. The advantage of the OSHA–NIOSH relationship is that it protects NIOSH scientific and technical staff from being too closely beholden to OSHA's political needs. This pressure clearly exists at EPA—sometimes overt, sometimes subtle, but never totally absent.[9] In my experience, such pressure rarely impacts the scientific and technical advice given to EPA regulators, but it is not uncommon for opponents of EPA's actions to publicly attack EPA on the basis of its science or scientists being too closely linked with the position of EPA's leadership.[10] Despite outside criticism, this proximity offers benefits to EPA: It fosters both formal and informal exchanges that promote EPA's efforts to base its regulatory decisions on the best available science and that encourage the incorporation of new science and technology into EPA's regulatory initiatives. In contrast, the wide organizational split between OSHA and NIOSH by its very nature decreases the likelihood that research will be relevant to regulatory needs. It seems unquestionable that in their forty-year histories, EPA has done a far

8. NIOSH has had recurrent difficulty maintaining its identity and independence in its location within the Centers for Disease Control. An attempt by the George W. Bush administration to merge NIOSH within a cluster of other CDC Centers was narrowly defeated. Denny Dobbin, *Where to Put NIOSH?*, MEDSCAPE PUB. HEALTH & PREVENTION, May 31, 2005, http://www.medscape.com/viewarticle/504483.

9. U.S. ENVTL. PROT. AGENCY, EPA/600/9-91/050, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS 37 (1992) [hereinafter SAFEGUARDING THE FUTURE].

10. *See supra* note 4 and accompanying text.

better job in establishing chemical specific guidelines aimed at protecting the health of the public than OSHA has done with regard to workers.[11] While other reasons may contribute to this major discrepancy, the organizational structure of science and technology within EPA likely deserves some credit for EPA's relative effectiveness.

II. HOW SHOULD ORD BE INTERNALLY STRUCTURED?

ORD has two major responsibilities with regard to EPA's needs: (1) the performance of pertinent scientific and technical research and (2) the translation of their own work and the work of the scientific community for use by EPA regulators and its stakeholders. EPA's budget contains funds for research and development (R&D) work by ORD's scientific and technical staff within EPA's headquarters and ORD's laboratories, and it also supports R&D by the broader scientific and technical community through an extramural program. The relative extent of intramural and extramural research has shifted through the years, partly through the decisions of ORD's leadership and partly through the congressional "pork barrel" process. Numerous funding processes have been used. Particularly pertinent to EPA's future in an era of increasing partisanship are those funding processes which provide a buffer between EPA's research selection process and those of the scientific community. An excellent example is the Health Effects Institute (HEI) which is funded equally by EPA

11. When it was formed, OSHA inherited its workplace air standards from the American Council of Government and Industrial Hygienists and the American National Standards Institute. Based on the accumulation of new toxicological information, in 1989 OSHA reduced the PELs for 212 toxic air contaminants and established PELs for 164 that were previously unregulated. These were all vacated in a 1992 Eleventh Circuit decision. *Am. Fed'n of Labor & Cong. of Indus. Orgs. v. U.S. Occupational Safety & Health Admin.*, 965 F.2d 962, 968 (11th Cir. 1992). *See also* Kent D. Strader, *OSHA's Air Contaminants Standard Revision Succumbs to Substantial Evidence Test*, 63 U. CIN. L. REV. 351 (1993–1994). As stated by OSHA in 1999, when announcing its intention to develop regulatory approaches to update the older standards, "The Court's decision to vacate the rule forced the Agency to return to the earlier, insufficiently protective limits." Permissible Exposure Limits (PELs) for Air Contaminants, 61 Fed. Reg. 62,104, 62,104 (Nov. 29, 1996). However, with a few exceptions, OSHA has been unable to manage the regulatory initiatives needed to update almost all of these antiquated PELs let alone deal with newer chemicals at the workplace for which PELs should be established. Comment of Adam Finkel, Univ. of Penn. Law School, Document ID No. OSHA-H022K-2006-0062-0401 (Dec. 29, 2009) (commenting on Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 74 FR 50,280 (Sept. 30, 2009)), *available at* http://www.regulations.gov/#!documentDetail;D=OSHA-H022K-2006-0062-0401;oldLink=false.

