The Lifeblood of our Community

Mississippi Valley Regional
Blood Center

3425 East Locust Street
Davenport, Iowa 52803-3500
319/359-5401
Fax: 319/359-8603
800/747-5401
www.bloodcenter.org

March 13, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, Maryland 20857

Re: Docket: Section 230.150 Blood Donor Incentives

To Whom It May Concern:

Thank you for the opportunity to comment on this document.

I find the concept "readily convertible to cash" superficially attractive, but operationally very difficult. In 1978 when the 43 FR 2142, 2143 defined paid donations as readily convertible to cash, the type of donor that the FDA was trying to exclude was a high risk, primarily HIV, behavior donor. This is less of an issue in the post-NAT era, I suppose, but incentives for donors is still an issue that needs to be addressed as today the type of donor that we are trying to exclude in some cases is the well heeled, altruistic donor who does not perceive him/herself as a risky donor. What we are seeking is a broader definition of those incentives that would, more likely than not, lead some donors to be less than forthcoming during the screening process, not just for HIV high risk behavior but for an increasing number of health questions about travel and medications that may not be obvious to the donor as to the risk they pose to the recipient. While it is recognized by all that incentives can be a slippery slope, as pointed out in a recent publication from the REDS group (Sanchez AM, Ameti DI, Schreiber GB, et. al. "The potential impact of incentives on future blood donation behavior". Transfusion. 2001. 41:172-178) that suggests incentives under some circumstances, might erode donor truthfulness, I don't know at what point one is on that slope. FDA must not give short shrift to this potentially critical issue by promulgating guidance to the field through the Office of Regulatory Affairs without extended public discussions of the issues. These discussion need to involve not only incentives that are readily convertible to cash, but also those issues regarding the dollar amount of non-convertible incentives, impact of incentives on the ability to recruit and retain donors and system development, by individual centers, to monitor the impact of incentives based on local, donor demographics with judgment of appropriateness of individual incentives left to the field inspection based on local risk analysis.

The assessment by individual centers would assist in providing a rational approach to such questions as "Why sports tickets are bad, but opera tickets are not?" The answer really depends on who you are and where

you are. Tickets to the Metropolitan Opera would be a far greater inducement than tickets to my local class A minor league baseball club. From a local standpoint, tickets for the class A minor league hockey club have value, but not those to the baseball teams games. The compact disc used to promote a record store is ok, but if the Blood Center buys them and just gives them away, it's not?

On the whole, this guidance does not address the real issue we are interested in, as stated above. While it would be cleaner for FDA to tell us it is unacceptable to give anything away, or anything with an arbitrary value greater than some threshold, the devil in such an extreme position would be to make incentives like paid time off unacceptable, which could substantial decrease donations in some areas. Many of us have clear experiences with industry, military bases, and other large donor groups that convince us that an afternoon off or community service points for donation is a powerful donor recruitment tool at a time when donors are scarce. I live with this conflict on a military reservation in my system because I have looked at infectious diseases marker rates and they are consonant with the rest of our donor base, both First Time Donors and repeats. Other centers may have incentives that on a local level can be proven do not carry increased risk but could be negatively impacted if a blanket disallowal of incentives were considered.

On the whole, it is not clear to me that this guidance accomplishes more than enshrining isolated field judgements from the examples listed while taking away the flexibility of field inspectors to look at each situation in a local context.

I would advocate reworking this document for one of two alternatives. First, would be to limit those incentives not specifically stated in the regulation as acceptable to $10.00 for all incentives. Then define instruction to the field to assess each instance based on local conditions and markets risk analysis. This risk analysis could include a center's baselines for First Time Donors, viral marker rates and deferral percentage with a process for evaluation against this baseline for incentives like raffles, sports tickets, trips, etc.

Second, as suggested above, FDA can convene a public workshop where all of the relevant issues can be discussed, and then promulgate guidance to industry through the Center for Biologics. While a workshop was held last year regarding donor recruitment the forum did not allow for discussion of the issues outlined in this letter.

Sincerely,

Linda E. Gerber for

Louis M. Katz MD
Medical Director

Federal Express

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