**UNITED VIRGINIA CHAPTER NHF**

**9801 Husting Terrace**
**Chesterfield, VA 23832**

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Fax: 804-796-9043
Email: PADER55@cs.com

## Upcoming Events

10/15 Picnic at Rockwood Park, Chesterfield County 3 pm—dusk

11/9—11/11—NHF Annual Meeting in Annaheim

December—Breakfast with Santa—Several will be arranged in Richmond, Tidewater and Charlottesville area.

12/2 Teen Seminar and Holiday Outing

## Membership

$10.00 Individual _____ $25.00 Family _____
$50.00 _____ $100.00 _____ $250.00 _____
$500.00 _____ Scholarship Fund $ _____ Research $ _____

Name _____

Address _____

City, State, Zip _____

Phone # _____ E-Mail _____

# Adults in Household _____ # Children in Household ____

Does a household member have a bleeding disorder? _____

Factor VIII _____ Factor IX _____ von Willebrand's _____

Other Disorder _____ Adult or Child _____
Would you like information about getting involved with the chapter?
Yes _____ No_____

United Virginia Chapter NHF

# Facts 'N' Factors

Volume 1, Issue 1 September - October, 2000

***Ricky Ray Checks Are Being Received***

***Beginning in early September claimants with the lowest numbers have started to receive the one-time compassionate payment of $100,000. By September 30, 670 claims are to be paid from the fund.***

**Inside this issue:**

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## Ricky Ray Law

**HHS Begins Notifying Ricky Ray Hemophilia Relief Fund Recipients of Payments**

WASHINGTON, Aug. 28 / U.S. Newswire/ via NewsEdge Corporation - HHS
Secretary Donna E. Shalala announced today that the Department of Health and Human Services began notifying the first eligible families that will receive payments from the Ricky Ray Hemophilia Relief Fund.

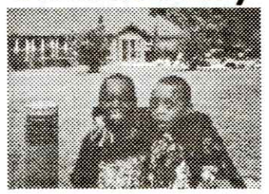
The initial recipients are being notified via letters as applications are approved, consistent with the process established by HHS' Health Resources and Services Administration (HRSA), in consultation with The National Hemophilia Foundation, The American Federation of Hemophiliacs and the hemophiliac advocacy group, The Committee of Ten Thousand. The application and payment process was developed by HRSA to assure that funds will be made available to eligible individuals as quickly as possible. More than 4,300 petitions were received since July 31, the first postmark day that petitions were accepted. Approximately 670 recipients will receive compensation with fiscal year 2000 funds.

"Congress should act now to fulfill our obligation to those who contracted HIV through contaminated blood products during the 1980s," said Secretary Shalala.
"Now, that the distribution system is in place, we will redouble our efforts to encourage Congress to fully fund the Ricky Ray Hemophilia Relief Fund so that all of the estimated 7,500 eligible individuals can receive compensation."

The Ricky Ray Hemophilia Relief Fund was authorized in 1998 to provide compensation payments of $100,000 to individuals with blood-clotting disorders, such as hemophilia, who contracted HIV from contaminated anti-hemophilia blood products between July 1, 1982 and Dec. 31, 1987. Spouses

Cont. Pg 2

## Camp Youngblood: A year 2000 Success Story



***James Vanover and Corey Baker share good times at Camp Youngblood***

Chesterfield County's Camp Baker, an ARC camp became ***Camp Youngblood*** once again for the children in the bleeding disorder community. August 15, 39 kids from Virginia, DC and Maryland arrived to begin a sensational camp experience. Each child was given and initial bag containing a disposable camera, pool towel and goggles to begin their day of ***fun in the sun.*** Camp Youngblood hosted 8 girls and 31 boys.

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# A Letter From The New President

Dear Chapter Families & Friends,

For many of us, spring is the time of new beginnings, but as a teacher, fall is my time for new beginnings. There's a new crop of children to get to know, teach and learn from and a new season of sports, church, educational and community activities to join. This year I add to my list of new beginnings that of President of the United VA Chapter of NHF. Some of you may know me as the chapter's treasurer for the past 2 years and before that as a parent volunteer.

