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# Newsweek

THE INTERNATIONAL NEWSMAGAZINE

November 5, 1990

# PILL PIRATES

**The Worldwide Epidemic  
of Counterfeit Medicine**

U.K. £1.30/Ireland (incl. tax) I£1.40



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# The Pill Pirates

**Fake pharmaceuticals are showing up in hospitals and pharmacies from Southeast Asia to Europe. The drugs look like the real thing, but they can be lethal.**

BY TOM MASLAND  
AND RUTH MARSHALL

**I**n Nigeria, 109 children died of kidney failure after ingesting an industrial solvent; hospitals had mixed it into a painkilling syrup thinking it was a pharmaceutical chemical made in the Netherlands. In Mexico, authorities confiscated 15,000 counterfeit burn remedies; many contained sawdust, coffee or dirt and caused raging skin infections. In Burma, scores of villagers may have perished after

taking spurious copies of a drug meant to combat malarial fever. In Europe, hospitals and pharmacies handed out millions of pirate doses of a cardiac medicine, some at only half the purported strength. (There were no known casualties.) In the United States last March, an Iranian-born chemist was convicted of what the sentencing judge called a "cruel and insensitive" crime: his fakes of the arthritis drug Naprosyn contained such ingredients as milk sugar and ordinary aspirin.

Over the last decade, the profits to be made in the \$150 billion pharmaceutical

market have inspired a new form of forgery: drugs that are not what they seem. The names are familiar. They include Zantac, the world's best-selling ulcer drug; Selokeen, a Swedish-made cardiac drug; Adriamicin, for leukemia; Fansidar, used against malaria. The counterfeits look like the real thing, right down to the labels, manufacturers' pamphlets and purity seals. In Africa, fakery is epidemic: pharmacists in Nigeria estimate that more than a quarter of all medicines on the market are phony or substandard. One, sold as an antibiotic, was "nothing but talcum powder."



der—perfume and all,” says Nigeria’s Health Minister Olikoye Ransome-Kuti. The cost to legitimate manufacturers is staggering—the theft of “intellectual property” worth billions of dollars. In a study published by the U.S. International Trade Commission, American manufacturers estimated that counterfeiting in the States alone was costing them \$16.2 million a year. The human cost is incalculable: “Hundreds if not thousands

of [Africans] have died,” says Susan Foster, a health economist at the London School of Hygiene and Tropical Medicine. “This is a really nasty business.” Says John Dunne, director of drug management for the World Health Organization in Geneva: “It’s mass murder.”

Who are the counterfeiters? They range from bathtub chemists in Southeast Asia to high-tech manufacturers in countries like Argentina and Greece, working with chem-

tant to acknowledge the problem. It’s “like asking someone how his wife is in bed,” as an attorney for a big U.S. drug firm put it. The companies spend millions paying their own detectives or experts like Carratu to fight the counterfeiters. But they deny that it’s even an issue. “We would not dream of saying we have a counterfeiting problem; otherwise nobody would buy our product,” says Jeffrey Foote, an attorney who recently retired from Wellcome, a British drug firm. But that may be changing. With counterfeits increasingly hitting their home markets, a few firms—notably Britain’s Glaxo and Switzerland’s Hoffmann-LaRoche—have signaled their concern by starting to work closely with the World Health Organization. “The companies are beginning to wake up to the fact that the problem won’t go away,” says Peter Lowe, head of investigations for the International Chamber of Commerce in London.

