How the press helps push prescription drugs, sometimes with deadly consequences

BITTER PILL

BY TRUDY LIEBERMAN

Last December, Sepracor, a company in Marlborough, Massachusetts, whose core business is concocting slight variations of the world's best-selling drugs, got the go-ahead from the Food and Drug Administration to sell Lunesta, a new sleeping pill that could be used for months without losing its effectiveness. To prime Wall Street for the drug's potential profitability, Sepracor's chief executive officer, Timothy Barberich, told analysts that insomnia is "one of the most prevalent and growing medical needs in our society," while David Southwell, the company's chief financial officer, described insomnia to the media as "underrecognized" and "undertreated," and estimated the U.S. market for sleep aids at $3.5 billion a year and growing. Following the industry's modern marketing script (create a need, then a drug to fill it) Sepracor soon began selling Lunesta to the public — with the help of the press.

As with most launches of drugs, Sepracor and one of the academic medical centers involved in testing the drug (in this case, Duke University) offered journalists sources they could call, including those with financial links to Sepracor. And the company got results. For example, some of the nation's most respected newspapers peppered their stories with quotes from Dr. Andrew Krystal, who conducted the Duke clinical trial of Lunesta and was the lead author of the study that reported the results. Krystal had designed and conducted other studies for Sepracor, and had also served on a company advisory board. Most of the news stories did not disclose his financial ties to the drugmaker.

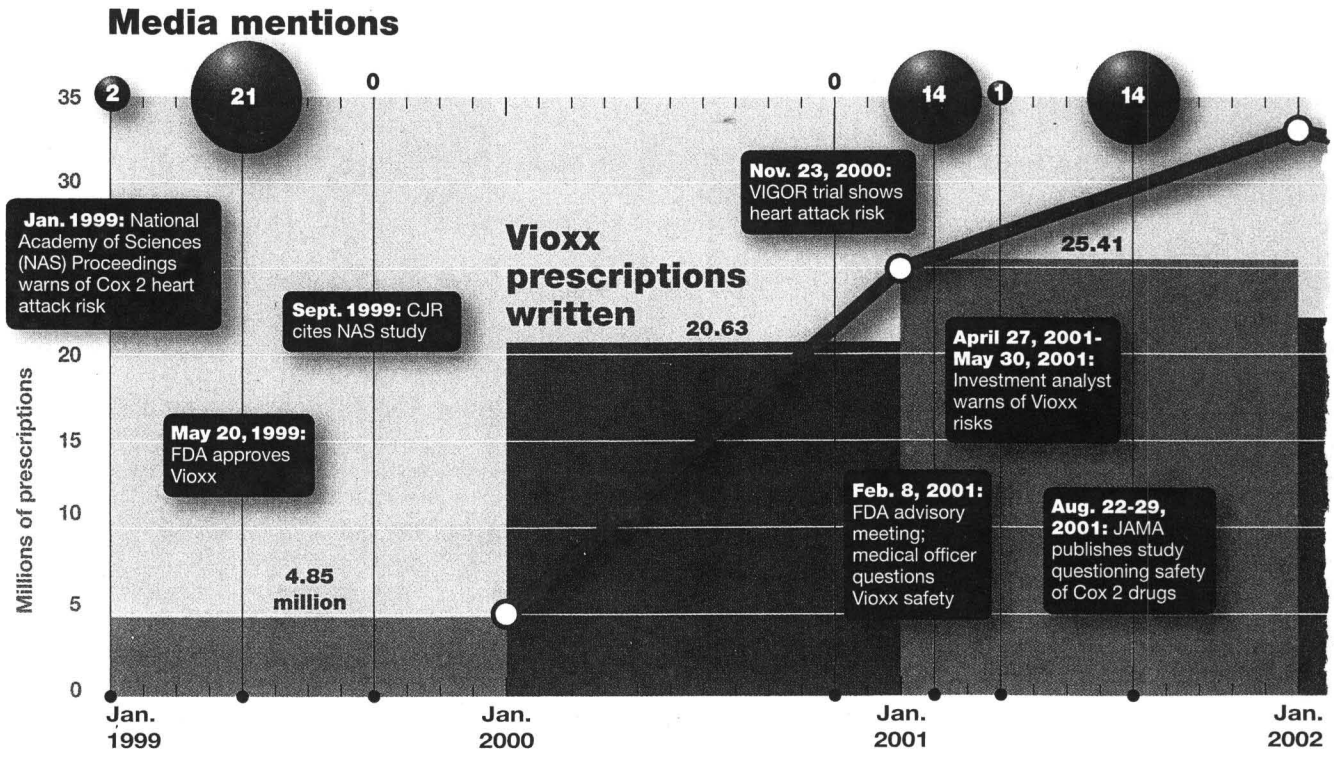
To humanize their stories about Lunesta, the *Los Angeles Times* and *The Washington Post* both featured Terri Bagley, a forty-three-year-old owner of a North Carolina cleaning business who had been paid to participate in the Duke trial, and who was offered to the press by Duke p.r. officials. Bagley told the *Times* that Lunesta could reduce "road rage" since "there'll be a lot more well-rested people out there." In the *Post* she said she was counting the days until she could get a prescription. A story headlined SLEEPLESS AT DUKE FIND CURE, appearing in the Raleigh *News & Observer*, a paper near Bagley's hometown, devoted several paragraphs to her sleeping problems.

