The Judiciary: What Role in Health Improvement?

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The wide compass of health touches the law at many points. The law of negligence, for example, encourages careful conduct where the public's health and safety are at stake. Medical malpractice and products liability bring courts face to face with the behavior of doctors, hospitals, and pharmaceutical companies. Courts are called upon to correct unhealthy conditions in prisons and mental hospitals. They restrict potentially dangerous uses of real property through the law of nuisance. Even contracts involve the court in health issues.

Most law students begin their study of contracts with the case of *Hawkins* v. *McGee*. There, a doctor guaranteed to restore his patient's burned hand to 100 percent perfection through the new technique of skin grafting. Unfortunately, Dr. McGee grafted skin from the patient's chest and produced a hairy hand instead. Hawkins recovered the difference in value between a perfect hand and a hairy hand, an amount set by the jury. The hapless doctor also lost his suit against his insurer. The insurer had agreed to cover only medical mistakes, not broken promises.

Emergent Health Problems

In this century, medical and scientific developments have broadened the court's role in health improvement. As infectious diseases are brought under control and life-spans grow longer, chronic diseases and accidents have become the nation's principal health problems. Revolutionary advances—in transportation, in the production of food, energy, and materials, and now in biology—have given rise to new risks and to a new awareness of existing risks, on a scale hitherto unimagined. Courts are still drawn into medicine's traditional battles: witness, for example, the crisis in medical malpractice or the litigation over the swine flu program. But federal court litigation also increasingly reflects the nation's concern with the supposed roots of chronic disease and accidents: environmental pollution, hazards of the workplace, food and drugs, and the "undesirable side effects" of energy, transportation, and consumer products. There is good reason to think that the courts will soon feel the impact of the genetic revolution.

Negligence law is simply inadequate to deal with these emergent health problems. To cite only one example, environmental pollutants are often impossible to trace to their source. Their health effects are uncertain, and their harms may not show up for years or even generations. Such uncertainty makes a finding of negligence liability unlikely, inappropriate, and therefore ineffective in protecting society from these dangers. Moreover, a case-by-case approach cannot match the scale of impact from pollution. Finally, any means of protecting the environment entails conscious and unconscious choices touching far more than the parties to a lawsuit:

- which products and industrial processes to favor;
- how to distribute burdens and benefits among populations and generations;
- whether to proceed in the face of uncertainty;
- how to value health and life itself.

Regulatory Decisions

These scientific and value questions are enormously complex and important. They cannot be left solely to the ad hoc and possibly inconsistent determinations of lay judges and juries. Congress has therefore assigned the task to regulatory agencies. It gives those agencies the resources and authority to employ and develop expertise and to make policy decisions pursuant to statutory mandate. It also requires them to elicit and consider the input of outside experts and of the public at large.

Within the limits of its statutory mandate, an agency must resolve fundamental issues of fact and value. To set a standard for maximal cotton dust in the workplace, for example, the Occupational Safety and Health Administration had to explore the health effects of various exposure levels, the feasibility of different control technologies, and the economic effects of meeting the standard for several industries. Such determinations require the agency to view health in broad terms: to consider expert evidence in epidemiology, pathology, engineering, and economics. The agency might also have to resolve value questions such as how much an industry should have to spend to protect an additional life. Finally, the agency must often decide what action to take when the answer to any of these questions is uncertain.

In reviewing regulatory decisions, the court does not reweigh the agency's evidence and reasons. Nor does it decide whether the factual conclusions and policy choices are correct. Courts lack the technical competence to resolve scientific controversies; they lack the popular mandate and accountability to make the critical value choices that this kind of regulation requires. The court's role is rather to monitor the agency's decision-making process—to stand outside both the expert and the political debate and to assure that all the issues are thoroughly ventilated. To survive the court's searching scrutiny, an agency must provide adequate notice and an opportunity for objections. It must consider and address those objections, making clear what it accepts, what it rejects, and, most importantly, why. Its record should disclose the full and precise basis of its decision:

- its evidence, its methodology, and the assumptions that underlie its empirical inferences;
- the risks, the costs, and the value it places on life, health, and environmental quality;
- the trade-offs it has made among groups and among generations.

Finally, I would especially stress that an agency should disclose the uncertainty that surrounds its determinations.

Full disclosure will undoubtedly improve the quality of information by exposing weaknesses to peer review, legislative oversight, and public scrutiny. But society also requires disclosure for the same reason—or the same democratic

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faith—that underlies informed consent for medical procedures and warning labels for drugs and other products. Absolute safety is impossible, and benefits usually entail risks. But the *electorate* must have an opportunity for the final say about which risks it will assume and which benefits it will seek. Elitists will say that most people are incapable of evaluating risks. Such a claim has no more place in an agency's decision-making than in an individual's choices about health care. Experts who are beyond reach and beyond view must never be allowed to arrogate those decisions to themselves.

