

July 19, 1999

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Dockets Management Branch (HFA-305)
FDA 5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir:

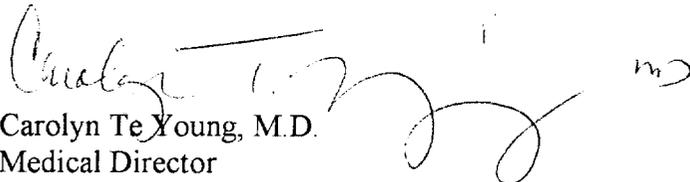
Comments Regarding the Draft Guidance on HCV Lookback (Docket #99D-1878)

I write to express concern regarding the FDA draft recommending targeted HCV lookback notification extending back indefinitely. The CDC public education has already encouraged all recipients of transfusions before 1992 to see their physicians about whether they should get HCV tested. The current guidance from September 1998 effectively addresses lookback to 1/1/88 or 1 year before last negative test. Our paper records go back to 1979 but are difficult to recover.

The major point of HCV Lookback, as I understand it, is to identify people infected with HCV to prevent the damage caused by chronic hepatitis in individuals who may not know they have HCV until serious damage has already occurred. This goal may be more effectively achieved by focusing efforts on public education and recommendations to abstain from alcohol or only consume in moderation in addition to warnings against using hepatic stimulating medications (or any medications) unnecessarily.

Thank you for the opportunity to submit my comments. Please call me at (401) 453-8393 if you have any questions.

Sincerely,

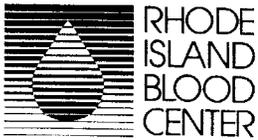

Carolyn Te Young, M.D.
Medical Director

CTY:kmp

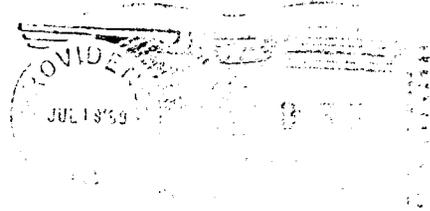
99D-1878

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