The Washington Post, *The New York Times*, and *Good Morning America* did offer an independent opinion. Dr. Gregg Jacobs, an assistant professor of psychiatry at the Harvard Medical School, said that other treatments for sleep disorders, such as talk therapy, may work better than sleeping pills. Jacobs himself, though, was amazed at the tone of the coverage. "You would think that, the way the media covered it, it was a new miracle drug," he says. "It's not even close."

Americans have always been obsessed with all things health-related, but today a drug can move almost instantaneously from medical research to miracle cure through news media that too often seem more interested in hype and hope than in critically appraising new drugs on behalf of the public. The problem has grown dramatically in recent years as direct-to-consumer advertising has increased, delivering ever-higher ad revenues to the nation's media. Instead of standing apart from the phenomenon and earning the public's trust, the press too often is caught up in the same drug-industry marketing web that also ensnares doctors, academic researchers, even the FDA, leaving the public without a reliable watchdog.

Consider the case of the National Sleep Foundation's annual poll to promote National Sleep Aware-

VIOXX AND HEART ATTACKS: THE PRESS MISSES THE CLUES



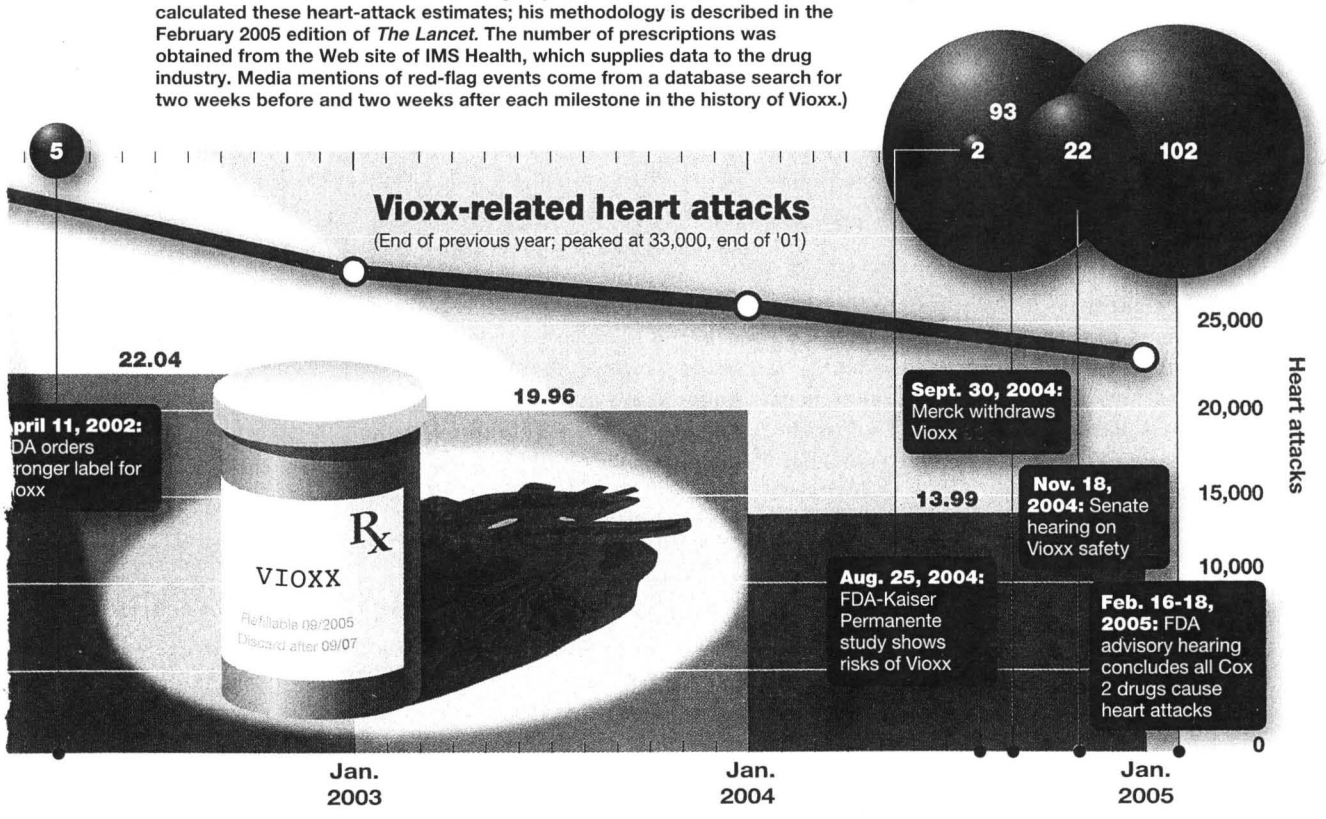
STANFORD KAY

ness Week. The poll, released in March, found that 75 percent of adult respondents said they had frequent difficulty sleeping, a problem serious enough, they said, to affect their sex lives. "It was an important story," says Richard Gelula, the foundation's chief executive officer. "The poll gets treated as news, and this year it got good news coverage" (at least twenty-four stories by CJR's count). As the poll gathered headlines, Sepracor was dispatching 1,250 sales representatives to physicians' offices to educate them about Lunesta, part of a $60 million advertising push. The foundation's mission, Gelula says, is to tell people what good sleep is, how to get it, how to recognize the signs and symptoms of sleep disorders, and to talk to their doctors if they have any of them. It is a message that dovetails with Sepracor's advertising pitch, which like all direct-to-consumer advertising instructs patients to talk to their doctor.

