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## MEDICAL NEWS

**FDA Plans Workshop on Factor VIII Inhibitors**

October 8, 2003

The Food and Drug Administration (FDA) has announced a workshop on factor VIII (FVIII) inhibitors scheduled to take place on November 21, 2003, in Bethesda, Maryland. The purpose of the workshop is to address regulatory concerns with regard to inhibitor antibodies to FVIII clotting factor products. These antibodies, ie, "inhibitors," arise in as many as 30% of patients with FVIII deficiency and make replacement therapy quite problematic.

The workshop will begin with a consumer perspective provided by a family whose teenage son has had inhibitors. Experienced hematologists in the field of hemophilia will also make several presentations. Regulatory authorities from Canada and the European Union will participate by discussing their experiences as well. Other issues to be discussed include an assessment of immunogenicity of therapeutic proteins, inhibitor incidence, differences in molecular structure between recombinant products and plasma-derived products that may affect immunogenicity and new products under development.

There is no registration fee for the meeting. Early registration is recommended on or before November 7, 2003, as seating is limited to 176 participants. Registration forms for interested individuals can be obtained on the FDA website at <http://www.fda.gov/cber/meetings/fctrviii112103.htm>.

**Independent Pharmacies Sue PBMs**

October 7, 2003

A proposed class action lawsuit filed in Alabama federal court targets the four largest pharmacy benefit management (PBM) companies charging abusive business practices including price fixing, artificially depressing prescription prices and accepting "kickbacks" in the form of rebates. The case, North Jackson Pharmacy, Inc. v. Medco Health Solutions, Inc., was filed in the United States District Court in northern Alabama on October 1, 2003. Defendants in the suit are Medco Health Solutions, Express Scripts, Caremark, Inc. and AdvancePCS.

According to court documents, the suit claims that PBMs use "systematic and deceptive practices" to force pharmacies into relationships that interfere with

the pharmacist-patient relationship. The complaints outline alleged "egregious business practices" such as:

- ♦ Fixing prices to be paid to pharmacies for drugs
- ♦ Accepting "kickbacks" in return for placing a manufacturer's drugs on the PBM formulary and then "pushing" these drugs on physicians and pharmacists
- ♦ Diverting health plan members to mail order pharmacies, which are owned by the PBMs
- ♦ Removing the physician and pharmacist from their role in the healthcare equation
- ♦ Requiring pharmacists to contact the prescribing physicians and patient if a nonformulary drug is prescribed and encouraging a change to a formulary drug

The Pharmaceutical Care Management Association (PCMA), a trade group representing PBMs, responded by attacking the lawyer filing the suit. "Reports that the trial bar is setting its sights on the best source of affordable prescription drugs for working families, seniors and the disabled—pharmacy benefit managers (PBMs)—reveal the depths of the trial bar's greed and will fail once the consequences of their agenda are fully known," PCMA said.

### **Bayer Announces Intention to Divest Plasma Business**

October 4, 2003

Bayer AG has announced it is initiating a process to divest its plasma business, which is part of the Biological Products (BP) division. However, Bayer reports their recombinant factor VIII blood coagulation business—comprising the Kogenate® product line—is not included in this initiative. The corporation also announced that a number of research initiatives to develop better treatments for hemophilia will also continue.

Source: *Bayer AG*

### **New Study of Hemophilia Drug Begins**

September 5, 2003

Octagen Corporation of Bala Cynwyd and Paris-based Beaufour Ipsen began human studies of a potential new hemophilia treatment last month. The study marks the first phase I clinical trial for Octagen, which was founded in 1997 to develop new therapies for hemophilia and other disorders related to the blood-clotting process.

Octagen and Beaufour Ipsen formed a research partnership in 1998 to develop a new drug candidate known internally as OBI-1. OBI-1, a genetically engineered molecule, was discovered by Dr. John Lollar, a hemophilia researcher and professor of medicine at Emory University in Atlanta. Five years ago, Octagen entered into an exclusive worldwide licensing agreement with Emory for the commercialization rights to the drug.

