NEW DRUGS

Tinidazole for Parasitic and Sexually Transmitted Diseases

The Food and Drug Administration (FDA) has approved tinidazole (Tindamax™, Presutti Labs), a second-generation medication for the treatment of trichomoniasis, giardiasis, intestinal amebiasis, and amebic liver abscess.

Trichomoniasis, the most common nonviral, sexually transmitted disease in the U.S., is caused by Trichomonas vaginalis in both men and women. Because this sexually transmitted disease has potentially serious consequences, partners of infected patients should be treated at the same time. In clinical studies, a single 2-g dose was effective in 92% to 100% of patients.

After four weeks, this dose was efficacious in 80% to 100% of patients with giardiasis, an intestinal parasitic infection.

In patients with intestinal amebiasis, 2 g of tinidazole once per day for three days achieved efficacy of 86% to 93%.

In patients with amebic liver abscess, the recommended dose is given for three to five days. Amebiasis is caused by the parasite Entamoeba histolytica.

The dosing regimens for giardiasis and amebiasis are shorter than those of other currently available therapies.

(Sources: FDA, September 9, 2004; www.presuttilabs.com)

Hydromorphone for Pain

The FDA has approved extended-release hydromorphone HCl (Palladone™ Capsules, Purdue) for managing persistent, moderate-to-severe pain in patients who need continuous, around-the-clock analgesia with a high potency opioid for a prolonged period of time (weeks to months) or longer.

Long-acting formulations are available in Canada, the United Kingdom, and Germany, but Palladone™ is the first long-acting hydromorphone formulation in the U.S. It can be taken once daily. Dosage strengths will be 12, 16, 24, and 32 mg, and the product should be in pharmacies in early 2005.

This medication should be used only by patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opioid medication equivalent to 12 mg of oral hydromorphone. The capsules are indicated for opioid-tolerant patients only and should not be used as the first opioid product prescribed for a patient. The drug is not intended for patients who require opioid analgesia for a short time; its use in non-opioid-tolerant patients may lead to fatal respiratory depression.

(Source: Purdue Pharma, September 24, 2004.)

Lubricant Drops for Dry Eye

Alimera Sciences has announced the arrival of Soothe™ Emollient (lubricant) Eye Drops, the market’s first multidose, emollient-based artificial tear product. The drops offer over-the-counter relief to the 12 million Americans with dry eye, a painful condition in which the body cannot produce enough tears to keep the eye surface lubricated.

Soothe™ features a lipid restorative (Restoryl™) that re-establishes the eye’s protective oily layer to reduce tear evaporation and to seal in essential moisture, giving patients up to eight hours of comfort.

Approximately 15% of the population 65 years and older have dry eye, and it is especially prevalent in women. Certain medications, contact lenses, the environment, and indoor air conditioning or heating can also affect moisture levels in the eye.


NEW FORMULATION

Disintegrating Tablets For Parkinson’s Disease

Schwarz Pharma AG has received final approval from the FDA to market carbidopa–levodopa (Parcopa™) orally disintegrating tablets.

The drug’s unique formulation dissolves rapidly in the mouth, thereby providing patients suffering from Parkinson’s disease with improved access to their medication.

In comparison with their current tablets, patients preferred Parcopa™ for several reasons associated with the daily challenges of managing this complex disease. Unlike conventional carbidopa–levodopa, the RapiTab™ technology delivers the medication without the need for water.

(Sources: Schwarz Pharma, September 27, 2004; www.epilepsy.com.)

NEW INDICATION

Duloxetine for Diabetes-Related Neuropathic Pain

The FDA has approved duloxetine HCl (Cymbalta™, Eli Lilly) capsules for the management of the pain associated with diabetic peripheral neuropathy. This is the first drug specifically approved for this indication.

Diabetic peripheral neuropathy is associated with long-standing poor glucose control. Peripheral neuropathy is the most common complication of diabetes mellitus. It is usually characterized by burning, tingling, and numbing sensations beginning in the feet and later affecting the legs or hands.

