

Health Policy Update

Federal Action

Medicare Patient Access

IVIG Access

The results of the November 2006 elections have prompted PPTA to take a fresh approach to advocacy in the 110th Congress. Since the newly elected Democratic Majority is traditionally more skeptical of the drug and biopharmaceutical industry, PPTA has in large part focused its efforts on educating Members of Congress and their staffs about the unique characteristics of plasma protein therapies that differentiates PPTA member companies' therapies from traditional pharmaceutical and biotechnology industries. However, along with education and other priorities such as Follow-On-Biologics, PPTA continues to advocate for permanent and comprehensive solutions to the IVIG patient access issue.

Moreover, PPTA is working closely with stakeholder organizations to identify possible legislative opportunities. Currently, the entire community of immunoglobulin (IG) users is eagerly awaiting the results of two government sponsored IVIG marketplace studies that were initiated as a result of the disruption in Medicare beneficiary access to IVIG that resulted from reimbursement methodology changes put in place by the Medicare Modernization Act (MMA). The results of the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and Assistant Secretary of Planning and Evaluation (ASPE) IVIG marketplace studies will be

pivotal in helping to shape PPTA and its consumer allies legislative strategy moving forward.

OIG Report on IVIG: The HHS OIG final report on IVIG, expected to address manufacturing, distribution, and physician/provider aspects of the marketplace, is reported to be complete and awaiting final review by Health and Human Services (HHS) and should be released during Q1 2007.

Note: the OIG Report is a document that was requested by Congress in August 2005. Several key policy makers have signaled a desire to wait to act on the IVIG access issue until this report is released. It is vital to the public debate and more important to restore patient access to IVIG Medicare beneficiaries that this report be released expeditiously. In your meetings with Members of Congress please consider asking for their assistance in assuring a timely release of this pivotal report.

ASPE Report on IVIG Access: This study, requested July 2006 and directed by HHS' office of the Assistant Secretary for Planning and Evaluation (ASPE), is being performed by an independent third-party group (Eastern Research Group), charged to develop an analysis of supply, distribution, demand, and access issues related to IVIG. As reported last fall, ASPE conducted a "Town Hall" meeting on September 28, 2006 in Arlington, Virginia where PPTA submitted written comments and also secured an oral presentation. In addition, Members of Congress have also recently weighed-in on the urgency of the ASPE study release. For example, at a February 8th Ways and Means HHS budget

hearing, with guidance from one of PPTA's member companies, Congressman Kevin Brady (R-TX) asked Secretary Leavitt when Congress can expect completion of the ASPE study on IVIG. Secretary Leavitt responded that he would have to consult with others within the agency to get an accurate timeframe for the study's release.

The completed ASPE study is reportedly awaiting final clearance by HHS and it is expected to be released in Q1 2007.

Congressional Oversight of IVIG

In a January 17, 2007 letter from House Committee on Ways and Means Chairman Charlie Rangel to House Government Reform Chairman Waxman and House Government Administration Chairman Millender-McDonald outlining the hearing and oversight topics for the full committee and the subcommittees, Chairman Rangel listed IVIG as an oversight topic for the Subcommittee on Health under Medicare Part A and Part B issues.

According to Ways and Means staff, this oversight letter is a House Rules requirement and included a "laundry list" of every possible hearing they are considering. During the 109th Congress, Ways and Means staff indicated that IVIG would likely be part of a broader hearing on Part B drugs. Ways and Means staff confirmed to PPTA that Subcommittee on Health Chairman Stark has not decided on exactly what hearings he will conduct during the 110th Congress, but stated nothing will take place until the budget process is complete. Moreover, PPTA would like to underscore that these are potential hearing topics for the entire 110th Congress, not just the First Session.

In addition, the House Ways and Means Subcommittee on Health staff have also informed PPTA that any potential oversight or hearing on the IVIG Access issue will not

likely occur until both the OIG and ASPE IVIG marketplace studies are complete. In preparation for committee activity and potential oversight of the IVIG Access situation, PPTA staff will continue its outreach to key members of the Ways and Means and the Subcommittee on Health to communicate and share information.

Follow-On-Biologics

The United States Senate Committee on Health, Education, Labor, and Pensions (HELP) held a hearing on follow-on biologics on Thursday, March 8, 2007. The scope of the hearing was on the broader issue of follow-on biologics, rather than the specific details of Senator Schumer's (D-NY) "Access to Life-Saving Medicine Act", S. 623. In the days leading up to the hearing, PPTA staff met with Senate HELP Committee staff to highlight the complexities and lack of interchangeability of plasma protein therapies and discuss the medicines' treatment in the European EMEA Biosimilar guidelines. PPTA's primary concern is assuring patient access to safe, effective, and high quality plasma protein therapies. PPTA discussions with Ranking Member Enzi's (R-WY) staff earlier in the week led to a question from Senator Enzi to Nicholas Rossignol, Administrator, European Commission Pharmaceuticals Unit. Senator Enzi asked Mr. Rossignol why plasma protein therapies are exempt from the EMEA Biosimilar regulations. Mr. Rossignol responded that while legally they are per se not exempt, they are however, complex proteins (plasma proteins therapies and vaccines) that are scientifically barred from generic application.

Similarly, over the past several weeks, PPTA has met with the staffs of the HELP Committee Chairman Kennedy (D-MA), Ranking Member Enzi (R-WY), Senators Dodd (D-CT), Murray (D-WA), Hatch (R-UT), Gregg (R-NH), Allard (R-CO) Isakson (R-GA) Mikulski (D-MD) on PPTA's

concerns with S. 623. Expressing safety concerns, Members on both sides of the aisle have expressed concern with the bill as introduced.

