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OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

**IMPLEMENTATION OF NAT FOR HCV AND HIV:
TESTING, DONOR AND PRODUCT MANAGEMENT**

STATEMENT OF AMERICA'S BLOOD CENTERS

BEFORE THE FDA BLOOD PRODUCTS ADVISORY COMMITTEE

March 15, 2001

**Presented by Celso Bianco, M.D.
Executive Vice President**

America's Blood Centers, or ABC, is an association of 75 not-for-profit, community based blood centers that collect nearly half of the US blood supply from volunteer donors. ABC thanks FDA's Center for Biologics Evaluation and Research for the opportunity to make public comments before the Blood Products Advisory Committee.

The implementation of NAT screening under an IND protocol has been a great success. In the past two years, we saw our independent blood centers work together to create seventeen laboratories that perform NAT screening for the 6.5 million units collected by the entire ABC network. Sally Caglioti and Michael Strong, from two of our centers, led the ABC efforts in the new enterprise. Everything was different from our routine donor screening: the handling of specimens for testing, the pooling of specimens under cGMP conditions, the logistics of sample transportation, test performance, and management of test results. The two manufacturers were extremely supportive and did not stint in their efforts to bring up the biggest research protocol ever in this country and probably the world. This confirms the value that healthy competition brings to the system. We are very happy to have received superb attention from Chiron-GenProbe and Roche, two major leaders in the field of diagnostics. Thirteen of our laboratories use the Roche system, three the Chiron-Gen Probe system, and one has an individual IND. The laboratories and the manufacturers have carried out the process exactly as they would with a FDA licensed test.

It worked! We have identified a significant number of individuals who were in the window of seroconversion for HCV, and a small but important number of individuals in the window for HIV. This has been a major milestone in the enhancement of blood safety, and we are very proud of being part of it.

FDA has provided substantial encouragement and support to blood centers and kit manufacturers. The implementation of the INDs for NAT constitute a great example of productive collaboration between regulators and industry, and we hope it will repeat itself many times as we confront new challenges in blood safety and availability.

There are a few issues that we would like to raise for consideration of the Committee and CBER

1. There is an immense amount of data available about both test kits. We hope that the INDs will soon come to completion and that the tests will be licensed as rapidly as possible. This will reassure the American people. They want to know that NAT is a real screening test, not a research protocol. Interestingly, we still get calls from our centers indicating that one of their hospitals refuses to pay for the cost of NAT because "this test is not licensed or mandated by FDA." This should be the highest priority both for the manufacturers and for CBER. Quick resolution of issues of licensure will also free manufacturers to continue development of better assay kits, particularly in the areas of sample preparation (RNA extraction) and automation.
2. We urge FDA to issue guidelines that address supplemental NAT for confirmation, and a rational process for donor reinstatement after documented false positive results.
3. We also urge FDA to modify other guidelines that require performance of supplemental serological tests that have been superseded by the NAT technology. For instance, a specimen that is positive for antibodies to HCV and positive on NAT for HCV does not need the performance of RIBA for HCV. The additional test delays the process of donor notification and counseling, delays the initiation of lookback, and is quite expensive. RIBA should be reserved for specimens that are repeatedly reactive on ELISA and negative on NAT.
4. Finally, we urge FDA to consider dropping the requirement for HIV-1 p24 Antigen for screening of whole blood and source plasma donors. The many millions of HIV NAT tests performed have shown that the antigen test does not contribute to the safety of the final product. This will free human and material resources that can be better dedicated to other aspects of donor screening.

ABC wants to congratulate all participants, FDA, the test manufacturers and the blood centers for their contributions to the success of this enterprise. We want to thank effusively our colleague scientists Susan Stramer and Roger Dodd from the American Red Cross for the spirit of collaboration and sharing of experiences. Finally, we want to thank our courageous and tireless volunteer blood donors. They put up with a painful screening process, informed consents, deferral files and call-backs for follow up, in order to help patients in need of blood in our communities and support the research protocols for NAT. Without them, we would not be here today.

We also want to emphasize that ABC members are committed to blood safety. ABC members are also committed to the preservation of the supply of safe volunteer donor blood for all patients in need, because no blood is a real risk, not a theoretical risk, and it threatens patient care.

Thank you again for the opportunity to comment.