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### **Congressional Action On Medicare Prescription Drugs Could Affect Reimbursement For Clotting Factor**

Congressional action to enact a Medicare prescription drug plan could result in a potential change in Medicare reimbursement for clotting factor. Currently, Medicare provides coverage for 450 physician or self-administered drugs, including hemophilia clotting factor. These drugs are covered under Part B of the program and paid at 95 percent of the average wholesale price (AWP).

Under the drug plan legislation passed last week by the House and the Senate, Congress would establish a new Medicare Part D to provide coverage for most prescription drugs. The plan would include a monthly premium, deductibles, and co-payments with an out-of-pocket cap of \$3,700. Currently covered drugs, like clotting factor, would be covered and paid outside of the new drug plan, but could experience a change in reimbursement under other bill provisions that would revise the AWP-based payment

### **Revisions to AWP**

Congress has weighed legislation to revise the current AWP-based Medicare reimbursement for Part B covered drugs for several years in light of reports of considerable overpayments by the Medicare program. The National Hemophilia Foundation (NHF) has worked with the Senate Finance Committee and the House Energy and Commerce and Ways and Means Committees to assist them in understanding the potential implications of changes in clotting factor reimbursement on the bleeding disorders community.

In the Medicare drug plan legislation approved by the Senate on June 27, Medicare reimbursement for currently covered drugs, including clotting factor, would be reduced from 95 percent to 85 percent of AWP. In addition to the payment reduction, the Senate bill requests the Secretary of Health and Human Services to develop a dispensing fee for clotting factor based on the General Accounting Office's recommendation to Congress earlier this year.

The House-passed bill would revise payment for currently covered drugs by replacing AWP-based reimbursement with a competitive bidding system. Clotting factor would be exempt from the competitive bidding process and continue to be paid at 95 percent of AWP. The House calls for the Medicare Payment Advisory Committee to make recommendations on payment of clotting factor, including the development of a dispensing fee.

## ADVOCACY UPDATE:

### **NHF Board Approves Recommendation on State-Based Advocacy**

Recognizing that reimbursements for prescription drugs and other healthcare costs are a target for state governments as they face deficits, the NHF Board of Directors at its June meeting approved a recommendation of its advocacy committee that direct support be provided for the state-based advocacy efforts of member chapters. The recommendation envisions that this assistance will ultimately include a system of regional field representatives and contract personnel with state lobbying and lobbying training skills. It also suggests a range of interim actions, including serving as a clearinghouse for state affairs information, drafting letters in support or opposition to state proposals affecting the bleeding disorders community, and taking a leadership role in channeling both community and industry efforts in this area.

### **NHF Calls for Strengthening of Proposed Bar Code Label Requirements**

In a June 12 letter to the Food and Drug Administration, NHF President Gina Shreve called for the strengthening of proposed bar code labeling rules for human drugs and biologicals. The letter asks that in the case of factor products, the bar code be required to appear on both the box and vial, and that the coded information include the product brand name, lot number, expiration date, and number of units contained in the vial. This is needed in part because people traveling with factor sometimes carry the vial separate from the box. And the information might be needed in the case of an adverse response or a product recall or withdrawal. The letter also asks for the development of similar labeling requirements for implantable medical devices, such as ports, central lines, and artificial joints

## BLOOD SAFETY

### **Government Agencies Issue Interim Guidance on Monkeypox, Ban Imports and Commerce in Potentially Affected Animals**

The Centers for Disease Control and Prevention (CDC) has issued interim guidance concerning infection control precautions and exposure management for monkeypox, a viral disease that in humans is similar to smallpox, although it is milder. The guidance will be updated as additional information about the epidemiology of disease transmission is better understood.

Monkeypox can spread to humans from particular species of prairie dogs and other primarily African rodents through an animal bite or direct contact with the animal's lesions or body fluids. The disease also can be spread from person to person, although it is much less infectious than smallpox. The virus is thought to be transmitted by respiratory droplets during direct and prolonged face-to-face contact. In addition, it is possible monkeypox can be spread by direct contact with body fluids of an infected person or with virus-contaminated objects, such as bedding or clothing. Current guidance focuses primarily on minimizing potential contact with infected animals. In addition, the import and sale of those species in which the virus has been clearly identified have been banned by the CDC and the Food and Drug Administration (FDA).

As of June 14, a total of 81 persons with suspected monkeypox had

been reported in the U.S., primarily in the Midwest. The virus had been confirmed by laboratory tests in nine persons. At least 14 of the people with suspected monkeypox had been hospitalized for their illness; there have been no deaths related to the outbreak.

The CDC did receive a report from a physician caring for a child with hemophilia with monkeypox. However, the child had a clear exposure to a pet prairie dog. Persons who think they may have been exposed to a person or an animal (e.g., pet prairie dog) with monkeypox should contact their health care provider and their state or local health department.