Senator Hillary Clinton (D-NY), however, is pressuring the committee to get the bill out of committee by March 28, 2007, or she will circumvent regular order and attach it as an amendment during that mark up on March 28, 2007 to the Prescription Drug User Fee Act, the Medical Device User Fee Act, the Grassley-Dodd Food and Drug Administration Act of 2007, or the Enzi-Kennedy Enhancing Drug Safety and Innovation Act of 2007, among other FDA bills coming out of committee. March is “FDA month” and there is a push to get many of these bills signed into law as soon as possible. Senator Clinton would also consider introducing S. 623 as an amendment on the Senate floor to a broad FDA reauthorization package of which many of the aforementioned bills would be a part – that broad FDA package would also likely include Drug Re-importation and the Mammography Quality Standards Act. Some Hill staff believe S. 623 is likely to be bundled into the FDA package regardless of what happens to S. 623 in committee. Many of these FDA reauthorization bills are “must pass” but it is unclear how invested Senate leadership is in a substantial floor debate which issues such as follow-on biologics and importation would create.

Members of the committee appear committed to work together to reach a compromise on language, but many see this timetable as problematic and would prefer more time to give proper consideration to the bill. PPTA will continue monitoring this issue as well as the Senate’s bicameral companion, House bill H.R. 1038 introduced by Congressman Waxman (D-CA). PPTA will continue to meet with Members of Congress from both the House and Senate to discuss the unique characteristics of plasma protein therapies to differentiate the life saving therapies from traditional

pharmaceuticals as they relate to the Follow-On-Biologics issue.

State Action

Universal Health Care Update

Universal health coverage has emerged as a central focus of state legislatures thus far in 2007. This focus is fueled by the increasing number of uninsured Americans (approximately 47 million or nearly 16% of the U.S. population). Other factors include the declining number of employers offering health insurance to their employees; improved fiscal conditions in some states; and perhaps most importantly, a lack of federal action. Universal health care initiatives in the states are notable for PPTA because they may provide an opening to also pass quality of care protections for patient populations who utilize plasma protein therapies.

14 years ago, the insurance industry was successful in defeating the so-called Clinton Health Care plan that would have guaranteed insurance for all Americans. Since then, with the exception of the late 1990s when managed care achieved some cost-savings, premiums have continued to rise much faster than overall inflation and the number of uninsured has risen nearly 20%. The next two years will likely be a crucial time in the history of the U.S. health care system. At least 13 states have introduced universal health care bills so far in 2007. Of these, seven are comprehensive legislation while the others either call for studies on how to design universal health care systems, care for all children or funding for the purchase of insurance for select populations.

Quality of Care Legislation

Since the beginning of 2007, PPTA has been focusing significant efforts on quality of care legislation. PPTA has held two stakeholder meetings—one on January 10th and the other on February 28th to discuss proposed legislation and to obtain input from key stakeholders. Through this process, we have built significant consensus on the draft language and identified strategies moving forward. Additionally, we have identified four first tier target states at this point—Minnesota, Florida, California, and Texas. PPTA will be contacting consumer groups in the coming weeks to plan legislative visits in these states in April and May to discuss the quality of care legislation, as well as the state resolutions we are pursuing, to raise awareness on key issues relating to access to plasma protein therapies.

Arizona IVIG Hearing

PPTA staff attended a hearing of the Arizona Senate Committee on Health hearing relating to Medicare access to IVIG. A representative from the Neuropathy Action Foundation introduced the panel of witnesses which included the mother of a consumer who utilizes IVIG, a physician treater, and a distributor. The primary message from the witnesses was that inadequate reimbursement in Medicare has resulted in impaired access to IVIG therapies. The outcome from the hearing is members of the Senate Committee on Health will sign on to a letter to the Arizona Congressional Delegation asking congress to take swift action in finding a solution to address the problems with access to IVIG. PPTA's statement prepared for the Hearing is attached for your review.

Other Issues

The Food and Drug Administration is requesting nominations for voting members to serve on Blood Products Advisory Committee in the Center for Biologics Evaluation and Research (see attached). Now is the time to nominate knowledgeable people who would not have unacceptable "conflicts of interest."

*****MARK YOUR CALENDARS*****

PPTA will host the following events:

1. North America Planning Meeting; March 20-21 in Washington DC.
2. PPTA Fly-in; May 8 in Washington DC.
3. Stakeholder Dinner Meeting; May 10 in conjunction with the Advisory Committee on Blood Safety and Availability meeting May 10-11, 2007. [The venue has not been published for the ACBSA.]
4. 2007 Plasma Protein Forum; June 5-6 in Reston, Virginia.

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PPTA Staff is always available to attend consumer organization functions, make presentations, and assist in developing advocacy strategies and messages, as appropriate, with consumers. Please contact PPTA Staff at any time to discuss these activities.

