Attention: Director

It is my understanding that recently the FDA has taken action to alleviate the chronic blood shortages in the United States by making it possible for blood banks to accept blood from Hereditary Hemochromatosis (HH) donors. People with hemochromatosis are eager to solve the blood shortages in this country with their blood donations. We want to be a part of the solution.

Victor Herbert, M.D. J.D. Professor of Medicine at Mt. Sinai College of Medicine and Chief of the Mount Sinai Hematology and Nutrition Laboratory at the Veterans Affairs Medical Center, Bronx, N.Y. stated that “there is a quick, easy and cost-effective way to solve the problem of the frequent U.S. national blood shortages - take advantage of the abundant supply of good, iron-rich blood from the more than 1 million hemochromatosis patients in this country. The problem would be solved overnight.” Dr. Herbert’s editorial titled “Short Supplies Would End If Iron-Rich Blood Weren’t Trashed” which appeared in the Sacramento Bee January 22, 1999, was distributed by Knight Ridder/Tribune Information Services. See Dr. Herbert’s web site at http://www.victorherbert.com for related articles.

The Advisory Committee On Blood Safety and Availability of the U.S. Public Health Service made the following recommendation in a unanimous resolution at its Eighth Meeting April 30, 1999 in Bethesda, MD.

“The committee recognizes that blood products obtained from persons with hemochromatosis carry no known increased risk to recipients attributable to hemochromatosis, per se, and therefore may be a valuable resource to augment the diminishing blood supply. The committee also recognizes that the obligate need for phlebotomy can constitute an undue incentive for blood donation due primarily to financial considerations. For this reason, DHHS should create policies that eliminate incentives to seek donation for purposes of phlebotomy. As such undue incentives are removed, DHHS should create policies that eliminate barriers to using this resource.”

A full text transcript of the meeting can be accessed in the transcript at the following URL http://www.hhs.gov/bloodsafety/transcripts/apr30_99.html

Much discussion at this 8th meeting centered on how to destigmatize blood that comes from healthy donors who have hemochromatosis, and who otherwise are qualified to become blood donors. The FDA subsequently ruled that if blood banks agreed to certain conditions by eliminating incentives to donate blood they could apply for a variance to CFR regulations that currently require blood from hemochromatosis donors to be labeled as such. Dr. Victor Herbert noted that the common practice in blood banks around the nation was to put biohazard stickers on HH blood, which committee members agreed was not appropriate. For a Meeting Summary by Victor Herbert, M.D., J.D. “Stigma Removed from Hemochromatosis Blood” See Appendix A
An AP story in USA Today, August 26, 1999 announced the changes in FDA rules which made it possible for people with HH to donate blood for free. The story stated that “The FDA said any blood bank that offers free bleeds to hemochromatosis patients can apply for exemptions from federal regulations forbidding use of hemochromatosis blood. Under the exemption, hemochromatosis patients would be treated like any other blood donor.” See Appendix B.

The transcripts of the Ninth Meeting acknowledge the AP story as well as FDA rule changes that made it possible for hemochromatosis blood to be accepted as donor blood. The transcripts show that one year ago July 15, 1999, Donna Shalala, Secretary of Health and Human Services accepted the resolution of the Advisory Committee on Blood Safety and Availability and directed its Chairman to develop guidelines for blood banks to follow in accepting HH blood in order to increase the nation’s reserve blood supply.

Documentation that the Secretary concurred with this resolution is at Tab B of the Summary of the Ninth Meeting of the Advisory Committee On Blood Safety and Availability August 26-27, 1999 at URL: http://www.hhs.gov/bloodsafety/

Since the FDA ruling two blood banks and perhaps more have applied for and have been granted authority to accept blood from hemochromatosis donors as they would any other donor blood: Mount Sinai in New York City, Morton Spivak, MD, Director and LifeBlood http://www.lifeblood.org Memphis, Tennessee, Gordon Wilson, Director. See Appendix C for a press release from LifeBlood, May 12, 2000.

