

# THE WALL STREET JOURNAL

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## The Calling

### John Paul's Frailty Stirs Emotional Debate Over Papal Retirement

#### Are There Limits to Tenure Of a Man Who Answers To No One but God?

#### Celestine and His Donkey

By Lisa Miller  
Staff Reporter of THE WALL STREET JOURNAL

ROME—Should he or shouldn't he? Pope John Paul II was in the Holy Land last week. Mr. Mastroianni was hanging out in the crowd of young people that gathers daily in the piazza near the Pantheon. The 79-year-old art student thinks the aging pontiff should resign his post. "Like all people—when they're old, they retire," says Mr. Mastroianni.

But Paolo Bondi, who is sitting nearby, disagrees. "He can be a good shepherd even though he's old and tired," says Ms. Bondi, who is 22 and a psychologist.

From the cobblestone streets near St. Peter's Square to rural districts in the American Midwest, people are debating a question that in many ways exemplifies the Roman Catholic Church's age-old struggle between tradition and modernity: Is the Holy Father so frail that he should step down?

Triggered by John Paul II's obviously declining health—in Jerusalem on Sunday he needed help rising from his knees in the Church of the Holy Sepulchre and was fueled by a German bishop's controversial public remarks on papal retirement early this year, the debate has reached a fever pitch. Both in private conversation and in the press, people are talking about canon law, God's will and one famous instance of papal retirement, in 1294. "It's a feeding frenzy," says Margaret Melady, president of the American University of Rome.

Even devout American Catholics such as Gerard Roche struggle with the question of whether John Paul II, who turns 80 in May, is too frail to lead the world's billion Catholics. On the one hand, last week's trip convinced Mr. Roche that the pope remains a powerful spiritual leader.

"On the other hand," Wight Corporation would put up with a CEO like this for long," says Mr. Roche, chairman of Helix & Strategies Inc., the New York-based headhunting firm.

Often photographed skiing and hiking early in his 22-year tenure, the pontiff now uses a trolley to transport him from one of St. Peter's Basilica to another. But although he is not quite the relentless traveler he used to be—in 1998 he visited Rwanda, Burundi, Tanzania, Cape Verde and Guinea-Bissau—John Paul II's public appearances nevertheless have the effect of inspiring world leaders to lead.

Similarly, as his career has progressed, his focus has moved from the world of geopolitics—ethnic diversity in the College of Cardinals and the fate of communist states, for example—to more internal, spiritual matters: the elderly, apostasy and reconciliation. And for three years now, his energy has been aimed at this year's Jubilee celebration.

Giuseppe DePasquale reflects the mood of many who watched John Paul II on his latest trip. "I'm awaiting a fight to Bangkok at Rome's Fiumicino airport on Sunday," Mr. DePasquale is riveted to the TV as the pope tours the Church of the Holy Sepulchre. "His body is no good," says Mr. DePasquale, a salesman. "But he's a great man, the most powerful man of the last 100 years."

Others, such as Bishop Raymond Lucker, of New Ulm, Minn., point out the considerable challenges of the position. Bishop Lucker, who himself is 73 and about to retire, supports a mandatory age for papal retirement. Since 1966, he notes, bishops have had to submit letters of resignation at age 75. And, he says, being a pope is harder than being a bishop. The pope presides over Vatican City, a country unto itself, as well as a massive international bureaucracy of 151 cardinals and about 4,400 bishops, not to mention museums, libraries, real-estate holdings, innumerable committees and councils, and an operating budget of about \$200 million.

"Once you pass the age of 70, you notice diminishing abilities. You have health problems, you need more sleep," Bishop Lucker says. "A person can have done a marvelous job as pope and then come to a point and say, 'I can't do this anymore.'"

This isn't the first time a pope has grown frail on the job, of course. Leo XIII, pope from 1878 until 1903, "was rumored to be dying for about 10 years," before he died at age 65, says the Rev. Gerald Fogarty, a historian at the University of Virginia.

