



Together, we can save a life

June 28, 2002

Office of the Secretary
Room 159
FTC File No. R411001
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

**RE: Telemarketing Rulemaking--User Fee Comment. FTC File No. R411001
(67 FR 37362; May 29, 2002)**

Dear Secretary Klark:

The American Red Cross Biomedical Services (Red Cross) appreciates this opportunity to provide public comment on the Federal Trade Commission's (FTC) proposed rule, *Telemarketing Sales User Fees*.

Description of the Red Cross and Our Request

The American Red Cross is an independent, non-profit organization dedicated to saving lives, easing suffering and restoring hope at home and around the world. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. Our primary focus is providing high quality blood and blood products to the patients who need them, but the Red Cross is also a large supplier of human allograft tissue including heart valves, skin, bone and associated connective tissues. Additionally, we are engaged in research and other efforts to support donation and processing of such human derived products as umbilical cord blood and bone marrow for use in treatment of malignancies and other serious diseases.

In our letter to the FTC on April 9, 2002 providing public comments on the related rule titled: *Proposed Rulemaking to Amend the Federal Trade Commission's Telemarketing Sales Rule* (TSR) Red Cross noted that, as a non-profit organization, it was our understanding that we would not have to access the proposed national "do-not-call" registry when solicitations for blood donations or charitable contributions were made by Red Cross employees. (See attached letter) Furthermore, it was our understanding that proposed changes to the TSR resulting from language contained in the USA PATRIOT Act (section 1011(b)(3)) would not apply to the Red Cross when blood donations and charitable contributions were being solicited by Red Cross employees. In our comments of April 9, 2002, we requested clarification on these two points. We further

requested an exemption from the proposed changes to the TSR (67 FR 4491, Jan. 30, 2002) for calls made by for-profit telemarketing firms on behalf of the Red Cross when soliciting blood donations.

As stated earlier and in the information provided below, there is an urgent need to ensure there are no impediments to making contact with blood donors. We wish to take this opportunity to reaffirm our request for clarification that for-profit vendors calling on behalf of the Red Cross for blood donations would not need to access a national “do-not-call” registry and are consequently not subject to the “user fee” proposal. Similarly, we request clarification that the exemption from the “do-not-call” registry would apply to solicitations by for-profit vendors for donations of human tissue.¹

Blood Donation and Usage

Our blood donors’ voluntary gifts make it possible for the Red Cross to collect, process and distribute nearly half the nation’s blood supply, over 6 million units of whole blood, each year. Blood collection for transfusion is conducted throughout the nation by 36 regional Red Cross blood centers, utilizing several hundred registered auxiliary collection sites, and daily mobile collection sites throughout local communities.

Units of whole blood are processed into specific components such as red blood cells, platelets, and other products that are distributed to thousands of hospitals and other health care providers in the United States. These products are used to treat patients who suffer from a range of serious conditions such as cancer, trauma, surgery, and sickle cell anemia.

Approximately 1,000,000 liters of plasma recovered from Red Cross volunteer blood donors are annually processed or fractionated into plasma derivatives. These plasma derivatives, including Factor VIII, immune globulin intravenous, and albumin, are distributed under the American Red Cross label to hospitals, hemophilia treatment centers, and other providers.

Factor VIII is a vital infusible drug for hemophilia patients administered for prevention and control of bleeding. Immune globulins offer critical therapy to patients with a range of serious debilitating immune deficiencies such as primary immunodeficiency disease, B-cell chronic lymphocytic leukemia, and idiopathic thrombocytopenic purpura. Dosing of these products can occur up to three times per week. The indications for the infusion of albumin include hypovolemia (with or without shock), hypoalbuminemia due to a wide variety of conditions such as malnutrition, burns, major injury, cirrhosis with ascites, nephrosis, and thyrotoxicosis.

Once the serious, and frequently life-threatening, nature of the health issues faced by the patients who use these products is understood, the need for maintaining an adequate supply of blood can

¹ The Red Cross also concurs with the statement made in the Comments of the Direct Marketing Association, Inc. and the U.S. Chamber of Commerce filed on April 15, 2002 which states: “*the Commission should apply only the disclosure provisions of the TSR to charities that employ... for-profit firms soliciting contributions for charitable purposes.*”

be appreciated. We hope this information will support our view of the urgent need to ensure there are no impediments to making contact with our donors, including contact by third parties, to support providing these products to the patients who need them.

Blood Shortages and Donor Recruitment

Blood donors are solicited through a variety of methods. Approximately 70% volunteer to donate by way of a blood mobile or a blood drive at another location, such as a workplace site. Approximately 30% of our donors are identified directly through telemarketing techniques.

Characteristically, the supply of blood is tenuous. While the Red Cross was able to maintain close to a 10-day supply for a number of months after the outpouring of generous gifts following the September 11th tragedy, as of this writing, our national blood inventory is nearing seriously low levels. Many Regions are reporting a day's supply or less of O negative blood and A negative and B negative blood at 1.8 and 1.5 days respectively. Our Rh negative inventories are at 50% of ideal levels. This trend is likely to follow a typical seasonal pattern of shortages keenly felt during the summer months, when many donors elect to spend time on vacations or are otherwise unavailable to donate.

