Human Pituitary-Derived Growth Hormone (11/25/87)

DATE: November 25, 1987

FROM: Director, Office of Biologics Research and Review

SUBJECT: Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone

TO: All Registered Blood Establishments

In April 1985, it was recognized that three young adults who had received human pituitary-derived growth hormone (pit-hGH) during childhood died of an extremely rare neurological disease called Creutzfeldt-Jakob disease (CJD). Since that time, there have been four more CJD deaths associated with pit-hGH, two in the U.S. and two in other countries. The likelihood of young adults developing CJD is so remote that it has been concluded that pit-hGH must have been inadvertently contaminated with the transmissible agent that causes CJD. The pit-hGH was distributed free of charge in the U.S. through a government program, now called the National Hormone and Pituitary Program. Approximately 7,000 U.S. children received therapeutic pit-hGH between 1963 through early 1985. Pit-hGH was also available from 1978 through early 1985 from two commercial sources, Serono (Asellacrin) and KabiVitrum (Crescormon). Also, there are unknown numbers of persons who may have used this drug non-therapeutically, e.g., during rigorous physical training. Distribution of pit-hGH was halted in the U.S. in 1985, but pit-hGH is till in use in some foreign countries.

Transmission of CJD is known to occur in direct tissue-to-tissue contact following transplantation but not by sexual means nor from mother to child across the placenta. Experimental evidence from animal studies does suggest that it may be possible to transmit CJD by blood transfusions from a person who has been infected with CJD but who is asymptomatic. Because there is a remote, but finite, chance that CJD may be transmitted through the blood of pit-hGH recipients who are asymptomatic yet harboring the agent, and because there exists no means of testing to detect such infected persons, prudence dictates that all persons who have received injections of pit-hGH should be permanently deferred from blood donation.

Blood establishments should develop and implement specific screening procedures to defer permanently recipients of pit-hGH from donating blood or plasma products. Such deferral is not necessary for recipients who have received only recombinant growth hormone available as an investigational new drug from several companies, or commercially since 1985 from Genentech, Inc. (Protropin), or since March 1987 from Eli Lilly and Company (Humatrope).

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has prepared and distributed a fact sheet on "Human Growth Hormone and Creutzfeldt-Jakob Disease" to human growth hormone recipients and pediatric endocrinologists who treated these persons. This fact sheet provides telephone numbers and names of persons who can answer additional questions. A copy of the latest revision, which includes an update about limitations on donations of tissues and organs as well as blood, is enclosed. This fact sheet should be retained in the donor screening area for ready reference.

Elaine C. Esber, M.D.