Department of Health and Human Services.

HIV-Infected Scientist Claims AIDS Vaccine Does Not Work

A French scientist going by the pseudonym of Philip Bertrand said that a prototype of a vaccine that is about to undergo human testing in the U.S. failed to halt the progression of his human immunodeficiency virus (HIV) infection. While conducting research in Africa, Bertrand claims he received the vaccine one week after he was infected with HIV when he accidentally cut himself on a glass tube that contained HIV. Bertrand said the vaccine was being developed under the direction of National Institutes of Health (NIH) researcher Dr. Robert Gallo and was sent to French scientist Dr. Daniel Zagury in Zaire for human testing. Bertrand charges that Gallo and Zagury knowingly omitted relevant facts about the vaccine's performance from a journal article they published concerning the efficacy of the vaccine in humans. Specifically, the article did not reveal that Bertrand had been infected with HIV before receiving the vaccine or that antibodies found in Bertrand's cells could be a result of contact with HIV rather than the vaccine.

A similar vaccine has been approved for human testing in the United States. Drs. Gallo and Zagury and an NIH spokesperson declined to comment.

FROM: ***Chicago Tribune.*** September 5, 1993.

CDC Offers Guidance on Drug-Resistant TB

The spread of drug-resistant tuberculosis (TB) has prompted the CDC to issue new treatment recommendations to curb further transmission. In a special report, the CDC advises the use of a four-drug regimen of isoniazid, rifampin, pyrazinamide, and either streptomycin or ethambutol for the initial empiric treatment of TB. The agency also says that directly observed therapy (DOT) should be considered for all TB patients because failure to take a full course of medication is the major factor in development of drug resistance. Critics of the new CDC guidelines say that DOT should be mandated, not "considered."

The new recommendations also call for in vitro drug susceptibility testing on the first isolate of *Mycobacterium tuberculosis* in all patients with TB to provide the basis for clinical therapeutic decisions, reporting the results to public health authorities. In addition, drug susceptibility testing will be important for identifying emerging drug resistance and helping to monitor control efforts in areas where resistance already is established.

'The new four-drug regimen and susceptibility testing go hand-in-hand," said Larry Geiter, chief of clinical research in the CDC's Tuberculosis Elimination Division. 'These new guidelines add a fourth drug to the previously recommended three-drug regimen. Pyrazinamide previously had been added to the TB drugs of choice, isoniazid and rifampin. Pyrazinamide allowed us to cut back to a six-month regimen, as opposed to nine months, and cuts the relapse rate to below 5%."

A four-drug regimen can be administered intermittently instead of daily. It is effective when given three times a week from the beginning of therapy or twice a week following an initial two-week phase of daily therapy. Clinicians should consider the three-drug regimen acceptable only in areas where isoniazid resistance is less than 4%.

Announcement of this recommendation also coincides with the renewed manufacture of streptomycin in the United States. After a two-year absence due to sterility problems in bulk supplies from a foreign manufacturer, Pfizer Pharmaceuticals Inc was to resume domestic production on July 6, 1993.

Drug resistance has added a chilling dimension to the recent resurgence of TB. In New York City, for example, 33% of TB cases were resistant to at least one drug, and 19% were resistant to both isoniazid (INH) and rifampin (RIF). Among recurrent cases of TB nationwide, 6.9% were resistant to both INH and RIF in 1991, compared with 3% during the period 1982 to 1986, according to the CDC.

These recommendations update previous CDC and American Thoracic Society recommendations for treatment of TB.

FROM: Centers for Disease Control and Prevention. Initial therapy for tuberculosis in the era of multidrug resistance: recommendations of the Advisory Council for the Elimination of Tuberculosis. ***MMWR*** 1993;42 (RR-7) :l-8.

Joint Commission to Make Hospital Performance Information Available to Public

Starting next year, the Joint Commission on Accreditation of Healthcare Organizations for the first time will release information to the public detailing how hospitals meet specific performance standards. Joint Commission President Dr. Dennis O'Leary says, 'This is a landmark issue for us, and it is very much in line with the reform environment. The change in the Joint Commission's confidentiality and disclosure policy, approved recently by the commission's board, recognizes the accrediting agency's obligation to share information with patients, purchasers, and other stakeholders in healthcare delivery systems."

