

## Perspectives

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Chairman and Chief Executive Officer

### Legislating Change: Opening the Door to Generic Opportunities

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Chairman and Chief Executive Officer  
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Mr. Snow took the reins as President and CEO of Medco, one of the nation's leading pharmacy benefit managers (PBMs), in March 2003, and added Chairman to his title in June 2003. Since then, he has led Medco's 15,000 employees to deliver world-class services that drive down the cost of pharmacy health care for its clients. Medco, a Fortune 50 company with nearly \$38 billion in 2005 revenues, has been recognized for setting new industry benchmarks for pharmacy dispensing quality in its automated mail order pharmacy and, through its acquisition of Accredo Health, operates the largest specialty pharmacy serving the needs of patients with complex conditions requiring sophisticated treatment.

Prior to Medco, Mr. Snow was President and Chief Operating Officer at Wellchoice, Inc. (formerly Empire BlueCross BlueShield). Throughout his vast career, he has served in executive leadership roles for several companies including Oxford Health Plans, American International Healthcare, Inc. and US HealthCare, Inc. He also co-founded and served as President and CEO of Managed Healthcare Systems, Inc., which was later re-named AmeriChoice.

Mr. Snow earned a master's degree in health care administration from Duke University in 1978 and a bachelor's degree in science and economics from Bates College in 1976.

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Between now and the next presidential election, we have an opportunity to help forge the future of prescription healthcare by supporting three initiatives that will drive greater access to generic medicines – medicines that are proven to provide more affordable healthcare for millions of Americans.

- First, we must compel Congress to approve legislation that establishes an approval process that will enable companies to market generic biotech medicines – so people with complex and chronic diseases can finally afford medicines that today could cost hundreds of thousands of dollars a year.
- Next, we should close bureaucratic loopholes that allow big drug companies to raise frivolous challenges that unnecessarily lengthen – by months or even years – the time it takes a generic to reach market.
- And finally, we need to adequately fund the government's Generics Office, which is currently backlogged with applications for medicines that could help people lower their prescription drug costs today.

Each of these initiatives separately stands on its own merit. Together they create an enlightened approach to lower costs for patients and payors alike – while creating a pool of funding for research into the next generation of miracle drugs.

Of course, not everybody appreciates generics. History tells us we've been here before.

In 1984, when Senators Hatch and Waxman authored the ground-breaking Drug Price Competition and Patent Term Restoration Act – now simply called the Hatch-Waxman Act – arguments were legion against authorizing an FDA approval process for generics.

The lobbying arm for the big drug makers, in congressional testimony, belloped the following:

"Whatever short-term savings may be achieved will come at an enormous long-term cost to the public in terms of reduced pharmaceutical research, fewer new medicines in the future, and ultimately higher prices because of the new product competition that is deferred."

Of course, the reality since 1984 has been quite different. Innovation clearly didn't stop. To the contrary, the pharmaceutical industry entered an unparalleled wave of innovation leading to a succession of new blockbuster drugs – drugs that handsomely rewarded investors who accepted risk, funded research and produced important medicines that enhanced our quality of life.

As a result, now we have a new wave – a wave of generics, as \$62 billion worth of branded drugs lose patent protection between 2007 and 2012, which represents an enormous opportunity for every one of us who contributes to covering the cost of health care.

We take it for granted today, but it would not have happened had Congress not displayed the courage and leadership required to do the right thing in 1984.

Today, we're facing virtually the identical situation on the biogenerics front. And here's what the big biotech drug manufacturers testified at a Congressional hearing recently:

"Biotech generics will skew investment away from biologics research and development, jeopardizing the development of future pioneering biomedical advances."

It's almost a replay of what we heard 20 years ago. Of course, that simply isn't the case.

Let's stop the nonsense. Now is the time to clear a regulatory pathway for biogenerics.

What we're experiencing is a classic development cycle – one that's not unique to the pharmaceutical industry.

In the early phase of the cycle, breakthrough innovation leads to rapid growth, maturity and, ultimately, decline as "the next big idea" creates a disruption and starts a new cycle of innovation.

The innovation that created new classes of drugs dependent on the science of chemistry is now at maturity, and heading into decline. We see that manifest by the shallow pipeline for traditional medicines, and a series of branded, blockbuster drugs, moving off-patent.

The science of chemistry has yielded to a new wave of innovation – a "disruptive play" with new science – biotechnology.

Today, biotech remains in a rapid-growth phase, although several drugs in key therapeutic categories, such as synthetic insulin and human growth hormones, represent the first biotech medicines heading toward maturity. These are the first biotech drugs whose period of patent protection – and their associated maximum profitability – should lapse. In fact, across Medco's book of business, 16 percent of current specialty drug spending is linked to medicines that have already gone off patent.

