—U.S. Medicine photo

Dr. Leon R. Jellerson
'We're changing our philosophy'

Coast Guard Focuses On Prevention

WASHINGTON—The Coast Guard's medical program now focuses on disease prevention—treating the cause of the disease rather than just the disease itself.

"With the increased cost of medical care it became imperative for us to take another look at the way we practice medicine and the way we deliver health services," Rear Adm. Leon R. Jellerson, chief of the Coast Guard's office of health services, explained in an interview.

"What we have looked at and discovered—and this is not new—is that waiting for someone to get sick and then take care of him is dumb, and terribly expensive. It makes much more sense, both from a social and economic point

(Continued on page 4)

Compromise On Animal Welfare, Biomedical Researchers Warned

WASHINGTON—A key House legislator in scientific matters has issued a stern warning to defenders of biomedical research: learn to compromise on animal welfare issues or forfeit your weight on Capitol Hill in the future.

Some defenders of the use of animals are becoming as inflexible as certain animal group activists, and they will pay a price later on, Rep. Doug Walgren (D., Pa.) warned science lobbyists here.

He is the chairman of the House Science, Research and Technology subcommittee, which has endorsed tightened controls over animal research supervision.

Rep. Walgren voiced his concerns at a meeting of the National Coalition for Science and Technology, a pro-science lobbying group representing education, training and research interests in technology issues.

He said he was distressed by the attitude of some scientific groups his subcommittee encountered in its work on new requirements for animal research supervision: Often it was simply opposition to change, he said.

Often missing from the legislative equation was a willingness of the scientific groups to compromise, he said, even when the staff felt it had satisfied "every legitimate representation."

They would not accept any change in the current system of National Institutes of Health guidelines and animal welfare laws, Rep. Walgren said.

—U.S. Medicine photo

Rep. Doug Walgren
Some scientific groups refuse to compromise on animal research issues

"That kind of approach to the legislative process is a very, very slippery slope for any organization to take," he said.

When such an attitude persists after every reasonable objection is met, the group's future credibility with other legislation is substantially impaired, he maintained.

As an example, he pointed to the American Institute for Biological Sciences, whose own newsletter indicated that institute objections to some legislation appeared to be met, but which still opposed any change in the status quo.

The only constructive road, he told the coalition, is to find common ground and work to develop it.

"People interested in this subject should weigh that instinctive feeling on the part of legislators and realize that (compromise) is one of the mechanisms of the legislative process.

"It's the old 'road to socialism' hogwash," he added.

"Organizations that take an absolute, 'We do not recognize the validity of any...' have already forfeited their claim to reasonableness," Rep. Walgren said.

In contrast, he said, a representative of the American Medical Association

(Continued on page 30)

Interagency Group Drafting Federal Policy On Animals

BETHESDA, MD.—A new interagency committee is drafting a statement of principles to toughen language on humane animal care that for the first time is aimed at both research-oriented and regulatory agencies.

Interest in a consistent, federal government-wide policy was intensified when the White House Office of Science and Technology Policy asked the interagency panel to draft principles that could guide agencies as diverse as the Agriculture Department and the National Aeronautics and Space Administration (NASA) in issues of testing, research and training.

The committee also is working on global recommendations for good practices of animal use and care at the behest

(Continued on page 8)

Organ Shortage Seen Increasing

By Judy E. Fox

WASHINGTON—Over the next decade the disparity between supply and demand in organ transplantation will increase dramatically, Dr. Harold Meryman, assistant medical director of the American Red Cross, warned.

Dr. Meryman, director of the organization's new tissue and organ preservation program, predicted the growing disparity will occur because one of the major problems in transplantation—organ and tissue rejection—soon will be overcome.

Two independent approaches to the elimination of graft rejection currently are being investigated, he told persons attending a National Institutes of Health conference on tissue and organ transplantation.

"First is the treatment of the graft itself through elimination of the passenger leukocyte that carries the antigen Ia in animals and D/DR antigen in humans. It seems to be generally agreed now that the Ia antigen is a co-stimulator of graft rejection and, if it can be eliminated in the graft, the graft would be accepted without rejection," he explained.

