Appendix C

Statement by David L. Bazelon

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When I was first invited to participate on this panel, I must confess, I was bewildered. I am not a scientist, and I know virtually nothing about neuroscience. I could not begin to describe the difference between a neuron and a beta-blocker. I called Dr. Cook-Deegan, intending to decline, When he later came to my chambers, I told him that, given my lack of technical expertise, I could never presume to advise a group of distinguished physicians and scientists as to the value of a particular line of scientific research. My sole involvement with science is in my capacity as a judge. Throughout my 34-year tenure as a judge on the U.S. Court of Appeals for the District of Columbia Circuit, it has been my task to review the decisions of a great many regulatory agencies grappling with the problems posed by scientific and technological development. These decisions involve, just to name a few, the critical socioscientific issues of acid rain, cotton dust and benzene levels in the workplace, exposure to asbestos and radiation, and the disposal of nuclear and toxic waste. I tried to impress upon Dr. Cook-Deegan that I was qualified to address nothing more than the role of the courts in monitoring public policymaking in the scientific arena. Much to my surprise, he assured me that this was exactly the focus he hoped I would bring to the panel.

I hardly need to tell a group such as this that with each new advance in neuroscience come previously unforeseen dangers. Neuroscience is not unlike any other field of scientific endeavor in this regard. Ironically, scientific progress not only creates new risks but also uncovers previously unknown risks. As our understanding of the world grows exponentially, we are constantly learning that old activities, once thought safe, in fact pose substantial hazards.

For example, new psychopharmaceutical drugs, capable of controlling antisocial behavior among large numbers of psychiatric patients, have been developed. Many of the drugs have known side effects and still others may be discovered in the future.

Similarly, advances in genetics offer the hope of eliminating many genetically transmitted diseases. However, with this hope comes the threat of introducing previously unknown and presently untreatable viruses and bacteria.

Nuclear power can provide a virtually inexhaustible supply of cheap energy. It may also reduce nationwide cancer caused by burning fossil fuels. But, it *may* increase cancer risks for those living near reactors, and our inability to dispose of radioactive waste safely may place future generations in jeopardy.

The question then is not *whether we* **will have risk at all, but rather how *much* risk, and *from what source.* Perhaps even more important, the question is who shall decide.**

In a democracy, such choices are reserved for the public. Thus it falls to the Congress, as our representative body, to guide the direction that scientific development will take in our society. But most members of Congress are no more scientists than am I. Congress often lacks the expertise to penetrate the deep scientific mysteries at the core of important issues of public concern. Consequently, it has chosen to address the problems and opportunities of this new age through regulatory agencies. It gives those agencies the resources and authority to employ and develop expertise and to make difficult policy choices in the scientific arena.

The legislature has not, however, granted these agencies wholly unbridled discretion. First, an agency must often act within the narrow parameters of a specific statutory mandate. For example, the Delaney Clause, an amendment to the Food and Drug Act, establishes an irrebuttable presumption against the safety of any food additive found to induce cancer in animals. Second, agencies must comply with statutorily created procedural requirements. For instance, each agency must provide ample notice of all proposed rules and regulations. It must also solicit and fully consider the input of both outside experts and the public at large. Finally, Congress has attempted to ensure agency accountability by establishing a mechanism for judicial review.

The exact nature of judicial review of agency action is all too often misunderstood. This was brought home to me in a conversation with Alvin Weinberg, a pioneer of the nuclear age. "Most people," he said, "have the idea that the court weighs the arguments and the technical evidence and decides which side has come nearest to the truth. If that's not what you do, you'd

better shout it from the roof tops!" So, I'm shouting it: that idea is wrong. It is wrong, first, because courts lack the technical competence to resolve scientific controversies. It is wrong, second, because courts lack the popular mandate to make the critical value choices that this kind of decisionmaking requires.

In reviewing regulatory actions, the court does not weigh again the agency's evidence and reasoning. Instead the court monitors only the process of decisionmaking, leaving factual conclusions and policy choices to the agency. The role of the judiciary is to stand outside the scientific and political debate and to ensure that all of the issues are thoroughly aired.

