

THE CASE FOR PHARMACEUTICALS

In the last twelve months, pharmaceutical investors watched the S&P 500 rise by 12 percent while their investment sector declined by 3 percent. Is the pharmaceutical industry sick – or is it being misdiagnosed? In CAN's view, industry lab tests are showing false positives, and the patient should be discharged. It's healthier than it looks.

Starting June 1, Medicare beneficiaries could use their new Medicare drug discount cards. For uninsured seniors, the cards are a confusing boon. Such seniors, probably with the help of their adult children, can surf the Medicare web page, enter their addresses and medications, and then make informed choices about which pharmacy benefit manager discount cards are best for them. It takes only a \$35 application fee to sign up. The Bush Administration anticipates that uninsured seniors can reduce their drug costs by an average of 15 percent by doing this. So far, few seniors have called their offspring for Internet advice. A pick up in demand will hurt performance of drug stores; the 15 percent discount will come out of their top lines – and bottom lines. However, this temporary dent in earnings is not a major issue for Big Pharma. The cards can be used only until December 31, 2005.

In 2006, the Buying Spree Begins

On News Years Day, 2006, the pharmaceutical industry gets to party. As estimated by the Congressional Budget Office (<http://www.cbo.gov/showdoc.cfm?index=3960&sequence=3>; Chapter 1, Table 2 and figure 2), three out of four groups of uninsured, or under-insured, seniors will face incentives to purchase more of their products.

Group One: Low Consumption, Annual Purchases Between \$0 and \$1,100

This group will be indifferent to the new Medicare plan because its members have no rational justification for purchasing even generously subsidized federal insurance. Their consumption is so low that it is cheaper to pay out-of-pocket for the few times they need medication than to pay premiums, a deductible, and a co-payment. This group is surprisingly large, comprising 38 percent of Medicare beneficiaries. Pharmaceutical companies will make no additional sales from them as a result of the new law.

Group Two: Moderate Consumption, Annual Purchases Between \$1,101 and \$2,250

In exchange for paying an annual premium of \$420 and a deductible of \$250, the prices that Medicare beneficiaries will pay on the next \$2,000 of drug spending will fall by 75 percent. There are few things that people choose not to buy in greater quantity if the price falls by 75 percent – and drugs that can save a life, or improve its quality, aren't among those things. Analysts should anticipate that members of this group will boost their pharmaceutical spending significantly. Many will buy more until the subsidy stops, at \$2,250 per person in total spending. Eighteen percent of Medicare beneficiaries have room to grow their expenditures; they currently

spend more than \$1,100 but less than \$2,250 now.

Group Three: High Consumption, Annual Purchases Between \$2,251 and \$5,100

For seniors who currently spend more than \$2,250 but less than \$5,100, the Medicare bill will be a good deal, but it will not encourage large increases in drug purchases. This group will pay for the first \$250 in pharmaceutical purchases out of their own pockets, and then submit the next \$2,000 in bills to their insurance companies, which will send back checks worth \$1,500. Each senior spending more than \$2,250 will show a “profit” of \$1,080 (\$1,500 in insurance checks reduced by \$420 in premiums). Since drug purchases above \$2,250 are not subsidized, seniors will again have to dig deep in their pockets to pay for purchases above this amount. They will buy more only if the network price is lower than the retail price they currently pay. Network prices are typically 15 percent less than the “retail rack rate,” so expect this subgroup to boost the quantity of pharmaceuticals by 15 percent. Drug companies will experience a mildly positive impact in sales, if you accept our premise that drug stores will take almost all of the 15 percent haircuts. This group comprises twenty-seven percent of beneficiaries.

Group Four: Very High Consumption, Annual Purchases Above \$5,100

After beneficiaries pay all of their own expenses between \$2,250 and \$5,100, catastrophic coverage kicks in. Taxpayer-subsidized insurance companies will pay 95 percent of expenses above \$5,100. Seniors with expensive chronic conditions, will indeed welcome this provision. In addition to having an insurance company pay almost everything above \$5,100, they will have the chance to use more pharmaceuticals for almost nothing. A drug that previously cost \$120 out-of-pocket will now cost \$6. Spending among this group could grow explosively. Seventeen percent of beneficiaries spend more than \$5,100 annually in pharmaceuticals.

