NEW DRUGS
Two Injectable for Radioactivity
The FDA has approved two injectable drugs, pentetate calcium trisodium (Ca-DTPA) and pentetate zinc trisodium (Zn-DTPA), for treating internal radiation contamination from plutonium, americium, or curium. The new drugs increase the rate of elimination of these radioactive materials from the body.

Ca-DTPA and Zn-DTPA have been used for several decades as investigational agents in contamination emergencies. In September 2003, the Food and Drug Administration (FDA) announced specific conditions under which these drugs could be approved through new drug applications.

Internal contamination from radioactive materials can occur through ingestion, inhalation, or direct contact through wounds. The goals of treatment with these new agents are to enhance the removal of contaminants and thus reduce the risk of future biological effects.

Ca-DTPA and Zn-DTPA should not be administered simultaneously. If both products are available, Ca-DTPA should be given as the first dose. If additional treatment is needed, patients should be switched to Zn-DTPA. This sequence is recommended because Ca-DTPA is more effective than Zn-DTPA during the first 24 hours after internal contamination; after the initial 24 hours, Zn-DTPA and Ca-DTPA are similarly effective.

These agents are usually administered into the bloodstream. Nebulized inhalation can be used when contamination has occurred only by inhalation.

The main side effect of Ca-DTPA is the loss of essential nutritional metals such as zinc, which can be replaced by taking oral zinc supplements. Zn-DTPA may also decrease the levels of nutritional metals but to a lesser extent.

Some people experience breathing difficulties after inhalation therapy with these products.

Combination Drugs Fight HIV
Two new combinations of medications have been approved to treat human immunodeficiency virus (HIV) infection. Patients with HIV infection and acquired immunodeficiency syndrome (AIDS) usually need to take three or more drugs from different classes simultaneously.

Epzicom™ (GlaxoSmithKline) combines abacavir 600 mg (Ziagen®) and lamivudine 300 mg (Epivir®). Truvada™ (Gilead) is a fixed-dose combination of tenofovir disoproxil fumarate 300 mg (Viread®) and emtricitabine 200 mg (Emtriva®).

DUOXETLINE: A Dual-Action Antidepressant
A new “dual-action” antidepressant is expected to be a blockbuster drug for Eli Lilly & Co. With the launch of duloxetine (Cymbalta™), the company hopes to reclaim the throne it lost when its fluoxetine (Prozac®) lost patent protection and became generic two years earlier than expected in 2001. Cymbalta™ is reaching the market more than a year later than Lilly had hoped because of regulatory delays linked to problems in the company’s manufacturing facilities.

The agent differs from the most widely used class of antidepressants, which affect only serotonin levels in the brain. It targets two brain chemicals thought to play a role in depression and mood—norepinephrine and serotonin.

This is the first new antidepressant to be approved since the debate exploded over the drugs and the possible increased risk of suicide, especially among youths. Like most other antidepressants on the market, Cymbalta™ includes a warning about suicide risk on its label, but it has not yet been tested in children.

Lilly is also seeking approval for the drug to treat stress urinary incontinence.

NEW PRODUCT
Natural Tampon for Vaginal Infections
Rostam, Ltd., has won approval to market the Ela tampon that releases a natural supplement to help ward off vaginal infections. The tampon absorbs menstrual fluid but also releases lactic and citric acids into the vagina. Some research suggests that maintaining higher acidity levels during menstruation might help prevent common vaginal infections. The acids are contained in a natural fiber strip woven into the tampon.

The FDA categorized the tampon as a medical device, not a new drug. Rostam simply had to demonstrate that the product was as safe and as effective as other tampons but did not have to show that it could treat a specific health problem. The key ingredient is a natural supplement, a category that isn’t tightly regulated.

Rostam plans to position the tampon as a “wellness product,” because FDA rules bar the company from making specific health claims without additional studies.