A transcript which maps out the FDA policy discussed at the 64th Meeting of the Blood Products Advisory Committee September 16, 1999 with regard to donation from hereditary hemochromatosis donors can be downloaded at http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3548t1.rtf

A 6-page Addenum to this letter excerpts the section of the transcript from the Sept. 16 meeting which details how blood banks can take advantage of opportunities and fulfill responsibilities to alleviate chronic blood shortages. See Appendix D

At the 10th Meeting of the Advisory Committee on Blood Safety and Availability, January 26-27 2000 Captain Mary Gustafson said that “the FDA will issue a Guidance on use of blood obtained from therapeutic phlebotomy of individuals with hemochromatosis by the end of May 2000.” FDA has already approved two applications for exceptions to its current regulations on this issue.” Transcripts of all Advisory Committee Meetings can be accessed at http://www.hhs.gov/bloodsafety/

I and others who have been diagnosed with hemochromatosis take pride as we look forward to the opportunity to become regular donors. We consider the use of our blood to be a gift to the health and well-being of the community.

The American Hemochromatosis Society (AHS) http://www.americanhs.org a leading national advocacy organization representing growing numbers of Americans diagnosed with hemochromatosis by genetic testing, is working for change in FDA policies to allow blood donation
from hemochromatosis donors. AHS has provided the supporting educational materials in the Appendix to document and clarify for patients and the community that official provision has been made for blood banks to accept hemochromatosis blood as donor blood.

In Appendix E you will find a form letter which you can send to the FDA requesting a variance so that this blood bank can accept blood from hemochromatosis donors as well as a copy of the approval letter granted to the Mt. Sinai Blood Bank.

Sincerely,

cc:
STIGMA REMOVED FROM HEMOCHROMATOSIS BLOOD: NOW, IN THE MILLENNIUM, WE CAN SAVE BILLIONS OF HEALTH CARE DOLLARS, AND MILLIONS OF PEOPLE FROM EARLY MORBIDITY AND MORTALITY, BY VOLUNTARY UNIVERSAL SCREENING FOR HIGH SERUM TRANSFERRIN SATURATION, SERUM FERRITIN, & THEN PHLEBOTOMY PREVENTION OF PHENOTYPIC IRON OVERLOAD DISEASE (HEMOCHROMATOSIS). V Herbert. Mount Sinai NYU Health System & Bronx V.A. Med Ctr, NYC, NY.

The April 29-30, 1999, meeting in Bethesda of Surgeon General Satcher’s Advisory Committee on Blood Safety and Availability (Exec Secy SD Nightingale; Chair A Caplan), after invited presentations by proponents V Felitti (S Cal Permanente Med Gp) and V Herbert (who had petitioned FDA to destigmatize hemochromatosis blood), unanimously recommended that, since “blood products obtained from persons with hemochromatosis carry no known increased risk to recipients attributable to hemochromatosis per se, and therefore may be a valuable resource to augment the diminishing blood supply...the Department should create policies that eliminate barriers to using this resource.” On 7/1/99, the New York Times published, under the heading, “Blood Donors’ Benefit,” a letter from Dr Herbert regarding a recent “Donors Needed to Help Avert Blood Shortage” article, stating that shortages need never occur if “Every healthy adult, for his or her own benefit, should offer to donate a unit of blood. For genetic reasons, 12% of all Americans (including about one in five Irish-Americans and one in three African-Americans) have too much body iron. Gradually, over the years, they suffer progressive multiple-organ damage unless they regularly get rid of the accumulating extra iron by giving a unit of blood about four times a year. When giving blood, one should ask the blood bank what one’s blood iron is, and if it is high, schedule another donation every few months until the blood iron falls to normal.” On 7/15/99, Secretary of Health Shalala wrote Dr Caplan that, in addition to “focusing additional efforts on retention of first-time donors...I also concur with your recommendation regarding blood donations by individuals with hemochromatosis. I am directing the Health Care Financing Administration and the Food and Drug Administration to identify strategies that would implement this recommendation.” In a 7/28/99, letter to Secretary Shalala, Dr Herbert noted her office could go a long way toward achieving the objectives stated in her letter to Dr Caplan by using her prerogative to issue a Blood Bank Guideline (i.e., a Model Standard for all US blood banks) stating that, in view of the Advisory Committee recommendation, each blood bank should advertise that, while 6% of Americans (mainly infants, small children, and fertile females) have low body iron, 12% have high body iron (0.5% to 1% have dangerously high body iron) (JP Kushner 12/4/99, ASH Ham-Wasserman Lecture), and, to prevent eventual possibly irreversible high-iron multiple organ damage, should get rid of the excess iron by regular blood donations. The Guideline would further state that the bank is looking for donors, and, as an incentive, instead of offering free T-shirts or tickets to various events, is offering free measurement of blood iron. Side note: Vitamin C in pills (but not naturally present food vitamin C) sharply increases iron overload morbidity (V Herbert. Mayo Clin Proc 1999; 74:531).
Rule change boosts blood donor supply

WASHINGTON (AP) - The government is taking the first small steps to address fears that serious, nationwide blood shortages could hit as early as next year.

