



Health Matters August 2006; Volume 1, Issue 2

2006 Generic Product Approvals by Amy Wetzel

According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies.¹ Even more money is saved when hospitals use generics. During 2006, there have been several generic drugs that have been approved by the Food and Drug Administration (FDA). Table 1 contains a brief overview of recently generic medications which have received tentative or final approval.

Zocor (simvastatin) is the third generic statin available on the market, following the generic versions of Mevacor (lovastatin) and Pravachol (pravastatin). It is the most potent of the three generic statins available. Zocor generated \$3.1 billion in United States sales last year, making it the second best selling statin drug in the United States behind Lipitor.²

The selective serotonin reuptake inhibitor (SSRI) category contains several generic alternatives. Sertraline (Zoloft) has been approved by the FDA, but is not on the market yet. It is expected to be available later this year. In 2005, Zoloft was the sixth highest-selling brand-name drug in the United States, with retail sales totaling over \$2.5 billion.³ An additional generic SSRI, escitalopram (Lexapro), has been

tentatively approved. In addition to these newly approved agents, Paxil, Prozac, Cefexa and Luvox all have approved generic alternatives on the market.

Generic medications account for 56% of all prescriptions that are dispensed in the United States, but only for 13% of pharmaceutical costs.⁴ As the FDA begins to approve more generic product applications faster, these numbers are expected to con-

tinue to rise.

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Table 1: New and tentatively approved generic drugs⁵

Drug	Classification	Status
Amlodipine (Norvasc)	Calcium channel blocker	Tentative
Amlodipine/benazepril (Lotrel)	Calcium channel blocker/ACE inhibitor	Tentative
Azithromycin (Zithromax, Z-Pak)	Macrolide antibiotic	Approved
Carvedilol (Coreg)	Beta blocker	Tentative
Cefprozil (Cefzil)	Cephalosporin	Approved
Ceftriaxone (Rocephin)	Cephalosporin	Approved
Cilostazol (Pletal)	Platelet inhibitor	Approved
Clopidogrel* (Plavix)	Platelet inhibitor	Approved
Colestipol (Colestid)	Bile acid resin	Approved
Divalproex sodium (Depakote ER)	Anticonvulsant	Tentative
Escitalopram* (Lexapro)	Selective serotonin reuptake inhibitor	Approved
Finasteride (Proscar, Propecia)	5-alpha reductase inhibitor	Approved
Fluticasone nasal spray (Flonase)	Corticosteroid	Approved
Granisetron (Kytril)	Serotonin receptor antagonist	Tentative
Isradipine (Dynacirc)	Calcium channel blocker	Approved
Lamotrigine chewables (Lamictal)	Anticonvulsant	Approved
Latanoprost (Xalatan)	Prostaglandin	Tentative
Losartan (Cozaar)	Angiotensin receptor blocker	Tentative
Losartan/HCTZ (Hyzaar)	ARB/thiazide diuretic	Tentative
Megesterol (Megace)	Progestin	Approved
Meloxicam (Mobic)	NSAID	Approved
Mometasone (Elocon)	Corticosteroid	Approved
Octreotide (Sandostatin)	Antidiarrheal	Approved
Ondansetron (Zofran)	Serotonin receptor antagonist	Tentative
Pantoprazole (Protonix)	Proton pump inhibitor	Tentative
Pioglitazone (Actos)	Thiazolidinedione	Tentative
Pravastatin (Pravachol)	HMG Co-A reductase inhibitor	Approved
Risperdone (Risperdal)	Atypical antipsychotic	Tentative
Rivastigmine (Exelon)	Cholinesterase inhibitor	Tentative
Sertraline* (Zoloft)	Selective serotonin reuptake inhibitor	Approved
Simvastatin (Zocor)	HMG Co-A reductase inhibitor	Approved
Sumatriptan (Imitrex)	Serotonin receptor agonist	Tentative
Terbinafine (Lamisil)	Antifungal	Tentative
Topiramate (Topamax)	Anticonvulsant	Tentative
Zolpidem (Ambien)	Hypnotic	Tentative

*Approved in 2006 but pending availability

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Tylenol® and Liver Failure in Healthy Patients by Phuong Le