NEW INDICATIONS
Stopping Migraine Before It Starts
The FDA has approved the daily use of the anticonvulsant drug topiramate (Topamax®, Ortho-McNeil) to prevent migraine headaches.

Stopping migraines before they start is controversial. The therapy may reduce the frequency of migraines but rarely eliminates them entirely.

In two studies of 900 patients who suf-
DRUG NEWS

NEW DRUGS


Meloxicam for Rheumatoid Arthritis

Meloxicam tablets (Mobic®, Boehringer Ingelheim) have been approved for the management of rheumatoid arthritis (RA). This nonsteroidal anti-inflammatory drug (NSAID) has been available in the U.S. since June 2000 to relieve signs and symptoms of osteoarthritis. Abbott Labs will co-market it.

In a placebo-controlled 12-week trial of 1,184 patients with rheumatoid arthritis, patients receiving meloxicam tablets at the recommended starting doses of 7.5 and 15 mg were more likely to complete the study than those receiving placebo. No incremental benefit was observed with 22.5 mg compared with 15 mg.

The starting and maintenance doses are 7.5 mg once daily. Some patients may benefit by increasing the dose to 15 mg once daily. Higher doses (22.5 mg and above) are associated with an increased risk of serious gastrointestinal events; thus, the daily dose should not exceed 15 mg.

Meloxicam is not indicated in patients with a history of asthma, itching, or allergic reactions after taking aspirin or other NSAIDs. As with all NSAIDs, serious GI toxicity such as inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine can occur without symptoms. The drug is not intended to prevent thromboembolic or cardiovascular events.

(Source: J Urol 2004;172:232–235.)

Hope for Patients with Kidney Cancer

Several new drugs are showing great promise in treating kidney cancer, a difficult-to-treat form of cancer. The drugs are “targeted” to attack certain molecular mechanisms that spur cancer growth.

The disease is usually resistant to chemotherapy. Only one drug has been approved for kidney cancer, interleukin-2 (IL-2). IL-2 can bring about complete remissions in 3% to 10% of patients, but it is overly toxic and most patients do not receive it.

Because the new data, presented at the American Society of Clinical Oncology meeting in June 2004, were mainly from small trials without placebo controls, doctors cautioned that the results might not hold up in larger, randomized trials and that the drugs might not prolong lives. Overall, however, the medications either shrank tumors or at least stopped them from growing in most patients.

SU 11248 (Sugen/Pharmacia, Pfizer) shrunk tumors by at least 50% in 21 of 63 patients and stopped tumor growth in 23 others. The Pfizer-sponsored trial involved 63 patients whose tumors had continued to worsen despite previous treatment with IL-2 or interferon.

BAY 43-9006 (Bayer/Onyx) caused tumor shrinkage or stopped tumor growth in 82 of 106 patients. Most of these patients had undergone earlier un-

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**NEW DRUGS**

**Successful Treatment:** Tumors shrank by 50% in 13 of those patients.

The two drugs used in concert were bevacizumab (Avastin™, Genentech), which is approved to treat colon cancer, and erlotinib (Tarceva™, Genentech), which has extended the lives of lung cancer patients. Avastin™ blocks the flow of blood to tumors, and Tarceva™ blocks epidermal growth factor receptor. In that trial, tumors shrank by at least half in 12 of 58 patients and shrank by a lesser amount or stopped growing in 38 others.

The newer targeted therapies generally have fewer side effects than older chemotherapy drugs.


**Unique Drug Fights Refractory HIV Infection**

Enfuvirtide (Fuzeon®, Roche/Trimeris) is a 36-amino-acid synthetic peptide that prevents completion of the HIV fusion sequence. Clinical trials suggest that adding this agent to a salvage regimen in heavily treated patients may improve virological response. Patients who are receiving two or more antiretroviral drugs, those who have received two or more antiretroviral drugs in the past, and those whose CD4+ cell count is above 100 cells/mm^3 appear to respond best. The most effective dose appeared to be 100 mg subcutaneously twice a day.