The safety and effectiveness of Cymbalta™ were established in two randomized, controlled studies of approximately 1,074 patients. Although the mechanism of action is unknown, patients receiving Cymbalta™ reported a greater decrease in pain than did those taking placebo. In these trials, 58% of patients taking...
Cymbalta™ reported at least a 30% sustained reduction in pain. In comparison, 34% of patients treated with placebo reported this magnitude of sustained pain reduction.

Side effects were nausea, dry mouth, constipation, diarrhea, dizziness, and hot flashes.

(Sources: FDA, September 7, 2004; www.duloxetine.com.)

**Ziprasidone for Bipolar Mania**

The FDA has approved ziprasidone (Geodon®, Pfizer) to treat acute bipolar mania. Nearly 4% of Americans have bipolar disorder, a condition that causes severe mood swings. Rapid control of acute mania is important, because patients are at increased risk for dangerous and impulsive acts, including aggressive and suicidal behavior.

This product causes little or no weight gain and is associated with fewer adverse changes in certain metabolic indices, such as lipid levels and glucose control, than other agents in its class. Significant improvements were typically seen within two days after treatment began.

According to a survey conducted by Harris Interactive® of 554 patients with bipolar disorder in the U.S. over the age of 30, most patients gained an average of 50 pounds while taking other bipolar drugs; 10% gained 100 pounds or more with other drugs.

Geodon® was approved for the treatment of schizophrenia in the U.S. in February 2001 and received approval for treatment of bipolar disorder in the U.S. in August 2004.

(Sources: www.pfizer.com; Diabetes Care 2004;27[2]:596–601; American Journal of Psychiatry.)

**Antidepressants and Suicide Risk in Youths**

The FDA supports the recent recommendations made to the agency by the Psychopharmacologic Drugs and Pediatric Advisory Committees regarding reports of an increased risk of suicidal thoughts and actions associated with the use of certain antidepressants in pediatric patients. The FDA has begun work to adopt new labeling to enhance the warnings associated with the use of antidepressants and to bolster the information provided to patients when these drugs are dispensed.

The advisory committees:

- endorsed the FDA’s approach to classifying and analyzing the suicidal events observed in controlled clinical trials and stated that the new analyses increased their confidence in the results.
- concluded that the finding of an increased risk of suicidality in pediatric patients applied to all the drugs studied (Prozac®, Zoloft®, Remeron®, Paxil®, Effexor®, Celexa®, Wellbutrin®, Luvox®, and Serzone®) in controlled clinical trials.
- recommended that warnings related to an increased risk of suicidality in youths should be applied to all antidepressants, including those that have not been studied in controlled clinical trials in pediatric patients because the available data are not adequate to exclude any single medication from an increased risk.
- voted to recommend a “black-box” warning related to an increased risk for suicidality in youths for all antidepressants.
- endorsed a patient information sheet for this class of drugs to be provided to patients or their caregivers with every prescription.
- recommended that the results of controlled pediatric trials of depression be included in the labeling for antidepressant drugs.

(Source: FDA, September 17, 2004.)

**Another Non-Solution To Gulf War Illness**

The complex of symptoms and disorders called Gulf War veterans’ illnesses has been a major medical puzzle for years. One hypothesis is that the complex is caused by an underlying systemic infection with *Mycoplasma* species, specifically *M. fermentans*, and that long-term treatment with doxycycline might work.

The U.S. Departments of Veterans Affairs and Defense conducted a randomized, placebo-controlled study of 491 veterans, all of whom had detectable...
Mycoplasma DNA in their blood. After 12 months of treatment and six months of follow-up, the veterans were, for the most part, no better off. In fact, long-term doxycycline therapy not only did not help but might have even harmed them.

