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When Advocates Become Regulators

Bush Has Installed More Than 100 Top Officials Who Were Once Lobbyists, Attorneys Or Spokespeople For The Industries They Oversee

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WASHINGTON -- In a New York City ballroom days before Christmas, a powerful Bush administration lawyer made an unprecedented offer to drug companies, one likely to protect their profits and potentially hurt consumers.

Daniel E. Troy, lead counsel for the U.S. Food and Drug Administration, extended the government's help in torpedoing certain lawsuits. Among Troy's targets: claims that medications caused devastating and unexpected side effects.

Pitch us lawsuits that we might get involved in, Troy told several hundred pharmaceutical attorneys, some of them old friends and acquaintances from his previous role representing major U.S. pharmaceutical firms.

The offer by the FDA's top attorney, made Dec. 15 at the Plaza Hotel, took the agency responsible for food and drug safety into new territory.

"The FDA is now in the business of helping lawsuit defendants, specifically the pharmaceutical companies," said James O'Reilly, University of Cincinnati law professor and author of a book on the history of the FDA. "It's a dramatic change in what the FDA has done in the past."

Troy's switch from industry advocate to industry regulator overseeing his former clients is a hallmark of President Bush's administration.

Troy is one of more than 100 high-level officials under Bush who helped govern industries they once represented as lobbyists, lawyers or company advocates, a Denver Post analysis shows.

In at least 20 cases, those former industry advocates have helped their agencies write, shape or push for policy shifts that benefit their former industries. They knew which changes to make because they had pushed for them as industry advocates.

The president's political appointees are making or overseeing profound changes affecting drug laws, food policies, land use, clean-air regulations and other key issues.

Government watchdogs call it a disturbing trend, not adequately restrained by existing ethics laws.

Among the advocates-turned-regulators are a former meat- industry lobbyist who helps decide how meat is labeled; a former drug-company lobbyist who influences prescription-drug policies; a former energy lobbyist who, while still accepting payments for bringing clients into his old lobbying firm, helps determine how much of the West those former clients can use for oil and gas drilling.

"When you go to work in lobbying, it is clearly understood and accepted that your job is to advocate for the interests of those who hired you," said Terry L. Cooper, a University of Southern California ethics and government professor. "When you go to work in government, you are supposed to be responsible for upholding and maintaining whatever you can identify as the public interest."

The Bush administration says the regulators were chosen for their abilities.

"The president appoints highly qualified individuals who make their decisions based on the best interests of the American people," said White House spokesman Jim Morrell. "Any individual serving in the administration must abide by strict legal and ethical guidelines, including full disclosure of past lobbying activities."

Six of the former industry advocates have faced ethics investigations or resigned amid conflict-of-interest charges. Those and at least 14 others have been lambasted by public- interest groups.

Government ethics standards are part of the problem because they don't fully address the kind of issues that now permeate Washington, Cooper and some inside government say. The rules focus mainly on direct financial conflicts. Other, more nuanced conflicts aren't addressed

"There are so many ways around, over and under these (ethics) bans ... they almost never work," said Paul Light, who for decades has studied the

appointment process for the Brookings Institution, a think tank in Washington. "There're more screen doors than steel doors."

A March 16 report from the Interior Department's inspector general, for example, concluded that department's "byzantine" conflict-of-interest rules were "wholly incapable" of addressing ethical questions involving a former energy lobbyist, J. Steven Griles, as the department's No. 2 official.

The report called the department's ethics system "a train wreck waiting to happen."

Bringing bias to a federal job isn't new. Presidents of all political persuasions have appointed people who shared their party's values.

As president, Bill Clinton peppered the federal bureaucracy with Democratic state officials, lawyers and advocates from various environmental or public-interest groups.

Only a handful of registered lobbyists worked for Clinton, however.

Bush's embrace of lobbyists marks a key difference because it allows "those who are affected by the regulations to determine what the ground rules should be," said David Cohen, co-director of the Advocacy Institute, which helps teach nonprofits how to lobby in Washington.

While previous Republican presidents hired lobbyists, "the Bush administration has made it rise in geometric proportions," Cohen said, meaning Bush is "capturing the instruments of government and using them for the ends" that favor Bush's political supporters.

"In the Bush administration," said U.S. Sen. Joe Lieberman, D-Conn., "the foxes are guarding the foxes, and the middle- class hens are getting plucked."

Republicans and their lobbying allies reject the idea that industry is embedded in the administration.

"Foxes? No," Vice President Dick Cheney told The Denver Post. "I think we have a good track record."

The clout of industry is balanced by the power of labor unions, trial lawyers and public-interest groups, said Jerry Jasinowski, chairman of the National Association of Manufacturers.

"The notion that somehow business gets everything and we've gotten a free ride is absurd," he said.

Still, the lobbyists-turned-policymakers control or influence health care, food safety, land use, the environment and other issues touched by government.

HEALTH CARE

Ann-Marie Lynch

The drug-industry lobbyist who fought price controls joined the Health and Human Services Department and has helped drug companies avoid the limits.

