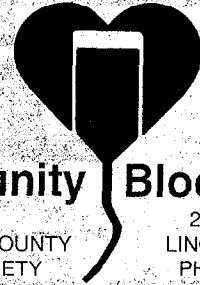


6293 '01 MAR 23 12:17



Community Blood Bank

OF THE
LANCASTER COUNTY
MEDICAL SOCIETY

2966 "O" STREET
LINCOLN, NE 68510
PH. (402) 474-1781
FAX (402) 474-5986

March 15, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: Blood Donor Incentives, Section 230.150

I would like to take the opportunity to comment on the FDA's current thinking on blood donor incentives as outlined in the Office of Regulatory Affairs' draft Compliance Policy Guidance for FDA Staff and Industry.

I appreciate the fact that ORA has undertaken a very difficult issue and is attempting to establish some parameters for evaluating donor incentives. The concept of maintaining a **volunteer** donor base while protecting the **integrity** of the donor's medical history is fundamental to our work to ensure the purity, potency and safety of the blood supply.

I agree that cash in any amount requires "paid donor" labeling. However, the evaluation of "readily convertible to cash" is difficult. ORA has provided several definitions but they seem to have inherent problems:

Transferability This is difficult to control in practice because even low incentive items like T-shirts and movie passes can easily be given to someone else.

Redeemable This is also difficult to control in practice as most things can be sold or bartered in some way (i.e. Pawnshops or newspaper ads).

Marketability The examples given, opera tickets vs. sports tickets, vary widely in how attractive they are to a recipient.

Readily Converted The significance of the effort involved in the conversion of an item to cash depends on the ingenuity of the seller and is difficult to evaluate or define.

00D-1679

C11



Although ORA dismisses as irrelevant whether or not an incentive is given to all who attempt to donate or only those who successfully donate, I must respectfully but strongly disagree. Our blood center has carefully guarded the integrity of the medical history. We do not allow a donor's "perception" of the value of an incentive to affect their choice of answers to medical history questions.

ORA also dismisses as irrelevant the cash value of an item. As the dollar value of an item increases, so does the individual's creativity in finding a market for the item. The cash value of an incentive can not be totally disregarded.

Although our blood center supports the idea exempting "time off work", I would suggest that you consider limiting the time off work to that needed for the donation process and reasonable travel time to and from the donation site. The time off work should coincide with the donation time to avoid increasing its value as an incentive.

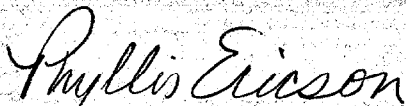
There are some incentives provided by parties outside blood collection agencies that are not readily convertible to cash or transferable but are problematic. These include:

- alternative sentencing,
- community service for parolees, and
- credit for improved grades in schools.

Our donor center policies consider these to be inappropriate incentives and I would like to see them addressed in the document.

This draft document is a welcome start. I look forward a more formal guidance to the blood industry by the Food and Drug Administration through the Center for Biologics Evaluation and Research.

Yours truly,



Phyllis Ericson

Chief Executive Officer

Community Blood Bank of the Lancaster County Medical Society

Lincoln, NE

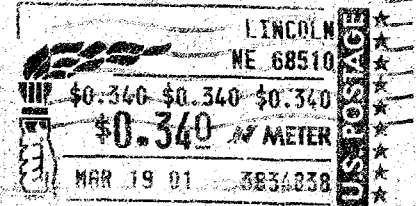
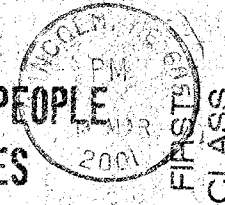


Community Blood Bank

OF THE
LANCASTER COUNTY
MEDICAL SOCIETY

2966 "O" STREET
LINCOLN, NE 68510
PH. (402) 474-1781
FAX (402) 474-3994

**CONNECTING PEOPLE
SAVING LIVES**



Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