### **French High Court Throws Out Lawsuits Against Doctors**

France's highest court recently threw out a more than decade-old case against 30 doctors and other health specialists accused of poisoning patients with AIDS-tainted blood in a scandal that once shook the public health establishment. The 30 defendants had been charged with poisoning or complicity in poisoning and involuntary homicide or injury. Nearly a year ago, in July 2002, a judge threw the case out. However, it was revived after shocked families likened the action to a pardon. Justice Minister Dominique Perben interceded and prosecutors lodged an appeal. More than 4,000 people, a majority with hemophilia, were infected by blood products tainted with the HIV virus.

The Court of Cassation ruled that doctors who prescribed tainted blood products before 1985 could not be accused of poisoning because they did not have "knowledge of the necessarily deadly character" of the products, which came from the state-run National Center for Blood Transfusions. The court also ruled that a crime can only be characterized as a poisoning if the person in question "acted with the intention to kill."

As for involuntary homicide and injury, the court ruled that the "initial contamination" occurred before U.S. and French AIDS tests were available and before the state-run National Blood Transfusion Center "to continue to distribute infected lots." Among the 30 people involved in the case was the former head of the National Blood Transfusion Center, Dr. Michel Garretta, who had been convicted twice, in 1992 and 1993, for his role in the scandal. He is one of a handful of officials to have served jail terms.

Source: Associated Press

### **MEDICAL NEWS**

#### **Interaction between HIV, alcohol, may accelerate disease progression**

In the United States, alcohol problems appear to be more prevalent among people with the human immunodeficiency virus (HIV) than among the general population. Both alcohol abuse and HIV infection are believed to compromise immune function. In fact, alcohol use may accelerate HIV disease progression.

Recent research, published in *Alcoholism: Clinical & Experimental Research*, has found that HIV-infected patients with a history of alcohol problems, who are receiving highly active antiretroviral therapy (HAART), and are currently drinking, have greater HIV progression than those who do not drink.

"Although we do not yet understand how alcohol directly interacts with the already compromised immune system of a human infected with HIV," said Amy C. Justice, a researcher with the University of Pittsburgh School of Medicine and the VA Pittsburgh Healthcare System, "nonhuman studies suggest that heavy alcohol consumption can immediately elevate viral load, presumably by decreasing the ability to kill virus."

Justice added that the indirect effects of alcohol are also cause for concern. "Heavy alcohol consumption is known to limit a person's ability to adhere to HIV treatment," she said, "and nonadherence is known to lead to more rapid disease progression. Further, alcohol is known to exacerbate common comorbid conditions among those with HIV infection, such as hepatitis C or chronic hepatitis B. Finally, heavy alcohol consumption may also lead to increased rates of serious toxicity from antiretroviral therapy as both can be toxic to the liver and bone marrow. Thus, heavy alcohol consumption may lead to nonadherence and even complete cessation of antiretroviral therapy through a multitude of mechanisms."

Source: AIDS Weekly

### **Survey Shows Stigma of Hepatitis C and Lack of Awareness Stops Americans From Getting Tested and Treated**

Americans' misunderstanding of the potential dangers of hepatitis C is causing many with risk factors to forgo testing and treatment, according to a survey commissioned by the American Gastroenterological Association (AGA). The survey is part of AGA's "Be Hep C S.M.A.R.T." (Shattering Myths And Reinforcing Truths) campaign to

educate the public and healthcare providers about the prevention, diagnosis and treatment of hepatitis C.

One survey finding shows that the stigma attached to hepatitis C is far less than those infected think. Although 74 percent of hepatitis C sufferers believe that most people think that the disease mostly afflicts drug addicts and people with unhealthy lifestyles, only 30 percent of the public actually holds this belief. Only 12 percent of the general public believes that people like themselves don't get diseases like hepatitis C.

Another myth relates to the ability for doctors to treat and cure the condition. While over half of hepatitis C cases are cured with treatment, 34 percent of Americans and 17 percent of hepatitis C sufferers are unaware that prescription medications are available to treat the disease. Only 24 percent of Americans, 24 percent of patients and 15 percent of primary care physicians believe that available treatments can cure some patients with the disease. In contrast, 65 percent of gastroenterologists and hepatologists say that hepatitis C can be cured in some patients.

The survey was conducted online by Harris Interactive(R) for AGA in the United States between February 19 and March 5, 2003, among a nationwide cross-section of adults ages 18 and older. Sample included 493 infected with HCV; 1,226 not infected with the condition and 415 physicians (198 primary care physicians and 217 specialists). Survey results are available on the AGA Web site, [www.gastro.org](http://www.gastro.org). The AGA Be Hep C S.M.A.R.T. campaign is funded through an unrestricted educational grant from Roche.

### M A S A C

### **NHF's MASAC Approves New Guidance Documents**

At its most recent meeting on June 7, 2003, NHF's Medical and Scientific Advisory Council approved four new documents. Document #143, "MASAC Recommendations Regarding Rare Coagulation Factor Disorders," urges Novo Nordisk to undertake the clinical development processes required by the FDA to obtain a label indication for the use of rFVIIa in factor VII deficiency. Other manufacturers are encouraged to consider obtaining approval in the U.S. if they have a product licensed to treat this disorder in another country. Finally, MASAC recommends the development of treatment products for other rare bleeding disorders.