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## What's News

### Business and Finance

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**Some brokerage firms** are ratcheting up efforts to pay upfront bonuses and provide other perks to brokers, potentially running counter to the spirit of a high-profile effort by SEC regulators to clean up conflicts of interest. (Article on Page C1)

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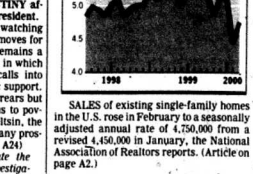
**The Academy Awards** drew 46.3 million viewers for ABC, a 2% increase from last year, according to preliminary numbers from Nielsen Media. (Article on Page B2)

**Lernout & Hauspie** will buy a maker of speech-recognition software, Dragon, for \$587 million in stock. (Article on Page B9)

### MARKETS

Stocks: NYSE vol. 876,257,909 shares, Nasdaq vol. 1,360,960,328. Dow Jones industrials 11,025.85, up 86.87; transportation 2667.81, up 20.34; utilities 290.76, up 3.43.
Bonds: Lehman Brothers Treasury index 8405.51, up 1.06.
Commodities: Oil \$27.74 a barrel, off 0.15; Dow Jones Industrial Average 11,025.85, off 0.02; DJ spot index 120.54, off 0.13.
Dollar: 106.74 yen, off 0.14; 1.0344 euros, up 0.0112; 2.0222 marks, up 0.0219.

## Existing-Home Sales



**SALES** of existing single-family homes in the U.S. rose in February to a seasonally adjusted annual rate of 4,500,000 from a revised 4,450,000 in January, the National Association of Realtors reports. (Article on Page A2)

### Guam's Roots Are So Deep in Spam, They're Hard to Find

The Mall Is a Place to Look—For Chamorro T-Shirts: The Layers of Assimilation

By Robert Frank  
Staff Reporter of THE WALL STREET JOURNAL

HAGATNA, GUAM—The brochure for this breezy Pacific outpost boasts of a "small island containing a world of cultures." On the main drag in downtown Hagatna, Japanese noodle shops thrive amid Dairy Queens, cha-cha clubs, Spanish-style Catholic churches and American strip clubs. There's even a Wild West-style shooting gallery that doubles as a wedding chapel for visiting South Koreans.

And what about the native culture of Guam? "Oh, gee, I'm not sure where to even look," says a Japanese conchie at the Guam Hyatt Regency. "Maybe the mall?"

### Cold War Castaway

Foreign Guam's confusion. Officially, this small volcanic island in the middle of the Pacific, which has been colonized three times in an unincorporated territory of the U.S. Unofficially, it's a Cold War castaway looking for a purpose. For decades, it was supported by the Navy, and more recently, by Japanese tourists looking for a nearby beach and duty-free Chanel bags. Through it all, people here have patiently accepted the language, food, clothing and religion of their invaders in hopes of being accepted.

Yet, with self-determination all the rage around the world, Guam is looking for

its inner Guamanian. Local residents are scheduled to vote in July on whether to remain part of the U.S. or become independent, setting the stage for a new round of talks with Congress on the island's status. Guam's indigenous Chamorros are battling outside to fight for Chamorro rights, Chamorro businesses and, most of all, Chamorro culture.

Leading the charge is the Chamorro Nation, a group of tattooed youths and tribal activists who seek to reclaim the country. Their method is as militant as from staging the occasional sit-in, they give beach tours and tauna feasts.

The group has gained widespread popularity on an island searching for its provincial roots. "We've had some tough times since Magellan landed" in 1521, says Eddie Benavente, leader of the Chamorro Nation, and a teacher at Guam's John F. Kennedy High School. "But now it's time to

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## Work Week

### A Special News Report About Life On the Job—and Trends Taking Shape There

**OSHA PUSHES** builders to improve workplace safety. Construction sites have always been dangerous places, but they're getting more so, as the tight labor market increases the number of inexperienced workers on the job. More than 1,200 construction workers were killed at work last year, up 25% since 1992.

In response, the agency is focusing more on eliminating safety violations through cooperative safety "partnerships" such as its recent accord with the Associated Builders & Contractors trade group. Contractors who meet strict safety and training standards set by the ABC will face fewer OSHA inspections, and will get a break on regulatory hassles over technical violations.

"We want to spend less time at sites where hazards are being controlled," says OSHA Administrator Charles Jeffrey, "and more at sites where they aren't."

**COUNT ME IN** plans "microloans" for U.S. women. In developing nations, microfinancing programs where women groups make small loans to poor entrepreneurs who can't qualify for conventional loans—have proven very effective. Today, newly formed Count Me In for Women's Economic Independence is kicking off a campaign to make such loans available in this country, specifically for women. The nonprofit is the brainchild of Neil Merino, creator of "Take our Daughters to Work Day."

The drive will seek to raise at least \$10 million by soliciting \$5 donations from women. The money will be used to help female entrepreneurs do "all the sorts of things work-related that we do now but lack a lack of credit history often makes it hard for women to qualify for standard loans, says it will provide a women-appropriate credit scoring" technique.

