mented evidence of cancer hazards," he says in his letter. "I cannot accept any longer a situation which in fact deprives the regulatory agencies, industry, labor, consumers and the scientific community of data of urgent public health value: it is *people* who are now exposed to toxic agents and who are not protected because the necessary support was not provided in time."

Sloppy Tests

Saffiotti considers that he has had "at best only a few opportunities to discuss and participate in major policy decisions at the Institute level." Rauscher, he says, has received advice from his program "at second or third hand." The problem, as he sees it, is layers of bureaucracy separating the NCI director from his scientific experts. "There is a huge bureaucracy in the front office—some 200 people, few of whom are active scientists—and our own division director has built up a small layer of people in his front office," Saffiotti says. "Essentially the direct involvement in research stops at our level and all the rest is bureaucratic overhead. This may be the inevitable result of the very rapid growth of the NCI's budget, but the fact is that it is so."

The observation is serious, if true, not least because one of the principal arguments for giving the cancer institute greater autonomy within the National Institutes of Health was to free it from encumbering layers of bureaucracy. Rauscher, however, says he has never refused to see Saffiotti. Peters observes that he is the only person between Saffiotti and the NCI director, and that he has a larger program but smaller staff than any other division in the NCI.

One apparent example of the exclusion of experts from their proper role is that of a proposed interagency committee on the assessment of carcinogens. Peters has nominated himself as the NCI member. Asked if Saffiotti wouldn't be better qualified, Peters says no, because the committee is a broad-based policy group. But the chairman of the committee, Roy Albert of the Environmental Protection Agency, says that the committee will be a technical group making scientific judgments. Asked why Peters was a member, Albert said, "It does look peculiar that he is on it without being an expert in carcinogenesis or having that background, but I view it as only on the basis of setting up a channel to the NCI's experts such as [H.F.] Kraybill and Saffiotti." Peters has designated Kraybill as an alternate on the committee.

The bureaucracy's actions are not always accountable to peer review by outside scientists, Saffiotti believes. For example, the division of cancer cause and prevention has disbanded the peer review group it used to have. Thus although there are peer review groups at the program level, the decisions taken at divisional level, such as on allocation between the three programs (carcinogenesis, virology, and epidemiology) are not subject to direct peer review. Peters says the divisional level peer review group was disbanded because it did not make sense to have experts in one program area reviewing work done in another. According to Rauscher, however, "Active researchers have probably never had a greater input to the NCI—we have 62 advisory committees and I don't know of a single recommendation from them over which I have control which I did not implement."

An attempt to test the opinion of scientists in the chemical carcinogenesis field and on the NCI advisory board produced general praise of Saffiotti's program—"He has done as well as anybody could possibly do," says one of the outside advisers to his program. There seems to be a general reluctance to comment on the specifics of the issue, about which most people expressed ignorance. Members of the NCI advisory board were unaware even of the way in which the NCI's 79 staff positions had been distributed. "Internal NCI affairs are very complex, and outsiders comment on them at their peril because there are so many political issues involved," observes Nobel laureate Howard Temin of the University of Wisconsin.

Saffiotti's complaints may or may not be fully justified, but his resignation has at the least drawn attention to what he regards as a critical shortage of support for the carcinogenesis program.

—NICHOLAS WADE

Clinical Labs: Bills Aimed at Correcting "Massive" Problems

In medical practice today, physicians and patients rely increasingly on the results of laboratory tests to tell them what is wrong. And what is wrong, it seems, in an appalling number of cases, is the test itself. It is almost impossible to get accurate data on the quality of work performed in the 64,000 to 94,000 clinical laboratories in the United States (no one is sure exactly how many there are), but the Senate has evidence that "from 7 to 26 percent of all lab tests may be in error."* Considering the number of laboratory tests performed in any year, that is a lot of error.

According to figures from the Senate subcommittee on health, chaired by Edward M. Kennedy (D–Mass.), 4½ billion lab tests were conducted in this country in 1975; that comes out to 12 million a day. By the end of the year, the nation's total bill for laboratory tests hit $12 billion, which is roughly equal to 10 percent of the entire cost of health care for that year. Reports by the Senate's Special Committee on Aging, which conducted an investigation of Medicare fraud in the lab business, the Senate's subcommittee on health, and others reveal that problems with clinical laboratories are "massive and widespread." As Kennedy has said, "Clinical laboratories perform inadequately and constitute a threat to the public health."

