

Many new drugs have strong dose of media hype

Full story: <http://seattletimes.nwsourc.com/html/health/sick4.html>

By Duff Wilson ·
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The full-page ad in Parade magazine showed a woman in a short skirt and high heels under a headline, "KILLER LEGS."

"Even young, healthy legs could hide a killer blood clot.... If the blood clot breaks loose and travels to the lung, it can be fatal," the ad said.

"Deep Vein Thrombosis -- a silent killer."

It was powerful marketing, tapping primal fears of death and disease, targeting the healthy for life-long use of blood thinners.

Variations of this warning were brought to newspaper and magazine readers, TV viewers and doctors across the world by Aventis Pharmaceuticals, maker of the blood thinner Lovenox.

When he saw the ad, Dr. H. Gilbert Welch, of Thetford, Vt., was deeply troubled -- not about getting clots, but about Aventis' scare tactics.

"From the ad, you might conclude that the disease affects women in their 30s," said Welch, editor of Effective Clinical Practice magazine. "In fact, it's a disease of people over 60" recovering from surgery, injury or immobilizing illness.

Such misleading marketing is a prime tool to expand the market for the medicines of drug giants such as Aventis.

To push its blood-clot drug, Aventis targeted a larger and far healthier population than elderly recovering from surgery: people who fly long distances.

"Deep vein thrombosis has become a hazard of air travel -- especially for those seated in the coach cabin, where there is minimal leg room; it has been nicknamed 'Economy Class' syndrome," Aventis' Web site said.

No matter that over the past decade, by best accounts, only four or five people on average, out of the 600 million annual passengers, have been shown to have died from blood clots caused by air travel.

Aventis has warned of "economy-class syndrome" on billboards at airports. It funded the Coalition to Prevent Deep Vein Thrombosis. It helped plant favorable stories in the media. And it enlisted the world's leading health agency, the World Health Organization, in its marketing efforts.

In March 2001, the WHO, which built its reputation battling disease in underserved areas, invited leading cardiologists and researchers to a two-day, closed-door conference on economy-class syndrome at its headquarters in Geneva. Aventis helped pay expenses.

Afterward, the WHO, which has a small cardiology staff, agreed to lead a four-year, \$11 million study of the risks of blood clots for 200,000 frequent fliers, paid in part by Aventis.

Fears about economy-class syndrome went mainstream when in the summer of 2001 Time magazine published a six-page article, "Perils of Passage: Coffee, tea or deep vein thrombosis?"

The article quoted unnamed doctors who suggested people with a predisposition to thrombosis should consider getting injected with a clot-busting drug before flying.

Despite the drug-company funding, the WHO, to its credit, eventually concluded there was "no evidence of a link between DVT and air travel itself, beyond a risk associated with any long period of immobility, often in turn associated with pre-existing medical conditions."

In other words, healthy people don't need to worry.

Dr. Shanthi Mendis, head of WHO cardiovascular programs, said economy-class syndrome, if it exists at all, "is a rich person's disease. Poor people don't fly."

By then, Lovenox, Aventis' No. 2-selling drug, was on its way, hitting \$1.88 billion in worldwide sales in 2003.

But Aventis didn't stop at the WHO. In February 2003, the company provided a \$100,000 "educational grant" to sponsor a conference on DVT for the federal Centers for Disease Control and Prevention and the nonprofit American Public Health Association, a 50,000-member group of public-health officials.

The association's executive director, Dr. George Benjamin, in a press release from Aventis, echoed the company's broad alarms about DVT. He said the disease was "an under-estimated, under-diagnosed and under-treated public health threat."

Despite lacking proof from scientific trials such as the WHO's frequent-flier study, conference leaders specifically listed long-distance travel as a risk factor for DVT.

Benjamin said Aventis played a proper role in the conference, identifying experts to give presentations and preparing a white-paper report that emphasized prevention.

Since the conference "didn't make an individual product endorsement, it was fine," he said of Aventis' involvement.

A month later, Aventis rolled out its "Killer Legs" campaign for doctors and patients, mailing out booklets that claimed, "Recent studies have shown that there are certain medications that can be taken prior to [long air or car] travel to prevent DVT."

Drug advertising takes off

Loosening of restrictions fuels surge in ads targeting consumers directly.

Aventis isn't alone in using fear to expand the market for its drugs. Starting in 1997, the FDA loosened restrictions on drug advertising, allowing the pharmaceutical industry more freedom to market its drugs directly on television and radio to potential patients.

In 2003, drug makers spent \$3.2 billion on direct-to-consumer ads, up threefold from 1997. Over that time, drug sales grew 10 percent a year to \$400 billion worldwide.

The United States and New Zealand are the only industrialized countries that allow drug makers to pitch their name-brand drugs directly to consumers.

In Europe, drug makers cannot name their products, but they use "silent killer" tactics to promote fear of certain conditions.

