



The Pharmacist Activist

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The Justice Department Should Not Settle with MEDCO!

There have been recent news reports that there may be a settlement between Medco Health Solutions and the Justice Department with respect to the latter's allegations of fraud and its litigation against Medco. The allegations include not providing prescriptions to patients within the time frame identified in its contracts, destruction of valid prescriptions (allegedly in an effort to avoid noncompliance with the terms of the contracts with its clients), changing prescriptions without the consent of the prescribers, falsely claiming they had contacted physicians regarding potential drug-related problems, billing patients for drugs they did not order, underfilling prescriptions, obtaining kickbacks from pharmaceutical companies, and paying kickbacks to health plans to obtain their business.

Medco is reportedly willing to commit \$163 million to settle the litigation and cover its legal costs. The amount of \$163 million suggests that the alleged fraud is extensive and that the problems are enormous in scope. However, Medco maintains that it has done nothing wrong and expects that a final settlement will include no admission of wrongdoing or liability. It indicates that the issues in question occurred years ago and that any concerns are based on the actions of some "rogue" employees who broke Medco's rules and were subsequently fired. Medco makes no mention of whether these situations were reported to state boards of pharmacy or law enforcement agencies, or how these situations were addressed (that is, if they were addressed) with the patients and clients who were the victims of the problems that occurred. However, that might be tantamount to acknowledging wrongdoing.

Why would a company be willing to pay \$163 million if it was not involved in any wrongdoing? Medco has issued a statement in which it indicates that reaching a settlement with the government "makes good business sense" and that "it is time to move on." Although Medco does not address it, the possibility exists that a judge

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Inspiration

The name Harvey Whitney is familiar to many of us because of the numerous journals and books that he has published, including *The Annals of Pharmacotherapy*. I hold him in very high regard as a very capable writer and editor, as well as a valued friend. He has the courage of his convictions and, on numerous occasions, has published commentaries and other communications that were too “sensitive” or “political” for some other organizations/publications to publish. Examples include his article, “Do Basic Scientists Fiddle While Clinical Pharmacists Burn?” and my article, “Mifepristone—Controversy, Beliefs, and Politics—Issues for Everyone.”

A little more than a year ago, Harvey experienced acute, life-threatening necrotizing fasciitis caused by group A streptococci (necrotizing subcutaneous infection, “flesh-eating” bacterial infection). To prevent the spread of gangrenous infection, his arm had to be amputated. He experienced toxic shock, kidney failure, liver failure, and, at one point, his heart stopped. He could not move his one arm for about three months, either leg

for about five months, and was unable to walk from February 18 to August 4 when he took two steps. He was on dialysis 12 hours a week for 10 months.

Today, Harvey is still recuperating but summarizes his experience by noting that he has been “blessed.” He is known for having a strong faith in God, but he notes that his faith has been strengthened even further by this adversity he has faced. What an inspiring example of faith and courage! And he has recuperated enough to resume a limited schedule of editing and publishing responsibilities. When asked if he could be back the way he was before February 17, 2005 when the infection started, Harvey responds, “Yes and no. Sure it would be nice to have two hands to button my shirt, tie my bow ties, etc. But no, because I have had such great spiritual, relational, and emotional experiences that I would never have had otherwise.”

Thank you, Harvey, for letting me share your experience for the purpose of encouraging and uplifting others as they face personal challenges.

- Daniel A. Hussar

(MEDCO Cont.)

or jury may reach a different conclusion, that is that there was wrongdoing, and that more severe penalties should be imposed. The risks associated with such a conclusion may be so great that Medco apparently is willing to pay \$163 million for the opportunity to not admit to any wrongdoing.

In considering the allegations made by the Justice Department, it is extremely difficult to conclude that there was not any wrongdoing. Indeed, Medco’s reference to “rogue” employees whose actions resulted in their being fired has to be considered an acknowledgment of problems. With respect to the possibility of a settlement, U.S. Attorney Patrick Meehan has noted that the case is pending in federal district court, and that the “final resolution of these matters requires written agreements which are approved by the Department of Justice.” He goes on to note that, “as we stated at the time the complaint was filed, pressure by an employer to reduce costs and increase profits must never be allowed to coerce pharmacists into ignoring their duties to patients.”