Uncertainty

But what if an agency lacks the knowledge to state risks with certainty? For some activities, the magnitude of potential harm and the probability of its occurrence may be essentially unknown. Epidemiologists, for example, may lack the measurement tools to discern the health effects of a substance in trace quantities. 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 NASA 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. Many times, however, an agency must act in circumstances that make a crap game look as certain as death and taxes.

Is it rational for an agency to act as if a tentative suspicion were a known risk? Scientists do not generally commit themselves to unproved hypotheses. And yet it would be ironic if agencies had to show a scientific consensus existed before they could act against suspected health and safety hazards. As I mentioned earlier, it was partly because uncertainties weakened the deterrent effect of negligence law that Congress created regulatory agencies. Moreover, agencies take a broad view of health, requiring input from numerous disciplines. To await certainty in all of these fields is to await eternity.

Theoretically, Congress determines whether an agency may regulate a potential hazard in the absence of conclusive proof of harm. Congress might cast the "burden of uncertainty" upon either the agency or the regulated activity. Too often in practice, however, the congressional intent is sufficiently unclear to invite judicial interpretation. The agency is frequently accorded wide discretion in allocating that burden. This circumstance makes full disclosure of uncertainties as important as full disclosure of known risks.

Perhaps those who seek to conquer uncertainty do not see eye to eye with those who must act in spite of it. A "pure" scientist is usually acutely aware of the tenuousness of his assumptions, the competing interpretations of his data, and the limits of his knowledge. He pressses outward upon the line between the known and the unknown. He does not resist disclosure; indeed, his career advances through it. If anything, the scientist is more likely to overemphasize uncertainty than to hide it.

Those who must make practical decisions, on the other hand—regulators, physicians, engineers—cannot always afford science's luxury of withholding judgment. Indeed, they may be tempted to disregard or even suppress uncertainty. Uncertainty is messy. It cannot be stated as an objective quantity or factored into a decision as if it were a risk of known probability. Decision-makers must consider data from many disciplines. 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." And yet, the decision-maker knows too well that delay is also a choice, with risks of its own.

The Case for Full Disclosure

I am told that, instead of disclosing uncertainty, decision-makers may want to compensate for it by intentionally inflating risk factors. For example, they may adopt conservative assumptions about the shape of a dose-reponse curve for low levels of a harmful agent. They may also set the standard for that substance at one-tenth of the lowest level for which harm can be observed. Engineers and physicians likewise choose to build in safety margins and err on the side of caution. I do not criticize these conservative decision rules; indeed, where health and safety are concerned, they are the only ones that make sense. But such rules cannot erase the uncertainty inherent in many decisions. A court may well find that disclosure is inadequate where substantial uncertainty is hidden on the excuse that risk has been inflated.

The case for full disclosure is especially strong where environmental statements are at issue. The National Environmental Policy Act sets no substantive standards for deciding which risks are worth taking. The procedure of considering and disclosing impacts is the *essence* of the act. Since agencies must evaluate and compare alternatives, there should be less reason to inflate the stated impact of proposed actions. Indeed, adding a safety margin may tilt the balance away from the best alternative. The goal is accurate forecasting and accurate disclosure. And where scientific estimates are highly tentative and hedged about with uncertainties, then those uncertainties must be disclosed and considered as part of the package. I have pleaded for disclosure many times before, and I am gratified that the Academy complex has undertaken to improve formal risk assessments. No doubt some of those assessment techniques will find their way into environmental impact statements. In the enthusiasm for quantifying risks for decision-making, however, we must never forget that honest disclosure sometimes means admitting our ignorance.

I am reminded again of poor Dr. McGee, who experimented with skin grafting. He might have stated the risks to his patient by disclosing the success rate of his technique. But without some indication of the uncertainties—for example, how many times the operation had been performed—the patient's knowledge of that success rate could hardly constitute the basis for informed consent. In fact, the doctor apparently wanted to perform the experiment and was afraid his patient would refuse if the uncertainties were known.

It will be argued that society likewise would balk if it knew just how blindly we march into the future. But false reassurances and unjustified confidence will only engender cynicism and destroy credibility. Our people have always been prepared to accept risks. Progress can hardly be achieved in any other way. To improve health in its broadest sense, society as a whole must make choices despite uncertainty. 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.