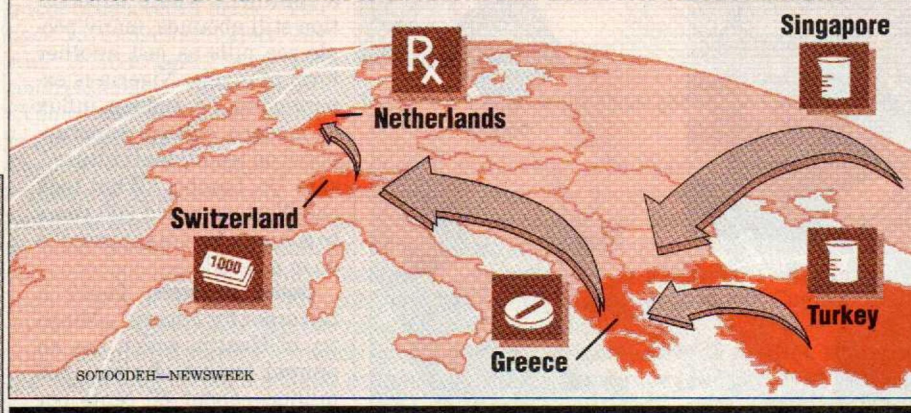
**‘Life or death’:** Drug piracy has hit the poorest nations like a plague. “If [the counterfeiters] would confine themselves to fake diarrhea pills or cough syrup, that would be one thing,” says Foster. “But it’s fake antibiotics, antivirals, insulin—and these are drugs the lack of which can mean life or death, especially for young children.” In the case of the Nigerian children, a pharmacist bottled the poison, labeled it as the product of a Dutch manufacturer and sold it to unwitting hospitals (box).

Most developing countries are ill-equipped to fight back. “Poverty—personal and national—provokes this sort of thing,” says Arturo Lomeli, director of the Mexican Association for Consumer Defense. “These governments have a hard enough time monitoring the legitimate laboratories, so how are they going to keep an eye on the underground stuff?” What enforcement there is turns up plenty of abuse. Four years after a 1984 natural-gas explosion brought tales of a new “wonder drug” for burns, Mexican authorities confiscated 15,000 products purporting to contain the burn cure, Tepezcohuite. Fake antibiotics seem to be nearly as prevalent, Lomeli said. Authorities discovered one lab in Hidalgo state that was diluting a bootleg drug with impure water, packaging it and selling it as Lincocin, an antibiotic marketed by Upjohn of Mexico. “In the end this is really not regarded as a social problem,” says Lomeli. “The penalties are generally benign.”

Part of the problem is the ready availability of cheap, look-alike drugs in more than 40 countries that permit their production. The 3,500 drugstores of Thailand are well stocked with copycat pharmaceuticals legally made by 180 local drug manufacturers and sold under Thai trademarks. Lexinol, a popular antibiotic from Switzerland, has 40 locally made competitors in Thailand. Argentine drug manufac-

## The Tale of the Trail

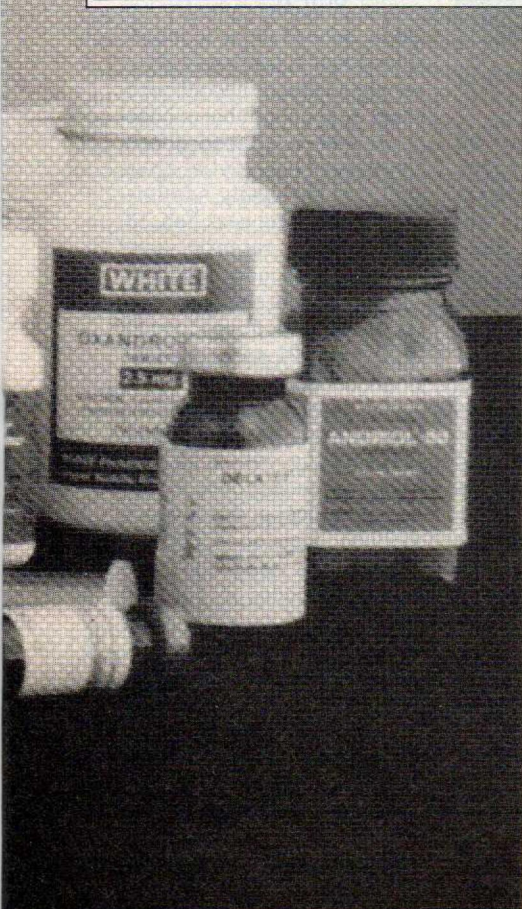
**A** recently discovered batch of counterfeit Zantac, the world’s best-selling ulcer drug, followed a typical trail: (1) The raw ingredients probably came from either Turkey or Singapore, according to Zantac’s manufacturer. (2) In Greece, a counterfeiter pressed the tablets, packaged them with fake labels and through a wholesaler (3) sold them to a Swiss pharmaceuticals brokerage. (4) The Swiss firm then sold the fake Zantac to an Amsterdam distributor called Pharmaxis.



