

they find time to see friends and go to basketball and ice hockey games together. She takes the car to school and he takes the bus, moving around with the aid of a collapsible white cane. Sheri reads aloud for them both as well as for him—currently they are plowing through *The Cancer Ward*. Hartman studies in a small den crowded with dozens of volumes of a Braille medical dictionary and many stacks of tapes identified with Braille tabs. He has a Braille typewriter and an Opticon, an expensive newly developed instrument about the size of a small cassette tape recorder that translates printed words, through a lighted sensor, into little upraised brushes that give the shape of each letter. Hartman finds the Opticon of limited use because it is very slow going, but is thinking about better applications for it—such as reading electrocardiograms.

After years of arduous work and planning and “wondering how crazy I really was” to choose a medical career, the future is looking pretty good.

Although Hartman sees himself as “pretty much average in medical school” he is in the top 20 percent of his class. Asked why it took so long for a blind student to be admitted to medical school, he attributes it partly to society’s

increased interest in opportunity for all, partly to the change in medical education that permits a person to specialize early. Extensive knowledge about everything is no longer required and “they don’t need that all-American completely physically healthy individual.” Temple also deserves considerable credit. It was founded at the turn of the century with the aim of bringing a medical education to the working man and others to whom it was not usually available. Sevey says its admissions committee is the hardest working committee at the school, and Beryl Lawn says the people there are exceptionally nice, making a special effort “to take the whole person into account.” Says Sheri Hartman, “If Temple hadn’t been willing to take the risk, he’d be just another blind person in psychology.”

Hartman, who’s always planning and has fallback positions for everything, has his next 5 or 6 years tentatively mapped out. He wants to do two residencies, one in rehabilitative medicine, the other in psychiatry. His plan is to do 1 year in the former field (“I want to be sharp on physical diagnosis”), then take 2 or 3 years in psychiatry and return to rehabilitation, the idea being that you can’t do rehabilitation in a psychiatric residency, but you

can apply psychiatric training to a rehabilitation residency. So far he doesn’t know much about psychiatry, having avoided it in the interests of getting as much physical medicine as possible under his belt. He hypothesizes, though, that people who are nervous about psychiatrists might feel more relaxed with him because they won’t feel they are being psyched out at first glance.

Hartman sees himself as working in a hospital setting but is also interested in doing family therapy (which he says is particularly important for disabled people) and in improving services for the poor. He is also interested in developing new techniques for evaluating the effectiveness of therapy.

His career will obviously include education of the nonhandicapped as well, whose ability to relate to handicapped people is often hampered by preconceptions about their limitations. Hartman believes that he could very possibly be an internist if he chose, and he thinks some way might even be found in the future for a blind person to go into surgery. “I don’t think anybody knows a blind or disabled person’s limitations,” says he. “There is no way a sighted person can tell me what I can or cannot do.”

—CONSTANCE HOLDEN

Scientists and Bureaucrats: A Clash of Cultures on FDA Advisory Panel

When scientist meets bureaucrat, the experience can be frustrating to both.

Consider, for example, the recent 2-day meeting of the Toxicology Advisory Committee of the Food and Drug Administration (FDA). This group of distinguished scientists—drawn primarily from the universities and government health agencies—has been grappling with the problem of determining the safety of the controversial color additive, Red Dye No. 2. It operates amid a swirl of conflicting interests and in full view of the public, thanks to recent laws that require much advisory committee business to be conducted in open session, where petty irritations and clashing egos lie exposed to all.

The committee was appointed late last year to give the harassed FDA greater ex-

pertise on issues involving the safety of chemicals in foods, drugs, cosmetics, and medical devices. It is considered one of the agency’s most important advisory bodies—one of only two such committees chaired by a high FDA official.*

