have any implications for human society," he says. "But the process has social impact because the announcement that research is being done is a political act."

The process by which the Sociobiology Study Group has pursued its ends is also political and is the subject of a serious countercharge by Wilson. In his letter of rebuttal to the *New York Review of Books* (11 December) he accused the group of "the kind of self-righteous vigilantism which not only produces falsehood but also unjustly hurts individuals and through that kind of intimidation diminishes the spirit of free inquiry and discussion crucial to the health of the intellectual community."

Wilson has a point. In addition to the group's attack, he has had his book labeled as "dangerously racist" by a Harvard-Radcliffe student group calling itself the Committee Against Racism. Citing the Sociobiology Study Group's critique, the committee declared in a recent broadsheet that "Wilson's gene-dependent culture notion amounts to international racism, implying technologically 'backward' cultures have backward genes" and urged readers to raise questions at an impending speech by Wilson. The Sociobiology Study Group has not endorsed the explicit accusation of racism.

"I have wavered about going to several lectures," Wilson told *Science*. "There has been clearly prearranged hostile questioning. Perhaps a braver soul would not have been concerned, but I find it intimidating." Wilson has since withdrawn from a public talk scheduled for 24 March because of the increasing mental strain on his family.

The group's answer to this charge is a mere denial that Wilson is or has any reason to be intimidated. "It is not our intention to frighten him off," says Lewontin. According to Gould, "We may have made some rhetorical mistakes, but we don't intend it as a personal attack. Tactically it would be very bad on our part to conduct this as a personal campaign because it would only make a martyr out of him." Gould adds that "Ed Wilson is a colleague whom we like."

If there is a disingenuous ring about these statements, it is because an attack of the type which the group has mounted on *Sociobiology* is bound to appear as an attack on the author as well, unless accompanied by specific disclaimers. But far from denying that a personal attack was intended, the group's letter to the *New York Review of Books* accuses Wilson of using "a number of strategies and sleights of hand," a phrase which implies deliberate deception, and of failing to separate out his "personal and social class prejudices." The personalization is taken further in the group's impending article in *BioScience*, which states: "It is no accident that the description of this underlying [human] nature bears a remarkable resemblance to the society inhabited by the theorist himself. In Wilson's case it is the modern market-industrial-entrepreneurial society of the United States." The group is thus apparently of the opinion that it is not a personal attack to accuse someone of having written a book which is vitiated by his personal political prejudices and deliberate efforts to gull the reader.

The group's manner of attack has not only intimidated Wilson but it could well act as a deterrent to others, particularly those less eminent and less able than Wilson to defend themselves. After all, the risk of being publicly compared with Nazi eugenicists by a cohort of Cambridge academics is not the most compelling of invitations to venture into a perplexed and largely uncharted subject.

Yet the group sees the debate as a political issue for which a political rhetoric is appropriate. That should be borne in mind by any who find their style overstated. The group has perhaps usefully drawn attention to the political dimensions of sociobiology and the field's susceptibility to distortion, even though they have had to do much of the distorting themselves to make the point. They would have a better defense against Wilson's countercharges of vigilantism and inhibiting free inquiry if they had argued their case in a less personalized and divisive fashion. But that, nonetheless, is the climate of discussion in which human sociobiology seems likely to develop.—NICHOLAS WADE