Doxycycline might have had a limited effect because there was no underlying infection, or the veterans’ illnesses might have been a consequence of previous infections, the researchers say. Some of the patients who improved at three months might have had another infection that doxycycline did help, or the drug might have had an anti-inflammatory effect.

Adherence to treatment declined after six months, dropping to roughly two thirds of both groups at 12 months. The researchers could not say whether better adherence would have led to more improvement.

(Source: Ann Emerg Med 2004;44:131–137.)

Benzodiazepines and Hip Fracture

Benzodiazepines are the 13th leading therapeutic class of medications in the U.S., even with their well-known potential adverse drug effects, such as hip fractures, in the elderly. But despite much research, the data on the relationship between benzodiazepines and hip fracture are conflicting, say researchers.

Two landmark case-control studies from 15 years ago suggested that the long elimination half-life of benzodiazepines might increase the risk of hip fracture in older patients. However, other studies found more risk with only short elimination half-life benzodiazepines, and some studies have found no relationship.

Although the high-potency benzodiazepines with a short half-life are often considered the best choice for older patients, they were associated with a statistically significant higher incidence of hip fractures, compared with no benzodiazepine use. However, the incidence of hip fracture was similar across benzodiazepine types. The risk of hip fracture was greatest during the first two weeks of starting benzodiazepine therapy, but the incidence declined by 26% after the first 15 weeks, through the transition to continued use.

(Source: Stroke 2004;35:1903–1907.)

Lumiracoxib, A COX-2 Inhibitor, Helps Osteoarthritis

For patients with osteoarthritis, particularly the elderly, lumiracoxib (Prexige®, Novartis) may be a better choice than diclofenac (e.g., Cataflam®, Volaren®, Novartis) may be a better choice than diclofenac (e.g., Cataflam®, Volaren®, Novartis). In an international study of 583 adults with knee or hip osteoarthritis, all doses of lumiracoxib (50, 100, or 200 mg twice daily or 400 mg once daily) worked just as well as diclofenac 75 mg twice daily. Even better, the once-daily dose made treatment easier for older patients who were following multidrug regimens.

Most adverse drug events (ADEs) were mild to moderate, with a similar incidence in all dosage groups and in the placebo patients. However, the diclofenac-treated patients were more likely to have at least one gastrointestinal-related ADE (41.5%) than the lumiracoxib (23.2%–26.5%) or the placebo patients (17.5%). ADEs included diarrhea, nausea, dyspepsia, and edema.

Even with its relatively short plasma half-life, lumiracoxib has a prolonged elimination half-life, lumiracoxib has a prolonged...
pharmacodynamic action, perhaps because, unlike the other currently available cyclooxygenase-2 inhibitors, it is an acidic compound. Acidic NSAIDs are retained over time at higher concentrations in synovial fluid compared with plasma.

(Source: Arthritis Rheum 2004;51: 549–557.)

**Bicalutamide for Prostate Cancer**

Given a choice, men with prostate cancer may prefer bicalutamide (Casodex®, AstraZeneca), a nonsteroidal antiandrogen, to leuprolide (Eligard™, Sanofi-Synthelabo), a gonadotropin-releasing hormone agonist. With bicalutamide, patients are more likely to experience increased bone mineral density (BMD), to accumulate less fat, and to suffer fewer side effects. Another advantage is that bicalutamide can be taken orally, whereas leuprolide is delivered intramuscularly.

Findings from 51 men showed that mean serum testosterone concentrations decreased from baseline by 96% with leuprolide but increased by 97% with bicalutamide within 12 months. Mean lumbar spine BMD and the total hip BMD decreased by 2.5% and 1.4%, respectively, in the leuprolide patients and increased by 2.5% and 1.1% in the bicalutamide patients. The findings suggest that bicalutamide might help reduce the risk of fracture.

Over the 12 months, fat mass increased by 11.1% in the leuprolide patients and by 6.4% in the bicalutamide patients. Changes in lean body mass and lower-extremity strength also tended to be less severe with bicalutamide.