On 8 and 9 March the committee members assembled at FDA offices in Rock-

*The committee is currently chaired by Mark Novitch, the FDA’s acting associate commissioner for science, and includes Thomas B. Clarkson, Wake Forest University; Thomas W. Clarkson, University of Rochester; W. Gary Flamm, National Cancer Institute; David W. Gaylor, FDA’s National Center for Toxicological Research; Eloise R. Giblett, King County Central Blood Bank, Seattle; Bert N. LaDu, University of Michigan; H. George Mandell, George Washington University; Sheldon D. Murphy, Harvard University; Edward A. Smuckler, University of Washington; Robert A. Squire, National Cancer Institute; Thomas R. Tephly, University of Iowa; and James G. Wilson, Children’s Hospital Research Foundation, Cincinnati. Not all members attended the recent meeting, which was chaired by John Jennings, the FDA’s associate commissioner for medical affairs.

ville, Maryland, to consider the safety of both Red No. 2 and its successor, Red No. 40. They heard presentations by FDA officials, debated the significance of experimental findings, and tried to reach a consensus on key issues. But they were plainly irritated at the conditions under which they were forced to operate. They complained repeatedly about having to debate complicated scientific issues at a public meeting—one that was jammed to the point of overheating by a crowd of bureaucrats, industry representatives, reporters, and a lone consumer advocate. Their chief fear was that off-hand remarks might be taken “out of context.” Nor did they appear mollified when an FDA official assured them: “The audience may be out there, but that doesn’t stop the monkeys in the zoo from playing.”

But mostly they railed against what they perceived as heavy-handed manipulation of the discussions by FDA officials who had certain questions they wanted answered—questions that did not always strike the committee members as sensible or appropriate. At one point the committee refused to take a yes-or-no vote on an issue it considered too com-

plicated for such treatment. At another point it flatly refused to answer a question posed by an FDA attorney, and later gave an industry lawyer the same cold shoulder. By the end of the second day the exasperated scientists staged a mini-revolt—winning the right to appoint one of their own kind as cochairman alongside the FDA representative to ensure that henceforth matters the scientists consider significant will get as much attention as questions deemed important by the FDA bureaucracy.

It was clearly a clash of two cultures and styles. On one side were the scientist advisers—fond of extended debate, resentful of efforts to force answers from questionable data, and prone to argue strenuously over the meaning of words before even agreeing on the appropriateness of a question to be posed. On the other side were the regulatory officials (many of them scientists as well)—beset by a new crisis every week, unable to wait for “all the facts” before acting, and obliged to operate in accord with a bewildering array of laws and regulations that often dictate the questions that must be asked and the decisions that must be made. Such collisions of representatives from different worlds are by no means uncommon. They occur with increasing regularity, as dozens of federal agencies reach into the research community to obtain the help of outside advisers. The tribulations of the Toxicology Advisory Committee provide a revealing glimpse of the strains and frustrations—some justified, some not—experienced by scientists who come to Washington to counsel the titans of government.

The committee was formed last October and was given two broad assignments—to develop standards for toxicity testing and to assess the safety of specific substances. In an ideal world, one would first establish the testing standards, then evaluate specific substances by those standards. That is what many members of the committee expected to do. But even before the group held its first meeting, the FDA, which was caught in the middle of sharp controversy over Red Dye No. 2, tossed the hot potato to the new committee for an advisory opinion. Thus the group’s first 2-day meeting—held last November—was devoted to an extensive review of the scores of studies that had been performed over the decades to test the safety of Red No. 2. Many of those present felt that Red No. 2 appeared innocuous on the basis of available evidence, and they proclaimed as much in the public session. But, just to be sure, they asked a few of their members to perform addi-

tional analyses. Then they adjourned, expecting to resume their measured deliberations at a future meeting.

Two months later the FDA commissioner announced a ban on Red No. 2 without even consulting the committee. In the interim, one of those additional analyses the committee had ordered up—a statistical analysis of a recent FDA study performed by David W. Gaylor, principal biological statistician at the FDA’s National Center for Toxicological Research in Jefferson, Arkansas—found a significant increase in the number of malignant tumors in female rats fed high doses of Red No. 2. Recognizing a potentially explosive new element in public debate over the safety of Red No. 2, the commissioner wanted an advisory opinion on the significance of Gaylor’s analysis, and he wanted it fast. The Toxicology Advisory Committee was deemed too cumbersome for rapid convening, so a “working group” of government scientists (three of whom were members of the advisory committee) was hastily assembled. It concluded that Gaylor’s statistical approach was valid but that someone should recheck the pathological data on which his analysis had been performed. The working group also stressed that the FDA study had been so badly “botched” in execution that it could never be used to demonstrate the safety of Red No. 2 (*Science*, 6 February). That bit of advice led the commissioner to ban Red No. 2, a decision that is now being contested in the courts by the manufacturers of color additives. But in the meantime, Red No. 2, which had almost won a clean bill of health from the Toxicology Advisory Committee in November, has been abruptly and dramatically sentenced to extinction.

