

electric] for non-burst power duty requirements." Wood has asserted that the APS committee was "informed that already deployed DOD [Department of Defense] solar-electric power systems were adequate to meet each and every one of these [housekeeping power] requirements," but Salgado says that "solar power cannot meet all of the 'housekeeping' power requirements for 'Star Wars' space-based assets."

A member of the APS committee says that it was told by SDI officials that the power requirements were on the order of 100 kilowatts, with some ranging considerably higher. The 700 kilowatt upper range cited in the report included power for radars, he said. Wood claims, however, that "SDI has no plans for radars on *any* of the satellites in *any* of its baseline architectures." The APS committee member says "for some of the architectures we were interested in, radars are definitely included," and Salgado's letter also notes that radar operation is one of the housekeeping power requirements.

Wood did not return several telephone calls from *Science*, but Gregory Canavan, a Los Alamos scientist who has worked closely with Wood on critiques of the APS report, says of Salgado's letter "that's a guy defending his program." Canavan argues that satellite power requirements are usually overestimated in the early stages of development. Thus, the debate over SDI has taken an ironic twist in which Administration officials have undermined the credibility of some of SDI's strongest supporters who themselves have undermined the credibility of a key SDI program.

It is not the first time that Woods' outspoken advocacy of SDI programs has raised controversy. Roy D. Woodruff, the former associate director for defense systems at Livermore, has accused Woods and Edward Teller of conveying "overly optimistic and technically incorrect" information on the x-ray laser program "to the nation's highest policy makers."

The accusations were made in a memo Woodruff wrote in April, 1987 as part of a grievance proceeding he initiated against Livermore director Roger Batzel. The memo was released recently without Woodruff's consent by the Southern California Federation of Scientists. Woodruff resigned as associate director in 1985 because, he claims, Wood and Teller "engaged in numerous actions that undercut my management responsibility for the x-ray laser program." He says he was subsequently demoted to an entry level position and Batzel failed to honor an agreement to make known within the defense and university communities the reason for his resignation. ■

COLIN NORMAN

New Questions About AIDS Test Accuracy

If routine testing of populations at very low risk for AIDS is carried out under present conditions, an increasingly high percentage of false test results can be expected

ACCORDING to recent testimony before a House subcommittee, blood tests for AIDS among low-risk individuals are even less accurate than critics have previously feared. In particular, an inexperienced laboratory's ability to do the Western blot assay—held by many to be the gold standard confirmatory test for having antibodies against the AIDS virus—is now under attack. At this point, however, it is difficult to evaluate the true extent of the problem because no one knows precisely how many blood tests for AIDS are being performed by highly qualified versus substandard laboratories.

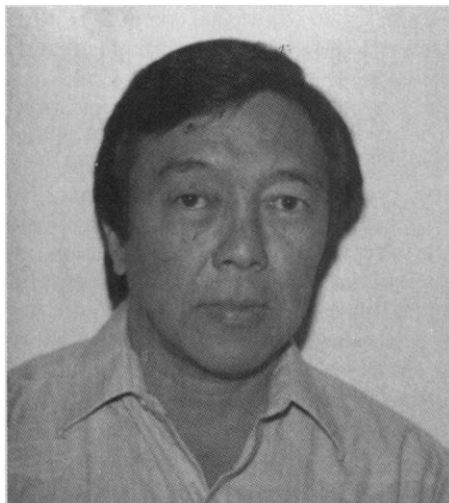
Nevertheless, two striking findings emerge from the hearing. First, the Western blot test, at least in the wrong hands, is not as reliable as many have assumed. And second, laboratory proficiency in performing AIDS antibody tests, especially the technically difficult Western blot, is highly variable and sometimes completely unacceptable. At present, these problems are compounded by the lack of quality control and differing standards for interpreting test results. An added concern is that the problem of false test results may worsen as a growing number of inexperienced laboratories enter the for-profit AIDS testing market.