Acetaminophen has been around for over 50 years and has been proven to be safe and effective if taken within the recommended dose. However, in a recent study appearing in the July issue of the *Journal of the American Medical Association*, healthy adults who took the maximum dose of acetaminophen for more than four days were found to have an elevated alanine aminotransferase (ALT) level.¹ This randomized, single-blind, placebo controlled study was designed to investigate the incidence of hepatotoxicity among people receiving acetaminophen alone, combination of opioid/acetaminophen, or placebo. 145 participants were randomized to receive either oxycodone and acetaminophen, hydromorphone and acetaminophen, morphine and acetaminophen, acetaminophen alone, or placebo. Liver chemistry was measured daily for the first eight days, then on alternate days thereafter. Acetaminophen concentrations were measured daily. Nearly 40 percent of participants taking acetaminophen or the combination displayed abnormal liver test results that indicated liver damage, while those taking the placebo showed no damage. This study suggested that ALT elevations were due to the acetaminophen daily dose-

and not the opioid. Limitations of the study include the high proportion of Hispanic individuals in the sample, high percentage of male participants and the young age requirements. According to a study conducted by Ioannou et al., these are three of the nine strong predictors for elevated ALT activity.²

Researchers reported that ALT elevation probably occurs within the first few weeks of daily treatment.³ Additionally, researchers indicated that it is possible that elevated readings may not be accurate indicators of risk. In response to this study, McNeil, the maker of Tylenol, released a statement in its defense. The statement noted that the Watkins' study is not consistent with previously reported studies. McNeil also said "it is important for patients and health care providers to recognize that isolated low-level ALT elevations in the absence of symptoms or other meaningful laboratory abnormalities are fairly common events in conjunction with analgesic treatment".³

Although patients in this study were not representative of the general population, the study provides a heightened awareness to the potential for liver toxicity with acetaminophen, and the need to be aware of daily doses, chronic therapy and patient

specific complications.

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Gardasil® Vaccine by Emily Bengford

On June 29, 2006 the Advisory Committee on Immunization Practices (ACIP), a subset of the Centers for Disease Control (CDC), unanimously approved adding Gardasil to its list of recommended vaccinations.¹ Gardasil® was approved for marketing by the Food and Drug Administration (FDA) on June 8, 2006.² Gardasil® is a vaccine against genital human papillomavirus (HPV) types 6, 11, 16, and 18, the most common types of HPV. These HPV types are associated with cervical cancer, precancerous lesions, and genital warts. The vaccine is approved for use in females aged 9 to 26 years old.² Although approved for girls as young as 9, the ACIP recommendations for the vaccination included 11 and 12 year old girls as well as women 13 to 26 years old who have not yet received or completed the vaccine series.¹ It is

only recommended for females because it is unclear if it will be effective and beneficial for males. Studies are currently underway to indicate whether it works to prevent HPV in males and if there are indirect health benefits for women.³

The approval of this vaccination is a large step in women's health. The CDC reports that over 20 million people are currently infected with HPV and about 6.2 million Americans are infected each year.² While there are about 40 types of HPV that are transmitted through genital contact, types 6, 11, 16, and 18 are the most common. Most people who come into contact with the virus will clear the infection on their



own, however some do not.³ Types 16 and 18 are the most common "high-risk" types and are associated with 70% of cervical cancers, and types 6 and 11 are the most common "low-risk" types which cause about 90% of genital warts.² The American Cancer Society predicts that this year in

the United States, around 9,710 new cases of invasive cervical cancer will develop and about 3,700 women will die from it.⁴

While a cure does not exist for HPV infection, Gardasil® would guard against four of the most common types of HPV. Other methods to guard against this virus include sexual abstinence or the use of condoms. It is unknown how much protection condoms provide against this virus, but it may reduce the risk of HPV and other sexually

transmitted diseases. Women who already have HPV should still get the vaccine since it cannot be concluded which type they have, and the vaccination guards against more than one type. Gardasil® is a recombinant vaccine so it does not contain any live virus. The vaccine, however, is not recommended for pregnant women because studies are lacking in this population. It is given as three intramuscular injections over a six-month period. The first dose can be given at an elected date, the second dose two months later, then the third dose six months after the first dose. The cost is \$120 per shot, or \$360 for the entire series.

If a patient will have trouble paying for vaccination, Merck, the marketer of Gardasil®, has created a new patient assistance program for the vaccine. Since it only protects against four types of the virus, infection with HPV may still occur. Thus, regular pap tests are still necessary. This immunization, however, is predicted to lower the number of cervical cancer cases seen in the United States each year.³

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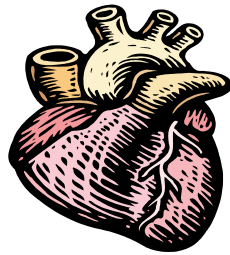
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AHA & ACC Secondary Prevention Guidelines by Kate Schemmel

