

BY ROBIN ROBINSON

"OBAMACEUTICALS"

→ The Good, The Bad, The Controversial, and The Undecided ←

Industry leaders review the elements of President Obama's healthcare reform plan and how these may affect the industry.

According to the Deloitte 2009 Industry Outlook report published in December 2008, the Obama Administration could make more changes to the nation's healthcare system than have occurred since the 1960s. While there are many government policy changes proposed, PharmaVOICE asked leaders from all segments of the industry to share their opinions on only a few of the more pertinent at this time.

It has been reported that President Obama expects to see a healthcare bill on his desk before the end of 2009, and the issue most likely to be addressed first in that bill is increased insurance access for the under- and uninsured.

Further healthcare reform issues, however, may be pushed to the back burner while the administration turns its attention instead to grappling with the economic crisis.

"Reports from Washington, D.C., suggest that a serious effort will be under way throughout the summer to craft a bill and get it to the President's desk for signature before the end of the year," says Kim Slocum, president of KDS Consulting. "Eliminating or at least significantly reducing the growing numbers of uninsured Americans will clearly be part of any legislation."

Industry stakeholders should use this slight reprieve to fully comprehend the ramifications of the proposed healthcare reform initiatives and to take part in the legislative process, since the industry will be feeling the impact of the new government programs — whenever they appear — for years to come.

THE GOOD: More Insurance Coverage, More Demand for Drugs

Under the good category, the increased demand for drugs through a universal healthcare program is generally seen as a positive step, not only for the benefit of U.S. patients but for the pharma industry. However, there are underlying circumstances that will muddy



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SUSAN DORFMAN
Skila

the waters, including healthcare accessibility, reimbursement, and availability of generics.

Michael Ruggiero, senior director, government policy and external affairs at Astellas Pharma US, is optimistic about President Obama's plan.

"We think there is great potential for healthcare reform to improve the overall health of Americans by changing the focus to prevention and management of chronic diseases,

including providing better access to biopharmaceutical therapies, and by promoting policies that will improve patients' ability to adhere to their prescription regimens," he says. "Studies have demonstrated that these policies can also have beneficial effects in terms of heading off more costly medical interventions that are required when conditions are poorly managed."

According to Susan Dorfman, VP of global marketing at Skila, there is a deeper discussion beneath the increasing demand for drugs through universal healthcare that needs to take place between policymakers and healthcare stakeholders. The first step the country needs to address before increasing insurance coverage and thus the demand for drugs is to make sure there is also timely access to healthcare professionals who will assess medical conditions and provide medications if necessary.

"The question we need to ask ourselves is: are there enough healthcare providers in the United States to ensure that the population of consumers in need of such care receive it in a timely manner," says Ms. Dorfman, who is completing her doctorate in healthcare administration this year. "Having coverage does not automatically mean having timely access."

Another fly in the ointment, brought to light by DrugWonks' pundit Peter Pitts, president of the Center for Medicine in the Public Interest and Partner and Director of global healthcare at Porter Novelli, lies in how much power the payer, whether private or government, has to overrule a physician's prescribing wishes to save money. (Drugwonks.com is the Web log of the CMPI, a forum offering rigorous and compelling research on the most critical issues affecting current drug policy.)

"If a universal insurance program is created that allows a patient to fill the prescription that the physician has requested and get reimbursed for it, I would say, 'That's wonderful,'" Mr. Pitts acknowledges. "But how socialized medicine usually plays out, especially in the United Kingdom, is that a physician prescribes a certain drug that he or she feels is best for the patient's personal medical condition and the

government or private payer will only reimburse for the less expensive generic version.”

At this point, the discussion is no longer focused on patient outcomes but rather on cost, Mr. Pitts says, and he finds this practice unacceptable.

“A reimbursement system that gives broader access to mediocre care as opposed to excellent care is not healthcare reform,” he says.

Mr. Slocum, former director, strategic planning and business development at AstraZeneca and self-proclaimed closet healthcare futurist, says universal coverage represents something of a mixed blessing for biopharmaceutical firms.

“The rollout of the Medicare Modernization Act in 2006 and the advent of Part D offer helpful lessons,” he says. “While insured people certainly consume more prescription products than those without coverage, the types of products covered under such plans have a great deal to do with how much benefit accrues to branded manufacturers. Part D produced an impressive one-year spike in industry revenue, but the windfall did not carry over into 2007 or 2008. Most of the gains in sales were racked up by generic products. Health plans with the largest enrollments were able to drive hard bargains with biopharmaceutical firms in exchange for market access.”

