The Pharmacist Activist

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Editorial

Pfizer SHOULD NOT be PERMITTED to Acquire Wyeth!

A headline for a story in *The Philadelphia Inquirer* (February 7, 2009) reads, "Pfizer Says The Time Is Right For Wyeth Deal." The "Deal" to which Pfizer and Wyeth executives have agreed is that Pfizer will acquire Wyeth for $68 billion, and is motivated primarily by Pfizer's concerns regarding an anticipated large decrease in revenues when the patent for Lipitor expires in several years. The anticipated "success" of this acquisition is largely predicated on billions of dollars in cost savings across many areas of responsibility, including research and development, and the loss of approximately 26,000 jobs.

To come up with $68 billion, it has been reported that Pfizer will borrow approximately $22.5 billion from a group of banks. In an acknowledgement of the difficulty that many banks are encountering in a very challenging economic environment, the CEO of Pfizer has stated, "It is good to see that the banks are doing what banks are supposed to be doing - lending money to advance the American economy and moving companies forward." However, the four US banks that are lending billions of dollars to Pfizer are among those that have been the beneficiaries of the bailout funds from the federal government.

It is my understanding that bailout funds are provided for the purpose of stimulating the economy and creating new jobs. However, Pfizer's acquisition of Wyeth will result in the loss of many thousands of jobs, a consequence that is in direct contradiction to the purpose of providing the bailout funds. The willingness of these banks that are receiving bailout funds to loan billions of dollars to Pfizer for an initiative that will result in the loss of thousands of jobs is occurring at the same time that thousands of loan applications from small businesses are being denied on the basis that banks and other financial institutions do not have the resources to lend. As a taxpayer, I strongly protest the use of taxes that I and others pay to facilitate an acquisition that will result in the loss of thousands of jobs, as well as other negative consequences. Pfizer should not be permitted to acquire Wyeth! This "deal" is wrong for just about everybody and may not even be "right" for Pfizer.

The employees

The most valuable asset of an organization is its employees, the individuals who demonstrate dedication and loyalty to their employer, as well as productivity in their responsibilities. Some companies experience such difficult financial challenges that layoffs are essential if they are to survive, and some others need to reduce positions to be efficient and profitable. However, both Pfizer and Wyeth can continue to be productive and profitable as separate companies and there is not a need for them to be merged into one huge organization that will result in the loss of many more thousands of jobs.

What responsibility and loyalty does an employer have to its employees? It would appear that some companies have concluded that their only responsibility is to their shareholders. It has been reported that one of the reasons cited by the Pfizer CEO to persuade the Wyeth CEO to agree to the acquisition is that it is in the best interest of the shareholders. However, I have seen no comment that even hints at any regret that 26,000 of their colleagues will be losing their jobs.

For the thousands of Pfizer and Wyeth employees who will lose their jobs, these circumstances

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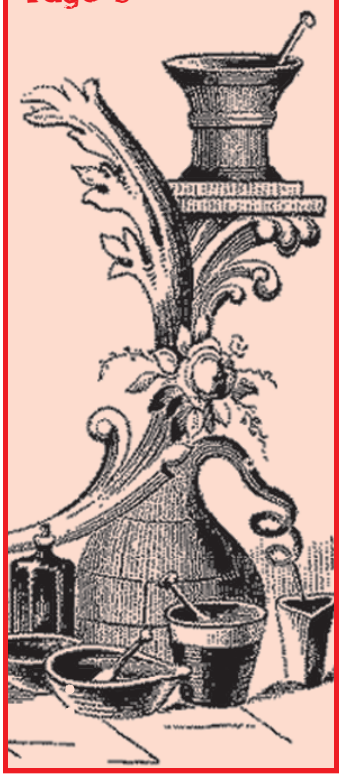


are devastating, particularly in today's economic climate. For the thousands of others whose jobs will be spared, the many months of anxiety in a position with a potential to be eliminated has a very negative impact on morale. How can their company expect their loyalty after what it has put them through? In a recent discussion with some veteran Wyeth employees I observed that the great anxiety about their jobs was exceeded only by their anger in learning about the acquisition on CNN.