Octagen and Beaufour Ipsen's phase I clinical trial will be conducted in up to 20 clinical centers throughout the United States and United Kingdom. The study is designed to compare the safety of single infusions of OBI-1 against a commercially available porcine factor VIII known as "Hyate:C," a product derived from pig plasma and sold by Beaufour Ipsen.

Source: *Philadelphia Business Journal*

## **CMS Releases 2004 Proposed Hospital Outpatient Prospective Payment System (HOPPS) Rule**

October 3, 2003

Centers for Medicare and Medicaid Services (CMS) released its proposed rule for 2004 Medicare reimbursement of hospital outpatient prospective payment services, including new proposed rates for clotting factor products. Similar to last year's final action, CMS is employing a "dampening" effect on the proposed rule to limit decreases in drug payment that would otherwise occur if reimbursement were based solely on hospital cost data. In 2003 CMS limited decreases to 15% for all non-pass-through drugs (those outside the prospective payment bundle), including clotting factor. The proposed 2004 rule sets a 10% limit on reductions for blood and blood products. Other non-pass-through drugs are subject to deeper reductions. The proposed Medicare payment rates for clotting factor products are provided in the chart below.

In its comments, CMS acknowledges the poor quality of hospital data for blood and blood products and specifically requests input from hospitals regarding their acquisition costs. NHF will be working with hemophilia treatment centers and hospitals to collect this data and will prepare comments in response to the proposed rule. The rule appears in the August 12, 2003, Federal Register and is also available online at: [www.cms.gov/regulations/hopps/2004p/change-cy2004.asp](http://www.cms.gov/regulations/hopps/2004p/change-cy2004.asp).

### **HOPPS History**

August 1, 2003

The Hospital Outpatient Prospective Payment System (HOPPS) was implemented by the former Health Care Financing Administration (HCFA, now referred to as CMS) on August 1, 2003, to replace the previous cost-based system of hospital payment for procedures performed in the outpatient setting. The HOPPS system relies on ambulatory payment classifications (APCs) to package procedures of similar resource costs into categories for fixed reimbursement, much like how hospitals are reimbursed in the inpatient setting under diagnostic related groups (DRGs).

HCFA's first proposal in implementing the HOPPS systems was to group all clotting factor products into a single APC with other drugs for reimbursement as an infusion service. Based on NHF's and other's concerns, HCFA later established separate APCs for each type of clotting factor as determined by

healthcare common procedure codes (HCPCs). Furthermore, HCFA placed these products into a category that allowed for pass-through payments for a period of up to three years. This temporary pass-through status enabled additional data about the costs of these products to be collected. Eligibility for the pass-through category status for clotting factor products ended on July 31, 2003.

Reimbursement for pass-through drugs was set at 95% of the median average wholesale price (AWP) of all products in an APC. In 2002 Congress imposed a cap on overall pass-through expenditures. This cap resulted in an across-the-board cut to all pass-through drugs and devices. This cut went into effect on April 1, 2002, and reduced reimbursement for clotting factor by as much as 27%.

Under the proposed 2003 update, reimbursement for clotting factor would have essentially been leveled across most products to \$0.52 per unit, regardless of whether the product was plasma derived or recombinant manufactured. NHF, its chapters and hemophilia treatment centers worked together to provide comments and data demonstrating the inadequacy of the proposed rates, which resulted in restored reimbursement for these products in the final rule that took effect on January 1, 2003.

An estimated 1,000 people in the United States with hemophilia receive Medicare benefits. While the Medicare population, according to the

General Accounting Office, utilized nearly \$10.5 million in clotting factor products in 2001, usage of these products in the outpatient setting is fairly limited. Data presented with the 2004 proposed rule indicates payment for just over six million units of clotting factor from April 1, 2002, through December 31, 2002 .