**HEAVY OVERTIME** can strain blue-collar families, researchers find. A study by Cornell University's School of Industrial and Labor Relations finds unionized hourly employees work an average of 6.3 hours overtime on top of their regular 40-hour week. But while many employees worked only a few extra hours per week, just over one-third worked more than 10 hours. Many of the overtime 4,300 workers in the study sought the overtime and still they would like even more hours. Why? The study cites "job insecurity and financial strain."

But workers' economic well-being may be greater than suspected, the study notes. Workers who put in more than 50 hours a week reported a lower incidence of "severe" work-family conflicts.

**Workers pressed into OT work** by supervisors showed "significantly higher rates of absenteeism, job stress, and burnout, the study found."

**ONLINE RECRUITING** accounted for one out of every eight new hires last year, according to Kforce.com's recent poll of 300 U.S. companies. The Web-based staffing company's poll says many companies plan to expand their efforts. Leading disadvantages they listed for online job searches: too many applicants, too many unqualified, and too many resumes. "We get a lot of junk" noted one respondent.

**HELL FREEZES OVER:** That's the tongue-in-cheek position on a recent AFL-CIO newsletter item noting that two traditional enemies—the United Farmworkers union and longtime foe the Western Growers Association—an agricultural industry group—had found a bit of common ground. Officials of both groups joined to publicly endorse a \$1.97 billion California water-improvement ballot proposal. The bond measure, which state voters subsequently approved, will fund a host of flood-control and water-use improvements. Some projects will benefit ever-thirsty agricultural interests, but farm-worker communities will get safer water and other benefits.

**IT COULD HAPPEN:** A KPMG International poll of college seniors found that fully 60% of the students expect to become a millionaire.

**FERTILIZER THIEVES** give farmers something new to worry about on a recent AFL-CIO newsletter item noting that two traditional enemies—the United Farmworkers union and longtime foe the Western Growers Association—an agricultural industry group—had found a bit of common ground. Officials of both groups joined to publicly endorse a \$1.97 billion California water-improvement ballot proposal. The bond measure, which state voters subsequently approved, will fund a host of flood-control and water-use improvements. Some projects will benefit ever-thirsty agricultural interests, but farm-worker communities will get safer water and other benefits.

## Safe and Effective

### Many Medicines Prove Potent for Years Past Their Expiration Dates

Since 1985, FDA Has Tested Military Drug Stockpile To Extend Shelf Lives

By Laurie P. Cohen  
Staff Reporter of THE WALL STREET JOURNAL

Do drugs really stop working after the date stamped on the bottle? Fifteen years ago, the U.S. military decided to find out. Sitting on a \$1 billion stockpile of drugs and facing the daunting process of destroying and replacing its supply every two to three years, the military began a testing program to see if it could extend the life of its inventory.

The testing, conducted by the Food and Drug Administration, ultimately covered more than 100 drugs, prescription and over-the-counter. The results, never before reported, show that about 90% of them were safe and effective far past their original expiration date, at least one for 15 years past it.

In light of these results, a former director of the testing program, Francis Flaherty, says that the results, never before reported, show that about 90% of them were safe and effective far past their original expiration date, at least one for 15 years past it.

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**Manufacturing Issue**  
"Manufacturers put expiration dates on for marketing, rather than scientific reasons," says Mr. Flaherty, a pharmacist at the FDA until his retirement last year. "It's not profitable for them to have products on the shelf for 10 years. They want turnover."

The FDA cautions that there isn't enough evidence from the program, which is weighted toward drugs needed during combat and which tests only individual manufacturing batches, to conclude that most drugs in people's medicine cabinets are potent beyond the expiration date. Still, Joe Davis, a former FDA expiration-compliance chief, says that with a handful of exceptions—notably nitroglycerin, insulin and some liquid antibiotics—most drugs are probably as durable as when the agency first tested for the military. "Most drugs degrade very slowly," he says. "In all likelihood, you can take a product you have at home and keep it for many years, especially if it's the refrigerator."

**Manufacturers' View**  
Drug-industry officials don't dispute the results of the FDA's testing, within what is called the Shelf Life Extension Program. And they acknowledge that expiration dates have a commercial dimension. But they say relatively short shelf lives make sense from a public-safety standpoint, as well.

