



How the media left the evidence out in the cold

Quest for cures in news coverage of drug trial was “a disservice to the public”

It is understandable that US newspapers and television stations would be interested in a story about a new drug for the common cold. Americans have one billion cold infections each year, losing millions of days of work or school (www.niaid.nih.gov/factsheets/cold.htm). What is difficult to understand is why and how so many journalists became cheerleaders for an investigational drug that, in the end, failed to pass the test of clinical trials.

The drug, pleconaril, was in clinical trials from 1997 to 2002. ViroPharma Inc, the drug manufacturer, submitted data to the Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee in March 2002, requesting approval to market the drug for common colds in adults.

The evidence showed that those who took pleconaril reduced the span of cold symptoms by about a day compared with those who took a placebo. (Non-whites had no statistically significant reduction in days of symptoms after taking pleconaril.) The drug appeared to be better than placebo only if taken in the first 24 hours of a cold—something committee members felt was unrealistic. More than 3% of women taking pleconaril and oral contraceptives experienced menstrual disorders, and two women also became pregnant while taking pleconaril and oral contraceptives (www.fda.gov/ohrms/dockets/ac/02/briefing/3847b1_02_FDA.pdf).

The FDA advisory committee unanimously recommended rejecting the manufacturer's application. The company announced that it was ending trials five months later. The FDA action came as no surprise to anyone with even a rudimentary knowledge of clinical trials. But the story must have shocked many journalists who had predicted imminent approval and availability to their readers and listeners. Evidence—and completing the trials—didn't seem to matter in many news stories.

It fell far short of what any rational person would call a cure. Yet hundreds of journalists called pleconaril just that—and more—in hundreds of news stories before the drug was ever submitted to the FDA for approval.

A review of four databases (Lexis-Nexis, Factiva.com, PR Newswire, and Vanderbilt University Television News Archives) showed that from 1997 to 2002 there were 982 stories on pleconaril in US newspapers and television newscasts. About a third of the stories

used sensational terms in describing pleconaril or made bold predictions about how and when the drug would be approved by the FDA and on the market. Journalists used an array of superlative terms for the drug—cure, miracle, wonder drug, super drug, a medical first. It was described as “good news for physicians and their patients,” “potentially huge,” and as a treatment that “may drastically help relieve your misery.” It was compared with the search for the Holy Grail and with man's landing on the moon. Regarding side effects, most stories included throwaway lines advising that the drug appeared to cause few side effects, none serious. Eight times more stories were reported during the giddy promise of the clinical trials than after the FDA vote.

In January 2000 the Associated Press wire service ran a story that was the impetus for at least two dozen stories across the country. The story quoted one ViroPharma-funded investigator saying, “This IS the cure for the common cold.” The next line of the story was, “Some might quibble over that word.” But the story—“cure” quote and all—was published by at least 25 US newspapers. Newspapers in Seattle, St Louis, Chicago, Orlando, Portland, Cincinnati, and

Philadelphia printed bold headlines calling pleconaril a wonder drug, an apparent cure that might be on sale within a year, and one that sent ViroPharma's stock soaring. The AP story is still available on the ABC News.com website more than two years later under the headline “The Miracle Virus Cure” (www.abcnews.go.com/sections/living/DailyNews/viruscure_000116.html).

The night after the AP wire report, NBC Nightly News broadcast a pleconaril report. Anchorman Tom Brokaw, with a graphic reading “Magic Bullet” over his shoulder, said the drug, “could eventually be a giant leap for mankind.” The next day then-ABC anchorman Aaron Brown said, “A cure for the common cold and a whole lot more could be coming ... The drug is called pleconaril and could be available within a year.” Fifty-two local television stations followed with stories.

In December 2001 CNN Headline News ran 23 stories on pleconaril in 24 hours. That month, ABC's *Good Morning America* programme reported, “a breakthrough in the search for the cure for the common cold.”

