



## **Committee of Ten Thousand**

*Advocates for Persons with HIV/AIDS*  
236 Massachusetts Ave., NE Suite 609 Washington,  
DC 20002 (800) 488-2688 [www.cott1.org](http://www.cott1.org) • [cott-dc@earthlink.net](mailto:cott-dc@earthlink.net)

### **COTTWEST**

622 Andamar Way  
Goleta CA. 93117 (805) 967-6679  
[cottwest@silcom.com](mailto:cottwest@silcom.com)

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### **A Thinking To Meet Emergent Threats**

The Committee of Ten Thousand has enjoyed a unique relationship with the DHHS Advisory Committee On Blood Safety and Availability. As the community based organization that first demanded a full investigation into the HIV/AIDS contamination of our nation's blood supply, COTT was able, through discussions with Senators Ted Kennedy of Massachusetts and Bob Graham of Florida, to gain a full study by the National Academy of Sciences, Institute of Medicine. The report "HIV and The Blood Supply; An Analysis In Crisis Decision Making" was published in 1995. The IOM made fourteen recommendations that became the guidance for changes in response to the AIDS/blood epidemic.

While we acknowledge that there certainly are more efficient and effective methods for structuring donor screening and deferral, we cannot approach change in a vacuum. We must view the blood supply as an integrated whole where one regulatory change must be considered in its impact on the entire landscape. Change must be based on improving the overall safety of the blood supply while developing donor deferral policies that impact all risky behaviors whether practiced by individuals in the heterosexual community, the MSM communities and all other donor communities.

It is with risk in mind that we quote Health Canada and their position regarding the expectations of the end users of blood and blood products,

*"Health Canada's position as the Regulator of the Blood System is to not approve changes in blood operations which will increase risk, it is to review and approve changes which will increase safety or at least maintain the current level of safety."*

In testimony before the ACBSA, Dr. Ganz of Health Canada stated that,

*"Health Canada recognizes that not all members of a particular risk group will share that group's high risk, but individualized health assessments for risk factors of every potential blood donor are not possible as part of Canada's voluntary blood donation system."*

While we support moving to more effective and individual, risky behavior, based deferrals, serious questions remain that can and should be answered before change is undertaken. It is not in the best interests of end users to implement change before we address answering important questions regarding the re-entry of previously deferred donors.

It is within this context that the end-user communities are again being asked to shoulder a potential increase in risk, by revising the current donor deferral policy regarding MSM donors. Where are the necessary initiatives for addressing problem areas if we are going to revise a policy that will result, according to the FDA, in an increase in the number of so-called hot units that will enter the overall collection system?

The end-users continue to wait for the blood community and the federal government to share in shouldering the risk of regulatory failure. That risk continues to be borne solely by those who will potentially be harmed by regulatory failure. Without strong initiatives to address the problems and who shoulders the risk, end-users have a very difficult time viewing the risk as shared by all the stakeholders associated with the blood supply.

Why do we continue to respond to failure without considering more humane policies and structures for addressing a given failure? Why do we view failure in the regulation of the blood supply so differently from the manner in which we address failures in vaccine safety? The general consensus remains that the vaccine injury act continues to serve an important societal goal, safe and available vaccines. Yet each and every time end-users raise the concept of a blood injury act, we are again met by an absolute unwillingness to act on the part of the federal government and the blood community.

It cost the federal government roughly between 600-800 hundred million dollars to address the impact of the HIV/AIDS infection of ten thousand members of the hemophilia community. This alone should motivate us all

to seek more humane and cost effective strategies for addressing regulatory failure in the blood supply.

In recommendation 3 the IOM addressed the question of developing a no-fault compensation program for those harmed by failures in the regulation of the blood supply

*“The federal government should consider establishing a no-fault compensation system for individuals who suffer adverse consequences from the use of blood or blood products.”*

We again call on the federal government and the blood community to take a share of the responsibility for failure. We are tired of continually being asked to accept any increased risk given the fact that we, the end users, will bear the burnt of regulatory failure.

Over forty percent of our nation’s blood is collected by the American Red Cross under a Federal District Court imposed Consent Decree. Why do we treat this as if it is an acceptable situation? Where is the will from ARC and the federal government to clean up what we view as an unconscionable situation?

Why would the end user communities consider any increase in risk, no matter how small given this reality? Those who depend on this nation’s blood supply to retain their health and wellness must be sure that any change is being undertaken in order to raise the overall safety of the blood supply. Regulatory change must be based first and foremost on the protection of all end users.