Although injection-site reactions have been common in trials, affecting from 69% to 98% of patients, these reactions were mostly mild or moderate, and only 2% of patients stopped taking the drug because of them. The authors suggest counseling patients to rotate injection sites in order to minimize reactions.

Enfuvirtide belongs to a class of antiretroviral agents called fusion (entry) inhibitors. It is approved for use in patients with HIV infection who still have evidence of viral replication despite treatment.

(Source: *Am J Health Syst Pharm* 2004; 61:1242–1247.)

**Infuser Care for Hepatitis C Patients**

A study by the Department of Veterans Affairs has found laboratory monitoring and duration of therapy to be “sub-optimal” for patients with hepatitis C infection. An “excessive duration” of therapy led to increased costs and exposed patients to “unnecessary” potential toxicity, the researchers say.

The researchers emphasized that excessive treatment exposes patients to unnecessary potential toxicity. These findings underscore the need for practitioners to adhere to the recommended guidelines for discontinuing therapy.

(Source: *Am J Health Syst Pharm* 2004; 61:1479–1482.)

**Steroids in Sepsis**

Is there a use for steroids in sepsis? The answer depends on whether studies were performed before 1989 or after 1997, according to researchers from the National Institutes of Health and Massachusetts General Hospital.

After evaluating findings from 14 studies, investigators noted that in eight of nine pre-1989 studies, glucocorticoids had no beneficial effects and actually had consistent, harmful effects on patient survival. The post-1997 studies revealed the opposite.

Before 1989, shorter courses of high-dose glucocorticoids were administered earlier in the patients’ septic episodes. After 1997, steroids were given in lower doses, to more severely ill patients, as late as 72 hours after vasopressor agents were initiated, and for a much longer time.

The researchers noted that they could not definitively identify the optimal dose or timing of steroid therapy. However, on the basis of their analysis of the findings, they advise that patients with established vasopressor-dependent septic shock for two to 72 hours might have a better chance of shock reversal and survival if they are given a course of steroids at 200 to 300 mg/day for five to seven days, followed by tapering over five to seven days.

(Source: *Ann Intern Med* 2004;141:47–56.)

**Simplifying Therapy for Deep Vein Thrombosis**

Researchers have come up with a suggestion for how to simplify treatment for patients with deep vein thrombosis (DVT): a once-daily subcutaneous injection of fondaparinux (Arixtra®, Organon/Sanoﬁ-Synthelabo) instead of twice-daily enoxaparin (Lovenox®, Aventis).

In a randomized, double-blind study in 2,205 patients in 154 centers worldwide, the two drugs were similar in efficacy and safety. Among the 1,098 patients receiving fondaparinux, 43 had one or more episodes of confirmed recurrent venous thromboembolism, compared with 45 of the 1,107 enoxaparin patients. Major bleeding complications occurred in 12 fondaparinux patients and in 13 enoxaparin patients.

During the study, 41 of the fondaparinux patients (3.8%) and 33 of the enoxaparin patients (3%) died. In the fondaparinux group, five died of pulmonary embolism, 24 of cancer, and seven of other causes. In the enoxaparin group, five patients died of pulmonary embolism, 19 of cancer, and nine of other causes. Two of the five fatal bleeding episodes in the fondaparinux patients occurred during initial treatment; the other three occurred during long-term treatment with vitamin K antagonists.

Fondaparinux comes in prefilled syringes, which might make home treatment easier. The researchers noted that although the use of self-administered continued on page 549
low-molecular-weight heparin is growing, it is subject to dosing errors by physicians or patients when body weight, dosage, or dose intervals are uncertain or when patients have trouble titrating prefilled syringes or withdrawing dosages from multidose vials.

(Source: Ann Intern Med 2004;140: 867–873.)

Exenatide from a Lizard: Control Blood Glucose and Lose Weight?

