RxCONNECTOR

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FDA OKs key new antidepressant for Wyeth

Wyeth recently won approval from the Food and Drug Administration for its antidepressant Pristiq, the drug maker's planned successor to its top-selling Effexor. Effexor XR, Wyeth's extended-release depression drug, last year pulled in $3.8 billion—17 percent of its total revenue. Cheaper generic competition is expected to start eroding those sales as early as this summer, so a new, patent-protected replacement is crucial.

Pristiq becomes the ninth drug in two similar, widely-used classes of newer antidepressants called selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs). Madison, N.J.-based Wyeth plans to launch Pristiq, approved in a 50-milligram dose, by June.

Wyeth said Pristiq has fewer interactions with other drugs than competing antidepressants. However, Dr. Alan Gelenberg, head of the American Psychiatric Association panel that develops guidelines for treating depression, said he's seen no data that Pristiq or any other antidepressant is better or safer than any other SSRI and SNRI.

"My impression is that marketing is very effective," swaying doctors as well as patients, he added. Experts also point out that Pristiq is a chemical cousin of Effexor XR.

Approval of Pristiq snaps a streak of refusals from the FDA. Since last spring, the agency has on four

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Adam W. Hamm
Insurance Commissioner

Welcome to the *RxConnector* newsletter!

Dear Friends,

This newsletter is designed to keep you up-to-date about the Prescription Connection for North Dakota program and to keep you in the know about the various prescription assistance programs that are available. From time to time, we may also include other items of interest related to Medicare and the Senior Health Insurance Counseling (SHIC) program.

As always, thank you so much for all that you do for the Prescription Connection program. Without your help, our work would be that much harder. Your efforts are valued and appreciated.

If you have items of interest that you think should be included in this newsletter, we would love to hear about them. Please contact Sharon St. Aubin at sstaubin@nd.gov or call her at 1.888.575.6611.

Adam W. Hamm
Insurance Commissioner

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occasions rejected an experimental Wyeth drug, demanded more data or made the company conduct an additional patient study.

"It's a relief for Wyeth, in general, and certainly for the shareholders who have been waiting for this product for nearly two years," said Lehman Brothers analyst Tony Butler.

Still, some analysts say Pristiq can never produce Effexor's revenue. Raymond James & Associates analyst Michael Krensavage noted insurers are getting tougher about coverage of expensive new drugs, giving preference to cheaper ones, especially when the new ones don't have big advantages. Generic versions of popular SSRI antidepressants—including Prozac and Zoloft—are available, and generic versions of Effexor XR will also be available this summer.

Source: Associated Press/AP Online

Google to announce personal health records website

Google recently announced a new website that will allow patients to store their personal health records (PHRs), the *Wall Street Journal* reports. According to an individual who has tested the website, which Google likely will call Google Health, patients can enter their PHRs on the site and electronically invite physicians to view the information. Google declined to comment on the website.

The website, which will compete with similar sites operated by Microsoft and Revolution Health Group, "could boost the nation's fledgling efforts to adopt electronic medical records," the *Journal* reports. Many "consumers have been slow to make use of services that allow them to set up" PHRs, in part "because of concerns about online privacy," and "medical experts say that the services must be able to compile information from different practices where someone has been a patient" and "accept information from the systems the medical practices use," according to the *Journal*. In addition, some health care professionals have raised concerns about the use of PHRs to sell advertisements and the possibility that the federal medical privacy rule issued after the enactment of the Health Insurance Portability and Accountability Act does not cover records stored online.

A Google spokesperson said, "For us, trust between Google and our users is one of the absolute cornerstones of our business. And we are absolutely committed to continuing that dedication in all of our efforts." George Scriban, product manager, consumer health platform for Microsoft, said, "We are trying to create an industry," adding, "We are humble in the face of how big this is."

(Lawton/Worthen, *Wall Street Journal*, 2/28).

FDA issues Tussionex safety alert

The U.S. Food and Drug Administration issued a safety alert, saying incorrect usage of a specific cough medicine can result in serious health risks.

The FDA said its alert concerns the safe and correct use of Tussionex Pennkinetic Extended-Release Suspension—a prescription cough medicine containing hydrocodone, a narcotic ingredient and the antihistamine chlorpheniramine. The product is approved for use in adults and children over the age of 6 and should be given no more frequently than every 12 hours.

There is a real and serious risk for overdosing if this medication is not used according to the labeling, said Dr. Curtis Rosebraugh, acting director of the FDA's Office of Drug Evaluation II.

Source: United Press International

Recent generic drug approvals

Each year, the Food and Drug Administration approves scores of generic drugs that treat a variety of conditions and help consumers save money.