In May of 2006, the American Heart Association (AHA) and the American College of Cardiology (ACC) presented their revisions to the 2001 Guidelines for the Secondary Prevention of Cardiac Events. Since the release of the guidelines in 2001, there have been a number of studies and trials that have afforded these organizations better information about preventing cardiac events. Additionally, the updated guidelines aggressive approach in secondary prevention reduces mortality, decreases the need for interventional procedures, and improves the quality of life for these patients.¹



The population at risk, and therefore the target of these new guidelines, are those individuals with established coronary and other atherosclerotic vascular disease, including peripheral artery disease, atherosclerotic aortic disease, and carotid artery disease.¹

There are tighter ranges for the control of blood pressure, blood glucose, and lipid values in these new guidelines. More detailed guidelines for smoking cessation, physical activity, and weight management are presented, as it is known that these factors contribute to cardiac events.

Recommendations for the use of medications, such as ACE-inhibitors (angiotensin-converting enzyme), beta blockers (BB), and anticoagulants are more clearly defined in these guidelines. Additionally, a new recommendation of the influenza vaccine in this patient population is included. The inactivated influenza vaccine is recommended for patients who have chronic disorders of the cardiovascular system because they are at increased risk for complications from influenza.¹ The application of these guidelines in practice will help clinicians and their patients achieve better cardiac care.

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Recommended Goal/Intervention Highlights	
Smoking	Goal = cessation and no exposure to environmental tobacco smoke. Develop a plan with patients for smoking cessation: 5 A's (ask, advise, assess, assist, arrange)
Blood Pressure Control	<140/90mmHg or <130/80mmHg for pts with DM or CKD (chronic kidney disease) All pts should initiate/maintain lifestyle modifications and those pts with above target BP or compelling indications should initiate drug therapy as guided by JNC-7
Lipid Management	Changes in the guidelines are similar to those already presented in JNC-7; note that further reduction of LDL-C to <70 mg/dL is reasonable
Physical Activity	30 minutes, 7 days/week – minimum of 5 days/week; encourage resistance training 2 days/week
Weight Management	Stress reductions in waist circumference: men <40 inches, women < 35 inches to reduce risks for metabolic syndrome Initial goal of weight loss therapy should be to reduce body weight by approximately 10% from baseline
Diabetes Management	Goal HbA1C < 7%
Antiplatelet agents/ anticoagulants	Start aspirin 75-162mgQD and continue indefinitely in all pts unless contraindicated **this is decreased from the 2001 recommendations of ASA 75-325mg QD** Start and continue clopidogrel 75mg QD in combo with ASA for up to 12 months in pts after acute coronary syndrome or stent placement Warfarin INR 2.0-3.0
Renin-Angotensin-Aldosterone System Blockers	ACE-Inhibitors: Start and continue indefinitely in all pts with LVEF ≤40% and in those with HTN, DM, or CKD unless otherwise contraindicated; consider for all other pts ARBs: Use in pts intolerant to ACE-inhibitors and have HF or have had an MI with LVEF ≤40% Consider in combination to ACE-inhibitors in systolic dysfunction HF Aldosterone blockers: Use in post-MI pts without significant renal dysfunction or hyperkalemia who are already receiving therapeutic doses of an ACE-inhibitor and BB, have a LVEF ≤40%, and have either DM or HF
Beta Blockers (BB)	Start and continue indefinitely in all pts who have had MI, acute coronary syndrome, or left ventricular dysfunction with or without HF symptoms; consider for all other pts

Exubera®: New Inhaled Insulin by Kelly Brewer

On January 27, 2006, the Food and Drug Administration (FDA) approved Pfizer's new inhaled powder insulin (insulin human [rDNA origin]), Exubera, for type 1 and type 2 diabetes. This is the first new insulin delivery system introduced since insulin's discovery in the 1920s.¹ Unlike other oral inhalers, the Exubera inhaler does not require a special inhalation technique. The patient inserts the unit dose blister pack into the specially marked slot on the Exubera inhaler, squeezes the handle to puncture the blister, presses the button to release the medication into the chamber, and takes a normal deep breath.²

Exubera is available in 1 mg and 3 mg unit dose blister packages, approximately equivalent to 3 and 9 international units of subcutaneous insulin.³ The blister packs are used in conjunction with the Exubera inhaler for oral delivery of insulin up to 10 minutes before a meal as its onset of action is akin to rapid-acting insulin analogs. Exubera's duration of action more closely mimics those of subcutaneous regular insulins.⁴ Given this activity profile, patients with type 1 diabetes should use Exubera in combination with a longer-acting insulin; type 2 diabetics may use Exubera as monotherapy or adjunctive treatment with oral agents or longer-acting insulins.