Under the new policy, standards-compliance rat-

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ings in such areas as nursing care, infection control, patient rights, and life safety will be provided on a comparative basis. Also available for comparison will be facilities' overall summary grid scores, which are the basis for accreditation decisions.

Healthcare organizations will be able to review and comment on the data in the Joint Commission performance reports prior to publication. Official survey reports will remain confidential.

Meanwhile, the Joint Commissions board recently approved plans to begin evaluating delivery networks by January 1994. In addition, the board decided to resume evaluating hospices and to ask hospitals to collect and provide data voluntarily next year for the Joint Commissions indicator monitoring system.

FROM: ***Trustee.*** Chicago, IL: American Hospital Association; July 1993.

Court Rules That Patient May Sue HIV-Infected Doctor for Emotional Distress

A California state appeals court, in reversing a lower court's decision, ruled that the fear of contracting AIDS (even without proof of contamination) constitutes a compensable injury, at least for the period between learning of the doctor's condition and receiving the patient's negative HIV test results. Setting out the limits for a "reasonable window of anxiety," the court added that the patient's claim became unreasonable and thus uncompensable once the patient had received reports that no exposure had occurred, received the negative HIV test results, and had the opportunity for counseling on the accuracy and reliability of the test methods and the remote possibility of seroconversion more than 18 months after exposure.

The case began in 1986 when a surgeon removed the fibroid uterus of one of his patients. In April 1988, the patient learned of the surgeon's condition after an announcement on a televised news broadcast. The broadcast was connected with an AIDS discrimination suit filed by the surgeon against his medical partners, who had refused to let him return to his surgical practice after recovering from an AIDS-related illness. The patient underwent an HIV test the next day and found out two weeks later that she was not HIV positive. Nonetheless, the patient subsequently sued for damages for emotional distress.

While noting that the majority trend among other state courts holds that emotional distress damages are unrecoverable without proof of actual exposure to the AIDS virus or if it is "substantially likely" the patient was not infected and will not contract AIDS, the court accepted that the patient's fear, at least initially, was a valid cause of action.

In light of this case, concern has been expressed that by taking action to terminate an HIV-infected physician, a medical group may expose itself to potential liability not only to the individual whose employment has been terminated, but also to members of the public who have been treated by that individual.

FROM: Kerins v. Hartley, California Court of Appeals, 2nd Appellate District, Div. 2, no. B 065917. July 30, 1993.

Physicians Liable for Taxes on Vaccine Inventories

President Clinton's new five-year federal budget includes amendments to the National Childhood Vaccine Injury Compensation Act. Besides creating a new immunization program for low-income children, amendments to the act reinstate the federal vaccine excise tax used to fund a compensation program for victims of adverse reactions from immunization. In effect since 1988 to address escalating liability concerns of drugmakers and providers, the tax lapsed late last year when former President Bush vetoed a bill that contained its renewal. Since January 1, vaccine manufacturers have not collected the tax.

The tax has been reinstated to previous levels: $4.56 per dose of diphtheria, pertussis, and tetanus vaccine; $4.44 for measles, mumps, and rubella vaccine; $0.29 for polio, and $0.06 for diphtheria and pertussis. It does not cover hepatitis B or *Haemophilus influenzae* type b vaccines because they were added to the childhood immunization schedule after the tax went into effect. The budget bill states that providers are liable for tax on vaccines they had in stock on August 10, 1993. The Internal Revenue Service has advised that the tax will be due by February 28, 1994, but has not offered any further details.

Once taxes on existing inventories are collected, the inconvenience for doctors should diminish because vaccine manufacturers will collect the tax on new shipments. But many doctors are unsure of how to handle the inventory problems. It may be easy to determine what was in stock on August 10 for those physicians who keep detailed records. However, this may be difficult for those physicians who do not keep detailed inventories.

Critics say that reinstatement of this tax is ludicrous because it adds to a $600-million fund for claims of adverse reactions from immunizations given after 1988, and the surplus is one of the reasons it was allowed to lapse. Even those who agree that funding should be reinstated say it could have resumed without taxing inventory.

This will create a nightmare for many states that