

productive and we moved America's business forward in a very positive way.

I know several people will have statements over the course of the morning, looking back over the past several weeks, in that we have had a very productive session that delivered to the American people.

CONCERNS ABOUT PRESCRIPTION DRUG ADVERTISING

Mr. FRIST. Mr. President, I would like to make a statement that I regard as a very important one because it reflects what I think is a needed change in behavior that affects health care across America. Let me begin with a few phrases: "Keep the spark alive," "The healing purple pill," "If a playful moment turns into the right moment you can be ready," "For everyday victories."

You turn on your TV anytime of the day and that is what you will hear and that is what you will see. These are the advertising tag lines for some of America's best selling and most advertised prescription drugs—in the last several weeks, months and years. We all know them when I read them. Some even have the images that pop up into their minds, because we see them again and again and again and again. We are barraged by them.

I mention this as a physician, because 10 years ago you would not have seen any of that advertising on television. We have heard them on our television sets, we hear them on our favorite radio programs, we see them in newspapers, we see them in magazines. Those who go to NASCAR races see them on the cars. You see them on billboards along the highways. We are barraged with this information. It is called direct-to-consumer advertising. When I was practicing medicine before coming to this body—note that long ago, in 1994—it didn't exist.

This is what direct-to-consumer advertising is. When drug companies, pharmaceutical companies, market their products, the marketing used to be done to physicians who could accumulate that information and help patients make decisions. But the direct-to-consumer goes over the heads of physicians with this advertising, direct to the American people, direct to the consumer. It is called direct-to-consumer advertising, or DTC is the terminology people use.

It is a two-edged sword. Obviously there can be huge health education benefits to such advertising because you are exposed to it, you are barraged with it, and information is provided, information to which you might not otherwise have access. But let there be no mistake, drug advertisements are fuel to America's skyrocketing prescription drug cost. It is a two-edged sword. The advertising is new over the last 10 years. Now it is time to assess the efficacy of advertising, but also potential damage that is done by this

proliferation, this skyrocketing of advertising to which we are being exposed.

These ads do influence consumer behavior; otherwise, drug companies wouldn't be putting money into them. Their real purpose at the end of the day is to have a drug that, yes, helps people, but also makes money for them. It affects consumer behavior and it also—though it is not said very much but I will speak to it here shortly—affects physician behavior in a way I think is detrimental. Physicians don't want to talk about it very much because it is a little embarrassing. I will come back to that. But it affects physicians' behavior in a way that I think is not healthy, as well as affecting consumer behavior.

These ads cause people to take more prescription drugs. They have the potential to create an artificial demand and thereby they can drive up health care costs for everybody listening to me as individuals, but also our overall health care cost for the Nation.

I believe it has reached a point where they—again, it can be very positive with the health education—are needlessly and wastefully driving up health care costs. Thus it is time for us to get more information but also address the issue.

Moreover, a lot of the direct-to-consumer advertising is misleading. I know, as people listen, you tend to believe, unfortunately, what you see on TV and that can be dangerous in certain cases. This direct-to-consumer advertising can oversell hope, and people want hope; it can oversell results; and it can also undersell the risk. Every drug has side effects. Every drug has a side effect. We may not know all of the side effects, but the idea of promoting a drug without adequately enumerating, spelling out, highlighting the risk is wrong. Misleading advertising, especially when we are barraged with it, when that is all we see—a little bit of hyperbole, on TV between shows, if it is misleading, hurts patients and definitely pressures doctors to overprescribe or to change prescribing habits in response to that request, that specific request from a patient.

So today I rise to urge all pharmaceutical companies to voluntarily restrict consumer drug advertising during the first 2 years that a new drug is on the market. Today I am also requesting a Government study into the cost and into the consequences and any potential benefits of direct-to-consumer advertising. It is time for the drug companies, I believe, when it comes to direct-to-consumer advertising, to clean up their act. If they do not, I believe Congress will need to act in this arena.

In its proper place, direct-to-consumer drug advertising gives patients, gives consumers, information. It empowers them to make decisions. It can give them the information they need in order to make informed decisions about their health, about the advan-

tages of a particular drug. It can instruct them and open their eyes to symptoms they have that might be very serious but they might not otherwise go to see a doctor about. It can inform them about new therapies, the breakthrough therapies that are so powerful—made in large part because of the research and development in our private sector by our pharmaceutical companies.