This year, the board members & I want to set some goals for the chapter that are specific and attainable. The goals are:

***To <u>Educate</u> our members concerning hemophilia and related issues.**

***To <u>Empower</u> those affected by hemophilia to take more control of their lives.**

***To <u>Enable</u> them and their families to participate more in chapter activities, including fundraising.**

The chapter has previously provided many opportunities to participate in educational programs fro all age groups and will continue to do so this year. We hope to add some new ones and would like to hear from you, the members, about topics you are interested in attending.

The chapter and the treatment centers are working together to empower the hemophilia community on what you can accomplish on your own and how to be self-sufficient concerning different needs that arise due to hemophilia.

The chapter would like to see **more participation** in the activities it provides for you as well as in its **fund raising efforts.** We realize that travel impacts participation in many of the activities and fund raising projects planned. We have therefore set up three regions for separate fun activities and fund raising leaders and projects: Richmond—Dorothy O'Connor, Tidewater—vacant, Roanoke—vacant. There will continue to be general activities for all to participate in such as the Annual meeting, King's Dominion, Summer Camp. Please read the article in the newsletter specifically about ***Fund Raising*** for more details about what's planned and how you can help.

My goal as the new president is not to set the world on fire, but to have more you participate in the chapter. You all have a talent that you can share—it just may not seem obvious to you yet. Please feel free to contact me on E-Mail at VOCON@earthlink.net. You may also call the chapter's 1-800-266-8438 toll free number to leave suggestions for me.

Last, but not least, the chapter needs **<u>TREASURER!</u>** Time & energy will not allow me to continue in both capacities.

Here's to New Beginnings.

Respectfully,

Dorothy F. O'Connor

# Ricky Ray Law Payments

.and children who contracted HIV from these individuals and certain survivors may also be eligible. In 1999, the Clinton-Gore administration worked with Congress to achieve a $75 million appropriation for fiscal year 2000.

"This is an important first-step towards fulfilling our commitment to helping people with hemophilia who have contracted this serious disease", stated John D. Podesta, chief of staff of the President of the United States. "But," he said, "we must do more and enact the President's proposal to fully fund the Ricky Ray Hemophilia Relief Fund for 2001."

The Clinton-Gore adminstration requested $100 million in the fiscal year 2001 appropriation bill, and $475 million in its proposal to restaore Medicare provider payment reductions enacted in the Balanced Budget Act authorized under the act to administer the program and compensate the estimated 7,500 eligible individuals. Cont. Pg 3



# Ricky Ray Payments

funding for the $750million
For more information on the Ricky Ray Hemophilia Relief Fund contact HRSA's Web site at **<u>http://www.hrsa.gov/bhpr/rickyray/</u>** or toll-free phone line at
**<u>1-888-496-0338.</u>**

***Calling All Teens:***

***According to research done by the CDC (Center For Disease Control), teens are the group that waits the longest to treat bleeds. We are all concerned about your joints. I am sure that there is a good reason for your reluctance and we would like to find out that reason.***

***The first Saturday in December you are invited to attend the first teen workshop followed by dinner and an evening of entertainment with other teens both boys and girls (yes, girls have bleeding disorders, too). Watch your mail for your invitation.***

## IMPORTANT ANNOUNCEMENT FOR ALL ADULTS:

**On Saturday, October 21, you are invited to Sharkey's at the Shops at Innsbrook for an evening of fun and fellowship. Plan to attend to see old friends and meet our young adults. We have reserved the billiard tables from 7:00 pm until 11:00 pm. There will be a limited number of rooms available on an as needed basis at Amerisuites.**

**RSVP as soon as possible to:**
**Art DeMario 804-862-8123**
**Karyn Walsh 804-828-2924**
**Chapter office 800-266-8438**

# Fund Raising: How you can be a part of the solution

Fundraising is one of the least liked parts of operating a non-profit organization. No one wants to sell anything, especially things no one wants or needs. Unfortunately, fundraising is a part of the non-profit life. We are no exception. With the many changes in insurance reimbursement, the possibility of greatly reduced Medicaid reimbursement, it is more important than ever that we become self-sufficient. We have begun several fundraisers that everyone can be a part of.