Pfizer and Wyeth recently sponsored a full-page advertisement in *The Wall Street Journal* (January 27, 2009) with the headline, "Creating the World's Premier Biopharmaceutical Company." The advertisement includes the statement, "The talented people we have the privilege of working with have a tireless commitment to improving the health of the patients we all serve." This tribute will be of little consolation to those who lose their jobs and, for those who remain, even a tireless commitment can be overwhelmed with the extra work needed to accomplish what was done by the employees who were fired.

The shareholders

A company must have sound financial management to not only survive, but to also be profitable and to attract investors. However, some companies are obsessed with the amount of the profit and the value of their shares. This situation has prompted an extraordinary response from Steven Korman (*The Philadelphia Inquirer*, February 15, 2009), the CEO of a housing development company based in the Philadelphia area. After watching an interview of the CEO of Pfizer regarding the Wyeth acquisition, he placed ads in several major newspapers denouncing the elimination of thousands of jobs by companies seeking "to improve the bottom line." He further urged companies to accept smaller profits and reductions in stock value "rather than affect the lives of our neighbors and their families as jobs are lost." Mr. Korman also sent letters with a similar message to the chief executives of 17 major companies whose stock he owned. I was further impressed by the following comment he made in an interview: "I just think that if you worked hard, and you're doing a good job, and your company is making money, you shouldn't be laid off because they want to make more." I hope that his wise advice will be heeded.

Reduction of research productivity

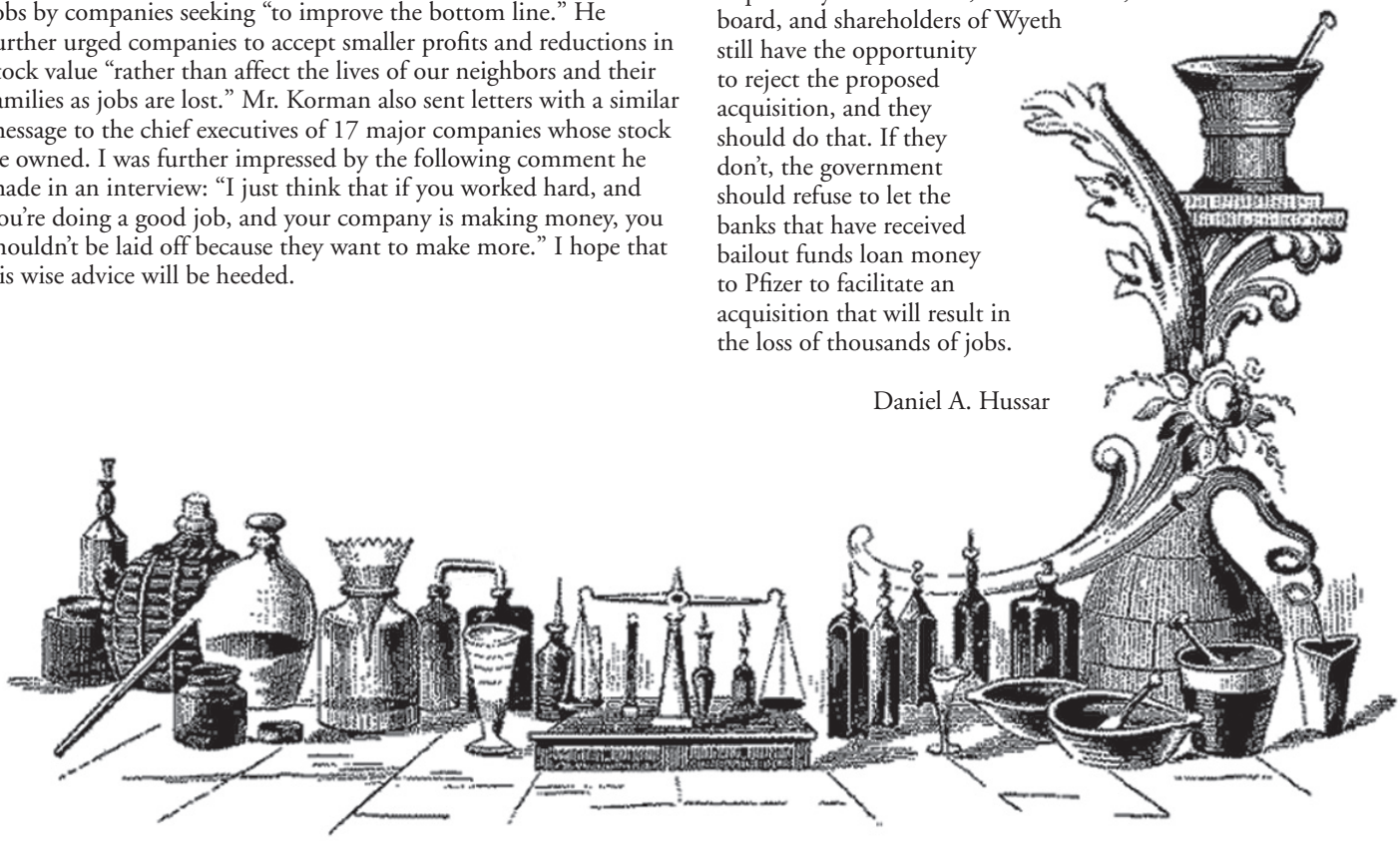
The acquisition of Wyeth by Pfizer also has negative consequences for the public and the country because the research funding and productivity of the two companies will decline substantially with the elimination of programs and thousands of jobs. The number of innovative new drugs and formulations developed by one huge pharmaceutical company can not be expected to match the productivity of two large companies that have a strong commitment to research.