The blood shortage has reached such critical levels that this week, the Red Cross and several other organizations, including the American Association of Blood Banks, America's Blood Centers, the American Public Health Association and the American Hospital Association have issued a joint appeal for blood donations. (See attached News Release)

In addition to the immediate shortages, the Red Cross and other blood collection establishments are facing more fundamental changes in the nature of the available donor population. These changes will continue to contribute to the difficulty of donor recruitment over the longer term. Among them are new restrictions on acceptable donors due to the need to avoid those with the potential exposure to newly identified transmissible diseases. Corporate downsizings have limited the number of people available for worksite blood drives, and restrictions on remaining employee time may also reduce the total donor pool.

All this occurs at a time when the demand for blood is projected to increase with the aging of the population and advances in medical technologies. These advances will improve the public's health, but present a challenge to blood organizations whose services help make the improvements possible.

The Red Cross is examining new, innovative, and cost-effective means of recruiting blood donors. New techniques for using electronic and other alternative media to recruit donors, as well as cold calling potential blood donors and increasing outsourcing to third parties are all under consideration.

It is far more cost-effective to hire a third party for a short-term blood donor recruitment program or to help alleviate seasonal shortages than to hire and maintain a full time staff of donor recruiters year-round. Such trained third party professionals offer expertise and operational

efficiencies that cannot be rapidly duplicated by Red Cross to respond to the volatile demand for blood. The Red Cross's greatest concern is that this rule would severely constrain our ability to outsource blood donor recruitment.

In addition to the urgent need to grant maximum flexibility to use third party telemarketing firms to help maintain an adequate blood supply, the Red Cross urges FTC to consider the following points in support of our request:

- The Food and Drug Administration (FDA) has already established a significant number of regulatory requirements designed, in part, to protect blood donors and consumers from the practices leading to the Telemarketing rulemaking. The donor must give of their time to come to an FDA registered donation center. Further, the Red Cross does not engaged in any donation pressure techniques. Such tactics are highly discouraged to avoid inclusion of unsuitable blood donors. Rather, donors must meet numerous FDA defined criteria designed to identify their suitability as a blood donor, as well as pass a mini-health exam. Any financial involvement is severely constrained by FDA's regulations for labeling the blood as "volunteer" versus "paid" which has the effect of banning any donor "incentive" that is readily convertible to cash².
- Many forms of blood donation recruitment communications are also subject to FDA regulations governing advertising and promotional materials, one of the purposes of which is to help limit the abuses the FTC rules were intended to control.³
- The requirement to obtain and "scrub" names based on the "do-not-call" registry will be prohibitively expensive for non-profit blood centers. On an ongoing basis, we will need to cross compare our continuously changing blood donor lists to the continuously changing "do-not-call" registry to ensure that our third party telemarketers avoid contacting anyone on the registry. Even if we overcame the financial limitations, the delays in contacting these donors while the lists are being continuously reconciled may result in further reducing the very fragile supply levels just at the time when blood donor telemarketing services are most needed to alleviate a shortage.
- The Red Cross and other blood collection centers follow very stringent donor confidentiality practices, including the standards set by the American Association of Blood Banks (AABB),⁴ the blood banking community's professional association. Depending on the information needed to perform the "scrubbing," we may not be able to carry out this function without risking a violation of these confidentiality practices.

² See 21 C.F.R. § 606.121(c) and FDA's *Compliance Policy Guidance for FDA Staff and Industry on Blood Donor Classification Statement, Paid or Volunteer Donor* [67 FR 35121; May 17, 2002]

³ See 21 C.F.R. §§ 201, 202, 606.120, and 606.122, as well as Sections 201, 502(a) and 502(f) of the Food Drug and Cosmetic Act.

⁴ See AABB standard 5.3.1 – *Care of donors; private and confidential donor qualification process*; 6.22.2 – *Confidentiality of donor and patient records*, and Hpc 9.3 – *Computer systems; provisions to maintain appropriate levels of confidentiality and privacy*.

- Blood donors may be forced to choose between placing themselves on the nationwide “do-not-call” registry and inclusion on our blood donor lists. This outcome would be particularly disastrous for our practice of maintaining a special list of donors with rare blood types and calling them when there is an urgent need to match a special patient who also has a rare blood type.
- Donor recruitment is one of many expenses associated with supplying hospitals and other health care providers with blood and blood products. The Red Cross will not be able to pay the anticipated user fees and additional expenses for maintaining the “scrubbed” blood donor lists without passing along at least some of those costs or reducing other expenditures such as research for new testing and treatment technologies.
- Additionally, the FTC telemarketing rulemaking could also require the Centers for Medicare and Medicaid Services, the Federal Agency that oversees these programs, and private party insurers, to increase expenditures for blood. This could further increase national expenditures and place additional economic burdens on the public at a time when both the federal government and private employers providing health insurance are diligently seeking fiscal restraint.

Conclusion

On behalf of the American Red Cross, thank you for the opportunity to comment on the proposed rule. We hope these comments are constructive in providing insight into the potential impact of these regulations on the American Red Cross and on the nation’s blood and tissue supply. If you have any questions, please contact one of us, or Anita Ducca, Director, Regulatory Affairs, Policy and Promotion at 703-312-5601.

Sincerely,

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Attachments