Our most exciting fundraiser has been a partnership with **Dominion Vendors.** In the partnership with Dominion Vendors, we simply look for locations in our community that would consider placing a soda machine. The machines are Coke or Pepsi. The only contact you need to make is to inquire whether they would be willing to discuss the possibility with the representative from **Dominion Vendors**. Currently the chapter has one machine placed that has raised $30 to $40 dollars per month. If everyone could get just one machine places we could guarantee the future of our programs such as **Camp Youngblood, King's Dominion,** the **Adult Retreat**, clinic lunches and many other services that are currently offered through the chapter. These events have been offered at no charge to the hemophilia community and have been well attended. Summer camp did not cost any camper a thing. We even arranged transportation for those kids that had no way to get to camp.

January 2001 will see a new charity run in the Richmond area. The United Virginia Chapter has partnered with **Richmond Roadrunners** running club to kick off our run to benefit **Camp Youngblood**. We are hoping to host several charity runs across the state. Plans are being made for a Chesapeake/Tidewater location and we are hoping for a Roanoke/Charlottesville site also. ***This is where we need your help. Is there a running club in your area? Check the phone book, call them to ask for their support. Put them in touch with the chapter office. It is as simple as that. You can do this.***

Do you have any ideas for fundraisers that haven't been tried? We want to hear about them. Is there a local club or organization that would be willing to partner with us to raise money? Many groups such as the Knights of Columbus, American Legions, Kiwanis Clubs raise money for the community. Are you a member of any of these? Is anyone in your family a member? Many will contribute because you ask them to.

What you need to ask yourself is, "Have you enjoyed the services provided by the chapter?" If the answer is yes, we need your help to continue to offer these fun events and educational programs. With your help we can accomplish anything. Thank you.

# *Camp Youngblood*

**The girls of Camp Youngblood**
**Back: Cassie George, Cynthia George, Gina Raymond-Duncan, Debbie Black, Front Row: Erica Fuller, Megan Vanover, Becca Hopkinson, Heather Jenkins, Rose DeRatto, Pat DeRatto**

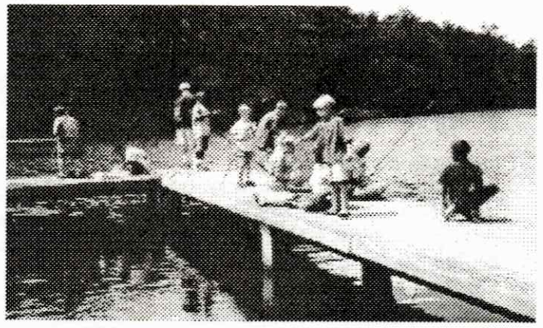
During camp, campers were given the opportunity to learn to self infuse. All of the campers that attended the infusion session were successful in preparing their factor and infusing themselves. One counselor attended and learned another spot to infuse himself.

Each of the kids got to spend plenty of time in the pool and on the playground. Every night, dinner had a theme. Tuesday we saw a Sci-Fi crew around the dinner table. Wednesday was Wacky Wednesday, and I don' t event want to begin to describe several of our counselors who seemed to have an identity crisis that evening. Cowboys and Indians corralled our tables Thursday and in true Greatful Dead fashion, tie dye and peace signs were the *in thing* for **Hippy Friday.** Thursday's craft activity included buckets of cloth dye and each of the kids (and counselors) created their own tie-dye designed shirts. Wednesday the kids were treated to several race cars and drivers that brought their cars to the camp for the kids to see and photograph.

The general consensus from the kids was that they planned to return next year. Leaving there were several tears shed.

A special thanks to the staff that gave their time to make this such a success: Rodrigo Salcedo, chapter board member, Axel Freese, adult with hemophilia, David Rice, adult with hemophilia, Jack Shoff, Bayer, Gina Raymond-Duncan, Aventis-Behring, Sheri Marshall, OptCare Plus, Debbie Black, Apex, Renee Zawisa and Beth Ireland, Gentiva, Buffy Stover, HHS, and a thanks to Baxter for Friday's Pizza Party.

