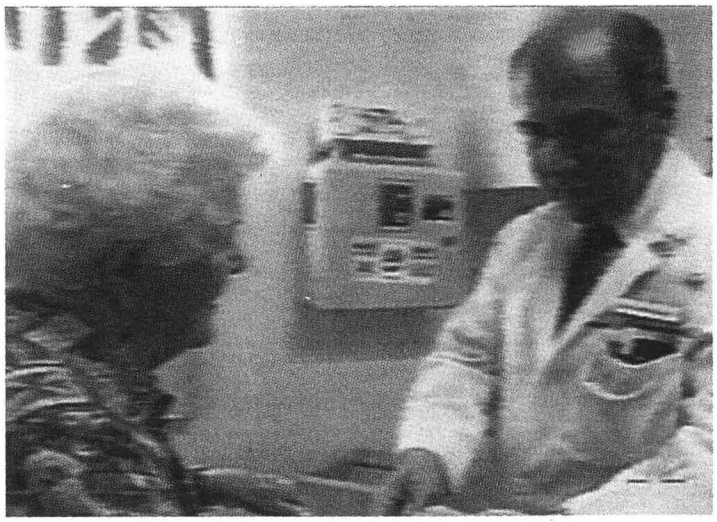
CJR upfront

MEDICAL REPORTING

NEW DRUGS: A DOSE OF REALITY

The Press Too Often Plays Up the Positive

Late last year NBC began trumpeting the virtues of a new "superaspirin," the drug Celebrex, which is jointly marketed by G.D. Searle and Pfizer Inc. and would soon become the fastest-selling new drug ever. On December 1, the *Nightly News* reported that a Food and Drug Administration arthritis advisory panel that reviewed the drug had recommended FDA approval. The segment featured Dr. Joseph Markenson, identified as "with the Hospital for Special Surgery in New York," saying that Celebrex, the first of a new class of pain-relief drugs, would "revolutionize the industry because it's a whole new group of drugs that are going to be safe."



NBC quoted Dr. Markenson on Celebrex without noting his link to the its maker

The next day on the *Today* show Dr. Steven Abramson, the physician who headed the advisory panel, downplayed the drug's potential side effects. "There may be some ulcers," he said, "though it's much less than the other drugs" that Celebrex was being compared with, the nonsteroidal anti-inflammatory agents (NSAIDS), such as aspirin and ibuprofen.

In January, after the FDA approved Celebrex, *Dateline NBC* brought back Markenson, saying he had closely monitored one of the patients featured on the show through the drug trials. While *Dateline* noted that the FDA "has insisted" on a warning label, it then featured Markenson giving a reassuring message.

Finally in February, *Nightly News* revisited Celebrex, with Tom Brokaw declaring that in clinical trials Celebrex "has proved to be very effective at treating the pain without any side effects."

NBC's stories were fairly typical of the reporting on Celebrex: the press tended to highlight the positive findings, often failed to report that there were unknowns, and slid past potential negatives. And sometimes, it did not disclose that its sources had financial ties to the drug company. For example, NBC failed to report that Markenson had helped test the drug as a clinical investigator for Searle. A Searle spokesman conceded that it is "standard industry practice to compensate physicians for time spent," but would not say how much. Markenson said money went to the hospital. "The contract was between me, Searle, and the hospital," he said. "The money pays for the time involved, nurses, physicians, special equipment needed. It's not all profit to the university or the investigator, but there is some profit or nobody would be doing it."

Journalists could have asked harder questions about the long-term effects of Celebrex. For example, a University of Pennsylvania study published in January in the *Proceedings of the National Academy of Sciences* discussed a possible risk of blood clotting, which can result in heart attacks and strokes. The study, which recommended larger clinical trials, was funded by Searle, though not mentioned in company press releases about Celebrex. (Searle says the study reached "highly speculative conclusions," though Dr. G. A. FitzGerald, its senior author, says it raised "a flag that people hadn't thought about before.") NBC did briefly mention potential cardiovascular risks on its January show, but not on its February show. A Nexis search turns up only scattered mentions of the study, most of them on local TV.