Top aides in the Department of Health and Human Services provide analysis and advice to the president on key consumer issues, including prescription-drug policies. In doing so, they consider the needs of pharmaceutical companies seeking revenue for future research, and consumers struggling to afford increasingly costly medications.

In June 2001 Bush installed Ann- Marie Lynch, a lobbyist for the drug-company trade group Pharmaceutical Research and Manufacturers of America, to help set those policies.

As a lobbyist, Lynch fought congressional attempts to cap prices for drugs. Price controls, she argued, would hamper medical innovation.

Thirteen months after Lynch became deputy assistant secretary in the office of policy, her division issued a report that praised brand- name drugs. It warned that "government- controlled restrictions on the coverage of new drugs could put the future of medical innovation at risk and may retard advances in treatment."

Consumer advocates say that's nonsense. Other countries innovate despite price controls, said Gail Shearer, director of health policy analysis for Consumers Union, nonprofit publisher of Consumer Reports.

"They haven't taken as seriously their job of making medicines affordable to all Americans," Shearer said. "When you talk about the need for (drug) innovation, you have to put it in the context of, will people get the wonder drugs?"

Critics say the report influenced congressional debate over a Medicare drug policy that, among other things, banned government from using Medicare's buying power to cut drug prices. The legislation will mean an extra $139 billion in profit over eight years to drug companies, Boston University researchers said.

Republicans in Congress used arguments that came "directly out of Ann-Marie Lynch's mouth" and from the trade group she previously worked for, said Rep. Sherrod Brown of Ohio, lead Democrat on the Energy and Commerce Committee's health subcommittee.

Lynch declined to talk to a reporter. HHS spokesman Bill Pierce said the report was not intended to sway Congress. Provisions banning Medicare from negotiating drug prices date to 2000, he said.

Lynch also blocked the release of about a dozen completed research reports that challenge drug-company claims, three former employees said. Pierce said Lynch decides research topics and which reports are released.

One 2001 report, for example, criticizes Medicare plus Choice (now known as Medicare Advantage). Its findings suggested that running the Medicare prescription-drug benefit through private health companies - the method the administration ultimately chose - would be more expensive and would not serve rural areas well.

"Very few of (the private companies) manage to bring in the benefit cost effectively," said Mark Merlis, the private health policy consultant who wrote the report.

Thomas A. Scully

The former hospital lobbyist presided over an agency that helped a chain he once represented win a favorable settlement in a Medicare fraud case.

Thomas A. Scully represented the nation's for-profit hospitals as a lobbyist before being hired by the Bush administration in June 2001 to head the federal Centers for Medicare & Medicaid Services.

Eight months after Scully arrived at the Medicare and Medicaid agency, it moved to settle final claims involving HCA Inc., a hospital chain that was the biggest member of Scully's former employer, the Federation of American Hospitals. HCA Inc. faced allegations it fraudulently overbilled the government for Medicare cases.

Under the terms agreed to in June 2002 by Scully's agency, HCA would have settled for $250 million. Medicare fraud cases typically are ironed out with Justice Department participation, but Scully agreed to those terms on his own, said John R. Phillips, an attorney who represented whistle- blowers in the case.

"The $250 million was a total sellout by Scully, who totally negotiated it

behind Justice's back," Phillips said.

It also was handled in a way that protected the company from a full review of its cost reports and the triple- damage civil fines that can be imposed in fraud cases, he said.

Sen. Charles Grassley, R-Iowa, asked Justice in October 2002 if that deal was "too lenient."

Justice delayed the settlement until June 2003.

HCA, the nation's biggest for-profit hospital company, eventually paid that $250 million, plus $631 million in civil penalties and damages and $17.5 million to states.

Scully's ethics agreement did not require him to officially avoid cases involving HCA. But Scully said he steered clear.

"I recused myself from everything involving HCA-specific issues or policy and was not involved in any way, shape or form," Scully said. "Every time anything came up (regarding) HCA, I left it to my deputies."

But Grassley in a June 25, 2002, letter to a Justice Department lawyer said comments by Scully "have given me great concern that there is an active, ongoing effort underway to change or modify enforcement (on Medicare fraud) policy that in my view could significantly undermine the (law)."

Scully has since left the administration for consulting jobs with a lobbying firm and an investment company that represent Medicare providers.

Daniel E. Troy

The lawyer who represented major drug companies still fights for causes that benefit them as chief counsel at the Food and Drug Administration.

Daniel E. Troy was well-known at the FDA before he arrived in summer 2001 to work as chief counsel, the top legal position in the department.

As a lawyer in private practice, Troy repeatedly sued the FDA, arguing that it had only limited ability to regulate drug companies. He filed those suits through the Washington Legal Foundation, a group funded by businesses, including drug companies. Donors include charitable foundations run by Pfizer Inc., Procter & Gamble Co. and Eli Lilly & Co.

Troy also represented Pfizer through his firm, Wiley, Rein & Fielding. Troy said in an e-mail to a reporter that his Pfizer work was mainly communications and insurance law, and averaged only 80 hours a year.

