

Public Citizen Thwarts Consumer Access to Promising New Drugs

Health Experts and Patient Advocates Criticize Naderite Group

By John Carlisle

Summary: Since 1971, Public Citizen has led the consumer activist movement in lobbying for government regulation to protect consumers against the alleged ravages of the marketplace. But often, Public Citizen advocates policies that undermine consumer safety.

Public Citizen has been a key organization in the “consumer rights” movement for over three decades. The organization founded by Ralph Nader and led by his longtime colleague Joan Claybrook has scored an impressive list of legislative victories: Dozens of federal laws now regulate the character of environmental protection, food safety, airline safety, drug safety, health care, auto safety and fuel efficiency. All are intended to shield Americans from the alleged ravages of the marketplace.

Public Citizen considers itself a guardian of consumer rights, but it frequently ignores consumer choices. Rather, its legislative lobbying and political advocacy have helped empower government officials to regulate the economy. Worse, its public policy positions have undermined consumer safety. For instance, Public Citizen’s successful advocacy to raise Corporate Average Fuel Efficiency (CAFÉ) standards for automobiles is estimated to have increased the death toll in auto accidents. So has its support for mandatory auto air bags. In these and other cases Public Citizen has harmed consumers in the name of protecting them.

Today, Public Citizen again directly threatens human life: It is denying quality health care to consumers by preventing



Consumer Activist Ralph Nader founded Public Citizen in 1971. Joan Claybrook has served as president of the group since 1982.

the production and distribution of promising new drugs that can alleviate ills once thought untreatable. Rather than encourage more drug development, Public Citizen routinely bombards the U.S. Food and Drug Administration (FDA) with demands for more rigorous review standards. New drugs already typically take more than a decade to win federal approval. But Public Citizen insists that it must stop over-eager government overseers from rushing through the approval of potentially dangerous drugs. Doctors and medical researchers say Public Citizen’s demands for more regulation are scientifically invalid. They fear the group will make it almost impossible to bring much-needed drugs to market.

What explains Public Citizen’s “holy war” against the pharmaceutical industry? Its spokesmen demonize the industry as callous profit-seekers. It issues studies charging companies with lying about the

high cost of research and development in order to inflate drug prices. And it uses the regulatory process to block the public’s access to drugs that treat heart ailments and other serious diseases that can ravage a patient’s quality of life. Advocacy groups for millions of individuals who suffer from life-threatening diseases and debilitating illnesses charge that Public Citizen is not doing them any favors by attacking new pharmaceuticals.

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Ralph Nader's Influence

Public Citizen is the creation of Ralph Nader, who burst onto the national scene almost forty years ago. In 1965, the 30 year-old Harvard Law School graduate attracted public notice by his searing attack on the Corvair automobile, produced by General Motors. He detailed his criticisms in a best-selling book, *Unsafe At Any Speed*.

Nader was the son of Lebanese immigrants from a small Connecticut town. At first, he seemed to be a child of his times—this was the era of student radicalism over civil rights, campus free speech and the Vietnam War. But Nader was unlike other activists; he wasn't interested in civil rights, but what he called "body rights." He was angry that government was not beating up on corporations. In the 1930s Nader might have been a militant union organizer. But in the face of falling union membership and increasing union bureaucracy and corruption, Nader sought a new constituency. He found it in "the consumer." (Despite his corporate bashing,

Nader reported in 2000 that he owned more than \$1.1 million of stock in Cisco systems.)

Nader launched his first great crusade against the auto industry and won a huge public relations victory when he forced executives at General Motors to recall the Corvair from the market. That marked the beginning of a series of successful anti-corporate campaigns. From 1966 to 1973 Congress passed 25 bills addressing consumer safety. The issues ranged from improving food safety to exposing corruption at the Federal Trade Commission. Nader played a role in most of the legislative battles.

In 1971, the heyday of government regulatory activism, Nader founded Public Citizen. He was joined by Joan Claybrook, who first teamed with him in 1966 to successfully lobby for passage of the Highway Safety Act and the National Traffic and Motor Vehicle Safety Act. These laws gave government the power to set auto safety standards and issue recalls for defective vehicles. In 1982 Claybrook became president of Public Citizen, which she still heads.