icals freely available on the open market. Often the point of origin is a nation that does not recognize international drug patents—India, for example, or Thailand. From there a finished drug or its basic chemical components may be shipped anywhere through a series of cut-rate brokers who function as middlemen. Thai counterfeiters working from a mobile factory five years ago flooded the Burmese market with worthless copies of Hoffmann-LaRoche’s Fansidar and Wellcome’s Septrin antibiotic. Hong Kong police have intercepted at least one shipment of Thai-made fakes bound for the United States, according to a U.S. congressional investigator. “The trail for a drug found in Britain may be Brazil, Chile, Argentina, Spain, Italy,” says Paul Carratu, a partner with his father, Vincent, in a London investigative firm currently handling 60 counterfeiting cases. “We’ve had cases covering six or seven countries, and the brokers have never checked the goods. Let’s say they don’t want to know.”

Multinational drug companies are reluc-

**A new form of forgery: Counterfeit products seized by U.S. authorities**



turers often beat foreign drug companies to the market with copies of their own newly patented drugs. Bringing these countries into line is a top priority for drug industry leaders. The Bush administration is pressing the issue in the Uruguay Round of negotiations on the General Agreement on Tariffs and Trade, which is to conclude in December. "You don't see a lot of counterfeiting in well-regulated markets," says Edward Pratt Jr., chairman of Pfizer Laboratories in New York. "Where you see the most is in the Third World countries where nobody checks what's sold."

Some governments condone such copying on the ground that the locally made drugs sell for one quarter to one third the price of the brand-name product. But the multinationals say the consumers are being shortchanged. Rutgers University recently compared Pfizer Laboratories' Fel-dene, a painkiller for arthritics, with a Thai-made copy called Felcam. The red and blue capsules were identical. But only 54 percent of the Thai version was absorbed by a patient's body, compared with 97 percent in the case of the Pfizer drug. In another study, 14 knockoffs of the lead-

ing SmithKline Beecham ulcer drug Tagamet were tested. Thirteen were under-strength, ranging from 5 to 80 percent of the stated potency. The 14th was twice as potent. A heart patient in Thailand died recently because the copycat pill he took was so dense that it went through his body without being absorbed.

**'A little bit of medicine':** Under extreme international pressure, the Thai government has promised to submit new patent legislation to Parliament—in 1992. "It's better for people to have a little bit of medicine than no medicine at all," Thailand's chief regu-

## Nigeria: Case of the Killer 'Aspirin'

The Nigerian children suffered from curable ailments like coughs, diarrhea and fever. A traditional African healer might have prescribed a concoction of ground roots and herbs, and perhaps some incantations or an animal sacrifice to appease the gods. But the parents of these children believed in modern medicine and their doctors recommended paracetamol, a drug similar to aspirin. The advice was fine, but the "medicine" was not. In several hospitals in at least two states, the paracetamol had been prepared with an industrial solvent. Four patients are known to have recovered. At least 109 children, age 6 months to 6 years, died of kidney failure.

That incident, uncovered in September, may be the most horrific story yet of pharmaceutical fakery in Nigeria. But the deaths are not surprising in a country where pharmacists estimate that more than a quarter of all medicines are fake or substandard. Bad medicines are "so prevalent that one of the first things you think of when a patient doesn't respond to treatment is that it's a fake drug," says Dr. Thomas Adeoye Lambo, a Nigerian who formerly served as the deputy director-general of the World Health Organization. Some of the fakes are physically harmless. A producer of one antimalarial drug may sell it in the package of



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**A quarter of Nigeria's drugs are fake or substandard: Chemist shop**

a more popular competitor. Other drugs contain some of the active ingredient but not enough. And some capsules contain nothing but talcum powder or starch. Nigerian children with malaria have reportedly died after taking "medicine" that contained no antimalarial agent.

**Unmarked container:** In the case of the paracetamol poisoning, a Nigerian pharmaceutical dealer bought what was supposed to be propylene glycol—a substance used to dissolve paracetamol into syrup—from another Nigerian agent. It came in an unmarked drum; the dealer tasted a drop, rubbed a little on his wrist and declared it was "glycol." He then bottled the substance, slapped forged la-

bels of a Dutch company on the containers and sold them, police charged. But instead of propylene glycol, the jars contained its fatal cousin diethylene glycol. The dealer and two employees were arrested, but too late for the children.

