LETTERS



A shift in command

Healthcare has always been stated as a priority with both political parties during an election year. Whether it's a presidential election year or a midterm election year, both Senate and House Representative candidates have promised to reduce costs of healthcare for seniors and the average family. One way that the U.S. government is making good on its promise is by approving Medicare Part D. The new Medicare Prescription Drug Benefit, Medicare Part D, is the result of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The program provides prescription drug coverage under Medicare and began Jan. 1, 2006. Medicare for the most part, however, benefits seniors. Although a great policy, this doesn't alleviate the costs of healthcare for the average family.

Both the Republican and Democratic candidates promised to reduce healthcare costs. One way, as some political commentators have stated, is by "going after the big Pharmaceutical Industry." There is, however, a level of skepticism that comes with these claims, particularly if one analyzes the amount of money being provided to both parties for election campaigns and funds. That being said, in the past the financial contribution from the pharmaceutical industry has been pretty much equal for both parties. This year the pharmaceutical industry's contributions from different sources showed that they contributed on average \$2.00 to the Republican party for every \$1.00 to the Democratic party. Is this a statement being made by the pharmaceutical industry? One may wonder if there is a reason behind the higher contributions for the Republican party compared with the Democratic party. No companies have stated what has led to the higher contributions to the Republicans

Changes in Washington: Will it Affect the Pharmaceutical Industry?

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— Patricia Santos-Serrao, RAC, Regulatory Advisory, Qumas

versus the Democrats. But, some indication can be found from statements on the Democratic party's Website (democrats.senate.gov/dpc/pubs/107-2-157.html).

"Democrats will ensure fair drug prices for all Americans, while Republicans would protect pharmaceutical industry profits." This statement notes that the Democrats' agenda is to reduce the cost of drugs. Some speculate that the pharmaceutical industry is trying to send a signal that it contributes to those who treat them more favorably.

This year was monumental for the Democratic party as it won back control of both the Senate and the House. Most would agree that the Democratic party's promise to reduce the cost of drugs wasn't a large factor in voters' minds. Though this means a political shift in government power, what does this mean for the pharmaceutical and biotech industries?

If the Democratic party stays true to its agenda to go after the industry, one way it can do this is by eliminating the loopholes that the industry uses to extend patents. Doing this would mean that manufacturers of blockbuster drugs would not benefit from extended periods of time in which they can keep their drug prices high because of exclusivity. Generic manufacturers would have a chance to produce and sell similar drugs for a reduced cost, forcing the original manufacturer to lower its price to stay competitive.

Generic manufacturers are able to provide similar drugs at reduced costs because they do not have to incur the cost of discovery. Generic companies also do not have to conduct lengthy and costly clinical trials to prove the safety and efficacy of their drugs; they simply have to prove that they are bioequivalent. Last, but not least, generic manufacturers benefit from being a default option for doctors, pharmacists, HMOs, and patients when the cost of the brand-name drug is too high. Therefore they benefit from the millions of dollars spent by the brand-name manufacturers.

The profit losses by the large brand-name manufacturers will be the gains of the generic manufacturers, unless of course they are one in the same. Large pharmaceutical companies are creating generic subsidiaries to produce bioequivalent versions of their own drugs in anticipation of patent expirations.

Another route that pharmaceutical companies may take to maintain profits is to apply for OTC approval for drugs that were only available through prescription. Schering-Plough (Claritin), J&J (PepcidAC), and Pfizer (Zantac) have all found success by going to OTC after patent expirations. (See related article on page 28.)

Whether the changes in Washington, D.C., will affect the pharmaceutical industry remain to be seen. The days of billion-dollar pills may or may not be over, but it's nice to know that one of the most profitable industries has a Plan B.

Patricia Santos-Serrao, RAC Regulatory Advisory Qumas

In Memorium

Lisa Helene Dzieglewicz, 35, died tragically on Friday, Dec. 1, 2006. Born in Plainfield, N.J., Ms. Dzieglewicz grew up in Bridgewater, N.J., and was a graduate of the Bridgewater class of 1989. She is listed with Who's Who of American High School Students.

She recently graduated from the University of Phoenix with a B.S. in marketing. For the past five years, Ms. Dzieglewicz had been working successfully as the marketing manager for inVentiv Health of Somerset, N.J.

She is survived by her parents, Ronald and Beverly (Alberino) Dzieglewicz and her sister, Deanna Bruh and her husband, as well as a host of aunts, uncles, cousins, and numerous friends and colleagues.

Donations in her memory may be sent to: The Humane Society of the United States, 2100 L Street, NW, Washington, D.C., 20037.

