FDA updates boxed warnings for rosiglitazone, other drugs

Alerts, warnings and recalls

The boxed warning for rosiglitazone (Avandia) was revised to reflect a potential increased risk of heart attacks. In August, the entire class of thiazolidinediones added boxed warnings saying the drugs may cause or worsen heart failure.

An updated boxed warning says epoetin alfa (Epogen, Procrit) and darbepoetin alfa (Aranesp) caused tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid and non-small cell lung cancer at doses that aimed for a hemoglobin level of 12 g/dl or more. In cancer patients, the drugs should be used only when treating anemia caused by chemotherapy. For kidney failure patients, the drugs should be used to maintain a hemoglobin level between 10 g/dl to 12 g/dl, as higher levels raise the risk of death and serious cardiovascular reactions.

Eleven deaths spurred boxed warnings for echocardiography contrast agents Perflutren Lipid Microsphere Injectable Suspension (Definity) and Perflutren Protein-Type A Microspheres for Injection (Optison). Four died by cardiac arrest that occurred within 30 minutes of drug infusion, while the others died within one to 12 hours. Medical professionals should monitor patients for 30 minutes after infusion, and shouldn’t use the drugs in patients with unstable angina, acute myocardial infarction, respiratory failure or recent worsening congestive heart failure.

Antifibromytic drug aprotinin injection (Trasylo) was temporarily pulled from the market pending review of study data suggesting an increased risk for death.

Physicians should tell patients taking etanercept (Enbrel) for type 2 diabetes to seek immediate care if they have unexplained and persistent severe abdominal pain. At least 30 patients have experienced acute pancreatitis after taking the drug.

Modafinil (Provigil) and armodafinil (Nuvigil) have a new bolded warning due to reports of serious rash, including Stevens-Johnson syndrome, which can lead to hospitalization for infection.

Erectile dysfunction drugs tadalaflit (Cialis), vardenaflit (Levitra), and sildenaflit (Viagra) received label changes to highlight potential risk of sudden hearing loss.

Approvals

Cetirizine and pseudoephedrine (Zyrtec-D), for nonprescription use to treat allergies in anyone age 12 and older. The drug has been available by prescription since 2001.

Agent endothelial tube clamp, which is coated with silver to prevent ventilator-associated pneumonia in hospitals. A multicenter trial found it reduced the percentage of patients who developed pneumonia from 7.5% to 4.8% when compared to an uncoated tube. It also delayed onset of pneumonia.

Kalegravin (Entresto), the first integrase strand transfer inhibitor, to treat HIV in combination with other antiretroviral drugs. The drug is meant for treatment-experienced adults with evidence of viral replication and with HIV strains that are resistant to multiple antiretroviral drugs.

The first generic versions of anticonvulsant oxcarbazepine (Trileptal) in 150-, 300- and 600-mg doses. It can be used alone or with other medications to treat partial seizures. Side effects may include serious skin reactions, dizziness and drowsiness.

A 500 mg intravenous infusion of doripenem injection (Doribax) to treat complicated urinary tract and intra-abdominal infections. Multi-center studies show the drug has a cure rate comparable to levofloxacin and meropenem.

Ixabepilone (Ixempra) to treat metastatic or locally advanced breast cancer. It can be used in combination with capcitabine in patients who no longer benefit from two other chemotherapy treatments that included an anthracycline and taxane, or alone in patients who no longer benefit from an anthracycline, a taxane and capcitabine.

Nilotinib (Tasigna) to treat Philadelphia chromosome positive chronic myeloid leukemia in adults whose disease has progressed or who can’t tolerate other therapies that included imatinib (Gleevec).

Nilotinib has a boxed warning for possible life-threatening heart problems that may lead to an irregular heartbeat and sudden death.

The Campaign Trail

Health care plank builds presidential platforms

Welcome to The Campaign Trail, a new ACP Internist column covering health care issues in the 2008 presidential campaign.

Over the next 10 months, I will try to update you on what the candidates have been saying about health care, suggest good resources for additional information on their positions, and, through a series of ACP InternistWeekly online polls, provide insight into your colleagues’ thoughts about the election.

According to the results of our first poll, readers are most interested in the candidates’ plans to expand health care access. Access resoundingly defeated cost, quality and the ever-popular “other” categories in our unscientific online survey (see graph “Readers decide: health care access”).

So are the candidates responding to physicians’ concern about expanding Americans’ access to health care? To find out, I decided to check out the campaign Web sites of six top candidates (the three Democrats and three Republicans who were polling highest as of press time).

If you evaluate the candidates solely on who puts the most emphasis on health care, the Democrats as a group are leading the Republicans, and underdog John Edwards takes top honors. Health care is the top item on the “issues” page of his Web site. Hillary Clinton’s site ranks it second after strengthening the middle class, and Barack Obama lists health care third, just after overseas policy.

What does Web site content and placement say about the presidential candidates’ plans to expand health care access?

And what about the others? Does it accurately represent their perception of their supporters’ interests or just the preferences of their Web developers? I don’t know. What I do know is that clicking though on the links doesn’t offer much information to differentiate the candidates on the issue of health care access.

The leading Democratic candidates have remarkably similar plans intended to provide “universal, affordable, quality” health coverage for all. Senators Clinton and Obama even explain their programs in the same way—providing all Americans with the same health insurance options that members of Congress receive. And Mr. Edwards has noted repeatedly how similar Sen. Clinton’s plan is to his own.

Likewise, Republican candidates are unified in their desire to keep health care in the private sector and use free-market strategies to expand access to insurance. Even their critiques of the Democratic plans sound the same—Mr. Romney presents his plan as an alternative to “a one-size-fits-all, government-run system,” while Sen. Thompson opposes “a one-size-fits-all Washington-controlled program.”

So how does a health-care-concerned primary voter choose the candidate who best reflects his or her views? You can get behind one of the long-shot but more activist candidates. (At the Democratic debate in Philadelphia, Dennis Kucinich explained his sponsorhip of legislation establishing Medicare for all: “There is no one else on this stage who is ready to take on the insurance companies directly,” he said.)

Or you can check out ACP’s new candidate comparison Web tool, which enables you to compare the details of all the candidates’ plans with the official positions of the College. The tool draws on recommendations for health care reform that were outlined in the College’s recent position paper, Achieving a High Performance Health Care System with Universal Access, published in the Jan. 1 issue of Annals of Internal Medicine. The tool looks at six different issues raised in the paper and evaluates where the candidates stand on each of them. The tool, online at www.acponline.org/advocacy/election2008, will be updated continually throughout the 2008 election cycle.