Virtually all the news stories about the poll failed to identify the National Sleep Foundation's ties to the drug industry. According to Gelula himself, nearly $1 million of his $3.6 million budget comes from makers of sleeping pills, including Sepracor, which gave the foundation a $300,000 grant to produce a series of "Sleep Medicine Alerts" — brochures designed to educate doctors about insomnia. Sepracor, along with other companies that make competing products, is also a $250,000 platinum sponsor of National Sleep Awareness Week. The foundation's own Web site reveals that the group is funded by drug companies, physicians, patients, medical centers, and makers of sleep aids, most of which have an interest in new drugs and treatments. But with the exception of *CBS Evening News*, the press did not disclose the financial link between the foundation and the companies that would benefit from the poll's results. "The media are victims of the same problem as doctors and patients," says Dr. Jerry Avorn, a professor of medicine at the Harvard Medical School. "Too often they get industry-sponsored sources of information that look like they are from unbiased, scientifically driven public-interest groups when in fact they are thickly veiled marketing activities."

In its public comments, Sepracor contends that Lunesta is safe because the older drugs from which it is derived have generated no safety problems. Like all drugs, though, Lunesta has side effects. For example, it apparently lingers in the body: the professional product label, written for physicians and pharmacists and not routinely seen by patients, warns users not to engage in any hazardous occupations that require complete mental alertness or motor coordination, such as driving a car or operating machinery, after taking the drug, and also to be cau-

By the time Merck pulled Vioxx from the market, up to 140,000 Americans had suffered heart attacks due to the drug, 61,000 of them fatal. Meanwhile, the press missed red-flag events that should have led to stories that warned users of the danger. (Dr. David Graham, an FDA drug safety expert, calculated these heart-attack estimates; his methodology is described in the February 2005 edition of *The Lancet*. The number of prescriptions was obtained from the Web site of IMS Health, which supplies data to the drug industry. Media mentions of red-flag events come from a database search for two weeks before and two weeks after each milestone in the history of Vioxx.)