First, courts must ensure that an agency's interpretation and application of its statutory mandate are reasonable and that the agency is behaving in a manner that is neither arbitrary nor capricious. Second, in the realm of science, courts can insist that the data be described, hypotheses articulated, and above all, in those areas where we lack knowledge, that ignorance be confessed. In the sphere of values, courts can ask that decisionmakers explain why a particular tradeoff is acceptable. Perhaps most important, in the nether realm, at the interface of fact and value, courts can help assure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon.

I have long argued that even society's most technical decisions must be ventilated in a public forum with public input and participation. In fact, I have been pushing this theme for so long that I worry that I may be a little like my friend the amateur cellist. One evening his long-suffering wife dared ask why cellists in the orchestra "move their fingers up and down the necks of their instruments, while you always keep your fingers fixed in one place." "Ah yes," my friend replied. "I'm glad you noticed that. They are looking for the right note. I have found it!"

Full disclosure of agency decisionmaking is in everyone's best interest, including that of the decisionmakers themselves. If the decisionmaking process is open and candid, it will inspire more confidence in those who are affected, further reducing the risk that important information will be overlooked or ignored. Finally, openness will promote peer review of both factual determinations and value judgments.

Agency resistance to the requirements of full disclosure may come from either of two sources. First, in reaction to the public's often emotional response to risk, agency experts are often tempted to disguise controversial value decisions in the cloak of scientific objectivity, obscuring those decisions from political accountability. I have heard scientists held in the highest regard say that they would consider withholding information concerning risks which, in the scientist's view, are insignificant, but which might alarm the public if taken out of context. This problem is not mere speculation. I am reminded of my involvement several years ago in a hearing on the development of guidelines to regulate recombinant DNA technology in the United States. Added to the heated controversy over the substance of the guidelines themselves was an equally heated debate within the National Institutes of Health concerning the degree to which the risks and reasoning underlying the guidelines should be disclosed to the general public. Speaking to the Royal Society Conference on Recombinant DNA in England, my good friend Donald Fredrickson, the distinguished Director of the National Institutes of Health, said:

> The hearing demonstrated the difficulties of holding a town meeting on molecular biology and exposed the full range of opinions on the risks of the new technology. It was apparent that our decisions would have to run the gamut of adversarial reactions and, in the end, might well be tested in the courts. After the hearing, the voice of Judge Bazelon lingered longest in my mind: "the healthiest thing that can happen is to let it all hang out, warts and all, because if the public doesn't accept it, it just isn't worth a good damn."

It is certainly true that the public's reaction to risk is not always proportionate to the seriousness and probability of the threatened harm. Nevertheless, experts must resist the temptation to belittle these concerns, however irrational they may seem. Regulatory agencies must not turn their backs on the political process to which we commit societal decisions. Scientists, like all citizens, must play an active role in the discussion of competing values. Their special expertise will inevitably and rightly give them a persuasive voice when issues are discussed in our assemblies and on our streets, But ultimately the choices must be made in a politically responsible fashion. To those who feel the public is incapable of comprehending the issues and, so, unable to make informed value choices, I respond with the words of Thomas Jefferson:

> I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion.

At times, however, agency resistance to public disclosure may derive not so much from a desire to keep the public "in the dark" as from the uncertainty that characterizes much of the process of risk assessment itself. To say the least, science is often incapable of stating risks with certainty. For some activities, the magnitude of potential harm and the probability of its occurrence may be essentially unknown. For example, another of my good friends, Dr. Theodore

Puck, a noted medical researcher, tells me that toxicologists have no way of establishing with certainty the permissible, as opposed to the lethal dose of a new drug. Engineering predictions may rest on untestable assumptions, such as the behavior of materials after thousands of years. Risk estimates may depend on future contingencies of human behavior or other highly complex and unpredictable variables. Historical experience may even be totally lacking, as when the National Aeronautics and Space Administration had to fix a quarantine period for returning lunar explorers. The best risk estimates are subject to an unknown degree of residual uncertainty and may thus overstate or understate the dangers involved. Indeed, many times an agency must act in circumstances that make a crap game look as certain as death and taxes.