If you can see yourself as a camp counselor or can help with any activity at camp, please call the chapter office. We will



***Fishing from the dock at nearby Camp Thunderbird YMCA***

Begin planning next year's camp session just after the first of the year. We will definitely need more help. We plan to have activity and game stations throughout camp next year with volunteers to man each station. This year it was necessary to turn away a large number of applicants due to lack of space. We are looking for a larger camp and with that will come the need for a larger staff. If you have a talent working with kids, you could be a large part of next year's Camp Youngblood. We will be looking for ideas for crafts, meals, activities and anything else you can think of. **Here is your chance to make a difference to a kid.**

***"Do you think that Chef Maxwell could cook this for dinner?' counselor Courtney asked about her catch.***

## Websites of Interest

NHF Www.hemophilia.org
Aventis Behring LLS AventinBehring.com/na/Index.asp
Baxter Hyland Immuno hemophiligalaxy.com/Bayer
Corporation hemophiliabayer.com/
Genetics Institute hemophiliavillage.com/home.Asp
Canadian Hemophilia Society hemophilia.ca/english/index.html
Hemophilia Federation of America hemophiliafed.org/
Kelley Communications kelleycom.com/
World Federation of Hemophilia wfh.org/
Hemophilia Home Page web-depot.com/hemophilia
FDA Center for Biologics Research & Evaluation fda.gov/cber/recalls.htm
Patient Notification notify1.com/info/ippia/Iippia.htm



## Next Generation Formulation of Recombinant Factor VIII (rFVIII) For Hemophilia A Available From Bayer Corporation

### New rFVIII Significantly Reduces Rick of Viral Transmission over Plasma Derived-FVIII Products

On September 6, 2000, Bayer Corporation announced the availability of Kogenate FS Antihemophilic Factor (Recombinant, Formulated with Sucrose (rFVIII FS), a new formulation of recombinant factor VIII for the treatment of hemophilia A that offers more convenient administration. This is a significant development for the nearly 13,000 Americans who are living with this life-threatening disease. Kogenate FS builds on the 10 year history of clinical experience with its predecessor, Kogenate Antihemophilic Factor (Recombinant), to offer significant new advancements:

- Kogenate FS does not add albumin in its purification or formulation. Therefore, Kogenate FS contains 1,000 times less human plasma protein (albumin) than Kogenate. Like Kogenate, Kogenate FS fermentation uses highly purified human plasma protein solution.
- Kogenate FS includes a solvent/detergent viral inactivation step, thereby reducing the potential risk of viral transmission.
- It has a higher concentration and smaller fluid volume for the larger dosage sizes, which reduces the intravenous infusion time, thus allowing individuals to infuse more rapidly.

As with other rFVIII products, Kogenate FS contains trace amounts of host cell proteins.

**Clinical Data Establish Kogenate FS Safety and Efficacy**

A Phase III clinical study conducted in North American and Europe demonstrated that Kogenate FS was effective in controlling or preventing bleeding episodes in patients with hemophilia A. In 24 months of home therapy, 71 patients ages 12 to 59, who were previously treated with other recombinant or plasma-derived factor VIII products received Kogenate FS. A total of 12,546 infusions were adminstered in this portion of the study, or 22.4 million units of Kogenate FS. Treatment of 2,585 bleeding episodes during the study period required 3,648 infusions of Kogenate FS. The majority of bleeding episodes (93.5 percent) were treated successfully with one or two infusions. Regularly scheduled treatment accounted for 75 percent of infusions administered on study.

"Clinical studies were performed according to international guidelines and standards and demonstrate that Kogenate FS provides excellent and safe hemostatic control of bleeding episodes in patients with hemophilia A. This new product is the latest example of Bayer Corporation's commitment to improve and extend the lives of people with hemophilia". Stated Ptere Larson, M.D. International Clinical Project Director for Kogenate FS.

**Enhancing Confidence and Patient's Peace of Mind**

Recognizing that the hemophilia community continues to endure chronic shortages of recombinant factor VIII, Bayer decided to distribute Kogenate FS exclusively through Bayer Direct, a unique product delivery service designed to help patients get the medicine they need, when and where they need it. Bayer Direct satisfies the demands of people with hemophilia A for stable supply, consistent pricing, convenience of delivery, and provides additional quality related services. More importantly, persons enrolled in the Bayer Direct program will have the confidence of knowing that an inventory of Kogenate FS is in reserve for them in the event of a temporary interruption in product releases—providing even greater peace of mind.

In the United States, Bayer will distribute the product under the trade mark Kogenate FS, while Aventis-Behring, Bayer's long-term partner for hemophilia products, will distribute it in the United States as Helixate FS. Currently Kogenate FS is also approved in New Zealand, Switzerland, the European Union and Canada, and is available in New Zealand, Switzerland and Germany. Recognizing there is a shortage of recombinant factor VIII, rather than delay this launch, Bayer chose to enter the U.S. marketplace with the two most frequently used product package sizes. This will allow patients to begin treatment as soon as possible, as well as help satisfy demand during this period of shortage.

