

STATE AND NATIONAL GOVERNMENTS AROUND THE WORLD

have spent the last few years wrestling with the worst global recession in more than 50 years.

This is causing decision-makers in some states of the European Union and the United States of America to consider cutting health-care costs when there are no more low hanging fruit to pick.

These decisions could have a negative impact on patient access to plasma protein therapies in certain areas of the world. Governments with the worst deficits pose the greatest threat to patient access since they must cut the most funding from their public programs. All those concerned with patient access to their medically appropriate therapy must watch these governments closely to ensure patients are not denied access to their life-saving therapies.

United States

Medicaid is a federal-state partnership that provides health care to more than 57 million low income individuals in the United States. The federal government and the individual states pay for the Medicaid benefits jointly, but the individual states make the decisions about what benefits are provided and how much is paid, as long as the decisions meet minimum standards established by federal law.

As a result of their role in the Medicaid decision-making process, and the historic deficits states are facing, it is important to closely watch the states as they hold their legislative sessions this year. During these sessions, the states will decide if they should increase taxes or reduce spending. States that choose to reduce spending will have to reduce Medicaid spending, since it is the second largest portion of most state budgets.

Particular attention should be paid to California. The state's deficit is \$6.6 billion for the current year, and \$12.3 billion for the next fiscal year. As part of his numerous reductions necessary to balance the state's budget, Governor Arnold Schwarzenegger has proposed cutting Medicaid expenditures by \$2.4 billion. Included in these reductions are utilization controls, provider rate decreases, and greater out-of-pocket costs for Medicaid recipients.

All of these cost-containment policies would have a negative impact on individuals that rely on plasma protein therapies. Utilization controls could involve step-therapy that would cause patients to switch therapies. Greater out-of-pocket costs could lead to patients not having enough money to procure their therapies or infusing less frequently than medically appropriate.

Similar cost-containment strategies are being considered by other states. Perhaps the greatest threat to patient access is the idea of sole-source providers for specialty pharmacies. Decision-makers in Iowa and Oregon have suggested the idea of having their Medicaid recipients receive their clotting factor from one supplier in one location in the state. PPTA is concerned that

limiting Medicaid recipients to one provider would require individuals to switch providers and to travel a great distance to reach the sole-provider. This policy could result in increased Medicaid costs because of increased hospitalizations, if patients find the sole provider is too far to travel or in increased usage of Medicaid transportation services to bring the patients to the sole provider.

Europe

Its not just country-level changes that are being watched. The public health care systems of Europe are going to have to bear the major impact the financial reforms sweeping the continent as a result of the global financial upheaval over the last two years.

Unprecedented national borrowing will be repaid on the basis of reduced spending and increased taxation. Several countries that will be highlighted in this article are those thought to be particularly exposed and where extreme spending controls are expected.

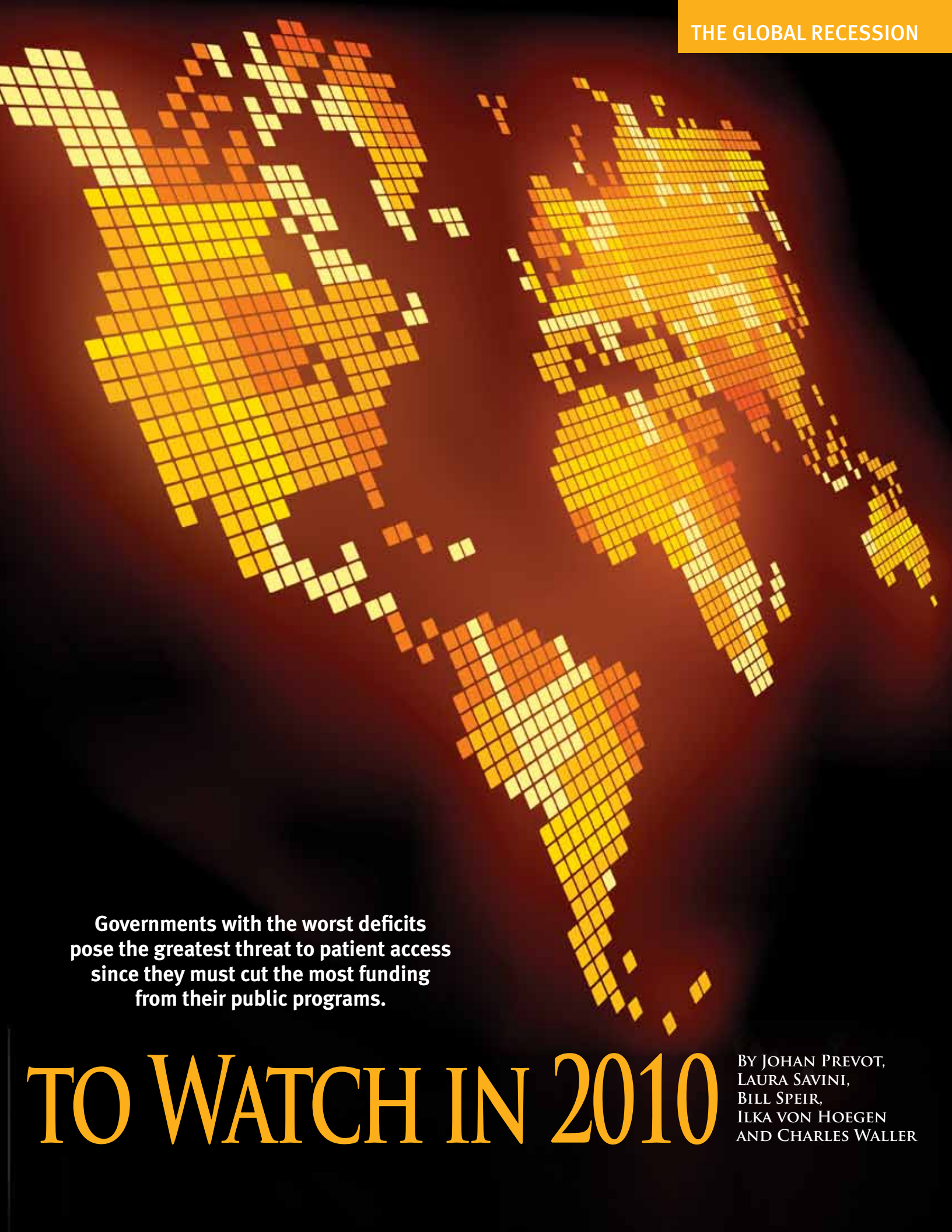
Signs of tighter spending on health are increasingly evident. Tighter controls in clinical guidelines, simple and strict caps to spending on certain high cost medical conditions, higher pharmaceutical taxes and single supplier contracts are just examples of the tightening of the fiscal purse strings.