Mr. Slocum believes that any type of universal coverage could follow the same path.

“Given the growing concerns about healthcare cost escalation and its long-term effect on the U.S. economy, it’s almost certain that adding almost 50 million people to the ranks of the insured will come with significant financial strings,” he says.

Companies expecting to benefit from coverage expansion should also be prepared to make a solid case for the value of their products or expect to offer the same types of discounts that were needed to access the Medicare market.

“This will require some new thinking about the meaning of marketing to managed care and new definitions of what makes up a successful pharmaceutical brand,” Mr. Slocum adds.

The Pharmaceutical Research and Manufacturers of America and Billy Tauzin, president and CEO of the organization, stand behind the idea that the U.S. healthcare system must be reformed to help transform the current sick-care system to a 21st century healthcare system that focuses on disease prevention and management.

“We support comprehensive healthcare reform to help assure that all Americans can access high-quality and affordable healthcare

coverage, but we also must do more to knock down financial barriers that stop too many patients from getting the treatments they need,” Mr. Tauzin says.

Mr. Tauzin would like high copays and cost-sharing for prescription medicines to become things of the past.

“Among healthcare services today that are covered by insurance, prescription medicines get the least coverage,” he says. “Even among Americans who have insurance, 14 million don’t have the type of insurance that covers the prescription medicines they need to live longer, healthier, and more productive lives.”

PhRMA also supported the reauthorization of the State Children’s Health Insurance Program (SCHIP).

“There are currently millions of uninsured and financially struggling families with children who qualify for help through SCHIP but have not yet enrolled,” Mr. Tauzin says. “We must do more to raise awareness of this fact because every child deserves a chance to be healthy, and SCHIP helps to provide this opportunity.”

According to the Centers for Disease Control and Prevention, the share of children who are overweight, one of the leading causes of health issues, has more than tripled in the United States over the last three decades. Other estimates suggest that by 2015, 24% of children in the United States will be overweight or obese.

This reality leads to additional problems: a recent study predicted that one in three children born in 2000 will develop diabetes over the course of his or her life, according to Mr. Tauzin.

SCHIP has provided comprehensive health insurance coverage to more than 7 million low-income children in the past year alone, Mr. Tauzin reports. This year’s expansion of SCHIP extends access to coverage to an additional 4.1 million children who would otherwise be uninsured. This is an important step toward the goal of helping all American children have access to the high-quality, affordable healthcare they need, he says.

“A healthy child is more likely to be a healthy adult, and SCHIP provides essential resources to keep children healthy,” Mr. Tauzin says.

HIT: Off the Insurance Radar But Still Important

Perhaps one of the most significant effects of



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PETER PITTS
Center for Medicine in the Public Interest

“Obamacare” may come from something that at first glance doesn’t seem relevant to biopharmaceuticals at all — healthcare information technology (HIT), Mr. Slocum says.

The American Recovery and Reinvestment Act contains a number of HIT-related provisions, collectively referred to as HITECH. In brief, the act provides a \$19 billion infusion to encourage doctors and hospitals to purchase interoperable electronic medical records and to build information exchanges so that patient data can be shared. While experts argue about whether or not all this new technology will save money, there is little disagreement that it will improve the quality of U.S. healthcare.

According to Mr. Slocum, widespread adoption of clinical HIT will have a profound effect on many elements of the biopharmaceutical industry’s business model. Perhaps the lowest hanging fruit is the idea of using electronic medical records to speed up clinical trial recruitment and to automate data capture, he says.

“This could save the industry literally hundreds of millions of dollars on each NDA,” Mr. Slocum hypothesizes. “Some glimmer of the power of HIT can be seen in the FDA’s efforts to harness the technology for postmarket surveillance under the Sentinel system, an initiative that uses information technologies, such as electronic health records, e-prescribing, and electronic decision support tools, to collect, manage, and share health-related information.”

Data on thousands of patients can be aggregated and monitored for potential safety issues and the agency is now extending its partner-



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MICHAEL RUGGIERO
Astellas Pharma US

ships with providers and payers to access even larger data sets, Mr. Slocum tells PharmaVOICE.

