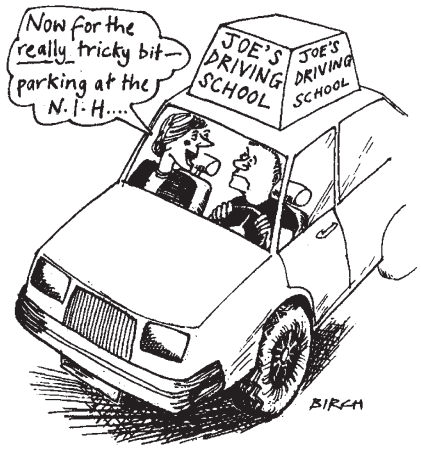
Culture clash inside the walls

Bethesda, Maryland

FROM the outside, the US National Institutes of Health (NIH) look like a troubled agency. Scientific misconduct, conflict of interest, funding shortages, White House meddling on fetal tissue research and a cancelled sex survey have all made headlines this year. Inside, things look different, but not necessarily better.

Last week, NIH researchers got their chance to sound off, when director Bernadine Healy held the agency's first 'town meeting' in hopes of avoiding a



growing crisis of morale. The agency's researchers turned out to be no happier about NIH than the average congressional investigator, but that was where the similarity ended. Paperwork, parking, and laboratory space are the things that keep intramural researchers up at night, not data fabrication and politics.

Indeed, congressional concern about government contracting abuses and conflict of interest have only made life more difficult at NIH, researchers complained. Paperwork and bureaucracy often consume a third of an NIH researcher's time. One example: NIH scientists are supposed to buy equipment from small companies whenever possible. A year ago, it was enough to note that one had checked with such a small company before going to a larger competitor. But last month a memorandum informed staff of a new rule: regardless of what their catalogues may indicate, at least two small companies must be telephoned and stock clerks questioned (and their names taken down) before it would be acceptable to go to a large company for a hard-to-find item.

"We are treated like naughty children who are wont to tell lies," complained yeast researcher Enrico Cabib. "In 20 years at NIH, I think I have earned the trust and respect of the scientific community. It is sad that I have not earned the trust of the people where I work."

Other researchers suggest that, rather than acquiescing while Congress passes new laws to regulate NIH, perhaps the agency could hire some good lawyers to get around those laws it is already saddled with. And nearly everybody mentioned the space problem, whether it be no place to put their car or no room but the hallway for their laboratory's autoclave. One researcher told of a colleague who worked on a plank over a sink in the crowded Bethesda campus before he was gratefully transferred to 'Siberia' — the NIH satellite facility in Frederick, Maryland. At least there he had his own workspace, even if he did have to drive an hour to get to it.

Healy's response to most of this was sympathetic agreement, and reassurances that almost all these concerns were already being addressed. She announced that a two-day director's retreat earlier this month had started the process of a new 'strategic plan' to reform NIH by cutting bureaucracy and streamlining operations. She said her staff were in the process of preparing the first 'site plan' in 20 years, something that could lead to a major new campus — 'NIH North' — to ease the crowding in the Bethesda laboratories. The procurement office is developing an 'action plan' to cut purchasing bureaucracy, she said. And she promised that the NIH's only lawyer — Robert Lahnan — would be getting reinforcements soon.

But she warned the researchers that red tape comes with the territory when one works for the government, especially when an agency has been the focus of a half-dozen congressional investigations in the past year. "Don't shoot the messenger," she said. "We can either break the law and go to jail, or try to improve the law." Presumably more lawyers would help. If not, she wryly joked, "I'm the only person on this campus who can be fired."

Christopher Anderson

Dingell to Healy: lighten up

BERNADINE Healy can rest easy for the moment. Whatever else may come of her running battle with the House Investigations and Oversight subcommittee under John Dingell (Democrat, Michigan), the NIH director will not have to go jail over her parking space.

Healy herself raised that spectre at the NIH 'town meeting' last week, after staff researchers challenged her over parking space shortages. Although she promised some 600 new spaces over the next six months, Healy pointed out that there are some things worse than having no space at all — a congressional investigation, for example. Dingell's staff descended upon NIH last month to investigate her handling of misconduct and other matters, she revealed, "and one of the things they looked into was my parking space."