tious of "potential impairment" in performing such activities on the day after taking the pill. Most of the press coverage did not discuss this drawback, which might make it problematic for patients to get to work the next day. Meanwhile, evidence is accumulating of problems with all sleep drugs, which reporters could have examined but did not. In a meta-analysis of all available research on sleep medicines, the *Canadian Medical Association Journal* noted that users of a drug similar to Lunesta were at increased risk of traffic accidents. The National Institute for Clinical Excellence, a British government watchdog for health spending, found no consistent difference in safety or effectiveness between the class of drugs Lunesta belongs to and older sleeping medications. What's more significant, an editorial in the *British Medical Journal* observed that no sleeping drug has yet to be shown more effective than placebos for improving the quality of life and daytime functioning, or for avoiding such outcomes as falls and fractures. Terri Bagley's testimonials that Lunesta made her feel better hardly count as medical evidence. The *British Medical Journal* editorial placed Lunesta within the overall scientific knowledge about insomnia and its treatment — vital context absent from U.S. press accounts, where the science of a new drug comes last, if at all.

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> — *Dr. Marcia Angell*

Press acquiescence to industry public relations stems in part from an American cultural belief in the inherent goodness of medicine and its corollary — that every new pill, every new treatment, works and should be treated as safe and effective unless proven otherwise. In his landmark 1982 book, *The Social Transformation of American Medicine*, Paul Starr explains how in the late nineteenth and early twentieth centuries the medical profession benefited from the cultural and social upheaval — including the embrace of science — to establish itself (and thus its money-making medicines) as the unquestioned authority on matters of health, a position it has enjoyed ever since.

Even without that cultural baggage, though, the pharmaceutical beat is a challenge. For one thing it is huge. The American pharmaceutical industry logs more than $250 billion in annual sales. Drug spending has been doubling roughly every five years; an increasing number of Americans will be taking medicines daily for the rest of their lives. And the public has a growing appetite for news about drugs. It's an industry, meanwhile, that produces many medicines that improve and extend lives, and sometimes save them, such as diuretics for high blood pressure, and drugs that mitigate the symptoms of Parkinson's disease or prevent blindness from glaucoma.

But not all the medicines these companies produce are beneficial, and some of them are dangerous. "The public is being allowed to believe that drugs are safer and more effective than they really are," says Dr. Marcia Angell, who for two decades was editor-in-chief of *The New England Journal of Medicine*. "Journalists, as well as the public and physicians, have bought hook, line, and sinker the idea that these drugs are getting better."

In reality, she says, based on research for her 2004 book, *The Truth About the Drug Companies*, of the 415 drugs approved between 1998 and 2002, only 14 percent were truly innovative, 9 percent were drugs that had been modified in some way, and 77 percent were simply "me-too" drugs, copies of medicines already on the market, created not necessarily to improve health but to fill a spot in a company's product portfolio.

The news media have tended to see drug coverage as fitting into two discrete compartments. The pharmaceutical industry is covered in the business pages and, sometimes, in the health sections. But a vast middle ground between business coverage and consumer health reporting and advice remains largely unexplored by the press — the territory of corporate marketing and sponsored scientific research that connects the bottom line to the latest "breakthrough." Reporters who want to write about this middle ground must be wary not only of the companies' sophisticated marketing techniques, but also of other competing interests that try to use reporters to pitch their journals and university medical centers, or spin their political positions about drug policy. "Everyone is in cahoots," says a woman who spent several years conducting medical-education activities for pharmaceutical companies. She asked to remain anonymous because she is currently consulting in the health-care industry. "The money spent is outrageous."

On the drug beat, the stakes are high, and sometimes they involve life and death. This is evident in an examination of the coverage of Vioxx and the other Cox 2 pain relievers, once hailed in the media as "super aspirin." In the case of Vioxx, thousands of people have died from heart attacks while taking the drug, making Vioxx the biggest drug disaster in U.S. history. In hindsight, few would argue that the public was well served by media coverage of any of the Cox

2 drugs, from the beginning when a Vioxx researcher told *The Buffalo News* it was inappropriate to provide precise statistics on side effects, to the end, last February, when reporters missed the point made by an FDA advisory committee whose thirty-two members unanimously concluded that all the Cox 2 drugs cause heart attacks. Reporters, instead, focused on a recommendation, narrowly approved by the committee, that Celebrex and Bextra remain on the market; some speculated that Vioxx might soon be back. Seven weeks later the FDA ordered Bextra off the market and issued the strongest possible "black box" warning for Celebrex, effectively curtailing further advertising for the drug.