The impact of clinical HIT tools will go well beyond R&D and regulatory issues, he continues.

“Health economics and outcomes research will be transformed by the availability of population level data on millions of individuals treated in real-world settings,” he says. “The clinical decision support capabilities imbedded in many electronic medical records will mean that physicians can be reminded to conduct appropriate screening tests and prescribe the most effective biopharmaceuticals for a particular patient right at the point of care.

“This could well alter the sales and marketing landscape in fundamental ways,” Mr. Slocum adds. “And finally, since all EMRs funded under HITECH will be required to have electronic prescribing capabilities, we will at last see the demise of one of healthcare’s most venerable icons: the prescription pad.”

Mr. Pitts, who was asked by the Obama Administration to act as an advisor to the FDA transition team, agrees wholeheartedly with Mr. Slocum on the benefits of HIT. From his regulatory perspective as former FDA associate commissioner for external relations, Mr. Pitts says HIT will prevent medical errors and reduce human cost of life, as well as healthcare costs.

“Health information technology is crucial

Bargaining With the Government is a Dangerous Proposition

ALLOWING THE GOVERNMENT TO NEGOTIATE DRUG PRICES GETS A STRONG NO VOTE FROM INDUSTRY LEADERS

According to Dr. Sandra Reynolds, pharmaceutical strategy senior analyst at Data-monitor in her recent report “Obama’s crusade to make U.S. healthcare work efficiently and effectively,” forcing the industry to negotiate prices with the government could have a dramatic affect on pharma profits as the government could literally dictate drug prices, leaving pharma companies with no option but to accept or lose out on one of its most lucrative markets.

“It is important to note here that a system such as the U.K.’s National Institute of Clinical Excellence will not fly in the United States because Americans are firm believers in limiting government control,” Dr. Reynolds states in the report. “This will also be a huge political battle for President Obama if he pushes for it because the current economic woes are much more important to the average American than price negotiations with pharma.”

“Repealing the non-interference clause in the Medicare prescription drug program and allowing the government to ‘negotiate’ drug prices threatens to do more harm than good for patients in need of potentially life-saving medicines because it could inhibit patient access to medicines,” says Billy Tauzin, president and CEO, Pharmaceutical Research and Manufacturers of America (PhRMA).

The non-interference clause of the Medicare Modernization Act also protects against the federal government limiting patients’ access to medicines they need. Even the current and two former Directors of the Congressional Budget Office have said government interference “would have a negligible effect on federal spending” and that the government probably could not negotiate lower costs than the powerful private sector purchasers already negotiating for lower costs.

“Many experts contend that the only way the government could effectively negotiate lower costs is to limit access,” Mr.

Tauzin says. “While we are committed to making the Medicare prescription drug benefit even better, we remain opposed to restrictive policies that would reduce access of medicines to patients in need and undermine the program’s clear success. And, the fact remains that 90% of seniors enrolled in the Medicare prescription drug program are satisfied and they are saving \$1,200 a year on average, according to the Centers for Medicare and Medicaid Services.”

“Negotiate with the government?” Mr. Pitts questions. “The government doesn’t negotiate — it imposes.”

The concept is unfair on many levels, he contends, and the biggest flaw stems from the fact that private health insurance is regulated state by state and does not have the ability to gather economies of scale nationally like the government does. And the same theory holds true here as with generics: if the prices are forced down, there will be a reduction in dollars for innovation

Like Mr. Tauzin, Michael Ruggiero, senior director, government policy and external affairs, at Astellas Pharma stands firmly behind the Congressional decision in the 2003 Medicare Modernization Act, which created a market-based competitive model for delivering prescription drug benefits to Medicare beneficiaries and prohibited the government from interfering in the negotiations between Medicare Part D plan sponsors and pharmaceutical manufacturers.

“Changing the policy now could put the Part D plan and its participants at risk,” he says. “This model has been working well to keep down the costs of the new benefit and to give Medicare beneficiaries good access to medicines they need. While the Part D program has been revised in various ways over the years, and this will undoubtedly continue, we think any fundamental change in the program’s market-based competitive structure would compromise Part D plans’

ability to deliver high-quality benefits at a reasonable cost, and could be disruptive to beneficiaries enrolled in Part D.”

The case, both pro and con, has been argued forcefully, says Kim Slocum, President, KDS Consulting. Playing devil’s advocate, Mr. Slocum points out the positive on both sides.