These are good things. These are the good things that advertising can do, that education can do, that knowledge can do. Indeed, I envision a health care system—and we are not yet there today, but I think we are moving in that direction, in part through legislation on the floor of the Senate, to move to a system that is centered not on big Government and not on us micromanaging from the floor of the Senate prices and decisions, but, no, move toward a system that is patient centered. We are moving toward a health care system that centers on the individual patient, that is provider friendly, and that is driven by three things. Those are knowledge or information that is given the patient, the individual, the opportunity to choose and make choices for themselves, and to make sure that patient is empowered, they have resources to make those decisions.

So if you are looking at a consumer-driven, patient-centered health care system, having timely information, accurate information, complete information, and balanced information has to be one of the major pillars.

Direct consumer advertising can be very helpful in that regard if that is the purpose and if it meets those standards. I don't think the advertising we see today—and I base this on people coming up to me all the time as a physician and policymaker—I don't think the advertising today meets those standards. I will have more to say about that issue.

With today's advertising, perhaps you are at a ball game with your family, going to a movie or to dinner—ask somebody about it—and today's advertising will likely leave parents having to explain to their young children, their 10-, 9-, 8-year-old, what erectile dysfunction is rather than a discussion of the importance of getting your blood pressure checked to see if you have hypertension so you will not have a stroke or heart disease. That would be useful information.

That is the problem. How did we get to this point? Prior to the 1980s, drug manufacturers almost always introduced and explained their products to physicians. Physicians had a body of knowledge and the training to make an assessment of whether, based on the information the drug companies gave them, this would be an efficacious drug, a useful drug to use, or whether the side effects would be appropriate for individual patients.

In 1981, just over 20 years ago, Boots Pharmaceuticals ran the first U.S.

print advertisement—just 24 years ago. It was directed to consumers for the ibuprofen product *brufen*. In 1980, print advertising picked up. In the 1990s, drug companies began to use more print advertisements to promote their products—again, directly to consumers, not going through physicians—and during that period they ran television advertisements sparingly. Rarely would consumers turn on the television and actually see an advertisement directed at the consumer on a drug.

Looking back over the last 40 years since 1962, the FDA has had a requirement—the FDA is the Government institution in charge of regulation and oversight. Since 1962, the FDA has required ads to include a brief summary of a drug's side effects, indications for use, the contraindications, the warnings and precautions.

Regarding the massive changes we are exposed to today, look back to the Clinton administration in 1997 when the disclosure rules for television ads were liberalized. The door was opened. That is not that long ago—3 years after I formally left the practice of medicine to come to the Senate. Rather than providing a full picture of a drug's risk and benefits, the new laws required only that drug companies disclose the most significant risk and then refer patients to a secondary source of information, leaving this whole inadequacy of the risk and adverse effects on the ad as presented.

As a direct result of this 1997 ruling, spending on direct consumer advertising skyrocketed 145 percent between 1997 and 2001. It passed the \$1 billion mark in 1997. It was almost nonexistent 7 years before that and skyrocketed to about \$1 billion in 1997. Then 4 years later, it kept skyrocketing and reached \$2.7 billion. Indeed, last year, the drug companies spent over \$4 billion advertising medications directly to consumers.

This 145 percent over that 4-year period from 1997 to 2001 for direct consumer advertising, reaching consumers, should be compared to an increase of only 59 percent for research and development for drugs—clearly, a heavy investment in direct consumer advertising. Why? Because that advertising increases utilization of that drug and sells more drugs.

The Clinton administration at the time they opened this door—under intense pressure by the drug industry—not only opened the door but opened the door too widely, and our regulatory body has not kept up with what has come through that door. As a result, the direct-to-consumer advertising exploded to levels that at least I did not anticipate. As we watched this unfold through the 1990s, I don't think anyone anticipated the level that we see when we turn on the television today. That drives up drug use, that drives up drug spending, and, of course, that will drive up the cost of health care generally.