In the Senate, Kennedy and Jacob K. Javits (R–N.Y.) have sought a remedy through the Clinical Laboratories Improvement Act of 1975, which is likely to go to the floor for action soon. Representative Paul G. Rogers (D–Fla.) has introduced similar, though not identical, legislation in the House. And the Administration, which is perfectly willing to concede there is a problem, is trying to block legislative action on the grounds that there already exist adequate powers to regulate clinical laboratories and that the government is now going to use them. But Congress is not going to hold its breath until that happens.

Nine years ago, Senator Javits in-

*"Fraud and abuse among clinical laboratories," a staff report prepared for the U.S. Senate's Special Committee on Aging, 1976.

NAE Elects 104 New Members

The National Academy of Engineering, established to share the responsibility given the National Academy of Sciences under its congressional charter to examine questions of science and technology at the request of the federal government, has elected 104 new members. This addition brings the total membership to 685. The new members are as follows:

H. Norman Abramson, Southwest Research Institute; **Harold M. Agnew,** Los Alamos Scientific Laboratory; **Clarence R. Allen,** California Institute of Technology; **Alfredo H. -S. Ang,** University of Illinois, Urbana-Champaign; **Horace S. Beattie,** IBM Corporation; **Daniel Berg,** Westinghouse Electric Corporation; **Donald J. Blickwede,** Bethlehem Steel Corporation; **John E. Breen,** University of Texas, Austin; **Charles M. Brinckerhoff,** Consulting Engineer, New York; **Frederick P. Brooks, Jr.,** University of North Carolina; **Donald B. Broughton,** UOP Process Division; **Bernard Budiansky,** Harvard University.

Joseph E. Burke, General Electric Research and Development Center; **Marvin Camras,** IIT Research Institute; **Dayton H. Clewell,** Mobil Oil Corporation; **Julian D. Cole,** University of California, Los Angeles; **John W. Coltman,** Westinghouse Research Laboratories; **Franklin S. Cooper,** Haskins Laboratories; **F. J. Corbató,** Massachusetts Institute of Technology; **Ruth M. Davis,** Department of Commerce; **Anthony J. DeMaria,** United Technologies Research Center; **Ira Dyer,** Massachusetts Institute of Technology; **Milton C. Edlund,** Virginia Polytechnic Institute and State University; **Lloyd E. Elkins,** Amoco Production Company; **Martin A. Elliott,** Energy Consultant, Texas; **Richard S. Engelbrecht,** University of Illinois, Urbana-Champaign; **Elliott M. Estes,** General Motors Corporation; **Joseph Feinstein,** Varian Associates; **Steven J. Fenves,** Carnegie-Mellon University; **Michael Field,** Metcut Research Associates Inc.

Merton C. Flemings, Massachusetts Institute of Technology; **Charles F. Fogarty,** Texasgulf Inc.; **Gerard F. Fox,** Howard Needles Tammen & Bergendoff; **Alfred M. Freudenthal,** George Washington University; **King-Sun Fu,** Purdue University; **Douglas W. Fuerstenau,** University of California, Berkeley; **Robert A. Fuhrman,** Lockheed Missiles and Space Company, Inc.; **Solomon W. Golomb,** University of Southern California; **John B. Goodenough,** Lincoln Laboratory; **Robert C. Gooding,** Naval Sea Systems Command; **Arthur G. Hansen,** Purdue University; **Edwin L. Harder,** Pittsburgh, Pennsylvania; **Milton Harris,** Washington, D.C.; **Herman A. Haus,** Massachusetts Institute of Technology; **Arthur Hauspurg,** Consolidated Edison Company of New York Inc.; **Heinz Heinemann,** Mobil Research & Development Corporation; **Joseph M. Hendrie,** Brookhaven National Laboratory; **Abraham Hertzberg,** University of Washington.

Wilmot N. Hess, National Oceanic and Atmospheric Administration; **William C. Hittinger,** RCA Corporation; **Charles H. Holley,** General Electric Company; **Joe W. Johnson,** University of California, Berkeley; **Robert L. Johnson,** McDonnell Douglas Astronautics Company; **Donald J. Jordan,** Glastonbury, Connecticut; **Joseph H. Keenan,** Massachusetts Institute of Technology; **Robert W. Keyes,** IBM T. J. Watson Research Center; **Lee A. Kilgore,** Consulting Engineer, Pennsylvania; **Gordon S. Kino,** Stanford University; **Leon Lapidus,** Princeton University; **Milton Levenson,** Electric Power Research Institute; **Joseph T. Ling,** 3M Company; **Ray K. Linsley,** Hydrocomp, Inc.; **John P. Longwell,** Exxon Research and Engineering Company; **Bruce T. Lundin,** NASA Lewis Research Center; **John D. Mackenzie,** University of California, Los Angeles; **Enrique A. J. Marcatili,** Bell Laboratories; **Hans M. Mark,** NASA Ames Research Center; **Sidney Metzger,** Communications Satellite Corporation.