Portugal

Portugal, the westernmost country of continental Europe, is best known for its beautiful sunny beaches and golf courses. Although it has been qualified as being among the top 20 countries in the world in terms of quality-of-life, the Portuguese economy, after having known a significant growth in the 1980s and 1990s, has recently been struggling with financial debts. Portugal officially has the lowest per capita gross domestic product (GDP) in Western Europe and has recently been described by *The Economist* as the "new sick man of Europe."

Despite the poor status of its general economic situation,

STATES AND COUNTRIES



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TO WATCH IN 2010

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patient access to plasma protein therapies has been improving in recent years and the treatment levels of patients affected by conditions such as hemophilia and primary immunodeficiencies have therefore been increasing. Portugal imports plasma protein therapies from PPTA companies and reportedly collects around 30-40,000 liters of recovered plasma per year although this plasma has been wasted in the past as it failed to meet European Union (EU) regulatory requirements in terms of quality. However the quality of Portuguese plasma has recently improved and collecting organizations are increasingly receiving EU certification. In 2009, a first-ever toll fractionation call for tender was organized but ended up being cancelled for logistical and organizational reasons.

Similarly, the current hospital purchasing framework for plasma protein therapies has been identified as an issue of concern by PPTA. An official statement from the authorities recently announced the cancellation of the national tender for plasma protein therapies launched toward the end of 2008. It seems that it is unlikely that another tender will be launched any time soon but also that there is no alternative clear framework on how appropriate patient access to plasma protein therapies will be guaranteed.

These issues highlight the need to monitor the Portuguese situation closely in 2010. PPTA has recently launched a Portugal Task Force through which these issues will be addressed.

Greece

The poor fiscal health of Greece has been a main concern for the European Commission and other European Member States during the last quarter of 2009. This worry increased with the country's inability to cut its deficit and service a massive debt load. Concretely, many companies have been affected by extremely long delays in payments from public Greek hospitals of three years and sometimes as much as five years. This has prompted them to inform relevant stakeholders about the threat to sustained access to plasma-derived medicinal products.

Last December 31, 2009, public hospital debts for medicines, including plasma proteins, for goods invoiced before June 2007 were paid. At the same time, it was announced that public hospital debts for pharmaceuticals invoiced prior to the end of 2008 will be cleared by the end of March 2010. Moreover, at the beginning of February 2010, the European Commission approved the new Stability and Growth Program submitted by Greece in January 2010. This plan contains a section focusing on public debt reimbursements outlining the government commitment to bring reimbursement delays up to European standards. Although there seems to be an improvement, PPTA will monitor closely the evolution of the economic and financial situation and the reimbursement delays in 2010.

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these governments closely to ensure patients are not denied access to their life-saving therapies.

Italy

Until 2005, Italian plasma had to be completely fractionated within Italy. The 2005 fractionation law widened and removed this restriction, but before coming into effect a separate law, implementing the 2005 law was needed. In 2009, a draft of this implementation law was presented to the Italian Parliament. Instead of completely opening the fractionation to all respected and qualified fractionators, as European Community law requires, it was proposed to take a first step and only open the market to three named fractionators, and specifically excluding other organizations.

Only companies that invest and provide employment in Italy or companies from countries that adhere to the voluntary unpaid donor principles would be permitted to tender for Italian plasma when the new law comes into effect. There is a weak stated intention to review and revise the law three years after it comes into effect and to allow all companies to tender for Italian plasma.

However, an opinion of the Italian Anti Trust authority questioned the legality and compliance of the draft law with Italy's other legal obligations. On the other hand, pressure from the influential Italian donors' associations has affected and continues to affect decision making in this area.

In the Senate Commissions, it was correctly proposed to no-

tify the European Commission of the proposed new text.

In addition, pursuant to article 2 of the GATT-TBT Treaty, Italy is also obliged to perform a similar notification to the World Trade Organization (WTO).

However, during the session of the 14th Senate Commission which took place in January 2010, the proposed notification to the European Commission was eliminated from the text.

PPTA continues to believe that the best way to ensure that Italian plasma for fractionation provides the maximum benefits to Italian patients is through extracting the most plasma derivatives possible. The three fractionation companies "preferred" in the legislation each use very high standards. They are highly valued members of PPTA. However, the draft law could result in time delaying litigation, if the draft law is not amended to comply with Italy and European treaty obligations. Through open tendering, Italian donors and patients can be sure that full use is made of Italian plasma. ☺

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