Four years before Merck, the maker of Vioxx, pulled the drug from the market on September 30, 2004, reporters could have discovered signs of trouble by reading about the Cox 2 drugs in the medical journals. In November 2000, for instance, the *New England Journal* published results of the VIGOR (Vioxx gastrointestinal outcomes research) study, which questioned the cardiovascular safety of Vioxx. Several months later *The Journal of the American Medical Association (JAMA)* published a study that examined all the research that had been done on the Cox 2 drugs and concluded that the "available data raise a cautionary flag" about the risk of heart attacks and strokes. Dr. David Graham, the associate director of the FDA's Office of Drug Safety, who testified before the Senate Finance Committee about the FDA's failure to protect the public from unsafe drugs, calculates that from the time Vioxx came on the market until its withdrawal 61,000 people died from heart attacks associated with the drug, and another 79,000 had nonfatal heart attacks. As the timeline on pages 46 and 47 shows, the press barely paid attention. In fact, as the chart demonstrates, the media missed a number of warning flags that might have led to stories that saved lives.

Rita Rubin, who covers the pharmaceutical industry for *USA Today*, tried to sound the alarm on Vioxx in a story published in early February 2001. Her story drew on the VIGOR study cited in the *New England Journal*, which found that patients taking Vioxx had five times more heart attacks than those taking the pain reliever naproxen, sold under the brand names Aleve and Naprosyn. In Rubin's story, an official from Merck challenged the VIGOR study's findings, insisting that since naproxen, like aspirin, helps prevent heart attacks, Vioxx hadn't *caused* heart attacks but rather naproxen had *prevented* them. Graham of the FDA and other scientists later pointed out that for naproxen to have had the effect Merck was claiming, it would have to be three times more effective at preventing heart attacks than aspirin. "That was completely beyond belief," Graham says. Yet at the time almost no one in the media was questioning the numbers, let alone Merck's damage-control campaign. "Some scientists were really scared of Merck," Rubin says. "They wouldn't go on the record about their concerns."

When a pharmaceutical company prepares to market a drug, it anoints medical "thought leaders," such as department heads at major universities who have expertise about the drug and the disease it treats. They and their institutions are paid by the drug makers to test their products. More importantly, these academic thought leaders have prestige. "The most senior experts at some of the most renowned institutions have financial connections to industry," says Marcia Angell. "They are precisely the people the industry wants to buy off."

Those are the experts drug companies and their p.r. agencies steer journalists to when they need sources who can provide quick explanations of complicated scientific material. Peter Rost, a Pfizer vice president of marketing who makes it clear he is not talking on behalf of his employer, describes what journalists are up against. "Even if you are a hard-digging reporter looking for the one clinic that's objective and has not taken company money and has credibility, it's like looking for a needle in a haystack," he says. "You're likely to find a clinic that is either directly or indirectly on the company's payroll."

The New York Times's Science section has set a standard for the news media by requiring its reporters to disclose their sources' financial conflicts of interest when appropriate — in effect providing the context for readers to better understand the comments scientists make. But such rules are rare. Scientists who test the drugs tend to talk up the product's strengths to the press. "It's not that scientists lie, but if they say certain things, they get rewarded," says Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington. If these experts speak favorably about a drug to the press, they tend to get invitations to speak about the drug at conventions for doctors and at educational seminars that hospitals offer for their employees, where they get a chance to further promote their study results. All these activities help enhance careers and bring good press to the clinic or the university. "It used to be death to get your name in the paper if you were an academic," says Sherrie Kaplan, associate dean of the College of Medicine at the University of California at Irvine. "Now academics are elbowing each other to get on the *Today* show." For those who learn how to market their studies, the visibility brings the next round of grant money. The more Congress and the public hear about the study, the more potential support from the National Institutes of Health, which awarded $22 billion in grant money in 2003, the last year for which a total is available. The more other drug makers hear about a scientist's study, the

more likely they are to seek out him or her for the next clinical trial. And the more likely journalists are to use that scientist again.