“On the one hand, opponents say private sector health plans were quite successful in negotiating prices that kept the costs of the Medicare Part D program under budget,” he contends. “On the other hand, proponents point to the prices obtained by the Veterans’ Administration and suggest the government could get similar prices for all Medicare beneficiaries if it were allowed to do so.

“Authority to negotiate pricing is only half the story, though,” Mr. Slocum says. “To drive a bargain, the Centers for Medicare and Medicaid Services also needs something with which to create negotiating leverage.”

According to Mr. Slocum, the most effective ways to accomplish this would be through a national Medicare formulary. Companies that refused to give CMS an acceptable price would have their products excluded, much like the discussions that go on routinely between private sector health insurers and biopharmaceutical firms now, he says.

“There has been little talk of creating such a formulary and absent that, or some other means of compelling manufacturers to bargain, CMS is not likely to be in a strong negotiating position,” he says. “Let’s assume that CMS somehow gets both the authority to negotiate and creates the needed leverage. Would this signal the end of free market pricing in the United States?”

Of course, he says, this depends largely on how one defines a “free market.” Unless the ability to set a price is matched by the willingness of someone to pay that price, the market is not truly “free.” As third-party payment has increasingly grown to domi-

nate the U.S. market, it becomes harder and harder to say biopharmaceutical companies truly have pricing freedom, he says.

“Over the past several years, aggressive cost shifting to consumers has resulted in more and more patients doing without medications,” he says. “This has limited both market growth rates and the freedom of companies to price products as they please. Admittedly, a governmental agency generally has bargaining tools that are not available to private insurers. Given the current trends in the market, it is difficult to state that the entry of CMS into this space would mark some sort of dramatic turning point for manufacturers.”

Dealing with government or private entities in price negotiations, reimbursements, and rebates is nothing new for the industry, says Susan Dorfman, VP of global marketing at Skila.

She points to an article featuring former President Clinton and his view that Americans should be proud of its drugmakers and their efforts to save countless lives.

“While former President Clinton believes that America can no longer subsidize pharma R&D, he blames the government of tacit agreements to subsidize R&D for years and discusses a new agreed-to model between the government and big pharma companies that would not require tax payers to spend more money than the rest of the world,” she tells PharmaVOICE. “The one element of focus for change was patent reform to ensure that the research and patent processes worked together.”

Another recommendation, which Ms. Dorfman found not so popular, was to lower margins to the level of those of Wal-Mart.

“Would pricing negotiations with the government put an end to a free-market economy for pharma or simply represent a larger customer in need of greater discounts based on quantity?” she queries. “I don’t think so, but we may want to study Wal-Mart for an answer to that.”

for many reasons, not the least of which is that it will reduce medical errors,” he says. “We live in the 21st century and to have physicians still writing paper prescriptions is a travesty.”

THE BAD: Generic Push, Comparative Effectiveness Research

President Obama’s healthcare reform includes lowering drug costs by allowing the importation of safe medicines from other developed countries, increasing the use of generic drugs in public programs, and taking on drug companies that block cheaper generic medicines from the market. A provision in the legislation that will likely see the light of day is the push for generic prescription use.

Mr. Ruggiero from Astellas says he can live with that.

“Generic drug use plays an important role in managing overall healthcare costs, and generic drugs, which currently make up more than 60% of prescriptions, are poised to account for an even larger share as intellectual property rights for widely used innovator products expire in the coming years,” he says. “In general, we think the existing framework for small-molecule generic approval strikes the right balance between providing sufficient incentives for innovation while allowing the system to benefit from lower-cost alternatives.”

At the same time, Mr. Ruggiero says he hopes policymakers and payers who promote generic drug use as a means to lower costs will also ensure that patients and physicians continue to have reasonable access to the medicines that they determine are best for the patient.

Ms. Dorfman says she is concerned that the push for more generic prescription use will turn the focus away from the patient and accentuate the need for cost savings, to the detriment of patient care.

“P&T committees are pressured to control drug-related expenditures, and thus the cost of the medication and not the patient becomes the main focus,” she says. “The consideration of all the costs associated with the provision of patient care, not just the cost of the medicine, must be included in the evaluation process.”

