THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

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Dr. Arthur L. Caplan, Chairman
Advisory Committee on Blood Safety and Availability
Center for Bioethics
University of Pennsylvania
3401 Market St., Suite 320
Philadelphia, PA 19104-3308

Dear Dr. Caplan,

Thank you for communicating to me the recommendations made by the Advisory Committee on Blood Safety and Availability at its August 27 and 28, 1998 meeting. Once again, your Committee has provided a thoughtful perspective on an important and complex health issue. Dr. Satcher and I are grateful to all of you for your efforts.

I am pleased that the first three of your recommendations for managing the transition from human-derived blood products to their recombinant analogs restate current Departmental policies and commitments. We will continue to promote this transition when it is technologically feasible and medically appropriate, support research in areas where this technology has not yet matured, and maintain and as necessary expand or intensify surveillance of blood donors and recipients for existing and emerging infectious diseases.

I concur with your directive to Committee staff to pursue ongoing dialogues with patients, industry, and experts within and outside the government to determine how best to monitor production and utilization of blood products, and how best to anticipate future demand. The latter will be a particularly challenging assignment. I would welcome further recommendations from the Committee that these dialogues should generate.

Testimony before your Committee confirmed the Department's ongoing commitment to provide, when medically appropriate, the benefits of recombinant technologies to all direct beneficiaries of Federal health insurance programs. I am directing Committee staff to work with the Health Care Financing Administration and other appropriate entities, including patient service organizations, to identify unmet needs of the privately insured for these benefits, and to identify effective and durable solutions for these individuals.

I appreciate the concerns that led your Committee to suggest regulating export of plasma and plasma derivatives, and in particular the concern that the burden of recent shortages on American consumers may have been disproportionate. At the same time, we must acknowledge the

obligations that come with the benefits of our participation in the global health care market. The solution to our current shortage situation is to increase supply, abroad as well as at home. Whatever actions we take should be consistent with this strategy.

I join the Committee in encouraging the further development of standards for the appropriate use of plasma derivatives, both as a means of alleviating product shortages and as a means of improving the quality of health care for all.

Finally, I will take under advisement your suggestion that I convene a meeting of manufacturers to discuss distribution strategies during product shortages. I am encouraged by reports of direct and ongoing communication on this subject between consumers and producers of blood products, and I feel these direct contacts offer the best hope of negotiating a just and durable solution to this problem.

Once again, thank you for your work. I look forward to receiving future recommendations from your Committee.

Sincerely,

Donna E. Shalala