While we should be transitioning to lower-cost bio-generics, patients and payors are still paying the premium brand price because there is no roadmap for the FDA to approve biogenerics.

It's a premium the drug companies don't deserve to earn, and a premium you shouldn't be required to pay. It is nothing short of an unearned windfall for big pharmaceutical companies.

Every day we don't act, it gets worse. Another \$10 billion worth of biotech products are going to move off-patent by 2010. But it's not as if the biotech companies didn't have any opportunity left on the table.

There are 250 biologics currently on the market, and more than 400 others in the pipeline. The market is growing at a compound annual rate of 34 percent.

To be sure, innovators in this space are entitled to rewards for ensuring these new drugs reach the market. But just as in the case of chemistry, there comes a time when generic competitors are allowed so that society can redirect capital into the next new science – and we can't do it without a generic pathway.

Congress is considering a plan that would authorize the FDA to approve generics in the biotech space, and it would give the FDA discretion to determine how much testing needs to occur before the biogeneric or so-called "biosimilar" is deemed safe for the market – a valid concern shared by everybody.

I've talked to a number of CEOs in the generic manufacturing space and I'm comfortable in their ability to develop large-molecule generics. The science is there to replicate and produce generic drugs – it's already being done in Europe. It's time for the FDA to establish the appropriate safety guidelines and move forward.

But just as investments moved from chemistry to biotech, once biotech generics reach market, capital will flow to genomics and nano medicine – both are fertile grounds that will produce enormous advances in pharmaceutical care.

Is it needed? Absolutely.

Is it doable before the next presidential election? Unquestionably.

Second, let's modify "The Citizen's Petition."

This well-intended mechanism was the ultimate in democracy, enabling any citizen to raise any concern about any drug in the FDA approval cycle. However, when an issue is raised – any issue by any person, organization or business – the entire FDA review process grinds to a complete standstill until there is a complete resolution.

The process, however, has been abused by special interests intent on unnecessarily delaying the approval process of a generic, or a competing brand – blocking important drugs from reaching the market and raising costs for all of us.

Congress is considering a bill that would amend the Citizen's Petition. When an issue is raised during the review period for a generic application, it's still completely investigated, but the review and approval process continues unabated – so that when the issue is resolved, the medicine is not delayed in reaching the patient.

Here's why that makes sense. Of the petitions filed between 2000 and 2005, 76 percent were dismissed without merit. The others were resolved amicably – without court intervention. In other words, not a single petition stopped a medicine from reaching the market – but they extracted their toll in throwing up bureaucratic roadblocks.

This change makes complete sense – it preserves the positive aspects of the citizen's challenge, and prevents self-serving interference – which was never intended.

Finally, we need to adequately fund the federal government's Office of Generic Drugs.

There are more than 1,200 generic drug applications currently backlogged – that's 1,200 opportunities to extend access to life-saving and cost-saving treatments.

When I recently attended the Generic Pharmacy Association Meeting, a representative of the Office said there's one simple reason they can't clear the backlog. It's not a lack of scientific knowledge or the inability to crunch enough data. It's more basic than that – they're simply understaffed and can't secure the appropriate funding.

Funding is always an issue, however considering the size of the Federal budget, this doesn't even add up to a rounding error.

Remember that we have an historic opportunity as branded medicines lose patent protection. Naturally, this has dramatically increased the number of generic applications. But The Office of Generic Drugs has been chronically underfunded, and the increased workload – which represents a massive opportunity – has made matters even worse.

They were looking for an incremental \$10 million in funding to clear the backlog and move these medicines through the pipeline. They received \$5 million, so they're resorting to developing a system of user fees.

Every day, we hear that Congress is appropriating untold millions to projects and programs that have little value and even less measurable return on investment.

Here's a case where the return is massive. Statistics have proven that every 1 percent increase in generic utilization yields about \$4 billion in savings to this country.

Consider what the government spends on medicines through Medicare and Medicaid alone. A \$5 million incremental investment to move new generic medicines to market would produce a return that would make any capitalist blush – and that's why this should make our "must do" list of Congressional priorities.

There are so many issues in healthcare that are challenging, complex and a few that could even be insurmountable.

It's rare that we can find three areas where common sense so obviously intersects with common interest.

Here's one healthcare crisis we can solve without breaking a sweat. It's time for Congress to do its part.

## Quick Facts: The Generic Opportunities

- \$62 billion worth of branded drugs will lose patent protection between 2007 and 2012
- 16 percent of current specialty drug spending is linked to medicines that have already gone off-patent
- \$10 billion worth of biotech products are going to move off-patent by 2010
- There are 250 biologics currently on the market and more than 400 others in the pipeline
- There are more than 1,200 generic drug applications currently backlogged
- Every 1 percent increase in generic utilization means about \$4 billion in savings to this country