Deferral of blood donors who have received Accutane
(2/28/84)

February 28, 1984

FROM: Director, Office of Biologics Research and Review
National Center for Drugs and Biologics

SUBJECT: Deferral of blood donors who have received the drug Accutane (isotretinoin/Roche;13-cis-retinoic acid)

TO: ALL ESTABLISHMENTS COLLECTING BLOOD,
BLOOD COMPONENTS AND SOURCE PLASMA

As you may know, the recently approved new drug Accutane (also known as isotretinoin or 13-cis-retinoic acid) has been shown to be a potent teratogenic agent, and appropriate warnings have been included in the labeling and in the package insert. This drug is indicated for the treatment of severe recalcitrant cystic acne but the possibility of use in other less apparent conditions exists.

It has come to our attention that if a donor who is receiving Accutane (isotretinoin) gives blood, and the donated blood is transfused into a patient who either is or soon becomes pregnant, there may be a risk to the developing fetus because of Accutane in the transfused blood. The blood recipient could also suffer significant side effects.

Although there are quantitative data available with respect to the period of time between receipt of the last dose of Accutane (isotretinoin) and the clearance of Accutane from the blood, it is not known what levels can be considered non-teratogenic. In addition, it is known that the clinical effects of Accutane can persist after the drug has been discontinued, but it is not known whether this reflects the presence of low drug levels in the circulatory system.

Taking into consideration the potency of the drug as a teratogen and the possibility that it may be present in the blood for long periods, we are advising that any donor taking Accutane (isotretinoin) should be deferred for at least one month from receipt of the last dose.

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