Table 4.1 Chronology of Fractionator License Applications and Approvals for Heat-Treated Factor VIII Concentrate

Plasma Fractionator and Method	Date Applied for FDA Licensing	Date License Granted by FDA
Baxter Healthcare (dry heat, 60°C for 72–74 hours)	June 1982	March 1983
Miles, Inc. (formerly Cutter Biological) (liquid pasteurization, 60°C for 10 hours)	August 1983	January 1984
(dry heat, 68°C for 72 hours)	November 1983	February 1984
Alpha Therapeutics (wet heat, 60°C for 20 hours)	December 1982	February 1984
Armour Pharmaceutical (dry heat, 60°C for 30 hours)	December 1982	January 1984

SOURCE: Persky 1995; Rodell 1982; Petricciani 1983; Hammes 1995; Mozen 1995; McAuley 1995; and Feldman 1994.

manufacturing processes to produce only heat-treated products at the time they were licensed by the FDA to produce heat-treated AHF concentrate.

ANALYSIS AND CONCLUSIONS

As with other areas of scientific investigation, technical advances to improve the safety of blood and blood products relies on the imagination and abilities of individual researchers, the availability of sufficient financial resources to encourage and support new research directions, and the encouragement or pressure applied by regulatory agencies or consumer advocates. Progress in improving the safety of AHF concentrate could have potentially been encouraged by a variety of sources including the plasma fractionation industry, the NIH, the FDA, and the National Hemophilia Foundation. In evaluating the adequacy of the response of each of these groups, the Committee reviewed the sources of technical innovation and research funding for viral inactivation technologies for

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