and the automobile industry.[12] It has its own independent board and separate committees to select among research proposals and to review the final research product in detail. At the request of EPA and industry, HEI has often provided specific reviews of controversial scientific subjects.[13] Congress also established the National Urban Air Toxics Research Center, also known as the Mickey Leland Center, which has also done good work but is chronically underfunded.[14]

Translation of science to meet EPA's regulatory requirements is most effective when it occurs early and often in the process leading to the regulations. A good model is how lawyers from EPA's Office of General Council (OGC) participate in regulatory development. EPA program offices regularly include an OGC lawyer in their deliberations. The OGC attorney has two key functions. One is to provide guidance about what is permitted by the specific law under which the new regulations are being drafted. The second is to convey to the rest of OGC and to their outside legal advisors areas of uncertainty for which clarification may be helpful in developing the new regulations.

In the same way, regulation development groups within EPA program offices should routinely involve an ORD scientist or engineer in doing their work. This individual could speak up when a proposed regulatory approach was not based on credible science. He or she would also be able to enlist ORD scientists and EPA's outside scientific community in obtaining or developing the scientific information needed to narrow scientific and technical uncertainties relevant to the regulatory development process. It is important that this information be exchanged early in the process. The amount of effort that is invested in regulatory development—often under a deadline imposed by Congress or by a court and with significant

12. Terry J. Keating, *Lessons from the Recent History of the Health Effects Institute*, 26 SCI., TECH. & HUMAN VALUES 409 (2001); David H. Guston, *Boundary Organizations in Environmental Policy and Science: An Introduction*, 26 SCI., TECH. & HUMAN VALUES 399 (2001).

13. For HEI activities, see its web page, HEALTH EFFECTS INST., http://www.healtheffects.org/ (last visited June 29, 2011). In the social science literature HEI is considered an example of a successful boundary organization. Guston, *supra* note 12, *at* 403. Its effectiveness has also been reviewed by Keating, *supra* note 12, at 409. Boundary organizations have also been proposed as appropriate for the controversial subject of climate change. Clark Miller, *Hybrid Management: Boundary Organizations, Science Policy, and Environmental Governance in the Climate Regime*, 26 SCI., TECH. & HUMAN VALUES 478 (2001).

14. For further information on NUATRC, see MICKEY LELAND NAT'L URBAN AIR TOXICS RESEARCH CTR., http://www.sph.uth.tmc.edu/mleland/ (last updated Apr. 3, 2011). Note that I have been involved at the management level of both HEI and NUATRC.

public scrutiny—makes it very difficult for any ORD qualms about the scientific credibility of the proposed regulation to be heard late in the process. Also, it is then too late to initiate the research that could have narrowed uncertainties if only EPA's scientific community had been aware of its need.[15]

ORD has an internal organizational issue that it shares with every R&D organization. Should it organize by its scientific disciplines, or should it organize by its clients' needs? In academia we organize by disciplines, in part because we believe this is the best way to advance our science—to promote a vibrant culture supporting cutting edge research and advanced educational opportunities. In contrast, industrial research tends to be organized to be responsive to the company's specific needs, often in a matrix structure in which those responsible for science and technology are in the same room with product designers and marketers. Initially, EPA organized itself both by disciplines and by client. The laboratories were placed in disciplinary divisions that corresponded to health science (primarily toxicology), environmental services (primarily ecology), engineering, and monitoring. Geography served to help meet the goal of client responsiveness. The laboratories in each division primarily concerned with air pollution were located in North Carolina near a major concentration of regulators working in the Office of Air and Radiation. Similarly, laboratories and programmatic activities related to water pollution were concentrated in Cincinnati near a component of the Office of Water. As risk assessment became more of a guiding factor in the agency's management practices, ORD was reorganized