### **NIH Roadmap for Medical Research**

September 26, 2003

Dr. Elias Zerhouni, director of National Institutes of Health (NIH), announced a series of far-reaching initiatives known as the NIH Roadmap for Medical Research on September 30, 2003. This plan intends to implement more effective approaches to accelerating fundamental medical discovery than are currently in place.

After an intense process of discussion and scientific review, the directors of NIH's 27 institutes and centers approved the NIH Roadmap, which features 28 initiatives to be carried out by nine implementation groups under three main themes.

New Pathways to Discover—the NIH Roadmap—addresses the need to understand complex biological systems. New Pathways will build a better "toolbox" for today's biomedical researchers.

Initiatives will provide a solid scientific foundation for new diagnosing strategies, treating and preventing disease. Implementation groups in this area are:

- ◆ Molecular Libraries and Molecular Imaging
- ◆ Bioinformatics and Computational Biology
- ◆ Nanomedicine
- ◆ Structural Biology
- ◆ Building Blocks and Pathways

Research Teams of the Future—Demands that scientists move beyond the confines of their own discipline and explore new organizational models for team science. Implementation groups in this area are:

- ◆ High-Risk Research—NIH Director's Innovator Award
- ◆ Interdisciplinary Research
- ◆ Public-Private Partnerships

Re-engineering Clinical Research—Over the years, clinical research has become more difficult to conduct. NIH recognizes there is a need to develop new partnerships among organized patient communities, community-based physicians and academic researchers. They intend to address this crucial area by promoting better integration of existing clinical research networks, encouraging the development of technologies to improve the assessment of clinical outcomes, harmonizing regulatory processes and enhancing training for clinical researchers. Implementation groups in this area are:

- ◆ Harmonization of Clinical Research Regulatory Requirements
- ◆ Integration of Clinical Research Networks
- ◆ Enhance Clinical Research Workforce Training
- ◆ Clinical Research Informatics: National Electronic Clinical Trials and Research Network (NECTAR)
- ◆ Translational Research Core Services
- ◆ Regional Translational Research Centers
- ◆ Enabling Technologies for Improved Assessment of Clinical Outcomes

Taken together, the components of the NIH Roadmap initiatives are an integral part of a well-thought out national portfolio of research to meet the health demands of the 21st century.

## BLOOD SAFETY

**FDA's Blood Products Advisory Committee Continues Discussion on West Nile Virus**

September 18, 2003

The Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) continued discussion from the March 2003 meeting regarding West Nile Virus (WNV) and the blood supply on September 18, 2003.

The FDA reported on the actions they have taken to decrease the threat of WNV in whole blood donors, including the start of nucleic acid testing (NAT) in mid-June 2003. The FDA has also participated in weekly meetings with the task force established by the blood banking community, which includes Centers for Disease Control and Prevention and National Institutes of Health, to coordinate the epidemiological data on WNV infection and to monitor the outcome of testing for whole blood donors. The FDA reported that NAT testing has removed more than 75% of infected blood donations from entering blood supply for transfusion.

Regarding WNV and plasma-derived products, the FDA addressed the issue of whether viral validation data on model viruses are sufficient to demonstrate WNV clearance. The FDA emphasized that viral clearance studies should be conducted using WNV, as opposed to model viruses. However, they noted that the level of WNV inactivation is comparable to that of bovine viral diarrhea virus (BVDV) based on WNV clearance data presented to the FDA by the Plasma Protein Therapeutics Association (PPTA). They further indicated that the level of inactivation shown in the studies, combined with the expected (but not yet determined) contribution of the removal steps in the manufacturing processes, are expected to be sufficient to demonstrate the safety of plasma derivatives with regard to WNV. The FDA noted that the second issue addressed by BPAC at the March meeting, whether the clearance steps in the manufacture of plasma derivatives obviate the need to screen donations of source plasma, would not be addressed, pending the FDA review of additional data requested of the plasma industry.