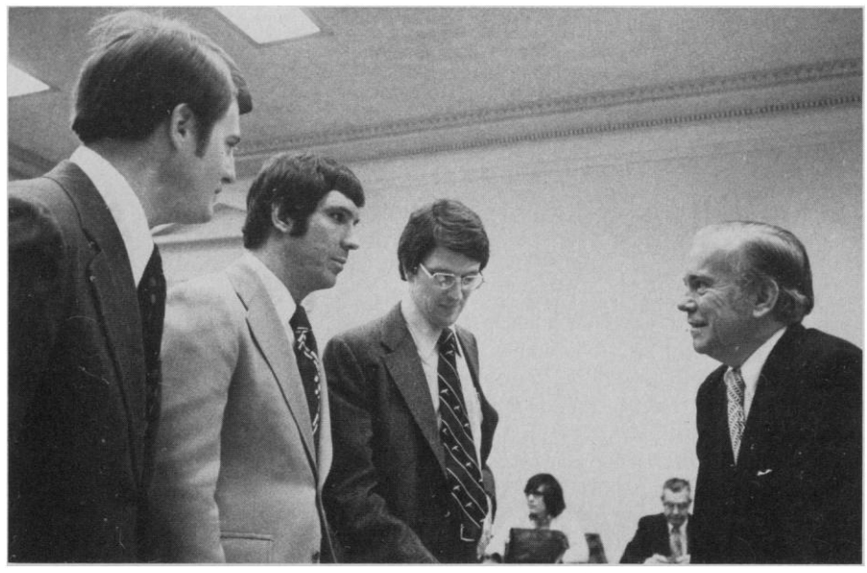
Pesticides: Three EPA Attorneys Quit and Hoist a Warning Flag

Administrator Russell E. Train of the Environmental Protection Agency (EPA) has been making an urgent case for passage of the Toxic Substances Control legislation now pending in Congress (*Science*, 13 February). But the irony is that, even as he campaigns for this legislation, his agency stands accused of responding to political and congressional pressures by backsliding in the regulation of pesticides—the one area of toxic substances control where the EPA has, at least in some instances, exercised strong authority under present law, as in banning most uses of DDT and aldrin and dieldrin.

The accusation has come from three young lawyers who have just resigned from the pesticides and toxic substances division of the EPA Office of General Counsel. "It is clear from recent actions," the three said in testifying before a congressional subcommittee "that the agency intends to refrain from vigorous enforcement of available toxic substances controls and to retrench from the few legal precedents which it has set for evaluating the cancer hazards posed by chemicals." Their criticism was broadly directed, touching on the implementation of the Clean Water Act of 1972 and the Safe Drinking Water Act of 1974 as well as the laws for the regulation of pesticides—but it is primarily with the latter that the attorneys have themselves been professionally involved.

Train and other EPA officials deny that there is any "retrenchment" under way. And, if things go as they predict, the agency will in the next year or two take action against dozens of additional dangerous pesticides. Nevertheless, the accusation by the three attorneys—Jeffrey H. Howard, 31; Frank J. Sizemore, III, 29; and William E. Reukauf, 31—is not to be lightly dismissed. They are in no sense run-of-the-mill government lawyers. In the words of an agency spokesman, "they led the charge for us" in the proceedings to restrict severely the use of aldrin and dieldrin and heptachlor and chlordane, two pairs of compounds found to be potent carcinogens.

Howard and Sizemore distinguished themselves in law school and, after a few years at Covington and Burling, one of Washington's most prestigious law firms, they came to EPA in early 1974. Reukauf had come to the agency about 6 months before that, having previously been an assistant federal district attorney in Washington with a record of successful prosecutions in criminal cases. In 1975, Howard was promoted to associate general counsel in charge of the pesticide and toxic substances division and Sizemore was made his principal deputy. Reukauf served the division as a senior trial attorney.



Former EPA attorneys William Reukauf, Frank Sizemore, and Jeffrey Howard with Representative William Moorhead (D–Pa.), chairman of Subcommittee on Energy, Conservation, and Natural Resources.

In an interview with this reporter, Russell Train suggested that the real explanation for the three attorneys' resignation did not lie in a dispute over issues of policy. "I think that what's happened is that, under new procedures I have set up, they saw that they weren't going to have as big a piece of the action as in the past," Train said.

Until recently, the Office of the General Counsel (OGC) was, with respect to the regulation of pesticides, a strong and relatively independent force within EPA. The agency's Office of Pesticide Programs (OPP), on the other hand, was looked upon by many people, both within and outside EPA, as something of a nullity. The attorneys in the OGC pesticide division regarded it not as an ally but as a bureaucratic obstruction to be sidestepped and ignored. But now, under the new procedures which Train has prescribed, things are to be different. The OPP, which was put under new leadership about a year ago, will initiate all regulatory actions and thus will have a chance to polish up its lackluster reputation.