For more information on this program, please contact your Hemophilia Treatment Center or the chapter office. For more clinical or technical information on Kogenate FS, contact Bayer Clinical Communications at 1-800-288-8371.

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**From Patrick Collins: NHF's position on Bayer Direct Fax dated September 18, 2000**

I just wanted to follow up on a memorandum I sent out last week with regard to the Bayer Direct program. Today, the Advocacy Committee met and unanimously approved two resolutions that are to considered by the NHF Board of Directors in an emergency conference call on Monday night, September 25.

The Advocacy Committee approved a resolution in the form of a statement condemning the Bayer Direct program. The statement has seven reasons for opposition:

**Violation of Patient Choice**
**Violation of a Competitive Marketplace**
**Exclusion of Underserved patients**
**No Alternative in case of Product Recall**
**Concern over Patient Confidentiality**
**Concern over Patient Emergencies**
**The ongoing crisis over inability to obtain recombinant FVIII**

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**National Hemophilia Foundation**

**September 11, 2000** **Medical Advisory #371**

**Ongoing Recombinant Factor VIII Shortage—Contingency Recommendations**

As you are most likely aware, the ongoing recombinant factor VIII shortage is growing in severity. NHF Medical Advisory #370 (August 30, 2000) provided the latest results of our survey of 20 hemophilia treatment centers and several of the larger home healthcare companies. Our findings were that brand switching of recombinant products was the norm and that supply was extremely tight. Since that time, we have received additional information indicating that the situation is continuing to worsen. Baxter Hyland Immuno is still awaiting licensure of their Suite B manufacturing facility in Thousand Oaks, California. Baxter notified NHF that this is taking longer than anticipated and will take at least another month, if not longer. Moreover, they Bayer Corporation has announced implementation of a Bayer Direct program (sole source distributor) for their product, Kogenate FS. This is expected to have a further negative impact on the overall supply of recombinant factor VIII. Lastly with the ongoing allocation of Aventis Behring products, Bioclate and Helixate, and the delay in launch of Genetics Institute's product ReFacto, the forecast for recombinant factor VIII supply in the immediate future is extremely bad.

NHF has received several reports from both product distributors as well as treatment physicians that they are unable to obtain any recombinant product at this time.

As a result, NHF and its Medical and Scientific Advisory Council recommend that treatment centers (in conjunction with patients and families) begin developing contingency plans for decreasing overall use of recombinant factor VIII for a period of time.

It is recommended that treatment center personnel review infusion practices (I.e. rFVIII units per dose) being used by I individual patients, with a goal of potential reduction in dosage if warranted.

For persons on long-term prophylaxis with rFVIII, treatment center personnel could consider increasing the interval between doses on an individual basis.

Elective surgery might be postponed.

Starting some patients on immune tolerance induction might be postponed.

Switching patients from monoclonal and other high purity plasma-derived products to recombinant products could be delayed.

Product usage could also be creased by greater use of continuous infusion for surgery and serious hemorrhages.

If such measures do not alleviate the shortage, it is suggested that children who have always received rFVIII (I.e. those who have never received plasma-derived concentrates) continue receiving it.

MASAC has recommended recombinant factor VIII as the preferred treatment since October 1995 (MASAC Advisory #48). Further, the Public Health Service Advisory Committee on Blood Safety and Availability has endorsed recombinant treatment as the standard of care. Despite these recommendations by the United States, as well as other countries, both Baxter Hyland Immuno and the Bayer Corporation have been unable to adequately predict usage far enough in advance to ensure adequate manufacturing facilities are on line. Bayer's recombinant factor VIII, Kogenate has been in short supply since 1998 and they have consistently been unable to five a timetable for when they will have adequate product. Baxter has been increasing Recombinate manufacturing capacity in Thousand Oaks, California but has incurred delays that coupled with relative paucity of Bayer product, cannot meet United States or worldwide demand. NHF had hoped Genetics Institute's ReFacto would fill the void but they are also unable to make sufficient product to meet worldwide demand. Further, Genetics Institute will not even begin marketing their FDA approved product in the United States until early next year.