“If we are going to institute universal care for the benefit of the patient, we must put patients first and prescribe what is right for them, not what is least expensive,” she contin-

Corporate tax benefit deferral will occur later rather than sooner

LEERINK SWANN RESEARCH PREDICTS THAT EVEN IF A TAX DEFERRAL BILL IS PASSED, IMPLEMENTATION WON'T OCCUR FOR UP TO TWO YEARS.

President Barack Obama proposed raising about \$190 billion over the next decade by outlawing three offshore tax-avoidance techniques used by U.S. companies. Healthcare companies are well-represented among those U.S. multinational corporations whose after-tax profits would be affected negatively by the changes envisioned to the U.S. tax code.



The political winds are too strong and uniform among Washington, D.C.'s Democratic leadership for deferral of foreign corporate profits by U.S. companies to remain in its current form.

JOHN SULLIVAN
Leerink Swann
Strategic Advisors

Drug companies, big biotech companies, and medtech companies are among those who have successfully exported technology-forward products to foreign markets. In some cases, deals with local governments have provided very low local tax rates in certain countries, setting an incentive to keep profits generated in those countries outside of the United States.

The good news is that according to Leerink Swann, a healthcare investment banking firm, the tax deferral on U.S. companies' foreign profits to be scaled back and that implementation will take longer than many anticipate.

"Democrats in Washington, D.C., are marching in lock step on scaling back U.S. multinational companies' ability to defer taxation on profits generated in their foreign operations," says John Sullivan, CFA, director of research and healthcare strategist, at Leerink Swann Strategic Advisors, a division of Leerink Swann LLC. "However, with strong proponents in Congress, such as Congressmen Rangel and Baucus, and in the Oval Office, some scaling back of this corporate tax benefit is likely, with higher tax rates among big healthcare companies an eventual possibility. Our view is that with the U.S. economy still quite fragile, implementation won't occur until fiscal year 2011 at the earliest.

"Since the Republicans' recent history (2004) of allowing an advantaged repatriation window was less than convincing in its economic benefits, we expect that Democrats view the time as ripe to redistribute after-tax income from corporations to individuals," he adds. "Republicans, corporate America, and shareholders will be fortunate to emerge with a deferral still in place but scaled back. We could see such a fallback position as the result of negotiation, especially if the Obama Administration begins to take credibly the threats of U.S. companies to move their country of domicile from the United States to a more tax-friendly jurisdiction."

Leerink Swann expects that denizens of Washington, D.C., will recognize the adverse near-term effects of a change like the one proposed on the economy, as higher taxes soak up dollars that might have been used for R&D, expansion, or capital spending.

Source: Leerink Swann. For more information, visit leerink.com.

ues. "After all, the concept of evidence-based medicine that is promoted by President Obama as part of healthcare reform is about allowing our prescribers to use their clinical expertise in combination with patient preferences and best research evidence."

Mr. Pitts is not a big proponent of blanket generic use, because he believes that many pay-

ers make the wrong assumption that generic and on-patent drugs are all the same.

"The problem stems from the basic misunderstanding by payers that a generic drug is the same thing as an on-patent drug and from not understanding that a patient might react quite differently to generic treatment," he says. "A statin is not a statin is not a statin."

On another note, Mr. Pitts says the amount of spending on brand prescriptions makes up only 8% of the country's total healthcare costs. Pushing generic use will reduce that percentage further, and therefore reduce the amount of revenue available to reinvest in the science of medicine.

"If legislation significantly decreases patent life on the 8% of healthcare spend, we are then essentially eviscerating healthcare innovation," he says.

In theory, generics serve a useful purpose by freeing up healthcare resources that can be invested in more innovative products, Mr. Slocum says.

"The problem facing manufacturers is that in recent years, the money that generics free up hasn't been flowing back to them in the form of increased revenue for newer and improved agents the way it used to," he says.

The first lesson manufacturers should learn from this challenge, Mr. Slocum says, is that demand for prescription products is more price elastic than many in the industry assume.

"Three decades of health policy literature show that sales of branded biopharmaceuticals can swing by as much as 20% to 30% based on how much a patient has to spend out of pocket to purchase them," he says. "The more steeply payer cost-sharing requirements tilt in the direction of generics, the more consumers will tend to gravitate to them, especially when economic times are tight."

The second and more important lesson for biopharmaceutical manufacturers, according to Mr. Slocum, is the importance of working with payers to better document the value of innovative agents.