In short, thirty-five percent of Medicare beneficiaries, members of groups 2 and 4, will have substantial incentives to aggressively increase their consumption of pharmaceuticals since someone else will pay either 75 percent or 95 percent of their next purchases. The actual number of beneficiaries who will be sending pharma “get well soon” cards will be less than 35 percent, however. Twelve percent of beneficiaries already have Medicaid coverage, which has co-payments rates lower than the new law; another three percent receive benefits from the Veterans Administration.. Furthermore, 26 percent of beneficiaries have pharmaceutical coverage under employer-sponsored programs, and a subset of these plans charge low co-payment rates. Members of these groups will find that a new, federally subsidized insurer offers them no powerful motive to purchase more drugs.

After taking the already well covered into account, more than 8 million uninsured or under insured ill people will have a strong motivation to buy the best drug therapies they can, because they now cost pennies instead of dollars. These 8 million already purchase 14 percent of all pharmaceuticals. That number could grow to as high as 25 percent in 2006 if they expand their purchases by 75 percent because the required beneficiary co-payments are insignificant.

Table One: The Fifty Drugs Seniors Spent the Most On in 2002

Manufacturer	Product	Strength	% of all \$	\$ Rank	Patent Expiration	Description
Astra Zeneca	Prilosec	20 MG	3.58	1	04/02	Gastrointestinal
Astra Zeneca	Nexium	40 MG	1.10	11	04/05	Gastrointestinal
Barr Labs	Tamoxifen	10 MG	0.33	49		Antineoplastic
Boehringer	Combivent	103/18	0.43	39	06/15	Respiratory
Bristol-Myers	Plavix	75 MG	2.76	2	07/03	Antiplatelet
Eisai, Inc.	Aricept	10 MG	0.82	15	11/10	Alzheimer's
Eisai, Inc.	Aricept	5 MG	0.72	18	11/10	Alzheimer's
Eisai, Inc.	Aciphex	20 MG	0.59	27	04/09	Gastrointestinal
Eli Lilly	Evista	60 MG	0.63	22	04/03	Osteoporosis
Eli Lilly	Zyprexa	2.5 MG	0.45	36	03/03	Antipsychotic
Eli Lilly	Zyprexa	5 MG	0.34	48		Antipsychotic
ER Squibb	Pravachol	40 MG	0.74	17	10/05	Lipid-Lowering
ER Squibb	Pravachol	20 MG	0.63	23	10/05	Lipid-Lowering
Forest	Celexa	20 MG	0.49	34	07/03	Antidepressant
Glaxo Smithkline	Paxil	20 MG	0.62	25	12/06	Antidepressant
Glaxo Smithkline	Avandia	4 MG	0.46	35	08/08	Anti-Diabetic
Glaxo Smithkline	Avandia	8 MG	0.39	40	08/08	Anti-Diabetic
GlaxoSmithkline	Advair	250/50	0.38	42	11/03	Fluticasone
Glaxo Smithkline	Paxil	10 MG	0.32	50	12/06	Antidepressant
Immunex Corp	Enbrel	25 MG	0.34	47		Arthritis
Merck	Zocor	20 MG	2.52	3	12/05	Lipid-Lowering
Merck	Fosamax	70 MG	1.62	7	08/07	Osteoporosis
Merck	Zocor	40 MG	1.16	10	12/05	Lipid-Lowering
Merck	Vioxx	25 MG	1.02	12	06/13	Anti-Inflammatory
Merck	Zocor	10 MG	0.62	24	12/05	Lipid-Lowering
Merck	Cozaar	50 MG	0.53	29	08/09	Angiotensin II Inhibitor
Merck	Singulair	10 MG	0.45	37	02/12	Respiratory
Novartis	Miacalcin	200 IU	0.53	30	03/15	Calcitonin Replacement
Novartis	Lotrel	5 MG	0.37	44	08/03	Ace Inhibitor/CCB
Ortho Biotech	Procrit	40000 U	0.49	33		Hematopoietic
Pfizer, Inc.	Lipitor	10 MG	1.93	6	09/09	Lipid-Lowering
Pfizer, Inc.	Lipitor	20 MG	1.51	8	09/09	Lipid-Lowering
Pfizer, Inc.	Norvasc	5 MG	1.26	9	07/06	Calcium Blocker
Pfizer, Inc.	Norvasc	10 MG	0.97	13	07/06	Calcium Blocker
Pfizer, Inc.	Zoloft	50 MG	0.79	16	12/05	Antidepressant
Pfizer, Inc.	Lipitor	40 MG	0.63	21	09/09	Lipid-Lowering
Pfizer, Inc.	Neurontin	300 MG	0.43	38	05/08	Anticonvulsant
Pharmacia	Celebrex	200 MG	2.25	5	11/13	Anti-Inflammatory
Pharmacia	Xalatan	0.05	0.67	19	07/06	Glaucoma
Pharmacia	Detrol LA	4 MG	0.50	31	01/12	Overactive Bladder
Pharmacia	Detrol	2 MG	0.36	45	01/12	Overactive Bladder
Pharmacia	Celebrex	100 MG	0.35	46	11/13	Anti-Inflammatory
Schering	Claritin	10 MG	0.54	28	06/02	Antihistamine
Takeda	Actos	30 MG	0.60	26	01/06	Anti-Diabetic
Takeda	Actos	45 MG	0.50	32	01/06	Anti-Diabetic
Tap	Prevacid	30 MG	2.45	4	05/09	Gastrointestinal
Tap	Prevacid	15 MG	0.66	20	05/09	Gastrointestinal
Warrick	Isosorbide	60 MG	0.39	41		Anti-Anginal
Warrick	Isosorbide	30 MG	0.38	43		Anti-Anginal
Wyeth	Protonix	40 MG	0.96	14	07/05	Gastrointestinal