The Wall Street Journal did some digging of its own. Using the results of a Freedom of Information Act request, the *Journal* reported April 20 that Celebrex had been linked to ten deaths and eleven cases of gastrointestinal hemorrhages during its first three months on the market. (The FDA responded that the product did not pose "some special risk" at this time. Searle said the drug was "performing as expected.")

NBC

Still, there were red flags on Celebrex that might have led to more balanced stories about it. For example:

■ The FDA approved the drug only for rheumatoid arthritis and osteoarthritis, not for acute pain, as the drugmakers had also wanted because, according to the FDA, there wasn't enough evidence to show it was effective for that use.

■ Despite the company's wish to avoid a warning label, the FDA required essentially the same label it requires for all NSAID products, noting the potential for gastrointestinal bleeding.

■ When the FDA approved the drug, it noted that "additional studies in many thousands of patients would be needed to see whether Celebrex actually causes fewer serious gastrointestinal complications than other NSAID products."

As Scott-Levin, a consulting firm, points out in its publication, *Pharmaceutical Quarterly*, Celebrex got a "lukewarm FDA endorsement." Yet with some help from the press, its sales have surpassed even Viagra, bringing in some $600 million in its first six months.

The press often does a poor job of reporting on new drugs. The results of a study conducted at Harvard Medical School — and funded by The Commonwealth Fund and the Harvard Pilgrim Health Care Foundation — suggest that the media coverage of Celebrex was hardly unusual.

The Harvard findings, which have been presented at two public conferences, looked at media coverage of Fosamex, a bone-building drug; pravastatin, a cholesterol-lowering agent; and the use of aspirin for preventing cardiovascular disease.

In a sample of 207 television and newspaper stories about new drugs aired or published between 1994 and 1998, the Harvard scientists found that 53 percent of them did not mention potential risks and side effects. And 61 percent of the stories that quoted an expert clinician or study with a financial tie to the drug companies, failed to reveal that link.

The study pointed out another serious deficiency in the coverage — how benefits of the drugs are often framed in the press. For example, the researchers found that when Fosamex was coming onto the market in 1996, all three network evening news programs reported that women who took the drug had 50 percent fewer hip fractures, or that the drug cut the risk of fractures by about half — a figure that indicates what is called relative risk.

Relative risk, while accurate, gives only a partial picture. It measures the risk of the adverse outcome in those who receive treatment divided by the risk in the control group. For example, in one trial of Fosamex, 2 percent of the women who took a placebo experienced hip fractures, while 1 percent in the group who took the drug did not. In relative terms, this is a 50 percent reduction.

But in terms of absolute risk — the risk of the adverse outcome in the control group *minus* the risk in the treatment group — the difference is only a 1 percentage point reduction. That sounds far less dramatic, and is not likely to appear in company press releases. But it may be more useful to a woman who is weighing the potential risks and long-term effects. "There are many circumstances in which relative risk doesn't convey the full picture," says Dr. Mark Chassin, chairman of the department of health policy at Mt. Sinai School of Medicine in New York.

The Harvard researchers found that of the 124 stories that quantified benefits, 83 percent used the more dramatic relative framing, and 3 percent used absolute framing. Only 14 percent presented both, which would give a reader or viewer the most tools to make a judgment.

"The distortion of numbers is our biggest bane for both physicians and patients," says Dr. Robert Rangno, associate professor of pharmacology and therapeutics at the University of British Columbia. Rangno tries to help physicians interpret the drugs properly, and his ideas also apply to journalists:

■ If the long-term consequences of taking the drug are not known, say so. Look at the FDA review documents, which are sometimes on the FDA's Web site.

■ Pay attention to warnings in FDA news releases and to *The Medical Letter On Drugs and Therapeutics*, a well-respected newsletter. On Celebrex, the *Letter* said short-term studies showed it caused fewer ulcers than older drugs, but cautioned that "whether serious gastrointestinal bleeding will occur less frequently with celecoxib [Celebrex] remains to be established."

■ Realistically interpret the benefits and risks, and don't rely solely on relative framing.

■ Ask the drug companies about financial ties to expert clinicians who are made available to discuss a new drug.

—Trudy Lieberman

Lieberman is health policy editor for Consumer Reports *and contributing editor to* CJR.