Auto safety made Public Citizen's reputation. But it also showed the group's disturbing ideological bent. Public Citizen constantly lobbied to impose stringent government regulations on corporations—even when the evidence showed that regulation could harm the individual consumer. When forced to choose between defending consumers and attacking corporations, Public Citizen picked the latter.

The auto air bag issue offers an infamous example of this mind-set. As head of the National Highway Traffic and Safety Administration during the Carter Administration, Claybrook declared that air bags were safe: "Air bags fit all different sizes and types of people and little children up to... very large males." Unfortunately, air bags have killed at least 86 children, many in low-speed accidents that they should have survived. But Public Citizen dodges responsibility by blaming the auto industry for faulty air-bag design.

Public Citizen's contribution to auto *unsafety* is also on display in its advocacy of higher Corporate Average Fuel Efficiency (CAFÉ) standards. The 1975 CAFÉ law mandates that cars have higher gas mileage. In the 1970s, it was argued that CAFÉ standards would reduce energy consumption and prevent oil shortages. Today CAFÉ is supposed to counter the unproven threat of global warming. But there is one problem when government requires higher gas mileage: it forces auto manufacturers to reduce car size and weight. They become less safe. A 2001 report by the National Academy of Sciences concludes that each year CAFÉ helps cause between 1,300 to 2,600 vehicle deaths. Amazingly, Nader and Claybrook are aware of this "tradeoff." As early as 1977, in testimony before the Senate Commerce Committee, Claybrook forthrightly accepted the sacrifice of safety that CAFÉ required. "There are going to be tradeoffs," she admitted.

On many other consumer issues Public Citizen has shown its willingness to put individuals in harm's way. Public Citizen accepts threats to life and limb as the price consumers must pay so that government can regulate business activity.

Green Party Politics in 2000

Ralph Nader left Public Citizen in 1980 but remains influential in the organization. Says Claybrook, "He has a million ideas a week." Nader has since gone on to set up another dozen or so consumer activist groups including the Public Interest Research Group and the Aviation Consumer Action Project. He is currently on the board of directors of the Center for Study of Responsive Law, another Washington, D.C.-based group that advocates consumers' rights regarding intellectual property, electronic commerce and other issues.

In 2000, Nader ran for president as the candidate of the Green Party. That candidacy greatly angered many erstwhile allies—namely, trial lawyers who blamed him for Al Gore's defeat. Said Fred Baron, then-president of the Association of Trial Lawyers of America, "I think what he did in the political arena will cost us for a decade." Several trial lawyers subsequently have

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withdrawn about \$100,000 in funding from Public Citizen and other Nader-linked groups. However, the loss is less than one percent of Public Citizen's \$12 million in recent annual revenue. Furthermore, Nader's partnership with the trial lawyers is too politically profitable for either to hold a grudge. "Most lawyers are intelligent enough to know these organizations are not dependent on Ralph politically," said Baron.

Still, trial lawyers want Public Citizen to steer clear of Green Party politics. Nader himself has not said whether he will be the Green Party candidate in 2004, but he is determined to make the party a powerful alternative to the Democrats.

Public Citizen Funding

Public Citizen is really two groups: Public Citizen, Inc., a 501(c)4 lobby group, and Public Citizen Foundation, a 501(c)3 public charity. According to their 2000 IRS Forms 990 (ending September 2001), Public Citizen, Inc. had \$3.4 million in revenue, \$3.7 million in expenses, and \$4 million in assets. Public Citizen Foundation, at the same Washington, D.C. address, had \$9.1 million in revenue, \$6.4 million in expenses, and \$9.1 million in assets.

The purpose of the Public Citizen Foundation, founded in 1982, is to support the "research and educational work of Public Citizen, Inc." Donors to Public Citizen Foundation include the Carnegie Corporation—\$25,000 (2000); Energy Foundation—\$26,700 (2000); Joyce Foundation—\$50,000 (2000); Peninsula Community Foundation—\$10,000 (2000); Rockefeller Brothers Foundation—\$100,000 (2000); Rockefeller Foundation—\$15,000 (2001); John and Florence Schumann Foundation—\$75,000 (2000); and the Surdna Foundation—\$50,000 (2001).