Television ads in France showed a couple celebrating a birthday, until the husband collapsed. "You may think you're healthy, but too much cholesterol in your blood can cause a heart attack," the ads said.

The ads were sponsored by Pfizer, maker of Lipitor, which cuts cholesterol.

Pfizer ran ads in Canada that displayed two corpses in a morgue, identified by toe tags. The tags indicated that neither person was overweight, both had died of heart attacks, and one was a woman, 52, the other a man, 42.

"Which would you rather have, a cholesterol test or a final exam?" the ad asked.

The drug industry says ads inform people about the latest medications and save lives.

"Consumer advertising empowers patients to learn about diseases and medicines that treat them; helps us fight the fact that millions of Americans suffer from diseases that go undetected and untreated; and still leaves the prescribing of life-saving therapies to doctors who know their patients best," Billy Tauzin, president of the Pharmaceutical Research and Manufacturers of America, said in a statement.

Yet many experts insist otherwise.

Dr. John Kitzhaber, a former two-term governor of Oregon who chairs the Foundation for Medical Excellence in Portland, said direct-to-consumer ads have created big problems.

The ads can turn healthy patients into the worried well, he said. Doctors, feeling pressured, prescribe more medicines and people spend more on health care. Sometimes those pills have worse side effects than potential benefits, he noted.

Kitzhaber's concerns are widespread. Four out of five doctors said such ads caused problems, according to a FDA survey in 2003.

If asked by patients for a specific drug, 57 percent of U.S. physicians said they prescribed it, the FDA said. Most doctors reported feeling pressured and wanted to please their patients.

"We have a system that nobody but Big Pharma is happy with," Kitzhaber said.

The "miracle" that never was

Common-cold "cure" rode a wave of media hype before crashing.

Besides using ads, drug companies often plant favorable stories in mainstream news outlets.

Take the case of Pleconaril, the supposed cure for the common cold.

Nearly 1,000 news stories hyped the ViroPharma drug Pleconaril from 1997 to 2002. One-third of them used sensational terms such as "miracle," "wonder drug," "a medical first," or boldly predicted when it would show up on pharmacy shelves, a survey by University of Minnesota journalism professor Gary Schwitzer showed.

Pleconaril hadn't even been tested in clinical trials, let alone submitted to the FDA for approval.

The Seattle Times took part in the media parade. A front-page headline for a wire-service story said: "Kiss that cold goodbye: Apparent cure for viruses may be on sale within year."

NBC Nightly News compared the news to a moon landing. ViroPharma's stock soared to more than \$100 a share.

Far fewer stories appeared after disappointing results in clinical trials of Pleconaril (The Times ran a follow-up on page A8) and fewer still after the FDA denied approval of the drug (The Times ran a brief).

ViroPharma stock closed yesterday at under \$7 a share.

Schwitzer says journalists should avoid the use of vague, sensational terms such as cure, miracle, breakthrough, promising, dramatic and hope.

That is unlikely to happen, Neil Munro, health-care reporter for the National Journal, said at a conference. "We tend to put hope up as the first thing," he said. "It's what readers want."

Drug companies also curry favor with some journalists by sponsoring trips and prizes:

• Pfizer paid all expenses for 15 journalists to attend a four-day seminar on cancer issues in 2002 and 2003. The events were organized by the nonprofit National Press Foundation and the National Cancer Institute. A Pfizer official welcomed reporters to the opening dinner.

"They are my idea of a terrific funder," said Bob Meyers, president of the National Press Foundation.

He said Pfizer paid \$50,000 for each of two conferences but never even talked to the program director.

"Nobody but us sets the agenda," Meyers said. "Nobody has suggestibility."

• Australia's top science writing award, the \$10,000 Pfizer Eureka Prize for Health and Medical Research Journalism, was paid by Pfizer, which partly judged the entries.

• Pfizer paid for a group of Australian journalists to go to a Paris conference on erectile dysfunction. They followed up the trip with a rash of stories about impotency, Melissa Sweet reported in The Bulletin, an Australian news weekly.

"As a journalist who has covered health for more than a decade, I have taken company-sponsored trips (to Sweden and Denmark courtesy of Astra Pharmaceuticals and to Berlin with Roche) and entered health journalism awards," she wrote. "But no more. With compelling evidence to show that close ties with industry can influence doctors' behavior, there's no reason to expect journalists would be any different."

(The Seattle Times does not accept such trips or awards.)

Trudy Lieberman, an editor for Consumer Reports magazine and president of the Association of Health Care Journalists, studied health-news reporting during a year at Harvard.

Lieberman learned that TV stations ran canned video stories about a brand-name test kit for cervical-cancer screening without revealing that its manufacturer had produced the \$50,000 video.

These infomercials, disguised as news, followed a formula, Lieberman said: Patient with a medical problem has it solved by a new test or a wonderful drug.

"In reality, many of the miracles are public-relations hype planted by drug or medical technology companies," she said. "The readers and viewers were unsuspecting pawns in this whole game."