New, more-beneficial drugs can be brought on the market more easily if the old ones are discontinued, they say. They say, Label redesigns work better when consumers don't have earlier versions to hand to create confusion. From the companies' perspective, any liability or safety risk is diminished by limiting the period during which a consumer might misuse or improperly store a drug.

"Two to three years is a very comfortable point of commercial convenience," says Mark van Arsdale, spokeswoman for pharmaceutical development at Pharmacia & Upjohn Inc. "It gives us enough time to put the inventory in warehouses, ship it and ensure it will stay on shelves long enough to get used." But companies uniformly deny any effort to spur sales through planned obsolescence.

**Why Not Longer?**  
Now that the FDA has found that many drugs are still good long after they have supposedly expired, why doesn't it advocate later expiration dates for consumer drugs? One reason is that the consumer market lacks the military's logistical reasons to keep drugs around longer.

Frank Holcombe, associate director of the FDA's office of general counsel, says that in many cases a manufacturer could extend expiration periods again and again, but to support those extensions, it would have to keep doing stability studies, and keep more in storage than it would like.

Mr. Davis adds: "It's not the job of the FDA to be concerned about a consumer's economic interest." It would be up to Congress to impose changes, he says.

As things stand now, expiration dates get a lot of emphasis. For instance, there's a campaign, co-sponsored by some drug makers, that urges people to discard pills when they reach the date on the label.

And that date often is even earlier than the one the maker set. That's because when pharmacists dispense a drug in any

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Dr. Reddy's Laboratories, Ltd., et al.



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### Challenges of the Position

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This isn't the first time a pope has given up the job. In 1879, Pope Pius XIII, pope from 1878 until 1903, was removed to be dying for about 10 years. He died at age 85, says the Rev. Gerald Fogarty, a historian at the University of Virginia.

But with 2,000 years of management experience, the College of Cardinals, for which holds limited control of the church in the absence of the pope, can take the reins as needed. And the Vatican's day-to-day

## What's News

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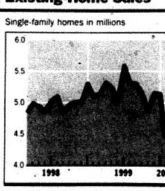
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By ROBERT FRANK  
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Yet now, with self-determination all the rage around the world, Guam is looking for a purpose of its own. Officially, this small volcanic island in the middle of the Pacific, which has been colonized three times, is an "unincorporated territory of the U.S." Unofficially, it's a Cold War Westway looking for a purpose. For decades, it was supported by the Navy, and more recently, by Japanese tourists looking for a beach and duty-free Chanel bags. Through it all, people here have patiently accepted the language, food, clothing and religion of their invaders in hopes of being accepted.

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## Work Week

A Special News Report About Life On the Job—and Trends Taking Shape There

OSHA PUSHES builders to improve workplace safety. Construction sites have always been dangerous places, but they're getting more so, as the tight labor market increases the number of inexperienced workers on the job. More than 1,200 construction workers were killed at work last year, up 25% since 1992.

Count Me In plans "microloans" for U.S. women. In developing nations, microfinancing programs—where aid groups make small loans to poor entrepreneurs who can't qualify for conventional loans—have proven very effective. Today, newly formed Count Me In for Women's Economic Independence kicks off a campaign to make such loans available in this country, specifically for women. The nonprofit is the brainchild of Neil Merlino, creator of "Take our daughters to Wall Street."

HEAVY OVERTIME can strain blue-collar families, research finds. A study by Cornell University's School of Industrial and Labor Relations finds unionized hourly employees work an average of 6.8 hours overtime on top of their regular 40-hour week. But while many employees worked only a few extra hours per week, just more than a fifth of the workers—sometimes referred to by co-workers as "overtime hogs"—work at least 11 and sometimes more than 20 hours of OT.

HELL FREEZES OVER: That's the tongue-in-cheek headline on a recent AFL-CIO newsletter item noting that two traditional enemies of the United Farmworkers union and longtime foe the Western Growers Association, an agricultural-industry group—had found a bit of common ground. Officials of both groups joined to publicly endorse a \$1.97 billion California water-improvement ballot proposal. The bond measure, which state voters subsequently approved, will fund a host of flood-control and water-storage improvements: Some projects will benefit ever-thirsty agricultural interests, but farm-worker communities will get safer water and other benefits.

IT COULD HAPPEN: A KPMG International poll of college seniors found that fully 16% of the students expect to become a millionaire.

FERTILIZER THIVES give farmers something new to worry about, associate director of the FDA's office of generic drugs, says that in many cases a manufacturer could extend expiration periods again and again, but to support those extensions, it would have to keep doing stability studies, and keep them in storage that it would like.