Safety and efficacy trials of inhaled insulin as compared with subcutaneous insulins have shown that both of these treatment options provide comparable decreases in hemoglobin A_{1c} scores from baseline.⁵ Clinical trials showed small lung function changes with inhaled insulin associated with immediate decline in lung function following inhalation. Lung function tests indicated changes were fully manifested after two weeks of Exubera use and resolved within two weeks of discontinuing treatment.⁶ Patients with underlying pulmonary disorders, such as asthma, COPD, or emphysema, should not use this medication. Exubera is also contraindicated in smokers as their systemic insulin exposure is 2 to 5 times higher than non-smokers.⁴

Overall, Exubera is well tolerated. The most common adverse effects were hypoglycemia and cough. Hypoglycemia is associated with any insulin, whether in-

haled or injected; however, occurrences of hypoglycemia with Exubera were less frequent than with injected insulins.⁵ The cough adverse effect tended to occur immediately following inhalation and usually dissipated with continued use of the product.⁴

Patient satisfaction scores following a one year study indicate that patients are happier with inhaled insulin than subcutaneous insulin. Fewer needle injections, increased flexibility in dosing in relation to meals, and decreased social stigmas are cited reasons for increased satisfaction amongst study participants.³

A medication guide is mandated by the FDA to be dispensed with Exubera. This guide reviews imperative patient counseling points. For example, patients need to be aware that three 1 mg blister packs are not equivalent to one 3 mg pack. In the event a 3 mg blister pack is not available, the patient should be informed to inhale two of the 1 mg doses.⁷ Additionally, patients should demonstrate proper inhalation and inhaler cleaning techniques. The Exubera website includes videos outlining the step by step process for each of these techniques.²

Exubera provides one more treatment option for diabetes type 1 and 2. The product is expected to be "priced competitively"



with injected insulin, although exact pricing has not been released. Exubera is expected to be available later this year.

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Ketek® Safety Concerns by Parham Bazrafshan

Ketek® (telithromycin), the first ketolide FDA approved antibiotic, has been under closer investigation due to the risk of liver toxicity with its use.¹ Ketek® was originally approved in the U.S in April 2004, with pre-marketing trials suggesting that its safety profile was similar to other marketed antibiotics.¹ Safety concerns increased as the *Annals of Internal Medicine* published an article in January 2006 concerning the risk of severe liver toxicity while taking telithromycin.² At the time of the release of the article, the FDA had started investigating telithromycin's safety

issues regarding liver toxicity.³

Clay and colleagues report three cases of severe liver toxicity while undergoing telithromycin treatment.⁴ One case involved a 46 year old white male with no reports of chronic liver disease. During therapy he presented with dark urine, jaundice and malaise. Telithromycin was withdrawn after three days of therapy, while the patient's liver function eventually normalized. Another case involved a 51 year old white female who had no previous liver function tests done. She was readmitted to the hospital with severe fatigue, muscle

weakness, and jaundice a month after a five day course of telithromycin, where her total bilirubin had increased from 9.5mg/dl to 24.1mg/dl and her INR had increased to 3.4. Eventually she required orthotopic liver transplantation. The last report was a 26 year old Hispanic male who was admitted to the hospital after eight days of jaundice, fever, melena, and hematemesis. He had been on a five day telithromycin regimen two weeks earlier, with a history of drinking eight 12-ounce beers every two weeks. He reported to the hospital very ill and his condition continued to worsen. By day three the patient was hypotensive and had continued refractory acidosis, became asystolic and died. The autopsy showed massive hepatic necrosis, and hepatomegaly.

The Annals of Internal Medicine publication prompted the FDA's Public Health Advisory to make several recommendations to healthcare providers and physi-

cians.² The recommendations included close monitoring of patients on telithromycin for signs or symptoms of liver problems, such as yellowing of the eyes or skin. As long as no concerning side effects were seen, the continuation of telithromycin was deemed appropriate by the FDA. At the end of June 2006, liver toxicity reports had increased to four deaths and one liver transplant, prompting the FDA to issue further warnings.⁵ Sanofi-Aventis, the manufacturer of telithromycin, will highlight the warning section of its label, in order to emphasize the potential of liver toxicity.³ Telithromycin's safety issue will be continued to be studied closely by the FDA and Sanofi-Aventis; as of now telithromycin's benefits are considered to outweigh its potential risks.³

Even though the reports of liver toxicity associated with telithromycin have been rare, those reported have been severe and are of major concern. The FDA has made

great effort with the manufacturer to bring awareness among health care providers. Telithromycin's safety profile will be continued to be monitored in the future for potential risks.