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*This PPTA publication aims to keep Stakeholders apprised of evolving state and federal health policy developments. Periodically, PPTA will provide updates via e-mail during the State and Congressional legislative sessions. **To provide feedback or to add colleagues to the distribution list, please contact Diana Krueger at the Association.***

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New Codes Established for Immune Globulin Products

On April 18, 2007, the Centers for Medicare and Medicaid Services (CMS) released a file containing Healthcare Common Procedure Coding System (HCPCS) code updates for the third quarter of 2007. This file reflects the establishment of new, brand specific HCPCS codes for four intravenous immune globulin (IVIG) products, a brand specific HCPCS code for a hepatitis B immune globulin product, and a brand specific HCPCS code for a Rho(d) immune globulin product. The new codes, which will be effective as of July 1, 2007, are as follows:

- Octagam – Q4087
- Gammagard – Q4088
- Flebogamma – Q4091
- Gamunex – Q4092
- Rhophylac – Q4089
- HepaGam – Q4090

Advocating for brand specific reimbursement for IVIG has long been an Association priority. Upon its review of a December 22, 2006 CMS transmittal that addressed reimbursement for sodium hyaluronate products, PPTA realized CMS put itself in a position to consider reimbursing several IVIG therapies according to their individual average sales price (ASP). The transmittal stated that CMS gave section 1847A of the Social Security Act (the ASP statute) “careful examination,” and reversed the earlier

decision to include all sodium hyaluronate products into a single HCPCS code, J7319, and “establish[ed] separate payment for sodium hyaluronate products that have come onto the market since October 2003.”

The HCPCS code changes for IVIG appear to be the first changes resulting from the agency's announcement in February of 2007 that it would conduct a review to ensure that it is treating drugs and biologicals appropriately under the ASP statute. CMS based this February announcement on the sodium hyaluronate decision. Although many Capitol Hill insiders believe political pressure and fear of legal action were behind CMS' willingness to finally acquiesce to the strong legal argument to maintain and provide brand specific reimbursement for some products involved in the sodium hyaluronate issue, this plain reading of the ASP statute provided an opportunity for manufacturers of similarly situated products to push their case as CMS had put itself in a position to listen. On February 21, 2007, PPTA sent a letter to the agency seeking clarification of this interpretation of the ASP statute in the sodium hyaluronate decision and its impact on IVIG therapies.

The ASP statute mandates that single source drugs and biologicals have their ASP payment rates computed based on their own ASP information unless they were in the same HCPCS code as another product as of October 1, 2003 (in which case they could be treated as a multiple source drug and have their ASP rate computed based on the ASP information of all products in the code). It appears that all of the code changes noted above are for products that were incorrectly being treated as multiple

source drugs because they were being billed in a code that, as of October 1, 2003, had more than one single source product in the same code. For each product, this coding change is the first step in the process of correcting the ASP payment rate, as the agency will have to compute the ASP rate for each product based on the ASP information submitted for each. This should appear in the ASP file CMS will release for the third quarter of 2007, likely in the latter part of June.

Calculating the ASP payment rate for IVIG therapies according to their own ASP information will improve Medicare beneficiary access because it affords physicians the opportunity to prescribe IVIG therapies based on the clinical efficacy for an individual patient, rather than on pricing considerations. The appetite on Capitol Hill and in the Administration to make additional reimbursement changes to IVIG to correct the shortfall physicians face in acquiring and administering these lifesaving therapies may be lessened in the near future as a result of this decision. Moreover, this decision is not as much recognition by CMS of the unique qualities of IVIG and its marketplace, but a proper legal interpretation of existing statute that the agency was forced to finally make for a variety of political reasons. PPTA, however, will continue to seek opportunities to improve access for Medicare beneficiaries requiring these therapies as well as work to prevent any efforts by CMS to seek legislation giving it legal authority to bundle all drugs into single HCPCS code and reimburse according to the volume-weighted average of that code.

“What Can I Do?”

On May 15, 2007, CMS will conduct its public meeting on HCPCS codes. Because some manufacturers filed applications for separate codes for some IVIG therapies, the HCPCS coding panel will formally consider these applications at this meeting. Although it will apply its recent coding decision when

it makes a final decision for these applications in November, PPTA asks that its members attend this meeting, thank CMS for its proper interpretation of the ASP statute, and urge CMS to convert the temporary Q codes that are effective July 1, 2007 to permanent J codes, effective by January 1, 2008. Explain that this change in reimbursement policy according to the plain reading of the ASP statute will help improve patient access difficulties, so CMS must give assurances to these Medicare beneficiaries requiring IVIG that CMS is committed to ensuring these patients receive therapies that best suit their individual needs and the establishment of J codes for these therapies will provide such assurances.

The following is the link to the Excel spreadsheet on the CMS web site:

http://www.cms.hhs.gov/HCPCSReleaseCodeSets/02_HCPCS_Quarterly_Update.asp#TopOfPage (see: [Other Codes July 2007 \[Excel ZIP 31KB\]](#))

OIG and ASPE IVIG Marketplace Studies

In order to better understand the origin of the access impediments for Medicare beneficiaries, on August 24, 2005, the Committees on Energy and Commerce and Ways and Means of the United States House of Representatives jointly requested in the summer of 2005 that the Department of Health and Human Services (HHS) Office of Inspector General (OIG) examine "the current state of pricing and supply of intravenous immune globulin (IVIG)." According to Herb Kuhn, acting deputy administrator of the Centers for Medicare and Medicaid Services, HHS commissioned a second study during the summer of 2006 for the purpose of "better understanding" the IVIG marketplace and "elevating access and reimbursement concerns from patients and physicians." The HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted with Eastern

Research Group to examine supply, distribution, demand, and access issues associated with IVIG. On September 28, 2006, ASPE conducted a Town Hall meeting for the purpose of obtaining public comment on IVIG access problems. An overwhelming majority of those patients and physicians commenting at the meeting argued that inadequate Medicare reimbursement for IVIG is the chief reason for IVIG access problems for Medicare beneficiaries.