In addition to all that, it has led to inappropriate doctor-physician pre-

scribing. We have to be careful because until we really study it, we will not know all effects. My doctor friends tell me again and again, when a patient comes in with a specific request for a drug written down and the doctor has 30 or 40 patients waiting outside, it is almost easier—I am embarrassed to say this—almost easier for a doctor to write the prescription and give it to them even though there may be a generic drug or a much less expensive drug. The patient comes in and says: I have to have this drug. This drug is what I have in mind, the hope for the cure for my disease.

This misallocation of resources and inefficiency that results from inappropriate prescribing from the physician's standpoint is something we can rip out of the system if we turn to a balance between very good and direct-to-consumer advertising, which includes patient education, but get rid of the inappropriate, imbalanced state we are in today.

If we consider the recent labeling changes in market withdrawals of just one class of drugs, the nonsteroidal anti-inflammatory, it tells a story. These drugs were the most heavily advertised in America. They were used by millions and millions of patients. Millions of patients benefited, I should say, from these drugs, but many people today believe—looking back at what happened in response to the advertising—that they were overprescribed.

In the case of one drug people have heard a lot about, *Vioxx*, 93 million prescriptions had been written since its approval in May 1999. Millions of prescriptions were also written for similar drugs such as *Celebrex* and *Bextra*. In the case of *Vioxx*, indeed, it was a better drug. It did prove to be better than competing products for patients who had gastrointestinal problems or stomach problems. America did conduct postmarket research that was not required by the Food and Drug Administration. Of course, we cannot foresee every risk. It does take time to accumulate information to fully assess risk.

Quite simply, we should always strive to make safety the top concern, not selling the most drugs through increasing utilization, through advertising, but ultimately to make safety our top concern, especially for newly approved products that are used for the very first time in millions and millions of patients. It takes time for the adverse reactions and side effects to be fully explored and to fully surface. Doctors should have more time to use the drugs to gain experience with them, to collect more balanced information, and to be able to weigh the risks and benefits of a product.

In a 2002 report on the practice, the Government Accountability Office, the GAO, highlighted two studies. The last time it has been studied—and that is why I want to study it now, because we have had this explosion—but in the two studies they highlighted in 2002, the

last report, each showed a 10-percent increase in direct-to-consumer spending within a drug class increased sales in that class by 1 percent. For one popular, very heavily advertised prescription drug, \$1 of consumer advertising translated into \$4 in increased sales—\$1 dollar in advertising, \$4 in sales. So we see the motivation from the drug companies in advertising particular drugs. It is no wonder the drug companies are flooding our airwaves today.

The GAO findings in that 2002 report were clear: Increased direct-to-consumer advertising has helped fuel escalating drug costs. These drug costs, as we know, are skyrocketing. In 2003, Americans consumed 134 billion prescription pills and spent over \$216 billion on prescription drugs. That is as much as Americans spent on gasoline and oil. During the past few years, drug costs have gone up more than twice as fast as inflation, faster than nearly all other health care items and services.

Congress has paid attention to these skyrocketing, escalating drug costs, and we have acted on the 2003 Medicare Modernization Act. We took major steps toward providing more affordable prescription drugs. I add the "more affordable" because we did a number of things.

First and foremost, recognizing the importance of prescription drugs, centrality of prescription drugs to health care delivery today, we provided seniors with an outpatient prescription drug benefit under the Medicare Program for the first time in history—something I feel strongly about, something I am very excited about as we look over the next year, couple of years, where implementation begins. We also established health savings accounts that allow individuals to own and take care of their own health care. We reformed patent laws and closed loopholes to help speed lower cost generic drugs to market and set standards to encourage more efficient electronic prescribing and improved patient safety. We provided funds to the Department of Health and Human Services to study the clinical comparative effectiveness of drugs and then take that information and share it with patients, to share it with consumers so they can make prudent decisions.

We have taken some good steps, moved in the right direction, but we clearly have a lot more to do. Part of this effort, and the reason I bring it to the Senate today, is a responsibility we have to look at prescription drug advertising. Unbalanced and misleading prescription drug advertising hurts the American people. We will look at it. It adds tension to the relationship between doctors and patients, the physician-patient relationship. It can lead to inappropriate prescribing, and it can overwhelm our current regulatory system.