That seems a bit extreme, even for the detail-obsessed Dingell. A call to the subcommittee shed some light on the subject: during their visit, Dingell investigators Peter Stockton and Bruce Chafin mistakenly parked in Healy's spot, prompting one of her staff to run out and shoo them away. Why, the investigators teased the aide, does Healy need a parking space, anyway? After all, she lives in a government-supplied house on the NIH campus, a few hundred yards from her office. Later, they also complained about the price of soft drinks in the NIH cafeteria. Was Healy, they asked, skimming off the top to furnish her mansion, "just like [former Stanford University president] Don Kennedy?"

All this was apparently relayed straight-faced back to Healy, who challenged the Dingell staff on the propriety of such 'investigations'. Now, among the subcommittee's other concerns about Healy, Stockton says, "we think she needs to get a sense of humour." **C.A.**

Popovic rebuts

Washington

UNABLE to prove that AIDS scientist Robert Gallo is guilty of misconduct in research leading to a blood test for the human immunodeficiency virus, the US National Institutes of Health (NIH) Office of Scientific Integrity (OSI) has turned its fire on Mikulas Popovic, the cell biologist in Gallo's laboratory who was the first to get an AIDS virus to grow in quantity. After the draft of the OSI's report on the case was leaked to the Chicago *Tribune* earlier this month, Popovic's attorneys released a copy of their rebuttal which accuses OSI of following unfair procedures, holding a "clear predisposition" to blaming Popovic for misconduct, and being just plain wrong in some of its interpretations of scientific data.

Once again, NIH have failed to keep confidential documents confidential and, once again, the case is being heard in the press.

Popovic's rebuttal criticizes OSI for withholding access to pertinent documents and blasts the integrity office for using the draft report itself as a vehicle for revealing previously secret information. Thus, Popovic's attorneys Barbara Mishkin and Edward Korwek write: "We now learn for the first time ... that OSI received written answers to interrogatories from Luc Montagnier and the editors of *Science* about the May 1984 publication in *Science* of the Gallo-Popovic paper confirming the viral cause of AIDS. "These answers to interrogatories are pertinent ... yet he was

never told of their existence, much less afforded an opportunity to review them."

Neither Gallo nor Popovic will release the OSI's draft report (in fact, Popovic may sue NIH over the unauthorized leak), but the rebuttal selectively reveals what the draft says. For example, it deals with the question of when and to what extent Gallo and Popovic grew the virus, then called LAV, that came from Montagnier's laboratory at the Pasteur Institute. According to Popovic's rebuttal, Montagnier acknowledged to OSI that as early as December 1983 Popovic told him that he had learned how to "handle" LAV. "Yet the Draft Report nowhere acknowledges this fact. Instead, it rambles for nine pages discussing what Gallo and Popovic may or may not have disclosed to Montagnier, leaving the strong impression that OSI could not confirm what Gallo and Popovic both asserted." Omission of this exculpatory evidence, Mishkin says, is but "one example of OSI's bias".

Then there is the matter of the word "continuous" which has captured the OSI's attention from the beginning of its inquiry. The paper says that Gallo's lab had HIV in continuous culture for five months, during which the culture was reinoculated with fresh cells and virus. OSI says that is not continuous. Popovic says it is, in the ordinary meaning of the word that once virus started growing, it did not stop. The culture always showed virus production.

In reaching a conclusion that Popovic is guilty of scientific misconduct, OSI apparently also takes issue with the reproducibility of his data. According to the OSI draft report, "reproducibility depends fundamentally on good laboratory records and accurate reporting of methods and results." Popovic, acknowledging that his paper could have been written more clearly, nonetheless contends that he has met the test of reproducibility because his experiments have, in real life, been duplicated by scientists around the world.

OSI's central claim against Popovic, based on information currently in the public domain, is that minor errors in the *Science* paper are scientifically "meaningless" but do "gild the lily" by giving the impression that the paper is more thorough than it is. According to Popovic's lawyers, OSI then reasons that gilding the lily constitutes a deliberate intent to deceive. Therefore, Popovic's meaningless errors are intentional. From what the lawyers call a "preposterous resort to baseless psychology", OSI concludes that Popovic has committed fraud.