15. It is not just a question of whether the regulation itself is based upon credible science concerning the adverse environmental effect; it also has to do with whether the regulatory target is appropriate to address the adverse environmental effect. Two examples of poor target-setting from the Clean Air Act are the setting of the original particulate standard by weight, even though it was known at the time that it was only the lower weight fine particles that could be inhaled deeply into the lung where the adverse consequences were occurring. This led to engineering approaches which met the total suspended particulate standard by targeting larger and heavier particles, but had minimal effects on the fine particles that were responsible for the health effects targeted by the standard. For example, Wilson and colleagues, in 1948, using radioactive particles of different sizes, had shown that only the fine particle size penetrated deeply into the lung. Bernard D. Goldstein, *Profiles in Toxicology: Sydney Laskin (1919-1976)*, 73 TOXICOLOGICAL SCI. 4, 4 (2003); H.B. Wilson et al., *The Relationship of Particle Size of Uranium Dioxide Dust to Toxicity Following Inhalation by Animals*, 30 J. INDUS. HYGIENE & TOXICOLOGY 319 (1948). Similarly, using a one hour averaging time for the ozone standard was the wrong target to protect children being exposed while playing out of doors all day long on the warm days on which elevated ozone levels typically occur. *See* Peter J.A. Rombout, Paul J. Lioy & Bernard D. Goldstein, *Rationale for an Eight-Hour Ozone Standard*, 36 J. AIR POLLUTION CONTROL ASS'N 913 (1986).

to focus on the elements of the risk assessment paradigm.[16] More recently, Paul Anastas, the EPA Assistant Administrator for R&D, has proposed a further reorganization of ORD based on sustainability—which he calls the "true north" of EPA and which would be part of a transition toward a broader, agency-wide focus on sustainability within EPA.[17]

A test of the value of ORD's organizational structure is its contribution to setting an effective research agenda. The interface between science and policy that results in setting the research agenda of a regulatory agency needs further exploration.[18] Ideally, EPA's R&D activities ought to reflect its policy needs, leavened with understanding of scientific feasibility. For example, the uncertainties crucial to the agency's highest policy priorities may not be resolvable in the foreseeable future due to limitations in scientific understanding, while the uncertainties relevant to a lower priority may well be resolvable with specific research activity. Accordingly, ORD's budgetary priorities may not reflect the Agency's priorities. ORD also needs the ability to act on issues that, though they cut across all of the program offices, are not looked upon by any one office as a particularly high priority.[19] For example, developing an improved predictive toxicology test to determine the likelihood of a

16. MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 66 (1999).

17. *Fiscal Year 2011 Research and Development Budget Proposals at the Environmental Protection Agency (EPA) and the National Oceanic and Atmospheric Administration (NOAA) Before the H. Comm. on Sci. & Tech.*, 111th Cong. 19 (2010) (statement of Paul Anastas, Assistant Administrator, Office of Research and Development, U.S. Environmental Protection Agency).

18. While I cannot back up this assertion with evidence, my impression is that when a Democrat is in power EPA tends to focus more on hazard identification while with a Republican administration the focus is on exposure assessment and dose response. Identifying hazards, such as the presence of chemicals in human breast milk, can be a driver for regulation, particularly under the precautionary principle. In contrast, as EPA already has built in a series of prudent default assumptions in its dose response assessments, the development of science that allows the agency to make decisions based upon actual data is believed by industry to produce less conservative risk values. As an example, following a well-publicized exposé of air pollution and US schools based upon modeling of industry emission data, *The Smokestack Effect: Toxic Air and America's Schools*, USA TODAY, http://content.usatoday.com/news/nation/environment/smokestack/index (last visited June 28, 2011), EPA developed a monitoring program to measure the air pollutant levels at 63 schools in 22 states. Based upon my review, with about half of the schools being completed, the actual measurements of pollutants in outdoor air have been found to be lower than modeled in virtually all. *See Assessing Outdoor Air Near Schools*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/schoolair/index.html (last visited Nov. 8, 2011).

