BY ROBIN ROBINSON

HEALTHCARE REFORM

COMPARATIVE EFFECTIVENESS

With a maze of new laws and legislation to comprehend, the industry needs to prepare for a tough year of disruptive change.

Terry Hisey
Deloitte
"CER will require new processes, skills, and governance models to be in place, making this truly a transformational aspect of healthcare reform."

We all know that R&D focus, pharmaceutical promotion, pricing, and reimbursement are all, or will be, critically affected by the biggest U.S. healthcare reform to occur in 40 years. The impact is going to be disruptive, but overall, experts says it will be a positive gain for the pharmaceutical industry. According to several reports published in March 2010, after the bill was passed, the financial impact on pharma will be negative to 2014, then turn positive between 2014 and 2019. Overall, research analysts predict that the net financial impact will be neutral. Processes and strategies, on the other hand, will need to change dramatically to adapt to new terms, and the industry needs to evaluate its responses to the new bill in three time frames: short-term, mid-term, and long-term.

According to Dave Provost, VP, post-approval services, INC Research, CER needs to be considered for its near-term as well as long-term impact.

"Long-term, the impact will be largely positive," he says. "It will drive more industry-sponsored comparative studies as manufacturers proactively assess the healthcare system value of their products alongside safety, efficacy, and patient-reported outcomes. Near-term, however, the potential for a negative impact is possible."

CER is a developing field without widely accepted study design guidelines and uniform methods for comparative measures. In such an environment, inaccurate or unreliable CER findings — results from studies that suffer from design flaws — may be communicated to physicians, patients, and payers and quickly erode a product's marketplace acceptance

Thomas Fussaro
Millennium
"Millennium welcomes improvements in the healthcare system that will enhance access to needed services."

and use. To address the problem, efforts to standardize CER research are in play, Mr. Provost says.

"One effort is the creation earlier this year of the Patient Centered Outcomes Research Institute, which will, at some point, publish research guidelines and help disseminate CER findings," he says. "Another is the role that the Agency for Healthcare Research and Quality (AHRQ) is playing in funding CER and disseminating CER results. As drivers of the CER initiative, it will be interesting to chart the impact of these two groups on the industry's approach to CER."

UNCERTAINTY AND DISRUPTIVE CHANGE TO FOLLOW

Necessary changes will be disruptive, but may overall be welcomed by the industry.

"At Millennium, we have a strong desire that cancer patients are not limited from receiving medically necessary services because of a lack of insurance coverage, and we welcome the improvements in the healthcare system that will enhance access to these needed services," says Thomas Fussaro, director, government relations and public policy, Millennium.

A major issue facing companies trying to address the new bill is that there is a fair amount of uncertainty surrounding the different elements of the new law and how these will play out, making it difficult to know which provision will have the most impact and which to focus on first. The one element of the healthcare reform law affecting the pharmaceutical industry and the patients it serves is the elimination of barriers to comprehensive insurance.

"CMS's Office of the Actuary has projected that the United States will have 2 million fewer uninsured this year and 26 million fewer in 2014, when the most far-reaching insurance reforms kick in," Mr. Fussaro says.

Sales and marketing strategies will have a major shake out starting next year and beyond, says David Merkel, senior VP, business development, J Knipper & Company.

"The calendar year 2011 will be especially challenging, and not just because of the laws or guidance themselves, but because of uncertainty," he says.

The Patient Protection and Affordable Care Act ups the ante in an already confusing collection of state laws spanning disclosure, ethic reforms, limits, and all out bans targeted directly at pharmaceutical promotional activities. The Physician Payment Sunshine Provision mandates that manufacturers must track all payments and other transfers of value by January 2012. This includes the name of the recipient, amount of the payment, and any other categories of information that DHHS deems appropriate. Therefore, the final rules in terms of the specific requirements of reporting have yet to be determined and the DHHS has until October 2011 to finalize the rules.

"The industry will experience confusion at the state level while it struggles through legislative language creating its own reporting requirements," Mr. Merkel says. "These trends will have a significant impact on sales and marketing decision-making for 2011 and the following years."

