



January 23, 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**

Dear Sir:

Thank you for the opportunity to comment on the "Draft" Compliance Policy Guidance for FDA Staff and Industry posted on the ORA web site on December 29, 2000. I trust my input regarding Blood Donor Incentives is of use to the Office of Regulatory Affairs of the FDA.

I appreciate that the status of a "volunteer donor" versus that of a "paid donor" is to be clarified by the new guidance document. While it is evident that a volunteer donor should be one who does not receive monetary payment for a blood donation, and that monetary payment includes cash in any amount or items that are readily convertible to cash, it is not as clear what a "paid donor" is. I believe it is time to change this latter term and refer to individuals who receive monetary payment, or items that are readily convertible to cash, as "paid sellers," not "paid donors."

Per Webster's Dictionary, 10th edition, please note the following definitions: (1) Voluntary: acting or done of one's **own free will without valuable consideration** (emphasis added) or legal obligation; (2) Pay: to give in return for goods or **service** (emphasis added); to make a disposal or transfer of (money); to make due return for services rendered or property delivered, (3) Seller: one that offers for sale.

In the draft policy, it states that incentives, e.g., "(1) time off from work," would not require the "paid donor" classification as long as such a benefit is not readily convertible to cash. I believe you should differentiate the "time off from work," into (a) whether or not it is incident to the donation process, or (b) separate from it, e.g., paid time off or vacation time (e.g., hours or half a day), which may be taken at another time, and may be converted to cash, should the person so elect to receive the equivalent in lieu of vacation time. The conversion of saved paid time off to cash is a relatively easy one today; for example, many institutions notify employees if they must take their vacation time or receive payment in cash, if they are unable to take the time off. Therefore, I suggest that "time off from work" be better defined and separated into whether or not it is part of the time allotted for the donation process, in which case the donor would be a volunteer, or if it can be saved and used at another time, so can be converted to cash, when the individual be considered "paid," and all components from that collection carry the label "paid."

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I would support some of the factors to consider “when determining whether an incentive is readily convertible to cash.” Thus, I would support item (1), but item (2) should be clarified. What if the incentive is, in part, redeemable for cash? For example, a voucher for a movie theater, which, if the entire amount is not used for the price of a ticket, and the residual may be refunded to the individual, then, that would make this redeemable for cash, and warrant the label of “paid.” I quite agree with the statement in item (3) that the existence of a market for the item whereby the donor could sell the incentive relatively quickly and easily makes the “paid” labeling necessary. Thus, I am curious to know why free tickets for movies, theater, symphony or opera performances are not considered “paid.” Just like tickets for sporting events, they may be sold prior to the performance or at the entrance to the facility for cash, and so should be considered items that make the blood components derived from that individual be labeled as “paid.”

If the individual does not need to donate to get the incentive, then they are not paid, because, in fact, they are paid for nothing, when they fail to donate. There should be differentiation between whether or not the individual must donate, or be successful in donating, to get the incentive, versus when all individuals who present to donate are given the incentive irrespective of whether they proceed even to try to donate.

I like the examples given of A. through D., and I agree with the interpretation provided. I think the keys are whether or not the incentives are transferable, salable and unrelated to some type of promotion of a business or entity. Item F., I believe, is also quite clear, and is appropriate. However, as noted above, this may also apply to movie passes and other free tickets, which are not restricted to the individual to whom they are issued, can be sold relatively easily, or can be exchanged in whole, or in part, for cash.

Item G. concerning “Escalating incentive programs” appears problematic. In the example given, would incentives for the first to the ninth donation, e.g., t-shirts and the like, be considered as not readily convertible to cash, but a watch given at the tenth or milestone donation be so considered, and thus make the tenth donation labeled “paid?” Does “readily convertible to cash” include taking items to a pawnshop, or items which a pawnshop would loan money on? It would seem that escalating incentives which relate only to the donor, with little monetary value to others, e.g., plaques or other items specifically inscribed or dedicated to the donor, would not make the milestone donation a paid one.

Again, thank you for the opportunity to comment on the Compliance Guidance on Donor Incentives. While most of the statements and examples are appropriate, I believe some need some modification, clarification or change. Most importantly, we should dispense



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with the term "paid donor" as these individuals are not really donating, i.e., giving something; they are selling (bartering or exchanging) their blood or blood components, and this should be recognized in their designation. A "paid donor" is an oxymoron.

Sincerely,

A handwritten signature in black ink that reads "Paul Holland". The signature is written in a cursive, flowing style.

Paul V. Holland. M.D.
Medical Director/Chief Executive Officer

PVH:rc 19.01

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