Dr. Meryman noted that transplants of animal thyroid tissue and islets cleansed of passenger leukocyctes have been performed without graft rejection.

The second approach to eliminating graft rejection is treatment of the graft recipient, Dr. Meryman said. "In this situation one attempts to simulate the relationship that exists between mother and fetus. The fetus is, after all, a transplant, and is phenotypically different from the mother," he related.

This approach was developed through studies of chronic spontaneous abortions, Dr. Meryman explained. The studies found that where chronic spontaneous abortions occurred, the phenotypes of the mother and the father were extremely similar and the mechanism that stimulated tolerance in the mother did not trigger, he explained.

It was later shown that an injection of white cells of the father intravenously into the mother while not pregnant would allow the subsequent pregnancy to go to term, he related.

"I think...one or the other—or perhaps both—of these approaches to the elimination of graft rejection...are really a certainty in the not too distant future," Dr. Meryman predicted.

But this will result in an increased demand for transplant capabilities, he warned:

"It doesn't take much imagination to think what the demand will be when transplants are no longer limited to end-stage diseases but would be available to

(Continued on page 26)

—U.S. Medicine photo

Dr. Harold Meryman
Elimination of graft rejection will result in increased demand for transplants

Halting Inpatient Care Proposed For St. Elizabeths

WASHINGTON—St. Elizabeths Hospital, the federal mental health facility here, would provide only long-term inpatient care under a new General Accounting Office proposal.

All short-term psychiatric inpatient care would be transferred from St. Elizabeths to District of Columbia general hospitals under the proposal.

Long-term care provided at St. Elizabeths would include intensive and rehabilitative psychiatric care, psychiatric nursing care and forensic psychiatric care, a GAO report outlining the proposal said.

The proposal ultimately would reduce St. Elizabeths' inpatient population from 1,700 to about 1,000.

The report emphasized that GAO developed the plan at the request of the House Committee on the District of Columbia. GAO recommended the system be implemented over a two-year period beginning on October 1, 1985.

If the program is implemented, St. Elizabeths' patient-care staff would be reduced by about 1,000 employes, GAO

(Continued on page 26)

Federal Animal Policy: 'Concerns' Targeted

(Continued from page 3)

of an international health group.

At a time when biomedical research is under increasing scrutiny from the public—and frequent attack by some animal welfare groups—the committee is developing recommendations in such areas as defining oversight responsibilities both of local animal care review committees and research facilities' top management.

Its draft statement of principles for international health organizations' consideration touches on such fundamental issues as condemning use of immobilizing muscle relaxant drugs in lieu of anesthesia as well as urging association of an attending veterinarian with any facility conducting animal research.

Its draft principles on U.S. animal research—for the report to OSTP—cover such issues as judicious use of animals in research projects.

"Sometimes too few is just as inappropriate (as too many)," one committee staff member noted. "If you do a study with too few animals and wind up with ambiguous results and have to repeat it, than that was just as wasteful as doing one with too many in the first place."

Directed and staffed by officials from the National Institutes of Health, the new panel is called the Interagency Research Animal Committee. The chairman is Joseph R. Held, DVM, chief veterinary officer of the Public Health Service and the director of the NIH Division of Research Services.

The committee hopes to establish guidelines that will demonstrate to the animal welfare community as well as to the biomedical research community that "there are certain situations that require certain concern," the committee's executive director, Thomas Wolfle, DVM, PhD, said.

The panel is the outgrowth of a nine-year-old committee whose activities largely supported preservation and reproduction of non-human primate populations, the Interagency Primate Steering Committee.

Nearly a year ago, assistant Health and Human Services secretary for health Edward N. Brandt Jr., MD, PhD, authorized an expansion of that role to the broad spectrum of animal research activities in all species.

Since then, the reconstitution of the panel has progressed through the bureaucracies of several agencies that were asked to participate, and last month NIH publicly proclaimed the Interagency Research Animal Committee (IRAC) conversion complete, describing it as the focal point for federal agencies' discussions of animal use in biomedical research and testing.

Previous members were HHS, DoD, National Science Foundation, the Environmental Protection Agency, and the Veterans Administration, with the Department of the Interior in "observer" status.