Anemia, fatigue, loss of sex drive, and vasomotor flushing were less common among the men in the bicalutamide group; however, breast enlargement and tenderness were more common. The researchers suggest that antiestrogens and aromatase inhibitors may reduce breast symptoms, although they tend to diminish the benefits of bicalutamide on BMD and body composition.

For more on prostate cancer, see Meeting Highlights on page 638.


**Long-Term Aspirin, NSAIDs, And Renal Function in Women**

Women can use aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) for years without suffering renal function problems, according to data from the Nurses’ Health Study. Acetaminophen is another story, but not a markedly worse one.

Researchers from Brigham and Women’s Hospital and Harvard University studied information from 1,697 women who responded to a questionnaire in 1999. The women’s blood samples, which were collected in 1989 and 2000, were also evaluated. The main outcome was change in estimated glomerular filtration rate over 11 years.

The researchers observed no association between lifetime use of aspirin or NSAIDs and the risk of decline in renal function, even among women who had consumed 3,000 g or more of the drug. In contrast, women who had consumed 100 g or more of acetaminophen over their lifetimes seemed to be at greater risk of losing “an important proportion” of their renal function, compared with those who had taken less than 100 g. Even so, most women who had consumed 3,000 g or more of acetaminophen did not have significant renal dysfunction, and the magnitude of the association depended on the formula used to estimate renal function. There was no apparent interaction between acetaminophen and aspirin.

(Source: Arch Intern Med 2004;164: 1519–1524.)

**Narcolepsy Drug Modafinil Useful in Palliative Care**

A drug that was initially approved for narcolepsy may help keep patients awake during palliative care, suggest physicians from the National Cancer Institute of Milan. As a relatively new drug, modafinil (Provigil®, Cephalon) induces wakefulness and inhibits sleepiness without affecting blood pressure or heart rate and without increasing dopamine-like activities in the brain areas that are usually influenced by amphetamines.

Modafinil has complex interactions with the dopamine and serotonin systems. It might be seen as a selective pharmacological modulator of specific arousal systems.

Researchers suggest that it might be used to improve cognitive function and excessive sleepiness in patients with Parkinson’s disease, fatigue associated with multiple sclerosis, and other forms of secondary disturbances of wakefulness. It holds promise for the opioid-induced sedation commonly seen in palliative care.

(Source: Pain Symptom Manage 2004; 28:97–99, Letter to the Editor.)

**Dual-Action ACE-Inhibitors Protect Artery Walls**

A popular type of blood pressure medication, called the angiotensin-converting enzyme (ACE)–inhibitor, appears to protect against heart attacks not only by lowering blood pressure but also by improving the health of the artery walls.

ACE-inhibitors ease blood pressure by reducing production of a chemical that squeezes arteries and also by preserving the delicate lining of the blood vessel’s wall, which repels plaque.

A study was conducted to test the benefits of perindopril erbumine (Aceon®, Solvay). Not surprisingly, the experiment showed that the drug widened the blood vessels by increasing amounts of an
Sudden Cardiac Death And Oral Erythromycin

Patients who took the antibiotic erythromycin along with medications that inhibited CYP3A enzymes, such as certain calcium-channel blockers, antifungal drugs, and antidepressants, had a five times greater risk of sudden death from cardiac causes than patients who did not take the drugs at the same time, according to a study co-funded by the Agency for Healthcare Research and Quality (AHRQ), the FDA, and National Institutes of Health (NIH).

Erythromycin is a commonly used antibiotic because it is relatively inexpensive and safe.

Researchers reviewed the medical records for Tennessee’s Medicaid program and identified patients who had experienced sudden death from cardiac causes from January 1, 1988, to December 31, 1993. After evaluating prescriptions for erythromycin, amoxicillin, and other medications, the researchers concluded that clinicians should avoid prescribing a combination of erythromycin and CYP3A inhibitors to patients at the same time.


Is High-Dose Simvastatin Helpful?