As consumers, we are all familiar with these ads. They adorn major magazines, Web sites, newspapers, and

flood the airwaves. Particularly on television, they present upbeat images, a parade of images that bring hope and beauty with these positive images, but often the warning and the cautions are in either fine print or as an afterthought. As I mentioned earlier, think how many parents have found themselves watching a sporting event with their son or daughter, only to be assaulted by an ad for erectile dysfunction.

Think back to advertising during this year's Super Bowl, the nature of those ads and the focus of those ads. Only rarely do these ads provide consumers with enough time to absorb the risk information. In a 2002 FDA study, nearly 60 percent of patients reported drug advertisements did not provide enough risk information. In that study, 58 percent of patients felt these ads portrayed products as better than they are. In another 2002 FDA survey, 75 percent of physicians said ads led patients to overestimate the efficacy of the drugs, and 65 percent of physicians noted that patients confused the risk and benefits of drugs advertised to consumers.

What this means is sometimes a patient may request a drug, even insist upon a drug, even if it does more harm than good. They may too heavily rely on a pill when an overall lifestyle change might be more appropriate. They may come in and demand the latest, most expensive medication when an old standby could do just as well.

Patients seeing the ads place new demands on their doctors. As I mentioned, when my medical colleagues are pressed for time, they tend to respond with the easy way of responding to a specific demand—even if it might not be either the most cost-effective or efficacious drug.

Thinking of one example, after one year of directly advertising the bone-mass-increasing drug Fosamax to consumers, physician visits for osteoporosis evaluation nearly doubled. That in some ways may be good because it shows the double-edged sword in that people go to the doctor and they ask appropriate questions. But then you have to ask the question: Did these ads provide the patients with the appropriate information to go see that doctor for the appropriate information on the side effects of that particular drug?

An interesting study from the University of California-Davis was where the researchers sent actors in good health to 152 doctors' offices in three cities to find out if they could get prescriptions for simulated symptoms. Half of the actors imitated patients suffering depression. The other half expressed symptoms of stress and fatigue.

The study found that if an actor requested Paxil, which is a heavily promoted antidepressant, he was five times as likely to walk out of the doctor's office with a prescription for the drug. The research suggested that direct-to-consumer advertising increases

patient demand for specific medications, even in situations where prescriptions are not needed.

Finally, we need to ask questions about how we regulate this drug advertising. Right now, the Food and Drug Administration simply has neither the resources to scrutinize direct-to-consumer advertisements nor the power to review them for accuracy before they are viewed by the public. In 2002, the FDA received over 137,000 pieces of promotional material for review. Some of these materials appeared on the airwaves or in print even before they arrived at the office of the FDA.

The entire division responsible for this oversight consists of 40 employees—just 40 employees—who have to review almost 40,000 complex, medically sensitive advertisements. It is not enough. The FDA knows it is not enough. We have not given them enough resources.

Two years ago, Dr. Janet Woodcock, then the FDA's Acting Deputy Commissioner for Operations, told the Senate Committee on Aging:

It would be impossible for the FDA to try to track the number of different broadcast advertisements that are aired.

Almost unbelievable to me is the fact that the FDA review comes after the fact. It cannot require drug companies to submit their advertisements before they appear on the airwaves or on the Internet or in print. The FDA simply cannot keep up.

Our failure, our Government's failure, to appropriately regulate drug advertising hurts the very people I believe the drugs are intended to help, and that is the patients. We are not serving the American people as well as we should.

Mr. President, 2 weeks ago, the pharmaceutical company Bristol-Myers Squibb announced a voluntary ban on advertising its new drugs to consumers in their first year on the market. The company said it wanted to give doctors more time to understand new products before patients start asking for them. I think this shows leadership. It shows responsibility. Bristol-Myers is setting an example in showing restraint in the industry.

I know PhRMA—that is the drug industry's trade association—has announced it will adopt an industrywide voluntary code governing direct-to-consumer advertising next month—another good move.