Yet, where Train sees a rational reordering and tidying up of agency procedures, the three attorneys see a bureaucratic quagmire in the making. They believe that an exaggerated sense of caution and an undue deference to farm interests and the agricultural chemicals industry will soon become manifest.

For a better understanding of the various factors and circumstances involved here, one must go back to EPA's beginning in 1970. Prior to that time, the registration or licensing of pesticides had come under the U.S. Department of Agriculture, which had discharged its responsibilities in this field poorly. This had perhaps been predictable, because pesticide regulation is often in real or apparent conflict with the USDA's primary mission, the promotion of farm production. With the creation of EPA, the new agency took from the USDA the responsibility for registering pesticides and from the Food and Drug Administration the responsibility for establishing tolerances for pesticide residues in food. And, as one would expect, EPA absorbed many of the people who had been engaged in pesticide regulation at USDA and FDA.

Fairly or not, many of these carry-overs from USDA and FDA have been regarded by people in the OGC, and by some people outside EPA, as not truly committed to the EPA mission. In any case, from 1970 until mid-1975, when new regulations were belatedly promulgated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) amendments of 1972, the registration of new pesticides continued to be done in a largely routine and pro forma manner. As for the setting of tolerances for pesticide residues in food, this program was so ineffectual and slow-moving as to be widely regarded as a joke.

One commonplace observation about the OPP and its past deficiencies is that its scientists have been disposed to great caution and indecisiveness, especially in confronting questions of chemical carcinogenesis, for which their training and experience simply had not prepared them.

It was into the bureaucratic vacuum resulting from the OPP's lack of aggressiveness that the OGC moved and began asserting itself vigorously. Indeed, according to some who have been intimately involved in trying to bring pesticides under effective regulatory control, one can hardly overstate the importance of the OGC's role in EPA's cancelling the registration of DDT and aldrin and dieldrin for most uses, and, more recently, its suspending most uses of heptachlor and chlordane as an "imminent hazard." "There would have been no cancellations or suspensions without the OGC to act as a catalyst," says William A. Butler, a Washington attorney for the Environmental Defense Fund.

From the inception of a pesticide cancellation or suspension action to its conclusion, OGC attorneys have had to look repeatedly beyond EPA for the technical expertise necessary to sustain their case. They have established close ties with Butler and other EDF attorneys and scientists and with prominent researchers in chemical carcinogenesis at the National Cancer Institute (NCI) and a number of medical schools. Umberto Saffiotti, the associate director for carcinogenesis at the NCI's Division of Cancer Cause and Prevention, is one of the scientists whom these attorneys have often looked to for help.

Although the bold and freewheeling behavior of the OGC flouted conventional bureaucratic mores and caused deep resentment in the OPP, it seemed for a long time to find favor with the EPA administrators, first William Ruckelshaus (at EPA from 1970 until the spring of 1973), then Russell Train.

Meanwhile, however, a backlash over pesticide regulation was developing in Congress, and especially in the House Agriculture Committee, which had retained its jurisdiction over pesticides even after the Executive Branch had transferred the responsibility for regulating these compounds from the USDA to EPA. With many of its members drawn from rural and small-town constituencies, the Agriculture Committee is unusually susceptible to pressures from such lobbying groups as the Farm Bureau, the National Agricultural Chemical Association, and the National Pest Control Operators Association.

Accordingly, the committee was attentive when these groups began lobbying hard last year to have the pesticide act—which was expiring—renewed in a form more acceptable to pesticide manufacturers and farm interests. The ban on major uses of aldrin and dieldrin and the move to suspend most uses of heptachlor and chlordane had, in particular, caused deep concern within the agricultural chemical industry. These actions were based largely on evidence that these pesticides had produced tumors in test animals and should therefore be regarded as potential carcinogens in humans. To the industry, such decisions by EPA were similar in thrust to the Delaney Amendment requiring any food

additive that is carcinogenic in test animals to be banned.

