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Eli Lilly's Sidney Taurel: 'Tailored Therapeutics' – the Pharmaceutical Industry's Next Blockbuster?

As Sidney Taurel prepares to retire as chairman and CEO of Eli Lilly, he predicts that significant changes at all levels of the health care industry will affect doctors, payers and patients alike. "I believe that the years ahead will amount to revolution much more than evolution," Taurel said during his keynote address at the recent 2008 Wharton Health Care Business Conference, whose theme was "Evolution: Soar or Surrender."

"It will not happen overnight, but we are already moving toward the barricades and headed toward a new business model," Taurel said. Headquartered in Indianapolis, Ind., Eli Lilly has approximately 40,600 employees and more than \$18.6 billion in sales. The company's top-selling drugs include Prozac, Cialis, Evista and Darvocet.

But the new business model for companies like Eli Lilly will likely move away from production of such "blockbuster" drugs and instead will focus on highly individualized solutions for patients, according to Taurel. It will emphasize therapies that work more often than not, as well as therapies that have a very clear benefit, thereby creating a more integrated system with greater economic and medical value. While some have dubbed the changes in health care "personalized medicine," Taurel prefers the term "tailored therapeutics."

Revolutions occur due to necessity and opportunity, or "push and pull," he said. "The push is a set of conditions that make change necessary, and the pull is the revolutionaries who seize the opportunity to create a different order, one that is an improvement over the old one." Taurel's talk of a revolution is timely, given that the pharmaceutical industry has seen the rate of drug approvals slow during the first half of this decade, even as it continues to face the challenges of rising costs, expiring patents and competition from generics.

The ultimate promise of tailored therapeutics is about "the individual patient, and we are prepared to stake our business on realizing that promise," Taurel said of Eli Lilly.

The Upside-down Pyramid

Health care costs are growing at an unsustainable rate, with an aging population as the driving force, according to Taurel. "Already, there are more people in Europe who are over 40 than under 40," while the median age in Europe is predicted to reach 50 by the year 2040.

Meanwhile, lower birth rates in the developed world have caused an inversion of the age pyramid, with too few younger, working people to help pay for the medical services being used by a growing older population. As the median age rises, so does the price of health care. "Indeed, turning the pyramid upside down wrecks the traditional model of health care payment," Taurel said, adding that Medicare faces an unfunded liability of \$30 trillion over the next few decades.

Another cause for concern: The value of health care products is coming into question, Taurel added, citing recent survey results showing that only 22% of consumers believe branded prescription drugs present a good value compared with more than 60% of consumers who think generic drugs are a good value.

The practice of medicine remains too much of a trial-and-error process that has not maximized the efficacy of prescription therapies, which work about half the time for the most common diseases, he said. "When our industry is better able to target our products to the patients who will really benefit, then our value proposition will surely grow. When medicines are used more optimally to reduce the trial-and-error nature of health care, then fewer resources will be wasted and the cost of health care will be sustainable."

'Tailoring' the Revolution

Taurel challenged the widespread notion that the key to the tailored therapeutics revolution is unlocking the secrets of the human genome. "Genomic medicine certainly serves to extend and, hopefully, to accelerate our goals, but the promise of this revolution is actually much broader and much more deeply rooted," Taurel said.

He used "biomarkers" – or biological indicators – as an example of one of the many modern advantages that will help drive the tailored therapeutics revolution. "Biomarkers are more pervasive and sophisticated than ever before, and they are coming into play in much earlier stages of drug development," Taurel said, noting that Eli Lilly now has biomarker strategies in place for nearly all molecules at the earliest clinical development stage.

Important benefits of biomarkers include the ability to weed out unpromising molecules early in the game, compress development times, run smaller and more focused trials and explore secondary indications earlier. "We hope that some of the beneficial effects of widespread biomarker indication will be shorter cycle times and lower costs in drug development," Taurel said.

Recognizing the difference between tailored therapeutics and personalized medicine is important, he added. He described tailored therapeutics as a larger concept that encompasses the many different types of personalized approaches to medicine. "A good tailor's abilities go well beyond alteration. The custom-made suit is his ultimate creation."