"If consumers tend to favor lower cost options such as generics, manufacturers need to do a better job of preventing a step cost spread from developing in the first place," he says. "In the current cost-conscious era, this is most likely to happen when manufacturers can show that a newer product actually does meaningfully improve clinical outcomes."

Mr. Slocum suggests that branded manufacturers must segment markets through tools, such as personalized medicine or use large population level databases to demonstrate how newer products work in real-world clinical situations.

PhRMA has always supported patients receiving the medicines that are best for them, including both brand name and generic drugs, Mr. Tauzin says.

“Clearly, both innovative medicines and generic drugs play a valuable role in the treatment of millions of American patients,” he says.

Like Mr. Pitts, Mr. Tauzin believes innovative new medicines play a very big role in improving health and quality of life, even though they remain a very small part of total health spending. Without innovative brand name drugs to legally copy, there would be no generic drug industry, he adds.

“The United States already has one of the highest rates of generic drug use in the developed countries,” he says. “According to IMS Health, 72% of prescriptions in America are now filled with a generic drug.”

THE CONTROVERSIAL: Comparative Effectiveness Research

One of the more controversial provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) was the allocation of \$1.1 billion to establish a center to conduct comparative effectiveness research (CER). In late March, an advisory panel of federal officials was created to begin the process of understanding how such research could best be performed. Millions of dollars are at stake, and whether the money ends up in the plus or minus column for pharma and medical-device manufacturers is still uncertain. This is an area where biopharmaceutical firms have significant contributions to make, Mr. Slocum says.

“With their deep reservoir of biostatisticians and long experience in analyzing large population-level data sets, industry members are natural partners in the process,” he says. “With the stakes as high as they are, this is an area that deserves the full attention of biopharmaceutical manufacturers.”

Mr. Slocum is optimistic that if done correctly, CER could actually be turned into a positive for the industry. While the prospect of even a quasi-governmental agency passing judgment on the value of its products has produced a very negative reaction from many biopharmaceutical executives, a properly run CER process could turn out to be a blessing in disguise, he says.

According to Mr. Slocum, throughout this decade the steady tide of cost shifting to consumers has washed away the foundations of biopharmaceutical sales growth.

The most recent IMS report from 2008



Healthcare information technology may be one of the most significant effects of healthcare reform.

KIM SLOCUM
KDS Consulting

suggests overall industry revenue stayed essentially flat. With health plans now beginning to eye the specialty pharmaceutical marketplace with plans to apply even more draconian payment plans, it is becoming more apparent that industry needs a “game changer.”

Mr. Slocum says he finds hope in the initial reports that are coming from the meetings of the advisory panel.

“There seems to be growing agreement that CER needs to focus on conditions rather than specific interventions, that clinical endpoints need to be the dominant consideration, and that the process needs to look beyond just drug, devices, and diagnostics to include providers as well,” he says.

If CER can focus on clinical outcomes and can be conducted in a relatively non-burdensome way, admittedly big ifs, Mr. Slocum says, the industry stands a chance of making a strong case for the value of truly innovative products. It also may help pave the way for “value-based” benefit designs in which cost sharing is tailored to the situation of individual patients.

One of the problems is that comparative effectiveness means lots of different things to lots of different people, says Mr. Pitts.

“To most people it means cost-effectiveness but what we really want to talk about is clinical effectiveness,” he says.

Mr. Pitts defines clinical effectiveness as the four rights: the right medication, for the right

patient, at the right dose, at the right time. A fifth “right” might be the use of 21st century genomic tools to determine comparative effectiveness.

“We are using tools that were not designed for comparing medicines, so one problem is that the tools are incorrect,” he says.

Mr. Pitts also doubts the government’s ability to conduct unbiased studies as the nation’s biggest payer.

“Quite amazingly, most of these studies determine that the older, less expensive drug is just as effective as newer, costlier treatments,” he says. “The problem is there is a predisposed bias because the government is focusing on cost, not the needs of the patient.”

Ms. Dorfman agrees with Mr. Pitts.

“I share Peter’s views on comparative effectiveness as being a short-sighted, short-term, and politically driven policy that may provide possible short-term savings in the provision of medication — although the cost of managing such studies may outweigh the savings — but will result in higher healthcare costs and lower quality of care over time,” she says.