If a reporter demands something more than the company line, however, the drug company p.r. machine often calls on its scientists to employ the hard sell, as CBS correspondent Sharyl Attkisson discovered when Crestor, a cholesterol-lowering agent, was making news late last year. In his congressional testimony, the FDA's Graham had said that Crestor was one of five drugs whose safety must be "looked at quite seriously." Public Citizen, a watchdog group, had petitioned the FDA to remove Crestor from the market, saying it had caused muscle breakdown leading to kidney failure in some patients. That was not the kind of publicity that AstraZeneca, the drug's maker, needed. To assuage an anxious public, it blitzed the airwaves with a catchy commercial set to the sing-song prose of Dr. Seuss. It also bought full-page ads in major newspapers, asserting that "the FDA has confidence in the safety and efficacy of Crestor," a claim the agency later said was false.

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— *Sharyl Attkisson, CBS*

CBS's Attkisson thought Crestor's troubles added up to a good story. While AstraZeneca was weighing her request for an on-camera interview, Attkisson began to receive unsolicited offers for interviews from doctors with financial ties to AstraZeneca. In one e-mail, a doctor from Rush University Medical Center in Chicago told Attkisson he had conducted numerous studies on Crestor and urged her to take him up on his offer "to ensure ALL the information about this important class of medication gets out to the public, and not just a selective interpretation of data." A second doctor, a nephrologist from the Cleveland Clinic Foundation, wrote to Attkisson that the accusations made by Public Citizen about Crestor's safety were false, saying it was "imperative" that her story "be both factual and accurate." AstraZeneca sent Attkisson examples of other press stories quoting doctors making positive statements about Crestor. Attkisson told the company she didn't need help finding independent experts. At that point, she says, AstraZeneca got pushy. "We got lobbied so hard on this story by doctors, two outside p.r. firms, AstraZeneca, and one crisis-management firm," she says. "They worked me and pushed me and contacted the executive producer and the president of the news division. But my bosses were generally supportive." Her Crestor story, when it finally aired in mid-December 2004, featured an AstraZeneca vice president but none of the doctors who had e-mailed Attkisson. Although the FDA decided to keep Crestor on the market, in March it ordered a stronger warning label for the drug stating that it may increase the risk of life-threatening muscle damage. The FDA's action generated little press coverage.

Like most regulators, the FDA has always had a somewhat cozy relationship with the companies it regulates. In the 1990s, that relationship grew closer with the passage of legislation that required drug makers to pay money to the agency to help finance the approval process. Another law lowered the bar for approval. The agency got the message: Congress wanted drugs on the market more quickly. The '90s legislation helped foster a climate at the agency in which drug companies are seen as clients, a culture that has continued to flourish. A columnist for the trade publication *Medical Marketing & Media* wrote in January that the Bush administration has made the FDA "an informal 'partner' to the industry." That partnership helps explain why some of the FDA's actions don't seem to have the public interest in mind — such as its tardiness in ordering a warning label for Vioxx; its approval of Vioxx for migraines, a new use, in March 2004, while evidence of safety problems was accumulating; or its approval of Vioxx for arthritis in children in August 2004, just weeks before Merck decided on its own to pull the drug, in September of that year.

The partnership also helps explain why some journalists, especially those who ask the tough questions, get frozen out. Agency officials have been known to play favorites with reporters, ignoring the ones who probe behind official pronouncements. After the Cox 2 debacle, Sharyl Attkisson noticed that the FDA had issued a public health advisory suggesting that patients at high risk for gastrointestinal bleeding may be appropriate candidates for drugs like Celebrex; yet in June 2002, the FDA had taken the recommendation of its advisory committee that Celebrex should continue to carry the standard warning about the risk of gastrointestinal bleeding. Attkisson wanted to understand the discrepancy between the agency's earlier conclusions about Celebrex and its latest recommendation, so she asked for an interview. An e-mail exchange over a period of seven days shows how the FDA stalled and finally refused to cooperate. A p.r. official demanded to know whom else she would be interviewing, and what the actual questions were, and then said that without this information the agency could not proceed with the interview. "The FDA is as obstructionist as the drug companies, if not more

so," Attkisson says. "That may be the biggest scandal behind these drug stories." Other reporters echo her observations. "People who don't cover the FDA may have an unrealistic idea of how open it is," says *USA Today*'s Rita Rubin. "I can tell you, it is not."