Source: Pennsylvania Department of Aging, http://www.aging.state.pa.us/aging/lib/aging/pace_02annl.pdf, Table 3.2A

When they can afford it, seniors are likely to buy more of what they are already purchase. “Quality of life enhancing” drugs, rather than “life saving” drugs, will fare especially well. Table One lists drugs that seniors buy most, based on data collected by Pennsylvania state agencies.

Kerry, Canada, and Pharmaceutical Industry Risk

Industry bears point to the “even money” chance that Senator Kerry has of becoming the 44th President next January. Senator Kerry supports repeal of the “noninterference” provision of the Medicare Prescription Drug Improvement and Modernization Act of 2003 which the bears believe would provide the federal government with the monopsony power to compel sharp reductions in the price of drugs bought by Medicare beneficiaries. As a “sole source” buyer, they believe the savings could be large.

This risk is unfounded, according to the Congressional Budget Office. In a letter dated January 23, 2004 to Senate Majority Leader William Frist (R-TN), the CBO Director wrote: “We estimate that striking that provision would have a negligible effect on federal spending because CBO estimates that substantial savings will be obtained by the private plans and that the (HHS) Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree. Because they will be at substantial financial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements.” In a subsequent letter on March 3, 2004 to Senator Ron Wyden (D-OR) discussing sole-source, sole-therapy pharmaceuticals, CBO did see some potential savings if the HHS Secretary negotiated on behalf of all private plans: “Nevertheless, there is potential for some savings if the Secretary were to have the authority to negotiate prices with manufacturers of single-source drugs that do not face competition from therapeutic alternatives.” However, monopsony naysayers claim that, in some cases when the federal government has had similar authority under the Medicaid program, it has paid *more* than the private sector would have as drug companies pressure regulators to raise prices!