A new class of drugs called incretin mimetics is offering hope to patients with type-2 (non–insulin-dependent) diabetes who have not been able to control their blood glucose levels after taking common oral regimens. Patients in phase III trials who received the investigational drug exenatide (synthetic exendin-4, Amylin/Eli Lilly) had lower blood glucose levels as well as improvements in markers of beta-cell function—and they lost weight to boot.

Researchers presented their findings from three studies at the 64th Annual Scientific Sessions of the American Diabetes Association.

In one study of 336 patients for whom maximal doses of metformin were not working, glycosylated hemoglobin (HbA1c) was significantly reduced from baseline measures with exenatide compared with placebo. At 30 weeks, 46% of those patients taking 10 mcg and 32% of those taking 5 mcg had levels below 7%, compared with 13% of patients taking a placebo. Side effects were mild or moderate, and usually gastrointestinal, such as nausea.

A second study included 733 patients whose blood glucose levels were not controlled with metformin therapy and a sulfonylurea. Again, exenatide reduced HbA1c from baseline, by about 8.5%, and also brought about weight loss.

Patients from both of these studies who participated in a 52-week open-label extension study received exenatide 10 mcg twice daily. Among 51 patients taking exenatide plus metformin, the average reduction in HbA1c was 1.1%; these patients also lost an average of 9.9 pounds. Among 77 patients who received extended treatment with exenatide and metformin/sulfonylurea, hemoglobin A1c levels declined by 1.0% and the average weight loss was 7.3 pounds.

Incretin mimetics are derived from hormone research. Exenatide is a synthetic version of exendin-4, a hormone found in the saliva of the Gila monster (a lizard). The lizard eats only four times a year. Its pancreas shuts down the remainder of the time, and exendin-4 is secreted to reactivate the pancreas.


Combo Drug Helps Heart Failure in African-Americans

“Compelling” benefits have led NitroMed to stop a phase III trial of its heart drug BiDil® a year ahead of schedule so that placebo patients in the study could take it as well. BiDil® is a combination of isosorbide dinitrate (e.g., Isordil, Wyeth), a nitric oxide donor, and hydralazine (Apresoline®, Novartis), an antioxidant and vasodilator.

The African-American Heart Failure Trial (A-HeFT) is the largest database of African-Americans with heart failure, according to the Association of Black Cardiologists, which co-sponsored the trial. The incidence of heart failure is disproportionately high among African-Americans, and they are more likely than white patients to die as a result.

(Sources: www.nitromed.com; www.pharmalive.com.)

Etomidate in Emergency Rooms

The data are sparse but mostly positive for the use of etomidate (Amidate®, Bedford Labs) in the emergency department (ED). After reviewing three observational studies and five prospective, randomized, controlled trials, researchers from the University of British Columbia noted that etomidate produced a faster onset and recovery time than midazolam (Versed®, Roche) and compared favorably with propofol (Diprivan®, AstraZeneca) and thiopental (Sodium Pentothal®, Abbott).

When etomidate was used to induce sedation during rapid-sequence intubation, it did not significantly alter hemodynamics, whereas propofol, thiopental, and midazolam were all associated with reduced (but not clinically significant) blood pressure. The authors suggest that etomidate might offer an advantage to patients whose blood pressure is low before they undergo procedures. Etomidate also appeared to have less effect on respiratory status during procedures than did propofol.

The most prominent adverse effect associated with etomidate was myoclonus, reported in 50% to 80% of patients, but most of these occurrences were brief and minor. In a few patients, the myoclonic episode was considered severe and was described as generalized rigidity or stiffness lasting approximately...
several minutes. None of the episodes, though, resulted in postprocedural myalgia or recollection of the event. Myoclonic events have the potential to delay determination of successful cardioversion, the authors caution.

(Source: Ann Pharmacother 2004;38:1272–1277.)

Can We Get Too Much Sleep?
A study from 2002 found that more than seven hours of sleep each night was associated with a shorter life span. When the subjects slept longer than seven hours a night, the risk of dying in that period rose. For people who slept for an average of eight hours each night, the chance of death rose by 12%.

