

# ENCORE

## S P E A K E R N O T E S

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### **The Implications of the New Medicare Prescription Drug Legislation for Pharmaceutical Market Structure and Profitability**

Uber management guru Tom Peters said, “anyone who claims to predict the future is either neurotic, borderline psychotic, or a glorious self-promoter.” Well, I’ve never been called a self-promoter, so you can take it from there...

I know it will come as no surprise to anyone in this room, when I say we are living through a period of massive transformation in the history of the pharmaceutical industry and healthcare. It’s a complex transformation; one that continues to evolve.

The first draft of this new healthcare novel will be hitting bookstores just prior to the 2004 vote. Get in line to get your copy...prices will vary.

Needless to say, this industry will face unprecedented challenges over the next year. Let me run through some with you:

- The U.S. is responsible for nearly half the global sales of drugs and most of its profitability. Yet, the unpopularity of formularies in managed care and public backlash against what is perceived to be runaway drug prices has reduced traditional profit margins.

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- Changes in regulations have made the entry of cheaper generics easier and earlier. New regulations have led to a reduction in exclusivity periods within popular therapeutic categories, thereby reducing the premium prices that can be charged.
- A total overhaul of our healthcare system as we know it today, will take place with the Medicare legislation going into effect in 2006.
- Despite what you may be hearing, many big employers will be cutting, and are cutting, healthcare benefits for their retirees. Which means the burden of paying for prescription drugs will fall to the federal government or Medicare. The questions are how are we going to pay for it? And what's the impact on big pharma?
- Drug importation from Canada will continue despite efforts of many manufacturers to cut back on exportation to Canada and more careful inventory control with Canadian drug distributors. This won't be a fad, it is a trend.
- Most of our friends are gone, including the Republican Congress and many in the Administration. The presidential campaign will focus on healthcare and the involvement of HMOs, PPOs... and will older retirees be able to still get the "old Medicare" as they knew it before.
- Obesity – our #1 health issue (at least in the U.S.) will cost this country \$75 billion annually. What's the payout here for pharma?

As George Clooney's character in the movie *O Brother, Where Art Thou*, oft refrained, "We're in a tight spot!"

As we sit here today, the facets of execution of the new Medicare legislation are being hammered out all over Washington by folks at CMM, the strategists at HHS, and, of course, the Congress.

We are now on the brink of providing this taxpayer-subsidized prescription drug benefit to 40 million+ Medicare beneficiaries.

We do know that some companies with many retired workers are expected to post big earnings gains for 2003 or 2004, thanks to accounting guidelines for subsidies under the Federal Prescription Drug Program. As many of you have read, when Congress approved prescription drug benefits for Medicare recipients last year, it granted benefits for the 65% of large employers with retiree healthcare plans, providing funds for companies that maintain their prescription drug coverage for retirees.

The program, immeasurably, is to encourage employers to retain prescription drug coverage. The companies are entitled to the subsidy regardless of how much of the cost they pick up themselves. As a result it does nothing to halt the current rush by some employers to shift more costs to retirees.

So here is the boon to the employer. If the employer and a retiree each pay \$1,000 towards the retiree's medical costs, the employer subsidy is calculated on the full \$2,000, bringing a company a subsidy of \$490, rather than the \$210 they would get if they were to receive a subsidy on its share.

As a result, you can imagine when combined with tax and accounting rules the program allows employers in some cases to use the subsidy to erase the entire cost of prescription drugs for retirees or even turn a profit from a drug plan. For instance, if the Medicare-eligible retiree's prescriptions costs are \$2,550, and his employer pays \$1,000 of it, under long-standing tax rules the employer can deduct its full \$1,000 for tax purposes meaning the after tax cost to the company is \$650 at a 35% tax rate.

Again, the two big questions are: how we pay for this and what does this mean for the pharmaceutical industry? Criticism begins to mount and will continue to throughout the campaign. The argument is put forth that it is unconscionable for companies to receive billions of dollars in corporate welfare courtesy of the American taxpayer by slashing prescription drug coverage and retiree health benefits.

Let's not forget, too, that AARP, which lost 45,000 members in '03 because of their support of the Bush bill, is weighing back in recommending the equivalent of dreaded government price controls over drugs.

The cacophony of divergent interests now become more shrill.

Drug makers want to see demand for their products increase but not if the nation's costs rise to the point where price controls are demanded and that is the key. Insurers, managed care plans and pharmacy benefit managers worry that restrictions in the law might make turning a decent profit tough, while employers hope for relief from the drug prices they pay for retirees' drugs as we mentioned before. And the elderly, and future elderly, wonder whether the drug benefit, which clearly won't pay all the costs, will take enough pressure off their pocketbooks. These are the major issues...whew!

Many analysts believe extending Medicare coverage to prescription medicines promises drug makers a huge financial boom. Both the House and Senate bills passed in June estimated at a price of \$530-\$580 billion over ten years and big pharma is likely to get a major piece of it. The big challenge is how are they going to do it? One answer to come!