19. SAFEGUARDING THE FUTURE, *supra* note 9, at 33.

chemical causing reproductive and developmental effects is pertinent to all while not necessarily being a sufficiently high priority to any one program office to get their endorsement over their shorter term R&D needs. This argues for the participation of senior EPA policy officials who can look across agency needs, both short term and long term, being involved in setting the research agenda. Ideally, ORD staff involved in translation of existing research findings to EPA leadership and to the program offices will also be heavily involved in setting the research agenda through an iterative process in which crucial uncertainties will be identified.

III. THE NEED FOR A SYSTEMS APPROACH IN EPA'S RESEARCH AND DEVELOPMENT AND THE ROLE OF PUBLIC HEALTH

There are a long list of commentators, commissions, and committees that have repetitively pointed out the need for integration across EPA's many different media-specific activities and laws.[20] Problems caused by the "stovepiping" inherent in media-specific approaches are well recognized. A cautionary example of a major problem caused by the failure to recognize cross-media issues is the use of methyl tert-butyl ether (MTBE) as a gasoline oxygenate. The EPA Air Office actively sought a mandate in the 1990 Clean Air Act Amendments for oxygenates to be added to gasoline.[21] The petrochemical industry pushed hard for that oxygenate to be MTBE rather than ethanol, which was the choice of the agriculture industry. The result was the rapid adoption of MTBE as a major additive to gasoline, at levels ranging from ten to fifteen percent by volume for a large portion of the nation's gasoline. But it was known by the petrochemical industry that MTBE would move more rapidly into groundwater than any other gasoline component, that it had a bad taste and smell, and that it was impervious to decomposition by usual soil bacteria. In view of the many leaking underground gasoline storage tanks, it should have been of no surprise that MTBE resulted

20. For one example, see *id.*

21. Adding an oxygenate to gasoline led to a decrease in carbon monoxide (CO) production. While effective, the CO standard would have been met in a short time without the addition of oxygenates just by the replacement of older polluting cars with newer cars. Advocacy of oxygenates also has been based on alleged improvement in ozone formation. Serap Erdal & Bernard D. Goldstein, *Methyl* tert*-butyl Ether as a Gasoline Oxygenate: Lessons for Environmental Public Policy*, 25 ANN. REV. ENERGY & ENV'T 765, 792 (2000); Bernard D. Goldstein, *MTBE: A Poster Child for Exposure Assessment as Central to Effective TSCA Reform*, 20 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 229, 229 (2010).

in major contamination of the nation's water supplies.[22] Yet the EPA water office officials responsible for protecting the nation's water supplies—located just one floor away from the EPA Air Office—did not appear aware of the major impact on water resources being engineered by their colleagues in the air office. To compound matters, MTBE was not a new compound and so was regulated under the provisions of the Toxic Substances Control Act dealing with existing chemicals. This led to a consent decree to perform two year animal studies. The finding that MTBE was an animal carcinogen occurred after the petrochemical industry's major investment in MTBE production,[23] which rapidly became one of the largest commodity chemicals in the world by volume.[24] Not surprisingly, an extensive amount of research funded by the industry was primarily aimed at explaining away these inconvenient findings rather than determining if they were correct.[25]

---

22. J. MICHAEL DAVIS ET AL., OFFICE OF RESEARCH & DEV., U.S. ENVTL. PROT. AGENCY, EPA/600/R-98/048, OXYGENATES IN WATER: CRITICAL INFORMATION AND RESEARCH NEEDS (1998); J. Michael Davis & William H. Farland, *The Paradoxes of MBTE*, 61 TOXICOLOGICAL SCI. 211 (2001); Erdal & Goldstein, *supra* note 21.

23. *See* Fiorella Belpoggi et al., *Results of Long-Term Experimental Studies on the Carcinogenicity of Methyl* tert-*Butyl Ether*, 837 ANNALS N.Y. ACAD. SCIS. 77 (1997); M.G. Bird et al., *Oncogenicity Studies of Inhaled Methyl Tertiary-butyl Ether (MTBE) in CD-1 Mice and F-344 Rats*, 17 J. APPLIED TOXICOLOGY S45 (1997).