Through its six policy divisions Public Citizen promotes "consumer rights, open government, corporate responsibility, clean energy, fair trade, environmental protection, and workplace safety." The divisions include the pioneer program in Auto Safety as well as divisions on Critical Mass Energy and Environment, which

lately lobbies "to protect the world's fragile water resources from commodification [and] privatization," and Global Trade Watch, which "educates" the public about the inimical impact of NAFTA and other free trade agreements. Congress Watch serves as Public Citizen's government watchdog division, while the Litigation Group handles its lawsuits. The Health Research Group spearheads Public Citizen's crusade against the pharmaceutical industry and "lax" federal health policy regulators.

The PC Attack on Drug Prices

Over the past decade, Public Citizen has exploited consumer frustration over rising drug prices by accusing pharmaceutical companies of greed and profiteering. Its chief spokesman and activist on pharmaceutical issues is Sidney M. Wolfe, M.D.,

a spokesman for the Pharmaceutical Research and Manufacturers of America ("PhARMA"), says R&D typically costs \$500 million at a minimum for a new drug. That's the conclusion of a 1991 study by economist Dr. Joseph DiMasi of the Tufts Center for the Study of Drug Development.

Public Citizen argues otherwise. In July 2001, it issued a debunking report, "Rx R&D Myths: The Case Against the Drug Industry's R&D Scare Card," which claims the drug industry spends only \$110 million on new drug research and development. Public Citizen says the \$500 million estimate unfairly includes tax-deductible expenses, "downplays" the extent of taxpayer funding of research, and overstates the market risk facing prospective new drugs. It also says the Tufts study erred by

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who directs the Health Research Group, which he co-founded with Nader in 1971. Wolfe has been the focus of intense criticism by the pharmaceutical industry. But he also is under attack by physicians, academics and health care advocates. The American Medical Association, for instance, dismisses many Public Citizen undertakings as publicity stunts. Yet despite attacks on its credibility, Public Citizen can boast that Wolfe's Health Research Group is responsible for removing 13 prescription drugs from the market.

The pharmaceutical companies contend that their massive capital investment in research and development is the major component in drug pricing. Jeff Trewhitt,

focusing only on the "most expensive drugs, not all new drugs." Concludes Frank Clemente, director of Public Citizen's Congress Watch, "The drug industry is stealing from us twice. First, it claims that it needs huge profits to develop new drugs, even while drug companies get hefty taxpayer subsidies. Second, the companies gouge taxpayers while spending millions from their profits to buy access to lawmakers and defeat pro-consumer prescription drug legislation."

Independent experts refute Clemente's charges. For instance, a report by the business management and accounting firm Ernst & Young concludes that Public Citizen used selective evidence to bolster its

claims. Public Citizen claimed tax-deductible expenses lighten the burden on pharmaceutical companies. But every industry makes use of the same R&D tax deduction. In fact, pharmaceutical companies lead all industries in the taxes they pay as a percentage of their revenues. Ernst & Young endorsed the Tuft's study finding: research and development costs are at least \$500 million per drug, not \$110 million.

The National Institutes of Health (NIH) has denied Public Citizen's claim that taxpayer-funded scientists conducted 55 percent of the research leading to the development of the top five best-selling drugs in 1995. NIH describes its research as complementary to drug company research. According to one NIH report, "Once a *potential* (italics added) drug is discovered, industry scientists conduct extensive in vitro and animal tests until they are ready to patent the invention and publish the results."

"This was a group that was supposed to be representing consumers, and we had to represent ourselves...The quality of life is so poor when you have IBS. [Public Citizen] failed to understand the benefits far outweighed any risks."