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AHA Guidelines for Reduction of Ischemic Stroke Risk by Vu Thach



In February of 2006, the Guidelines for Prevention of Stroke in Patients with Ischemic Stroke were published by the American Heart Association (AHA) to provide evidence-based recommendations for the prevention of recurrent ischemic stroke among survivors of ischemic stroke or transient ischemic attack (TIA). Issues addressed in the recommendations include the control of risk factors, interventional approaches for atherosclerotic disease, antithrombotic treatments, cardioembolism, and the use of antiplatelet agents for noncardioembolic stroke.¹

There are an estimated 700,000 people with stroke in the United States, with 200,000 of them having experienced a recurrent stroke. According to the AHA guidelines, the primary intervention for reducing the ischemic stroke is risk reduction, such as hypertension, diabetes management, hyperlipidemia, smoking, weight management, and physical activity.¹

It is estimated that approximately

50,000,000 Americans have hypertension. Meta-analyses of randomized controlled trials confirm an approximate 30% to 40% stroke risk reduction with blood pressure (BP) lowering.¹ A meta-analysis also showed significant reduction in recurrent stroke with diuretics alone and in combination with ACE-inhibitor, but not with B-blockers or ACEIs used alone. The choice of specific drugs and targets should be individualized on the basis of reviewed data and consideration of specific patient characteristics.¹

Diabetes is estimated to affect 8% of the adult population and is a clear risk factor for stroke. In a community-based stroke study, the Oxfordshire Stroke Project, diabetes was one of two factors independently associated with stroke recurrence and investigators estimated that 9.1% of the recurrent stroke were attributable to diabetes.¹ Data on the efficacy of glycemic control on macrovascular complications, including stroke, are more limited.¹

Hypercholesterolemia and hyperlipidemia are not well established as risk factors for stroke. However, patients with ischemic stroke or TIA with high cholesterol, comorbid coronary artery disease or evidence

of atherosclerotic origin should follow the National Cholesterol Education Program (NCEP) III guidelines. The primary goal for blood lipid management in this population is LDL-C <100mg/dL. Very high risk patients (i.e., cardiovascular disease plus diabetes or severe and poorly controlled risk factors or multiple risk factors of the metabolic syndrome), should aim for an LDL-C <70 mg/dL.^{1,2}

There is strong evidence that cigarette smoking is a major independent risk factor for ischemic stroke. Observational studies have shown that the risk of stroke decreases after quitting and that the elevated risk disappears after 5 years. Counseling, nicotine replacement products and oral medications have been shown to be effective in smoking cessation.

Obesity, defined as a body mass index (BMI) of >30kg/m², has been established as an independent risk factor for coronary heart disease and premature mortality. Weight management through diet, exercise and lifestyle activity may be considered for overweight ischemic stroke and TIA patients.

Prevention remains the best approach to reducing the burden of ischemic stroke.

These guidelines should assist in targeting those individuals who are at risk for stroke. Prevention of Cardiovascular Disease and Stroke.2002;106:388-391.

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ADA Position on Inpatient Diabetes & Glycemic Control by Doug Besch

Diabetes has grown to substantial proportions in the United States, affecting over 20 million Americans.¹ In February 2006, the American Diabetes Association (ADA) in conjunction with the American Association of Clinical Endocrinologists (AACE) released a position statement outlining strategies for identifying and treating high blood glucose levels in the inpatient population. There were ten other major medical associations co-sponsoring the statement at a joint consensus conference.

One out of every four hospitalized patients has diabetes and one third of them are unaware they have the disease.² Moreover, hyperglycemia is an independent predictor of infection in patients with diabetes undergoing heart surgery, and according to the ADA and AACE statement, one third of cardiac patients have diabetes. Studies have also shown that intensive insulin therapy reduces morbidity and mortality in patients in surgical intensive units.³

According to the consensus conference, evidence shows that tight glycemic control reduces complications and infections,

shortens hospital stays, and saves lives and money.³ Conference recommendations for controlling blood glucose and achieving positive outcomes in this population include:

- Identify elevated blood glucose in all hospitalized patients
- Establish a multidisciplinary team approach to diabetes management in all hospitals
- Implement structured protocols for aggressive control of blood glucose in both intensive care units and other hospital settings
- Create educational programs for all hospital personnel caring for people with diabetes
- Plan for a smooth transition to outpatient care with appropriate diabetes management



Not only is obtaining tight glycemic control in the inpatient setting a must, the committee also strongly recommended planning ahead for a smooth transition to the outpatient setting. This is especially important for the population discovering their diabetes in the hospital.

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Health Matters August 2006; Volume 1, Issue 2

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