THE CHECKOFF: Smoke packs: Work-place smoking restrictions and soaring re-

## Safe and Effective

Many Medicines Prove Potent for Years Past Their Expiration Dates

Since 1985, FDA Has Tested Military Drug Stockpile To Extend Shelf Lives

What the Dates Really Mean

Drugs really stop working after the date stamped on the bottle? Fifteen years ago, the U.S. military wanted to find out. The U.S. military stockpile of drugs and facing the daunting process of destroying and replacing its supply every two to three years. The military began a testing program to see if it could extend the life of its inventory.

Manufacturers' View: Drug-industry officials don't dispute the results of the FDA's testing, which is what is called the Shelf Life Extension Study. The results show that expiration dates have a commercial dimension. But as they say, Label redesigns won't better when consumers don't have earlier versions to compare.

Why Not Longer? Now that the FDA has found that many drugs are still good long after they have supposedly expired, why doesn't it allow later expiration dates for consumer drug? Consumer advocates say that consumer market lacks the military's logistical reasons to keep drugs around longer.

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# Many Drugs Prove Potent Long Past Expiration Dates

Continued From First Page  
 cines goes to replace expired ones. But in a poll done by The Wall Street Journal by NPD Group Inc. of Fort Washington, N.Y., 70% of 1,000 respondents said they probably wouldn't take a prescription drug after its expiration date; 72% said the same after over-the-counter remedies.

"People think that, upon expiration, drugs suddenly turn toxic or lose all their potency," says Philip Alper, professor of medicine at University of California at San Francisco. In his own practice, Dr. Alper says, "I frequently hear—from patients who can't afford medicine—that they have thrown away expired drugs." He says companies should be required to test drugs for longer periods and set later expiration dates when results warrant.

Some manufacturers first began putting expiration dates on drugs in the 1960s, although they date back to 1979, the main effect was to set uniform testing and reporting guidelines required by the FDA. A so-called stability testing analyzes the capacity of a drug to maintain its identity, strength, quality and purity for whatever period the manufacturer picks. If it can't pass a two-year expiration date, it means it test beyond that.

Testing for a two-year expiration doesn't initially entail holding a drug for two years. Rather, the drug is tested by subjecting it to extreme heat and humidity for several months, then chemically analyzing each ingredient's identity and strength. After the date is set and the drug is marketed, testing continues for the full two years.

The FDA also uses chemical analysis in testing for possible shelf-life extension; it doesn't test on human subjects. Testing conditions are such that any medicine that passes, say, the standards for a one-year expiration date probably lasts longer, the FDA and drug companies agree.

**Still Good**  
 Consider aspirin. Bayer AG puts two-year or three-year dates on aspirin and says that it should be discarded after that. Chris Allen, a vice president at the Bayer unit that makes aspirin, says the dating is "pretty conservative"; when Bayer has tested four-year-old aspirin, it remained 100% effective, he says.

So why doesn't Bayer set a four-year expiration date? Because the company often changes packaging, and it undertakes continuous improvement programs. "Mr. Allen says. Each change triggers a need for more expiration-date testing, he says, so testing each time for a four-year life would be impractical.

Bayer has never tested aspirin beyond four years. Mr. Allen says. But Jens Carstensen has, Dr. Carstensen is an emeritus at the University of Wisconsin's pharmacy school, who wrote what is considered the main text on expiration, he says. "I did a study of different aspirins, and after five years, Bayer was still excellent. Aspirin, if made correctly, is very stable."

Only one report known to the medical community linked an old drug to human toxicity. A 1981 Journal of the American Medical Association article said degraded tetracycline caused kidney damage. Even this study, though, has been challenged by other scientists. Mr. Flaherty says the Shelf Life program encountered no toxicity with tetracycline and typically found batches effective for more than two years beyond their expiration dates.

**Plea From the Air Force**  
 The program dates to a U.S. effort begun in 1981 to increase military readiness by buying large quantities of drugs and medical devices for the armed forces. Four years later, more than \$1 billion of supplies had been stockpiled. The General Accounting Office audited Air Force troop hospitals in Europe and found many supplies at or near expiration. It warned that by the year 1990, more than \$100 million would have to be spent yearly on replacements.

The Air Force Surgeon General's office asked the FDA if it could possibly extend the shelf life of these drugs. The FDA had the equipment for stability testing. And because it had approved the drugs' sale in the first place, it also had manufacturers' data on the testing protocols.

