

Statement of the Greater New York Hospital Association to the U.S. Food and Drug Administration's
Transmissible Spongiform Encephalopathies Advisory Committee

June 28, 2001

Good morning. I am Susan C. Waltman, Senior Vice President and General Counsel of the Greater New York Hospital Association (GNYHA), which represents the interests of over 200 hospitals and continuing care facilities in New York City and surrounding areas, including Long Island, the lower Hudson Valley of New York State, and Northern New Jersey. All of GNYHA's members are either not-for-profit, charitable organizations or publicly sponsored institutions that provide state-of-the-art, acute tertiary care while, at the same time, often serving as the principal source of primary care in their service areas. GNYHA members and their related medical schools also provide extensive medical education and training and undertake cutting-edge medical research that will benefit generations to come. Finally, GNYHA members often act as the anchor for their communities by providing not only health care but also other needed social services, employment, and community and urban development.

I thank you for the opportunity to appear before you today to discuss possible restrictions on blood donors who have lived or traveled in European countries and restrictions on the importation of blood due to concerns regarding transmission of bovine spongiform encephalopathy (BSE) in humans through blood transfusions. GNYHA is quite concerned about the impact the proposed restrictions on certain European travelers and a prohibition on the importation of blood from Europe would have on the public health of all of those who receive care in our immense service area, as well as on the orderly operations of our members. I would like to state at the outset that GNYHA is supportive of the FDA's efforts to determine the possible risk of transmission of BSE through blood transfusions. However, GNYHA strongly urges that as the FDA considers what action it should take that it also consider the very real and severe negative impacts upon the public health that would result from the drastic reduction in blood availability in hospitals in the New York City area. Therefore, GNYHA urges if the FDA should adopt the proposals it is considering, the FDA affirmatively take steps to ensure that the blood supply that would be lost would be replaced. To do otherwise would be to create a serious and very real public health crisis for an area with a population estimated to be 18 million persons. The attached June 27, 2001, New York Times article highlights GNYHA's serious concerns regarding the impact of the proposals that the FDA is considering.

I. IMPACT OF THE PROPOSAL ON THE NEW YORK CITY AREA'S BLOOD SUPPLY

The current proposals that the FDA is considering, which would prohibit the importation of blood from Europe and prohibit persons who have spent certain periods of time in Europe since 1980 from donating blood, would have a serious negative impact on the New York City metropolitan area's blood supply. The New York Blood Center estimates that it provides approximately 75-80% of the total New York City area's blood supply, with the remainder consisting of blood from hospital collections and other providers. Thus, GNYHA members are highly dependent on the New York Blood Center's ability to provide them with an adequate and safe blood supply. According to the New York Blood Center, there is currently an unmet need for red blood cells and the Blood Center estimates that if the FDA adopts the proposal under consideration, as much as one-third of the blood supply in the New York City area would be eliminated.

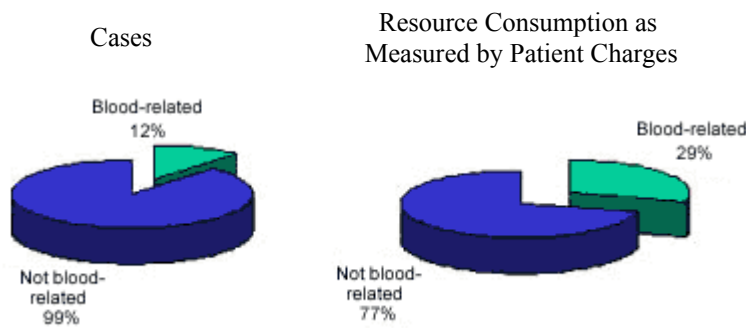
Currently, according to the New York Blood Center, 25% of the blood distributed by the New York Blood Center is imported from Europe ("Euroblood"). The New York Blood Center had previously imported larger amounts, and its target for elimination of Euroblood is 2004. Since Euroblood is only imported for use in the New York/New Jersey area, the proposal under

consideration would have a disproportionate impact on this region. In addition, the New York Blood Center estimates that it stands to lose 10-13% of community donations from the restrictions on travelers in the American Red Cross proposal, due to the frequency with which persons who donate blood in the New York City area travel to Europe. Adoption of this proposal by the FDA would mean that perfectly healthy individuals who might donate blood regularly would no longer be able to donate blood.

