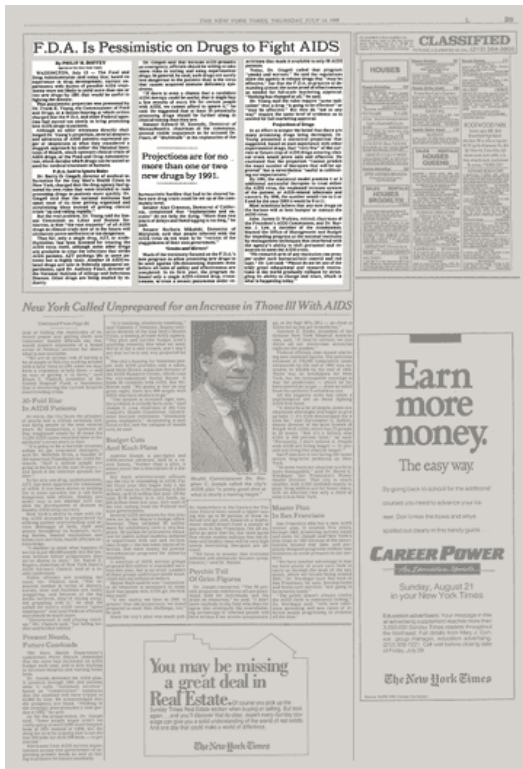


# F.D.A. Is Pessimistic on Drugs to Fight AIDS

By Philip M. Boffey

July 14, 1988



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The Food and Drug Administration said today that, based on experience in drug development, current experiments with dozens of possible AIDS treatments were not likely to yield more than one or two new drugs by 1991 that would be useful in

fighting the disease.

That pessimistic projection was presented by Dr. Frank E. Young, the Commissioner of Food and Drugs, at a Senate hearing at which critics charged that the F.D.A. and other Federal agencies had moved too slowly to bring promising new AIDS drugs to patients.

Although no other witnesses directly challenged Dr. Young's projection, several senators and advocates of AIDS patients expressed anger or skepticism at what they considered a sluggish approach by either the National Institutes of Health, which sponsors clinical trials of AIDS drugs, or the Food and Drug Administration, which decides which drugs can be tested or used for medical treatment in humans.

F.D.A. Said to Ignore Rules

Dr. Barry D. Gingell, director of medical information for the Gay Men's Health Crisis in New York, charged that the drug agency had ignored its own rules that were intended to rush promising drugs to patients more quickly. Dr. Gingell said that the national institutes had spent most of its time getting organized and scrutinizing ideas instead of getting clinical trials "up and rolling rapidly."

But the real problem, Dr. Young told the Senate Committee on Labor and Human Resources, is that "the vast majority" of all AIDS drugs in clinical trials now or in the future will ultimately prove ineffective or too dangerous.

Thus far, only a single drug, AZT, or azidothymidine, has been licensed for treating the AIDS virus itself, although some other drugs are available to treat the infections that strike AIDS patients. AZT prolongs life in some patients but is highly toxic. Another 18 AIDS-related drugs are now in federally sponsored experiments, said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Disease. Other drugs are being studied by industry.

Dr. Gingell said that because AIDS presents an emergency, officials should be willing to take more risks in testing and using experimental drugs. In general, he said, such drugs are surely less dangerous to the patients than is the virus that causes acquired immune deficiency syndrome.

"If there is even a chance that a candidate AIDS therapy could be useful, that it might buy a few months of extra life for certain people with AIDS, we cannot afford to ignore it," he said. He suggested that at least 10 potentially promising drugs should be further along in clinical testing than they are.

Senator Edward M. Kennedy, Democrat of Massachusetts, chairman of the committee, showed visible impatience as he accused Dr. Fauci, of "doubletalk" in his explanation of the bureaucratic hurdles that had to be cleared before new drug trials could be set up at the community level.

Senator Alan Cranston, Democrat of California, complained that "explanations and excuses" do not help the dying. "More than two years of delays and footdragging is too long," he said.

Senator Barbara Mikulski, Democrat of Maryland, said that people infected with the AIDS virus do not want to be "victims of the sluggishness of their own government." 'Smoke and Mirrors'

Much of the testimony focused on the F.D.A.'s new program to allow promising new drugs to be used against life-threatening diseases even before all tests of safety and effectiveness are completed. In its first year, the program released only a single AIDS-related drug, trimetrexate, to treat a severe pneumonia under restrictions that made it available to only 89 AIDS patients.

Today, Dr. Gingell called that program "smoke and mirrors." He said the regulations allow the agency to release drugs that "may be effective," but that the F.D.A. in practice is demanding almost the same proof of effectiveness as needed for full-scale marketing approval. "Nothing has changed at all," he said. Dr. Young said the rules require "some indication" that a drug "is going to be effective" or "may be effective." But they do "not in any way" require the same level of evidence as is needed for full marketing approval. Projections of Drugs

In an effort to temper the belief that there are many promising drugs being developed, Dr. Young presented a statistical projection that suggested, based on past experience with other experimental drugs, that "very few" of the current or

future crop of AIDS drugs entering clinical trials would prove safe and effective. He cautioned that the projection "cannot predict the exact number of therapies that will be approved" but is nevertheless "useful in calibrating our expectations."

By 1991, the statistical model predicts 1 or 2 additional successful therapies to treat either the AIDS virus, the weakened immune system of the patient, or AIDS-related infections and cancers. By 1995, the number would rise to 5 or 6 and by the year 2000 it would be 9 to 11.

Most scientists believe that any new drugs on the horizon will at best hamper or contain the AIDS virus.

Adm. James D. Watkins, retired, chairman of the President's AIDS Commission, and Dr. Burton J. Lee, a member of the commission, blamed the Office of Management and Budget for impeding progress at the national institutes by management techniques that interfered with the agency's ability to shift personnel and resources to meet the AIDS crisis.

"No research arm of any institution can prosper under such bureacucratic control and red tape," Dr. Lee said. "Please do not let one of the truly great educational and research institutions in the world gradually collapse by strangling its ability to change and react, which is what is happening today."

Special to The New York Times

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A version of this article appears in print on , Section B, Page 9 of the National edition with the headline: F.D.A. Is Pessimistic on Drugs to Fight AIDS