The idea of creating treatment guidelines based on comparative effectiveness studies of how well treatments work seems interesting at first, but there are two simple questions to consider: how treatment works on whom; and what other confounding factors may be involved?

This is where the complications of human nature outweigh the benefits of the proposals, particularly for patients, she says.

“What we need is a model that allows us to look at patients as individuals and measure their unique responses to treatments based on a variety of factors, including those that are clinical, genetic, and demographic,” she says. “As Mr. Pitts says, a one-size-fits-all model is outdated, and comparative effectiveness should be less about the cost of a drug and more about the appropriate provision of care for each and every individual.”

THE UNDECIDED: New HSS Boss, Drug Importation, and More

Many other elements of the proposed healthcare reform are still up for debate regarding their impact on the industry, and those include the new HSS Secretary Kathleen Sebelius, importation, marketing exclusivity for biologics, tax deferral on foreign profits, and

last but not least, the plausibility of negotiating drug pricing with the government.

HHS Secretary Sebelius: Industry Friend or Foe?

Ms. Sebelius was sworn in as the 21st Secretary of the Department of Health and Human Services (HHS) on Tuesday, April 29, 2009. According to the HHS Website, Secretary Sebelius has more than 20 years of experience in state government and has been a leader on healthcare issues for more than a decade. Our leaders in the industry heartily recommend her post and expect her to work for better health outcomes for patients nationwide.

According to PhRMA's Mr. Tauzin, former Kansas Gov. Sebelius is a wise choice to guide the President on shaping healthcare reform. Gov. Sebelius combines the vital combination of skills that it will take to accomplish this challenging job: toughness and an intimate understanding of the healthcare challenges that face our nation in these tough economic times.

"The healthcare agenda of the Obama Administration, as it has been articulated in the campaign and to date during the President's term of office, contains a number of elements widely supported by pharmaceutical stakeholders, a number of elements that have caused concern, and a considerable amount of fluidity and flexibility," Mr. Ruggiero of Astellas says. "Governor Sebelius does not yet have a long track record on many of the key federal healthcare issues, but her statements and past decisions at the state level suggest that her views are broadly consistent with those of the administration generally. The pharmaceutical industry has been strongly supportive of the key element in the administration's agenda — the call for expanding coverage to the uninsured — and has welcomed the signs from the administration that it could show flexibility on its approach to this and other issues to achieve a healthcare reform package with broad support.

According to CMPI's Mr. Pitts, if Secretary Sebelius is a thoughtful friend of public health, she will be a friend to the industry.

"She needs to realize we cannot work to advance public health without creating a table that has room for everyone and the opportunity for everyone to have a say," he says. "Pharma companies need to be at the table, because the industry is not the enemy, disease is the enemy."

Obamacare: A Guide to Reform

HEALTHCARE REFORM SOURCES THAT WILL HELP YOU UNDERSTAND AND MONITOR THE LATEST LEGISLATIVE PROGRESS.

- Alliance for Health Reform
allhealth.org
- The Health Policy Consensus Group
galen.org/content/consensus-group.html
- Institute for Health Policy Solutions
ihps.org
- Institute for Healthcare Improvement
ihi.org/ihp
- Kaiser Family Foundation
kff.org
- Markle Foundation
markle.org
- Robert Wood Johnson Foundation
rwjf.org
- White House blog
whitehouse.gov/blog/
- White House site on healthcare issues
whitehouse.gov/issues/health_care/
- White House Weekly updates on Healthcare Reform
healthreform.gov/

Source: PharmaVOICE

Biosimilars and Exclusivity: 5, 7, 12, or 14 years?

Biosimilars or follow-on biologics, whichever name you prefer, are at the center of one of the hotly debated portions of the new reform bill. There are several biosimilar bills up for discussion, each with a different exclusivity period. Previous attempts by Congress to create a biologic approval pathway contained no exclusivity clause.

It appears everyone is onboard to allow biosimilars into the United States, especially since safety concerns have subsided because of the EU's success with biologics, but the point of contention is how much exclusivity should be granted.

A bill introduced by Rep. Henry Waxman (D-Calif.) allows innovator products that are approved after the legislation is enacted to have five years of data exclusivity, with an additional three years possible, plus another

six months for pediatric exclusivity and another six months for a significant therapeutic advance.