Some substandard medicines are imported to Nigeria, where the country's long borders are checked by customs officers and policemen who can easily double their wages (\$150-\$250 a month) with a single bribe. Nigeria has only about 6,000 pharmacists to serve its 110 million people, so unlicensed shops and street hawkers fill the void. Fake drugs, often sold at far lower cost than the real thing, are easy to sell in a country where the 1989 per capita income

was \$270. Pharmacists sell drugs without prescription and illiterate vendors sometimes give advice—and even injections—to sick clients. On a continent where superstition still abounds, many people see pills as just another form of magic. Nigeria is experiencing "a sudden influx of modern culture superimposed on traditional culture," says Dr. Lambo. "What took the Western world 200 years to achieve, we are supposed to do in a decade."

**Limited resources:** That's a tall order for Nigeria's Ministry of Health, which has an annual budget of about \$66 million—about 60 cents per capita. Still, the ministry has taken several steps to combat fake drugs. A confusing array of more than a thousand medicines is now available in Nigeria, but officials have drafted a list of just 410 essential drugs that can be legally administered beginning next Feb. 13. The ministry recently spent \$2 million on new drug-testing equipment and has created special task forces in each of Nigeria's 21 states to arrest producers and dealers of counterfeit drugs. "Closing down the illegal outlets selling drugs is the only solution," says pharmacist Dere Awosika. "A radical problem needs surgical excision." Yet the federal task force in Lagos has no vehicles of its own and many of its state offices don't have telephones. Without more support, the ministry's attempt at surgery is probably doomed to fail.

JEFFREY BARTHOLET in Lagos

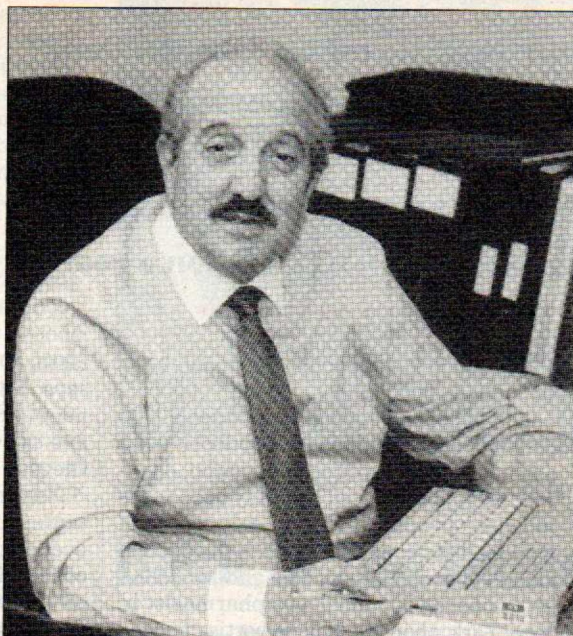
lator told one U.S. visitor. Thai health officials declined to comment.

Systems like Thailand's give piracy a legal starting point. But Europe and the United States offer counterfeiters the biggest potential profits. Patent protection in the industrial countries allows drug manufacturers to set their own prices, reflecting development costs. The big firms can easily spend \$125 million before bringing a new product to market, to which they add marketing expenses and their own profit. The result can be a gap of almost 2,000 percent between the cost to a counterfeiter of making a pill and the legitimate drug's retail price. "You have to understand that this stuff is like gold," says the congressional investigator. "You're talking about name-brand products under patent. They're sold for ridiculous markups."

Cases of counterfeiting are becoming more common throughout Europe—or are at least getting more publicity. In the Netherlands, officials recently discovered counterfeits of Seloken, Adriamicin and Zantac. In the Dutch Zantac case, the Amsterdam distributor Pharmaxis bought the bogus pills through a Swiss drug-brokerage firm called Rodion, which said it bought the Zantac from a reputable Greek wholesaler. But the pills, it turned out, were pressed by a Greek counterfeiter, who had bought the raw materials from Turkey or Singapore. Chemically, the fakes were almost perfect.