Another result will be the shift of budget dollars toward infrastructure projects to modify existing systems and information to comply with the requirements, he adds.

"Perhaps most daunting is the challenge of dealing with disparate systems across the enterprise that need to talk to each other," he

CLEAR ACTIONS FOR MEETING THE CHALLENGES OF CER

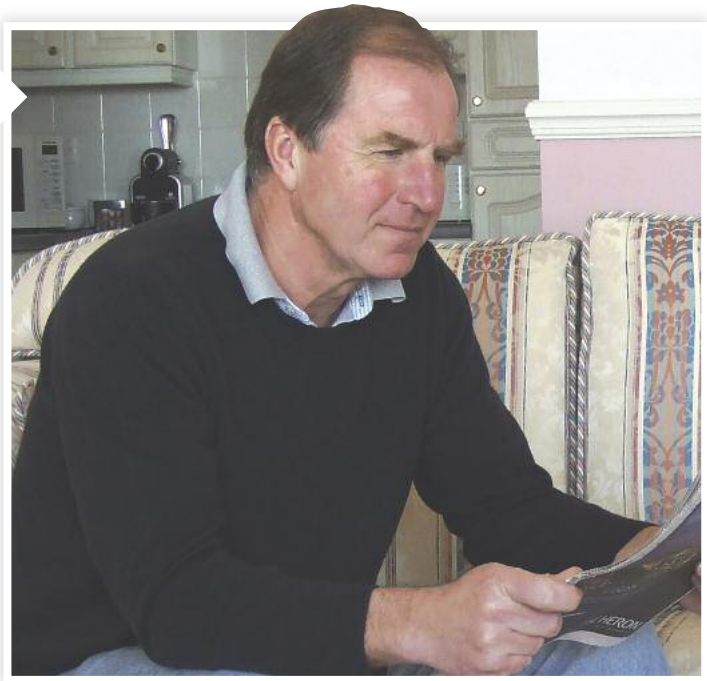
To operate successfully in the midst of economic comparisons to alternative technologies and in the face of safety studies that produce false positive signals, companies need to consider these actions to prepare for the new drug development and commercial environment:

- Involve HEOR, pharmacoepidemiology, and commercial teams in clinical development decisions. Clinical, commercial, pharmacoeconomics, and HEOR (health economics and outcomes research) teams need to work together, starting early in the development process to consider relative value as a condition of go/no-go development decisions. This involves simulating the product's effectiveness — through advanced trial simulation and comparative effectiveness models — driving it to fail quickly, if indeed it is going to fail.
- Apply the CER lens to development decisions. Companies need to decide what products they are going to pursue based on either the results of their own head-to-head comparative study completed in Phase III or what they expect will happen when someone else does the study after launch. This involves simulation modeling, scenario testing, and looking at different product profiles to assess the risks.
- Design Phase III studies with competitive positioning in mind. Phase III studies should be set up to support what a company wants to see happen, post-marketing approval. Obviously, this may result in some products losing their commercial attractiveness because they cannot be adequately differentiated in post-marketing, real-world CER studies. Again, trial simulations can be a relatively inexpensive way of managing the possibilities.
- Prepare, before launch, for the possibility of false-positive adverse event signals. This involves benchmarking and understanding "class effects," reexamining dose-related adverse effects, and having the staff and other resources to better understand and manage post-marketing safety concerns.
- Manage expectations. Too often, companies cling to the results of an early forecasting model, even if they subsequently have new information about the product's performance from a Phase III study or from simulation models. Instead, they should reset expectations to reflect an altered view of reality.
- For late-stage products, find clear differentiation. Acceptance and adoption are measures of success just as much as, if not more, than registration. So, to succeed, companies need to design their trials to address pricing and stratification.
- Don't be afraid to contract aggressively for undifferentiated products. If a product does not prove to be substantially different from another therapy, the manufacturer will need to be clever in its contracting strategy to encourage uptake.