Herbert L. Misch, Ford Motor Company; **James K. Mitchell,** University of California, Berkeley; **Gordon E. Moore,** Intel Corporation; **Ben Moreell,** Pittsburgh, Pennsylvania; **Richard S. Morse,** Massachusetts Institute of Technology Development Foundation, Inc.; **Albert G. Mumma,** Short Hills, New Jersey; **Peter Murray,** Westinghouse Advanced Reactors Division; **Eugene F. O'Neill,** Bell Laboratories; **Henry J. Ongerth,** California State Department of Health; **Jack S. Parker,** General Electric Company; **Norman F. Parker,** Varian Associates; **Thomas H. Pigford,** University of California, Berkeley; **Egor P. Popov,** University of California, Berkeley; **Jacob Rabinow,** Department of Commerce; **Eric Reissner,** University of California, San Diego; **James B. Reswick,** Rancho Los Amigos Hospital; **Allen S. Russell,** Aluminum Company of America; **Robert S. Schechter,** University of Texas, Austin; **Reinhardt Schuhmann, Jr.,** Purdue University.

David Slepian, Bell Laboratories; **William P. Slichter,** Bell Laboratories; **Arthur C. Stern,** University of North Carolina; **Archie W. Straiton,** University of Texas, Austin; **Morgan C. Sze,** Lummus Company; **Harold A. Thomas, Jr.,** Harvard University; **Chang-Lin Tien,** University of California, Berkeley; **Milton Van Dyke,** Stanford University; **Henning E. Von Gierke,** Aerospace Medical Research Laboratory; **John B. Wachtman, Jr.,** Department of Commerce; **William M. Webster,** RCA Laboratories; **Johannes Weertman,** Northwestern University; **Roy F. Weston,** Roy F. Weston, Inc.; **Richard T. Whitcomb,** NASA Langley Research Center; **J. Ernest Wilkins, Jr.,** Howard University; **Amnon Yariv,** California Institute of Technology; **Alfred A. Yee,** Alfred A. Yee & Associates, Inc.

troduced the first piece of legislation covering the operation of clinical labs—the Clinical Laboratories Improvement Act of 1967. That law, intended to guarantee high quality lab work, authorized the Center for Disease Control (CDC) in Atlanta, Georgia, to test the proficiency of clinical labs; but its authority was restricted to those laboratories that engage in interstate commerce, estimated to be a mere 6 percent of the total. CDC officials believe that those 900-odd labs that come under their purview represent the best in the country, but the Center's own analyses of the labs' performance indicates that all is not well, even among the best.

As part of its quality monitoring program, CDC sends sample specimens of various sorts to laboratories to see if they are identified correctly. Sometimes the laboratories know they are being tested, sometimes not. Among recent discouraging findings are these:

- Thirty-one percent of labs, which knew they were being tested, failed to identify sickled red blood cells.
- Leukemia was mistakenly diagnosed by more than 10 percent of labs in one test.
- Mononucleosis is incorrectly diagnosed as much as one-third of the time.
- Seventeen of 22 laboratories correctly identified drugs in urine samples when they knew they were being tested, but 16 of those 22 labs missed the drug identification 60 percent of the time in a repeat quiz when they received urine labeled as patient specimens rather than as CDC test material.
- Five to 12 percent of the time, laboratories "find something" when CDC sends them slides that contain nothing of consequence.

Sometimes the errors are trivial, but sometimes they are of more than passing consequence. Even people in the laboratory business acknowledge problems of error and some capitalize on them, as is shown in an advertisement in the November–December 1975 issue of *Cadence* (the journal of the American Society for Medical Technology), which is devoted to the issues of achieving quality assurance by legislation. A two-page ad shows a dramatic sketch of a young woman lying in a hospital bed, her husband, head bowed, staring out of the window. The ad, in bold letters, reads, "She searched her conscience, conferred with her husband and went through with the abortion. But there was no fetus there." The ad is for a particular pregnancy test that is claimed to meet a "high standard of accuracy."

The Senate has reached the conclusion that the reason for all these sorts of problems is that clinical laboratories and labo-

ratory personnel are not sufficiently regulated. For the past couple of years, Kennedy and Javits have been thinking about an overhaul of the 1967 Clinical Laboratories Improvement Act, but nothing much happened until last year, when H. David Banta and Arthur Viseltear, participants in the Institute of Medicine's Robert Wood Johnson health policy fellowship program (*Science*, 19 Sept. 1975) appeared on the scene. As one Senate staffer said in reply to a question about the timing of the new legislation, "Suddenly we had some extra manpower to help us with health legislation, so we were able to take the clinical labs bill off the shelf."

