The 2004 Frankel Symposium

Shaping Environmental Policy: Science in Context

Keynote Address[1]

Donald Kennedy[2]

Introduction by Susan Westerberg Prager:

I'm sorry to disrupt your conversations. My name is Susan Prager and I'm the former Dean of the UCLA Law School. I appreciate Sean Hecht asking me to introduce Don Kennedy today. For that, I thank you, and I think all of us thank you for putting together such an important program today . . . I was thinking of this challenge of introducing a person that I've known for a very long time in a number of different contexts. . . .

Don, one of the most impressive things to me about your teaching and your life is the countless people that you have taken the time to mentor over the decades. Don't be fooled, by the way, by that "Emeritus" label on this man's bio. He happened to mention to me in passing that very recently he has taught at the request of five different faculty members at Stanford portions of their courses—doing this at the same time as he has these very significant responsibilities at *Science* magazine. For those of you

1. The 2004 Frankel Symposium was held on March 12, 2004 at the UCLA School of Law. The symposium included panels on such topics as science and values, new source review, the role of science advisory boards, and public participation, expertise, and risk. It was presented by the Evan Frankel Environmental Law and Policy Program at the UCLA School of Law, in cooperation with the Ralph & Goldy Lewis Center for Regional Policy Studies at the UCLA School of Public Policy and Social Research, and the UCLA Institute of the Environment. This is a transcript of the keynote address of the symposium, given by Dr. Donald Kennedy. For information on upcoming Frankel symposia and other environmental programs, please visit http://www1.law.ucla.edu/~environment/events.htm.

2. Dr. Donald Kennedy is President Emeritus and Bing Professor of Environmental Science and Policy Emeritus at Stanford University, and is Editor-in-Chief Science Magazine.

who are lawyers who've never looked at *Science* magazine, I urge you to think about it as a part of your broader education, because . . . while it is reporting on truly cutting-edge scientific research, it is done in a way to make it acceptable to a much broader community than the things that might appear in other scientific publications. There's much to be learned from Don Kennedy's career about his qualities as a leader. During his twelve-year presidency at Stanford he accomplished so much. He clearly had an agenda and it included, just to name a few things, a drive to insure that there was a renewed institutional focus on undergraduate education. He managed to do that at the same time as Stanford was driving forward its research capacities and its achievements in research in a very big way. He was a bold campus planner on the facilities side. And what Stanford is able to do today is in very significant part due to the physical plant for engineering and science that was marked out by Don and his colleagues during his presidency. But this type of achievement, important as it is, is not the only picture about Don Kennedy.

Don has something that too few of our leaders embrace and even fewer actually live. His leadership is not about him. And he is a very open, non-defensive leader, and as a consequence, people love working with him and for him. I've had many conversations over the years with those who've been in that role and they talk about how Don has this quality of liberating those who work with him to take positions that they might think he wouldn't like and to have a true open-airing of the direction in which a particular problem ought to be resolved. We may take that kind of climate for granted in some disciplines, but it's very hard in a leadership position to do that day in and day out. This also played itself out in a way that was a very dramatic and public one, and that was when Stanford was in the midst of a controversy over indirect cost charges to the federal government.

. . . Going back many, many decades, Don's life has been interdisciplinary. Interdisciplinary before it was fashionable, before anyone was talking about it as a value in higher education. Our first panel today brought home the difficulties of achieving interdisciplinary work, but five years after Don arrived at Stanford in 1960, to become, in his words, "one of the workhorses of the core curriculum in biology," after he had spent four years teaching at Syracuse, he and a handful of others on the campus began to create an innovative program which has survived to this day: the

Human Biology program. It became, for a very significant time, I believe, *the* most popular major at Stanford. And now, together with the Biology major, these are the two most popular programs.

It was a program that was ahead of its time in another sense. It was a program oriented toward a broader training to develop a greater literacy about science. Words that we use today, but words that weren't used then. This program has been emulated at other institutions since and it is still as vibrant and exciting at his institution today.

So I will conclude with saying, Ernie [Frankel], I can't think of a more perfect Keynote Speaker for a program that you brought about. And, Don Kennedy, President and Professor Emeritus, former FDA Commissioner, Editor-in-Chief of *Science* magazine, extraordinary teacher, mentor, and leader, and vital, productive example of non-retirement: this podium is finally yours. [Applause]

Keynote Address by Donald Kennedy:

Well, I want to thank Susan Prager and Sean Hecht for the invitation and to announce that I am deeply flattered to her comparison [to Ernie Frankel] and I will do my best. It's not difficult, I think, to draw out a theme from the wonderful program we have had, and that will continue this afternoon. Let me touch on a few of the issues in sequence.