II. IMPACT ON THE NEW YORK CITY AREA'S HEALTH CARE SYSTEM

If any of these proposals are adopted without mechanisms to replace the blood supply that would be lost, New York City area hospitals would be incapacitated due to dangerously low blood availability. The lack of blood products would create a public health crisis that would jeopardize patient safety in a service area of approximately 18 million persons. GNYHA members utilize blood products for a variety of procedures, including many emergency procedures. Therefore, if this proposal is implemented without a replacement for the blood supply that would be lost, the limited remaining blood supply would have to be rationed within institutions. With a limited blood supply, emergency procedures would likely receive priority and elective surgeries would likely be eliminated. In the past three years, out of an average of approximately 2.4 million inpatient admissions in New York State, blood products were utilized in approximately 285,000 admissions. Those cases represented approximately 29% of the overall inpatient resources in hospitals as shown in Figure 1.

Figure 1. Blood-related Cases and Resource Consumption As Measured by Patient Charges in 1998, 1999, and 2000



Source: Statewide Planning and Research Cooperative Systems (SPARCS), 1998, 1999, 2000.

Figure 2 shows the top 10 procedures in which blood products were utilized in 1998, 1999, and 2000, while the top 100 procedures are listed in Appendix A. Eliminating or significantly curtailing those procedures as well as other procedures in which blood products are utilized would seriously jeopardize the health of the many persons who receive their health care in the New York City area. In addition, GNYHA members believe that implementing any of the proposals under consideration will have the effect of increasing autologous blood donations, as patients become concerned about the safety of the blood supply. In addition to being more labor-intensive to process, autologous blood donations have the effect of decreasing the donor pool, as persons are excluded from donating due to their recent autologous donation. Further, due to regulatory requirements, autologous donations that are not transfused cannot be used on other recipients, and therefore must be discarded, resulting in wasting of precious blood resources.

Figure 2. Top 10 Procedures Using Blood-related Products in 1998, 1999, and 2000

		Cases	Charges (\$ in Mils)
1	222 Blood transfusion	25,936	361
2	70 Upper gastrointestinal endoscopy, biopsy	13,495	227
3	44 Coronary artery bypass graft (CABG)	11,894	537
4	153 Hip replacement, total and partial	10,385	238
5	216 Respiratory intubation and mechanical ventilation	10,326	651
6	231 Other therapeutic procedures	8,227	178
7	152 Arthroplasty knee	7,703	164
8	146 Treatment, fracture or dislocation of hip and femur	7,625	173
9	134 Cesarean section	6,654	66
10	78 Colorectal resection	6,386	257

Source: SPARCS.

III. FINANCIAL CIRCUMSTANCES FACING GNYHA MEMBERS

The adoption of any of the proposals without a reasonable means of replacing the blood supply that would be lost will have a serious negative impact on GNYHA members' already fragile financial condition. Due to the economics of the market, the price of the remaining blood supply would rise as it becomes more scarce. GNYHA members, already financially fragile, would be unable to pay the New York Blood Center or other providers for the service fees of processing blood products as the fees rise, if the products are available at all.

The vast majority of our hospital members are teaching hospitals, which means that in addition to providing patient care, they also train a considerable number of medical residents. They provide a significant amount of uncompensated care to the large numbers of uninsured and underserved individuals who rely on our member hospitals for health care. These two "public goods," medical training and charity care, for which New York City hospitals are known nationwide, have taken their toll. The following describes the resulting circumstances facing our hospitals.

The Worst Margins in the Country. Notwithstanding the high esteem in which GNYHA member hospitals are held, they are, as a group, the most financially fragile hospitals in the country. For years, New York City's hospitals, both voluntary and public, have had the worst margins and other financial indicators of hospitals anywhere in the United States. For example, in 1999, New York hospitals ranked 42nd (out of 45 states reporting) for bottom-line margins and cash flow to total debt ratio. This situation stems in part from the historic tight rate reimbursement system imposed by New York State. However, more recently, the Federal Balanced Budget Act's Medicare cuts, the overnight deregulation of the State's hospital reimbursement system, and managed care abuses have also contributed to the poor financial circumstances facing area hospitals.