Because the model for the way postmarket information is developed is changing, the risk-reward calculus for drug development is changing as well. Knowing that downstream they will face comparative effectiveness research and increased safety scrutiny, manufacturers need to invest heavily in their processes for early commercial risk planning. Developers and brand managers, with the help of HEOR and other professionals, need to begin picturing their products in a postmarketing environment in which someone else controls the comparative effectiveness and safety information that is made public. To the extent that they can do this, companies will make business decisions that benefit all.

Source: IMS Health. For more information, visit imshealth.com.

Stephen Webb
Registrat-MAPI
"A new focus on value proposition of products and comparative effectiveness research will require companies to perform better lifecycle planning, clinical development, and risk assessment."



says. "Also, the industry will react to the unknown legislative requirements in a naturally conservative manner; more restraints on sales and marketing options may be imposed in the future."

Further changes in the law — for instance, provisions eliminating or limiting preexisting condition exclusions and annual and lifetime caps on benefits — will prevent under insurance from impeding access to services by those who are insured, Mr. Fussaro says.

These changes will break down barriers that now prevent both the uninsured and the insured from receiving needed medical services.

"Of course, among these services that will be impacted is access to prescription drugs," Mr. Fussaro says. "The Institute of Medicine has found that uninsured individuals use one-half to two-thirds fewer services than individuals with insurance, so elimination or reduction in barriers to needed services should help improve access to pharmaceuticals."

COMPARATIVE EFFECTIVENESS: FROG IN A HOT POT

One of our experts aptly described the industry's reaction to comparative effectiveness research as at a tipping point.

"So far, CER can be compared to the frog in the pot of gradually warming water, the change has been bearable, bearable, bearable, and then, at some moment, begins warranting an aggressive response," says Jonothan Tierce, general manager, health economics and outcomes research (HEOR), IMS.

While the reflex reaction may be to assume that CER will be used as a club against manufacturers, this becomes less of a concern when the concept is considered in the broader context of the government's goals and steady march toward improved, transparent safety, and technology assessment. The United States is grappling with the same conflict every other advanced society is also confronting, which is how to ensure that everyone has access to a fundamental level of quality healthcare while at the same time, containing costs.

"Viewed in this light, CER is one more step along a clearly defined path, but a step over which manufacturers have only a limited amount of control," Mr. Tierce says. "And therein lies part of its significance."

Until recently, most of the information available about pharmaceutical products has been owned and released by manufacturers. In the future, in addition to the premarketed studies required for FDA approval, and some company-sponsored Phase IV and/or registry studies, the landscape will be increasingly populated by a new breed of studies, according to Mr. Tierce.

"These will be multi-stakeholder, transparent, publicly funded, or health plans sponsored studies designed to provide safety and comparative effectiveness information about manufacturers' products," he says. "Or stated differently, in the future, the postmarketed environment will be dominated by nonproprietary product information to which manufacturers will likely need to react."

The American Recovery and Reinvestment Act of 2009 provides for investment of more than $1 billion in federal funding for comparative effectiveness research, underscoring the important role CER will play in transforming the U.S. health system.

Mark Gianforcaro
i3
"The industry needs to build CER considerations into research at an earlier stage to ensure product commercialization."

"The industry will need to build these considerations into research at an earlier stage to ensure product commercialization," says Mark Gianforcaro, chief marketing officer, i3.

With the creation of a public-private partnership — through the nonprofit PCORI, the Patient-Centered Outcomes Research Institute — to oversee CER, the postmarketing environment has shifted noticeably. The CER provision of the newly passed healthcare reform legislation, along with the FDA's Sentinel Initiative, mean that beyond Phase III, manufacturers will have little to no control over the studies conducted, and the results published about, their products, Mr. Tierce adds.

"The very model for the way evidence is produced on the safety and effectiveness of products is changing, which is, in turn, shifting the risk/reward ratio for product commercialization," he says. "Clinical development decisions should be reflecting this fact."

The industry needs to prepare for the power to shift out of its hands as knowledge of comparative effectiveness spreads outward, according to Carolyn Buck Luce, global pharmaceutical leader, Ernst & Young.