Certain blood banks will be allowed to use blood from people with a genetic disease called hemochromatosis that causes them to build up too much iron, the Food and Drug Administration said Thursday.

Giving blood regularly alleviates iron buildup. That blood is healthy, but today it’s thrown away because it’s a medical treatment patients pay for - donations must be altruistic.

The FDA said any blood bank that offers free bleeds to hemochromatosis patients can apply for exemptions from federal regulations forbidding use of hemochromatosis blood. Under the exemption, hemochromatosis patients would be treated like any other blood donor.

Experts have estimated the change could provide up to 300,000 more pints of blood a year.

Also, the National Institutes of Health is beginning a program to monitor how much blood the nation has on hand each month, something not currently tracked. Experts hope the program could offer better information about pending shortages.

The steps, announced at a federal blood meeting Thursday, come amid increasing worries that blood donations are steadily dropping. The National Blood Data Resource Center predicts that next year, Americans will donate just under 11.7 million units of blood - but that hospitals will need 11.9 million units.

Concern increased last week, when the FDA banned donations by people who lived or traveled frequently to Britain during that nation’s “mad cow disease” crisis, a ban estimated to cut the blood supply another 2.2%.
For Immediate Release

Lifeblood to take part in the first annual
National Hemochromatosis Awareness Week

Memphis, TN (May 12, 2000) — May 13 through May 20 is the first annual National Hereditary Hemochromatosis Genetic Screening & Awareness Week. Few people have ever heard the strange, long word, hemochromatosis, before. However, hereditary hemochromatosis (HH), more commonly referred to as iron overload, is the #1 genetic disorder in America today. One in 8 people are silent carriers of the HH gene mutation, and one in 100-200 are at high risk for developing full blown Hemochromatosis. Most of the 1.5 million Americans who have HH don’t know it, but it can be diagnosed easily and quickly by your doctor. If discovered early, hemochromatosis is often easily treated by routine phlebotomy (blood letting). Lifeblood provides hemochromatosis phlebotomy as a community service at no charge and today joins this national effort to raise awareness on a little known hereditary condition that if left untreated can cause premature death.

Hemochromatosis is a hereditary condition that causes a malfunction in the way iron is absorbed from food in the intestinal tract. Too much iron is absorbed and then stored in various organs of the body. Although certain vitamins and minerals are normally stored in the liver, too much can damage the organ. With hemochromatosis, iron overload leads to the increased storage of iron in the liver and other organs and tissues, especially the heart and pancreas, causing damage that can lead to an array of disorders and premature death. Although HH can develop at any age, symptoms resulting from damage to the liver and other organs (from long-term storage of excessive iron) usually occur at middle age. Women with HH often develop these symptoms at a later age than men, probably because women lose significant amounts of iron through menstruation and pregnancy.

Treatment of HH before experiencing symptoms of iron overload is desirable. Your physician can detect HH in advance. Once diagnosed, successful treatment is often just routine phlebotomy (blood letting) to reduce iron overloading. Once normal iron levels are re-established, HH is treated with ongoing phlebotomy at a frequency determined by your physician.

Recently the Food and Drug Administration (FDA) determined the HH condition alone does not pose a threat to the safety of the blood supply if the HH blood donor meets general blood donor suitability criteria. Lifeblood has met all FDA requirements to provide HH blood donors with the opportunity to participate in the community blood program in accordance with the guidelines and criteria for all volunteer blood donors. For more information on hemochromatosis ask your doctor or visit the American Hemochromatosis Society web site www.americanhs.org. For more information on blood donation, call Lifeblood at 522-8585 or visit the web site at www.lifeblood.org.