Warnings missing

News articles frequently don't list side effects, studies show.

Certainly not all stories about drugs and disease are flawed or the result of corporate marketing. Stories have alerted people to medical problems, made them see a doctor, and helped to improve lives.

But many news accounts about drugs are incomplete. A 1998 Harvard study of 207 articles on drugs for cholesterol, osteoporosis and heart disease found that fewer than half mentioned side effects. One-quarter of the articles cited studies or experts funded by drug makers without disclosing the industry connection.

A survey of 193 Canadian newspaper articles on five new drugs found that two-thirds failed to mention a single side effect, according to the study's author, Alan Cassels of the University of Victoria.

"Journalists have a duty not to raise unrealistic expectations or to participate in disguised advertising," he wrote. "Because the news is such a trusted source of health information, journalists need to inject a higher dose of 'healthy skepticism' into their reporting."

Pharmaceutical firms sometimes set up lobbying front groups, or what is known in the business as "Astroturf" -- fake grassroots.

The 2002 Sleep in America poll from the National Sleep Foundation, for instance, surveyed 1,010 people and concluded that as many as 47 million Americans were risking injury and behavior problems because they weren't sleeping enough.

"Epidemic of daytime sleepiness linked to increased feelings of anger, stress and pessimism," said the headline of the press release.

The survey findings ended up on NBC's "Today," ABC's "Good Morning America," CNN, National Public Radio, and dozens of local print and broadcast outlets.

Unreported in all of them: The National Sleep Foundation is sponsored by companies making the sleeping pills Unisom, Sonata and Ambien.

Facts in hiding

Even medical journals sometimes fail to reveal the full story.

Doctors, journalists and the public often rely on peer-reviewed medical-journal articles for reliable information about new drugs. But they may not always get a complete picture.

Dr. Drummond Rennie, a deputy editor of The Journal of the American Medical Association (JAMA), one of the most respected, said drug companies try to bury negative results from clinical trials of new drugs well before publication.

"To prevent publication of unfavorable results, companies have threatened researchers, stopped trials, and blocked publication," Rennie wrote. "The consequence is biased reporting, resulting in biased treatments."

For example, JAMA published a favorable article about the drug Celebrex, based on a clinical trial funded by its manufacturer, Pharmacia. Only later did JAMA editors learn that researchers had omitted some side effects and failed to include six months of results from the yearlong trial, concealing data that the drug was associated with causing ulcers.

By then, Pharmacia had distributed 30,000 reprints of the favorable JAMA article, claiming Celebrex was safer than ibuprofen for relief of arthritis pain.

Most medical journals rely heavily on money from drug-company ads. JAMA received \$27 million in advertising revenue in 2003, according to market research firm PERQ/HCI. Much of it came from drug companies.

Journals also make big money selling reprints of studies that drug makers like.

"Sometimes they will spend more than \$1 million on reprints of a single study, and the profit margin to the publisher is huge," wrote Richard Smith, former editor of the British Medical Journal. "These reprints are then used to market the drugs to doctors, and the journal's name on the reprint is a vital part of that sell."

Toothless watchdog

FDA rules on drug claims are far from air-tight.

The FDA has the task of making sure that drug companies do not make misleading claims in their ads, whether in medical journals or in mass-market Parade. But the regulatory agency, with part of its budget dependent on drug-company funding, has little firepower.

When the FDA reviewed drug ads between 1997 and 1999, it found that more than half were inaccurate. It asked companies to change them, and in most cases they did.

When companies refused and the FDA took them to court, the agency lost eight out of 10 court challenges on grounds of free speech.

The FDA doesn't have the authority to fine companies, either. The agency can go to court and ask a judge to fine them, but it has never done so, FDA spokeswoman Laura Alvey said last week.

The FDA cited Pfizer four times in four years for false claims about its cholesterol drug Lipitor. Pfizer's ad agency won marketing awards for the ads, nonetheless. Lipitor is now the world's top-selling prescription drug, with \$11 billion in sales last year.

The FDA requires drug makers to mention side effects and adverse reactions anytime they advertise a drug by name. But drug companies can avoid those disclosures by selling the dangers of a disease without mentioning the drug they want to sell.

Another way around side effects: Pitch the drug -- "the purple pill" -- without saying its name or what it treats.

In New Zealand, the only other country that permits companies to market brand-name drugs to consumers, health minister Annette King says she plans to halt the drug ads later this year. She made her decision after a panel of medical experts told the nation's health agency that direct-to-consumer ads are very effective -- but also very biased. The ads overpromote the benefits of new drugs, convince people that normal aging and everyday conditions are diseases, and ultimately compromise patients' safety, the panel said.

Some public-health experts here would like to see consumer drug ads halted, too.

"I'd love to put the genie back in the bottle," Kitzhaber, the former Oregon governor, said. "But I don't think there's any way to do that. They'd scream First Amendment."

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