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AdvaMed
Advanced Medical Technology Association

A Proposal for Regulatory Relief Without Compromising Donor or Product Safety

BPAC, June 13, 2002

Ladies and Gentlemen:

I am here today representing the Advanced Medical Technology Association (AdvaMed). AdvaMed represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually. Some of our member's manufacture products that contribute to the national effort to improve the safety and availability of blood and blood products in the U.S. As the committee considers standards for recovered plasma, AdvaMed would like to take this opportunity to propose to the Committee a means of meeting the increasing demand for plasma without compromising donor or product safety.

Today, licensed facilities collecting whole blood and preparing fresh frozen plasma (FFP) may, at any time, re-label the product "recovered plasma" and ship for further manufacturing use. No separate license is required.

Facilities licensed to collect FFP as a by-product of red blood cells or platelets by apheresis, however, do not have this option. Currently a separate license is required to ship, for further manufacturing use, plasma collected as a by-product of cytapheresis. The plasma by-products of cytapheresis are treated the same as plasmapheresis products (that is, Source Plasma), *despite the fact that these products are not collected by plasmapheresis*, as stipulated in 21 CFR 640.60. The products are further distinguished from plasmapheresis products in that due to restrictions on the frequency of red cell and platelet donations, the products are collected from "infrequent donors".

As you are well aware, the Agency, the blood community, and industry are looking for ways to address the continuing blood shortage problem in the US.

Increasingly, blood centers are moving towards apheresis as one means of addressing the country's blood supply problem. Current FDA policy requiring an establishment to obtain a Source Plasma license in order to ship the plasma by-products of cytapheresis for further manufacturing use, represents a substantial barrier to volunteer donor centers that are already licensed for apheresis collections.

We propose that *FDA allow plasma by-products of infrequent cytapheresis procedures, that is, red cell or platelet apheresis collections, to be labeled as recovered plasma.*

Because these products are not collected by plasmapheresis, a formal change to the regulation is not required. The short supply provisions of 21CFR 601.22, which are applicable to plasma by-products of whole blood collection, can be applied to plasma by-products of infrequent cytapheresis procedures. This would reduce the burden on the blood community, and on FDA reviewers, and would increase the availability of plasma products for fractionation into therapeutic derivatives. The policy change should permit fractionators simultaneously to amend contractual agreements to permit this change in source material definition and labeling.

We ask that the Committee seriously consider this proposal and recommend this policy change to FDA.

Thank you for your consideration.