Learning from the pleconaril story: guidelines for medical reporting

- Quantify the magnitude of the benefit. If results of clinical trials of pleconaril had been quantified clearly and consistently—namely, that this drug reduced the span of symptoms by one day compared with placebo—then it would have been evident that use of the term “cure” was inappropriate.
- Avoid naïveté about side effects. Journalists should learn from the case of pleconaril that a manufacturer is under no obligation to share all information about side effects with journalists before the company's submission to the FDA. But journalists should also be aware that some drug side effects are not discovered until after the drugs are on the market and used by many people. To report—without qualification—that a drug has few side effects when it is only in clinical trials is wrong.
- Journalists who don't understand clinical trials should not report on them. A television station or newspaper with no one on staff with specialised training in health journalism should consider leaving such reporting to others. Because of the smaller numbers of people typically involved in phase I and II trials, and because they occur earlier in the testing cycle, it may be prudent for journalists to avoid reporting on these early phases of trials.
- Journalists must think about the possible links between the sources of information (studies or experts) and those (such as the manufacturers) who promote the therapy. It is not acceptable to report a healthcare story after speaking with only one source. If that source is a company scientist or even someone whose work is funded by the manufacturer, the risk to quality journalism should be clear. Quotations from a drug maker or from investigators in a clinical trial cannot go unchallenged.
- Journalists should avoid the use of vague, ill defined, sensational terms such as cure, miracle, breakthrough, promising, dramatic, hope, and victim (www.tc.umn.edu/~schwiz/The7words.htm). These terms clouded underlying issues in stories about pleconaril.
- Journalists have an obligation to follow up on healthcare stories. Journalists who used sensational language in positive news reports concerning pleconaril failed, for the most part, to report negative news when it occurred.
- Journalists covering health/medical news must apply the same scrutiny and scepticism that they would apply in any other news story. Instead of asking, “How long will it be until this is on the market?” journalists should consider asking, “What are the potential barriers that could keep this from being on the market?”
- Editors, producers, and news directors must be responsible for the total news package. Newspaper reporters often explain that they don't write the headlines. Television reporters don't create all of the graphics, the promotional “tease” copy, or the anchor introductions that embellish their stories. But someone in a news operation has to assume responsibility for what impact these elements have on the final story that is delivered to readers and viewers. In the case of pleconaril, each of these elements helped create a sensational tone for coverage of this drug.

These guidelines are modified from principles listed in an article by freelance journalist Ray Moynihan and colleagues (*New England Journal of Medicine* 2000;342:1645-50).

Now the hype has died and another embarrassing chapter in health news coverage is buried amid other stories of Raelian cloning claims, Botox, and “the hurried woman syndrome.” But there are important lessons from this episode.

Dr Ronald B Turner of the University of Virginia once conducted some research for ViroPharma. He thinks journalists should be concerned about how they covered the pleconaril story and he called the news coverage a disservice to the public, contributing to the public’s science illiteracy.

“People can’t distinguish between valid results and charlatanism,” he told me. “This kind of story dulls the borders. It allows the public to distrust science. You pick up the paper one day and read that cholesterol causes heart attacks and you pick it up the next day and read that it doesn’t. It becomes easy for people to feel that scientists don’t know what they’re doing.”

Few journalists covering pleconaril questioned basic assumptions about the safety and effectiveness of a drug that was still in clinical trials. The trials were treated almost like mere formalities on the path to what was often portrayed as almost predictable final marketing approval.

In his book, *Science, Money and Politics* (University of Chicago Press, 2001), Daniel Greenberg wrote, “The press, on its own, if it chooses, can make the transition from cheerleaders of science to independent



Headlines hailing pleconaril as a wonder drug sent ViroPharma’s stock soaring

observers ... The journalistic trumpeting of medical cures on the basis of wisps of evidence, even though accompanied by sober cautions against optimism, deserves to be severely throttled back, in recognition of

an unfortunate reality: though news is sold around the clock, major advances in medicine come along infrequently.”

Perhaps by seeing the number of times journalists inappropriately used sensational language on this one drug story, broadcast news managers and newspaper editors will apply stricter guidelines to the coverage of drug news and all medical news (see box). Journalists who follow just a few recommendations may avert another embarrassing episode such as the coverage of pleconaril.

An Associated Press newswire story is an appropriate footnote to the pleconaril story. “A federal judge has authorized a class-action lawsuit that accuses a Pennsylvania biotechnology company of misleading investors into believing its experimental common-cold drug would be approved by the Food and Drug Administration,” AP reported on 9 April 2003. The story added, “ViroPharma’s lawyers argued that the company had no duty to predict the FDA’s decision, nor to disclose drug interaction data from its birth-control study” (www.cbsnews.com/stories/2003/04/09/health/main548595.shtml).

With cheerleading journalists predicting FDA approval and making bold drug safety statements before all the evidence was reported, journalism, too, is on trial in this case. Drug companies are now spending more than \$2bn (£1.2bn; €1.7bn) a year on direct to consumer advertising for prescription drugs. It is not the job of journalism to contribute free advertising to that total.

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