als obtained by a genealogic study would constitute an authoritarian public health measure that would infringe on individual liberty and privacy. CNIL is concerned that circulating the names of potential carriers of genes predisposing to diseases might lead to discrimination in hiring or insurance.

CNIL bases its legal case on a 1978 law that states that individuals about whom information is collected must know how the information will be used. The law specifically notes that "even in the domain of medical research, such information can, in certain cases, cause prejudice to a patient because it informs him he is affected by a severe disease." Although a proposal was floated in 1989 to change this legislation to permit some types of data to be released to protect public health, it was rejected because "they did not provide for a satisfactory equilibrium between the interests of public health, the respect of fundamental liberties, and the rights of men, notably the right to respect privacy," CNIL president Jacques Fauvet wrote at the time.

Meanwhile, Evin, whose jurisdiction includes health, has forced a public debate on the INED study. During a congress on ethics organized by the Conseil National de l'Ordre des Médecins, the French National Medical Association, last month, he said, "The use of informatics can be felt as a threat....But techniques of genealogical studies in France allow the identification of thousands of persons at risk for certain diseases that can perfectly well be prevented." Evin specifically mentioned the INED study, which previously had been kept under wraps. The press picked up the story and effectively launched a public information campaign. Now Chaventré says he is getting telephone calls directly from individuals willing to participate in the study and in a screening program.

Officials from INED, CNIL, and the ministry plan to meet soon to try to find a way to solve this ethical quandary. While those efforts are under way, the Laboratory of Molecular Genetics of the Brest Blood Transfusion Center is undertaking a search for the precise gene or genes for glaucoma, using blood samples from 100 glaucoma patients and 100 relatives who are not afflicted with the disease. Identification of the gene could lead to a pre- or postnatal diagnostic test for the disease and, perhaps, to the development of drugs to counteract its effects. But all this will be of little use unless a change in the privacy law can be effected. Only then will the 30,000 families of potential victims be safe from blind justice.

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A Fix for the FDA

When the Food and Drug Administration (FDA) came under fire last year because some of its employees had accepted bribes from generic drug company officials, Secretary of Health and Human Services (HHS) Louis W. Sullivan appointed a blue ribbon panel of outside experts to find out what was wrong with the beleaguered agency. The panel has now completed its year-long study and identified a wide range of defects—including the fact that Sullivan and his predecessors are a big part of FDA's problems. They have failed to give the agency enough status, support, and independence, the commission has concluded. "FDA suffers from its placement as a third-tier agency within HHS," according to a draft report released last week. "With few exceptions, the essential departmental support has unfortunately not been forthcoming."

As a result, the panel of 15 experts that has come to be called the Edwards Commission, after its chairman, Scripps Clinic and Research Foundation president Charles C. Edwards, is making the bold recommendation that FDA be removed from the Public Health Service and be elevated in status within HHS—a step that was urged by 35 different witnesses who testified before the committee in the past year. "You can't put the commissioner of the FDA on the third or fourth level [of HHS] and expect him to carry the weight of an agency," says Edwards. "Where he stands determines the power he has." And Edwards should know: He was commissioner of the FDA from 1969 to 1973. The panel's report also says that the FDA must be given more authority to issue its own regulations and enforce them. And if Sullivan doesn't move quickly to carry out those recommendations, then the panel advises Congress to intervene and consider removing FDA from HHS altogether, making it a free-standing, independent executive agency, much like other regulatory agencies, such as the Environmental Protection Agency and the Federal Trade Commission.

That is just one of two dozen far-ranging recommendations made by the panel, which released its draft report earlier than planned after it had been obtained last week by *The New York Times*. Interviews with panel members and staff confirm that essentially the same recommendations will be made in the final report to be delivered to Sullivan in May. And the panel's diagnosis of the FDA—an agency in unusually poor health—will not change. "Although the FDA has routinely lived with controversy, the magnitude of current pressures is unprecedented in nature and scope," says the report. Those pressures come from all sides—Congress, AIDS activists, consumer advocates, drug company officials, and the media (*Science*, 12 April, p. 200). Even the current scientific advances in drug development and biotechnology are making it more challenging for the FDA to regulate those industries and their new products. Yet the report notes that the FDA is having trouble keeping its labs and technology up-to-date, particularly in the division that inspects food.

The cure prescribed by the panel has several parts. It advises Congress to stop heaping new responsibilities on the agency without considering the costs that would be incurred. And it warns the agency to take better care of itself: The FDA leadership should improve its system for setting priorities and for managing employees and limited resources; invest in new computers to track the approval of drugs and other products; and beef up the FDA's inspections of industries and enforcement of laws and regulations. Finally, it suggests that the FDA seek new legislation to ensure that its regulations preempt those approved by state governments, which have perceived the FDA as slow-moving and unresponsive. A couple of years ago, for example, California's Proposition 65 required much broader warnings than the FDA did for labeling carcinogens in foods and over-the-counter drugs.

There has been no official reaction so far because Sullivan and other officials say they are waiting for the final report. But the Administration has openly opposed moves to give the agency more independence. It was the Reagan Administration, in fact, that sharply limited the FDA commissioner's authority to issue regulations in 1981. That makes it all the more noteworthy that the panel, six of whose members come from the industries the FDA regulates, called for new enforcement authority. Finally, much will depend on the reaction of the new FDA commissioner, David A. Kessler. But it's doubtful that any of the recommendations come as a surprise to him: He was a member of the Edwards Commission until he was nominated for the top FDA job last October.

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