First, we heard about the important matter of science and values, a domain which the Congress regularly enters in a kind of crouch with the utmost reluctance to define values with any precision, so as to leave agencies and their scientists to grope about for meaning. Wendy said it very well this morning when she said that the key question is: how protected do we really want to be? That is at the core of what we're talking about today. Then we heard about new source review, raising the old problem of how to treat the old and the new fairly, of grandfather clauses which haunted me a little in my time at FDA, and surely must haunt EPA much worse today. Then there comes the role of science advisory boards in making policy, which at once puts me in mind of all of the difficulties of finding who can serve, what criteria we should use in selecting them, and how we can avoid conflict-of-interest issues. Finally, there's the touchy and fascinating matter of public participation: how do we get it done? Have the Administrative Procedure Act and the notice-and-comment rulemaking

process outlived their usefulness? Why is "stakeholder" the buzzword of the decade? Is "reg neg" here to stay? Well, I don't qualify as an expert on any one of these issues, but I do have some experiences that might bear on them, so maybe a couple of lunchtime narratives will get you thinking about these problems in a somewhat different way, with examples in front of you.

I want to begin by way of introduction by saying that in terms of the science and values issue, as we think about working in the interest of the public health, presumably the policy is supposed to tell us something about values and the elected representatives then interpret those views for us. It's hard to think of a more important value than how much risk we are willing to have others put on ourselves. Yet, when the Congress is heard from on that problem, it has repeatedly been unable to say much more than "reasonable certainty of no harm," or "substantial margin of safety." So who picks up the pieces? Well, first the scientists have to go through some exercises in risk assessment, with all of the rather questionable boundaries that surround those estimates, and then, in the end, a group of folks in the agency have to make the acceptable risk determination and then take the consequences—the consequences often coming in the form of unpleasant hearings before some of the very same people who made the laws in the first place. So that's what I want to be talking about and I'm going to use a couple of stories by way of examples. Think of these as two brief excursions into the choppy waters in which science and law and policy meet.

Here's the first case. When I got to FDA, people were talking about a regulation that was being developed called "SOM." I feared that that was about sadism or masochism; "What the hell is this?" I asked everybody. They said, "It's called Sensitivity of the Method." Well, it turns out that when the Congress made the food safety laws in the late '30s, they were a little vague about risk, using phrases like the ones I cited to you a moment ago. But then, for once, they got worried enough about cancer to attach a real number to acceptable risk. That was, of course, the law known to everyone in this room as the notorious, newly-deceased Delaney clause, which said that the acceptable level of cancer risk—explicitly cancer risk—was zero, zilch, nada, nothing that you put into the food supply in America can have been shown to cause cancer in man or in any laboratory animal.

Well, it turns out that even arbitrary values like that can collide with other values, and so there's a little following history. The

Congress noticed, in fact their attention was called to it by the meat industry in America, that for some time cattle had been raised on the feedlots of America with gross promotants, often slow-release ear tags that release estrogenic compounds, explicitly diethyl stilbestrol. They suddenly realized, and made the Congress realize, that that circumstance meant that if the Delaney clause was to be interpreted as written, their industry was dead. So the Congress passed something that we know as the DDS proviso, which said, as long as no residue is found in the edible portions of the steer (well, it didn't say steer), as determined by a method acceptable to the secretary, that's enough. In those days, the Commissioner of the FDA was not a statutory appointment, so I had to be the Secretary of HEW [Health, Education and Welfare]. Well, we need a method that will be acceptable to the FDA that will be used to detect whether the meat contains any amount of this carcinogenic substance. Well, you know what the industry would have favored: visual inspection, the collect colorimeter. Enthusiastic regulators and the consumer folks would have wanted something enormously more sophisticated, just about as sensitive as you can get. So FDA started to work on this progress, believing that work on methodological development would go so slowly that they might not have to make up their minds. Then we get the news that a research team in a Department of Agriculture laboratory is working hard on methods. They are doing scary things. They are doing immunoprecipitation detection methods; they are doing high-pressure liquid chromatography and mass spectroscopy. The threshold is going down, down, down, down. Indeed, one of the great problems that you're discussing this morning is that analytical chemistry goes like this, and toxicology lumbers along. So we had to do a "Sensitivity of the Method" regulation. Please understand what this means. It means that with some kind of risk assessment methodology, based on larger doses of estrogenic compounds in laboratory mammals, we will make the usual assumptions about animal testing, and we will say that so-and-so much of this stuff might give so-and-so many Americans lifetime cancers.