Continued Financial Deterioration. Given the foregoing factors, the financial condition of New York City's hospitals continues to deteriorate. For example, for a study sample of 48 hospitals in the metropolitan New York area, their aggregate bottom-line margin was -0.49% for the first three quarters of 1999, but it had fallen to -0.86% for the first three quarters of 2000. In addition, while 28 of the hospitals had a negative margin in 1999 (58%), this number increased to 31 hospitals in 2000 (65%). This financial deterioration has been widespread, and if it continues, New York City hospitals will have to make further cuts in service.

Caring for the Area's Uninsured. One of the biggest problems contributing to the poor financial performance by New York City hospitals is the large number of uninsured and underinsured individuals cared for by our hospitals as well as the nature of the problems that those patients present. The proportion of New York's population that is uninsured has grown faster than the national average, such that 28% of the under-65 population in New York City is uninsured. Most of these uninsured individuals have incomes that are too low for them to pay directly for their medical care, and therefore hospitals provide a significant amount of uncompensated care. Although the State provides a funding mechanism for covering some of these costs, voluntary hospitals receive less than half of what they spend on care for the uninsured.

Providing Services to Special Needs Populations. GNYHA's members also serve large numbers of special needs populations, including a large proportion of Medicaid and indigent patients and individuals suffering from AIDS, substance abuse problems, and mental health problems. Given the lack of primary care in many areas of the City, GNYHA members also often act as the sole source of health care for the patients in their service areas and have created extensive outreach and community health services. Their patient populations are of course reflective of the diverse populations that live in New York City, and GNYHA's members have developed and continue to develop new programs and services to meet the health care needs of this culturally and linguistically diverse area.

IV. MITIGATING THE IMPACTS OF THE PROPOSAL

If the FDA does adopt any of the proposals that are being considered, GNYHA urges the FDA to ensure that the New York City area continues to receive the same level of blood that is currently available. This is vital to the public health. The FDA may achieve this by developing a system of resource sharing whereby surplus blood from other regions of the United States would be transported to the New York City area. In addition, the FDA should consider taking the following steps to mitigate the impacts of the proposal:

- The FDA should consider a timeframe for implementation of several months to a year so that the New York Blood Center, other blood providers, and GNYHA members will have as much time as possible to prepare for the reduction in the blood supply, especially in light of the fact that there has been no identified case of transmission through blood transfusions. In the past, when implementing new blood policies, the FDA has provided for an implementation date of several months to a year later. This is particularly important in light of the fact that the New York City area always experiences a blood shortage during the summer months, and implementing this proposal over the summer would dramatically exacerbate the shortage. The FDA should consider different implementation dates for the restrictions on travelers and the prohibition on the importation of Euroblood so that the New York City area does not experience the effects of both policies at once.
- The Federal government should provide funding for research to develop a test to detect BSE in the blood supply, as well as research into more efficient utilization of limited

blood resources.

- The Federal government should engage in a massive nationwide public education campaign to encourage blood donations from eligible donors.

In addition, GNYHA has alerted members to the possibility of a severe blood shortage and urged them to encourage their employees to donate blood. Finally, GNYHA has alerted the New York City Mayor's Office of Emergency Management to the potential blood shortage, and if necessary will be working with them to undertake a citywide blood donation campaign.

V. CONCLUSION

GNYHA urges the FDA, as it considers the current proposals, to consider the public health impacts of the blood shortage that would result from adoption of the proposals. If any of the proposals are adopted, GNYHA also urges the FDA to take affirmative steps to ensure that the New York City area continues to receive an adequate blood supply.

Thank you for the opportunity to appear before you today to discuss this important proposal. We stand ready to work with the FDA to devise solutions to the blood shortage that will occur if the proposed restrictions that the FDA is considering are adopted.