A new trial of simvastatin (Zocor®, Merck) has raised a caution flag for patients taking high doses of statins. In a large study, simvastatin failed to show a benefit for very high-risk heart patients; however, it did increase the chances of rhabdomyolysis, a rare but dangerous side effect.

The study is likely to steer some doctors to try other drugs. In particular, atorvastatin (Lipitor®, Pfizer) might benefit. However, this new trial did not reveal any problems with the safety or effectiveness of simvastatin for most patients, and it did not evaluate the most common use of simvastatin in patients with elevated risk of heart attacks or other cardiovascular problems who take 20 to 40 mg/day.

The trial, which included 4,500 patients, tested an aggressive cholesterol-lowering strategy compared with a moderate approach for patients with severe unstable chest pain. The aggressive treatment was 40 mg of simvastatin for one month, followed by 80 mg for the next 23 months. The moderate approach was four months of a placebo, followed by 20 mg of simvastatin.

In a similar study reported in March 2004, 80 mg of atorvastatin, the highest recommended dose, was more effective in reducing low-density lipoprotein-cholesterol (LDL-C) and the risk of serious heart problems than 40 mg of pravastatin (Pravachol®, Bristol-Myers Squibb).

Cardiologists expected aggressive treatment with simvastatin to reflect the atorvastatin findings, especially because the control group was treated with a placebo during the first four months of the two-year trial. But even though their LDL-C levels fell to 62, patients treated aggressively with simvastatin showed no difference in heart attacks, in deaths from heart attacks, in strokes, or in hospital readmissions for heart problems at the end of four months than patients taking placebo whose LDL-C levels were twice as high.

After two years, 14.4% of patients receiving aggressive therapy with simvastatin had suffered negative outcomes compared with 16.7% on the moderate regimen, but the difference was not considered statistically significant.

High-risk patients taking simvastatin 80 mg experienced no heart health benefit after four months, no significant benefit after two years, more cases of muscle pain, and three cases of rhabdomyolysis.


Rosuvastatin Improves Metabolic Syndrome

The statin drug rosuvastatin calcium (Crestor®, AstraZeneca) reduces low-density lipoprotein-cholesterol (LDL-C) by 49% and raises high-density lipoprotein-cholesterol (HDL-C) by more than 10%. The findings were presented at the 40th Annual Meeting of the European Association for the Study of Diabetes in Munich, Germany, the first international prospective study of statin therapy for the metabolic syndrome.

This syndrome is a cluster of three or more risk factors, including abdominal obesity, low levels of HDL-C, increased levels of triglycerides, elevated blood pressure, and elevated blood glucose.

Rosuvastatin is taken once daily as an adjunct to diet to treat lipid disorders.

The 12-week Comparative study with rosuvastatin in subjects with Metabolic Syndrome (COMETS), which was conducted at 68 centers in seven countries,
compared a 20-mg dose of rosuvastatin with both atorvastatin (Lipitor®, Pfizer) and placebo.

Noting that the rising number of people with the metabolic syndrome has serious implications for public health, one of the study’s investigators, from Baylor College of Medicine, said that rosuvastatin was effective for high-risk patients and that it offered significant benefits.


**Estrogen and Cognitive Function in Older Women**

The use of estrogen does not reduce the risk of dementia in older women and might even increase it. A trial suggests that hormone replacement therapy (HRT) might increase health risks in postmenopausal women. The study’s authors, from Wake Forest University School of Medicine in Winston-Salem, North Carolina, recommend against using HRT to prevent dementia in women aged 65 or older.

Previous research had shown that women using an estrogen–progestin combination were also at an increased risk for dementia or age-related functional impairment, including Alzheimer’s disease, and that HRT had no effect on mild cognitive impairment or memory loss. That research, part of the Women’s Health Initiative (WHI), was halted two years ago amid indications that HRT did more harm than good.