Whether or not these issues will have any

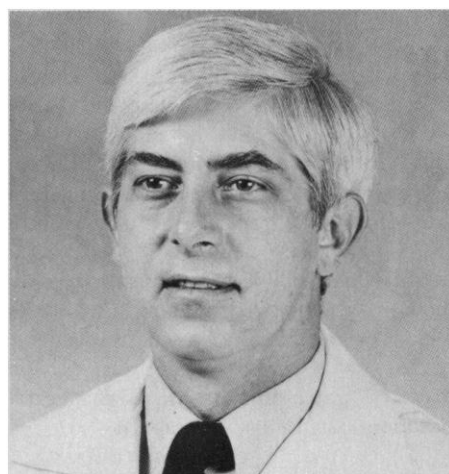
impact on President Reagan's proposal for states to do routine testing of marriage license applicants, patients entering hospitals, and prisoners is still unclear. But politicians opposed to the notion of federally mandated testing can use the "accuracy-in-testing" issue as ammunition.

The accuracy of AIDS testing was explored at a hearing last month by the subcommittee on regulation and business opportunities of the House Committee on Small Business chaired by Representative Ron Wyden (D-OR). "I think we are going to need more testing," said Wyden in an interview with *Science*. "I am not antitesting. But to me the prerequisite is to increase the accuracy of testing." Wyden also stated that he would support legislation now being drafted by Representative Henry Waxman (D-CA) that calls for increased federal funds for voluntary testing and counseling, as well as protection of confidentiality and nondiscrimination of people who test positive.

Most blood tests for AIDS measure antibodies against human immunodeficiency virus (HIV), the virus that causes the fatal disease. At present no method exists for measuring the virus directly. The first in a series of blood tests is an ELISA, or enzyme-linked immunosorbent assay, which mea-



Lawrence Miike. OTA official sees a high ratio of false positives in AIDS testing



Donald Burke. Army researcher favors testing low-risk groups: "We can make it work."

tures total antibodies against HIV. If a first and second ELISA are positive, then typically the blood is tested by Western blot, which is designed to confirm or deny the presence of antibodies against specific viral proteins.

Under ideal laboratory conditions both the ELISA and Western blot are capable of achieving greater than 99% sensitivity and specificity, which means that the tests correctly identify blood samples with and without antibodies more than 99% of the time. But studies indicate that in many laboratories, these tests are not performed under ideal conditions. Neither the exact number of laboratories performing inaccurate tests nor the number of inaccurate tests is known.

Lawrence Miike of the congressional Office of Technology Assessment (OTA) presented the most alarming analysis of the current state of AIDS testing. He estimates that among people at very low risk for AIDS, nine out of ten who test positive would not really be infected with the virus, a so-called false-positive result. But Miike himself has not actually measured the false-positive rate. Instead, he used published data on the prevalence of HIV infection in various populations and projected a series of test error rates based on laboratory proficiency data compiled by the College of American Pathologists and the American Association of Blood Banks.

The pathologists' College monitors the performance of most major laboratories in the United States, approximately 800 of which voluntarily participated in their recent evaluation of HIV testing. Miike's estimate of the false-positive rate is significantly higher than previous reports have indicated, perhaps because it is based on actual laboratory performance data rather than on estimates that assume ideal laboratory performance. Miike calculates that in a population at high risk for AIDS—with 10,000 of 100,000 (10%) persons truly infected with the virus—984 of the 10,000 (9.8%) would be missed if laboratories performed according to the College of American Pathologists' analysis.

But the perception of how inaccurate the tests are depends, to some extent, on how the numbers are calculated and presented. For example, the study cited by Miike assumes that in a low-risk population of blood donors from the Midwest, about 10 of 100,000 are infected with HIV, a prevalence of 0.01%. Miike estimates that one of these 10 people will be missed after both ELISA and Western blot screening, and that an additional 80 will be falsely identified as HIV-positive. Thus, 80 of 89 people identified as positive are false positives, an error rate of 90%. But another way to express the

same data is to say that 80 people out of 100,000 will be falsely identified as positive, an error rate of only 0.08%.