Moreover, industry observers looked on uneasily as EPA moved to adopt the new regulations that would establish a presumption against new or continued registration of any pesticide producing evidence in laboratory or field tests of oncogenicity or teratogenicity. Although the presumption would be "rebuttable," the applicant for registration would have to show either that the risk was not so great as initially indicated or that it was outweighed by potential economic benefits.

The lobbyists' major aim was to amend the pesticide act in such a way as to give the Secretary of Agriculture a veto over the EPA administrator's decisions on which pesticide uses should be allowed or banned. Train denounced this veto proposal as an "administrative nightmare," and,

Penicillin G: Suddenly a Shortage

On Friday evening, 27 February, the Johns Hopkins Hospital almost ran out of intravenous penicillin G. Hopkins was not alone. No one is certain of the scope of the problem, but at scattered hospitals throughout the country, pharmacists were informing startled physicians that they were out of, or almost out of, one of the most widely used antibiotics. It is not the sort of thing one expects, yet queries to the Food and Drug Administration (FDA) and the Pharmaceutical Manufacturers Association (PMA) revealed that spot shortages of fairly common drugs are not all that uncommon. During the past 2 or 3 years, there have been passing shortages of ampicillin (another common antibiotic), quinidine (a heart regulator), heparin (an anticoagulant), and insulin. So far, none of the shortages has been extensive enough or prolonged enough to constitute a major health hazard, but certainly the possibility is there and the phenomenon of even temporary shortages poses difficult questions. Paul Lietman, a clinical pharmacologist at Hopkins, recounted what happened at his hospital, which buys most of its intravenous penicillin G from E. R. Squibb & Sons of Princeton, New Jersey. Squibb's pipelines had run dry, and Hopkins, which realized the shortage was coming 3 weeks in advance, began looking around for another supplier. It found one that could sell it enough penicillin G to last a couple of weeks, no more. So, Lietman explained, when it became apparent that the hospital really was virtually out, they put aside a small stockpile for the rare patient (someone with bacterial endocarditis, for instance) for whom intravenous penicillin G is essential and began using a substitute antibiotic for most patients. "Fortunately," says Lietman, "because we have so many substitutes, this shortage has not caused serious health problems."

What happened to the supply of penicillin G? It seems it has to do with a proposed FDA regulation and a Squibb plan to move some facilities from New Jersey to Maryland that did not go smoothly. The FDA, which requires drug companies to operate in compliance with Good Manufacturing Practices (GMP), is proposing a regulation that says there can be, as bureau of drugs director Richard Crout put it, "zero" penicillin contamination of other drugs. On the face of it, it certainly sounds sensible. After all, who wants penicillin contaminating his tetracycline, or his vitamin C? But keeping penicillin in its place apparently is not that simple. As Crout notes, it gets into the air with the greatest of ease and, therefore, can travel around a manufacturing plant. Furthermore, assays for detecting penicillin are good; even the tiniest bit of it where it does not belong can be discovered. With FDA proposing to tighten its GMP standards from a low tolerance of penicillin contamination to "zero" tolerance, industry faces new demands on its engineering capabilities.

One solution to the FDA proposal is to fight it, as being too costly and unnecessary to the public health. Crout expects some firms will take that course. Another is to consider redesigning plants, installing new air filtering systems, and the like. A third—the one Squibb seems to have taken in anticipation of the regulation—is to process penicillin in a facility that is physically separate from places where other drugs are prepared. Now, although Squibb will continue to maintain its fermentation vats in New Jersey, it will handle other aspects of production in Maryland, where a subcontractor will package penicillin G under sterile conditions.

Squibb shut down its New Jersey penicillin operation, without announcing this to its competitors who might well have increased their own production, and moved to Maryland. Problems in maintaining usual supplies arose when the company encountered unanticipated difficulties in resuming operation. Meanwhile, hospitals were ordering the drug as usual from distributors, whose stock became depleted. By now, the Maryland plant is in operation and the FDA has begun certifying batches of penicillin G there, but it will be a couple of more weeks before the pipeline is full again. And, as one FDA staffer noted, buyers may not be aware that the shortage is over and may be living still with "psychological panic."