"Comparative effectiveness will get fundamentally reinvented by payers and patients as large volumes of information enable widespread data mining to demonstrate value in comparative-effectiveness decisions," Ms. Luce says. "Such value mining will be done far more cheaply and quickly than biomarker

identification, which takes years of bench research."

According to Richard Gliklich, M.D., president and CEO, Outcome, the industry could come to a crossroads as companies either learn to be more proactive in developing comparative effectiveness and other postmarketing data, including working with broad stakeholder coalitions in such areas as registries, or reacting to a tidal wave of data from all too many directions.

"PCORI may significantly alter which products end up being successful in the U.S. market as drugs that are not shown to be more effective will find it increasingly difficult to achieve market access at a reasonable price," Dr. Gliklich says.

Comparative effectiveness should not be used to deny patients access to therapies based upon broad-brushed judgments about whether drugs should be available to patients, nor is it an appropriate basis for FDA approval decisions, Mr. Fussaro says.

"Given the funding recently provided for comparative effectiveness, and the interest in research on the part of payers, such research is undeniably an important factor in healthcare," he says. "However, it is important that such research be conducted and analyzed using rigorous scientific standards, and with input from relevant stakeholders. Moreover, comparative effectiveness research is different from issues of access and cost-effectiveness."

Health Economics and Outcomes Research (HEOR) will also play an increasingly important role in pre- and post-approval design of clinical and adaptive trials and observational research from which data are more generalizable to the targeted population. Because of the impact of comparative effectiveness research, and the need for more post-approval research, more data on products will likely be generated post-approval rather than pre-approval.

"An increase in customer needs and expectations of customers — regulatory and governmental agencies, payers, patients, and healthcare professionals — and focus on value proposition of products and CER will require companies to perform better life-cycle planning, clinical development, and risk assessment/management that will provide better real-world evaluation and evidence-based science," says Stephen Webb, president, North America, Registrat-MAPI.

The universal coverage created by the bill will by far have the greatest impact, and will also adversely affect healthcare providers so that there will need to be a greater effort by the pharmaceutical industry to target and communicate with these clinicians.

"The additional coverage will severely stretch the already dwindling numbers of primary-care physicians," says Melissa Hammond, managing director, Snowfish. "Therefore, we will likely experience an increase in the number of non-physician providers, including nurse practitioners and physician assistants, who are indicated by name within the language of the act, in the delivery of primary-care services."

Comparative effectiveness will prove to be the tipping point in the life-sciences industry as it relates to product marketing, product development, and portfolio optimization, reports Terry Hisey, vice chairman, U.S. life sciences leader, Deloitte.

"In an era during which facts beat messaging it will be critically important for individuals and organizations to use the facts and insights available to them to optimize care decisions and asset use," he says.

Comparative effectiveness will help to enable post-market surveillance to both provide for earlier detection of potential product issues as well as play an important role in safety monitoring and the introduction of REMS-based products.

"In the future comparative effectiveness, done right, will define a company's level of competitive effectiveness," Mr. Hisey says. "It will require new processes, skills, and governance models to be in place, making this truly a transformational aspect of healthcare reform." ✦

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BY ROBIN ROBINSON

» HEALTHCARE REFORM

THE IMPACT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

The PPACA contains provisions that establish, for the first time ever, an abbreviated regulatory approval pathway for biosimilars.

Closing the Medicare coverage gap is also a component of The Patient Protection and Affordable Care Act (PPACA). Our opinion leaders discuss how these and other elements of the act will influence the industry in the future.

The abbreviated pathway aspects of The Patient Protection and Affordable Care Act are important first steps in establishing the realization of lower cost follow-on biologics in the market place, says Terry Hisey, vice chairman, U.S. life sciences leader, Deloitte.

But while this is a core step, it is not the entire journey.

"It is our belief that the BLA process will continue to prevail and the pursuit of follow-on biologics will gain traction only upon greater clarity and definition," he says. "There is quite a substantial level of regulations that still need to be defined by the government and other regulatory bodies."

Even after defined, the likely scientific and regulatory hurdles beg the question of whether those returns are justified through the follow-on biologic pathway or if a company would be better off pursuing a traditional BLA approach, given that the product is fundamentally different, Mr. Hisey adds.