Miike's method of presenting error rates leads Herbert Polesky, director of the Memorial Blood Center in Minneapolis, Minnesota, who also testified at the hearing, to protest the OTA's use of the College of American Pathologists' data. "I think people are overreacting to the data," he said in an interview with *Science*. "The error rate for false positives is probably about 5 or 6%, and in the worst case it is probably twice that." He emphasizes that blood tests to detect HIV—particularly the ELISA screen—were originally designed to keep the blood supply safe. In that context, errors in identifying a blood sample as positive when it is not are acceptable, as long as all of the truly infected blood is correctly identified. But when the same system is applied to test large numbers of people at low risk for AIDS, the false-positive rate becomes unacceptable.

Ten of the 19 laboratories that applied to the Army to conduct blood tests on at least one occasion could not analyze samples to a level of 95% accuracy.

This problem has led many to question whether it is possible to do widespread screening for HIV infection accurately. Donald Burke of the Walter Reed Army Institute of Research in Washington, D.C., told House members that it is not only possible, the Army has been doing it for 2 years. "I share the view that testing people in low-risk populations is more likely to yield false-positive results," said Burke in an interview with *Science*. "But I am a strong advocate of testing in low-risk populations. It can be made to work. We made it work."

Since October 1985, the Army has screened more than 1.4 million civilian applicants for military service and 800,000 personnel in training and on active duty. Overall, the prevalence rate for HIV infection is about 1.5% (1.5 infected people in 1000 tested), and the false-positive rate is extremely low. Burke testified that the Army analyzed a low-risk population similar to the one described by Miike and identified 15 of 135,000 people as positive for HIV antibodies. Further tests showed that one of

them was not truly infected, a false-positive rate for the Army of 1 in 135,000 or 0.001%. (However, if Burke analyzed the same data by Miike's method, 1 of 15 or 6.7% would be expressed as false positives.) Burke cites the Army's rigorous control and regular checks over the laboratory that processes its samples as important factors in the accuracy of their tests.

Despite this record of accurate HIV screening, Burke also testified that many laboratories have performed too poorly to be considered for the military contract to analyze blood samples. Over the past 2 years a total of 19 different laboratories have applied for the contract to test Army applicants and personnel for HIV. Ten of the 19 (59%) on at least one occasion could not analyze test samples to a level of 95% accuracy and were therefore rejected.

Miike says that the problem with Western blot inaccuracy is twofold. First, the number of commercial laboratories doing the Western blot testing is increasing rapidly so that a greater percentage are inexperienced. In 1985, for example, only 18 laboratories did Western blot testing; today about 70 perform the tests. A second problem is identifying the criteria that indicate a test is positive. Until recently, some laboratories considered that having antibodies to one protein from the AIDS virus, either p24 or gp41, meant that a test should be considered positive. Now, most laboratories require that a combination of antibodies to two or three different viral proteins must be present to constitute a positive test.

What it all amounts to, says Burke, is that no one is willing to accept responsibility for overseeing the quality of tests for HIV. "Right now there is no attention paid at a federal level that testing should be done as well as possible." The Food and Drug Administration (FDA) only reviews products (as opposed to laboratory procedures) that are identified in applications for licenses. The Centers for Disease Control does not monitor the accuracy of laboratory procedures, either. In short, no federal oversight is currently in practice.

As things now stand, FDA has approved only one Western blot test kit or product, which is made by Du Pont. The kit is so expensive—it costs about \$45 to assay a blood specimen compared to the Army's carefully monitored \$4 procedure—that very few commercial laboratories are using it.

Most of the witnesses at the recent hearing recommended that HIV testing accuracy should be improved and subjected to stiff quality-control measures before widespread testing—voluntary or routine—occurs. ■

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