Production lapses at U.S. plants are not the only reason for drug shortages. For quinidine, for example, we are dependent upon good trade relations with Indonesia, home of the Cinchona tree, from whose bark the drug is extracted. For drug production in general, we are dependent, at least in part, upon the Middle East, as Crout points out. He recalls that during the gasoline shortage a couple of years ago, FDA and PMA officials contemplated large-scale and very serious shortages if pharmaceutical companies were unable to get acetone, alcohol, and other solvents essential to drug manufacture, or plastics necessary for packaging, intravenous tubes, and such. With no answer at hand, the issue went away with the normalization of the oil supply. But it could come up again.

There is no body in the United States that systematically monitors the drug supply to anticipate shortages, although there has been talk about one. However, the Department of Commerce has looked into the drug supply question in light of pending proposals for National Health Insurance. Last summer, the department's domestic business policy analysis staff asked Booz, Allen & Hamilton, management consultants, to study the matter. They did so in just 4 weeks and turned in their report on 2 September. Among their conclusions was this: "There do not appear to be any major barriers to meeting national health insurance induced demands for prescription drugs." Booz, Allen & Hamilton told Commerce that there is no reason to anticipate shortages created by increased demand as long as the current cost-price relationships between production and sales are allowed to continue. They said that, with available production capacity, pharmaceutical manufacturers could probably increase their production by 10 percent in a normal year.

But we still have shortages.—B.J.C.

ultimately, it was rejected by the Agriculture Committee as too far-reaching to have any chance of House passage.

Later, the House itself rejected the proposal, but it did so by a surprisingly narrow margin. Train and other officials at EPA took this as disturbing evidence that all the talk by congressional spokesmen for farm interests about the agency choosing moths over trees, boll weevils over cotton, and fire ants over people had led to a serious erosion of support for the pesticide regulatory program.

Early last September, just as the House Agriculture Committee was about to reach the critical vote on the veto proposal, Russell Train set up a small ad hoc group within EPA and instructed it to review the agency's procedures relating to pesticide cancellations and suspensions and to recommend ways to resolve the conflicts between the OPP and the OGC. It was evident, he said, that "major disagreement exists as to the adequacy of scientific input in the decision-making process under our pesticide cancellation procedures."

On 10 October, Train accepted the ad hoc group's recommendations, which called for decision-making in the field of pesticide regulation to follow the same pattern followed in EPA's programs for air and water quality, noise abatement, and solid waste management. The OPP would assume the dominant policy-making role, with the OGC limited largely to functioning as legal counsel. The OGC could continue to speak up on policy questions, but now, instead of developing policy more or less independently and taking its case directly to EPA's top officials, its attorneys would have to live with the normal bureaucratic frustrations of trying to make themselves heard in endless committee meetings.

For Howard, Sizemore, and Reukauf the very thought of serving as legal hand maidens to the OPP presented such a dreary prospect that they began then and there to think of resigning. Their discouragement and concern was all the greater because Train, again in keeping with the ad hoc group's recommendations, called for the adoption of a formally stated agency policy on cancer risk assessment.

Although this latter directive was prefaced by an expression of confidence in the soundness of past pesticide decisions (later, in his heptachlor/chlordane suspension decision of 24 December, Train formally reaffirmed his faith in the carcinogenicity principles previously applied), the report of the ad hoc group had contained some observations that seemed curiously equivocal. The group said, for instance, that "the perception that EPA is unwilling to accept any cancer risk from pesticides is reinforced by the failure to provide [prior to formal adversary hearings] an open mechanism for evaluating and comparing risks and benefits and by the belief that the 'middle of the road' scientific testimony on the subject does not get introduced at the hearings . . ."