Those who must make practical decisions may be tempted to disregard or even suppress any lack of confidence they may have. Ignorance is messy in decisionmaking. It cannot always be stated as an objective quantity or factored into a decision as if it were a risk of known probability. Decisionmakers must assimilate data from many disciplines, And yet uncertainty detracts from simplicity of presentation, ease of understanding, and uniformity of application. To focus on uncertainties is to invite paralysis; to disclose them is to risk public misunderstanding, loss of confidence, and opposition. Even though some uncertainty is inevitable, pointing it out will always create pressures for "just one more study." But the decisionmaker knows too well that delay is also a choice, with risks of its own.

Combined with the uncertainty inherent in scientific risk assessment itself is the lack of specific guidance provided to administrative decsisionmakers. Often Congress, faced with its own inability to foresee the course that technological research and development may take, is forced to speak in broad generalities when providing statutory direction to regulatory decisionmakers. At times, legislators embroiled in conflicts of political ideology may intentionally employ vague and ambiguous language so that each faction may claim its own "victory. " I point, for example, to the "cost-benefit" analysis required of agencies by numerous statutory schemes. Such analysis often calls for controversial quantitative valuations of human life and health. It frequently presumes to compare incomparable) such as the harm of radiation exposure versus the benefits of nuclear power. And, perhaps most troubling of all, cost-benefit analysis breaks down completely at one of the most crucial points in the decisionmaking process: How can one quantify the impact of utterly unknown risks?

This quandary was vividly illustrated in the recent *Vermont Yankee* cases. Confronted with the unenviable task of quantifying the hazards posed by the construction and operation of a nuclear reactor, the agency assigned a value of zero to the risk of exposure to radioactive waste products. Apparently, this assessment was based on the assumption that some safe method of permanent waste disposal, not presently available, would be developed at some time in the future. This supposition may well prove to be correct. However, all efforts to date to develop such technology have failed miserably, and if the hypothesis that future efforts will succeed proves false, the damage could be inestimable. Yet nowhere in the agency's environmental impact statement was this assumption, or the foundations upon which it was based, explicitly revealed.

If courts reject this sort of administrative sleight-of-hand, they are not attempting to obstruct the path of scientific progress. Rather, they are merely attempting to carry out Congress's mandate that decisionmaking be honest, open, thorough, rational, and fair. As we confront the perils and promises of this scientific age, both democracy and human dignity demand that we be told of the risks, uncertainties, and value choices that are made in our names.

In primitive societies, when the need to choose between cherished but conflicting values threatened to disrupt the community, the simplest path was decision by a shaman or wizard, who claimed miraculous insight. In our time, some would invoke the special wizardry of those who wear a scientist's lab coat, a judge's black robes, or a risk assessor's business suit rather than religious garb. But the genius of our system is its checks on centers of accumulated power. Whatever its price, nothing but full disclosure can guarantee that the regulators or the new guild of risk assessors will not become the new elite.

If the Supreme Court's most recent opinion in the *Vermont Yankee* case portends a new trend of judicial indulgence toward agency nondisclosure, Congress may need to reaffirm its intention that the administrative decisionmaking process be subject to a searching and meaningful judicial review. In any event, when undertaking an assessment of technological development in neuroscience-or in any other area of scientific endeavor—the Office of Technology Assessment must take care to see that the risks are treated openly and evenhandedly, In this regard, I might note that, in the draft document we are considering today, * con-

• The draft document referred to was reviewed at the OTA workshop. Some parts of the draft are reprinted in the working papers for Impacts of Neuroscience.

siderable attention has been devoted to the benefits promised by neuroscientific advances, while treatment of the attendant risks has been confined primarily to a scant five pages in the introduction and scattered references elsewhere in the manuscript. Finally, I would like to add my own endorsement to the proposal that OTA undertake an independent assessment of the adequacy and openness of decisionmaking processes in the scientific arena.

Some may argue that society might balk if it knew just how blindly we march into the future—and at what cost. But false reassurances, unjustified confidence, and hidden agendas will only create cynicism and destroy credibility. Our people have always been prepared to accept risks and to pursue the larger good of society. Progress can hardly be achieved in any other way. Choices will be made despite uncertainty and despite the social disruptions and dislocations. To choose rationally, however, society must be informed about what is known, what is feared, what is hoped, and what is yet to be learned.