On April 26, 2007, HHS released the OIG Report, *Intravenous Immune Globulin: Medicare Payment and Availability*. The ASPE study, however, has not yet been released. The OIG Report had two objectives: (1) to determine whether hospitals and physicians could purchase IVIG at prices below the Medicare payment amounts in 2005 and 2006; and (2) to determine whether IVIG was readily available to physicians and distributors in 2005 and 2006.

The OIG demonstrated a strong understanding of the unique characteristics of IVIG therapies and their marketplace, including the allocation of therapies. The report indicated that the increase in IVIG sales at prices below the Medicare payment in the last quarter for which it collected data is a positive trend. Specifically, during the third quarter of 2006, the OIG reports that 56% of IVIG sales to hospitals and 59% of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amount. The OIG attributed this substantial increase in sales at or below the Medicare price to the payment amounts for IVIG catching up with the actual sales price because of the six month lag.

The OIG cautioned that across-the-board price increases will cause doctors to continue to struggle for the subsequent six months, before catching up. CMS wants to explore this six month lag in relation to

distributor markups, which it heavily criticized.

Because the average sales price calculations include sales to all classes of trade and do not explicitly include the markup, which may cause the actual acquisition cost of IVIG to exceed the Medicare payment amount, Medicare beneficiaries using IVIG may have increased difficulty obtaining this therapy in the preferred site of service. In Q4 of 2005, the OIG reported that distributor markups for non-contract sales (sales of IVIG by distributors to providers) ranged from 5 to 49%. CMS also wants to compare IVIG distributor markups to that of other drugs and noted "if distributor markups are materially higher for IVIG than for other drug and biologicals, it could have a significant impact on IVIG availability." The OIG explained that distributor markups have a greater effect on non-contract prices because contract prices are set, prenegotiated prices between the GPOs and manufacturers. OIG also noted that some manufacturers place limits on these markups in contracts with distributors.

The OIG also expressed concern that physicians and distributors are reporting problems with availability. The OIG recognized contractual obligations of manufacturers to allocate therapies and reimbursement shortfalls as contributing factors to these access problems, while indicating that the federal agencies and most providers believe supply is sufficient.

CMS urged the OIG to explore the increase in off-label use by providers, as well as the secondary market.

PPTA will await the release of the ASPE study.

The following is the link to the OIG Report:

<http://oig.hhs.gov/oei/reports/oei-03-05-00404.pdf>

Follow-On-Biologics

Congress is making a legislative effort to authorize the Food and Drug Administration (FDA) to approve abbreviated applications for a license of a biological product. Although follow-on therapies in the plasma protein industry is very unlikely at this time, because plasma protein therapies are not interchangeable and have a high risk of immunogenicity in patients, PPTA does not believe the creation of an abbreviated pathway is appropriate for these therapies.

The majority of activity has occurred in the Senate. Although Chairman Ted Kennedy (D-MA) did not include follow-on biologics language in the April 18, 2007 mark up by the Senate Committee on Health, Education, Labor, and Pensions (HELP) of the Prescription Drug User Fee Amendments of 2007, S. 1082, which includes the reauthorization of the Prescription Drug User Fee Act, as well as drug safety, and FDA reform language. This bill is being debated on the Senate floor during the week of April 30th. At press time, leadership has not reached any agreements on the scope of amendments, meaning there are no limits on the number of germane amendments that may be considered, but all can be filibustered. This could provide an opportunity for Senators Hillary Clinton (D-NY) and Chuck Schumer (D-NY) to offer a revised version of S. 623, the Access to Life-Saving Medicine Act, as an amendment to the FDA package. Chairman Kennedy and Senator Orrin Hatch (R-UT) have also developed alternative language. There is, however, a strong belief that an agreement to consider follow-on biologics and prescription drug importation separately from this FDA bill, most likely in June.

Because PDUFA expires on September, 30th and the FDA would lose a tremendous size of its budget without the user fees paid by brand name pharmaceuticals to expedite

reviews of new drugs and biologics, Capitol Hill insiders see it as “must pass legislation,” which is why drug safety and FDA reform are already attached to it, and why there is a strong interest on the part of proponents of follow-on biologics and importation to attach such language to this broad package.

Meanwhile in the House, Energy and Commerce Committee Chairman Dingell (D-MI) is expected to determine whether or not a compromise follow-on-biologics bill will be attached to the House of Representatives PDUFA reauthorization bill. Chairman Dingell does not want to include anything in the PDUFA reauthorization bill that will stall the critical FDA prescription drug user fee program from passing and the inclusion of H.R. 1038 as currently drafted will likely cause a significant delay in passing the bill. A decision of whether follow-on-biologics will be included the House PDUFA reauthorization bill will not be decided until the Energy and Commerce committee holds a hearing on the issue which is scheduled for Wednesday, May 2, 2007.

PPTA has been very active in meeting with the leadership of the Senate HELP Committee by educating them on unique characteristics, complexity, and lack of interchangeability of plasma protein therapies and the need to give them special consideration in any follow-on-biologics legislation. PPTA meetings on follow-on biologics that have taken place in the last two months include Representative Henry Waxman (D-CA), Senate HELP Chairman Kennedy, Ranking Member Mike Enzi (R-WY), Senators Chris Dodd (D-CT), Tom Harkin (D-IA), Barbara Mikulski (D-MD), Patty Murray (D-WA), Hillary Clinton (D-NY), Chuck Schumer (D-NY), Judd Gregg (R-NH), Johnny Isakson (R-GA), Orrin Hatch (R-UT), and Wayne Allard (R-CO). PPTA also has key meetings on follow-on biologics scheduled at the fly-in with Senators Sherrod Brown (D-OH), Richard Burr (R-NC), and Pat Roberts (R-KS), as well as a meeting on May 10, 2007

scheduled with Senator Jeff Bingaman (D-NM).

