



Committee of Ten Thousand

Advocates for Persons with HCV-HIV/AIDS

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TESTIMONY before the
FDA Blood Products Advisory Committee
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Donor Re-Entry When Repeatedly Reactive HBV Core Antibody Tests are Followed by Negative Nucleic Acid Tests

The Committee of Ten Thousand (COTT) is pleased to be able to address the committee on this important new proposal to relax current lifetime deferral criteria.

The basis for the proposed change and the re-entry of these previously deferred donors is the issue of false positives in testing for antibodies to HBV Core Antigen (anti-HBc). With the more sensitive NAT (Nucleic Acid Test) testing now widely in use, donors who were deferred for repeatedly reactive anti-HBc tests may be eligible for re-entry as donors: past less-sensitive anti-HBc tests had false positive rates higher than today. COTT supports the concept of donor re-entry, where safe -- NAT testing showing an earlier reactive anti-HBc test was a false positive may suffice; we would view it as necessary although perhaps not sufficient.

A positive result on a Surface Antibody test usually identifies a person who has cleared the virus. If a person has cleared the virus, he/she will produce surface antibodies. An isolated positive Core antibody test result is harder to interpret. For one thing, it may clear in time, or it may not. In the absence of nucleic acid or antigenic evidence of active infection it may be caused by pathologies unrelated to hepatitis, such as auto-immune conditions. However, people with high-risk behaviors for contracting HBV infection frequently have isolated core antibody positivity, suggesting that they were indeed infected with HBV.

In the early days of AIDS, or GRID, Hepatitis C had not been identified, nor had HIV. However the disease sweeping one community, and appearing with alarming frequency in ours, bore enough similarities to a hepatitis that clinicians were beginning to use testing for antibodies to HBV Core Antigen as a surrogate for one or both of these conditions – clearly they were both blood-transmissible. It would not be too long before clinicians and regulators alike realized that this blood transmission was coming from the blood supply itself – threatening the entire nation.

However, clinician astuteness was not followed up by agency alertness. Anti-HBc testing as a surrogate marker for HCV and/or HIV was never mandated. The Committee members are well aware of how many lives were lost in our community subsequently.

We developed a healthy (sic) respect for the certainty that a positive anti-HBc conveyed, in light of the marker value it had at the time. Therefore there is still an extent to which we have a visceral reaction on hearing a person tests positive for it.

A positive anti-HBc test in the past, when used as a surrogate marker, suggested intravenous drug use. It did not indicate that, of course, but at the time, when Non-A Non-B and HIV were

proliferating though tests were not available, the tendency was to take any suggestion of blood-borne contagious pathogens as a basis for excluding donors.

Today that is far less of a concern as other tests have been developed, and especially since the onset of widespread PCR testing. However, our earlier point remains, that a positive (or indeterminate) anti-HBc test may be triggered by other factors. If we no longer rely on this test, which means its use will be discontinued, we will lose that small indication of other risks.

We encourage the committee to consider a 6 to 12 month delay in acting on this proposal while further study offers clarification on the risk of loss of informative data should the anti-HBc test be discontinued.

Units testing positive or negative for key viruses are then placed in appropriate channels. We remind FDA/CBER and the blood industry that humans run the computers, and humans move the supplies around, so humans will still make errors. The ongoing inability of the American Red Cross to fix its operating procedures, correctly screen donors and get its overall blood operations in order, even after tens of millions of dollars in fines, proves our point. COTT continues to counsel caution when changes in donor screening and eligibility are proposed.

We are mindful of the need to expand the nation's donor pool. However, without the political will necessary to connect blood donation to good citizenship, the situation will remain difficult and the donor pool will not grow significantly enough to meet projected demand. The blood industry and our political leadership should teach our children in the schools the importance of regular blood donations. In this election year we need to put regular blood donations on the political table. If former Presidents Bush and Clinton can raise awareness about Hurricane Katrina in television spots, then it is also possible for our leaders to regularly and repeatedly encourage donation.