The three attorneys looked dubiously at the work of the agency's new Cancer Assessment Group headed by Roy E. Albert, who in July had taken a two years leave from his regular position as professor of environmental medicine at the New York University Medical Center to join EPA's Office of Research and Development. A researcher of good standing and reputation in the field of carcinogenesis, Albert is well regarded even by people such as Saffiotti with whom he is in disagreement on certain major issues. But, from a legal and regulatory standpoint, any significant changes which Albert's group proposed in the agency's cancer risk assessment policy might undercut principles already applied in the aldrin/dieldrin and heptachlor/chlordane proceedings. EPA's central position on carcinogenesis—that any compound shown to cause tumors, "benign" or malignant, in test animals at any dosage level must be considered a potential human carcinogen unless proved otherwise—has been defended successfully and repeatedly on cross examination before administrative law and appeals court judges.

The several drafts of the "Preliminary guidelines for cancer risk assessment" which Albert has circulated have received mixed comments from reviewers. Apart from the skepticism and concern voiced by the three attorneys who have now left the agency, the comments from within EPA appear largely favorable. But the comments of one prominent outside reviewer, Samuel S. Epstein, professor of environmental health and human ecology at Case Western Reserve University, have been strongly critical. In a letter to Albert on 29 January, Epstein said in part:

> It . . . appears that the purpose of this document is to attempt to produce a gradation of carcinogens, based on your proposed interpretation of animal data . . . Once there is agreement that carcinogenicity data have been developed in well designed experimental systems, the limits of scientific discretion are thereby reached. . . . You are here attempting to take this discretion one stage further and to suggest on allegedly scientific grounds that regulatory distinctions may be made between supposedly different classes of human carcinogens. . . . May I suggest that you make every effort to resist the apparent pressures on you to "bend" the science of carcinogenesis for alleged regulatory needs. . . . Your very considerable talents might be put to far better use in EPA if you were free to concentrate on problems relating to judgment on the validity of scientific data, rather than on developing a new doctrine of chemical carcinogenesis.

Saffiotti has made no written comment on Albert's drafts, but, as he has indicated to this reporter, he is no less emphatic than Epstein in rejecting the idea that carcinogens can be graded as to potency and level of human risk on the basis of extrapolations from animal data. On this issue Albert regards him as an "extremist," but, in Saffiotti's opinion, it is Albert who is outside the mainstream of scientific thinking.

Upset at the downgrading of their roles and convinced that the agency was drifting off course, Howard, Sizemore, and Reukauf decided by early February that they would resign and form a law partnership. Their sharp criticism of the EPA in a public statement released at the time of their departure gave rise to some cynical comment within EPA, and even among some of their former colleagues in the OGC, that they were making a splash to promote their law firm. That is not, however, the way their motivation has been perceived on Capitol Hill. Staff people of five different House and Senate subcommittees have talked to them at some length, and in every instance they seem to have come across as credible and conscientious. The staff of the House Government Operations Subcommittee on Energy, Conservation and Natural Resources thought their criticisms of the agency to be important enough to justify the holding of a special hearing at which they testified on 11 February.

Attempts to evaluate any particular set of bureaucratic arrangements before they actually have been tested can be an idle exercise, and the three attorneys could well be proved wrong in their judgment that the new arrangements affecting the pesticide program represent a "retrenchment." "I've made it absolutely clear to Ed Johnson [the new deputy assistant secretary for pesticide programs] that, if they don't move ahead aggressively, I'm going to revise the procedures again and take the authority away from them," Train told *Science*. And, as for the three attorneys' expressed concern that EPA may be on the point of compromising its position on chemical carcinogenesis, Train says this is simply nonsense.

Nonetheless, the track record at EPA on the regulation of pesticides is sufficiently mixed that any warning flag hoisted by competent individuals should be heeded. Furthermore, the processes whereby regulatory vigor is sapped and dissipated, either by design or inadvertence, can be subtle. By their resignation and public outcry, Howard, Sizemore, and Reukauf have served notice that there are things going on at EPA which will bear watching.

—LUTHER J. CARTER