24. While I am somewhat of a skeptic about the precautionary principle—see, for example, Bernard D. Goldstein, *The Precautionary Principle: Is It a Threat to Toxicological Science?*, 25 INT'L J. TOXICOLOGY 3 (2006), and Bernard D. Goldstein, *Problems in Applying the Precautionary Principle to Public Health*, 64 OCCUPATIONAL & ENVTL. MED. 571 (2007)—the MTBE situation is a good example of the precautionary importance of shifting the burden of proof to industry to prove safety rather than the government to prove harm. In this case, the trigger should have been recognition that the sudden jump in exposure to over 100 million Americans was sufficient to ascertain that the compound was harmless before major investments were made. Instead, a decision to remove MTBE from gasoline was delayed through the repetitive formation of multiple commissions and panels. Another example of the importance of exposure levels in decisions about sufficient information to allow a chemical to be used is the dispersant used in the Deepwater Horizon oil spill which had also been used before but never close to the million gallon level suddenly employed in the Gulf. The dispersant revealed another weakness in TSCA, as the secrecy about its composition was a great concern to the general public and probably contributed to the psychosocial impacts. Bernard D. Goldstein, *The Gulf Oil Spill*, 364 NEW ENG. J. MED. 1334, 1334 (2011). However, it was revealed later with little fanfare that the "organic sulfonic acid salt (Proprietary)" listed on the dispersant's material safety data sheet was in fact a commonly used stool softener which is usually ingested at a far higher dose than any level likely to be present as a result of its being sprayed on the Gulf—although whether the dispersant contributes to ecological effects is not fully resolved. *Id.* at 1338.

25. Now, MTBE has been largely phased out of gasoline, in part because of pressure exerted by the Clinton administration. *See* Methyl Tertiary Butyl Ether (MTBE); Advance Notice of Intent to Initiate Rulemaking Under the Toxic Substances Control Act to Eliminate

Systems approaches at EPA are needed, not just among the program offices, but also within ORD. Modern environmental problems require an R&D approach that cuts across many different scientific disciplines.[26] Whether called "multi-" or "trans-" or "inter-" or "cross-disciplinary," there needs to be cooperative interaction among scientific and technical experts in order to understand and provide the basis for approaching any environmental issue, whether the control of a specific air pollutant or major all-encompassing environmental problems such as global climate change.[27]

Public health fits well with a systems approach to issues, as it is inherently a multidisciplinary field. For accreditation, graduate public health education must provide five required core areas: epidemiology, biostatistics, health policy and management, behavioral and community health science, and environmental health. The core disciplines of the faculty range from social science and economics to laboratory science, applied mathematics, medicine, and law.[28] The milieu of a school of public health is one where experts in any of these disciplines have an enhanced opportunity to interact with others—in

---

or Limit the Use of MTBE as a Fuel Additive in Gasoline, 65 Fed. Reg. 16,094 (Mar. 24, 2000). But the industry has finally mounted another two year animal study whose results are only slowly being released. *See supra* note 22. This time brain cancer was observed, which again is being explained away rather than studied for what it might tell us about an actual risk. Note that I am an expert witness in a plaintiff's suit concerning MTBE groundwater contamination.

26. Two of the disciplines central to EPA's R&D mission, toxicology and epidemiology, are subjects of review chapters in the Federal Judicial Center's Reference Manual on Scientific Evidence. *See* Michael D. Green, D. Mical Freedman & Leon Gordis, *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333 (Fed. Judicial Ctr. ed., 2d ed. 2000); Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, *supra*, at 401. A separate chapter on exposure analysis is planned for the forthcoming edition.

