SCIENCE|BUSINESS
SPECIAL REPORT
Brussels | Washington D.C. | 1 September 2011

Experts urge US, EU to work together in healthcare technologies

Biosimilars, e-health among areas targeted for collaboration in Science|Business panel in Washington

Georgia Republican US Rep. Phil Gingrey called for greater collaboration on electronic medical records. Image: House Republican Conference

When it comes to healthcare, if the US and Europe worked together they could cut costs, spur innovation, and tackle their common health problems, according to a group of experts that met in Washington July 12.

"If we would find ways to have an overall common approach in healthcare we could achieve much more," according to Alexander von Gabain, an Austrian biopharma entrepreneur and chairman-elect of the European Institute of Innovation and Technology. "We have to find ways of getting healthcare costs down – by working together, expanding best practice, and cooperating intellectually and financially," agreed Bart Gordon, former chairman of the US House Committee on Science and Technology and now a partner at Washington law firm K&L Gates.

The call for transatlantic cooperation in healthcare came at a meeting on Capitol Hill that was organized by Science|Business and hosted by Rep. Phil Gingrey, a Georgia Republican who is also a doctor. Gingrey called for greater collaboration on electronic medical records. He praised a $19 billion US e-health effort, included in the 2009 economic-stimulus bill, and suggested it add a global dimension. "If you go into an emergency room where you don't speak the language, or maybe you can't even talk because of injuries, for the doctors to be able to take your card and swipe it" to get an instant medical history – "this can be very important. It should be there globally."

Together, Europe and the US make a vast market for healthcare: more than 800 million people, with a similar range of health problems. Yet they have different regulatory systems, payment methods and market conditions. In recent years, Washington and Brussels have been trying to collaborate more in a few specific areas. In e-health, they have begun developing common technical standards. And there is regular sharing of information, and occasional joint calls for grant proposals, between US and EU agencies that fund basic biomedical research.

But cutting costs and improving healthcare will require much more collaboration, the experts said. The meeting, supported by the Sandoz International division of Novartis, was held to air some specific proposals for cooperation. Four emerged: caring for the ageing population, stimulating innovation, regulating new biological medicines, and studying the economics of e-health.

Idea 1

Work together to care for the ageing population

Proposed by Harriet Wallberg-Henriksson, President, Karolinska Institutet

On both sides of the Atlantic, the population is growing older. Between 2000 and 2030, the percentage of people 65 or older will rise in North America from 12.6 per cent to 20.3 percent. In Europe, it is projected to climb from 15 per cent to 24.3 per cent. But at the same time, there are serious health challenges, such as smoking and a sedentary lifestyle. "So the conclusion isn't clear whether these people will age in good health or in bad health," said Wallberg-Henriksson, whose Stockholm medical university names the Nobel Prize in Medicine or Physiology.

"What can be done?"Already, she noted, the US and Europe separately are ratcheting up their efforts to cope with this ageing, increasingly infirm, population. The European Commission is this year launching a "Healthy Ageing" project to coordinate research, regulation and policy that touch on the problem in the EU; and in the US the Centers for Disease Control and the National Institutes of Health are at work on it. But better still, she said, "the US and Europe can develop shared methodologies and coordinate efforts."

A particularly fruitful area, she said, would be in the use of information and communications technologies – for healthcare management, social care, tele-care, electronic monitors and alarms. This could entail joint calls for research grant proposals from the NIH and the European Research Council. Or, she said, it could entail new funding schemes for e-health technologies for the aged, to stimulate innovation. A joint planning group, she said, would get it started.

Idea 2

Coordinate, and focus on, broad innovation policies

Proposed by Alexander von Gabain, co-founder, Intercell AG, and Chairman-Elect, European Institute of Innovation and Technology

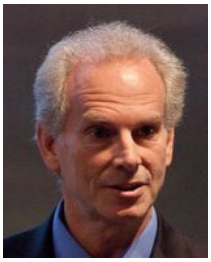
Most transatlantic collaboration to date focuses on research and education – and it misses the broader aspects of innovation: "You need entrepreneurs to take up the ideas" from the lab and bring them to the marketplace, said von Gabain – himself the co-founder of a successful Viennese vaccines specialist company, Intercell. "Innovation needs the knowledge triangle": the interplay of research, education and business. This dynamic, while operating in the US, is "underutilized" in Europe, he said. To succeed, "we have to get a much more holistic approach."

A good place to start, when trying to improve the whole innovation system, is with the regulators, von Gabain said. At his own company, which developed a vaccine for Japanese encephalitis, "I know the pain to get an FDA (Food and Drug Administration) license, an EMA (European Medicines Agency) license, an Austrian license… It would simplify things a lot if we could take the synergies of these different systems" to speed drug approvals globally. Another barrier to global innovation, he said, is the complexity of trying to raise capital from one market to another. "We should come to a more unified system" of capital markets. Finally, he said, greater collaboration on cross-disciplinary innovation is needed on both sides of the Atlantic, because the complexity of many health problems now requires input from statisticians, the food industry, hygienists and other disciplines besides traditional pharmaceutical researchers. Today, he said, "the innovative space is more than just first-class basic research."

Others concurred. "We have to focus on the whole chain of getting to market; it's not just basic research" that matters, said Ulf Dahlsten, principal advisor to the European Commission's Director-General for Information Society and Media. "We are living in a competitive world. If we and the US are going to be successful we have to shorten the time to market."