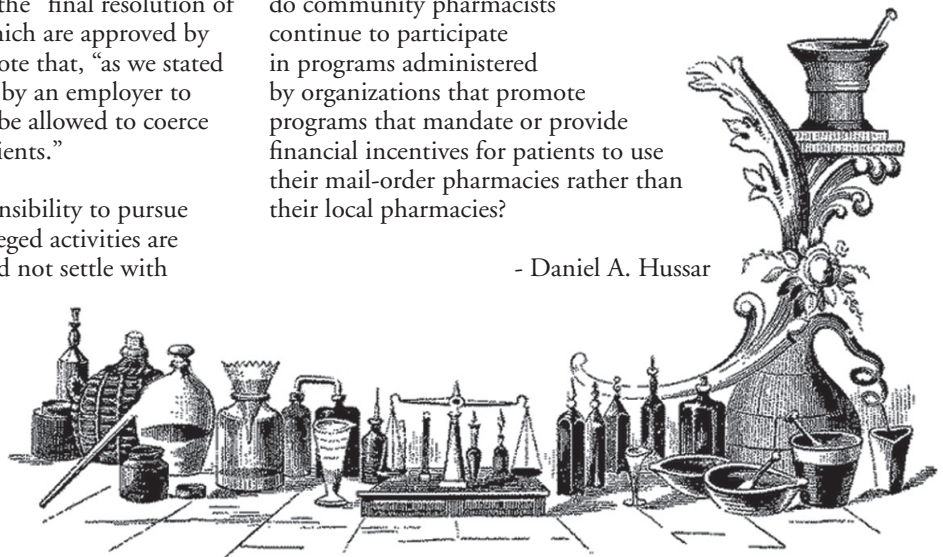
The Justice Department should have a responsibility to pursue a definitive determination of whether the alleged activities are wrongdoing or are not wrongdoing. It should not settle with Medco. Medco should not be permitted to buy immunity, even for \$163 million, against having anyone else decide whether it was involved in wrongdoing. The case should go to trial which has been scheduled for June.

In the meantime, Medco continues its aggressive business practices. A recent

front-page story in the *Wall Street Journal* (“Selling Generic Drugs by Mail Turns Into Lucrative Business,” May 9, 2006) reports on Medco’s plans to promote generic simvastatin when the patent for Zocor expires by faxing letters to 50,000 physicians and “to waive co-payments for six months for Zocor patients who switch to its mail-order pharmacy from a retail store.”

The irony of this situation is that Medco, in addition to its mail-order pharmacies, must have a network of community pharmacies in its prescription programs because it cannot provide medications needed for immediate/prompt treatment (e.g., antibiotics, analgesics) from its mail-order pharmacies on a timely basis. Why do community pharmacists continue to participate in programs administered by organizations that promote programs that mandate or provide financial incentives for patients to use their mail-order pharmacies rather than their local pharmacies?

- Daniel A. Hussar



New Drug Review

Varenicline tartrate (Chantix)

New Drug Comparison Rating (NDCR) = 5
(Important Advance)
 in a scale of 1 to 5,
 with 5 being the highest rating

Indications:

As an aid to smoking cessation treatment.

Comparative drugs:

Bupropion sustained-release (e.g., Zyban)

Advantages:

- Has a unique mechanism of action
- Higher effectiveness rate has been demonstrated in comparative studies
- Not likely to cause serious adverse events
- Not likely to interact with other drugs

Disadvantages:

- More likely to cause nausea
- Experience is more limited (when used alone or in combination with other medications for smoking cessation treatment)
- Recommended dosage guidelines include one more titration step

Conclusions:

Varenicline is an important addition to the small group of agents that have been demonstrated to be effective in helping individuals stop smoking. It has a unique mechanism of action and has been demonstrated to be more effective than bupropion in studies in which the two drugs were directly compared. Although it has not been directly compared with nicotine replacement therapy (NRT), the results of studies with the individual products suggest that varenicline is as effective as or, probably, more effective than the NRT formulations.

Varenicline is not likely to cause serious adverse events or to interact with other drugs. Approximately 30% of patients experience nausea with its use but this is seldom serious enough to result in discontinuation of treatment. Its favorable safety profile provides an important advantage over bupropion with which there are risks that include seizures, suicidality, and a potential for interaction with numerous other therapeutic agents.

Varenicline should be the medication of first choice to help individuals stop smoking. It is more effective and safer to use than bupropion. None of the nicotine replacement therapy (NRT) formulations (gum, lozenge, transdermal patch, inhalation system, nasal spray) provides the optimum balance of onset of action and duration of action and, even though the use of NRT is much safer than continuing to smoke, it represents a continuing source of the agent (nicotine) to which the individual is addicted. Therefore, varenicline should also be preferred to NRT for first-line use in helping people stop smoking.