Other researchers have found that life expectancy declines as the amount of sleep falls below seven hours but does not drop as steeply as with eight hours or more. Some think that people who sleep longer might have illnesses that cause fatigue and earlier death.


Unexpected Risks for Spironolactone, Heralded Heart Drug
A drug that was shown in a landmark clinical trial five years ago to save the lives of patients with heart failure may have taken lives instead.

In 1999, researchers showed that a little-used, 40-year-old drug significantly reduced death and hospitalization for patients with congestive heart failure. Those results were so compelling that the trial was hailed ahead of schedule. Now Canadian researchers are reporting that spironolactone (Mylan Labs) might have had a much different effect. (The brand-name drug, Aldactone®, is made by Pfizer.)

The publication of the 1999 study resulted in a greater than fourfold increase in prescriptions for the generic drug over an 18-month period. That surge in use was accompanied by a tripling of hospital admissions and of deaths resulting from dangerous elevations of potassium (hyperkalemia), a known side effect of spironolactone. Highly elevated potassium levels can cause severe muscle pain and can disrupt electrical conduction in the heart, causing sudden death.

Canadian researchers noted that, among heart patients after 1999, the number of prescriptions for spironolactone, the number of hospital admissions for hyperkalemia, and the death rate attributed to hyperkalemia all increased.

Researchers said that the culprit was not the drug itself but, rather, the willingness of doctors to prescribe it for patients who were already at an increased risk for the potassium problem. Furthermore, these patients were not carefully monitored for hyperkalemia. Before the 1999 study, the drug had been used mainly as a diuretic and for liver patients.

The new findings offer a provocative look at the difference between clinical trial results and real-world medicine—and the potential dangers of applying trial results too widely. Patients in clinical studies are usually carefully selected to maximize the chance of showing a benefit and to minimize side effects. Trial patients represent only a subset of the types of patients whom doctors treat in their offices.

In the new study, researchers found that patients taking spironolactone in the aftermath of the 1999 study were, on average, 13 years older than participants in the original trial and were more likely to have diabetes. Older patients and those with diabetes are at higher risk for elevated potassium levels. The average dose in actual practice was 30 mg, whereas the study dose was 25 mg, perhaps reflecting how doctors tend to prescribe higher doses if an initial lower dose is ineffective.

Pfizer is now marketing eplerenone (Inspra®), a second-generation version of spironolactone, for patients with heart failure after a heart attack.

The study is not iron-clad proof of cause and effect, in part because researchers did not specifically match individual patients taking the drug with poor outcomes. The lead author emphasized that spironolactone can be beneficial to appropriate patients and that risks can be managed by selecting patients carefully, monitoring potassium levels, and adjusting medications to minimize adverse effects.


Maggots Make a Medical Comeback
Maggots are being used to help clean out wounds in sick patients after unsuccessful high-tech treatments.

This therapy has been quietly championed since the early 1990s by a California physician known as “Dr. Maggot.” Dr. Ronald Sherman’s maggots became the first live animals to win the FDA’s approval to clean out wounds. They are defined as a “medical device” because they remove the dead tissue that impedes healing “mechanically,” by chewing. In the mere two to three days during which they live in a wound, maggots also produce substances that kill bacteria and stimulate growth of healthy tissue.

In June 2004, leeches were also approved to help save severed body parts by removing pooled blood and restoring circulation during plastic surgery. In the spring, University of Iowa researchers reported early evidence that drinking whipworm eggs might soothe inflammatory bowel disease.
Civil War surgeons noted that soldiers whose wounds harbored maggots seemed to fare better. In the 1930s, research at Johns Hopkins University sparked routine maggot therapy until antibiotics came along a decade later. One specialist in Chicago who first tried maggot therapy about seven years ago has since used it on several hundred patients.