Taurel cited examples of Eli Lilly's work in tailored therapeutics, such as its use of new technology in protein engineering to design a molecule that could reach a large percentage of non-Hodgkin's lymphoma patients who don't respond to current therapy. Eli Lilly is also working to help doctors better identify patients who can benefit from specific treatments. All these efforts, while achieving the primary goal of practicing good medicine, also create a more stable financial environment in the health care industry. "Good medicine lines up with good business in every case," Taurel said.

Despite his optimism about the future of tailored therapeutics, Taurel acknowledged that some in the industry worry about the current business model being overturned – specifically, that the lack of blockbuster drugs will reduce big pharma's ability to pay for the next generation of research and development.

Taurel said a more effective, targeted treatment has the potential to increase repeat prescriptions, as opposed to the current trend away from repeat prescriptions due to the lack of efficacy. Tailoring also bodes well for reducing costs and thus contributing to the bottom line. "The net result of sales can be quite virile. Instead of getting a relatively small slice of a large pie, the tailored model promises a larger share of a more segmented pie."

Confidence and Collaboration

"Confidence and collaboration" are two major concepts that will help the health care system work within the new tailored therapeutic business model, Taurel suggested. Confidence will be built by learning to understand what's really in the way of optimal outcomes for patients, whether it's resistance to medication, failure to follow dietary requirements or the inability to pay.

As part of the new approach, companies must learn to turn down potential business if the effectiveness of treatment is not high enough, Taurel said. "Our future will depend quite literally on walking away from some business. Our goal should be to make sure that all the patients who should use a certain drug are using it, while those who should not be taking the drug are not." Lining up the right patient with the right drug is already being used as a motivator in Minnesota, where part of the health care reimbursement compensation is doled out in proportion to patient improvement ratios, Taurel said.

He described confidence as a two-way street that needs to start with education about the nature of genomes and the use of that sensitive data. He said IBM had instituted a policy not to use genetic data to exclude employees from health coverage. "A new spirit of collaboration is needed to help realize the promise of tailored therapeutics."

Collaboration is needed not just between government and industry, but between companies within the industry as well, Taurel added, suggesting that a significant hurdle would be breaking down inappropriate barriers to data collection. "Public payers, private health plans, drug companies, physicians and hospitals, and even the patients themselves all have particular reasons to be guarded in their collection and sharing of data, but in truth, all would be better off, once patient privacy is assured, if insights from clinical practice were available more quickly and easily."

While Taurel stressed the importance of protecting the intellectual property that drives much of their revenue, he said pharmaceutical companies need to look for new ways to collaborate and share information. "One laboratory's discarded failure may be the missing puzzle piece to another lab's effort to understand a patient group or disease pathway."

In 2004, Eli Lilly became the first such company to disclose all clinical trial results on the Internet, whether positive or negative. "At the time it was a somewhat frightening step, but others have followed suit. It not only helped us learn from each other's work, it also helped the credibility and the confidence that the public has in our research," he said.

Confidence in the pharmaceutical industry overall has taken a hit in recent years with several high-profile lawsuits filed against the manufacturers of blockbuster drugs. Eli Lilly, for example, agreed to pay up to \$1.2 billion to settle lawsuits filed by consumers who took the anti-psychotic drug Zyprexa and developed diabetes or other diseases. Another settlement is in discussion over consumers' claims that the drug was wrongly marketed for uses not approved by the FDA.

In addition, Eli Lilly announced last week that it is canceling trials of its AIR insulin product, which, according to an article in the *Wall Street Journal*, "had promised to offer diabetes sufferers more convenience and comfort than using a needle and syringe." A company spokesperson said the cancellation, which will result in Eli Lilly taking a charge of between \$90 million and \$120 million in the first quarter of 2008, was due in part to "new uncertainties in the regulatory environment," according to the *Journal*.

Taurel referred briefly to his upcoming retirement. With Philadelphia as a backdrop for the conference, he cited Ben Franklin as his role model for his part in the revolution of tailored therapeutics. "He helped set things in motion and continued to offer ideas until others took the reins," Taurel said of Franklin. "I also understand he had an enjoyable retirement."