

AIDS Clinical Trial to Go Ahead

The long-delayed trial of an immune preparation that may prevent women infected with the AIDS virus from passing the infection to their infants is finally getting back on track. The trial, which was due to begin in July, was derailed when Abbott Laboratories—the sole manufacturer of HIV hyperimmune globulin (HIVIG)—insisted that the company be completely protected from any lawsuits that might arise from use of the treatment (*Science*, 17 July, p. 316). Now, under threat of a lawsuit alleging breach of contract, Abbott has relinquished its rights to HIVIG and two other groups are vying to supply material for the test.

For more than 2 years, researchers at the National Institutes of Health and three dozen sites around the country had worked with Abbott to design the HIVIG trial. But a few weeks before it was due to start, Abbott officials suddenly balked, saying they were worried that HIVIG—a mix of concentrated antibodies from healthy, HIV-infected people—could conceivably enhance the risk of a baby becoming infected with the AIDS virus.

Mark Rosenbaum, general counsel at the Southern California branch of the American Civil Liberties Union, read a press account of the controversy and contacted one of the

principal investigators, E. Richard Stiehm of the University of California, Los Angeles. Rosenbaum told Stiehm that the researchers might have a legal case against Abbott, and Stiehm and four other would-be HIVIG investigators signed up to be plaintiffs in an effort to force Abbott to provide HIVIG for the study. Through the Freedom of Information Act, Rosenbaum obtained thousands of pages of National Institutes of Health (NIH) documents, which convinced him that the company had indeed breached an oral contract. "There was a paper trail of Abbott's commitment going back to 1989," says Rosenbaum, who secured the pro bono help of two high-profile law firms and drafted a complaint.

In the meantime, in an attempt to get the clinical trial under way, NIH advertised for new manufacturers of HIVIG. The New York Blood Center (NYBC) and the Miami-based North American Biologicals Inc. (NABI) both expressed interest. NABI, a leading plasma supplier, had already been helping Abbott make HIVIG. It hired the head of Abbott's HIVIG program and on 8 October acquired the rights to the product. But Abbott added a stipulation to the agreement: The liability issue must be resolved before NABI could provide HIVIG for the trial. (NYBC is

not bound by Abbott's terms because it plans to produce HIVIG by a different process.)

Three weeks later, an attorney working with Rosenbaum notified Abbott and NABI that they were about to file the breach of contract lawsuit. Abbott subsequently changed its position, announcing on 4 November that it had transferred HIVIG to NABI with no strings attached. According to Abbott spokeswoman Traci Lance, "The threat or knowledge of any pending legal action had no bearing on Abbott's actions or decisions."

NIH currently is evaluating the NABI and NYBC proposals and will not say when a decision will be made about which will get the contract to supply HIVIG for the trial. "We're unusually capable of doing it and doing it well," says NYBC virologist Alfred Prince, who has shown that HIVIG can protect chimpanzees from HIV infection. NABI, which has an inventory of HIVIG, the facilities to produce more, and approval from the Food and Drug Administration to begin the trial with the existing stock, may have the inside track, however. Whichever group wins the contract, investigators hope the trial will be under way by next summer.

As for liability concerns, "We don't think it's a serious issue at all and our insurers don't think it's a serious issue," says Prince. NABI's president, David Gury, says it is simply "a risk of doing business."

—Jon Cohen

VIOLENCE RESEARCH

NRC Panel Provides a Blueprint

Louis Sullivan, secretary of Health and Human Services (HHS), has spent the past several months defending his department's proposal for a "violence initiative" against charges that the plan is racially motivated (*Science*, 9 October, p. 212). Now Sullivan, in his final days in the top HHS post, has gained a powerful (if perhaps unwitting) ally in his defense of the effort, which would pull together federally sponsored research on the biological, psychological, and social underpinnings of violence. Last week, a panel of the National Research Council (NRC) released a 400-page treatise on violence research that could easily be mistaken for a blueprint for the proposed initiative.

The report, "Understanding and Preventing Violence," summarizes what's known about factors that might underlie violent behavior and recommends several strategies to overcome what the NRC panel and Sullivan see as a fundamental problem: an inability to link various lines of violence research "in a manner that would provide a strong theoretical base on which to build prevention and intervention programs." Says committee member Gregory Carey, a behavioral geneticist at the University of Colorado, "The panel

takes a lot of disparate pieces and puts them into a coherent whole by integrating biological and social phenomena."

Most of the recommendations from the panel, which was headed by Yale sociologist Albert J. Reiss Jr., are unlikely to ruffle feathers. These include a call for systematic studies on how to deter violent acts such as commercial robberies, sexual abuse, and prison violence. And the report proposes an ambitious longitudinal study that would attempt to clarify the relationship between aggressive and violent behavior. Of course, the report also calls for more funding for violence research—it states that in 1989, the government spent a mere \$20 million on such research, or only \$3.41 for every victim of violence in 1988.

The report treads carefully around recommendations for research on the biological determinants of violence, a minefield that recently blew up plans for a conference on the subject: Last summer, after some black community leaders criticized a proposed conference on genetic factors of crime that was to be held at the University of Maryland, NIH Director Bernadine Healy withheld funds for the conference (*Science*, 11 Sep-

tember, p. 1474). Against this backdrop, the report does contain at least one controversial recommendation: a call for "systematic searches for medications that reduce violent behavior without the debilitating side effects of 'chemical restraint.'" Such drugs might correct imbalances of serotonin, a brain neurotransmitter, which have been correlated to violent behavior. That's a red flag to some critics of the violence initiative such as Peter Breggin, a psychiatrist in Bethesda, Maryland, who have claimed that the hidden goal is to pacify black youth. "This opens the way to more drugging of our children," charges Breggin.

The report's other recommendations seek out a middle ground on biological research: The authors call for more research on genetic factors that might underlie violence but express doubts about whether such factors exist. "If genetic predispositions to violence are discovered, they are likely to involve many genes and substantial environmental interaction rather than any simple genetic marker," the report states. That language pleases Healy, who has tried to dispel any notions that NIH research on violence is seeking a "crime gene." "The discussion of genes [in the report] is responsible and correct," she told *Science*.

—Richard Stone