Mr. President, what should we do? I believe, at a minimum, the pharmaceutical industry should include a voluntary restriction on the direct-to-consumer advertising of prescription drugs in their first 2 years on the market. This restraint is important because a typical clinical trial for a drug includes about 5,000 patients. A blockbuster drug can attract as many as a million patients in the first year on the market. But since no drug is free of a side effect, we may not fully know what those side effects are. Doctors and patients need time to learn about

the new treatments to be able to assess their benefits and find out more about the risk. Education should come before persuasion. Patient safety should be paramount, not the bottom line.

So what should we do? Three things.

First, we should give the FDA prior review and approval authority for all direct-to-consumer drug advertising. By the time the FDA reprimands a company for running a misleading drug commercial, that advertisement may have already deceived consumers. Advertising should boldly and responsibly address safety head on, replacing the upbeat fantasyland images with a frank discussion of a product's risks and benefits.

Second, we should increase resources devoted to reviewing advertising, to determine the advertisement's accuracy and to ensure all standards are met.

The FDA must have the resources, must have the capability to more thoroughly monitor drug advertising and make sure that companies fully comply with the advertising guidelines.

The American people assume this is being done today when they see those ads, and it is not. A staff of 40 is simply not sufficient.

And third, we should give doctors and patients greater access to clinical data and postmarketing surveillance efforts about drugs after they become available.

For the drug industry, which has long touted the educational benefits of its advertising and of its mission, it has to know that the success of their mission inherently depends upon the quality of information they give to physicians and patients—not just the enticing images, but the quality of information.

Mr. President, in closing, as a doctor who has witnessed both the good but also the bad in this explosion of drug advertising direct to the consumer, I feel I have a responsibility to watch this issue closely. If the pharmaceutical industry's voluntary restrictions are not strong enough, I will support congressional action to make sure consumers get the protection they deserve.

In the meantime, today, I am asking the Government Accountability Office, the GAO, to investigate FDA's oversight of prescription drug advertising, the pharmaceutical industry's spending on such advertising, and this advertising's impact on utilization, health care spending, and patient education and awareness.

Wherever I go—whether it is to meet with a group of doctors at a medical meeting at the Harvard Medical School or back at the University of Tennessee or at the Coca-Cola 600 in Charlotte—people come to me and say the direct-to-consumer advertising has gone overboard.

We have to return balance. I believe we can and we should move into a health care system that is centered on the patient, where they have appropriate information to make decisions—

a consumer-driven, provider-friendly, patient-centered system.

I know my colleagues share these or similar priorities. I believe the steps I have proposed today will be to the benefit of patients. It will save money. It will save lives. Prescription drugs, I believe, are the most powerful tools in American medicine today. We really could not and should not do without them. But we have to use them and market them and promote them with care.

Mr. President, I yield the floor.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period for the transaction of morning business, with Senators permitted to speak for up to 10 minutes each.

Mr. FRIST. Mr. President, I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. FRIST. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

RETIREMENT OF JUSTICE SANDRA DAY O'CONNOR

Mr. FRIST. Mr. President, I rise to pay tribute to a truly distinguished American—U.S. Supreme Court Justice Sandra Day O'Connor, who announced her retirement earlier this morning.

The current group of nine Justices, including Justice O'Connor, represented the longest serving Supreme Court since the 1820s.

Today marks a great loss for America. But it is also a day to reflect on all that we have gained because of Justice O'Connor's service to our country.

For nearly 23 years, Justice O'Connor lent America her brilliant mind and her fair and impartial judgment.

Sandra Day O'Connor, who turned 75 this year, was born in El Paso, TX.

The daughter of Harry and Ada Mae, she was raised on her family's cattle ranch, in southeastern Arizona.

Sandra Day O'Connor began her academic journey at Stanford University.

Upon earning a bachelor's degree in economics and graduating magna cum laude, she stayed on at Stanford, pursuing an education in law.

And at Stanford she thrived. She earned a coveted position on the Law Review's Board of Editors and completed law school in only 2 years. Not only did she graduate in record time, but she finished third in her class.

Coincidentally, she finished with a man who would later become her colleague on the highest Court in the land—Chief Justice William H. Rehnquist.

It was during law school that Sandra Day O'Connor met her future husband, John Jay O'Connor.

Seeking her first job as a young, female attorney, Sandra Day O'Connor faced many challenges in a male-dominated law profession.