**Odd-looking tablets:** The counterfeit Seloken followed a similar route, according to the Swedish manufacturer, Astra. It found the fake while surveying its products in the Dutch market; an Astra chemist noticed that the trademark imprint on some tablets looked odd. It turned out that some of the pills were only half strength. Again, Pharmaxis had bought the pills from Rodion, which bought them from a factory near Milan. Dutch authorities are investigating the deal. The counterfeit involved millions of tablets that must have been sold in other countries, says Tony Dockheer, head of Astra's Dutch operation. "We have been drawn into bad situations beyond our control," Rodion director Mikhail Segui told NEWSWEEK. He denied any wrongdoing.

In France, a judge is investigating allegations that a French firm counterfeited the leukemia drug Adriamicin and



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ROBERT BURROUGHS

**Trying to track down the illegal goods: Investigators Carratu (left), Halpern**

marketed it in France, Belgium and Holland. The drug's American distributor, Baxter Health Care Corp., confirms it tipped off the French to the fake after testing a lot it was importing. Germany reports finding counterfeit Euglucon, an antidiabetic.

A consignment of Ventolin, an anti-asthma inhaler, was intercepted at London's Heathrow Airport last year. Britain's Glaxo, one of the world's largest drug manufacturers, has discovered four counterfeits of its products in the last 18 months, including Zantac and Ventolin. "In all honesty, I just cannot tell you if the next time we pick up a packet [of Zantac] from the pharmacy down the road, it will contain nothing, something potentially very serious to someone with a recurring ulcer, or if it will contain arsenic," said Michael Bailey, managing director of Glaxo Laboratories.

Italy may be the world headquarters of pill piracy. Prior to 1978, it did not recognize international drug patents. Investigators say some firms in the chemical-industry hub of Milan have kept on copying patented drugs—for export. "There's quite

definitely organized-crime involvement," said Paul Carratu. "It's a modest investment in equipment with enormous profits." Prosecution has proven difficult. Many drug companies settle cases against counterfeiters out of court—then get the court records sealed—in order to avoid publicity that would steer consumers away from their products. And among Italian officials, "there just doesn't seem to be any drive to prosecute people with fraud," says Eric Ellen, director of the International Chamber of Commerce. Carratu says 80 percent of the fake drugs his company has investigated came from Italy.

**Nothing to prosecute:** In 1987, a reporter from the Sunday Times of London posed as a pharmaceutical dealer to investigate an Italian firm which he said specialized in "producing copies of well-known drugs for Third World countries." The Sunday Times tested one drug and found it contained only half the stated amount of the active ingredient. But Italian officials say they investigated the firm and found nothing to prosecute. The tablets were being exported in bulk and packaged abroad, so the importer was responsible if the tablets were mislabeled, says Romano Capasso of the Italian Ministry of Health's pharmaceutical division.

Most counterfeits reaching the United States have been distributed by discounters. Between 1981 and 1984, more than a million counterfeit Ovulen-21 birth-control pills made in Barcelona and Guatemala were brought into Miami from Panama. They moved

**In Africa, deadly mixtures sold as remedies have cost 'hundreds, if not thousands' of lives, says British health economist Susan Foster. This is a really nasty business.'**

quickly. Within a week, one batch of pills sold to a Miami wholesaler at \$1.50 per 28-pill cycle was resold four times, finally reaching drugstores in Chicago at \$11.50. Some of the pills were understrength, others were worthless. Seven people were convicted or pleaded guilty. U.S. authorities say they don't know how many women may have become pregnant as a result of the scam.

The U.S. Congress addressed the problem in 1988 when it passed a tough new law that shut down a \$500 million "gray market" in prescription drugs. The law outlaws the reimportation of drugs sold overseas. (The Ovulen-21 had entered the country as returned goods.) It also prohibits resale of samples and drugs donated to charity or sold to hospitals. And the law requires brokers to keep extensive documentation of their dealings; faking any component of a drug or its packaging is deemed counterfeiting.

The reform was also a response to two recent U.S. enforcement cases in which drug shipments were illegally diverted—becoming counterfeits under U.S. law. In 1986, a liquid antibiotic called Pipril, destined for Latin America, was relabeled as Pipracil—the same product—and 50,000 vials were distributed to hospitals throughout the United States; the FDA recovered 17,000. The same year, a prescription antibiotic called Ceclor, bound from Britain to Malaysia, was apparently relabeled and diverted to America. Yet the problem of counterfeiting persists, thanks in large part to the emergence of a \$100 million

## Legitimate drug makers lose billions of dollars a year to counterfeiters. In the United States alone, says one study, the illegal trade costs manufacturers \$16.2 million a year.

black market in counterfeit anabolic steroids.

