

PATIENT COLLABO

BY JULIE BIRKOFER AND LAURA SAVINI

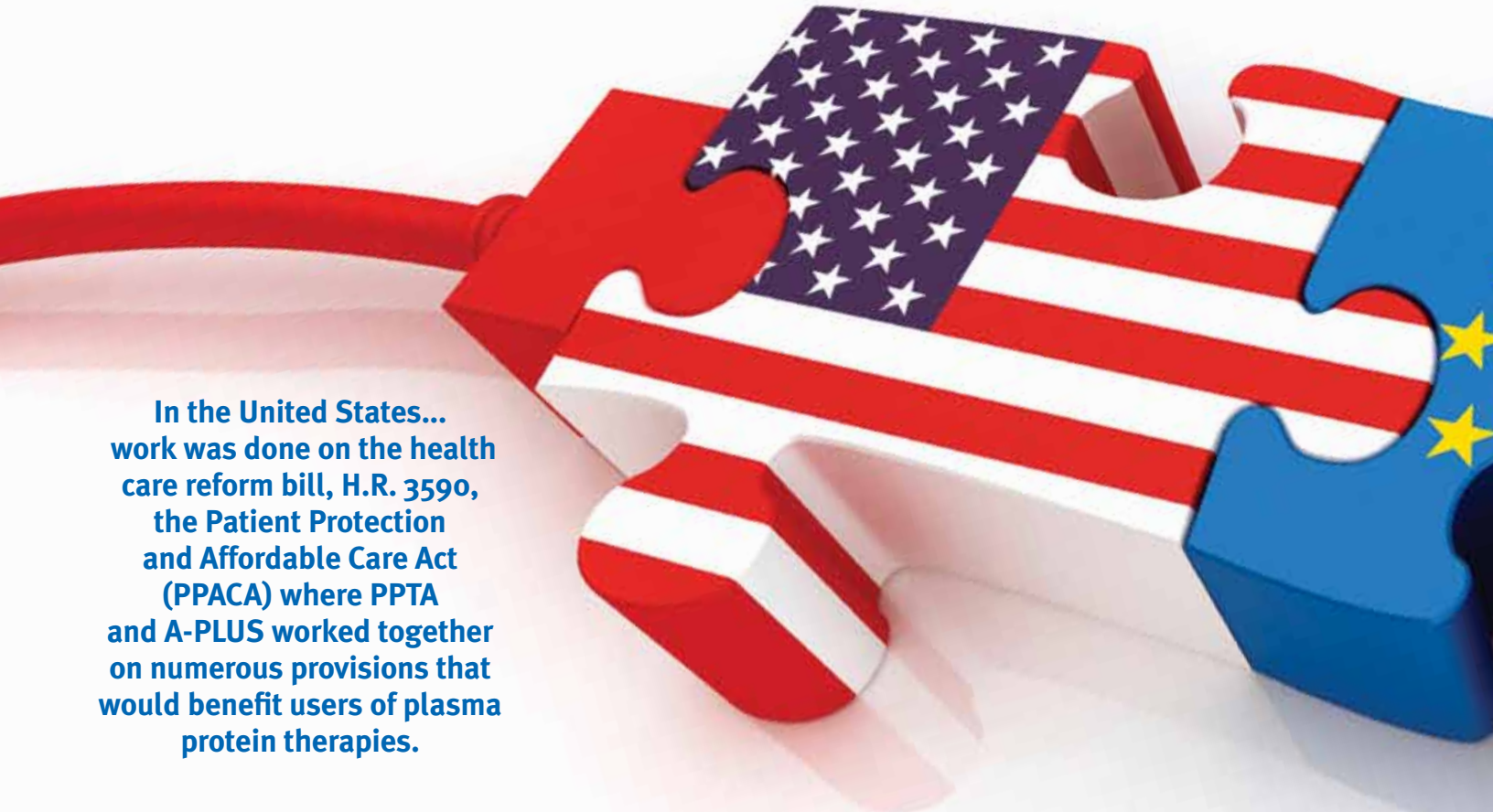
AROUND THE WORLD, COUNTRIES ARE STRUGGLING TO PROVIDE PATIENTS

with access to needed health care, while simultaneously managing intense budgetary pressure. This pressure has generated several responses from stakeholders to continue to receive the same amount and level of service as before. As a result, both in Europe and in North America, patient groups are joining forces to collaborate on advocacy projects with common goals.