Jeffrey Roberts, Patient Advocate

Public Citizen also completely ignores what economists call the "opportunity cost of capital." An "opportunity cost" is the risk any company incurs when it invests money with no guarantee of a financial return. Pharmaceutical companies risk hundreds of millions of dollars over many years when they attempt to develop a potential drug. Clemente dismisses the risk when he charges that the industry grossly overstates the cost of research and development. But it takes from twelve to fifteen years for a drug to pass through testing required by FDA's regulatory approval process. Says Trewitt, "That's a long time to have a hefty capital investment tied up with no return and no guarantee that you're going to be successful." And there is a high probability that a prospective drug will not be approved. In fact, four out of five proposed medicines

do not pass beyond the stage of human clinical testing.

Finally, Public Citizen fails to understand the role of creativity in drug development. Rising R&D expenditures reflect the tremendous scientific advances that make it possible for companies to produce drugs for conditions once considered largely untreatable. Industry scientists constantly search for "drug discovery targets"—cells or proteins that may in some way be the cause or occasion for a disease that a drug can potentially address. The mapping of the human genome and other scientific advances has dramatically increased the number of "drug discovery targets" from about 500 to 10,000. Of course, this increases research and development costs. But it also makes possible the development of new and better medicines that can tackle serious health conditions such as cardiac disease. In the 1990s, pharmaceutical companies added a total of 370

new treatments to the market, up from 233 in the 1980s.

Dramatic scientific advances and the needs of a growing and aging population dramatically increased drug R&D spending—from \$2 billion in 1980 to \$26 billion in 2000. In 2001, drug companies are expected to spend more than \$30 billion on R&D. This is more than the budget of the National Institutes of Health that is supposedly doing the industry's heavy lifting.

Since 2000 many studies have corroborated the Tufts \$500 million estimate, or consider the estimate too conservative. A study by Lehman Healthcare estimates that average R&D spending is now over \$600 million per drug. The Boston Consulting Group says 2001 drug R&D expenditures should average between \$590 and

\$880 million. DiMasi has updated his own research; in a new November 2001 report he concludes that the R&D cost is now \$802 million per drug. The new Tufts study finds that the factor most propelling drug price increases is the search for drugs to treat chronic conditions such as cardiovascular disease.

Public Citizen is oblivious to this data. In a 2001 interview on National Public Radio, Clemente maintained that the \$500 million R&D figure "is highly misleading if not outright fraud."

The PC Campaign Against Meridia

Public Citizen's attack on the anti-obesity drug Meridia (sibutramine) provides one illustration of how it is waging war on the pharmaceutical industry. Relying on bad science and alarmist claims, it is attempting to hurt the drug manufacturer, intimidate government regulators, and frighten the public.

In March 2002, Public Citizen filed a petition with the FDA demanding that it withdraw Meridia from the market. Public Citizen claimed the drug was responsible for 29 deaths and 357 "serious adverse reactions" among users between 1998 and September 2001. In a letter to the FDA, Public Citizen said Meridia dangerously increases blood pressure and heart rates, substantially increasing the risk of heart attack. Moreover, it asserted the drug doesn't work. Said Sidney Wolfe, "Not only does this drug contribute to major cardiovascular problems, but its effectiveness in lowering obesity is meager."

Wolfe claimed the FDA was aware of Meridia's health risks. The FDA was too lax, Wolfe said, and it should toughen its standards for approving all "diet drugs." Public Citizen also accused Abbott Laboratories, Meridia's manufacturer, of covering up the drug's health risks, claiming that the company "withheld information" about the deaths of eight people taking its prescription product. It urged the federal government to file criminal charges against Abbott Labs for failing to report the deaths to the FDA.

In August 2002, the FDA concluded that Abbott did violate federal regulations by not making timely reports on possible Meridia-related deaths. However, it said the company was not involved in a criminal cover-up. That's because both the company and the FDA were well aware that Meridia could pose a potential hypertension risk to some patients. Dr. Eric Colman, an FDA medical officer responsible for Meridia oversight, said the agency considered it reasonable to approve the drug because its warning label clearly stated that some patients had small increases in their blood pressure and heart rate that needed to be monitored. Still, doctors, patients and anti-obesity advocates overwhelmingly endorsed Meridia, finding it safe and effective.