Is bigger even better for Pfizer?

In a *Wall Street Journal* article (January 27, 2009), it is noted that "Pfizer has grown by buying up smaller rivals and their products, then laying off many of their employees, closing their labs and shuttering their plants." Just within the last decade Pfizer has already made two huge acquisitions, Warner-Lambert (including Parke-Davis) and Pharmacia (including Upjohn that had already acquired Searle). Even with blockbuster drugs like Lipitor and Celebrex that came with these acquisitions, Pfizer is apparently not satisfied with its current and projected financial status. Parke-Davis, Pharmacia, Upjohn, and Searle each, at one time, had excellent research programs. These programs and companies no longer exist and, even after acquiring these companies, Pfizer's research program is mediocre at best for a company its size.

Some already doubt that Pfizer will be in any better position after acquiring Wyeth than they are now, and Wyeth will become just a memory. I do not expect Pfizer to back away from its plan to acquire Wyeth. However, the executives, board, and shareholders of Wyeth still have the opportunity to reject the proposed acquisition, and they should do that. If they don't, the government should refuse to let the banks that have received bailout funds loan money to Pfizer to facilitate an acquisition that will result in the loss of thousands of jobs.

Daniel A. Hussar



New Drug Review

Milnacipran hydrochloride (Savella – Forest; Cypress)

Agent for Fibromyalgia

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages) in a scale of 1 to 5, with 5 being the highest rating

Indication:

Management of fibromyalgia.

Comparable drugs:

Duloxetine (Cymbalta), pregabalin (Lyrica).

Advantages:

- Is a more potent inhibitor of norepinephrine reuptake than serotonin reuptake that may be advantageous in some patients (compared with duloxetine);
- Is not a controlled substance (compared with pregabalin that is in Schedule V);
- Less likely to interact with other medications (e.g., CYP1A2 inhibitors, CYP2D6 inhibitors) via pharmacokinetic mechanisms (compared with duloxetine that is a substrate for these metabolic pathways);
- Less likely to cause hypersensitivity reactions and angioedema, edema and weight gain, and creatine kinase elevations (compared with pregabalin);
- May be used (in reduced dosage) in patients with severe renal impairment (compared with duloxetine);
- May be used (with caution) in patients with hepatic impairment (compared with duloxetine).

Disadvantages:

- Fewer labeled indications (duloxetine is also indicated for the acute and maintenance treatment of major depressive disorder, the acute treatment of generalized anxiety disorder, and for the management of neuropathic pain associated with diabetic peripheral neuropathy; pregabalin is also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, the management of postherpetic neuralgia, and as adjunctive therapy for adult patients with partial onset seizures);
- Must not be used in patients who are allergic to tartrazine (FD&C Yellow No.5);
- Dosage titration is more complex (compared with duloxetine for which just one dosage adjustment is recommended);
- More contraindications (i.e., interactions with monoamine oxidase inhibitors [MAOIs], patients with uncontrolled narrow-angle glaucoma) (compared with pregabalin);
- Greater risk of hepatic adverse events (compared with pregabalin);
- More likely to cause increased blood pressure and heart rate, serotonin syndrome, abnormal bleeding, nausea, and urinary hesitancy/ retention (compared with pregabalin).