“What Can I Do?”

Because a legislative carve out is extremely unlikely to occur, according to the key Members of Congress involved in this debate, PPTA has developed Report Language on plasma protein therapies for Congressional consideration. At the upcoming fly-in meeting on May 8th, PPTA will provide participants with draft report language that the participants should advocate Members of Congress to consider including in any Report Language it may draft as the follow-on biologics debate moves forward.

State Action

Quality of Care

PPTA has led efforts aimed at raising awareness as to the importance of quality of care legislation by working to enact proclamations and resolutions in Minnesota, Florida and Maine calling for increased awareness of the importance of access to quality care for patients who utilize plasma protein therapies. PPTA views the proclamations and resolutions as an important incremental step in laying the groundwork for legislation addressing quality of care for the plasma protein therapies community.

PPTA staff attended a meeting at the Alabama Medicaid Department regarding reimbursement of hemophilia factor concentrates on February 20th. The Department is seeking input from representatives of industry, home care providers and patient groups in developing a reimbursement methodology that ensures access to quality care. The Department has indicated its commitment to including quality of care protections in any new regulations. PPTA, with input from member companies and consumers, will work closely with

Alabama Medicaid on this issue. The Department has circulated a draft proposal based on feedback from the various interested parties.

PPTA staff and representatives from member companies attended the Hemophilia Awareness Day on April 17th in Harrisburg, Pennsylvania organized by the Delaware Valley and Western Pennsylvania chapters of the National Hemophilia Foundation. The event included a press conference and visits with key members of the Pennsylvania legislature. PPTA staff had the opportunity to meet with four members of the legislature, including the chairman of the House Finance Committee. The primary purpose of the event was to garner support for legislation that was introduced in the Pennsylvania assembly yesterday HB 1105, "The Hemophilia Standards of Care Act" (attached). If enacted, the legislation would require insurers in Pennsylvania to: 1) provide access to state recognized hemophilia programs; 2) provide access to specialized coagulation laboratories; 3) provide access to the full range of blood clotting factor therapies; 4) provide access to full-service pharmacy providers and home care services; and 5) require screening for von Willebrand's disease in women who are facing a hysterectomy for excessive menstrual bleeding. The legislation has been referred to the House Health and Human Services Committee. HB 1105 currently has 72 cosponsors. 102 members of the Pennsylvania House constitute a majority. The introduction of this legislation represents another important step in the efforts undertaken by the consumer community and industry to address quality of care.

Patient Access

PPTA attended a press conference in Sacramento held by the Neuropathy Action Foundation on March 28. The primary

purpose of the press conference was to ask key members of the California legislature to contact the California Congressional delegation to urge Congress to take swift action to address IVIG patient access issues. The press conference included remarks from the Neuropathy Action Foundation, a representative from the California Medical Association, and a member of the California Assembly. Members of the legislature signed a letter to the California Congressional delegation explaining the issues affecting access to IVIG and urging action. Several IVIG consumers were also in attendance but did not make remarks. An article highlighting IVIG access appeared in the Monday, April 3, 2007 edition of the Sacramento Bee (attached).

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PPTA will host the following event:

- 2007 Plasma Protein Forum; June 5-6 in Reston, Virginia.

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A significant achievement on behalf of patient access to blood clotting factor therapies was achieved when PPTA challenged the federal Medicare reimbursement agency Centers for Medicaid & Medicare Services (CMS). The CMS published a list of the top 20 physician-administered multiple source drugs dispensed under the Medicaid program in terms of dollar volume. Factor viii (J7190) and Factor viii recombinant (J7192) were included in the "Medicaid Top 20 Multiple Source Physician-Administered Drugs" list (published in December 2006). At the direction of PPTA staff, PPTA's counsel sent a February 2007 letter to CMS objecting to listing these therapies as multiple sources. PPTA argued for removal from this list based on the fact that these therapies meet the applicable definition of "single source drugs" of the U.S. Social Security Administration and should not be included in a list of multiple source drugs. CMS acknowledged it was an error, and assured PPTA that Factor viii and Factor viii recombinant would be removed from the multiple source lists and correctly categorized as sole source. This is significant for patient access because it further emphasizes that plasma protein therapies are not interchangeable, are not generic and physicians must have access to all therapies so they can prescribe what is most efficacious for their patients.

Follow-on Biologics Update

On June 27, 2007, the U.S. Senate Committee on Health, Education, Labor, and Pensions reported out the "Biologics Price Competition and Innovation Act of 2007." This bill provides an abbreviated application and approval process for follow-on biologics if the applicant demonstrates its product is either biosimilar to or interchangeable with the reference product. The bill is seen as a compromise between Chairman Edward Kennedy (D-MA), Ranking Member, Michael Enzi (R-WY), Hillary Clinton (D-NY) and Orin Hatch (R-UT). Moreover, the legislation does not provide for any exemptions to a specific product class.

The Senate bill has bypassed all floor action and it will be added to the FDA Revitalization Act, S. 1082, once a conference committee meets to reconcile the differences between the Senate and House versions of the FDA bill. However, On July, 11 the House passed its own FDA package that includes the must-pass Prescription Drug User Fee Act (PDUFA) reauthorization. Energy and Commerce Chairman Dingell (D-MI) did not include follow-on biologics in the final package, thus, it is unclear if the House will raise any points of order to block follow-on biologics from the final FDA package in the House and Senate conference.