PPTA presented their three-part approach to addressing WNV including (1) risk assessment, (2) viral clearance verification studies and (3) monitoring existing donor screening and surveillance. They reported

on their meeting with FDA in April 2003 where they supplied company-specific data and strongly expressed their position that WNV testing of plasma donors is not warranted for WNV given the epidemiology of the disease and significant margin of safety demonstrated through viral inactivation studies. PPTA provided their WNV study conclusions, which included: (1) WNV is not detected in the majority of plasma manufacturing pools, (2) when detected, titers are low, consistent with the risk assessment and (3) further dilution may occur as plasma manufacturing pools may be combined with others for production of final products. They also provided their risk assessment considerations including plasma viremia and its prevalence in the population. PPTA concluded that when present, WNV plasma manufacturing pool loads are low; that current manufacturing processes assure the safety of plasma derivatives, and WNV polymerase chain reaction (PCR) testing would not add a meaningful margin of safety for plasma derivatives.

BPAC recognizes the critical need for more data and consistent surveillance of the impact of WNV on the nation's blood supply. The committee, the FDA and the industry have agreed to continue working to diminish this threat

and will review any advances at their December 2003 meeting.

Source: *The Washington Post*

#### ADVOCACY UPDATE

### Senate Approves Family Opportunity Act

October 4, 2003

On September 10, 2003, the Senate Finance Committee approved the Family Opportunity Act (S. 622) on a voice vote. This act provides families of disabled children with the opportunity to purchase coverage under the Medicaid program.

The bill addresses the dilemma many families face when they lack adequate insurance to cover much-needed health services for their child—choosing between living in poverty or giving up custody to the state so that the child can obtain the comprehensive services available through Medicaid. In order to avoid giving up custody, many parents turn down hard-earned promotions and pay increases, effectively spending down to remain impoverished and therefore eligible for Medicaid coverage.

The Family Opportunity Act adds a new optional eligibility group for disabled children for the Medicaid

program. It calls for a Medicaid buy-in program for families who have children under 18 who meet the disability definition for children under the Supplemental Security Income program (SSI), yet have income above the financial standards for SSI. Those families that fall below 250% of the federal poverty level (approximately \$45,000 for a family of four) would pay a premium not exceeding 5% of their adjusted gross income and receive in return the Medicaid services not covered by their private insurance. Families would be required to continue their private insurance coverage. States would be allowed to have eligibility levels greater than 250% of poverty, but federal funding would not be provided to cover these families.

The House equivalent was referred to the House Committee on Energy and Commerce in April and remains in the Subcommittee on Health as of April 24, 2003.

### California Governor Signs Mandated Coverage Legislation

October 5, 2003

California Governor Gray Davis (D) signed landmark legislation on October 5, 2003, requiring employers of 50 or more employees to provide health insurance or pay into a state purchasing pool. The bill, sponsored by Sen. John Burton (D), is expected to provide coverage to at least one million California workers and their families, or almost half the total of uninsured workers in California.

"Today, California takes a bold and balanced step forward to reform healthcare as we know it," Davis said. "Lack of health insurance increases costs and harms the uninsured because they receive less preventive care, use the emergency room more and are diagnosed at more advanced stages of disease." Although the legislation's effective date is January 1, 2004, the mandates will go into effect over several years.

Employers with more than 200 workers have until January 1, 2006, to provide coverage for workers and their dependents or pay a fee per worker into the State Health Purchasing Fund. Employers of 50 to 199 must provide coverage to employees only beginning Jan. 1, 2007. The law will apply to employers of 20 to 49 only if the state adopts a tax credit available to those employers equal to 20 percent of the net cost

of the program per employee.

Employees must work at least 100 hours a month for at least three months for the same employer to be eligible. Temporary employment agencies and farm labor contractors are considered employers.