27. I was AA for ORD in 1984 when the first funding was received by EPA specifically on the issue of global climate change. ORD's proposal was for the Corvallis laboratory to use its greenhouses to study the impact of increased carbon dioxide levels on ecosystems. Instead, the funding was given to the Office of Air and Radiation which primarily used it to develop computer models related to carbon dioxide accumulation and temperature. In my view this typifies what mistakenly has been a relative overemphasis on understanding the global geochemical processes at the cost of studying the impact of global climate change. Both are needed—but it is unreasonable to expect the American public to respond unless it is aware of the impact.

28. Schools of public health are the only schools on campus that require coursework and programs in environmental health for accreditation. All graduates must have at least a core course in environmental health, and those sitting for the core certification examination can expect a substantial number of questions related to environmental health. National Board of Public Health Examiners. *See* COUNCIL ON EDUC. FOR PUB. HEALTH, ACCREDITATION CRITERIA: SCHOOLS OF PUBLIC HEALTH 10 (2005), *available at* http://www.ceph.org/pdf/SPH-Criteria.pdf.

fact there is a mantra that such interaction is required as there are no major public health problems that can be solved by any one discipline acting alone. ORD already has much of this mixture in place, although better representation of social sciences is needed.[29] Of note is the recent formal development of a Public Health organizational structure within ORD that focuses on the importance of the environment to human health and its implications to health care.[30]

The relation of public health to sustainability was implicit in Administrator Lisa Jackson's description of sustainability as equivalent to pursuing wellness rather than treating disease.[31] The interface between environmental health and social science in public health is particularly pertinent to considerations of environmental justice, which are also of particular concern to Administrator Jackson. Underlying the research approach to environmental justice are three generalizations: there are more environmental health hazards in disadvantaged communities, there are more individuals with poor health in disadvantaged communities, and individuals with poor health tend to be more susceptible to environmental hazards. [32] If one defines the core issue in environmental health research as defining and demonstrating cause and effect relations between environmental factors and adverse health endpoints, than it seems obvious that the best place to evaluate potential causal relations is in a community with the highest level of environmental problems, and with a population that is at greatest risk of developing the adverse consequences. As a corollary, to achieve success in this research, it is necessary to work with the community. Accordingly, ORD and other

---

29. For a discussion of how EPA functions in a public health mode, see Bernard D. Goldstein, *EPA as a Public Health Agency*, 8 REG. TOXICOLOGY & PHARMACOLOGY 328 (1988), and Barry L Johnson, *The USEPA as an Agency for Public Health*, 16 HUMAN & ECOLOGICAL RISK ASSESSMENT 1209 (2010).

30. *See Environmental Public Health Division*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/aboutepa/nheerl.html#ephd (last updated June 8, 2011).

31. Lisa Jackson, U.S. Envtl. Prot. Agency, Prepared Remarks to the National Academies of Science (Nov. 20, 2010), *available at* http://yosemite.epa.gov/opa/admpress.nsf/12a744ff56dbff8585257590004750b6/1c893e457b3cbb25852577ec0054048c!OpenDocument.

32. For a discussion of research need in the field of environmental justice, see COMM. ON ENVTL. JUSTICE, INST. OF MED., TOWARD ENVIRONMENTAL JUSTICE: RESEARCH, EDUCATION, AND HEALTH POLICY NEEDS (1999), *available at* http://www.iom.edu/Reports/1999/Toward-Environmental-Justice-Research-Education-and-Health-Policy-Needs.aspx.

In essence, the broader issue of NIMBY (not in my back yard) is replaced by that of WIMBY (why in my back yard) when disadvantaged communities discover that a hazardous waste center or other unwanted source of environmental problems has already been sited in their community without their knowledge or consent.

environmental research organizations should be focusing their research activities on community based approaches in disadvantaged communities.