Physicians who endorse the safety of Meridia like Dr. David Heber, director of the UCLA Center for Human Nutrition, conclude "the [fatality] numbers are lower than one would expect in a similarly ill obese population." Dr. Judith Korner, an assistant professor of medicine at Columbia University's College of Physicians and Surgeons, says she would be dismayed if Meridia were banned: "I've not had any problem with it at all. But I select my patient population very carefully."

More than eight million people in 70 nations use Meridia, which had \$200 million in sales in 2001. The global mortality rate for Meridia users is about 2 per 100,000 patient-treatment years. But this is far less than the mortality rate for the obese patient, which is 390 per 100,000 patient years. Moreover, Abbott Labs has followed FDA regulations by issuing warnings that Meridia should not be given to patients with a history of hypertension. Abbott officials point out that in clinical trials on more than 12,000 people, less than one-half percent of users had to discontinue the medication because of hypertension.

Public Citizen has inaccurately claimed that two deaths caused the Italian government to remove Meridia from the market. But Italy only suspended Meridia sales to 300,000 Italian users pending a statistical analysis of the drug's safety. The Italian Obesity Society endorses the safety and

effectiveness of Meridia, and so do health officials in Sweden, Germany, Denmark, and the Netherlands. A Merrill Lynch statistical analysis also finds that two deaths out of 300,000 users is not a cause for concern.

Experts point out that the drug is not necessarily at fault when an obese person taking Meridia dies. Terrence Gaffney, a lawyer who represented American Home Products in fen-phen lawsuits, says many obese people suffer from hypertension before taking weight-loss drugs like Meridia. The preexisting condition, not the drug, causes death. Says Gaffney, "That is a perfect example of a high-risk population claiming an injury known to exist in the population before the drug combination was invented." Gaffney dismisses Public Citizen's claim that Meridia is responsible: "The science is there and this high-risk population clearly has a higher rate of heart disease, vascular disease, diabetes, strokes – all those things that go along with being overweight."

Many health care advocates also are angered by Public Citizen's seeming indifference to the urgent need for treatments of obesity, a major U.S. health problem. Meridia is recommended for individuals who need to lose at least thirty pounds, and studies show that in the majority of obese patients it reduces excess weight by five to ten percent, in combination with diet and exercise.

The American Obesity Association (AOA) has asked Health and Human Services Secretary Tommy Thompson to reject Public Citizen's petition. AOA executive director Morgan Downey says it is "based on faulty reasoning, poor science and disregard for the lives and well-being of 65 million Americans with obesity." Downey takes particular issue with Public Citizen's assertion that Meridia's demonstrated ability to reduce weight in the obese patient by five to ten percent is "meager" and "ineffective." He points out that in December 2001 the Surgeon General noted that a weight loss between five and ten percent of excess body weight "reduces the risk factors for at least some diseases, particularly cardiovascular dis-

ease, in the short term."

The AOA pointedly criticizes Public Citizen for calling Meridia a "diet drug." In his letter to Thompson, Downey says "such labeling trivializes a life or death disease and implies a superficial effort to lose weight driven by vanity." He observes that physicians and their patients can evaluate the risk of using Meridia – risks the FDA and manufacturer make readily known to the public. And he strongly criticizes Public Citizen's demand that weight-loss drugs somehow prove the benefit of weight loss measured against mortality and health. AOA said this standard for drug approval is unprecedented and no new drugs would be developed under these conditions.

Despite many medical endorsements, Public Citizen maintains that Meridia is "unacceptably dangerous," and its risks far outweigh its benefits. FDA is still considering Public Citizen's petition to withdraw the drug from the market.

The PC Campaign Against Lotronex

In 2001, Public Citizen conducted a similar campaign to keep the drug Lotronex off the market. FDA regulators consider the drug safe, physicians approve its use, and consumers have strongly petitioned for its approval. But Public Citizen petitions to prohibit its sale and distribution.