How much cancer is OK suddenly becomes the problem. The FDA has the job of figuring out what is an acceptable cancer risk for the first time, as far as we know, in all of recorded history. So after lengthy conversations, and consultations with the scientists, and examinations of the risk assessment conversion, the FDA

publishes a Notice for Comment and says that it thinks the right number is 10^{-6}. One in a million lifetimes. Well, that's 240 Americans. You'd worry if a jet plane went down with that many people on it. But it didn't sound like too many; it sounded like a reasonable sort of proposition; but everybody was hunkered down waiting for the storm and there wasn't one. Very little comment. Everybody seemed to think it was reasonable. Those who noticed—it might have been a dozen people. And 10^{-6} became a kind of standard. It's used in lots of places. Astonishing to me that it created so little public fuss, yet it was a watershed event that has become a kind of de facto standard for others. Does it have any scientific precision behind it? Not much. Does it reflect the normative consensus judgment by the polity? Absolutely not. It is, like the number three for the number of primary colors, a good number, sufficient unto the day.

The second illustration, I hope to use to show how complex the management of an environmental risk can be when a large number of institutional players become engaged. I think maybe you had an idea of that from this morning's sessions. I'm going to promise you that this will break the record in terms of numbers of interests. So let me give you a little background, which you already will know quite a lot about, because the Clean Air Act got a good working over this morning. One aspect of the Clean Air Act is NAAQS (National Ambient Air Quality Standards), which the Congress instructs the EPA to set for each of these pollutants. It asks them to do it every five years. And we're going to talk about two criteria of pollutants.

We're going to talk about ozone. Don't get me wrong, this is not good ozone, the stuff up in the stratosphere. This is bad ozone. Ozone in the troposphere. An important product of some industrial and power-producing activities, but much more prominently of mobile source emissions. And particles. Particles. Originally, particles are relatively undefined as to size, but we will hear more about the different sizes of particles in a moment.

Now, EPA has a lot to do; indeed, every regulatory agency has a lot to do, and Congress asks it to do a lot and it does not appropriate funds in proportion to what it asks agencies to do. So the Commissioner of the FDA and the Administrator of the EPA are always explaining to committees why this hasn't been done. Those NAAQS have not been reviewed for much more than the five-year statutory limit, and the American Lung Association,

which is interested in your health, began to petition the Agency to get it done. The Agency said, "Yes, we will." Then it didn't happen. Then they petitioned again. And it didn't happen. Finally, they took them to court and a black-robed agency manager—they get a lot more done than the rest of us—instructed the EPA to move quickly on the NAAQS for ozone and particles.

So in the early '90s, we see some work going forward, and it's going forward through the work of EPA staff, which is looking at the literature to find out what has changed and what the problems may be with respect to ozones and particles, and it's also relying on the judgments of two advisory committees, the Scientific Advisory Board of the EPA and the Clean Air Act Science Advisory Committee (CAASAC). What are they finding out? They're finding out, in the first instance, that there are really two kinds of particles. In fact, if you filter a cubic meter of this air here, you'll find some small ones and then a distribution of large ones. The small ones are largely, not entirely but largely, the product of mobile emissions, and they are much more serious in terms of health consequences, because they go much farther into the bronchioles, wind up in alveoli, develop areas of hyperplasia there, can produce emphysema or eventually, if there's much hyperplasia, lung cancer or mesothelioma. We don't like the small particles, it turns out.

Second, there is a rather important study—in fact, one of several, but the one that gets most of the attention is something called the Harvard Sick City Study, produced by a group from the Harvard School of Public Health, led by Dennis Docker. Now, that study is of great interest to everybody, because it turns out that it's going to be a major feature of the proposed new rule. So the industry goes to Harvard and says, "We want to see that study. We don't want to just see the paper that Docker, et al. published; we want to see the underlying data tapes so that we can subject them to our own careful, quantitative, statistical evaluation and reach our own, possibly different, conclusions about it." Harvard says no, citing medical privacy. I have to say of my alma mater that that was not an entirely convincing claim, never mind that when they made it, it looked as though it was going to stick, at least that's the way it appeared for a while. An enormous brouhaha arose and two issues followed. One, the Health Effects Institute, which I mentioned in a question this morning, and which is an organization that gets half its funding from EPA and half its funding from the motor vehicle industry on the basis

of a per-unit displacement contribution, said, "Look, we understand everybody's a little bit uneasy about Harvard not letting anybody look at this study. Why don't we go in, we'll appoint a distinguished panel of academic experts, they'll go in, look at the primary data, supply their own analysis, and issue a public report that says all you need to know about whether this is OK." Industry says, "Yeah, well, maybe. . ." Everybody else says OK.