Opponents of the bill, however, are already planning to contest the new law. The California Chamber of Commerce continued to argue that the measure is a misguided approach to solving the problem of uninsured workers and could be illegal. Chamber of Commerce President Allan Zaremborg said, "The California Chamber of Commerce believes that [Senate Bill 2] violates the state constitution because it implements a tax on both employers and employees, yet was passed with only a majority vote in the legislature, not the two-thirds vote constitutionally required. We also believe it is pre-empted by federal law, the Employee Retirement Income Security Act. The Chamber is reviewing all options to stop [Senate Bill 2] from becoming law, including court challenges and a potential referendum campaign."

### **Census Finds Many Lack Health Insurance**

September 30, 2003

The number of Americans lacking health insurance climbed 5.7% in 2002 to 43.6 million, the largest single increase in a decade, according to figures to be released today by the Census Bureau.

Overall, 15.2% of Americans were uninsured last year, up from 14.6% in 2001. The largest jump was seen among people who had previously received health benefits through their jobs, but were laid off or had their coverage reduced. Young adults and Latinos were again the least likely to have medical coverage. Primarily because of government-run health programs, children and the elderly have the highest rates of coverage.

Coupled with a report last week showing a similar rise in poverty, the health insurance data help illuminate the human toll of the nation's stalled economy.

Since President Bush took office, the United States has lost 2.7 million jobs, and household incomes have fallen three years in a row. Administration officials suggest those trends have begun to turn

around, but Democrats have seized on economic issues in their quest to defeat Bush in the 2004 presidential election.

Advocates of comprehensive healthcare coverage said leaders in both political parties need to focus more energy on the uninsured and rising medical costs.

"These figures and those on the poverty level in the United States indicate our country has a profound challenge in front of it, namely how, with all the wealth and power we have aggregated, can we ensure that all Americans are at the table of economic opportunity and have access to healthcare," said Rev. Michael Place, president of the Catholic Health Association of the United States. "What we need from leaders is the same type of focus that can win a war in Iraq."

"The president is committed to getting the economy growing faster so the number of unemployed and uninsured Americans will go down," said White House spokeswoman Claire Buchan.

Health policy experts expected the number of uninsured Americans to grow, but many expressed surprise at the size of the increase. Not since 1992 has the nation experienced such a steep drop in healthcare coverage, an issue Bill Clinton capitalized on in his successful cam-

paign against President George Bush in 1992.

"These numbers are a real wake-up call to the fact that lack of insurance is a growing problem in the United States," said Diane Rowland, executive director of the Kaiser Commission on Medicaid and the Uninsured, a bipartisan health policy institute.

The most startling story line behind the census figures is the ongoing loss of health benefits in the workplace. For the second year in a row, the proportion of people who received insurance through an employer fell, from 62.6% in 2001 to 61.3% in 2002. Cost to employers and employees appeared to be the primary reason for the decline.

"Employment-based coverage is getting really expensive," said Kate Sullivan, director of health-care policy at the U.S. Chamber of Commerce. "Either the company doesn't make it available or individuals are turning down coverage at work because they can't afford it. That's very alarming."

The average cost of a family health plan rose from \$8,000 in 2002 to more than \$9,000 this year, and is expected to exceed \$10,000 in 2004, said Helen Darling, president of the Washington Business Group on Health, which represents 180 major corporations.

"When you think about the average wage in this country being only \$27,000, somebody's going to say, 'Wait a minute, I can't afford an employee at that level,'" Darling said.

"It wasn't just low-wage workers who struggled to afford health coverage," said Sullivan, noting that 900,000 full-time workers lost insurance in 2002. "The number of people earning over \$50,000 without coverage is rising," she added. "This shows they're not immune."

The situation could have been far more dire. Were it not for the growing numbers of people who either purchased their own insurance or enrolled in a government-subsidized program, the data showed the total number of uninsured Americans would have been 2.9 million greater.