In the Executive Branch, the Department of Health and Human Services opposes many of the provisions in the Senate bill: In a recent letter from Secretary Michael Leavitt to Chairman Ted Kennedy (D-MA) the Secretary expressed specific concern with including "vaccines and blood products," the

interchangeability language, and lack of mandatory guidance. The letter explains the "science does not exist to adequately protect patient safety and ensure product efficacy through an abbreviated follow-on pathway for all biologic products, and questions exist whether some products, such as vaccines or blood products, would ever lend themselves to such a pathway." Leavitt calls for the Kennedy-Enzi-Clinton-Hatch bill to be "amended to specifically exclude products such as vaccines or blood products, and to require periodic reports to Congress advising on the state of the science and whether science supports expanding the scope of the legislation." This position is consistent with what PPTA has advocated and consistent with bills introduced by Rep. Jay Inslee (D-WA) and the Gregg-Burr-Coburn bill introduced in the Senate.

In the coming weeks, PPTA will continue to meet with members of the House Committee on Energy and Commerce and advocate to exempt plasma protein therapies.

Congress Introduces H.R. 2914, the 'IVIG Medicare Access Act'

Through the tireless efforts of the Immune Deficiency Foundation (IDF), the 'IVIG Medicare Access Act' or H.R. 2914, was introduced in the House of Representatives by Congressman Kevin Brady (R-TX) and 17 other original co-sponsors from both sides of the aisle. This bipartisan legislation directs the Secretary of Health and Human Services to review the OIG and ASPE reports and other surveys to update the Medicare payment to provide appropriate reimbursement related to the furnishing of IVIG. In addition the bill also provides for an IVIG home infusion benefit that will help Medicare beneficiaries with primary immune deficiency diseases access IVIG in their homes. Lastly, the bill requires CMS to conduct two beneficiary surveys over three years to measure changes in patient access

to IVIG and providers, as well as changes in health outcomes.

Currently, legislative opportunities for H.R. 2914 are extremely fluid so PPTA and others in the IVIG community will be actively working with Members of Congress in addressing this current patient access priority.

"What Can I Do?"

Readers are encouraged to log onto to the IDF's website at www.primaryimmune.org and click on the 'Action Alert' banner on the right hand side to find your local U.S. Representative and urge them to support this important piece of legislation.

New Codes Implemented for Immune Globulin Products

The CMS implemented new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG products and two other immune globulin products in response to PPTA's February letter to Health and Human Services CMS Division's General Counsel requesting that IVIG products that were not on the market as of October 1, 2003 be treated similarly to certain sodium hyaluronate products and be assigned separate codes to be consistent with the average sales price (ASP) statute.

PPTA has long advocated for product specific Health Care Common Procedural System (HCPCS) codes for intravenous immune globulin (IVIG) products. CMS' decision granting new product specific codes for lifesaving IVIG is critical to patient access and a significant victory for the IVIG community.

340 B Expansion Initiatives

Recent legislation has been introduced in both the House and the Senate that would expand the 340B Drug Pricing Program in several instances. PPTA is in the process of outreach to the drafters of the 340B

Program Improvement and Integrity Act of 2007, S. 1376, introduced by Senators Jeff Bingaman (D-NM) and John Thune (R-SD), and H.R. 2606, introduced by Representatives Bobby Rush (D-IL), Jo Ann Emerson (R-MO), and Bart Stupak (D-MI). The staff of these Members with whom PPTA has already met have expressed an interest in pushing the use of this legislative language to help pay for the reauthorization of the State Children's Health Insurance Program (SCHIP).

It has been reported that Senate Finance Committee leaders have reached a compromise on the SCHIP at five years for an estimated cost of \$35 billion, primarily offset by a 61-cent hike in the federal tobacco tax. Finance Chair Max Baucus (D-MT) will reportedly drop the bipartisan bill on Friday, July 13 for a markup the following Tuesday.

In the House, Democrats are expected soon to unveil a \$90 billion omnibus bill that includes SCHIP reauthorization, Medicare Advantage cuts, physician payment and Part D reforms. This has led to speculation that the Democratic strategy is to pass a clean SCHIP bill in the Senate, then load it up with other Medicare provisions during conference. To help offset the costs of expanding the SCHIP program, tobacco tax hikes and scaling back Medicare Advantage are likely in the House reauthorization efforts.

The Administration has clearly indicated that they do not favor the Democratic led Senate and House SCHIP expansion programs as the Administration sees the efforts as an attempt for universal health care coverage and a threat to private insurance markets. President Bush has urged Congress to take greater steps to make private insurance more affordable through tax reforms, rather than crowding out private coverage with government-run programs.

As the SCHIP program is a top legislative priority in both the House and the Senate,

PPTA will continue to monitor and seek to improve the 340 B legislative initiatives in Congress in coming weeks and months.

State Action

Quality of Care

The Minnesota Senate introduced SF 2290 focusing on ensuring quality of care for all patients utilizing plasma protein therapies on May 10. The legislation is being referred to the Senate Health, Housing and Family Security Committee. With this bill introduction, there are now two states (Pennsylvania is the other) actively considering quality of care legislation based upon the existing New Jersey law. The Minnesota legislation would, if enacted, require that:

- 1) Consumers have access to qualified home care providers with the requisite expertise;
- 2) Consumers have access to specialized laboratories; and
- 3) Screening for von Willebrand's disease prior to undergoing a complex gynecological surgical procedure.