There is no way for the scientific community to sort this out absent direct access to the many documents in OSI's possession—something it is not likely to get. However, a second OSI report, written with the Gallo and Popovic rebuttals in mind, is now in preparation.

Barbara J. Culliton

End of an era

Washington

SOME 30 years after the US Congress passed landmark legislation decreeing that the only acceptable cancer risk in food was none at all, lawmakers are starting to have second thoughts. Three bills have been introduced this year to overturn US risk-assessment policy, and at least two others are on the way. Spurred by lawsuits from environmentalists and an impending National Academy of Sciences (NAS) report on risk assessment, this Congress may be the one to finally kill the controversial 'Delaney Clause'—the 1958 'zero-risk' provision in US food safety law that many researchers believe has since been rendered obsolete by science.

Last week the Washington-based Institute for Science in Society released a report* comparing the various congressional proposals with current practice and reforms proposed by the White House. The surge of legislative activity, coupled with a growing scientific consensus, "suggests that this Congress may resolve some of the long-standing statutory problems" of US risk assessment, the report concludes. For the researchers, consumer groups and industry associations who have for decades criticized federal risk-assessment policy in general, and the Delaney Clause in particular, such a resolution will come not a moment too soon.

The problem with the Delaney Clause is not that pesticides and food additives are no longer a cancer threat, but that researchers are now too good at spotting carcinogens. Whereas analytical methods for detecting cancer-causing compounds were still primitive enough in 1958 to miss levels that might actually have a health impact on the population, today's methods are sophisticated enough to detect risk levels in the range of one in a thousand million and even lower. In public health terms, such risks are considered negligible. But they are, strictly speaking, non-zero, and a literal reading of the Delaney Clause requires that a food additive or pesticide residue that presents any risk at all be prohibited.

In practice, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) have in recent years chosen to apply a *de minimus* exception to the Delaney Clause, arguing that the spirit of the legislation is to prohibit any *real* risk, a level they defined as greater than 10^{-6} — one in a million.

Hoping to force reforms, however, several environmental and consumer groups have recently sued the agencies on that interpretation, arguing that it is technically in violation of the Delaney Clause and in practice leads to erratic rule-making — FDA and EPA, for example, have often disagreed on the meaning of the term 'negligible risk'. Perhaps the strongest of the suits, that filed by the Natural Resources Defense Council (NRDC) against the EPA, has won several favourable court rulings and could be decided in NRDC's favour as early as the end of the year.

There is also the issue of just whose risk is to be calculated. Current EPA policy is to base the regulations on the risk to an average consumer, a method that takes into consideration changing consumption patterns over a lifetime. A bill introduced last month by Representative Terry Bruce (Democrat, Illinois) would essentially codify that policy. But Representative Richard Lugar (Republican, Indiana) is expected to introduce another bill that would set a '90th percentile of consumption' level — that of a person who eats more of the particular food than the lower 90 per cent of consumers, but less than the upper 10 per cent. And matching bills introduced in May by Representative Henry Waxman (Democrat, California) and Senator Edward Kennedy (Democrat, Massachusetts) would set the risk levels to that of the most sensitive population group, including infants and people with compromised immune systems.

In general, all the bills would continue to define risks of 10^{-6} as 'negligible' for adults, although the Kennedy–Waxman legislation would set even higher standards when children are at special risk. Critics of the bill say that the practical effect of that provision is to make children the benchmark across the board. "Nobody is going to make food with labels that say 'not for use by children or the immune-compromised'," says Greg Thies, a Senate staff member who is working on the competing Lugar bill.

Nevertheless, thanks to the NRDC lawsuit and the forthcoming NAS study, the Kennedy–Waxman bill is considered the most likely to pass, either this year or in the 102nd Congress's second session next year. If NRDC wins its suit, it will argue for EPA's regulations to be replaced with something akin to the Kennedy–Waxman bill, says senior NRDC attorney Erik Olson.

"If the NAS also concludes that children are at higher risk," says Theis, "I think we'll be looking at a flood of public sentiment and a groundswell of support for the Kennedy–Waxman bill." If so, the Lugar bill (which generally reflects Administration policy) may help to moderate the strict Kennedy–Waxman bill enough to avoid White House opposition.

Christopher Anderson

* *Unraveling Delaney's Paradox: Challenges for the 102nd Congress*, Institute for Science in Society, September 1991.