

this country, it is largely in the hands of private enterprise. Thus, it may be understandable that the working group is concerned about gene therapy data being secret. Nevertheless, in its zeal to protect the public interest, it is asking would-be gene doctors for information that their colleagues in other areas of medical research are not asked to supply.

Of the final set of questions—those that are “optional”—this is the most extraordinary. “Is it likely that somatic-cell therapy for human genetic disease will lead to: (a) germ-line gene therapy, (b) the enhancement of human capabilities through genetic means, or (c) eugenic programs encouraged or even mandated by governments?”

If one accepts the judgment that so-

matic cell therapy for the cure or alleviation of disease is fundamentally no different from other risky forms of treatment (chemotherapy and radiation therapy in cancer, for instance), it follows that these last questions become the focus of people's anxiety about where this new research may lead. The idea that one's identity is intimately tied to one's genetic makeup have been a deeply embedded part of our culture since Mendel discovered genes. The eugenics programs of an earlier time, particularly the horrors perpetrated in Hitler's Germany, raise a specter over genetic manipulation that may never be banished altogether. The questions need answering, the possible misuse of the technology needs to be anticipated.

In the absence of any other duly con-

stituted body, the Working Group on Human Gene Therapy has become the locus for broad social discussion of these issues. All of its deliberations are intended to be open, particularly in the beginning if, as expected, the first protocols it has to review do not include proprietary information. According to LeRoy Walters, its job includes educating the public on the technical aspects of gene therapy and also on the significance of the research.

Says Senator Gore, who backs the working group but would also like to see Congress create a presidential commission with oversight in this area, “Genetic engineering shouldn't surprise us. We can see it coming, so we should be examining our choices and their ethical implications.”—**BARBARA J. CULLITON**

Legislative Paralysis on the Environment

Four major environmental laws are up for renewal; EPA would like more administrative flexibility, but Congress may give it less

When legislators closed the books on the 98th Congress, they had renewed only one of five major environmental laws. As a result, the new Congress, which gets down to business this month, faces the need to rewrite the basic laws governing air and water pollution, the cleanup of hazardous waste sites, and the regulation of pesticides.

If William D. Ruckelshaus, who resigned recently as head of the Environmental Protection Agency (EPA), had his way, Congress would modify these laws in a way that would give the agency more flexibility in carrying out its mandate of guarding the environment and public health. But Congress is more likely to do the reverse. In part because of the mistrust left over from the way Ruckelshaus's predecessor, Ann McGill Burford, ran the agency, Congress will probably attempt to limit the Administration's room to maneuver by prescribing in detail how EPA should carry out environmental laws.

Ruckelshaus justly says that the agency “has now been righted” after its stormy days under Burford. Now attention has focused on environmental policy rather than personalities. On his last day as EPA administrator, Ruckelshaus argued in a wide-ranging interview with *Science* that Congress over the years has saddled the agency with unduly prescriptive laws, making it difficult for the

administrator to carry them out effectively. This highly detailed legislation, for example, identifies dozens of specific chemicals or pollutants that the agency must regulate and then imposes deadlines. “That's all wrong in my judgment,” Ruckelshaus said. He argues that detailed laws contribute to the ponderous pace of issuing regulations and run counter to wise decision-making.

Ruckelshaus cites as an example the one piece of environmental legislation Congress recently rewrote, which governs hazardous waste disposal. “I'm not sure [this legislation] is such an advancement,” Ruckelshaus said. It states that EPA must reach specific goals by specific deadlines. “If you don't meet a deadline, certain bad things happen to you. . . . If you don't identify certain chemicals, then they can't go into landfills.” As a result, he said, the agency will probably have to identify these chemicals “with imperfect information and try to regulate them. I don't think that's good public policy.”

Ruckelshaus also contends that Congress should modify the mandate of the agency to take into account the cost of regulations. “We must balance [the benefits] against the other social concerns that society has to deal with,” he said. Some of the statutes, such as parts of the Clean Air Act, do not give the administrator that discretion, but say he

must provide “an ample margin of safety.”

All of these explicit orders from Congress stem from mistrust, Ruckelshaus said. “Their argument to me is, well, you're all right, but how do we know who's coming after you and look who was in there before you. But if you treat somebody as though they're not to be trusted, it isn't very long before your mistrust is warranted.” The problem, however, is not with Ruckelshaus, who was widely respected as the first administrator of EPA in the early 1970's and is regarded as the healer of a battered agency under this Administration. Congressional sources and other players in environmental issues say that the reluctance to give the administrator more rope is because of the agency's inability under previous presidents to write regulations expeditiously and because of the meddling by the Office of Management and Budget (OMB) under President Reagan.

“I understand what he's saying,” says Senator David Durenberger (R-Minn.), who is chairman of the Senate's environmental oversight subcommittee. “If this was an ideal world, we might give him more flexibility, but it's not. Do I think the answer [to achieving greater progress] is more flexibility? No.”

Senate and House aides who monitor EPA also say Ruckelshaus's desire for more flexibility is not unreasonable. In

theory, "I have no quarrel with it," said Ronald B. Outen, who is an aide to the Senate Environment and Public Works Committee and previously worked 3 years in EPA's toxic substances office. He and other congressional aides acknowledge that detailed legislation cannot anticipate all the problems EPA will confront. Some deadlines, such as the scheduling included in the Superfund legislation, are "probably overdone," said an aide to the House energy and commerce oversight subcommittee. But the aides point out that EPA historically has not performed well without specific legislation spurring it into action. "Flexibility has not gotten the job done," Outen said.