# #
APPENDIX D

Excerpted from: BLOOD PRODUCTS ADVISORY COMMITTEE
64TH MEETING
VOLUME I
Pages 12; 150-165

A Summary relating to the issue of hemochromatosis blood donation

The complete file is available for download at
http://www.fda.gov/ohrms/dockets/ac/99/transcript/3548t1.rtf

Dr. Hollinger remarked “I would say briefly, only to cover what was discussed at the Advisory Committee, the government response was initiated at two meetings. The first was the prior meeting of the Advisory Committee on Blood Safety and Availability on April 28th and 29th. That was the meeting at which Ms. Marian Sullivan, the National Blood Data Resource Center, presented her projections of future supply and demand for red blood cells. In response to that projection and other information presented to the committee, the committee had recommended that the Food and Drug Administration reevaluate its policies in reference to blood donations by individuals with hemochromatosis.”

pp. 150-165

The next recommendation is to remove restrictions to safe donation. Some healthy donors are restricted from donation for transfusion by existing government or blood center policies. The PHS should investigate whether all current deferrals are necessary to protect the public health.

In terms of hemochromatosis, the PHS should move proactively to determine whether hemochromatosis patients can donate as normal donors. The patient group is very active and would like to be able to donate. Medical data support that hemochromatosis patients are not less safe because of their disease, however, there are questions about the voluntary nature of their donations because people with hemochromatosis require phlebotomy as therapy.

The obligate need for phlebotomy introduces an incentive to donate blood for transfusion because most patients are charged for the therapeutic removal of blood. The concern is that a financial incentive to donate at no cost rather than be phlebotomized therapeutically might cause the donor to be less truthful about acknowledging risk behaviors. Removing patient costs for therapeutic phlebotomy would alleviate that concern.

The working group recommended that DHHS identify and remove barriers to providing reimbursement support for all therapeutic phlebotomies.

I will take a moment to tell you what has been done in the area of donations by the hemochromatosis patient.
At the April PHS Advisory Committee, the committee made this recommendation to the Department of Health and Human Services, that the Department should create policies that eliminate incentives to seek donation for purposes of phlebotomy, and that the Department should create policies that eliminate barriers to using this resource.

Following the meeting in July, Dr. Shalala, the Secretary of DHHS, sent a letter to Dr. Kaplan, the Chair of the PHS Advisory Committee on Blood Safety and Availability in which she concurred with the recommendation and said that she was directing Health Care Financing Administration and the FDA to identify strategies to implement the recommendation.

Further, Dr. Satcher sent memoranda to Health Care Financing Administration and FDA with the action item, identify strategies to implement the Advisory Committee recommendation.

On August 10th, Dr. Jane Henney, who is the Commissioner of FDA, responded to Dr. Satcher with strategies that were developed by the Center for Biologics Evaluation and Research and the Office of Blood.

Those strategies include consider on a case-by-case basis exemptions under Title 21, Code of Federal Regulations, 640-120, which is our exemption clause, exemptions from existing regulations when phlebotomy is performed at no cost to the phlebotomy.

These are regulations that require the label to state the disease that required the phlebotomy and also the regulation that limits the frequency of whole blood collection under normal circumstances to once every eight weeks.

We included the request that there be conditions for the exemption, and those conditions are that we would expect the blood center to submit to us safety data, and these are data that would be collected on donors anyway, on viral marker rates, seroconversion rates, post-donation reports, and any donor recipient adverse events.

It was pointed out at the PHS Advisory Committee that we may not get data that we would be able to evaluate in a meaningful way, and the truth is that the blood supply is safe. The risk is so low that collecting this type of data on the number of persons may not give us data, however, it is a change, and if we don’t look and we don’t specifically collect the data and look at it nationwide, we won’t have any information at all.

Additionally, we in the FDA had said that we would review any funding plan proposed by our sister organization, Health Care Financing Administration, to determine the adequacy in removing the financial incentive.

We understand more now maybe than we did even a month ago in terms of the Health Care Financing Administration and their limitations. They are limited by their statutory authority and also in their scope of jurisdiction.

HCFA is responsible for implementation of Medicare entirely and it cooperates with the States in the implementation of the Medicaid program. There are still a vast number of persons who will not fit into these programs including persons insured by private insurance providers and, unfortunately, persons who are not insured in this country.

So, for the foreseeable future, the responsibility of removing financial
incentives appears to fall on any blood center wishing to collect blood from donors with hemochromatosis. So, as we will have a case-by-case determination of requests to remove or to exempt the regulations, each blood center will have to do an evaluation also in terms of the advantages to them to entering these donors into their donor pool.

[Slide.]