Another bill, introduced by Rep. Anna Eshoo (D-Calif.) allows for 12 years for innovator drugs, with an additional two years possible, plus another six months for pediatric exclusivity. According to many reports, the President Obama's Administration is aiming for seven years. The Biotechnology Industry Organization (BIO) is advocating for 14 years, as is PhRMA.

"Because of the research-intensive nature of the biotechnology sector, appropriate incentives for continued investment in innovation include both robust patent protections and a base period of data exclusivity of at least 14 years," Mr. Tauzin says on behalf of PhRMA.

PhRMA continues to support an abbreviated approval pathway that protects patient safety, is based on sound science, and recognizes the unique role of the biotechnology sector in providing hope to patients and as a valuable contributor to the U.S. economy.

"It is crucial to strike an appropriate balance between making room for additional competition and maintaining strong incentives for the investment needed to seize the extraordinary opportunities for medical advances and economic growth offered by the biotechnology sector," he says.

According to Mr. Pitts, this debate is more politically driven than public health focused, because it is a continuation of a cost-based healthcare strategy versus a patient-centric healthcare strategy.

"The debate is definitely over property exclusivity of biosimilars, but this also applies to small molecules," Mr. Pitts says. "If the number of years of patent exclusivity is reduced, then the ability of the innovative company to make back its investment is reduced and the amount of money companies have to reinvest in innovations is restricted. Essentially, it's a case of trading tomorrow for today."

Mr. Ruggiero won't enter the numbers fray, but does comment that Astellas is "hopeful" that if biosimilars are included, the policy will follow the bipartisan approach crafted by Sens. Kennedy and Enzi, which provides an appropriate term of exclusivity for innovator biologics and takes a careful approach to ensuring patient safety.

"With increasing concerns about the overall cost of healthcare reform, we expect Congress to consider including biosimilars



We support comprehensive healthcare reform to help assure that all Americans can access high-quality and affordable healthcare coverage. We also must do more to knock down financial barriers that stop too many patients from getting the treatments they need.

BILLY TAUZIN
PhRMA

provisions in health reform legislation as a ‘pay for,’” he says.

The Debate on Drug Importation Continues

Mr. Pitts wants to make one thing perfectly clear: “First of all, there is no such thing as drug re-importation.”

“The term is a political one that is factually incorrect,” he says. “Re-importation implies that drugs that have already been approved by the FDA are being moved out of the United States and sold back in. In its current use, the term refers to the practice of allowing drugs from other countries that have less regulatory control to be sold to U.S. patients. That is drug importation.

“For example, in Great Britain 20% of drugs are parallel traded with Portugal, Greece, Latvia, in other words, countries that don’t have as robust a regulatory regime as the United Kingdom, the United States, or even Canada,” he adds. “The drugs a patient gets from an Internet U.K. pharmacy are not legal in Canada, let alone the United States. Patients are led to believe they are getting the same drug and they are not.”

Reports show that drug importation would reduce drug prices over 10 years by less than 0.1%, Mr. Pitts says.

“Importation is a great sound bite, but at the end of the day, it has serious safety considerations and doesn’t save a bit of money,” he says. “I don’t think HHS Secretary Sebelius would ever say these drugs are safe and put her signature on a bill that does.”

From the insider’s corner, Mr. Ruggiero doesn’t expect that drug importation will gain any more traction this year than it has in the past nine.

“We expect that Congress and the Obama Administration will focus first on the safety risks that are associated with prescription drug

importation, and on the new technologies and other safeguards that would have to be in place before a responsible dialogue about expanding importation could begin,” he says. “Creating a safety infrastructure that is strong enough to make expanded importation a responsible option to consider will be a costly and long-term endeavor.”

Not surprisingly, Mr. Tauzin is also opposed to prescription drug importation, citing safety concerns.

“We should not pursue policies that could expose Americans to substandard drug products and potentially weaken the FDA by crippling the agency’s ability to fulfill its mission

in protecting public health and safety,” he says.

Mr. Tauzin cautions that opening the door to prescription drug importation would create more opportunities for the worldwide counterfeit threat to knock at America’s door.

“If the recent recall of foreign products has taught us anything, it is that Congress must better equip and fully fund the FDA so that the agency has the resources to do its job,” he says. “The safety and integrity of our nation’s drug supply system will be at even greater risk if prescription drug importation becomes a reality. Now is not the time to weaken the FDA by moving forward with prescription drug importation.” ♦

Experts on this topic

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