Irritation on the Committee

Not surprisingly, when the committee was finally reconvened early this month, some members were miffed at the way they had been bypassed; one grumped that the committee itself should have been used as the “working group.” They were also upset that the analysis that initiated the downfall of Red No. 2—the one done by Gaylor, a member of the committee, at the request of the committee—was leaked to reporters and then officially released by the FDA before most members of the committee had even seen it. “Red 2 was tried in the press,” said Edward A. Smuckler, professor of pathology at the University of Washington’s medical school, who complained that the committee’s own contribution—notably Gaylor’s analysis—was “compromised” by failure to treat the is-

sue in a proper scientific forum. “It’s wrong that this should hit the media before it hits the table,” agreed Thomas R. Tephly, director of the Toxicology Center at the University of Iowa’s College of Medicine. Several committee members suggested that all communications involved in their work should be kept confidential lest they be distorted or taken out of context. But they received no assurances from the FDA that this would always be done. John Jennings, the FDA’s associate commissioner for medical affairs, who chaired the meeting, apologized for not being able to get Gaylor’s analysis to the members “before it hit the fan,” and he pledged to “do our damndest to stop leaks.” But he noted that leaks seem inevitable in some cases, and that other documents must be made public under “the infamous Freedom of Information Act.” That act—and a companion measure, the Federal Advisory Committee Act—are designed to open previously secret government processes to public scrutiny, but many bureaucrats and scientists balk at the idea of performing in public, where their advice can be second-guessed or, as some would put it, “misconstrued.”

Nor did the committee members get much satisfaction when they raised the possibility of holding closed meetings. The FDA had decided to open the meetings on Red No. 2 rather than face a possible legal challenge to closed proceedings, and FDA officials told the committee it would just have to learn to “live with” the new spirit of openness. At one point Jennings tried to close the meeting so the committee could air its gripes about organizational matters in private, but he backed down when Anita Johnson, an attorney for Ralph Nader’s Health Research Group, quietly protested violation of the Federal Advisory Committee Act, then stoically sat through the discussion of housekeeping trivia to establish her point.

The entire first day and part of the second was spent trying to reach a consensus on certain questions about Red No. 2. The committee voted unanimously that the FDA’s crucial “botched” experiment was not of a quality that could be used to demonstrate the safety of Red No. 2. That verdict essentially endorsed the conclusion previously reached by the “working group,” and it upheld the most important basis for the FDA commissioner’s decision to ban Red No. 2, namely that there is no experiment in sight that could exonerate the dye. Then the committee was asked to vote on whether the results of the botched study provide “evidence” of

the carcinogenicity of Red No. 2. But what did that mean? *Any* evidence? *Significant* evidence? *Substantial* evidence? No agreement was reached, so the committee member who framed the question, W. Gary Flamm, of the National Cancer Institute, solved the problem by declining to add any modifier. The committee itself refused to take a yes-or-no vote; each member gave a brief personal answer using whatever definition he felt comfortable with. Observers from the FDA, the industry, and the journalistic pool kept their own informal counts, reaching a consensus that six committee members felt the experiment was so bungled it provided no evidence of carcinogenicity (or much of anything else for that matter), while only four committee members detected some evidence of carcinogenicity, however tainted it might be. The majority seemed to repudiate the significance of Gaylor's analysis that had triggered the banning of Red No. 2, and it undercut the FDA commissioner's assertion that the botched experiment had raised again "certain safety questions."