Testing for the Air Force began in late 1985. In the first year, 58 medicines from 127 different manufacturing lots were shipped to the FDA from overseas storage, including penicillin, lidocaine and lactated Ringers, an intravenous solution for dehydration. After testing, the FDA extended more than 80% of the expired lots, by an average of 33 months.

In 1992, according to the FDA, more than half of the expired drug batches had been retested in 1985 were still fine. Even now, at least one is still in use.

Such results came as a revelation for Army Col. George Crawford when he took over military oversight of the program in 1997. He is a pharmacist, but "nobody tells you in pharmacy school that shelf life is about marketing, turnover and profits," he says. (The drug makers don't agree that it is, however.)

**How It Works**  
 The military's base for the program is a 100,000-sq-ft barracks room in Fort Detrick, Md., a group headed by Air Force Lt. Col. Russell, who recently took over from Crawford, tracks drugs that are near expiration at defense facilities all over the U.S., selecting many for retesting. They are shipped to the FDA, which sends them to its laboratories.

The FDA's lab in Philadelphia recently tested five automatic injectors containing an antidote to chemical poisoning, which were purposely held for three months in conditions even better and more humid than the FDA requires in consumer testing of drugs. The FDA tested the drug contained in the injectors, pralidoxime chloride, by separating its ingredients and measuring the strength and quality of each, then applying a computer to newly determine whether a shelf-life extension was warranted.

The injectors' original expiration date

## 'Expired' Drugs That Are Still OK

The FDA tests batches of drugs—the armed forces' stockpiles that are near their expiration dates, and in most cases finds them still potent and gives them a new, later expiration date for military use. Here are examples:

DRUG (GENERIC NAME)	MAKER	ORIGINAL EXPIRATION DATE	EXTENDED TO	TYPE OF DRUG
Chlorophes Phosphate Tablets (Aralen)	Wyeth	Nov. '90	Dec. '99	Anti-malarial agent
Chlorpheniramine Tablets (Chlorpheniramine)	Wyeth	Jan. '95	Dec. '99	Anti-malarial agent
Chlorpheniramine Tablets (Chlorpheniramine)	Ayerst	Nov. '85	Jan. '91	Anti-malarial agent; pesticide poison antidote
Chlorpheniramine Tablets (Chlorpheniramine)	SmithKline Beecham	Dec. '96	July '00	Anti-psychotic
Chlorpheniramine Tablets (Chlorpheniramine)	EL Lilly	April '93	July '00	Anti-coagulant
Ciprofloxacin Tablets (Cipro)	Bayer	Mar. '89	Dec. '01	Antibiotic
Clozapine Tablets (Clozaril)	East-West Squibs	Mar. '95	April '00	Antibiotic
Clonidine Injections (Katonam)	Roche	June '94	Dec. '00	Muscle relaxant; tranquilizer
Clonidine Injections (Katonam)	Schering-Plough	June '94	Dec. '99	Counteractives chemical agents (also used for dilating pupils)
Sodium Chloride Injections	Abbott	Jan. '93	Nov. '98	Fluid replacement
Leucovorin Injections	Baxter	Sept. '92	Dec. '98	Fluid replacement

1. Lot part of Synthes/Schering SA. 2. Now part of the Wyeth/Ayerst unit of American Home Products. Source: FDA and Defense Department

made by Ayerst Laboratories, now part of American Home Products Corp.'s Wyeth Ayerst unit, is 18 years old. It is 15 years beyond the expiration date applied by Ayerst. The FDA found it still good.

A spokesman for Wyeth-Ayerst says it "uses scientific data to establish expiration dates" and "tries to have the longest possible dating on products that scientific data supports." The company is aware of the FDA retesting program. It says it can't comment specifically on the injectors tested by the FDA.

**A Few Fall**  
 Shelf-life extensions are "intentionally conservative," the FDA's Mr. Flaherty told military brass in a 1992 speech. He says military use of drugs is different from civilian use. The military has found that water-purification tablets and mefloquine hydrochloride, for malaria, routinely fail stability testing beyond their expiration dates, so it has removed them from the program.

Also excluded are large-volume intravenous solutions, such as saline. "We don't like to test those," says Col. Crawford. "Not because we can't, but because it would be politically sensitive if G.I. Joe was lying in bed and we had originally expired three years ago."