About 40 % of Medicare's 40 million beneficiaries have no drug coverage of any kind. And many of those who do have a drug plan either import them from Canada or often ration off the benefit of branded prescriptions to generics to cut their costs. With the help of the new Medicare benefit, the sheer numbers of users could send drug volume soaring.

Dr. Dan Vasella, Chairman and CEO of Novartis, said recently, "Financially, the benefit will probably be fairly neutral for the industry. Though drug volume will increase, they will be offset somewhat by discounted prices. Somehow let's expect the private insurers, that will discount the Medicare benefit, will extract 10-15% discounts from pharmaceutical manufacturers, similar to what the Medicaid program commands, possibly even more.

The bill calls for Medicare recipients to bear a major share of the prescription drug cost by a mix of deductibles, premiums and benefit caps. All of this before catastrophic coverage would kick in. The estimate is about \$3,600 per year for the 65+ set...still a big number for many.

I won't go through the details of the program since most of you are keenly aware of all the provisions.

So, with all that you have heard and read about vis a vis the impact of Medicare legislation and the call from most of the Democratic presidential nominees for universal healthcare coverage, what will be the overall impact on the pharmaceutical industry?

I believe that one can safely bet that with the increasing pressure to reduce healthcare costs and there will be, there will be more intense pressure on physicians to prescribe generic drugs. This pressure will come not only from CMM, PPOs and HMOs, but the Congress as well. I believe too, that the FDA will promulgate, faster than ever, switches of prescription drugs to OTC. The first areas might be cholesterol products and prescription allergy products.

And given the nature of the new study reported by Advance-PCS (August 25, 2003) which said that "specialty pharmaceuticals and/or biotech therapies" disproportionately affect healthcare costs, the whole ball game is changing.

So, one of the greatest challenges this industry faces will be the writing and dispensing of generic drugs. State formularies, HMOs, PPOs, and the litany of payors will be on the same generic drug track. In fact, some estimate 80% of all drugs for hypertension, hypercholesteremia, antibiotics, depression, allergy, and insomnia will be written and/or dispensed generically.

How do we respond? While we did take a stab 20 years ago at getting into the generic drug business, you may recall—some companies succeeded, most did not. It seems to me there must be a new business model forged to start selling generic drugs for those companies with weak pipelines in the immediate future.

Many traditional pharmaceutical executives will scoff at the idea of getting a 25 to 35% margin while they are getting 80 to 85% right now. But, make no mistake, those same people need to understand that they're either going to get 25 to 35% on generics or they will lose great volume very, very, quickly with their in-line branded products. Traditional branded primary care products will be squeezed. We could be going back to a diuretic as a drug of first choice for the hypertensive patient. A nickel a day versus \$3.

So once again, thinking transformationally, how do you build a new business model for the generic explosion?

Well, couldn't we think about doing a three-way generic drug enterprise? Here's one way it could work: a pharmaceutical manufacturer is the producer of a full generic drug line; it partners with Cardinal Health as its wholesale distributor and partners again with Walgreen's as the dispenser of these generic drugs. Each is a one-third owner of the new venture. So here you have a new kind of entity built with the prescription drug value chain of manufacturer, wholesaler, and chain.

Here also is one potential way of protecting your balance sheet and participating in what will become the new drug dispensing and distribution system.

The lawyers, of course, immediately will step in...apologies to all the lawyers in this room...and say, "Oh my god, are you crazy? We can't do that!" Maybe we are crazy but we're innovative thinkers too...and of course, we can do just that!

Consumer goods producers and distributors like P&G and Wal-Mart do it all the time using the value chain to produce and distribute...why can't we?

Generic drugs will be the wave of the future, as the government tries to find ways and means to reduce the burgeoning healthcare costs. They can't hit physicians, hospitals, or HMOs anymore; so we're in for it!

The industry has to come up with the big ideas to help our government officials accomplish their goal. The industry does not want to leave it to HMOs, nor do we want to leave it up to an angry Congress.

Big pharma must come up with innovative ways to reduce drug costs and curb importation from other countries. Big pharma must remain a self-controlled industry that is seen as one of our country's treasures to the public and to the government.

There are other transformational ideas that have been part of that...one of them has to be the pharmaceutical industry partnering much more closely with HMOs.

Consider the staff-model HMOs and the opportunity for us to partner with them as a J.V. in the production of a total generic drug line with the HMO branding on it. Why not? I think Kaiser and the Harvard Community Health Plan would embrace such a partnership. It's clearly a win-win situation.

All right, you say. Get on with the big crazy question Flaum, Who's going to be left in 2008? How many major drug companies will there be? Can any big pharma companies, as we look at the future today, follow the Pfizer business model where share of voice and share of doctor's time has become the benchmark?

The majority of analysts agree, other than possibly J & J, Novartis and Merck, most other companies can't possibly compete with the massive Pfizer battleship.

There is a lot of uncertainty about M&As today, but most analysts again would say that big pharma companies we will see standing and thriving in 2008 will be Pfizer, Aventis, Merck, Novartis, Wyeth, and Astra Zeneca.

It is more than likely that the others will either be whales, continuing to survive through clever and strategic acquisitions, or they will be fish being swallowed by one of the whales that exist today. It will be "Survival of the Fastest!"