Health and Human Services Secretary Tommy G. Thompson said the growth in Medicaid and the Children's Health Insurance Programs (CHIP) demonstrates the administration's commitment to helping children and families obtain care. By giving states permission to experiment with these programs, Thompson said HHS has helped expand coverage to 2.4 million people. Today, nearly one in four children receives care through Medicaid or CHIP.

Still, analysts say it is hard to see how financially-strapped states can sustain the costly health programs.

"All across the country states are experiencing fiscal crisis and a good number are considering cutting their Medicaid programs," said Ron Pollack, executive director of the liberal consumers group Families USA.

As always, there were wide variations among the states. Minnesota showed the greatest success, with 92% of its residents having been covered by private or government programs. Texas has the highest number of uninsured residents—24.7% over a two-year period, according to the Census Bureau.

Source: The Washington Post

### **Genetic Discrimination Legislation Set to Pass**

September 29, 2003

When the United States Senate returns to Washington, DC, next week,

its first order of business will be to vote on legislation barring employers from using an individuals' genetic information when making hiring, firing, job placement or promotion decisions. The legislation would also apply to health insurers, preventing them from using individuals' genetic information to deny coverage or determine rates or premiums. The bill is expected to pass by an overwhelming vote.

NHF has been a strong supporter of genetic discrimination protections. Passage of the bill will cap more than six years of negotiations to achieve consensus. Unfortunately, the House is likely to move more slowly. Senate leaders hope the House committees with jurisdiction over the bill will use the Senate version as a starting point, but there has been no indication that House members will do so.

Senate leaders on this issue have worked carefully with the business community in an attempt to curtail employers' liability from potential complaints. Employers insist they should not be made liable for genetic information that they unwittingly learn from or about employees. The Senate bill currently states that if employers "inadvertently" gain genetic information, they would not be considered in violation of the law.

The bill defines genetic information as information about a person's genetic tests, a family member's genetic tests or "the occurrence of a disease or disorder in family members of the individual."

Plaintiffs who sue for genetic bias under the bill would be able to seek the same remedies available under the Americans with Disabilities Act (ADA). Under the ADA, damages for individuals can not exceed \$300,000.

## NHF NEWS

### **NHF to Conduct Online Auction of Celebrity Blue Jeans**

October 10, 2003

National Hemophilia Foundation has announced an upcoming fundraising event called "Blue Jeans for Genes." The event consists of an online auction of beloved, autographed blue jeans donated by celebrities from the worlds of movies, music, television, sports, literature and politics. All winning bids benefit NHF. The auction will take place on

November 10 to 19 on eBay:  
<http://www.ebay.com/charity>.

Signed jeans (or other autographed items) have been donated by the following celebrities: Antonio Banderas, Lance Bass, Jim Belushi, Yogi Berra, Bow-Wow, Lorraine Bracco, The cast of "Camp", Mario Cantone, Dave Chappelle, Kenny Chesney, Chippendales of Las Vegas, Joan Collins, Patricia Cornwell, Rah Digga, Taye Diggs, Mike Ditka, Eve, Joely Fisher, Bela Fleck, Sarah Michelle Gellar, Whoopi Goldberg, Melanie Griffith, Josh Groban, Mariska Hargitay, Tommy Hilfiger, Hugh Jackman, Garland Jeffreys, Jane Kaczmarek, Calvin Klein, Barry Manilow, Reba McEntire, Tim McGraw, Rosie O'Donnell, Gwyneth Paltrow, Bernadette Peters, Freddie Prinze, Jr., Denise Richards, Paul Schaffer, Tom Seaver, Jamie-Lynn Sigler, Carly Simon, Michael Stipe, Ichiro Suzuki, Marisa Tomei, Bradley Whitford and many more!

For more information, write to: [jeans@hemophilia.org](mailto:jeans@hemophilia.org)

### **NHF Announces 2003 Laboratory Grant Recipient**

October 8, 2003

NHF is pleased to announce that David Scott, PhD, is the recipient

of its 2003 Laboratory Grant. Scott is the head of the department of immunology at Holland Laboratory of the American Red Cross in Rockville, Maryland. He will be awarded \$150,000 over a period of three years for his project entitled "Induction of tolerance to factor VIII (FVIII) inhibitor formation." This study is also supported by the National Heart, Lung and Blood Institute.