The most dramatic U.S. counterfeiting case involved a mainstream arthritis drug and a fast-talking young pharmacist. Javid Naghdi was sentenced last May to 14 years in prison in what the judge called "one of the most callous, cruel and insensitive crimes I have ever seen." Naghdi, an Iranian immigrant, trained as a pharmacist in New York, then used his expertise to copy Syntex Laboratories Inc.'s popular Naprosyn. The packaging was perfect—right down to the bar code that pharmacists scan electronically to verify a drug's authenticity. The orange tablets contained only milk sugar, dye, acetaminophen—the generic equivalent of Tylenol—and cheap aspirin. The fakes were potentially fatal to those with aspirin allergies.

**Compliant printers:** While working as a pharmacist's assistant in Los Angeles, Naghdi conned two local wholesalers by saying he had overstock Naprosyn from a big family export business to sell at a 40 percent discount. He found compliant printers for the packages and made fakes in a machine shop using readily available tab-

letting equipment. He had soon sold 1,201 bottles—500 tablets each—or more than half a million pills, and had contracted to export 700,000 more bottles before he was arrested in March, 1987. His expenses: \$21,185. The take: \$192,680. His fake Naprosyn reached Texas, Oregon, Washington state and California. The tip-off: a California druggist thought the medicine smelled odd and told the manu-

facturer so. "I think we got most of it back," says Assistant U.S. Attorney Phillip Halpern in San Diego, who prosecuted Naghdi and two accomplices. Syntex won't discuss the case.

Naghdi pleaded guilty, but on the day of sentencing he flew to London and set up an even bigger counterfeiting operation. He offered discount prices on 9 million bottles of three best-selling drugs: SmithKline Beecham's ulcer drug Tagamet, its antibiotic Anspor and Naprosyn. Naghdi contracted to sell \$579 million worth of the drugs to an Austrian distributor who planned to sell the drugs to Iran—before a U.S. Customs Service sting operation brought Naghdi down. Naghdi told an undercover agent the pills were waiting in Tampico, Mexico, but when detectives got there most of the containers had been shipped to Japan. They arrested Naghdi, but have never found the pills.

During an interview last week at the U.S. Penitentiary in Atlanta, Naghdi, 30, claimed the whole London operation was a smoke screen for arms dealings with Iran. But he admitted putting fake Naprosyn on the U.S. market. He did it because he learned that the American drug business is deeply corrupt, he said. The dealers who bought his fakes "knew it wasn't from the manufacturer," he said. "Half the drugs in this country are counterfeit," he added—a claim the industry rejects as nonsense.

**Strength and virility:** Still, it is a cautionary tale. Counterfeiting, says Halpern, is "a growing problem that people don't recognize." His 100 steroid prosecutions have revealed "counterfeit labs popping up all over the place" to serve a fringe market in drugs for virility and strength. "I've always wondered what happens if they turn their attention to the real money-makers," says Halpern. "The ease with which Naghdi was able to obtain his raw materials is frightening." Asked if there are other Naghdis still at large, he says: "Certainly there are."



Developing countries are ill equipped to fight back: French officials help inoculate African children

SYGMA

What to do? In Britain, manufacturers want mandatory batch-testing of imports and strict licensing requirements for dealers. (Carratu once surveyed 100 drug brokerage houses to see how many would sell to a firm with an impressive letterhead but no license; 20 agreed.) But the importers say testing is too expensive. Meanwhile, some manufacturers are trying partial measures. Glaxo's Dutch and British subsidiaries have begun selling Zantac with a harder-to-copy—but expensive—hologram on the packet. Counterfeiters already have copied the hologram on other products. Hoffmann-LaRoche brings out new pills in unusual shapes—oblongs or V's—to discourage counterfeiters, who usually use standard tableting equipment. Greece now requires a national "authenticity seal," but European experts say it, too, would be easy to copy.