After having difficulty finding a job in the private sector, she began her legal career as Deputy County Attorney of San Mateo, CA.

When her husband was drafted into the JAG Corps in 1953, the young couple moved to Frankfurt, Germany, where she worked as a civilian attorney for the U.S. Army.

After 2 years in Europe, Sandra Day O'Connor returned to Maryvale, AZ, where she experienced difficulty finding employment in the legal world. As a result, she decided to start her own legal practice.

After practicing law for 2 years, Sandra Day O'Connor took a break from her career to start a family. She and her husband raised three sons—Scott, Brian, and Jay. I must say, as a father of three sons, this may be her greatest accomplishment—certainly, one of the most challenging.

In 1965, Sandra Day O'Connor transitioned from the private sector, to the public, when she became Arizona's Assistant Attorney General.

In this capacity, she served for 4 years before being appointed to fill an unexpired seat in the Arizona State Senate. Her constituents agreed it was a good match—as they elected her twice more.

In the Arizona Senate she rose to the highest level, becoming majority leader and the first woman ever to hold such an office in the United States.

As majority leader of this body, I understand the challenges and rewards of being leader and admire Justice O'Connor for her tremendous achievement.

In 1975, Sandra Day O'Connor was elected, judge of the Maricopa County Superior Court and served until 1979, when she was appointed to the appellate bench in Arizona.

There she served, until late President Ronald Reagan appointed her Associate Justice to the Supreme Court.

On September, 21, 1981, the Senate unanimously confirmed her nomination to the Supreme Court. And that day, Sandra Day O'Connor made history. She became the first female Justice in the Court's history.

This 51-year-old Arizona-Court of Appeals judge shattered the 190-year-long tradition on the High Court of addressing Justices: "Mr. Justice."

When asked for her reaction to her nomination, Sandra Day O'Connor said:

I can only say that I will approach [my work on the bench] with care and effort and do the best job I possibly can do.

Most would agree that she has done just that.

Since 1981, Justice Sandra Day O'Connor has served with distinction on the U.S. Supreme Court. She has served as an example to all Americans—demonstrating that through persistence and hard work anything is possible.

In the face of obstacles—including being a woman in a male-dominated law profession—she never surrendered her determination nor did she surrender her Southwestern pride and love of the outdoors when she moved to the city. Rather, she brought it with her.

Anyone who has entered the inner confines of Justice O'Connor's Supreme Court office is familiar with a sign that reads "Cowgirl Parking Only: All Others will be Towed."

Fiercely proud of her heritage, Justice O'Connor and her brother, H. Alan Day, authored a best selling memoir "entitled Lazy B: Growing up on a Cattle Ranch in the American Southwest."

Having grown up in the South—in Nashville, TN—I appreciate Justice O'Connor's pride in her roots. She has not forgotten where she came from.

The values she learned through life on the range were values that left their brand mark. Indeed, hard work, self-reliance, and survival are the core values that make Sandra Day O'Connor the successful woman she is today.

As she writes in her memoir, working alongside cowboys on the Lazy B, she learned a system of values that was "simple and unsophisticated and the product of necessity."

Throughout her tenure on the Court, she has not wavered from her well-grounded views.

I've had the privilege of meeting Justice O'Connor on various occasions during my time in the United States Senate.

Each time that I've had the opportunity to interact with her, I've found her to be thoughtful, kind, and extraordinarily intelligent.

To echo the words of Ronald Reagan on the day he appointed Sandra Day O'Connor:

She is truly a "person for all seasons," possessing those unique qualities of temperament, fairness, intellectual capacity and devotion to the public good which have characterized the 101 "brethren" who have preceded her.

Today, more than 23 years later, President Reagan's words still ring true.

When she took the oath of office as the 102nd Associate Justice, she pledged to uphold the Constitution, and since this time, Justice O'Connor has proven her steadfast commitment to uphold the Constitution.

During her confirmation hearing, she emphasized that the court's role was to interpret the law and not to make public policy.

Her record demonstrates that she has lived up to that commitment, respecting the rule of law and judiciously interpreting the Constitution.

Often cited as the "swing vote" on many important cases, Sandra Day