Only a few drugs have no therapeutic competitors, and any change in the “noninterference” law would require congressional approval, which is unlikely to be given any time soon since Congress explicitly put this provision in the law only last December. Therefore, pharmaceutical bears are making too much of this “Kerry threat.”

Canadian reimportation presents greater risk to the industry. For example, seniors spend more on Prilosec than any other drug. In the U.S., Prilosec retails for \$144.99, but it can be had for \$58.36, 60 percent less, from a Canadian mail order pharmacy, according to the National Legislative Association on Prescription Drug Prices. NLAPDP reports similar discounts for several other drugs it surveyed (http://www.nlarx.org/index.php3?price_comparison). Another widely cited study, prepared by John Graham and Beverly Robson, found retail savings of 28 percent ([www.fraserinstitute.ca/admin/books/files/PrDrgPr1\(42\).pdf](http://www.fraserinstitute.ca/admin/books/files/PrDrgPr1(42).pdf)). Whether drugs are 28 percent or 60 percent cheaper in Canada, the profitability of the U.S. pharmaceutical industry collapses if its domestic revenues fall by such magnitudes because all Americans get their prescriptions filled in Ottawa at deeply discounted prices.

The reimportation threat becomes real if two things happen. First, President Bush or President Kerry must agree to assume responsibility for the safe importation of pharmaceuticals into the U.S. Second, Congress must pass a law that prevents drug companies from taking preemptive action to thwart reimportation.

The first condition is a more daunting demand than it appears. Congress gave the Clinton Administration the right to authorize drug importation on October 28, 2000 as part of P.L. 106-387. With three months left in office, Bill Clinton elected not to proceed because he could not certify that importation would be safe as required under this law. When Congress passed the Medicare reform bill last December, it left this certification requirement in place. Since President Bush took office in January 2001, his administration also has elected not to certify because of safety issues. Currently, there is no way to ensure completely that foreign suppliers would not ship stale or counterfeit drugs into the U.S. Still, most observers believe that President Kerry would certify “safety” – and he would do so even if Congress does not provide sufficient appropriations to the Food and Drug Administration to set up the administrative machinery necessary to confirm the continuous physical control of drugs entering the U.S. and also confirm the manufacturing process used to create these drugs.

Even if Kerry is elected and he certifies “safety,” an effective law also must clear Congress that will induce pharmaceutical companies to cooperate for the industry to be threatened. Drug companies know the base level demands for their products overseas. If demand jumps unexpectedly abroad while it falls here, they will conclude that their products are being diverted back into the U.S. Unless prevented, they can prevent the diversion by scaling back foreign shipments. Alternatively, drug manufacturers could alter the color, shape, or dosage amounts of their products. Companies might also raise prices abroad, eliminating the incentive to reimport. While things could change, the probability of a coercive bill becoming law before Congress adjourns this year appears small. Although another ineffective bill could pass this fall, only one significant Senate Republican, Senate Finance Committee Chairman Chuck Grassley (R-IA), has proposed effective “strong arm” legislation. On April 8, 2004 he introduced S.2307, a bill that provides a 20 percent increase in the research and development tax credit to pharmaceutical companies than do not interfere with reimportation, and also denies advertising deductions to companies that are found to be interfering. If Grassley succeeds in moving his bill through the Senate, then investors should worry. However, green lights will turn to flashing red only if the House leadership and Ways and Means Chairman Bill Thomas (R-CA) also become serious about leveraging the industry.

Pharma investors have good reason to like the new Medicare reform bill. It could boost sales by 10 percent above baseline projections in 2006 and beyond. Enjoy the good times – but remain vigilant until Congress adjourns, probably in October.

For further analysis or information, contact Capitol Analysts Network, Inc. at:

4405 Bradley Lane

Chevy Chase, Maryland 20815

website: www.capitolanalysts.com

Phone: 301-951-9161

Fax: 301-652-5831

Email: capnet@xecu.net

© 2004 Capitol Analysts Network, Inc. All rights reserved