This represents an important victory in the efforts of the community to ensure that consumers receive high quality care. It is the result of members of the patient community and industry working together to achieve an important goal.

PPTA staff participated in the Hemophilia Council of California annual legislative day on May 16, 2007. More than 100 people took part in this important event in Sacramento. Attendees included consumers and their families, industry representatives, and physician experts. PPTA staff had the opportunity to meet with key members and staff of the California legislature, including the office of the House Appropriations Committee Chairman. PPTA is continuing its work with the Hemophilia Council with an

eye toward joint introduction of quality of care legislation in California in 2008.

Patient Access

A member of the Texas House of Representatives approved a resolution aimed at raising awareness as to the importance of access to IVIG on May 29. The resolution was the result of the cooperative efforts of the consumer community and industry. This accomplishment represents a further incremental step in the community's efforts to ensure access to therapies and quality of care. In Texas, it is hoped that the resolution will be an important first step in outreach efforts to policymakers and the media.

Universal Access to Health Care

There has been a significant amount of activity in 2007 relating to universal access to health care initiatives in the states. At least 20 states have considered some type of universal access legislation in 2007. Initiatives have passed in Indiana and Washington state although neither of these are comprehensive plans but rather incremental in nature. Indiana's new law provides tax credits for certain employee wellness programs and expands the scope of the state's high risk pool. Washington's law expands access to coverage for children through state-run programs but does not yet reach 100% coverage for children.

The California Legislature is also attempting to address the problems of the uninsured. The California Assembly passed the California Health Care Reform and Cost Control Act (AB 8) on June 7, 2007. The bill is now moving through the Senate. The Senate Committee on Health recommended its passage on July 11, 2007. This bill is attempting to reform the health care system by making broad changes to the California system of health care delivery.

AB 8 requires employers to contribute funds towards health benefits for their employees. The bill allows children that do not qualify for federal funds because of their immigration status to participate in Medicaid and SCHIP programs and raises the income eligibility standard for these programs to 300% of the federal poverty level. Finally, the bill includes a requirement that state health care programs implement best practice standards for chronic diseases.

With health care being considered the leading domestic policy issue in the coming presidential campaign, activity in the states in this area is likely to continue through 2008.

PPTA Staff is always available to attend consumer organization functions, make presentations, and assist in developing advocacy strategies and messages, as appropriate, with consumers. Please contact PPTA Staff at any time to discuss these activities.

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Health Policy Update

Federal Action

Medicare Patient Access

PPTA works with Congress, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) in communicating the importance of unfettered consumer access to all plasma derived and recombinant analog therapies (collectively plasma protein therapies) while at the same time educating policymakers on the unique, niche biologics industry that produce these lifesaving medicines.

CMS Releases CY 2008 Final Rules for both the Physician Fee Schedule and the Hospital Outpatient Prospective Payment Systems

On November 2, 2007, the Centers for Medicare and Medicaid Services (CMS) published its CY 2008 Final Rules for both the Physician Fee Schedule (PFS) and the Hospital Outpatient Prospective Payment System (OPPS). In the OPPS Rule, PPTA was successful in its efforts in advocating for permanent Healthcare Common Procedural Coding Systems (HCPCS) for the reimbursement for several products of intravenous immune globulin. Effective July 1, 2007, CMS created new Q codes for 6 immune globulin therapies. All such therapies will now receive permanent J codes effective January 1, 2008. PPTA has long advocated for product specific reimbursement as an effective way for consumers to get the best treatment available to them based on clinical efficacy decisions, not provider reimbursement factors.

In addition, as requested by PPTA, CMS will continue to provide reimbursement for IVIG preadministration-related services under both the PFS and the OPPS. Although CMS will continue this payment code, G0332, at the current PFS level under the PFS in CY 2008, it will reimburse this code at about only half of the current OPPS level under the OPPS for CY 2008. This reduction in reimbursement in the hospital outpatient department setting is a result of CMS moving G0332 from a New Technology Ambulatory Payment Classification (APC) to a Clinical APC, which requires reimbursement to be based on hospital claims data. PPTA strongly objected to this payment reduction in its OPPS comment letter on the proposed rule not only because of the hospital billing errors that led to the use of flawed data by the agency but also because of the current patient access problems reported by consumer organizations as well as by the Department of Health and Human Services (HHS) in two separate studies of the IVIG marketplace it conducted earlier this year. PPTA had the ability to make these arguments regarding the data used by CMS because it had contracted with a third party vendor to analyze the 2006 hospital claims data that the agency used to justify the provider payment reductions.

Although CMS validated this independent third-party analysis, specifically that hospitals only billed for G0332 on 49% of claims dates on which IVIG administration was billed, the agency balked at changing its course from its proposed rule. In describing its unwillingness to recognize the impact of the improper billing by hospitals during the relevant period, CMS reasoned that annual coding changes are a “well-

established and predictable process that has been in place for some time. Hospitals are well aware of this practice because they have successfully implemented these changes each year.” In its efforts to advocate for consumer access to all plasma protein therapies, PPTA will be reaching out to hospital billing departments to inform them of the underutilization of the IVIG preadministration related services payment code.