The size of the wound determines how many maggots are used and how many cycles of therapy are needed. In one study, 80% of maggot-treated wounds showed that all dead tissue had been removed, compared with 48% of wounds that were surgically debrided.


Warning for Colorectal Drug

The FDA and Genentech, Inc., have issued an important warning to health care providers about bevacizumab (Avastin™) in relation to an increased risk of cerebrovascular accidents, myocardial infarctions, transient ischemic attacks, and angina. The risk of fatal arterial thrombotic events is also increased.

In studies of patients with metastatic colorectal cancer, the risk of a serious arterial thrombotic event was approximately two-fold higher in patients receiving infusional 5-fluorouracil-based chemotherapy plus the bevacizumab.

A revised package insert with more details on arterial thrombotic events is under development.

The FDA has questioned the safety of imported drugs, but it has not taken legal action against any of the states with importation Web sites.

(Source: The Wall Street Journal, August 6, 2004.)

Illinois Program to Promote Imported Drugs

Governor Rod Blagojevich of Illinois has set up a plan to help residents order prescription drugs from Canada, Ireland, and the United Kingdom through a Web site and a toll-free phone number.

The program, expected to be launched in September, comes as legislative efforts to create a national drug-importation structure appear stalled. Several states have launched Web sites to ease purchases of prescription drugs from Canada, where they tend to be less expensive than in the U.S.

A spokeswoman for the governor said that the three countries had very advanced and safe pharmaceutical systems. The state will inspect the pharmacies and wholesalers involved and expects to contract with a pharmacy benefit manager (PBM) to establish a list of pharmacies and wholesalers in the three countries. The PBM would then enroll the state’s residents. The program would handle 100 of the most popular drugs that treat chronic conditions. The state would waive co-payments for its employees and retirees who use the program.

The FDA has questioned the safety of imported drugs, but it has not taken legal action against any of the states with importation Web sites.

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

More Stents Recalled

Boston Scientific Corp. has again expanded its recall of coronary stents. The latest recall, which involved an additional 3,000 of the Taxus drug-coated stents, was blamed on an error in quality-inspection processes.

To date, the company has issued three recall notices involving a total of 99,200 stents. Since the last recall, on July 16, 2004, the company has reassured doctors that the remaining stents are safe.

Within a month of the stent’s availability, doctors were complaining of occasional problems in deflating the balloon after the procedure—which, in severe cases, can result in emergency surgery to remove it. Several major hospitals had suspended use of the stents following the recall.

Because the problem arises in the surgical-implantation procedure, all patients who have successfully received the stents need not worry about the recall.

The company initially blamed the deflation problems on doctors’ errors, but in early July, it said it had discovered a manufacturing defect. It maintains that a manufacturing change, instituted in May and June, fixed the problem. However, the company did learn that a microscope eyepiece with the wrong size calibration had been used in inspections. All stents made on those days (3,000) are being recalled.

(Source: The Wall Street Journal, August 6, 2004.)

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Sculptra™

Manufacturer: Dermik Laboratories, Berwyn, PA

Approval Date: August 3, 2004

Use Classification: Sculptra™ (poly-L-lactic acid [PLLA]), when injected into the skin, increases the thickness of the skin. It is used as therapy for lipoatrophy (facial fat loss) in patients with human immunodeficiency virus (HIV) infection who are actively being treated for the disease.

Description: Sculptra™ is an injectable PLLA implant in the form of a sterile, freeze-dried preparation. After the powder is mixed with water, it is injected into the skin. The microparticles of PLLA are biodegradable. PLLA is a biocompatible synthetic polymer from the alpha-hydroxy acid family. A physician injects the product into areas of the face where fat has been lost.

Purpose: The product temporarily adds volume to facial tissue and restores a smoother, fuller appearance to the face. After the initial treatment series, further injections may be needed to maintain the...
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Effect, which lasts for about one year.