So most companies, if they are to stand alone and survive, need to recreate a different business model.

Looking at the future in the near term, the trend is toward more R&D in the specialty drug area. Hypertension has pretty much been tapped out, as well as broad-spectrum antibiotics. We will see great focus on obesity, Alzheimer's, oncology, MS, psychosis, diabetes, ADHD, and HIV. We will continue to see a slew of acquisitions and long-term partnerships with biotech and biopharm firms with promising early Phase 2 products.

In the last few months, we saw Aventis do a deal with Regeneron for its cancer drug, Sanofi now for the whole package, and Genentech do a similar deal with Biovitrum for its diabetes compound.

Those big pharma companies with bright and aggressive business development people, who are out there every day looking at the data and sniffing out the potential strategic partnerships, will do well. One only needs to look at Forest Laboratories with no R&D, as an example of a monumental success...with its Lexpro and Namenda.

They are a consummate example of how great business development people operate. It's the same way that the Marion Labs of the 70s and 80s past prospered with no R&D—they became one of the great pharmaceutical companies by having extraordinary business development and licensing people. That's a trend and it's clearly transformational.

This is a remarkable industry that has been able to overcome great adversity only because it does the right thing; it discovers drugs that keep people alive and healthy.

We seem to have forgotten to tell this story and take pride in its achievements.

We have fallen prey to lawyers and lobbyists, and as of today, we're not making much headway, and that has got to change.

Transformational products and services have brought U.S. consumers new added value at prices they never complain about because the value is understandable, and appreciated.

One only has to look at defense industry products, the computer business, PDAs, iPods, Starbucks coffee, a carton of cigarettes at \$45 and, of course, Tivo...to name a few!

Transformational concepts have been the rock on which this industry was built. From a quirky experiment which gave us penicillin, to the discovery of the standard for breast cancer treatment today, Taxol, which came off the bark of a yew tree.

There is enough brain power in our industry to deliver the kind of value to the world everyday that is unparalleled. There also lies within us the creative ability to make the value of what we do better understood and appreciated by the general public and our elected officials.

Our industry is suffering from a perception problem and we are marketers...

Has a mission ever been quite so clear?

We must become our own advocates. We must do this not simply in courts of law, and in Congressional chambers; but in the much more diverse and the inherently more powerful courts of public opinion.

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And as a strategist and marketer, I can say this: a clever ad campaign won't do it alone. As Stephen Covey said, "You can't talk your way out of a problem that you behaved your way into". The industry must behave its way out of this one. We must roll up our sleeves and use all our ingenuity and gumption to turn a crisis into an opportunity for unprecedented growth... we've done it before. The business model exists! Let's get out there and execute in the only way we know how to...relentlessly and magnificently.

Thank you.

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Sander heads up Flaum Partners, a consultancy focused on transformational thinking for the pharmaceutical and biotech industries, and serves as Adjunct Professor of Management at the Fordham University Graduate School of Business where he chairs the Fordham Leadership Forum. He is the former Chairman of Euro RSCG Life and CEO of Robert A. Becker. Sander also serves on the boards of Fisher College of Business at The Ohio State University, Fordham Graduate School of Business, Neopharm Corporation, Viasys Healthcare and St. Christopher's Foundation for At-Risk Children.

Prior to coming to the consultancy side, Sander served 18 years with Lederle Laboratories (which was merged into Wyeth in 1994). During his tenure with this pharmaceutical manufacturer, he served in several capacities, including Marketing Director of ethical and biologic products. He was responsible for the introductions of most of the Lederle prescription and biologic products from 1974 through 1982. In all, he has directed 58 product launches.

A speaker on *Pharma 2005* (the future of the pharmaceutical industry), *Prospecting for the Big Idea*, *The 9Ps of Leadership*, and *Darwin 2005: Survival of the Fastest*, he is a published author with over 25 articles to his credit on marketing, management and leadership.

He has been a featured speaker at several domestic and international marketing conferences, most recently at the American Management Association, the National Managed Health Care Congress and the Pharmaceutical Marketing Research Group annual meeting. He is also a frequent guest on CNN and MSNBC on marketing and management issues. Sander was also the Commencement Speaker at the 2001 graduation ceremonies at the Fordham Graduate School of Business.

Sander received his undergraduate degree from The Ohio State University, and his MBA from Fairleigh Dickinson University (magna cum laude).

**Flaum Partners, Inc.**

Flaum Partners (FPI) introduces processes to transform the way clients think about products, customers, markets, and themselves.

Flaum Partners are experienced leaders in healthcare and pharmaceuticals, business development and communications, international trade and licensing, financial strategy, reimbursement, managed care, human resources, and consumer trend insights, who create inventive business-building concepts that companies can put to work.

FPI people are credited with developing more big ideas for pharma and health than anyone in the field: the first direct-to-consumer TV spot for an ethical product (Rogaine), the first compliance and persistency program (BuSpar), as well as the first indigent patient offering and the first patient guarantee program. These, and other breakthrough inroads have produced positive and long-lasting results for global and domestic corporations.

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