In addition to the cuts in the IVIG preadministration code under the OPSS, CMS also finalized its proposal to reimburse drugs and biologicals without pass-through status that are not packaged at ASP 5%. CMS will now pay for most physician administered drugs in the hospital outpatient department at ASP +5% rather than the current ASP +6%. The APC Advisory Panel at its September 2007 meeting even recommended that CMS at the very least maintain ASP+6% reimbursement for IVIG and blood clotting factor. CMS did not agree with this recommendation and also dismissed PPTA arguments for consistent reimbursement across both the physician office and hospital outpatient department sites of service.

For blood clotting factor, pursuant to statute, because of a 4% increase in the CPI for medical care for the twelve month period ending in June 2007, both final rules announced that the furnishing fee for blood clotting factor will be \$0.158 per unit of clotting factor for CY 2008. CMS finalized its proposal that beginning for CY 2009, beginning for CY 2009, CMS will announce the updated blood clotting factor furnishing fee via program instructions and via a Web posting. PPTA supported this proposal.

IVIG Medicare Access Act (H.R. 2914)

Last June, Representative Kevin Brady and 17 original co-sponsors introduced H.R. 2914, the IVIG Medicare Access Act. Since the bill's introduction, the Immune Deficiency Foundation (IDF) has worked

tirelessly with other stakeholder organizations including PPTA to increase awareness of this legislation in both the House and the Senate. Currently, the total numbers of sponsors in the House of Representatives is 31. This bipartisan legislation directs the Secretary of HHS to review its recent studies of the IVIG marketplace and other surveys in order to update the Medicare payment to provide appropriate reimbursement related to the furnishing of IVIG in both the physician office and the hospital outpatient department. In addition the bill also provides for an IVIG home infusion benefit that will help Medicare beneficiaries with primary immune deficiency diseases access IVIG in their homes. Lastly, the bill requires CMS to conduct two beneficiary surveys over three years to measure changes in patient access to IVIG and providers, as well as changes in health outcomes.

Because legislative opportunities for H.R. 2914 are extremely fluid as the end of the First Session of the 110th Congress rapidly approaches, PPTA will continue to work with its members and others in the IVIG community to ensure Congress considers some of the language in H.R. 2914 in any broad Medicare legislation.

“What Can I Do?”

Readers are encouraged to log onto the IDF website (www.primaryimmune.org) and click on the ‘Action Alert’ banner on the right hand side to find your local U.S. Representative and urge them to support this important piece of legislation.

Outreach/Education

Over the past few months, PPTA ran a series of ads (see attached) in *Roll Call* and *The Hill*. The ads serve the dual purpose of: educating policymakers on unique, life saving plasma protein therapies and the importance of patient access to care as well as differentiating these therapies from traditional pharmaceuticals.

State Action

Market Access (State Medicaid)

For the remainder of 2007 PPTA will focus on pursuing quality of care legislation in Minnesota and Pennsylvania as well as opposing Medicaid reimbursement reductions that would negatively impact patient access to plasma protein therapies (i.e., Washington and Alabama).

Washington

PPTA staff was informed that the state of Washington has been reimbursing Medicaid pharmacies for alpha-1 proteinase inhibitors at the multi-source rate of average wholesale price (AWP) – 50%. In furthering the Associations goal of improving patient access, PPTA staff contacted Washington Medicaid to discuss the issue. PPTA opposes applying a "generic" reimbursement to sole source drugs and biologics. Convincing Washington State Medicaid to change the reimbursement level is clearly precedent setting. Numerous phone calls and e-mails with Washington's Medicaid Pharmacy Unit resulted in steps that could be taken to increase the reimbursement to the single-source rate of AWP -14%.

Alabama

On September 28, 2007 after months of both internal and external discussions, the Alabama Medicaid program promulgated two proposed regulations relevant to the provision of blood clotting factor therapies for individuals with bleeding disorders. As you will recall, the patient community, distributors, and PPTA voiced objections to plans by the state early in 2007 to implement pricing that closely resembled 340B pricing for all bleeding disorders patients in the state Medicaid program. In response to those comment letters, the state of Alabama withdrew its proposal and began a dialog with various interested

parties to craft a solution that would not negatively impact quality of care. These regulations were developed based on the input from these parties. In a clear victory for the community, Alabama Medicaid decided to propose standards of care for management of hemophilia. These standards were developed based upon input from the National Hemophilia Foundation the existing New Jersey law, and the PPTA model quality of care language, among others.

On November 9, 2007, the Alabama Medicaid agency released its response which indicates that it is committed to ensuring access to care. In a clear victory for the community, the Agency has decided to adopt standards of care for management of hemophilia and a reimbursement mechanism that should help ensure access for residents of Alabama. Alabama's adoption of these regulations represents an important development for the bleeding disorders community and the goal of ensuring access to high quality care. PPTA believes that the activities that occurred surrounding this issue, including coalition building, open lines of communication with regulators, and achieving consensus on comments and positions; represent a valuable case study and precedent in addressing future reimbursement proposals in the states.

Conferences

PPTA recently exhibited at the National Hemophilia Foundation Annual meeting. The exhibit booth was a great success as numerous consumers and other industry representatives stopped by to discuss issues of importance to them. As part of PPTA's continued efforts in working with the plasma protein therapies consumer community, PPTA plans to exhibit at future national consumer organization meetings.

Attachment: Advertisement (STKH07029a)

PPTA Staff is always available to attend consumer organization functions, make presentations, and assist in developing advocacy strategies and messages, as appropriate, with consumers. Please contact PPTA Staff at any time to discuss these activities.

This PPTA publication aims to keep Stakeholders apprised of evolving state and federal health policy developments. **To provide feedback or to add colleagues to the distribution list, please contact Diana Krueger at the Association.**

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