These uncertainties will minimize the overall impact of the act, says Claudia Wiatr, senior principal, Wolters Kluwer inThought.

"The new aBLA process for biosimilars does not favor the manufacturers of generic biologics," she says. "Because of unclear requirements for clinical data and the need for public disclosure of proprietary data, manufacturers of generic biologics are unlikely to take advantage of the aBLA process, opting instead for a standard BLA."

Another factor lies in the fact that physicians will be skeptical about the ability to substitute for the parent biologic in the absence of head-to-head clinical trial evidence. Payers are likely to have varying metrics for preference of the parent compound vs. the biosimilar.

"These issues, coupled with insufficient price discounts, will translate to a vastly different dynamic for brand erosion of a biologic compared with a small molecule," Ms. Wiatr

Dea Belazi
Wolters Kluwer Pharma Solutions
"With the potential increases in demand through access, the industry has also escaped drug importation and government price controls, which should further add to the positive affects of the new legislation."

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"The abbreviated pathway aspects of The Patient Protection and Affordable Care Act are important first steps, but it is not the entire journey."

IMS PROVIDES ANSWERS TO MEETING THE CHALLENGES OF CER

IMS's Jonothan Tierce, General Manager, Health Economics & Outcomes Research, offers tips on how manufacturers can approach comparative effectiveness in their new environment.

• **Inline Products.** It will undoubtedly take several years for CER studies to be conducted and disseminated on products already on the market. In the meantime, much information will be drawn from meta-analyses as they are relatively easy to do, compared with comparative trials or retrospective data analyses. Once CER is performed on these products, there will clearly be winners and losers.

We could predict that products that can only show limited incremental benefit relative to other branded and generic competitors will have a difficult time maintaining formulary status and market share. The recent experience with the ENHANCE [fn: Kastelein JJ and the ENHANCE investigators. Simvastatin with or without ezetimibe in familial hypercholesterolemia.]N Engl J Med. 2008 Apr 3;358(14):1431-43. Epub 2008 Mar 30.] study, an imaging trial sponsored by Merck on Vytorin and simvastatin, suggests that payers are willing to make decisions based on single studies that call into question the cost justification for a branded product over a reasonably good generic alternative.

Similarly, nothing prevents studies with significant improvements in clinical benefit from taking advantage of this additional opportunity to demonstrate value in the real-world setting.

• **Late-Stage Products.** Products in late-stage development now face the prospect of a CER upon entering the market. Here is where manufacturers can get out ahead of payer- and publicly funded studies. By conducting their own CER studies, especially if they follow the CER model of transparency and arms-length oversight, manufacturers can gain a comparative advantage. Here, the adage in retrospective studies should be remembered: "real-world studies are messy studies." Because of the "noise" in the real-world environment, for instance, patients are not identical to the clinical trial profile, patients don't take all of their medications, and so on, the typical finding in these head-to-head comparisons is non-significant. IMS's experience in using retrospective claims data in post-marketing studies comparing the effectiveness of two "worthy" competitors is that it is very difficult to differentiate one from the other.

Products for which studies produce neutral or negative conclusions will present companies with challenges that have to be addressed in their marketing, contracting, and pricing.

• **Early-Stage Products.** Companies with products deep in the pipeline —more than 10 years out — actually have an opportunity to benefit from the perspective brought to them by the prospect of CER. If they have the foresight and resolve to abandon product concepts that are unlikely to differentiate themselves in postmarketed CER studies, they will be able to concentrate on those advances that move the needle. Companies will not bother with products that offer only incremental improvements over existing therapies; they will want to bring out only guaranteed hits. This suggests the reemergence of the blockbuster.

Through the Sentinel Initiative, the FDA is developing an electronic system that will transform the agency's ability to track the safety of marketed drugs, biologics, and medical devices. The system will complement the agency's existing means for tracking reports of adverse events, the AERS (adverse event reporting system) program, by testing signals it generates and by scanning the environment for additional, possibly weaker, AE signals. Nonetheless, it will be game changing in the number of studies that will be conducted, the number of signals that will be generated, and in the transparency of the process. Although just how and when reports of AE signals will become public is under discussion.