The committee members clearly felt uncomfortable about squabbling in public. Two even alleged that Gaylor's failure to attend the second day's proceedings was due to "embarrassment" over the way things were handled. But Gaylor told *Science* such allegations were absurd—he had to leave for a previous speaking commitment in Texas. As far as Gaylor is concerned, those who voted in the majority didn't fully realize that the errors in the botched experiment would tend to mask the harmful effects of Red No. 2—thus if there is a hint of carcinogenicity, Gaylor said, it should be considered even stronger evidence than if the experiment weren't botched. Gaylor also

speculates that some members were antagonistic toward the analysis partly because "they were ticked off at being bypassed by the commissioner" in the decision to ban the dye, and partly because, like all scientists, they are enthusiasts for good experimental work and don't want to rely on a flawed experiment.

The practical effect of the majority's vote against Gaylor is expected to be negligible. An FDA attorney said that if even four of ten experts see a hint of cancer, it supports the commissioner's case, and an industry attorney agreed that the FDA came out ahead as a result of the various votes at the meeting.

In addition to the cancer issue, some committee members expressed concern that Red No. 2 might be having an adverse effect on the general health and mortality of test animals, and many were disturbed by hints that one of the metabolites of the dye might conceivably be mutagenic. But consensus was reached that the dye has no adverse effect on reproduction.

On the second day, yet another vote was taken. The committee agreed unanimously that, based on all the evidence from all the tests it had reviewed, it could not *approve* the safety of Red No. 2. All very well and good, but could the committee *disapprove* the safety of Red No. 2? asked an industry attorney, hoping to receive a negative answer that might strengthen his case that the FDA had no good reason to ban the dye. He got nowhere. The committee concluded it had talked long enough and taken enough votes. "My time is valuable," Smuckler said.

In the intermittent gripe sessions, various members complained that the chairman had been too rigid in pushing them

toward votes, that they did not have time to fully debate the issues and argue among themselves, and that they were forced to respond to the perceived needs of the FDA—particularly its legal counsel—with little opportunity to frame issues in terms they thought desirable. "I don't feel we were allowed yesterday to discuss the issue of Red 2 in full open scientific debate," Tephly said. "I felt we were being pressured to say, Is Red 2 a carcinogen, possibly a carcinogen, not a carcinogen, or whatever," agreed Sheldon D. Murphy, associate professor of toxicology at Harvard School of Public Health. "... There seemed to be an implication that we had to define black and white questions and yes or no answers." Chairman Jennings pleaded guilty to "clumsy chairing," but he noted that there are occasions when the FDA simply has to put particular questions to its advisory groups whether they like it or not.

The clash of scientists and bureaucrats did not seem disabling. Despite all its grumbling, the committee managed to perform its tasks in a way that the FDA found useful, and that, after all, is the only point in having such a committee. Some of the complaints seemed to verge on the prima-donnaish, while others reflected a misconception that overtakes many advisory groups—the unconscious assumption that the advisory group should, in fact, be the decision-making group. The airing of gripes seemed to leave both sides in good humor. As a final gesture, after complaining bitterly about "poor communications" and "lack of information," the committee members heaped lavish praise on their FDA staff support for keeping them well informed.—PHILIP M. BOFFEY

NSF: Science Education Is Still in the Spotlight

It might be said of the National Science Foundation that for the last year the tail has been wagging the dog. Criticism of NSF's science education program has led to the most thorough examination of that program since the Foundation was established a quarter century ago. Spending on science education activities

amounts to only about 10 percent of the NSF budget, and perhaps 10 percent of that is spent on the curriculum improvement projects which have drawn the criticism. But NSF has been embarrassed by evidence of serious lapses in management in these programs, and the matter has engaged the attention of Congress

and heavily occupied the NSF hierarchy over the past year.

As the first returns on the new congressional budget processes are posted, however, it appears that NSF's troubles have not seriously damaged its budget prospects. The House Science and Technology Committee on 9 March approved and sent to the House of Representatives an authorization bill (see box) providing just \$1 million below the \$802 million requested in President Ford's budget, and including a substantial increase next year for basic research. As for science education, the House committee, in fact, proposed that funds be increased by some \$9 million over last year to \$74 million, although it recommended some cuts