Lotronex is prescribed to treat Irritable Bowel Syndrome (IBS), a chronic disorder whose symptoms are abdominal pain, constipation, diarrhea, and bloating. An estimated 30-40 million Americans suffer from IBS. The condition is considered severe for more than one million sufferers whose daily activities are sharply curtailed by pain and diarrhea. Lotronex was introduced in February 2000 and was enthusiastically welcomed by IBS sufferers.

However, the drug was implicated in cases of ischemic colitis, a potentially life-threatening condition caused by loss of blood flow to the colon. Fifty people were hospitalized and there were two deaths. In August, Public Citizen petitioned the FDA, and the manufacturer, GlaxoSmithKline, voluntarily withdrew the drug from the

market in November.

Thousands of IBS sufferers, particularly women, immediately began a campaign on behalf of Lotronex. Janet Woodcock, director of the FDA Center for Drug Evaluation and Research, supported reintroducing the drug to the market. She did deny not the safety issue, but believed it could be solved. "Most of the problems with Lotronex, like other new drugs in safety trouble, stemmed from inappropriate prescribing," said Woodcock. The answer was to learn why patients displayed adverse health effects and to issue new usage instructions to physicians.

Woodcock added that any drug has risks and absolute safety cannot be guaranteed. But she noted that 10,000 people in the U.S. die each year from the gastrointestinal effects of non-steroidal anti-inflammatory medicines for arthritis (NSAIDs). "That's a magnitude that blows away the side effects of Lotronex," said Woodcock. "So if you say Lotronex is totally unacceptably toxic, that means so are most of the antibiotics, all the anticonvulsants, and the NSAIDs."

Public Citizen dismissed the evident risk-benefit ratio when it argued that Lotronex should not be reintroduced to the market under any circumstances. It even went so far as to attack the FDA for listening to the objections of patient groups. In an April 18, 2001 letter to the FDA, Public Citizen complained: "Because of pressure from the drug industry and patient groups, the FDA is apparently considering putting Lotronex back on the market." FDA's Woodcock answered that Lotronex had become "just a tool" for Public Citizen to pursue its political agenda. But she said it was a "poor tool" to attack the pharmaceutical company: "I've heard from people all over this country, university professors, CEOs, government employees, housewives." They were all demanding Lotronex.

In June 2002, the FDA authorized the return of Lotronex to the market. Under new prescription guidelines, doctors must state that they are qualified to diagnose IBS and that they understand the risks

associated with Lotronex use. One new guideline calls for patients to start using the drug at half the originally approved dose, allowing physician monitoring of potential complications as the dosage is increased.

Dr. Victor Raczowski, director of the FDA's Division of Gastrointestinal and Coagulation Drug Products, has said the agency's decision "represents the FDA trying to balance access to effective therapy for disabling conditions against trying to protect the public from harm due to adverse effects." Raczowski emphasizes "that there weren't other effective therapies for [IBS] patients to turn to."

Public Citizen is uninterested in balancing risks, and it dismisses the lack of alternative patient therapies. "We are quite fearful for patients," said Larry Sasich, a Public Citizen research analyst. "Unfortunately, the FDA's action will almost surely lead to more injuries and possibly deaths."

But IBS patient advocates are more fearful of Public Citizen. Jeffrey Roberts, president and founder of the IBS Self Help Group, is strongly critical of Public Citizen. He began taking one milligram of Lotronex a day and experienced almost immediately an end to a quarter-century of pain. "The symptoms went away in three days. Something I hadn't achieved ever. It was a little odd I have to admit. I had to get used to the new freedom."

Roberts doesn't understand what motivates Public Citizen: "This was a group that was supposed to be representing consumers, and we had to represent ourselves." Roberts agrees with Woodcock and other FDA officials who recognize the need to assess drug risks and benefits. "The quality of life is so poor when you have IBS. [Public Citizen] failed to understand the benefits far outweighed any risks."

Medical experts applaud the market reintroduction of Lotronex. Ray Crouse, a professor of medicine at Washington University in St. Louis, says the drug is unlike other available treatments in helping control the multiple symptoms associated with

IBS. Dr. Lawrence Brandt, an official with the American College of Gastroenterology, praises Lotronex as one of a new wave of drugs: "These are drugs that significantly change people's lives for the better."