So John Samet, from Johns Hopkins, is appointed Chair of a large and very distinguished panel, including some extremely good statisticians. A dozen people or so. They go and they take the data apart and they publish a report, which essentially validates the interpretation that the Harvard group made, with a few changes, but those changes were largely at the margin. What else was happening was happening in the United States Senate. It was happening at an interesting time. It was happening at almost midnight, when Senator Shelby, of Alabama, introduced an amendment, now called by everyone the Shelby Amendment, which essentially said, "If your study is supported by federal funds, then the research data from that study must be made available to requestors under the Freedom of Information Act." Well, from academia there was a gasp of horror among at least that subset of people who worry about such things, and the task fell to the Office of Management and Budget to issue regulations under the provisions of that statute. So it engaged in a notice and comment rulemaking procedure, and there were at least two postings of that notice before there was a final rule. The final rule made it clear that there would be some limitations to this accessibility. That it would apply only if not only was the research federally supported but if it was destined to apply to a rulemaking or federal policy of significant economic impact. Thus causing gasps of relief from biomedical researchers supported by the National Institutes of Health, who thought their competitors were going to stage an all-out assault on their research plans.

Here we are. There's a Shelby Amendment; it's followed by the Son of Shelby, which is the name some of us have for something called the Data Quality Act, which gives challengers a right to question federally posted or disseminated data. It's concerned the consumer and environmental communities that what these two new provisions allow is for industry, or those opposed to regulation, to enter the lists, extract primary information, reanalyze them, and then engage essentially in a political disagreement

with the regulatory consequences of the information. As you can see, it's not easy to make an argument against that. The argument for it can be made to sound quite plausible, but it does suggest an enormously enhanced complexity in the whole system.

Well, so what happens next? Well, one of the organizations most concerned with the small particles and ozone issue is the American Trucking Association. These are the guys who send big diesel trucks around the country carrying things, and they are not eager to see harsh emissions limitations put on them as a consequence of the small particle and ozone regulations. They first petitioned and then eventually they go to court. Their lawsuit against the Environmental Protection Agency is heard in the Court of Appeals for the D.C. Circuit, which always hears such regulatory complaints. A three-person panel is drawn to hear that case. It has a two to one majority of judges who had been appointed by President Reagan and one, David Tatel, who had been appointed by President Clinton. There was a lengthy set of arguments about this; I know that Sean filed, when he was a Deputy Attorney General for this state, an amicus brief on behalf of the state of California in that case. He tells me that that was one of a large flurry of amicas briefs. Maybe it was first there, and then later in the Supreme Court. Or did you wait until it reached the Supreme Court? Oh, you waited until the Supreme Court, OK. What the D.C. Circuit did was to decide two to one that the EPA had set an arbitrary line where there was no defensible scientific reason for the particular value of ozone and small particles that it had set. Tatel dissented and wrote up a long, passionate, and, I thought, well-articulated dissent. The case then went to the Supreme Court and, surprise, surprise, the Supreme Court accepted the EPA's position and at least in substantial part Tatel's argument unanimously. And surprise, surprise, surprise, the author of the majority decision was Antonin Scalia.

There you have the story. What, I hear you cry, is the point of this story? It provides an answer to a terrifically important question. The question is: how many institutions does it take to get regulatory science right? The answer to the question is: eleven, and they're not finished! Because the process is toiling on; the Agency now is looking toward 2005 resolution of these NAAQS, but a final National Ambient Air Quality Standard isn't out there yet. Now let me search for a common theme from both of these examples. Each case starts with a congressional provision about

risk, but without any indication about what level of risk might be acceptable. In each case, some science is applied to assess the magnitude of that risk and a determination has to be made that says something about acceptability. Because now that we have at least some vague sense of the magnitude, we need to find out how much is OK. In each case, the exercise of risk assessment, of course, has yielded a wide range of possible risks. In each case, a point on that continuum has to be chosen. That's the sensible thing for the regulatory agency to do under the circumstances. In the first of the cases I've laid before you, that judgment is quietly accepted and goes down and is widely used. In the second, because there's a lot of money at stake, it yields congressional action, a major lawsuit that eventually occupies the attention of the highest court in the land. I used to think that this kind of mess can be cleaned up; now I'm not quite so sure. It seems to me it would require a more definitive statement by Congress on what is an acceptable risk, and that is just about as politically unlikely as anything I can think of. So the Congress and the agencies and the courts will continue to have to sort these matters out at the end, often painfully; that's the bad news. But I want to end on a more cheerful note, so here's the good news. The built-in ambiguity that's entailed in the business of determining acceptable risk and of assessing risks is an intellectual bonanza for the community of scholars and commentators who are seriously considering public policy. What, I ask you, would we ever do without you? Thank you very much