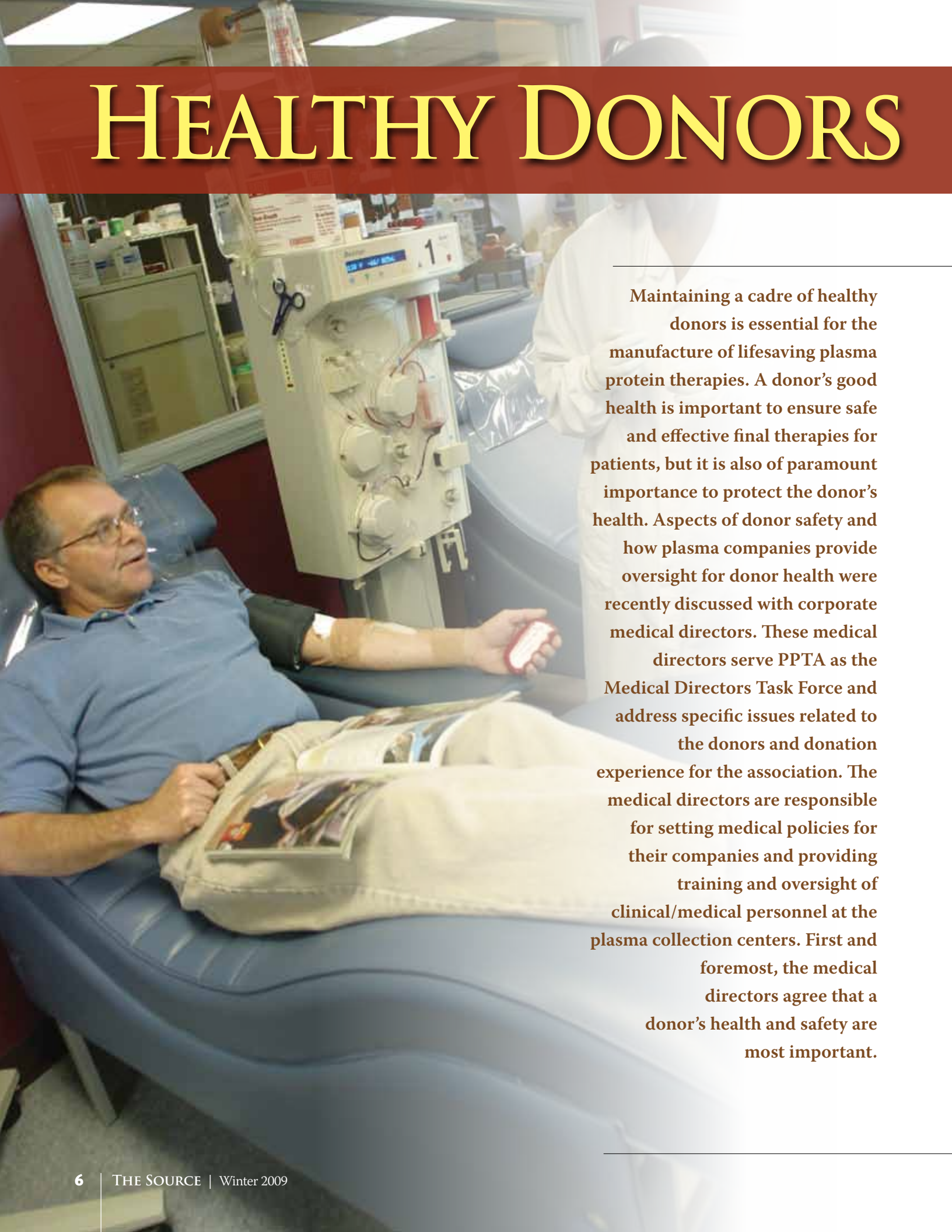


HEALTHY DONORS



Maintaining a cadre of healthy donors is essential for the manufacture of lifesaving plasma protein therapies. A donor's good health is important to ensure safe and effective final therapies for patients, but it is also of paramount importance to protect the donor's health. Aspects of donor safety and how plasma companies provide oversight for donor health were recently discussed with corporate medical directors. These medical directors serve PPTA as the Medical Directors Task Force and address specific issues related to the donors and donation experience for the association. The medical directors are responsible for setting medical policies for their companies and providing training and oversight of clinical/medical personnel at the plasma collection centers. First and foremost, the medical directors agree that a donor's health and safety are most important.

THE CORNERSTONE OF PLASMA THERAPIES

BY MARY GUSTAFSON AND JOSHUA PENROD

Donor health is a primary consideration in the donor selection process. Prospective donors are screened using a health history questionnaire and a physical examination designed to ensure that the donor is healthy, both for the plasma donated and for the donation procedure. During this process, donors are provided information about plasma donation including: general health parameters, tests that are performed both to ensure the safety of the plasma collected and that the donor is healthy to donate, and any risks associated with donating plasma (informed consent). The one-to-one opportunity for the prospective donor to be interviewed and examined by the center's clinical/medical personnel is considered most important in determining the donor's fitness for donation. This time also is used to help educate the donor about the center's deferral policies as they relate to health. For example, the donor is informed that the trained center staff will monitor the donor's plasma protein levels to ensure that the donor replaces proteins lost in the plasma donation. If the plasma protein drops below a certain level, the donor will be deferred from donating until an acceptable plasma protein level returns.

In addition to monitoring protein levels, the center personnel provide guidance on the importance of maintaining a healthy diet with adequate protein and fluids. This helps minimize the

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possibility of the donor's level dropping below the acceptable level and encourages donors to make healthy food choices. Donors are asked about medical treatments and medications, as this information may point to an underlying condition that would indicate a potential difficulty with the donation. While the donor answers a donor history questionnaire at each donation, it is in the context of the physical examination (performed initially before a donor starts a donation program and at least annually thereafter) that valuable information is obtained about the donor's health that helps the center determine

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whether the donor is healthy enough to donate and provides the center the opportunity to educate the donor about how to maintain a healthy lifestyle.

One of PPTA's voluntary standards is the Donor Education Standard. This standard requires that plasma collection centers provide information to the donor regarding risk behaviors (protecting the safety of the plasma) and also encourages that information be provided on steps to be taken by the donor to have a healthy lifestyle (helping to protect the donor.) This information may include pointers on nutrition, hydration, and smoking cessation.

It is important to note that donor education is of paramount importance. However, center staff are careful not to cross the line between education and diagnosis. Whenever a question arises as a result of the physical examination, test results or medical history, the donor is referred to his personal physician. In fact, it is common practice to include the donor's physician in deciding whether the donor can start or continue a plasmapheresis program whenever there is a question of whether or not the donor is healthy to donate. If a prospective donor does not have a personal physician, he is referred to local clinics.

Concern about the safety of the donor continues to the plasmapheresis procedure itself. Donors are constantly observed and monitored while donating. Plasma donation is a very safe process, in large part because of the care exerted by the staff and the elaborate safety and quality measures that have been developed through regulation, voluntary industry standards, and best industry practices.

Donors are the cornerstone of our industry. Without donors committed to participate, there would be no plasma protein therapies for the patients whose lives depend on it. Keeping donors healthy through education and monitoring is an important function of the medical staff of the collection centers. Healthy donors are in everyone's best interests, and nothing is taken more seriously by plasma collection facilities than the safety and welfare of plasma donors. ☁

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