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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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To Whom It May Concern:

This letter is in response to a call for comments regarding the Draft Compliance Policy Guidance for FDA Staff and Industry, Chapter 2 Section 230.150 – Blood Donor Incentives. I am writing as a member of the general population, as a potential blood donor and a potential recipient of donated blood in a large metropolitan area that experiences seasonal blood shortages.

Upon studying the *Federal Register* Notice published January 13, 1978, it is apparent that the paid/volunteer blood labeling requirement was mandated by the FDA to promote the safety of the nation's blood supply. The labeling requirement is based primarily on published data that established donors who receive cash in exchange for their blood donation are more likely to be carriers of transmittable disease. The labeling requirement is intended to make physicians aware if the donor source of the blood they are prescribing, to increase the demand for volunteer donor blood, and to foster the public policy favoring an all-volunteer blood donation system.[1]

In the 1970's when these regulations were being initially discussed, hepatitis transmitted by blood from paid donors was perceived to be the main threat to the safety of the nation's blood supply.[2] Today, the list of transmittable diseases has grown to include HIV and HTLV, among others.[3] The sophisticated laboratory tests that have been developed to screen blood for these transmittable diseases are not foolproof. Diseases can still be transmitted from donor to recipient if the donor was in a seronegative window period of infection when she or he donated, if a laboratory error occurred, or if current testing was not able to detect the infection involved.[4]

The Draft Guidance attempts to define whether an incentive is readily convertible to cash. An incentive that can be readily sold or converted into cash is considered monetary payment. Thus, the blood from a donor who receives such an incentive requires a "paid donor" label. Theoretically, such an incentive will encourage more people in an at-risk population to donate blood in order to receive the incentive.

Under this line of reasoning, the four factors set out in the draft guidance make sense. However, on further examination, there seem to be shades of gray in determining which incentives are readily convertible to cash. For instance, the Center for Biologics Evaluation and Research's list of example incentives includes, among others, symphony or opera performance ticket vouchers, compact discs compliments of a music store, reduced hotel room rates, and sports game tickets or vouchers. These incentives are not considered readily convertible to cash unless an accessible market exists and they are transferable. What exactly is an accessible market and who determines if the market is accessible? Further, the market could possibly be accessible to some donors and inaccessible to others – which one of these donor's blood is labeled as "paid donor"?

Determining if the incentive is relatively easily convertible to cash and thus a monetary incentive requiring the paid donor label does not address the incentives that are considered non-monetary yet are the primary motivation for the donor to give blood. The donor could value the incentive to such a degree that he/she would misrepresent his/her medical or behavioral history on the initial screening in order to qualify as an eligible donor and receive the incentive. The instances when this could arise involve giving away non-transferable tickets to a sporting event, meal/drink vouchers, or clothing items.

Two studies highlight this problem in particular. A study done in 1992 focused on an annual blood drive promoted by a hard rock radio station that offered T-shirts to all donors. The study found that some infectious disease markers were higher in the donor population. The results suggest that non-monetary incentives may influence donor motivation and have adverse affect on the safety of the donated blood.[5] Dr. Alan E. Williams cited an example of a blood drive on a college campus sponsored by the Panhellenic Council. The blood center provided organizational and "hands on" help, agreed to reimburse the Panhellenic Council for t-shirts given to all who showed up to donate, and sponsored a party including food, soda, and a local band. The university Faculty Council agreed to contribute $5 for each unit of blood donated. In order to meet their party budget, the Panhellenic Council decided to stamp the hands of successful donors, entitling them to free beer at the party. Revelers with unstamped hands had to pay fifty-cents per cup of beer. Dr. Williams suggests that the scenario presented strong peer pressure and incentives that could cause donors to inappropriately donate blood or misrepresent facts about their medical and/or behavioral history.[4]

In the above examples, some incentives that are not readily convertible to cash may indeed induce the blood donation and undermine the paid/volunteer donor label distinction. The T-shirt offered to donors in connection with the hard rock radio station, as well as the T-shirt offered to the college students were not readily convertible to cash, but could have effected the donation. On the college campus especially, the T-shirt could have effected the donation by peer pressure and the well-known need to be a part of a group. The hand-stamp, although not readily convertible to cash and not transferable (under the draft guidance framework), did have a monetary value (fifty-cents per cup of beer). Dr. Williams categorized the stamp as a payment or inducement under the American Association of Blood Bank Bulletin #94-6 incentive framework, and thus prohibited.[4]

Paragraph nine of the Draft Guidance states that the nature of the population attracted by the incentive is not relevant. However, the nature of the population attracted by the incentive may be quite relevant in maintaining the safety of the blood supply. An article authored by Strauss et al. reports the results of their study of paid cytapheresis donors and volunteer whole blood donors. They found that paid cytapheresis donors, when managed in a formal system that ensured education, scheduled donations, and repeated screening and testing, do not have a higher infectious disease history or higher rate of infectious disease test results than volunteer donors.[6] Several scientists have pointed out flaws in the study by Strauss et al.[7,8] Dr. Huestis, in an editorial that appears in the same issue of *Transfusion* as the study, points out that the rigors of the study (education, repeated scheduled visits) and the location of the study (small, relatively isolated community that supports a large hospital and medical school) attracted subjects from a higher socioeconomic class.[7] This observation leads one to question if the same results could be duplicated in a lower socioeconomic community located in a struggling metropolitan area. Similarly, one could question whether a higher incidence of infectious markers would be found

in a donor population that responded to a National Public Radio station blood drive promotion that included a T-shirt give-away to all donors.

The primary goal of the paid/volunteer labeling mandate stems from a concern that people with transmittable disease are more likely to donate blood for cash or for incentives that are readily convertible to cash. The draft guidance attempts to define what is an incentive that can be readily convertible to cash so that a donor who receives such an incentive will have his labeled as a "paid donor." The draft guidance should attempt to define more clearly what an "accessible market" is and to whom the market is accessible; it should also define who is responsible for making such a determination. Recent research has also shown that monetary payment, or the equivalent thereof, does not necessarily correspond to transmittable disease markers found in blood donated by recipients of such incentives. As more research is performed in this area, the FDA should reconsider the paid/volunteer donor distinction and revisit the "paid commercial donor" and "compensated volunteer donor" label options discussed in the *Federal Register* Notice.[1]

Thank you very much for your consideration of these issues.

Sincerely,

A. Thom

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References

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