The National Hemophilia Foundation will continue to closely monitor the supply situation and would like to enlist everyone's help in this effort. Moreover, NHF will continue frequent communications with the manufacturers of recombinant factor VIII and the FDA in a concerted effort to get product onto the market as quickly as possible. In the meantime, NHF urges all concerned to avoid inclination to hoard product.

*This material is provided for your general information only. NHF does not five medical advise or engage in the practice of medicine. NHF under no circumstances recommends treatment for specific individuals , you should consult your physician or HTC.*



September 13, 2000
Camille Sorosiak (301) 897-2620
Nancey McCann (703) 591-2220
Richard Green (202) 789-5170

**Patient Advocacy Group To Launch Targeted Ad Campaign on Patients' Bill of Rights**

**Washington, D.C. – The Patient Access Coalition and the American Medical Association announced today that they will launch a national TV advertising campaign in support of Senate passage of a real patients' bill of rights. The ads will appear initially in Michigan, Missouri, Pennsylvania, Delaware, Washington State, and Washington, D.C. on Thursday, September 14.**

The campaign represents the beginning of a major push by the Patient Access Coalition to persuade U.S. senators that voters want a real patients' bill of rights passed before Congress adjourns.

The Senate missed the opportunity earlier this year to pass a real patients' bill of rights – a bill similar to that passed by the House by a bipartisan majority last fall. Instead, some senators have chosen to hide behind a bill that is all headlines and little substance – an HMO protection act. According to a Luntz/Laszlo poll, 87 percent of registered voters believe that it is important that Congress enact a patients' bill of rights this year. The Patient Access Coalition is encouraging those senators not to let their last vote on patients rights be their final vote.

"The Patient Access Coalition has been fighting for nearly seven years to ensure that patients in managed care plans are guaranteed choice and access to specialty care and the ability to hold HMOs accountable for their medical decisions," said George A. Beller, M.D., F.A.C.C., president of the American College of Cardiology. "It is time for the U.S. Senate to stop listening to the insurance industry and to start listening to patients, doctors, and other health care professionals fighting to ensure that all patients are guaranteed basic protections."

The Patient Access Coalition represents 67 patient, doctor and health care provider organizations fighting for the enactment of comprehensive and meaningful patient protections this year.

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**NHF's position on Bayer Direct**
Further, the Advocacy Committee approved a resolution recommending to the Board of Directors that NHF refuse any and all funding from Bayer until this sole vendor program in dropped and Kogenate FS is made available through broader distribution channels.

Both of these resolutions are to be considered by the Board of Directors next Monday night.

**Medicare Will Not Implement New AWP Pricing**

The Health Care Financing Administration (HCFA) has prepared and forwarded a memorandum to private insurance companies that process Medicare claims directing them not to use the new average wholesale prices (AWPs) established by the National Association of Medicaid Fraud Control Units. Also, HCFA is sending a memo to the state Medicaid offices to let them know that Medicare will not be implementing these new rates. Further, HCFA is asking Congress to legislate a reimbursement rate of AWP plus a dispensing fee.

In May 2000 the National Association of Medicaid Fraud Control Units proposed a set of newly revised AWPs for over 400 types of medicines, including products for treating bleeding disorders. Since Medicaid is a state run program, each state has the discretion as to whether to implement the newly revised AWP pricing.

Several states have decided not to implement the new prices but instead maintain the old prices in setting reimbursement rates. Moreover, several other states have implemented the new AWP prices but dropped an additional percentage discount that was in place. Some states have implemented the new rates along with a continued discount that further reduces reimbursement rates.

The recent furor over AWP is due to reimbursement of product. Before May 1, 2000, AWPs were set at a higher price that provided a greater degree of reimbursement for a product. The new AWPs were launched on May 1, 2000, and under these new rates, reimbursement levels were cut significantly. Some providers of product claimed that the new rates would not provide any profit margin whatsoever, thus forcing them not to purchase those products. As a result, these providers claimed treatment options would be reduced and the patients would suffer.

On the federal level, the Health Care Financing Administration (HCFA) announced that Medicare would not implement the newly revised AWP prices for reimbursement. While Medicare does not pay for most prescription drugs, it does cover medicines that are used on an outpatient basis.

**Note: AWP reimbursements will affect all insurance eventually. If your insurance reimburses less than cost, you may have NO access to factor. Keep yourself informed on this issue.**