As with almost all new drugs, the use of varenicline requires a prescription. However, the importance of the consequences of smoking and the benefits of stopping smoking, coupled with the effectiveness and apparent safety of varenicline, justify an exception. Varenicline should be available without a prescription in pharmacies, and pharmacists should be required to personally discuss the dosage instructions and maintain appropriate records.

Varenicline is expected to reach the market in the early summer. Information regarding its cost is not available at this time.

Discussion

Smoking cigarettes represents the most preventable cause of death in the United States. Pharmacologic options to help individuals stop smoking are limited and include the nicotine replacement therapy (NRT) formulations and bupropion sustained-release (e.g., Zyban).

Varenicline tartrate (Chantix-Pfizer) has been recently approved as an aid to smoking cessation treatment and has a unique mechanism of action. The new drug is a partial agonist selective for $\alpha_4\beta_2$ nicotinic acetylcholine receptor subtypes. It binds with high affinity to these receptors and its agonist action is thought to reduce the craving to smoke as well as the withdrawal symptoms from nicotine. By occupying these receptor sites, varenicline prevents the binding of nicotine if the individual smokes while receiving treatment, thereby reducing the satisfaction associated with smoking.

The effectiveness of varenicline has been demonstrated in six clinical trials involving more than 3,600 chronic cigarette smokers. In two of these studies, the new agent was compared with both bupropion sustained-release and placebo. Abstinence from smoking was evaluated during weeks 9-12 of the studies and varenicline was determined to be effective in 44% of the participants, compared with 30% of those receiving bupropion and 17% of those receiving placebo.

In one of the placebo-controlled studies, individuals who had stopped smoking by week 12 were provided either varenicline or placebo for an additional 12 weeks and then followed for 28 weeks post-treatment. The continuous abstinence rates through week 24 were 70% for those receiving varenicline and 50% for those who were switched to placebo after 12 weeks. Following the 28-week post-treatment period, the abstinence rates were 54% in the group who had received varenicline for the first 24 weeks and 39% in the group who had received varenicline for the first 12 weeks and placebo during weeks 13 to 24.

Varenicline is well tolerated by most individuals and its labeling is noteworthy in that it does not contain sections on Contraindications and Warnings that are included in the labeling for almost all therapeutic agents. Nausea was the most

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frequently experienced adverse event, occurring in 30% of those treated with the recommended dosage. Most of these individuals described the nausea as mild or moderate and it was often transient. Three percent of patients discontinued treatment prematurely because of nausea. To reduce the occurrence of nausea, treatment should be initiated at a lower dosage and increased in two increments to the recommended maintenance dosage.

Other commonly reported adverse events include insomnia (18%), abnormal dreams (13%), constipation (8%), flatulence (6%), and vomiting (5%). Varenicline is classified in Pregnancy Category C and should be used during pregnancy only if the anticipated benefit outweighs the risk to the fetus. Its use in nursing mothers should be avoided, and its use is not recommended in individuals less than 18 years of age.

Following oral administration, varenicline is almost completely absorbed. The drug is metabolized to only a minimal extent and approximately 92% of a dose is excreted unchanged in the urine. The dosage should be reduced in patients with severe renal impairment and in those who are undergoing hemodialysis.

Because smoking may induce enzymatic pathways involved in the metabolism of certain therapeutic agents (e.g., theophylline, warfarin [e.g., Coumadin]), the action of these agents should be closely monitored when a patient stops smoking.

In using varenicline, the smoker should determine a date to stop smoking and varenicline treatment should be initiated one week before this date. The drug should be administered after eating and with a full glass of water. The recommended initial dosage is 0.5 mg once a day on Days 1-3, followed by 0.5 mg twice a day in the morning and evening on Days 4-7, followed by 1 mg twice a day from Day 8 until the end of treatment. A course of treatment should continue for 12 weeks. For patients who have stopped smoking at the end of 12 weeks, an additional 12-week course of treatment is recommended to increase the likelihood of long-term abstinence.

Varenicline tartrate is supplied in tablets in amounts equivalent to 0.5 mg and 1 mg of varenicline base. Packs containing the appropriate numbers of tablets of both potencies are available to facilitate accurate dosage titration.

- Daniel A. Hussar

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