Additionally, most blood centers and blood collecting facilities are accredited by the American Association of Blood Bank, and the AABB has the standard still that prohibits use of blood from therapeutic collections.

[Slide.]

After having a program of case-by-case evaluation and exemption from current regulation, and after financial incentives are removed with favorable outcomes of surveillance data, FDA will propose revisions to regulations.

If you could go back about six slides to the Remove Restrictions, if you can’t find it, that’s okay. It just lists our other, more longer term strategies or our other strategies, and that is to review the donor deferral policies in terms of the history of male-to-male sex.

We have had workshops, we have had BPAC discussions on this issue, and we need to move forward in making a decision on whether this should be a lifetime deferral or whether there is some other deferral time that will be adequate from a safety standpoint.

Another longer term strategy would be to look at donors who are hepatitis B core antibody positive to see whether these donors could be reentered into the donor pool. It has been suggested that the hepatitis B core antibody testing offered only a limited benefit and about 0.5 to 1.5 percent of the donors exhibit reactivity, however, data are not available which specifically address the safety of eliminating the test.

Also, there are no figures which indicate the number or percent of donors who are eliminated solely because of their HBc antibody reactivity especially after readjustment of the cutoff for the test to improve its specificity, and the task group recommends further studies in this area.

[Slide.]

Our final strategy was to address the economic issues facing the blood industry. Throughout all of the discussions of the task group and with the industry participants, concerns were repeatedly expressed about the economic distress of the blood industry.

Reimbursement practices and competitive pressures of health care today make it difficult for blood banks to recover the cost of new innovations even when such measures are required.

These economic limitations are a strong disincentive for change. The task group recognizes that the economic issues associated with changes of the blood industry need to be addressed. They were addressed, as Dr. Nightingale told you, at the August meeting of the PHS Advisory Committee on Blood Safety and Availability, and as he also said, there are continuing actions beyond the scope of this committee and also beyond the scope and jurisdiction of the Food and Drug Administration.

In conclusion, the success of any national effort to affect the blood donor supply will depend on improving the bond between the blood industry, the blood donor community, and the Federal Government.

Effective leadership by government and cooperation of the blood industry are needed to ensure that the American public can depend on a safe and readily available source of blood therapies.

Thank you.
DR. HOLLINGER: Thank you, Captain Gustafson.

Dr. Boyle.

DR. BOYLE: Just one point of clarification. The task group has laid out strategies, short term and long term, for trying to improve the blood supply. Given the fact that this is brought about by estimates that that demand will exceed supply by next year, we have not said that any of these short-term strategies will alleviate that shortage next year, isn’t that correct, we are taking a position on what are the best strategies, not that we are actually not going to have a blood shortage next year?

CPT GUSTAFSON: That’s right, and I think that is limitations of the report. I think it is also limitations of the study, that it was based on a couple of points from 1994 and 1997, retrospective data, and mainly the projections were made showing if there were no changes, and we know that the blood community over the years has been very reactive to changes in terms of recruiting donors and alleviating problems.

DR. HOLLINGER: Dr. Buchholz.

DR. BUCHHOLZ: Mary, I certainly applaud the efforts in this area, and I think collection of data is always very admirable, but I am a little puzzled by the committee’s recommendations with respect to hemochromatosis.

It looked to me like there was a certain extent of data collection for the purpose of data collection. I mean there is obviously some issues of is this a safe procedure for the donor.

Well, in this case, the donor is a patient who would require this therapy, and whatever events happen, presumably, would happen to that donor on the basis of a therapeutic procedure being performed whether that blood was thrown out or used for transfusion.

The second thing is it looked like there was a lot of data that I assume is in some way incremental to the routine collection of that same data on infectious disease and so forth, and I am not sure, I am a little confused as to what the purpose of that is.

I mean are we saying that we don’t have faith in our infectious disease testing, because I think that probably is not the reason, and if we did have faith in that testing, why are we doing this incremental data collection for this particular group of patients. I may have missed something here along the line.

CPT GUSTAFSON: I think the data collection is done anyway, and what we would be asking as a postmarketing surveillance or making an exemption from our regulations, and we are making the exemption, quite frankly, not on prospective data, but on the findings. We have had presentations that the disease state itself does not cause any safety concerns, however, we have over time been concerned about undue incentive to donate and the fact that there is a financial incentive in this case.

