national news

AIDS research under fire

Group identifies misspending, recommends restructuring National Institutes of Health program

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by Bob Roehr

A panel of outside experts has sharply criticized government-funded AIDS research efforts and recommended detailed structural changes to correct those deficiencies.

The Levine Group, named for its chairman, Arnold Levine, a professor of microbiology at Princeton University, conducted a 15-month review of past and current National Institutes of Health-sponsored AIDS research and issued its report on March 14.

AIDS researchers and activists greeted the report warmly, but cautioned that without full implementation it will only be worth the paper it is printed on.

NIH Director Harold Varmus placed the report "in the context of general strategy" as one of a series of evaluations of the NIH.

The group, officially known as the NIH AIDS Research Program Evaluation Working Group of the Office of AIDS Research Advisory Council, asked "How are we doing as an institution [in the war on AIDS]?" and "Which fronts need more supplies; which should we retreat on?"

The report offered a mixed review of NIH efforts, now funded at $1.4 billion a year, which is "85 percent of the worldwide public sector investment in AIDS research."

It acknowledged NIH successes such as identification of the HIV virus and its natural history, treatment for some opportunistic infections, and molecular modeling of the virus necessary for development of protease inhibitors.

But the group concluded that "a substantial proportion of NIH AIDS funds has been previously and is presently inappropriately classified as AIDS or AIDS-related."

Gary Rose, treatment analyst with the national group AIDS Action Council, said "a disgusting chunk of the money should be spent in other ways." But he agreed with Levine's general thrust of how and why misspending occurred.

"Most of it is not malfeasance," Rose said, it is research moving on, causing a particular study to become irrelevant.

The report also "found marked differences in the quality of research supported by AIDS funds," faulting the status quo for not matching grants to AIDS priorities and citing "numerous instances where the process unfortunately appears to have failed in the identification of the most promising research projects."

The group charged that the National Cancer Institute's Developmental Therapeutics Program "essentially replicates that found in the pharmaceutical industry."

And in a thinly veiled rebuke of the seemingly endless variations of AZT trials, the report said, "NIH-sponsored trials programs should not study investigational or marketed agents unless these studies will test novel hypotheses and would not have otherwise been conducted by industry."

The group also said it experienced difficulty in obtaining and evaluating data during its review.

"The lack of a complete, accurate and reliable information database is simply an unacceptable situation that hampers the OAR director and the NIH director from being able to fulfill their responsibilities in directing, managing and accounting for the AIDS research portfolio."

By far, the bulk of the report focused on providing "a blueprint for restructuring the NIH AIDS research program to streamline research, strengthen high-quality programs, eliminate inadequate programs, and ensure that the American people reap the full benefits of their substantial investments in AIDS research."

The group recommended doubling the percentage of money going to support unsolicited investigator-initiated research, generally from outside the Institutes. Those activities now constitute only 20 percent of NIH-sponsored AIDS research. The typical non-AIDS research portfolio is divided roughly evenly between inside and outside work.

The Levine Group acknowledged that internal research made sense in the early days of the epidemic when there were few resources and minimal outside interest in investigating HIV. But those conditions have changed. It called continuation of this approach "an impediment to progress."

The group advised encouraging younger, more prestigious and broader participation toward "the nurturing of novel research approaches" subject to "informed peer review of research proposals" and said that would require "redirection of funds."

Levine emphasized "prevention science—biomedical interventions, behavioral and social interventions, and vaccine research—as the cornerstone."

The group offered a revitalized and restructured approach to finding a vaccine as "the only cost-effective way" to deal with the disease in many developing nations.

The group said adult clinical trials programs should be integrated into a single network "with concentric layers of research expertise and capability" and placed under the primary sponsorship of the National Institute of Allergies and Infectious Diseases, which is run by Dr. Anthony Fauci.

Spencer Cox, a member of the New York-based Treatment Action Group who sat on the Levine Group subcommittee reviewing clinical trials, agreed.

"Currently NIH runs 12 separate networks to study potential treatments for AIDS. This is inefficient and slows down progress," Cox said. "By consolidating these networks and incorporating the best of each, we will speed the search for effective treatments."