**Benefit:** Sculptra™ restores shape and contour deficiencies in areas of facial lipoatrophy.

**Cautions:** Side effects include raised bumps of skin (nodules), bruising, swelling, pain, and tenderness.

**Source:** www.fda.gov/cdrh/mda/docs/p030050.html.

Name: Architect® Stat Troponin-I Test
Manufacturer: Abbott Laboratories, Abbott Park, IL
Approval Date: August 18, 2004
Use Classification: Troponin-I is a protein that is released from dead or severely injured heart muscle cells after a cardiac event.

**Description:** The device system is a troponin-I test for use on Abbott’s Architect® i2000SR® Immunoassay System and its Architect® ci8200™ Immunochemistry System.

**Purpose:** The test has excellent functional sensitivity and precision for detecting troponin I. The automated immunoassay system can perform up to 200 tests per hour and can provide results within 18 minutes.

**Benefit:** According to the American College of Cardiology, troponin has become the gold standard in diagnostic testing for myocardial infarction. The device enables rapid turnaround time of troponin I results, enabling physicians to quickly diagnose chest pain and treat patients.


Name: Merci® Retriever
Supplier: Concentric Medical, Mountain View, CA
Approval Date: August 16, 2004
Use Classification: A tiny corkscrew is threaded through an artery to remove blood clots and to restore blood flow.

**Description:** The device is a flexible, tapered nitinol wire with a helix-shaped tip. There is also a platinum coil for radiopacity.

**Purpose:** This device removes clots, restores blood flow, and provides a new method of treating ischemic stroke patients with no other therapeutic options.

**Benefits:** This is the first FDA-approved medical device for removing blood clots from the brain in patients experiencing an ischemic stroke. The device can also eradicate foreign bodies in the vessels.

**Sources:** www.pharmacyonesource.com; www.ahaf.org/whatsnew/H_First-Device_Aug_2004.htm

Name: Intrinsic™ Dual-Chamber Implantable Cardioverter-Defibrillator
Manufacturer: Medtronic Inc, Minneapolis, MN
Approval Date: August 12, 2004
Use Classification: This implantable cardioverter-defibrillator (ICD) is a device with a new pacing mode.

**Description:** A feature called 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:** The pacing mode promotes natural heart activity and reduces unnecessary pacing in the lower right chamber of the heart. Patients who receive ICDs need them because they are at risk for sudden cardiac arrest, a condition in which the lower chambers of the heart (the ventricles) may start beating too rapidly and stop pumping blood to the body. However, in most patients with ICDs, the heart beats normally most of the time, sending electrical signals from the upper chambers to the lower chambers in a coordinated fashion. In these patients, it is ideal to allow this normal electrical conduction to continue, something the MVP mode is designed to do.

**Benefit:** The device represents a significant benefit because unnecessary pacing has been shown to be harmful in some patients. The ICD provides help when the heart needs it, allows the heart to function naturally when it does not require support, continually monitors each heartbeat, and recognizes when normal conduction is present.

**Sources:** www.pharmacyonesource.com; http://biz.yahoo.com.

**Controversy over Acid Reflux Device**

August 13, 2004: The FDA reviewed a recent death and six serious injuries after patients were treated with Boston Scientific Corporation’s Enteryx® device for managing acid reflux disease, as documented in The Wall Street Journal (August 13, 2004). The device is used to inject a plastic substance into the esophagus.

The Enteryx® review was triggered when an elderly woman died three weeks after she was treated with the device. Her aorta was ruptured, and she bled to death. The FDA is investigating whether physician technique or the device itself was responsible for the event.

Physicians use the kit’s syringe to inject a gel into the wall of the esophagus. The gel is intended to strengthen the organ and to help it contain the stomach’s fluids. Boston Scientific said that it was working with the FDA to include additional warnings.

August 21, 2004: The company stated that doctors could resume using Enteryx® to treat acid reflux disease because the test yielded a false-positive result, but The New York Times (August 21, 2004) reported that the FDA is still looking into the treatment.

**Source:** www.boston.com/yourlife/health/diseases/articles.