This trend is also seen among patients treated with plasma proteins: the coalitions PLUS¹ (Plasma Users) and A-PLUS² (American Plasma Users Coalition) set a recent example of this phenomenon.

In the United States, A-PLUS and PPTA have been working on several articles. For example, work was done on the health care reform bill, H.R. 3590, the Patient Protection and Affordable Care Act (PPACA, where PPTA and A-PLUS worked together on numerous provisions that would benefit users of plasma protein therapies. Stakeholders led the advocacy efforts to eliminate lifetime limits on insurance benefits and to combat the denial of insurers to cover illnesses based on preexisting conditions. These insurance reforms will help to give all Americans access and maintain the medical care they need. Furthermore, PPTA

and A-PLUS are working together on the annual pharmaceutical fee issue, a tax provision contained in the law. Several members of A-PLUS have weighed in with Members of Congress. Here is content from one letter from a Stakeholder: *"Upon review of PPACA's language concerning the pharmaceutical fee and the way in which orphan drugs are exempted, however, we remain concerned that the language of the exemption for orphan drugs, as constructed, does not protect all products that treat only rare diseases. Although the provision does exclude 'sales of any drug or biological product with respect to which a credit was allowed for any taxable year under Section 45C of the Internal Revenue Code of 1986,' it does not take into account those products that treat only rare diseases that were not eligible for that tax credit. This*



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would leave patients and their physicians with no alternative therapies and hinder increased research and development.”

In Europe, PLUS has created a space for stakeholders involved in plasma proteins to meet and discuss their differences. For the past two years, stakeholders such as representatives from patients' groups, blood donors, and the industry have used the PLUS platform to meet in Dublin to discuss common issues. One of the key outcomes from this meeting has been the recognition for patients to be an integral part of political and regulatory decision-making related to plasma protein therapeutics, especially on issues concerning sustained supply of these therapies. This could not have been achieved by one patient group alone and shows the power behind patients' cooperation.

However, in order to work together, patient groups need to first be recognized as valuable stakeholders, which is well established in North America but is a recent trend in Europe. As stated by the European Patient Forum (EPF), an European coalition of 44 European patient organizations: “it was during the G10 Process and the Review of the Pharmaceutical Legislation in 2001/2003, [that] patient groups realized they were not appropriately represented at EU level and at the same time appreciated how difficult it was for the EU institutions to nominate a European patient representative.” For example, the European Medicines Agency (EMA) only

began involving patients in some of its working groups in 2006. In its Road Map to 2015 the EMA states that “An element of growing importance is the involvement and participation of civil society representatives (patients/users of medicines and healthcare professionals) in the Agency's activities.” This shows not only a change in attitude from government and European agencies but also in patients' attitudes, as they are empowered to make their voice heard. Taking part in official committees at the EMA and similar bodies also means being able to represent patients on a broader level, and to gather other patients' views and opinions on certain topics, as explained by one of the patients' representatives on these committees at a recent PPTA meeting.

Patient cooperation is a trend that is bound to grow. The industry will need to continue taking it into account in order to keep the dialogue with patients groups alive and relevant. 

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1 European Hemophilia Consortium, International Patient Organization for Primary Immunodeficiency.

2 A-PLUS represents: GBS/CIDP Foundation International, Committee of Ten Thousand, Hemophilia Federation of America, Immune Deficiency Foundation, Jeffrey Modell Foundation, National Hemophilia Foundation, Platelet Disorder Support Association, Patient Services Incorporated.



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