In February 2004, the National Institutes of Health halted another study involving estrogen-only therapy because the risk of stroke was considered to outweigh the benefit of possible protection against coronary heart disease.

Wyeth, the maker of hormone therapies, said that doctors should consider the data as they assess patients’ needs and emphasized that the data might not apply to newly postmenopausal women. (Sources: JAMA 291[24]:2959–2968; The Wall Street Journal, June 23, 2004.)

**Infliximab Effects and RA**

In a small study from Spain, infliximab (Remicade®, Centocor) dramatically improved endothelial function in patients with rheumatoid arthritis, but the effect was relatively short-lived.

Researchers from Lugo and from the University of Cantabria in Santander measured endothelium-dependent and endothelium-independent vasodilation in seven patients who were being treated with infliximab for at least one year.

The patients were receiving intravenous infliximab every eight weeks. After the infusion, the percentage of endothelial-dependent vasodilation rose (from 2.8% to 9.4%) and stayed high for days, but values returned to baseline measures by four weeks later.

Infliximab is an anti-tumor necrosis factor (TNF)–alpha antibody. The rapid positive effect of the drug highlights the importance of TNF-alpha in the mechanisms of atherosclerosis mediated by endothelial dysfunction in rheumatoid arthritis, the researchers say. The small sample size might have been associated with the negative findings but not with the positive findings.

(Source: Arthritis Rheum 2004;51:447–450.)

**Implantable Lenses For the Nearsighted**

The FDA is expected to approve a tiny corrective lens, to be implanted directly in the eye, for severely nearsighted patients. These patients are not candidates for laser surgery because the laser would destroy too much of the cornea.

Over time, the procedure might be used for those with more mildly impaired vision and may become competitive with procedures such as LASIK (laser-assisted in situ keratomileusis), in which corneal tissue is reshaped with a laser. At first, the new surgery would not be approved for people with astigmatism.

Implant surgery is performed in a sterile operating room. One eye is treated at a time, and patients wait weeks or even months for the next operation. With LASIK, both eyes are usually treated at the same time.

Complications can be more serious than with LASIK because the interior of the eye is involved. If a patient’s natural lens is knocked during surgery, there is a concern that cataracts—a clouding of the eye’s natural lens—can form.

For a long time, surgeons have treated cataracts by removing the lens and implanting a new, artificial one. With implant surgery, doctors do not disturb the natural lens; they make an incision in the eye and insert the lens through the incision.

Two lenses will be available:

- The Verisyse lens (AMO, Inc.) sits behind the cornea and in front of the iris, far from the natural lens that is vulnerable to cataracts. It is made of hard plastic, and a large incision is needed. The Artisan® lens has been available for more than a decade in Europe.
- The Visian lens (Starr Surgical, Inc.) is placed in front of the eye’s natural lens. It is made from a soft, foldable material. An incision of only 3 mm is needed.

The current treatments are as follows:

- LASIK: for nearsightedness, farsightedness, and astigmatism. Cost: $900 to $2,800. May cause night vision complaints and dry eyes.
- Photorefractive keratotomy (PRK): for mild-to-moderate nearsightedness, farsightedness, and astigmatism in patients with thin corneas. Cost:
$1,000 to $1,800. It is less invasive than LASIK, a longer healing time is needed, and it is more painful.

- Laser epithelial keratomileusis (LASEK): for nearsightedness, farsightedness, and presbyopia when corneas are too thin or too flat for LASIK. Cost: $900 to $2,800. Visual recovery is faster than with PRK but slower than with LASIK; there is less dry eye than with LASIK.

- Conductive keratoplasty (CK): Non-invasive surgery uses radio waves to reshape the cornea in farsighted or presbyopic patients. Cost: $1,200 to $2,500. It is safe, but the benefits may be temporary.

- Intacs: corneal rings for mild nearsightedness. Cost: $1,700 to $2,600. These implants can be removed.

(Source: The Wall Street Journal, August 17, 2004; AllAboutVision.com.)