The PC Campaign Against Anti-Cholesterol Drugs

Many Americans are concerned about high levels of cholesterol in their blood that put them at risk for coronary heart disease and heart attacks. Having found that no amount of exercise and dieting can reduce it to acceptable levels, they and their doctors welcome the introduction of cholesterol-lowering drugs called statins. Popular statins include Zocor, produced by Merck, and Lipitor, a Pfizer product.

Yet in August 2001, Public Citizen petitioned the federal government to force pharmaceutical companies to place ominous warning labels on statins. Public Citizen warned consumers that statins were more dangerous than they appeared. Said Sidney Wolfe, "Most people taking these drugs aren't aware that they could sustain serious muscle damage and could even die."

Public Citizen's demand came shortly after the German company Bayer withdrew Baycol, its statin drug, from the market. Four years after FDA approval, Baycol was found to have caused 31 deaths from a muscle-destroying side effect. In its FDA petition, Public Citizen claimed five other statin drugs on the market had caused the same side-effect and were responsible for an estimated 81 deaths since the first statin was introduced in 1987.

Public Citizen made inaccurate claims and exaggerated the health threat of statins. The negative side effect is already known. Dr. Sidney Smith of the American Heart Association says physicians are well aware of the problem and discuss it with patients: Statins in some instances give rise to a rare condition that causes muscles to decay and release muscle cell contents into the bloodstream that can damage the kidneys. Statin drugs currently carry a warning label telling patients with sore muscles to contact their doctor.

After the Baycol recall, Public Citizen exploited reports to frighten consumers about the potential condition. “We really don’t know the extent of injury due to these drugs,” said Public Citizen’s Sasich. “Only one in 10 to one in 100 of serious adverse effects is ever reported.” Wolfe said he arrived at an estimate of 81 deaths caused by rhabdomyolysis – the medical term for the muscle-weakening side-effect—after analyzing the occurrence since 1997 of over 1,000 FDA-recorded cases of the disease in conjunction with the six statins sold in the U.S. Wolfe urged an FDA order that statins carry “black box” warning labels, the toughest the agency can mandate.

FDA officials dispute Public Citizen’s estimate of statin-related deaths. Dr. John Jenkins, an FDA drug review official, said the agency investigated the FDA reports cited by Wolfe in his claim. It found duplicates cases and identified patients who had died of other causes. The actual number of rhabdomyolysis cases, concluded Jenkins, was 18.

Once again, Public Citizen was raising health fears about the pharmaceutical industry despite the benefit statin drugs bring millions of people. An estimated 13 million people take statins. Though there is a side-effect risk, it is one most patients can live with. Dave Davis, a 71-year-old retiree, has started taking statins. He is not a risk-taker by nature, he says, and doesn’t play the lottery because the “percentage of winners is so low.” But as for statins: “If the risk is in the same ballpark, I won’t worry about it.”

Says Dr. Stephen Fortmann, director of the Stanford Center for Research in Disease Prevention: “These are actually very safe medicines. They are a lot safer than a lot of the medicines people take all the time, including aspirin.”

The scientific community believes in the health benefit of statins. In 2001, NIH changed its heart disease prevention guidelines and recommended that doctors encourage more Americans to take the cholesterol-lowering drugs. Specifically, it urged boosting the number of users from 13 million to 36 million.

Conclusion

In waging war on corporations in the name of the consumer, Public Citizen often makes bogus scientific claims and pushes for onerous regulatory policies. But when it wages war on pharmaceutical corporations, Public Citizen takes a more dangerous step. It aims to stop the development of innovative drugs that combat debilitating diseases. If Ralph Nader’s flagship advocacy group succeeds, doctors won’t be able to treat patients with remedies that improve their quality of life – and save their lives.

The problem confronting U.S. drug safety regulation is not corporate greed. It’s Public Citizen’s ideological vanity.

John Carlisle is the Editor of Organization Trends.