NHF's Laboratory Grant was established in 1998 under the "It's Time for a Cure" campaign, which has raised over \$8 million for research specifically on cures for bleeding disorders. First given in 2001, the Laboratory Grant awards up to \$300,000 per year for up to three years to a team of researchers searching for a cure.

Scott and his colleagues will attempt to block the formation of or eliminate antibodies to FVIII through the use of B lymphocytes to present FVIII fused to a carrier protein called IgG. The Scott laboratory has previously utilized IgG-linked proteins delivered via viral vectors to induce tolerance in several experimental autoimmune models. The technology will be applied in mouse models of hemophilia and then extended to the rhesus monkey. The researchers will also examine the effect of tolerance of newly designed FVIII molecules with improved lifespan. An effort will be made to apply this approach

to reverse ongoing responses to FVIII in mice with hemophilia and later in monkeys as an important step toward future clinical trials involving the simple treatment of patients' B cells.

### **Call for Nominations for the NHF Board of Directors**

October 9, 2003

NHF is seeking candidates for its 2004 Board of Directors. Candidates should have:

- ♦ Experience with national boards
- ♦ Demonstrated leadership capabilities
- ♦ Clear understanding of how large organizations operate
- ♦ Ability to access financial resources and raise funds
- ♦ No conflicts of interest
- ♦ Ability to work with volunteer leadership and staff

If you would like to nominate a person to serve on the NHF Board of Directors, complete a nomination packet for the candidate and mail to NHF postmarked no later than November 19, 2003. To request a nomination packet via mail, please contact Gary Widlund at 212-328-3737 or [gwidlund@hemophilia.org](mailto:gwidlund@hemophilia.org).

Deadline for nominations is November 19, 2003.

### **NHF Responds to Proposed Hospital Outpatient Payment Rates**

October 6, 2003

NHF sent comments to the Centers for Medicare and Medicaid Services (CMS) on proposed 2004 Medicare payment reductions in hospital outpatient reimbursement for clotting factor. The August 12, 2003, Federal Register issued by CMS proposed 10% reductions in place of the reductions that would occur if CMS were to rely upon data provided by hospitals on clotting factor costs.

CMS has repeatedly acknowledged the poor quality of the hospital-reported data for clotting factor. Application of payment reduction lim-

its, as proposed in the 2004 rule, has prevented serious reimbursement reductions from impacting access to clotting factor for Medicare beneficiaries with hemophilia and other bleeding disorders. NHF, however, stated it is "concerned that continued erosion, experienced over the last two years as 10% to 15% reductions annually, will limit beneficiary choice of products and eventually restrict use of clotting factor products in the outpatient setting." The proposed 2004 rates fall at or slightly below acquisition costs for many clotting factor products.

To correct this potential payment shortfall, NHF has requested CMS strongly consider reevaluation and modification of the outpatient payment system for clotting factor. NHF points to three potential options for 2004 hospital outpatient payment:

- Base reimbursement on the current Single Drug Price to prevent variation in payment between hospital settings.
- Provide reimbursement based on actual costs of acquiring and providing the product, as recommended by the Department of Health and Human Services' Advisory Committee on Blood Safety and Availability at its August 22, 2003, meeting.
- Adopt the recommendation of CMS' Advisory Committee on Ambulatory Payment Classification Groups to maintain payment for blood and blood products at the 2003 hospital outpatient level. NHF endorses this recommendation if it is interpreted to include all clotting factor products.

NHF worked with hemophilia treatment centers and hospitals to provide data demonstrating the potential loss/gain per infusion if the 2004 proposed rates are implemented (see NHF's comments). CMS intends to publish its final rule by the end of the year with an effective date of January 1, 2004.