Mr. Flaherty has said that while he tested a handful of drug batches, he did not even make it to their expiration dates, most drugs were "surprisingly durable." In one instance, he says, drugs labeled for 100°C temperature storage had been kept for two years in a warehouse in Oman that averaged 135 degrees Fahrenheit in the daytime. Upon expiration, the drugs, which included the local anesthetic lidocaine and atropine, a nervous-system antidote also used by eye doctors to dilate pupils, "were well within the standards for potency and other quality characteristics," he says.

**Stable Molecule**  
 One medicine the FDA has endorsed for shelf-life extension is chlorpheniramine hydrochloride tablets, an antibiotic marketed by Bayer as Cipro. One batch had an expiration date of March 1989. More than 8½ years later, the FDA found the tablets stable. It then extended some of them for 18 more months and others for 24 more months.

Albert Poirier, quality-assurance director for Bayer's pharmaceutical division, says he isn't surprised because Cipro "is a stable drug molecule" in tablet form. "We go for a shelf life that will be safest for patients," he says. "We want the drug to be used up within three years. We wouldn't want a patient to have it for 10 years because they're taking the drug in a package that might omit new information or contraindications and because 'we have no control over how they'd store the drug during this time.'"

Another extended drug is Thorazine, a tranquilizer chemically known as chlorpromazine tablets. Batches bearing December 1996 expiration dates were tested and approved, as is the case with all drugs evaluated in the Shelf Life program—were tested in July 1998 and extended for two years. A spokesman for the Baker, SmithKline Beecham PLC, says it applies an expiration date 24 months after manufacture. "We think that is the appropriate expiration date," he says. "We don't benefit from short expiration dates."

Some other drugs the FDA has extended at least two years beyond their expiration dates are diazepam, sold as Valium; cimetidine, sold as Tagamet; phenytoin, sold as Dilantin; and the antibiotics tetracycline and penicillin.

**Big Savings**  
 On a cost-benefit basis, the program's returns have been huge. The first year, the Air Force saved the FDA \$78,000 for testing and saved 59 times that sum by not needing to replace the drugs. After other services joined, the military from 1993 through 1998 spent about \$3.6 million on testing and saved \$83.4 million on drug expense, according to Lt. Col. Russell.

Says Mr. Flaherty: "We've cost the pharmaceutical companies hundreds of millions of dollars in sales of new stuff to the Department of Defense." In 1997, he says, the military saved \$1.1 billion by extending shelf lives instead of "destroying large quantities of still-useful medical products."

Mr. Flaherty says the FDA has been aware that if its methodology was flawed, or its results incorrect even once, its credibility would be attacked. Yet FDA officials

have liked what we were doing, but they weren't able to challenge it," he says.

While the military is finding it can keep most drugs longer, civilians hear quite a different message. For instance, a campaign called the National Expired and Unused Medication Drive has collected and destroyed 36 tons of drugs since 1991, says its founder, Kathleen Champlin. Ms. Champlin, of Colorado Springs, Colo., says her interest derives from experience working with the elderly and seeing how hard it was for them to keep track of all their medications. She says she wasn't aware of any FDA program to extend drugs' shelf lives.

Her group has gained sponsorship from the some big drug retailers, including Wal-Mart Stores Inc. It sponsors the campaign to be "a good corporate citizen," says Frank Seagraves, vice president of pharmacy merchandising. "We believe that people should dispose of unused prescription medicines a year after they get them," he says, adding that Wal-Mart sometimes gives people a free bottle of vitamins if they bring in expired drugs.

**Monsanto Co.**  
 NutraSweet to Be Acquired  
 By J.V. Childs Associates  
 Monsanto Co., St. Louis, cleaning house before its planned merger with Pharmacia & Upjohn Inc., said it agreed to sell its NutraSweet business to J.V. Childs Associates LP for \$10 billion. The NutraSweet business makes the no-calorie sweetener aspartame for use in beverages and food.

J.V. Childs, a Boston investment firm which owns medium-size food and personal products companies, said the chief executive of its NutraSweet business with be Nick E. Rosa, who has been a senior vice president of Monsanto, a crop-biotechnology and pharmaceutical concern. Monsanto said it also agreed to sell its stakes in two European makers of the artificial sweetener for \$67 million to Ajinomoto Co., its Japanese partner in the ventures. The moves bring to \$2.3 billion the sum Monsanto has raised paying off assets since July to help pay down \$7 billion in debt.