Understanding and mitigating environmental problems in disadvantaged communities is also pertinent to EPA's sustainability initiatives. Sustainability has been adopted by EPA leadership as a way to move EPA toward meeting its ever more complex challenges.[33] Sustainable development became accepted internationally, and acceded to by the United States, at a 1992 meeting in Rio de Janeiro of the UN Commission on Environment and Development. In essence, a third pillar of the environment was added to the two pillars on which development was based: economic and social.[34] For EPA to include sustainability as a major driver within its existing legal mandates, EPA will need to transform its culture from its current focus on reducing risk to one that maximizes benefits. To achieve such a transformation, EPA must develop an operational framework and organizational practices with an eye towards sustainability, as well as tools that allow measurement of benefits and costs among the environmental, economic and social dimensions of the agency's actions.[35] Challenging issues must, therefore, be addressed, including transgenerational equity and valuation of natural resources. EPA will also need to take advantage of modern advances in molecular biology that will permit starting with adverse human or ecosystem endpoints and working back to causes. All this will require a culture change that will take time.

Sustainability will not replace risk assessment. The latter will remain a useful tool for the analysis of environmental risks. Of pertinence has been the recent expansion of risk assessment toward concepts that are consistent with sustainability. These include the focus on the context of the risk assessment as a determinant of its

33. EPA has funded an NRC Committee on Incorporating Sustainability at the US Environmental Protection Agency. Its charge can be summarized as providing a "Green Book" for sustainability practices much like the 1983 NRC "Red Book" on risk. NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

34. *See* United Nations Conference on Environment and Development, Rio de Janiero, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), Annex I (Aug. 12, 1992).

35. For an overview of sustainability issues, see AGENDA FOR A SUSTAINABLE AMERICA (John C. Dernbach ed., 2009). In this conceptual approach, health is subsumed under the social pillar. *See also* Joseph Fiksel, *Sustainability and Resilience: Toward a Systems Approach*, 2 SUSTAINABILITY SCI. PRAC. & POL'Y 14 (2006).

complexity, transparency, the inclusion of stakeholders, and the iterative nature of the process.[36] In public health terms, risk assessment works best as a form of secondary prevention, i.e., the risk is already in place; while sustainability has more of a focus on primary prevention, i.e., the risk does not occur.[37]

IV. EPA'S FIFTIETH ANNIVERSARY: THE ONLY CERTAINTY

I have briefly touched on a number of R&D and policy issues in this eclectic review and oversimplified account of ORD's complex history. EPA's R&D program is facing many new challenges, ranging from nanotechnology to global climate change.[38] Virtually the only certainty for EPA's fiftieth birthday is that I have missed an important issue. This is consistent with my previous track record of failing to accurately predict major environmental issues. I am also certain that it is not just my own failure of foresight—that ten years from now there will be major issues that virtually no one now predicts. The implication is that our track record of shortsightedness must be taken into account in our planning. To respond to the unexpected we need a vibrant ORD with state-of-the art expertise capable of anticipating or rapidly reacting to new environmental threats and at the forefront of innovative approaches toward a sustainable environment.

---

36. *See generally* NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009); NAT'L RESEARCH COUNCIL, TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY (2007).

37. I was AA of ORD soon after the Red Book appeared. My standard speech about the then new risk assessment paradigm contained the assertion that it would take ten years before we would know whether risk assessment was of value to the agency. I suspect that a similar time will be needed for sustainability.

38. Nanotechnology presents a direct challenge to the toxicological principles on which risk assessment is built. The first law of toxicology is that the dose makes the poison. Thus the higher the dose, the greater the effect. But for nanoparticles a smaller total dose, when administered in nano-sized particles, can have a greater effect than a larger dose administered in larger particles. The second law of toxicology is that each chemical or physical agent has specific effects that can be identified by study in defined biological systems. The claim that a chemical compound can have completely unexpected effects when in nanoparticle size is frightening to predictive toxicologists. Bernard D. Goldstein, *The Scientific Basis for the Regulation of Nanoparticles: Challenging Paracelsus and Pare*, UCLA J. ENVTL. L. & POL'Y 7, 16 (2010). Global climate change presents challenges to standard risk assessment/risk management by virtue of its high stakes, high uncertainty about impacts, the equity implications of differential causes and differential impacts—all beyond that of the challenge posed by the need for multi-disciplinary and trans-disciplinary science to understand and mitigate the effects.