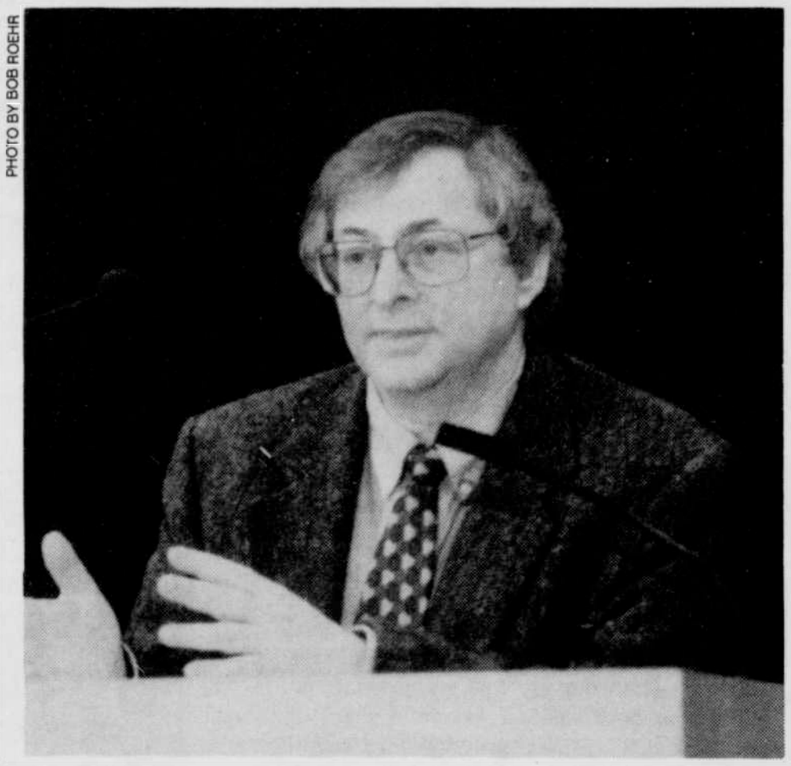

PHOTO BY BOB ROEHR

Dr. Arnold Levine

Pediatric AIDS is likely to lose funding, the report said. Congress earlier mandated that significant funding be directed to the issue, but increased success in preventing infection *in utero* and after birth means there are fewer infected infants to enroll in these programs.

Coupled with charges against the National Cancer Institute's Developmental Therapeutics Program, the group recommended "a substantial decrease in the size and funding" of that department.

A separate report on total operations of that Institute lambasted many NCI activities. A new NCI director is already moving to implement changes.

Another key recommendation is creation of standards and databases to maintain biomedical specimens, track clinical trials and monitor grant-funded activity. At present there is not even common coding and classification among the 24 Institutes of the NIH as to what is AIDS or AIDS-related research.

"Right now, business as usual is keeping information away from the other guy," Rose said.

He said opening up that data would radically change both the grant process and clinical trials.

The Levine Group unanimously recommended preservation of line item budgetary authority for the Office of AIDS Research, which was created in 1988 and strengthened by an act of Congress in 1993 as "an institute without walls" to coordinate AIDS activities across the various divisions of NIH.

Some Institute directors have resisted that authority, wanting a free hand within their fiefdoms. And last year Republican House subcommittee Chairman John Porter acted to remove the OAR line item from the budget of NIH. Most observers think that action greatly weakened the OAR. The matter is an unresolved element of the remaining budget impasse now before Congress.

Members of the group and senior NIH officials are thoroughly committed to the OAR structure and reject the idea of creating an Institute of AIDS. NIH Director Varmus called the idea "disruptive."

Levine said he saw "a real vitality in the breadth of research" being conducted by 24 separate Institutes, but he said "it is easier to make suggestions, it is far more difficult to implement them."

Mark Harrington, a leader of Treatment Action Group and a member of the Levine Group, said, "The danger is that we have 24 Institutes over here and OAR over here. So I'm just crossing my fingers that Varmus will throw his full weight behind [the report]."

Some observers have indicated that OAR Director William Paul will resign the post if he does not receive sufficient backing from Varmus to implement the recommendations of the report.

"It leaves a dark pit in my stomach to think of all the ways this can go wrong," Rose said. "But this is our job. For the AIDS treatment community, for the next five years, we have to make sure this happens. We have to make sure the recommendations get implemented."