Given that the drug companies stack the deck on journalists, and that the academic community and the top government regulator can be too close to drug makers, the question becomes: how high a priority is it for the nation's news media to get the full story about pharmaceuticals? The question has loomed even larger since the drug makers realized in the late 1990s that direct-to-consumer advertising on TV and in newspapers and magazines could drive sales figures to new heights. For one week in April CJR monitored the evening newscasts of CBS, NBC, and ABC. During that week, network viewers saw an average of sixteen commercials for prescription drugs and an average of eighteen for over-the-counter medicines each night. In 1999, the five networks, including CNN and Fox News, received $569 million in advertising revenue from pharmaceutical companies, according to TNS Media Intelligence. In 2004, that number had nearly tripled, to $1.5 billion. Drug ad revenue is less for print outlets, but still nothing to dismiss. At the end of 2004, for example, drug-company ad revenue for *Time* magazine totaled $67 million; for *Newsweek* $43 million; and for *The New York Times*, $13 million. This doesn't mean that news executives consider such income when they make story assignments, but in places where the wall between the news side and the business side has weakened, the temptations are stronger than ever.

Cultural pressures within news organizations, meanwhile, also work against the nuanced and more balanced stories that the drug beat demands. Science doesn't usually fit neatly into categories of all good or all bad. It's ambiguous and changing. As the Cox 2 pain relievers show, a finding that seems conclusive one month can be dead wrong the next. Ambiguity is troubling to editors. And stories trumpeting new drugs are an easy way to get on page one or on the air, especially if the ambiguity is ignored. The coverage of an older drug called donepezil, marketed by Pfizer under the brand name Aricept, is a case in point. In April, *The New England Journal of Medicine* published a study about how Vitamin E and donepezil affected patients with mild cognitive impairment from Alzheimer's disease. The study had three conclusions: first, Vitamin E did not work; second, donepezil did not slow the progression to Alzheimer's after three years of treatment; and third, the drug was "associated" with a lower rate of progression after one year of treatment. Dr. Jeffrey Drazen, who edits the *Journal*, says the study showed that donepezil "had a little bit of an effect," but adds that "the major conclusion had to do with Vitamin E." ABC News, though, didn't see the study that way. On both *World News Tonight* and *Good Morning America*, the network focused on the shred of positive data about donepezil, making it sound like a major breakthrough. ABC's Dr. Tim Johnson, the network's physician-reporter, recommended that people who have pre-Alzheimer's disease take donepezil even though the *Journal* study on which the ABC segment was based did not support such a clear-cut recommendation.

Many of the reporters interviewed for this story complained about editors who were inclined to defer to the FDA, which makes it hard for them to write negatively about a drug that has the agency's approval, or to investigate the agency itself. "I have had editors of major papers say to me that if I cover the FDA on a daily basis, I can't investigate it at the same time," says Alicia Mundy, a Washington correspondent for *The Seattle Times* who has written about the drug industry for a variety of publications. "My answer is that they are saying that one reporter is allowed to be a shill and the rest are allowed to be reporters."

To be sure, news organizations have published some fine stories about bad drugs stories that have transcended the drug company spin and other reportorial pitfalls. Reporting in 2000 by David Willman of the *Los Angeles Times* helped push the dangerous diabetes drug Rezulin off the market, and his reporting in 2003 and 2004 sparked reforms concerning financial conflicts at the National Institutes of Health. But this sporadic good work is negated by the more frequent puff pieces about new drugs, like the one the *Los Angeles Times* Health section published in January about Lunesta. That story featured Terri Bagley's testimonials, but failed to disclose its main source's ties to Sepracor or present any independent opinion. The veteran journalist Donald Barlett has observed that there is much more investigative reporting going on today than ever before, but stories that appear once or twice a year do not reverse the damage done by the parade of daily stories that fail to give readers and viewers balanced and in-depth information about their medicines.

Late last year *USA Today* asked in a front-page headline: CAN AMERICANS TRUST THEIR MEDICINE? If there are more disasters like Vioxx, the answer may be no. And if we in the media do not press the FDA and cover its warnings, if we don't challenge the industry's persistent efforts to hide negative information about clinical trials, then we risk fostering a backlash in which the public will reject the very drugs that *do* make their lives better — in essence, the real breakthroughs. ■

Trudy Lieberman is a contributing editor to CJR. *The magazine gratefully acknowledges support for this article from the Fund for Investigative Journalism.*