**New Thrombosis Guidelines Cover Travelers**

The American College of Chest Physicians has introduced new guidelines for preventing and treating thrombosis and now offers specific recommendations for long-distance travelers.

Antithrombotic and thrombolytic therapies are used to prevent thrombosis or blood clotting in the arteries, veins, or heart. Thrombosis can ultimately lead to a potentially fatal blockage in the lung, or venous thromboembolism (VTE).

The last version of the guidelines was published in 2001. Approximately 230 recommendations have been added.

An anticoagulant, fondaparinux (Arixtra®, Sanofi-Synthelabo), is recommended as an alternative to the standard anticoagulant, low-molecular-weight heparin (LMWH).

To avoid “economy class syndrome,” travelers should be informed as follows:

- For flights longer than six hours, patients with or without risk factors for VTE should avoid dehydration and constrictive clothing around the lower extremities and waist and should frequently stretch the calf muscles.
- Patients at risk for VTE should consider using graduated compression stockings or taking LMWH or fondaparinux before departure.
- Aspirin is not recommended for preventing VTE associated with travel.

For coronary intervention, the revised recommendations now advise against using the platelet inhibitor ticlopidine (Ticlid®, Roche), if other treatments are available, because of its adverse effects.

For most patients with unstable angina or a minor heart attack, clopidogrel bisulfate (Plavix®, Bristol-Myers Squibb/Sanoﬁ), in combination with aspirin, is recommended.

For patients with non–heart-related stroke, tissue-plasminogen activator should be used only within three hours of stroke onset.

Guidelines recommended against the sole use of aspirin to prevent thrombosis for all patient groups.


**DuPont’s $130 Million Facility**

DuPont has opened a new facility in Old Hickory, Tennessee to produce a nonwoven composite fabric (Suprel™). Used for hospital operating gowns and patient drapes, the fabric combines the strength of polyester and the softness of polyethylene. It offers greater freedom of movement and comfort for patients.

(Source: www.netcomposites.com; www1.dupont.com.)

**ID Band to Prevent Errors**

A new product, called ShrinkSafe® ID Bands (EPS, Inc.), is available to help reduce medication errors involving look-alike drugs. The band is designed to easily wrap around virtually all 10-ml vials containing paralytic agents. Its bright orange color alerts practitioners that special handling is required for the drug.

A quick exposure to heat shrinks the band to the vial’s shape and still permits easy viewing of the manufacturer’s label. To dispense, one simply peels the band’s pull-tab, and the drug is ready to use.

(Source: www.medi-dose.com.)

**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Intrinsic™ Dual-Chamber Implantable Cardioverter-Defibrillator

**Manufacturer:** Medtronic, Inc., Minneapolis, MN

**Approval Date:** September 6, 2004

**Use Classification:** The pacing mode promotes natural heart activity and reduces unnecessary pacing in the lower right chamber of the heart.

**Description:** Managed Ventricular Pacing (MVP™) enables the defibrillator to automatically adapt the way it paces, allowing the heart to function normally as often as possible.

**Purpose:** Patients at risk for sudden cardiac arrest are candidates for receiving the device because of the possibility that the lower chambers of the heart (the ventricles) might start beating too rapidly and stop pumping blood to the body.

**Benefit:** Disrupting normal electrical conduction with unnecessary ventricular pacing can lead to heart failure and atrial fibrillation. The device continually monitors each heartbeat and recognizes when normal conduction is present, thus allowing the patient’s natural heartbeat to take over most of the time. The device provides backup pacing only as needed.