Interior now holds full membership, as do two other agencies now added to the roster, the Agriculture Department and NASA.

Even with the name change and mission expansion, Dr. Wolfle said, the committee continues to monitor with concern the non-human primate supply.

"As a single species, the non-human primate still requires far more effort on the part of the committee. However, during the past six or eight months the committee has been asked by the Council for International Organizations on Medical Sciences (CIOMS) headquartered in Geneva to draft a set of international principles on animal care," Dr. Wolfle said.

Dr. Held traveled to Geneva six months ago to meet with world health leaders on how to raise international consciousness about appropriate principles in animal care and use.

The committee is working on a draft submission to CIOMS, which will submit its recommendations to the World Health Organization (WHO). If approved, the principles would be submitted to member countries.

"They are, admittedly, very broad. The guidelines, or principles, are the easy part. The policy statements to which the principles will be appended will be more difficult, and we've not begun those yet; we felt we had to develop the principles first," Dr. Wolfle said.

It is challenging to describe principles that will truly influence behavior, he indicated. For example, he said some countries conceivably may not be able to tolerate a recommendation that there be a licensed veterinarian associated with each facility.

"Admittedly, the committee does not see itself as an animal welfare committee, but for the past few months, a lot of the activities have been in this area," Dr. Wolfle said.

"The desire to draft these principles is directly the result of the current interest in animal welfare and the pressures of the animal welfare movement to restrict some use of animals."

The U.S. principles of animal care and use will be similar to those being produced for CIOMS, Dr. Wolfle predicted.

He said the committee hopes to get its work on the U.S. principles approved in time for their inclusion in the NIH GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS, which currently is being revised (see related story).

"Before that is finalized," Dr. Wolfle predicted, "these (new principles) will be inserted in there and public comment will be solicited. When it is finally published as a PHS policy, these new principles will be inserted in place of the ones that are in there now."

He called the NIH guide "the Bible that we work with, and that NIH requires that its grantees subscribe to in their assurance statements."

While the revision of the principles may cover some new ground, such as encouraging officials or researchers to consider whether the numbers of animals proposed for a project is judicious, it may, at the same time, tone down the language so that the principles can meet the OSTP test for government-wide policy.

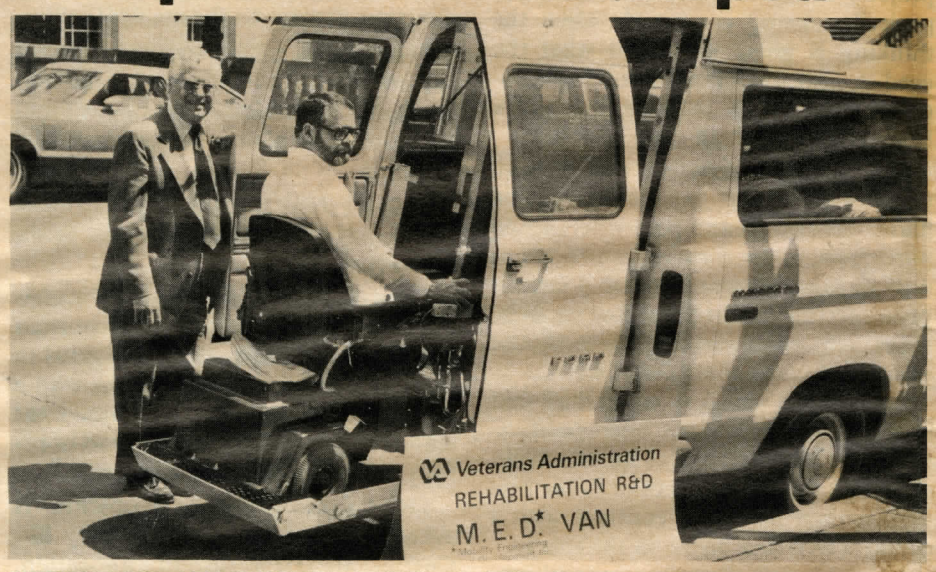
Currently, it would be difficult for other agencies to adopt the NIH principles as policy because of their use of such terms as *must* and *shall*, which, if immediately applied to the regulatory agencies' requirements of industry, could "absolutely drive their lawyers up the wall," he said.