In the United States, Congress has progressively tightened the rules for drug sales. But the fight against pill piracy remains the poor stepchild of law enforcement. Rep. John Dingell, the industry's chief congressional regulator, charged in June that a "conspiracy of incompetence" was hampering enforcement. In a bureaucratic squabble, Health and Human Services Secretary Louis Sullivan last January stripped his inspector general of authority to investigate felony violations of the Food, Drug and Cosmetics Act, which governs counterfeiting and drug diversion. An "emergency" bill offered by Dingell would have restored the investigative authority; otherwise, "the FDA will continue to be vulnerable to fraud and corruption," he said. The Dingell bill died this month.

**'Scoundrels out there':** All the same, industry associations minimize the risk to consumers. Though druggists don't routinely test what they buy, they have moved increasingly away from dealing with cut-rate wholesalers, says Leonard Demino, vice president of pharmacy for the National Association of Chain Drug Stores. "There were some scoundrels out there," he admits. "For the most part, they have been driven out of the legitimate market."

In the Third World, prospects are bleak. The World Health Organization is strengthening its reporting requirements. National regulatory agencies must certify that the source of a drug being exported is a legitimate, licensed firm. But the certificates are often faked. The WHO has warned governments about the problem and issued dockside testing manuals for customs officials that can help them determine whether a drug contains any active ingredients. Governments are concerned that "the counterfeit situation is getting completely out of hand," says the WHO's Dunne. Recognizing the problem is at least a first step.

with bureau reports



GIDEON MENDEL—MAGNUM

**Color line:** Ronnie Watson (with ball) got death threats for playing rugby with blacks

## Back in the Games Again?

### South Africa seeks re-entry into the sports world

Zane Moosa was born to an Indian father and a mixed-race mother in September 1968, just five days after Prime Minister John Vorster prohibited a visit by an English cricket club with a mixed-race South African on its roster. The ban provoked a boycott that has isolated South Africa from the sports world ever since. For most athletes of Moosa's generation, international competition once seemed a prospect almost as remote as a black government in Pretoria. But President F. W. de Klerk's reforms have got Moosa, a star midfielder for the Mamelodi Sundowns soccer club, thinking about a day when a South African eleven will compete in a future World Cup round. "We don't talk about it much, but I hope it can be soon," says Moosa. "It would be an honor for [our fans] just to see us play internationally."

Rugby officials are already talking up the prospect of the first overseas tour by the Springbok national team since 1981. Last month Anglican Archbishop Desmond Tutu voiced support for a partial removal of the boycott in sports already desegregated inside South Africa. And this week South Africa may take a first step toward re-entry into the Olympic community at a meeting in the Zimbabwean capital of Harare between South African sports officials and representatives of African national Olympic committees. Not since the 1960 Summer Games in Rome has South Africa appeared at an Olympiad.

A suspension of the sports boycott could slow the erosion of de Klerk's popularity among white voters. They have abandoned the ruling National Party by the thousands since the legalization of the African National Congress and release of Nelson Man-

del. But many diehard segregationists are also rabid rugby fans who long to see the Springboks take on the sport's longtime top dogs, the All-Blacks of New Zealand. For whites "sport is an almost mystical experience," says Kader Asmal, an ANC official and legal adviser to the South African Non-Racial Olympic Committee. "Taking part in a [cricket] test match or a world [championship] rugby match is much more important than the re-establishment of . . . relations with other countries."

**Obscure legacies:** South Africa's isolation will not end without approval from the ANC and sports organizations sympathetic to it. ANC officials have conditioned consent on several factors, from proof that political change is "irreversible" to the creation of multiracial governing bodies in each sport. Among apartheid's more obscure legacies is the existence of rival white and nonwhite bodies in rugby, cricket, tennis, basketball, boxing and track and field. "There is change," says Moss Mashishi of the National Olympics and Sports Congress, "but it has not been sufficient."

As the most popular team sport among blacks, soccer could be the first to benefit from a selective rollback, perhaps even in time for elimination matches that will decide which African teams journey to the United States for the 1994 World Cup. As for the Olympics, most officials do not expect to see South Africa take part until the 1996 Summer Games in Atlanta. "It's better to wait and not expect anything," says Zane Moosa. "But . . . you want to play at the highest level and see how you fare." Nelson Mandela, once an accomplished boxer, would readily understand that.

JOSEPH CONTRERAS in Johannesburg