Post-marketing surveillance will thus be transformed into a proactive search for weaker signals, and the research will likely generate many "false positives" that will need to be validated or invalidated. The axiom in such research is that "you rarely find what you're not looking for, and generally find what you are looking for." As signs of adverse events, whether valid or false positives, may eventually be identified in the public arena, manufacturers clearly need to be on the defensive and prepare for this possibility prior to launch.

Overall then, the clear trend is toward subjecting drugs to a new level of scrutiny on their health outcomes, beginning in Phase III and continuing post-marketing. This scrutiny is driven by adequate funding from the government and is governed by a transparent, public-private partnership model. Ultimately, this high-pressure, higher-risk environment will likely:

- Reduce the number of drugs reaching the market compared with the number that would reach the market using today's approach.
- Cause indications to become narrower.
- Strengthen safety labeling.
- Color promotion, uptake, and access with safety concerns.
- Increase development costs and diminish the probability of success.

Source: IMS Health. For more information, visit imshealth.com.

Thomas Fussaro
Millennium
"We think the impact of the legislation will be positive if biosimilars are held to high scientific standards to ensure safety and effectiveness."

says. "Our estimates indicate that biosimilars in both the United States and in Europe will result in a loss of revenue of 30% over five years for a typical branded biologic, compared with the 90% to 95% revenue loss for a typical generic small molecule."

With high development costs, complex manufacturing, and numerous legal obstacles to overcome, the development of biosimilars is not a low-cost proposition.

"Companies will still develop follow-on biologics, but because the BLA process requires significant clinical studies, companies are likely to look for claims of superiority to the parent compound rather than mere equivalence, opting for 'biobetters' over biosimilars," Ms. Waitr predicts.

Dea Belazi, consulting practice leader, Wolters Kluwer Pharma Solutions, outlines three major direct financial costs to the pharmaceutical industry over the next 10 years as a result of the new act.

First, he says, the increase and expansion of Medicaid rebates — estimated at $38 billion; the 50% discount in the Medicare Part D donut hole — estimated at $32 billion; and the industry fee — or excise tax, estimated at $28 billion. Second, indirect financial costs to the industry, he says, are the 12-year patent protection for follow-on-biologics, and third, is the expansion of the 340b pricing for qualified clinics and health centers.

"On the positive side, however, rests the potential higher demand for pharmaceuticals for those attaining access to healthcare insurance and the affordability of brand drugs in the Medicare donut hole," Mr. Belazi says. "With these potential increases in demand through access, the pharmaceutical industry also has escaped drug importation and government price controls, which should further add to the positive affects of the new legislation."

Another potential negative is the language in the legislation that describes the biosimilar or follow-on biologic and the patent life of the innovator product, which is 12 years.

"Compared with small molecules, which usually have a patent life of at least 17 years, biologics will now have a shorter patent life, therefore ultimately affecting lifetime sales," Mr. Belazi says. "Although this may seem to be a significant loss to biopharma, it is actually much better than some of the proposed patent lengths of 10 years or less."

Thomas Fussaro, director of government relations and public policy, at Millennium: The Takeda Oncology Company, agrees that the 12-year data exclusivity period for innovator biologics was a critical and necessary component of this legislation, and will be helpful in ensuring continued innovation.

"We think the impact of the legislation will be positive if biosimilars are held to high scientific standards to ensure safety and effectiveness," Mr. Fussaro says. "The new biosimilars pathway should not be a shortcut to market that endangers patient safety. The FDA should require extensive clinical data in such submissions, as well as careful postmarket surveillance activities to ensure biosimilar safety and effectiveness."

Mr. Fussaro suggests that the industry should become involved with the hearings that surround this act, to deliver input that will ensure that the FDA's implementation of the law is both protective of patients and the rights of innovators. The FDA is already moving forward in finalizing the regulatory pathway for approval and the industry should be fully engaged in this regulatory process. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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