**Sources:** www.medtronic.com; www.pharmacyonesource.com.
**NEW DRUGS**

**Name:** Carotid Artery Stent  
**Manufacturer:** Guidant Corporation, Santa Clara, CA  
**Approval Date:** September 1, 2004  
**Use Classification:** The stent is intended to prevent stroke by treating blockages in the carotid artery, the main blood vessel leading to the brain.  
**Description:** During angioplasty, the stent is threaded up to the neck artery via a catheter inserted in the groin. Patients usually require only local anesthesia. The system can be used with a tiny filter that opens like an umbrella. The filter is used to catch and remove the debris that is stirred up during the stenting procedure before it floats to the brain, where it can trigger a stroke.  
**Purpose:** The device, the first of its kind, can be used in patients who have had symptoms of a stroke or whose carotid artery is at least 80% blocked.  
**Benefit:** Currently, blockages in the carotid artery are treated with carotid endarterectomy, a procedure in which surgeons cut into the neck artery to remove the blockage and for which general anesthesia is required. This stent is indicated for patients who are not suitable candidates for endarterectomy.  
**Sources:** www.pharmacyonesource.com; www.fda.gov.

**Name:** NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit  
**Manufacturer:** PerkinElmer Life and Analytical Sciences, Inc., Norton OH  
**Approval Date:** August 25, 2004  
**Use Classification:** This laboratory blood test helps doctors screen newborn infants for a variety of inherited diseases. It is the world’s first FDA-approved kit for use in the global standardization of metabolic screening with tandem mass spectrometry.  
**Description:** Blood from a newborn heel-stick is tested. This is the same kind of sample that is used for state-mandated newborn screening tests. The sample is measured for levels of amino acids and substances called free carnitine and acylcarnitines.  
**Purpose:** Although small amounts of these substances exist in everyone, abnormally high amounts may indicate different disease states called inborn errors of metabolism. They include phenylketonuria, maple syrup urine disease, medium-chain acyl-CoA dehydrogenase deficiency, isovaleric acidemia, homocystinuria, and hereditary tyrosinemia.  
**Benefit:** Although each of these disorders is relatively rare, as a group they are fairly common. These diseases can cause developmental delay, seizures, mental retardation, and death. With early identification, many of the effects of these diseases can be reduced, with improved long-term outcomes and quality of life.  
**Sources:** www.pharmacyonesource.com; www.fda.gov.

**Name:** SonoPrep®  
**Manufacturer:** Sontra Medical Corp., Franklin, MA  
**Approval Date:** August 17, 2004  
**Use Classification:** This simple, painless 15-second treatment, when followed by an application of topical local anesthetic lidocaine cream, temporarily anesthetizes the skin in five minutes. By itself, lidocaine takes one hour to work. An ultrasonic method is used to make the skin temporarily more permeable.  
**Purpose:** Ultrasound is used to accelerate the administration of lidocaine for temporary pain relief.  
**Benefit:** This simple method speeds up the action of lidocaine, which is commonly used for children and critically ill adults who must endure repeated needle-sticks. The device may become standard procedure in doctors’ offices and hospitals.  
**Sources:** http://web.mit.edu; www.pharmacyonesource.com.

**Name:** da Vinci Endoscopic Instrument Control System  
**Supplier:** Intuitive Surgical, Inc., Mountain View, CA  
**Approval Date:** July 7, 2004  
**Use Classification:** A robot-like system assists in coronary artery bypass surgery in which there is direct access to the chest via either a mini-thoracotomy or a sternotomy.  
**Description:** When the device is ready for use, the surgeon sits at a console with a computer and video monitor, using the console’s handgrips and foot pedals to control three robotic arms that perform the surgery with various tools. These arms, which have a “wrist” built into the end of the tool, give the surgeon additional manipulation ability, enabling easier and more intricate motion and better control of tools.  
**Purpose:** The “robot” allows surgeons to perform heart surgery while they are seated at a console.  
**Benefits:** The development of this system for use in the heart is a step forward in new robotic technology that may eventually change the practice of heart surgery. The FDA’s clearance was based on a review of clinical studies of the system’s safety and effectiveness during endoscopic coronary artery bypass surgery and other surgical procedures.  
**Sources:** www.pharmacyonesource.com; www.fda.gov.