# Needy Countries, Prompted by WHO, Reject Drugs Nearing Expiration Dates

By LAURIE P. COHEN

Staff Reporter of THE WALL STREET JOURNAL  
 In the U.S. military, expired drugs are routinely left on the shelf after FDA testing shows they are still safe and effective. Meanwhile, charitable groups and developing nations often reject drug-company donations of much-needed medications that are nearing their expiration dates.

The World Health Organization in 1986 urged countries to refuse free drugs that didn't have at least a year left before expiration. WHO said there had been many "inappropriate donations."

The \$5 million in drugs contributed to Armenia after a 1988 earthquake was the "wake-up call to the donor world," says Jonathan Quick, an official of WHO. Many had already expired, according to WHO. The issue grew hotter in 1997, when the New England Journal of Medicine reported that at least half of the drugs donated during the last year were unusable, in most cases because they had reached their expiration dates. The article said the effort "may have been used to dump outdated supplies" to gain fax breaks and avoid millions of dollars of disposal costs.

Reflecting the new militancy on the issue, officials in Haiti, Kenya, Egypt and Peru in 1998 refused more than two million cartons of antibiotics and pain relievers because were due to expire within a year.

The same year, the Catholic Medical Mission Board turned away \$2.4 million in drugs because some had only eight months to a year left before expiration.

Yet most drugs the Food and Drug Administration rejects for the U.S. military program safe and potent long past their expiration dates. And even Philippe Attier, a doctor who was an author of the New England Journal article, says he has used expired antibiotics in the Indonesian jungle. "We know that most expired drugs will pose no danger, so when we have no other choice, we use them," he says.

Asked why drugs with less than one year to expiration are shunned by international medical groups, Robin Gray, a WHO medical officer, says that recipients of donated drugs deserve the same protections as U.S. citizens. If expired drugs weren't potentially harmful, he reasons, the FDA wouldn't require expiration dates. He says he wasn't aware of the FDA retesting and extending of drugs for the military.

Some see a political agenda lurking in the issue. "This is an anti-pharmaceutical industry, anti-U.S.-motivated attack," contends Glenna Crooks, a former Reagan administration health-policy adviser who is a consultant to several drug companies. "Are we destroying drugs that could be used? Yes," she says.

To the suspicion that companies donate short-dated drugs to get tax deductions and save disposal costs, the companies respond that they also can get deductions for destroying drugs. But the deductions aren't as large.

Some U.S. pharmaceutical companies and aid organizations, regarding the WHO guidelines as too restrictive, banded together in 1997 to work with WHO on revising them. Their Partnership for Quality Medical Donations eventually endorsed the guidelines after WHO changed them last year to allow for occasional exceptions to its one-year rule.

The FDA's Shelf Life Extension Program for the military has been used only on drugs for a civilian relief effort. With medicine critically scarce in Russia after the Soviet system collapsed, the FDA tested expired batches of an intravenous solution for dehydration called Lactated Ringers, extending its shelf life before it was sent abroad by Project Hope.

Jack Bode, an official of the Woodlawn, Va.-based relief group, says that in the current environment, the shipping of expired drugs, even those whose dates had been extended by the FDA, "wouldn't happen."

Yet Mr. Bode, who has spent the past eight years working with refugees in Somalia, Rwanda and elsewhere, has this observation: "Has anyone been harmed by expired drugs? Maybe. But I can definitely tell you that a lot of people died because they didn't get expired drugs."

## Lucent, MetroMedia Plan Video Start-Up

By THE WALL STREET JOURNAL Staff Reporter

MURRAY HILL, N.J. — Lucent Technologies Inc. and MetroMedia Fiber Network Inc. are expected to announce today details of a start-up company that will offer speedy video services over an all-fiber network.

The new company, GeoVideo Networks Inc., New York, is a product of Lucent's internal venture-capital arm, Lucent New Ventures Group. GeoVideo aims to deliver "real-time" video over the Internet, using a high-speed fiber network at speeds of more than 10 gigabits a second. MetroMedia, a White Plains, N.Y., builder of fiber-optic telecommunications networks, will supply the fiber.

GeoVideo executives said business customers will be able to use the technology to deliver all sorts of services such as video conferencing or high-definition television programming over a "private" network. Internet-based video services have typically been slow, because the service requires huge amounts of space on the network. Setting up a "private" network would route the video signals away from the heavily trafficked Internet and significantly increase speed.

GeoVideo plans to introduce the services in about 27 markets, including New York and Los Angeles, in the coming months. Pricing has yet to be determined.

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