Document #144, "The Role & Responsibilities of the Principal Investigator in Bleeding Disorder Clinical Trials," contains detailed guidelines for study investigators. Document #145, "MASAC Recommendation on Funding of the Office of Cellular and Gene Therapies," encourages the Food and Drug Administration to allot sufficient resources to its OCGT to allow for a collaborative relationship to accelerate the development of innovative clinical studies and rapid review of translational research from academic institutions and industry.

Lastly, Document #146, "MASAC Recommendation Regarding Medicaid Inpatient Clotting Factor Replacement Therapy Reimbursement for Hemophilia" stipulates that Medicaid inpatient reimbursement for clotting factor concentrates for persons with both congenital and acquired hemophilia be the same as that provided by other federally funded programs such as Medicare.

The four documents have been submitted to the NHF Board of Directors and must receive final approval before they can be distributed to the community.

## NHF NEWS

### **NHF Hosts Successful Weekend of Events in New York City**

NHF kicked off a very busy weekend of events on June 6th with the opening of its 5th Annual New York Leadership Weekend (NYLW) for 54 chapter staff and board members representing 30 chapters/associations from around the country, including Guam. The weekend is an annual event providing numerous networking opportunities between participants, NHF Leadership and NHF staff. The first day of events include a leadership forum, providing an opportunity for dialogue between local and national leaders and staff. Also featured that evening was an open house/donor reception at NHF offices, with over 150 people attending, including NYLW participants, NHF board members and staff, donors, industry and homecare representatives and friends of NHF.

On Saturday, a training for chapter staff focused on leadership development, HTC/chapter relations and industry, homecare and chapter relations in light of the report. By the Office of Inspector General

Offering Gifts and Inducements to Beneficiaries. NYLW participants asked questions of a panel of industry and homecare representatives on their interpretation of the report and how it affects their support of chapters. It was also an excellent opportunity to open communication channels about industry and homecare policies that affect chapters.

The main events continued Saturday evening with NHF's Third Annual Gala, in the elegant Starlight Roof at the Waldorf=Astoria in New York City. A diverse audience of chapter representatives, donors, members of the medical community and volunteers gathered to celebrate the accomplishments of Dr. Bruce Lee Evatt, Chief of the Hematologic Diseases Branch at the CDC. The program highlighted Dr. Evatt's groundbreaking research identifying the specific dangers of HIV to the hemophilia community and his lifelong commitment to improving the lives of those suffering from bleeding disorders worldwide. The event raised well over \$300,000 to support NHF's work on behalf of the bleeding disorders community. NHF extends particular thanks to the gala sponsors whose support and participation made the evening possible: Presenting Sponsor: Novo Nordisk Pharmaceuticals, Inc.; Platinum Sponsors: Bayer, Baxter; Gold Sponsor: Aventis Behring; Silver

Sponsors: Alpha Therapeutics Corporation, The Bender Family, The Moscowitz Family; Bronze Sponsors: Wyeth, Delaware Valley Chapter.

Fundraising activities continued past the weekend as the first stop in NHF's 2003 golf tour took place on Monday. The venue was beautiful Minisceongo Golf Club in Pomona, New York, where the weather was picture perfect at the shotgun start of the game. Participants enjoyed lunch and a great day of golf, followed by dinner and an awards ceremony honoring the day's star players. Approximately 60 golfers participated in the event, which also included a raffle and auction, proceeds of which benefited NHF. NHF expresses gratitude to all of our corporate sponsors and to members of the golf committee and participants for their participation and efforts.

The program highlighted Dr. Evatt's groundbreaking research identifying the specific dangers of HIV to the hemophilia community and his lifelong commitment to improving the lives of those suffering from bleeding disorders worldwide.

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### **NHF on the Road: Last Stop Philadelphia**

NHF hosted its third and final NHF on the Road training and conference in Philadelphia June 13-14. The Philadelphia on the road was the culmination of a successful three city/chapter tour stopping in Chicago, April 4-5, Los Angeles, May 2-3, and Philadelphia June 13-14.

At all three venues the two day event began with a Friday training in prevention education for HTC and chapter staff, and select consumers, followed by a Saturday conference for the local bleeding disorders community.

### **Last Chance for On Line Early Registration Discount for NHF's Annual Meeting**

On-line registration for NHF's 55th Annual Meeting in Salt Lake City is continuing. Those registering by June 30th will receive a 10% discount off the registration fee, so please visit [www.hemophilia.org](http://www.hemophilia.org) now to take advantage of this special offer. Registration booklets are now being printed and will be distributed across the country in the next few weeks. For more information about the Annual Meeting or to register on line, please visit [www.hemophilia.org](http://www.hemophilia.org)