I think we are not aware of any long-term studies being published on the patients or donors although I think there are places who have collected the data.

So, it would be a request from us to stratify the data on these donors separate from just the regular donor population and provide it to us to have a national surveillance effort because we don’t really know the numbers from data that have been published.

Transfusion in June had a couple of articles that indicated that there may be a big jump in the donor population, but there has been other reports that, in fact, there may not be a huge number of donors that would be entered into the system.

So, in order to provide a surveillance activity in the absence of long-term
studies, we would like to see this type of data.

DR. BUCHHOLZ: Just a second question that I was a little surprised you
didn’t mention relative to some of the newer techniques in blood collection that involve
automation, for example, platelet collection with the various several blood cell separators
out there that, in fact, can get a therapeutic dose of platelets from a single donor, and now
there are beginning to be on the market instruments that will allow for two units of red cells
or a unit of red cells and two units of plasma, that sort of thing.

I am a little surprised the committee did not take a more proactive stance
against some of these applications, which I think can have a tremendous impact on
alleviating the supply problem. Certainly, if you are looking for a 15 percent incidence of
return donors, implementation of two units at once would sound very attractive.

DR. HOLLINGER: Also, on the issue about hemochromatosis, as well, the
incentive actually for patients with hemochromatosis to donate is because of their health.
Personally, I don’t think it would matter whether it is being paid for or not being paid for.
The issue is to prevent them from developing cirrhosis.

So, they are going to go in for their iron removal on a regular basis at least
until the iron is removed, and then they can’t, like anyone else, once that iron is removed,
donate any more frequently. It is going to result in the same problems they had before, that
is, in terms of developing anemia and other things.

So, up until that point, though, they could donate on a weekly basis for a year
or two or more, as long as if they have very high concentration or iron in their blood. But I
don’t think it is the incentive for whether it is going to be paid or not, to me would be an
issue.

Dr. Mitchell.

DR. MITCHELL: I guess I understand that the reason for collecting the data
would be to see if that group is at higher risk of other risk factors that might impact the
safety of the blood because of their incentive to donate for health reasons and also for
financial reasons. So, I think it is very important to collect the data on that if they are at
higher risk than average.

DR. HOLLINGER: One clear thing is, again, back in the hemochromatosis,
because a lot of the patients with hepatitis C, who have iron overload as either an aspect of
their disease or not, because the iron makes a difference, a lot of them are sent to the blood
bank for therapeutic phlebotomies, so obviously, one does have to make a conclusion of
whether you really have hereditary hemochromatosis versus somebody with iron overload,
which is a lot different.

Dr. Nelson.

DR. NELSON: It seems to me that you might remove the incentive if the
policy was changed that all hemochromatosis patients, despite whether or not the blood was
used for transfusion, the financial burden was removed, so I would not link the cost as to
whether or not if a person had hepatitis C or HIV and the blood was tossed out, they still
didn’t have to pay for this.

It seems to me that that would probably obviate the financial incentive. Is
that not what was being considered?

CPT GUSTAFSON: Yes, that is where we are going is to eliminate the
charges for the therapeutic bleeds, and it would more or less level the playing field, and not
give an incentive to maybe perhaps not give totally truthful information during the donor
history part of the donor screening.
Dear Captain Gustafson:

I am requesting a variance from both of the following as provided by 21 CFR 640.120 for the Blood Bank (registry # ):  

21: CFR 640.3  
21: CFR 640.3 

1. No hemochromatosis donor, either self referred or referred with a prescription from a physician, will be charged for a phlebotomy even if their history and physical examination causes them to be rejected as a routine blood donor. In short, no hemochromatosis patient will be charged for therapeutic phlebotomy.

2. The informed consent for hemochromatosis patients is enclosed.

3. Records will be kept for all hemochromatosis donations for a minimum of ten years so that we can evaluate whether there is any increase in viral markers for this group and report any data accumulated regarding recipient seroconversion if any occurs.

If any other information is required, please do not hesitate to contact me.

Sincerely,

Hemochromatosis Donors Informed Consent

There will be no charge for any hemochromatosis donations even if the donor does not qualify to be a routine blood donor after a history and physical examination. This applies to all patients with hemochromatosis whether they are referred by a physician or self referred. In short, there will be no charge for a therapeutic phlebotomy for hemochromatosis.

________________________________________
Phlebotomist

________________________________________
Donor

Date