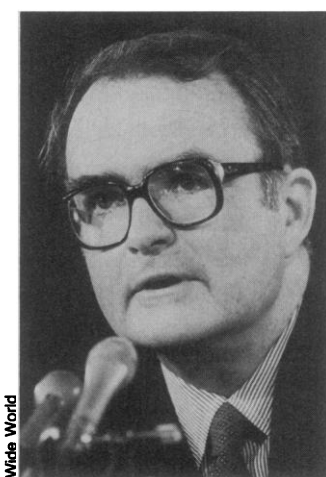
Most of the environmental laws were initially broadly written when passed in the early and mid-1970's. EPA, however, under the leadership of Democratic and Republican administrators alike, has been slow to develop regulations for a variety of reasons. The process of rule-making has always been tortuous, given the numerous parties battling each other. Sometimes the laws did not define EPA's role clearly enough. In other instances the science on which to base a regulation was not well developed. Five years after the Clean Water Act was passed in 1972, EPA still had not drawn up regulations. So Congress went ahead and passed revisions that ordered the agency to regulate 128 specific pollutants. Similarly, Congress has revised the Clean Air Act of 1970 to include more deadlines. In 1976, the hazardous waste disposal law was passed; in 1980, regulations were finally written; in December, a very prescriptive version was passed. "The agency had gone for years without doing anything [on hazardous waste disposal]," said an aide to the House energy and commerce oversight subcommittee.

The Reagan Administration has exacerbated the situation. Even with Burford gone, congressional staff and environmentalists note that OMB continues to block EPA's regulatory proposals. Their concern intensified when OMB recently announced a plan to review regulatory proposals with greater scrutiny. Even if the agency administrator were given more flexibility, "there's OMB and it's planning to go further now [in its review]," said the House aide.

Others outside the agency are similarly concerned. Jonathan Lash, a senior attorney at the Natural Resources Defense Council, said, "I'm torn whether the administrator should have more flexibility." Perhaps it would make sense, he said, to let the administrator, for exam-

ple, pick which landfills can accept certain hazardous wastes. On the other hand, he too worries about intervention by the Reagan budget office and the agency's slowness in general to implement legislation. Doug Costle, the EPA administrator under President Carter, said that although he agrees that the head of EPA should ideally have more leeway, many factors would hamper efforts to that end. One major problem, for example, is that Burford generated political mistrust. "Credibility is one of the most elusive things in this town. Burford ruptured it for EPA," he said.

Ruckelshaus says that if people believe OMB has overstepped its bounds of authority, then Congress should write legislation that restricts its power, not



William D. Ruckelshaus

EPA's, or legislators should conduct more oversight hearings.

A House subcommittee aide said that legislation to restrict the powers of OMB "might" be introduced this year. John Dingell (D-Mich.), chairman of the Energy and Commerce Committee, is said to be considering such a measure, and a subcommittee aide notes that the time might be right this session to try to pass restrictions on OMB because Congress no longer has the power of legislative veto.

Congress is likely to take up quickly the reauthorization of Superfund and the Clean Water Act. Even so, legislative gridlock may ensue as in the past session. Ruckelshaus said that, in the long run, change in the statutory base can only come if the way in which regulators and legislators analyze risk is improved. As administrator, he repeatedly exhorted EPA staff to distinguish between evaluating risk and deciding what to do about it. He gave currency to the words "risk assessment" and "risk management." To him, these two concepts provide "an

intellectual framework" that will ultimately permit substantive and rational change in legislation that "more closely reflect scientific and social reality."

Congress needs to reform the major environmental laws, he says. The assumptions Congress and others made when the laws were passed 10 to 15 years ago have now changed. "We assumed we knew what the bad pollutants are, at what levels they cause adverse environmental or public health threats. We [assumed] we knew how to drive them down to a no-effect level, how to measure them, how to control them at a reasonable cost. All you needed was an enforcement presence that was sufficiently strong." Except for the need for enforcement, "all those assumptions were wrong."

If a legislative stalemate persists, Ruckelshaus said, then a bipartisan commission perhaps should be formed to examine "how the agency currently manages risk and how we ought to do it." Its members would be selected as "wise persons," who are independent thinkers and do not have a vested interest in the outcome. He is not sure whether the group should be formed by the Administration or created by several foundation groups.

While these "big, dramatic" legislative changes will come slowly, Ruckelshaus said, EPA goes about its business day to day. "What we are doing is making progress in the environment the way we always make it, and that is incrementally." People focus their attention on problems like ethylene dibromide, but "what they miss is that there are steps being taken every day in thousands of different ways throughout the agency that will result over time in significant environmental improvement." He looked out his 12th-floor windows and pointed to the Potomac River. "That river wasn't cleaned up in a week or a year. It was cleaned up over a 10-year period."

The regulatory pendulum has swung wildly under this Administration, he said. "There was an effort to swing the pendulum far towards the economic side. That failed and became discredited. Then there was a wild swing back in the other direction as a result of backlash. What I'm hoping is that the pendulum now starts to swing back towards the middle. I'm hoping that we're now coming to a point at which we can stop these kinds of swings and we can keep making steady, incremental progress." That will be the job of Lee M. Thomas, Ruckelshaus's own choice as his successor.

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