Idea 3

Harmonise the regulatory process for biosimilars



Proposed by Mark McCamish, Global Head of Biopharmaceutical Development, Sandoz International

The past few decades have seen great growth in the variety and use of so-called biologicals – medicines in which, through recombinant DNA technologies, researchers trick a cell into making a hormone, an anti-cancer therapy or other biologically active molecule then used as a drug. These are expensive to develop; and "that expense limits the access of patients to use them," said McCamish. In response, his company and others develop 'biosimilars' – in essence, high-quality clinically-equivalent forms of the medicine that can come to market at a lower cost when the original patents expire.

The impact of biosimilars can be profound. For instance, he cited the case of GCSF, granulocyte colony-stimulating factor, a medicine that stimulates the bone marrow to produce more stem cells and boost white blood cell production. This can counteract the immunosuppressive effect of chemotherapy in cancer patients. But GCSF is so costly that it is generally used by doctors only after loss of white blood cells has already occurred and patients are getting sick from infections that they cannot fight without those white cells; better, experts said, would be to administer GCSF from the start of chemotherapy to prevent the problem from appearing at all. When Sandoz launched a biosimilar GCSF in the UK, it was at half the price of the original drug – and the result was a 25% increase in appropriate use of the medicine, including prophylactically, to benefit patients. "There was a cost-benefit," he said. However biosimilar GCSF has yet to become available in the US.

"My idea is to collaborate to a greater extent on the global development of biosimilars," said McCamish. At present, he said, US and European regulators take different approaches to the licensing of biosimilars – resulting in expensive duplication of research on both sides of the Atlantic that dramatically increases the costs, and delays the patient benefit of these medicines. Generally, to clear a biosimilar for market one must show it is functionally the same or equivalent to the original medicine; however, both agencies generally require comparison to the original medicine labeled for use in their own region, even if the medicines were manufactured in the same plant and comparable in all aspects. In other words, the regulatory approach is to consider that the label you put on the bottle is more important than what is in the bottle.

In addition, in Europe there are now 14 'guidances' published by regulators for the process. In the US, however, the FDA is just developing its approach to regulating biosimilars and seems reluctant to adopt the European approach. For example, there is disagreement even over how to name a biosimilar. The EU has been following a World Health Organization standard for naming of biologics (a system in place since 1953 for all medicines), while the FDA is considering requiring a different naming protocol that could confuse physicians, pharmacists, and insurance companies regarding which product they are giving a patient. That makes it harder to enable use of these cost-effective medicines and to share and compare results, McCamish said.

Idea 4

Working together on the economics of e-health

Proposed by Walter van Dyck, Associate Professor of Innovation Management, Vlerick Management School, Belgium

Increasingly, healthcare agencies have to study the overall cost of keeping people healthy, rather than how much they spend on pills or hospitals alone. That requires health economics – and in Europe, where the taxpayer is footing most of the bill, there is already a strong tradition. "With all our little governments and small budgets, we have more practice at this than in the US," said van Dyck. And the importance of health economics will only grow as the technology of healthcare shifts beyond medicines to include more computer and communications technologies – for monitoring patients, diagnosing disease and handling treatment in the home. "My proposal would be to focus collaboration on e-health economics," he said.

As an example, he cited preliminary results of a study he led of the economics of e-health in breast cancer treatment. A Roche medicine already on the market, Herceptin, is known to be effective at treating certain types of breast cancer; and DNA tests can accurately identify those types. What if, van Dyck's team at Vlerick Management School asked, doctors used patient databases to sort people at risk, and more quickly identify people who should and should not get the new medicine? The result, he found in a computer simulation, would be an overall savings in average treatment costs of nearly 30 per cent. The study was conducted for Science|Business, as part of a research project on healthcare costs in Europe supported by the COST Office of the European Science Foundation, Pfizer, Speedo International, NXP, the Royal College of Physicians, Vlerick, and the Medical University of Warsaw.

Van Dyck cautioned against drawing too strong a conclusion from any individual study, but overall he said the field of e-health economics can help policy makers better manage the cost of healthcare. Sharing data and methods across the Atlantic, he said, could benefit both healthcare systems.

How to move forward?

What are the barriers to US-EU collaboration? There are, of course, fundamental policy and market differences that can't be bridged: The US won't nationalise healthcare, and Europe won't privatise it. But the proposals aired during the meeting were more practical – sharing information, coordinating drug approvals, commissioning joint research, and the like. Even for those, however, there are still some fundamental gaps that need bridging:

- Regulatory views of costs and benefits differ. Because they pay the bills, European healthcare agencies naturally look at the economics of new medicines. The FDA, by law, does not.
- There is a natural tendency to parochial, not-invented-here, thinking - especially among inward-looking US health regulators. It's nobody's job to push for collaboration.

So how to overcome the barriers to collaboration? One answer is focusing some high-level attention to the problem: It would take a push, for instance, from the powerful US Office of Management and Budget to break through the not-invented-here attitude of the Food and Drug Administration. Another answer is money: Budgetary pressures on both sides of the ocean will force healthcare authorities to look for new ways to do more with less – and that could include sharing information, knowledge and costs with others.

"We're cutting. The Europeans are cutting. The message for this is: How can you save money" through collaboration, said Gordon. "The mutual threat to our standards of living will force us to come together.

Healthcare Innovation: Can a global approach cut costs, and improve health?

The meeting reported here was part of a series of transatlantic dialogues in Washington July 11-14, 2011, which were organised by the Transatlantic Policy Network. For more information, see **www.transatlanticweek2011.org**. Science|Business wishes to thank in particular the Rt. Hon. James Elles, Member of the European Parliament, and Hon. Bart Gordon, former Chairman of the US House Committee on Science and Technology.