Most important risks/adverse events:

Risk of suicidal thinking and behavior in children, adolescents, and young adults (boxed warning [is not indicated for use in pediatric patients]); contraindicated in patients being treated with an MAOI or within 14 days of discontinuing treatment with an MAOI; treatment with an MAOI should not be initiated for at least five days following discontinuation of treatment with milnacipran; use is contraindicated in patients with uncontrolled narrow-angle glaucoma; serotonin syndrome (risk is greater in patients who are also treated with other drugs that may affect serotonergic systems [e.g., selective serotonin reuptake inhibitors {SSRIs}, serotonin and norepinephrine reuptake inhibitors {SNRIs}, triptans, tramadol {e.g., Ultram}], or drugs that impair metabolism of serotonin [MAOIs]); elevated blood pressure and heart rate (should be determined prior to initiating treatment and periodically during treatment); hepatotoxicity (should not ordinarily be prescribed for patients with substantial alcohol use or evidence of chronic liver disease); abnormal bleeding (risk is increased in patients also taking an anticoagulant, aspirin, or anti-inflammatory drug); activation of mania; hyponatremia; may affect urethral resistance and micturition (risk is greater in men with benign prostatic hyperplasia); should not be used in patients who are allergic to tartrazine (FD&C Yellow No. 5); Pregnancy Category C; patients should be advised to avoid consuming alcoholic beverages.

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New Drug Review (cont.)

Most common adverse events:

Nausea (35%), constipation (16%), dizziness (11%), hot flush (11%), hyperhidrosis (8%), palpitations (8%), hypertension (7%), vomiting (6%), dry mouth (5%), increased heart rate (5%), headache (19%, but at a similar incidence with placebo).

Usual dosage:

Recommended maintenance dosage is 50 mg twice a day; treatment is initiated with a single dose of 12.5 mg on the first day, followed by 12.5 mg twice a day on days two and three, 25 mg twice a day on days four through seven, and 50 mg twice a day thereafter; dosage may be increased to 100 mg twice a day based on individual patient response; in patients with severe renal impairment, the usual maintenance dosage should be reduced to 25 mg twice a day; treatment should not be abruptly discontinued following extended use, but rather the dosage should be gradually reduced.

Products:

Tablets – 12.5 mg, 25 mg, 50 mg, 100 mg.

Comments:

Fibromyalgia typically develops in early-to-middle adulthood, and is most often experienced by women. The most common symptoms are muscle soreness and tenderness, flu-like aching, dull pain in the muscles, morning stiffness, fatigue, and problems sleeping. The American College of Rheumatology has identified criteria for a diagnosis of fibromyalgia that include widespread pain that lasts for at least three months, plus pain present at 11 or more of the 18 parts of the body called "tender points."

Milnacipran (Savella) is the third drug to be approved for the management of fibromyalgia, joining pregabalin and duloxetine. Like duloxetine, venlafaxine (e.g., Effexor XR), and desvenlafaxine (Pristiq), the new drug is a serotonin and norepinephrine reuptake inhibitor (SNRI). Milnacipran is a racemic mixture and its active enantiomer, d-milnacipran, inhibits norepinephrine uptake with approximately three-fold higher potency in vitro than serotonin uptake. Its effectiveness in the management of fibromyalgia was demonstrated in two placebo-controlled studies in which a larger proportion of the patients treated with the drug experienced a simultaneous reduction in pain from baseline of at least 30% and also rated themselves as much improved or very much improved based on a patient global assessment. In addition, a larger proportion of patients treated with milnacipran met the criteria for treatment response, as measured by the composite endpoint that concurrently evaluated improvement in pain, physical function, and patient global assessment.

The drug-related problems, warnings, and precautions associated with the use of milnacipran are generally similar to those of duloxetine and the other SNRIs, as well as the SSRIs. However, unlike duloxetine, milnacipran undergoes minimal metabolism via cytochrome P450 pathways, and is less likely to interact with other medications via pharmacokinetic mechanisms. In the clinical studies, 23% of the patients discontinued treatment prematurely due to adverse events, compared with 12% of those receiving placebo.

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**Caitlin Bilbow is a candidate (May, 2009) for the Doctor of Pharmacy degree at the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia.*