Significant approvals granted by the FDA's Office of Generic Drugs during the past year included:

• **Alendronate sodium tablets—**used for treating and preventing types of osteoporosis Originally marketed as: Fosamax, by Merck & Co.
Date approved: Feb. 6, 2008

• **Carvedilol tablets—**used for treating hypertension and heart failure. Originally marketed as: Coreg, by SmithKline Beecham, now GlaxoSmithKline.
Date approved: Sept. 5, 2007

• **Cetirizine HCl tablets—**used for treating symptoms of allergies. Originally marketed as: Zyrtec, by Pfizer
Date approved: Dec. 12, 2007

• **Granisetron tablets—**used for preventing nausea and vomiting related to chemotherapy and radiation. Originally marketed as: Kytril, by Roche.
Date approved: Dec. 31, 2007

• **Oxcarbazepine tablets—**used for treating certain kinds of seizures and epilepsy. Originally marketed as: Trileptal, by Novartis.
Date approved: Oct. 9, 2007

• **Pravastatin sodium tablets—**used for treating elevated cholesterol and preventing coronary events. Originally marketed as: Pravachol, by Bristol-Myers Squibb.
Date approved: Apr. 23, 2007

• **Zolpidem tartrate tablets—**used for treating insomnia. Originally marketed as: Ambien, by Sanofi Aventis.
Date approved: Apr. 23, 2007

Generic drugs cost about 20 to 70 percent less than their brand name counterparts. The Congressional Budget Office has reported that generic drugs save consumers an estimated $8 billion to $10 billion a year.

Generic drugs are identical to their brand-name equivalents in dosage, safety, strength, quality, performance characteristics, intended use and the way they're administered to patients.

Drug manufacturers develop their new drugs under patents that protect their firms' investments in the products. When patents or other periods of exclusivity on the drugs expire, manufacturers can apply to FDA to sell generic versions.

In October 2007, FDA launched the Generic Initiative for Value and Efficiency (GIVE) to help increase the number of approvals of generic products.

GIVE will use existing resources to help FDA modernize and streamline the generic drug approval process. GIVE will also increase the variety of generic drug products available.

For more information

FDA's GIVE Initiative
www.fda.gov/oc/initiatives/advance/generics.html

FDA's Office of Generic Drugs
www.fda.gov/cder/ogd

Generic drug approvals
www.fda.gov/cder/ogd/approvals/default.htm

File early for N.D. renter's refund

Low-income senior citizens and disabled persons may be able to receive a refund for part of the money they paid as rent for their home or apartment in 2007, announced State Tax Commissioner Cory Fong. Mobile home residents may be eligible for a refund of part of the lot rent they paid. The deadline for filing for the refund is May 31.

"Even though the deadline is a few months away, we want to do what we can to make certain that everyone who is eligible knows about the deadline," said Fong.

The Tax Department offers the refund to renters who are 65 or older, or permanently and totally disabled at any age, and whose 2007 income was not over $17,500. And, if 20 percent of the total amount of rent paid is more than four percent of their 2007 income, they could be eligible for a refund. The maximum amount of refund is $240.

Stimulus payments: help spread the facts

More than 130 million households will receive economic stimulus payments under the Economic Stimulus Act of 2008, beginning in May. In most cases, taxpayers will not have to do anything extra this year to get the rebate. Just file a 2007 tax return and the IRS will do the rest. You do not need to call or fill out any other special forms. If you qualify, the IRS will automatically figure your payment, send you a notice showing the amount and send it to you.

For more facts and to read some Q&As, visit the Information on Stimulus Payments web page at www.irs.gov.

Those who normally don't file must file to receive a stimulus payment. This includes:

- Low-income workers
- Social Security beneficiaries
- Certain railroad retirees
- Those who receive certain benefits from the Department of Veterans Affairs

There are special filing instructions and a sample Form 1040A (pdf file) that highlight the simple, specific sections of the return to fill out.

Low- and moderate-income workers, including veterans, can get free tax help through the Volunteer Income Tax Assistance (VITA) program. Call 1-800-906-9887 to locate the nearest VITA site.

The Tax Counseling for the Elderly (TCE) Program provides free tax help to people age 60 and older. As part of the IRS-sponsored TCE Program, AARP offers the Tax-Aide counseling program at more than 7,000 sites nationwide during the filing season. To find an AARP Tax Aide site, call 1-888-227-7669 or visit the AARP website.

Nexium approved for children ages 1–11

The FDA announced in February its approval of the short-term use of Nexium in children 1 to 11 years old for the treatment of gastroesophageal reflux disease (GERD). The agency approved Nexium in two forms: delayed-release capsule and liquid.

"This approval provides important information for appropriate dosing for children ages 1–11 years with GERD," says Julie Beitz, M.D., Director of the Office of Drug Evaluation III in FDA's Center for Drug Evaluation and Research. "Children prescribed this drug should be monitored by their physicians for any adverse drug reactions."

Nexium (esomeprazole magnesium) is part of a class of drugs known as proton pump inhibitors. These drugs decrease the amount of acid produced in the stomach and help heal erosions in the lining of the esophagus.

Albuterol inhalers available

Rx Outreach has removed abuterol inhalers from their covered meds. Similar products are Proventis and Pro Air®, which are now available at SP Cares and Teva.

Train your brain

Do you ever wonder about games that may be a good stimulus for your brain? If you have a computer connected to the internet, games are just a click away. AARP has a section of games titled "Train Your Brain: 25 New Online Games." In the middle of the screen, click on Get Your Game On.

There are 25 free online games that are fun to play as well as good for the brain. These games include puzzles, arcade, card games, sport games and word games. These games can be stimulating for many age groups.