Notably, the current NIH policies have no bearing on other federal agencies—as the new priniciples will if accepted by OSTP, Dr. Wolfle said.

"Then it will be up to each of those agencies to implement them as NIH does for its contractors and has now done with an intramural policy," he said.

At NIH, funding can be cut off to grantees if principles are blatantly disregarded and policies abridged, he noted.

Special Van Developed



VETERANS ADMINISTRATION rehabilitative research contractor Charles Scott, left, developed a van equipped for wheelchair-bound patients. It includes a variety of power devices for van operation, which is controlled at the driver's seat, as well as a rear wheelchair lift, demonstrated above by VA employe Larry Sour of Falls Church, Va., who works in the Office of Construction at VA headquarters. The van developed by Scott, president of Mobility Engineering and Development Inc. of Van Nuys, Calif., was part of a Capitol Hill demonstration of prosthetic devices and research accomplishments in the VA sponsored by Rep. Robert Edgar (D., Pa.).

Compromise Advised On Animal Regulation

(Continued from page 3)

has been quoted as opposing "excessive" regulation in the area, which suggests there is ground to find some legislative compromise.

A bill that advanced in his committee would have required gradual modernization of animal research facilities, but because of its financial cost, it did not pass the House, he said.

However, other legislation that has passed the House and is pending in the Senate does include some new requirements, such as inclusion in local animal care committees of at least one person from outside the university.

It encourages development of promising alternatives to *in vivo* research, he noted, though it does not go as far as physical lab standards.

It is difficult to develop legislation in the animals-in-research issue, but it is reasonable to believe some will be passed, he told the coalition.

NIH programs likely to be funded will support development of non-animal approaches and attempt to eliminate duplication, he said. They also will assure that labs have standards and that mechanisms to manage pain are "literally in place at all times."

He predicted that it will increasingly be viewed as a role of government, not exclusively the domain of the individual investigator.

A staff member for Sen. Edward Kennedy (D., Mass.), Dr. Wesley Clark, said the NIH, already responding to the public debate over animal care, has acted administratively to improve monitoring of animals in research.

(For example, the proposed guideline changes, if made final, would incorporate the "outside" member on review committees that Rep. Walgren cited.)

"From our point of view these changes may be sufficient. We don't know," Dr. Clark said. The loss of grant funds for non-compliance with NIH requirements could be a good motivator, he said: "You may be achieving quite a bit."

Sen. Kennedy's staff is concerned not only about humane care, but also feels there shouldn't be an excessive use of animals in duplicative research, Dr. Clark said.

Anne Griffin, PhD, associate professor of political science at the Cooper Union for the Advancement of Science and Arts, said the proposed NIH guideline changes may deflect attention from the legislative process.

The proposals may scatter some of the demand for action, she said, noting that in addition to the requirement for an "outside member" on local animal care committees, the new guidelines would also require there be a non-scientist member.

Other components of the proposed changes include giving the local animal care committees authority to halt an experiment not in compliance with policies and requiring that tests involving prolonged restraint or unusual methods of euthenasia be reviewed and approved by the local committees.

Until the various interest groups involved in the public debate can at least agree on a set of goals, the debate will continue, Dr. Griffin predicted.

Rep. Walgren noted that the issue became a priority when a Maryland researcher using National Institute of Neurological and Communicative Disorders and Stroke funds was convicted of animal cruelty, a conviction thrown out on appeal over questions of the applicability of state law to federally funded research.

While many researchers are annoyed that government action should be prompted by anecdote, the fact is that the Maryland prosecution opened eyes in Congress, Rep. Walgren said.

"That has to be a jolt to anybody who is feeling responsibility for the use of federal funds," he told the coalition.

His instinct, he said, is that members of Congress have been reacting with common sense, notwithstanding the danger that a few cases of widespread publicity could prejudice public support for scientific inquiry

He said he does not believe that federal inspections are the best way to ensure animal welfare, particularly since the facilities may be spruced up when the inspector comes around.

At a minimum, he said, he supports university assurance that researchers are following standards and that questions of abuse immediately trigger internal reviews and raise flags to appropriate outside bodies.