RESTRICT CONSUMER DRUG INFORMATION, SAYS PUBLIC CITIZEN

Even if Public Citizen can’t stop consumers from buying new and innovative drugs, it hopes to keep consumers from learning more about them. Public Citizen has in the past decade repeatedly urged FDA to tighten its already restrictive consumer advertising regulations and increase enforcement. Public Citizen’s Health Research Group criticizes consumer drug ads and touts questionable Public Citizen studies that urge putting limits on the information pharmaceutical companies can provide consumers about their products. Dr. Sidney Wolfe, director of the Health Research Group, has been one of the left’s leading spokespersons on the need for far more FDA oversight of drug ads.

“Public Citizen’s actions constitute a true health hazard, and demonstrate a disdain for free speech rights and the concept of an empowered consumer,” says Glenn Lammi, chief counsel of the Washington Legal Foundation’s (WLF) Legal Studies Division. WLF, a public interest law center, is an institutional counterweight to Public Citizen at regulatory agencies, in the courts, and with the media. “What’s so wrong about truthful ads that tell consumers to ‘ask your doctor’ about FDA-approved drugs and their uses?” asks Lammi.

BrieflyNoted

United Way of Tampa Bay canceled a March event featuring actress Susan Sarandon as its keynote speaker after it received dozens of donor complaints about her outspoken opposition to the U.S. war against Saddam Hussein. Months ago Sarandon was asked by her brother to speak at the \$75-a-plate dinner about the role of women as donors and volunteer leaders. She was to receive a \$20,000 speaker's fee. But criticism of her selection swelled soon after invitations went out earlier this year. United Way board chairwoman Robin Carson rescinded the invitation and cancelled the event. Said Carson, "The focus of our whole meeting had shifted to whether or not we were creating a political platform for Susan Sarandon. That is not our purpose. That's not what we're about." Said invitee Louis Spiegel III, "(Sarandon) is welcome to her opinion, and I'm welcome not to listen to it."

The National Legal and Policy Center (NLPC) has written NASCAR officials asking the auto-racing organization to end its financial support for the Rev. Jesse Jackson and his network of activist groups because of his opposition to the war in Iraq. Last year, NASCAR was a "Platinum" sponsor of Jackson's Rainbow/PUSH and Citizenship Education Fund Annual Conference, a major source of revenue for Jackson's nonprofits. NASCAR reportedly donated \$100,000. In the letter to NASCAR Chief Executive Officer William France, NLPC president Peter Flaherty wrote, "You have stated that NASCAR fans are the 'kind of people who go to war and win wars' for America." Noting that branches of the armed services are NASCAR sponsors, Flaherty said, "NASCAR's support for our troops is undercut by your support for Jackson...when Jackson is leading anti-war protests in foreign countries."

People for the Ethical Treatment of Animals (PETA) is criticizing the U.S. military's use of dolphins and seals in the Persian Gulf to detect Iraqi mines and the presence of chemical weapons. Since the war's start, the U.S. Navy has used 75 dolphins and seals to detect mines. Dolphins can hone in on specific sounds and, unlike human divers, make repeated deep dives without experiencing decompression sickness. To date, dolphins have helped detect 22 mines, helping clear the way for humanitarian relief to reach the Iraqi port of Umm Qasr. But PETA is not convinced. In a complaint to Defense Secretary Donald Rumsfeld, PETA says: "Wars are human endeavors. While a person, a political party, or a nation may decide that war is necessary, the animals never do... These animals never enlisted, they know nothing of Iraq or Saddam Hussein, and they probably won't survive." PETA should know that the Navy "pays" dolphins for their services – about 20 pounds of fish per day.

Sons of the late Senator Paul Wellstone (D-MN) have announced they are forming a nonprofit organization to continue the work of their parents, killed in a plane crash last October. **Wellstone Action** has applied for 501(c)3 and (c)4 status; it will focus on political organization, training and issue advocacy. David and Mark Wellstone serve as co-chairmen of the new group's advisory committee. Other committee members include Senator Tom Harkin (D-IA), actors Robert Redford and Warren Beatty and comedy writer Al Franken.