Kennedy says there are a lot of things wrong with the way the clinical laboratory business is regulated and notes the following defects:

- Only interstate labs are regulated under the 1967 act.
- At least 26 states have no mandatory lab program and only five states have what are considered to be "good" programs. In some states, just about anybody can open a lab, whether he or she has credentials or not.
- Fewer than a dozen states license clinical laboratory personnel.
- Intrastate labs now are regulated only if they participate in Medicare. [Senate investigations of labs participating in Medicare reveal widespread fraud, including a practice of charging more for tests done for Medicare patients (paid for by the government) than for private patients.]
- Hospital labs undergo only periodic checks for quality.
- Physician-office laboratories operate without any agreed-upon standards and often employ persons with no qualifications for the laboratory work needed.
- "Bureaucratic infighting" among those agencies in the Department of Health, Education, and Welfare (HEW) that have authority to regulate laboratories under either the 1967 act or Medicare regulations makes HEW's activities in the area largely ineffectual.

If Congress has its way, national standards will be established for all labs and personnel, including those in physicians' offices. And there will be created somewhere within HEW an Office of Clinical Laboratories with ultimate authority to implement the law. At present, the CDC and the Bureau of Quality Assurance within HEW and the Bureau of Health Insurance within the Social Security Administration (SSA) have responsibilities for controlling clinical labs, but conflicts among them have been notable.

In fact, relations have been so bad that HEW has tried to straighten things out by getting them each to sign an interagency agreement that Assistant Secretary for Health Theodore Cooper euphemistically says, "more clearly defines and clarifies the functions of each agency." Kennedy is not persuaded. Writing in *Cadence*, he says, "Previous documents of similar intent have all too soon been disregarded." He quotes an HEW memo as evidence that the differences among the three agencies are too great to be resolved by any concordance and offers it as added proof that a new federal office is needed. The memo says:

> We believe that past delays in improving laboratory regulation are not due to bad faith or poor performance on the part of SSA, the Bureau of Quality Assurance, or CDC. Rather, the delays stem from honest philosophical differences on how to proceed, a natural reluctance to engage in open confrontations or raise disputes to the Secretary or Under Secretary for final decision and, finally, the absence of any action-forcing mechanism to spur policy resolution.

Congress believes that a central office could be that spur. The Administration heartily disagrees. "The proposed legislation to set up a new governmental entity in the clinical laboratory field would be no more capable of progress than the authorities already on the books," says Cooper, in what can, in view of the present situation, only be seen as a disheartening assessment. The Administration does not want a central office, but already there is infighting about where in HEW such an office should be located were Congress to succeed in forcing its creation. In the Social Security Administration, or the Bureau of Health Insurance, or the Center for Disease Control? Thus far, the draft legislation is silent on this point, but there is lobbying for it from all sides.

Whatever the final nature of new legislation may be, the job of improving the quality of thousands and thousands of laboratories, large and small, sophisticated and simple, is not going to be easy and eliminating error may be next to impossible. One obvious, but unwieldy, solution would be to have all tests done twice. Clearly, as a matter of national policy, such a practice would be ridiculous. Still, it might be worth thinking twice about in at least some individual cases. One Senate staffer already has. Not long ago, he received a test result that said he was OK, but symptoms of ill health persisted and, wondering whether the lab had been wrong, he returned for a second test. That, too, proved negative. "I guess I was satisfied," he says. "Anyway, eventually I got better."

—BARBARA J. CULLITON

Clean Air Act: Congress Deliberates on Amendments

Both houses of Congress this month are scheduled to vote at long last on 1976 amendments to the Clean Air Act. The act was scheduled for review in 1974 but this was postponed a year because of the impeachment turmoil. New bills were introduced last year which have been subjected to more than a year of deliberations by the Senate Public Works Committee and the House Interstate and Foreign Commerce Committee.

The bills now awaiting floor action allow for additional delays in enforcing emission standards both for automobiles and for stationary sources—that is, heavy industry, primarily power plants. The most significant aspect of the proposed measures is that they explicitly put into law regulations pertaining to "significant deterioration." These control development in areas of the country that now enjoy air quality better than that required by the national ambient air quality standards.

The bills have had a tortuous progress, including over 130 markup sessions, through subcommittees headed by Representative Paul Rogers (D–Fla.) and Senator Edmund Muskie (D–Maine). They have been subjected along the way to terrific lobbying pressures from business, heavy industry, utilities, and automobile interests. "This is one of the most intensely lobbied bills I have ever seen," said one Senate staffer. Attempts have been made by industry to portray the amendments as thinly veiled federal