At the FDA, Troy still is fighting for causes that benefit drug companies.

It's unclear whether any of pharmaceutical firms responded to his December request for lawsuits the FDA might get involved in.

By the time Troy made that offer, he had already intervened in three drug-company cases as FDA chief counsel. One involved Pfizer.

In court briefs, the FDA argued that it determines which warnings a drug company must give consumers. Lawsuits filed in state courts arguing that drug-company warnings are inadequate therefore were invalid, the FDA says. One of the cases Troy challenged involves thousands of consumers who say they were harmed by painful withdrawal from an antidepressant.

Lawsuits accusing drug companies of telling consumers too little about side effects constitute the largest category of cases against drug companies, law professor O'Reilly said.

If Troy's legal position prevails, O'Reilly said, it would be catastrophic for consumers hurt by drugs. He said it would bar cases like the one filed against the makers of fen-phen, the combination of diet medications tied to heart problems. The makers of those drugs are settling with consumers for $14 billion. That case predates Troy's policy.

Troy, who declined to be interviewed, said in a written statement that the FDA is intervening in the lawsuits to protect "the safety, effectiveness and availability of important medical products."

He said that would be "adversely affected if judges and juries acting under state law had the power to substitute their judgment for the expert determinations made by FDA scientists."

Clinton's Justice Department, he added, took the same legal position, arguing that federal law pre-empts state law.

But prior to Troy, professor O'Reilly and one FDA official said, the government got involved only when a judge asked. Troy, in contrast, is seeking cases in which to intervene.

And the FDA now is staking a new legal claim, experts say: that its authority to determine drug labeling always trumps any claims made in state court.

The FDA is "taking sides in private litigation," said Thomas McGarity, a University of Texas Law School professor and president of the Center for

Progressive Regulation, which supports government regulation on health and safety issues.

The FDA asks drug-company attorneys to alert the agency to cases because otherwise "our rules might be undermined by contrary state findings" the agency is unaware of, said Peter Pitts, an FDA spokesman.

He added: "For people to infer that (FDA) decisions are made with anything but the public health as our focus is untrue, unfair and very ill-considered."

FDA officials also say they want to discourage frivolous lawsuits, which drive up costs.

A former FDA chief counsel in the Nixon administration, Peter Barton Hutt, said he supported the FDA's legal position but added, "I probably wouldn't be out there encouraging" lawsuits.

Troy oversees other FDA changes that provoked accusations that he is siding with drug companies.

In October 2001, the Health and Human Services Department gave Troy's office final approval over warnings telling companies they could be in violation of FDA rules. Those had previously been sent out by the FDA's drug-marketing division and district offices.

After that change, the number of warnings of questionable claims by pharmaceutical companies quickly dropped from an average of seven a month to two.

FDA spokesman Pitts said fewer letters were sent because the process was centralized.

"If you torture statistics long enough," Pitts said, "they confess to anything."

Others see this as dangerous to the public.

"This ... may be a welcome development for the drug industry, but it poses serious dangers to public health," Rep. Henry Waxman of California, the top Democrat on the House Committee on Government Reform, said in an Oct. 1, 2002, letter to HHS Secretary Tommy Thompson.

Waxman said the bad policy decision was "exacerbated by the appointment of Daniel Troy."

The investigative arm of Congress, the General Accounting Office, in October 2002 also found that, under the new system, warning notices "have taken so long that misleading advertisements may have completed their

broadcast life cycle before FDA issued the letters."

Waxman described the delays as "a development that benefits the powerful pharmaceutical industry at the expense of consumers."

FOOD SAFETY

Charles Lambert

As a USDA official, the former lobbyist for the meat industry who opposed labeling told a hearing that mad cow disease was not a threat.

Mad cow disease had yet to surface in the United States last June when a U.S. Department of Agriculture official - a meat- industry lobbyist only eight months earlier - bet his job on the promise that the ailment couldn't sneak into the country through imports.

Congress had just passed a law requiring meat labels to state which country a cow lived in before slaughter. Food safety groups say those labels could, among other things, help consumers avoid buying beef from countries with mad cow disease.

The USDA opposed such labeling. The person making the agency's case, Deputy Undersecretary Charles Lambert, knew the arguments against such labels. He'd made them as a lobbyist for the National Cattlemen's Beef Association.

Lambert spent 15 years at the Cattlemen's Association working in Denver before coming to Washington, D.C., where he worked as lobbyist and chief economist. He left in December 2002 to join the USDA as undersecretary for marketing and regulatory programs.

When asked about mad cow and the labels, Lambert said mad cow disease wasn't a threat.

"Is there a possibility that it could get through?" Rep. Joe Baca, a California Democrat, asked Lambert at a hearing last June.

Lambert answered, "No, sir."

"None at all?" Baca asked.

"No," Lambert replied.

"You would bet your life on it - your job on it, right?"

Lambert answered, "Yes, sir."

The disease was discovered in the U.S. six months later - apparently brought here by a cow from Canada.

Lambert now says, "I overstated my case."

More than a dozen other high-ranking USDA officials appointed under Bush also have ties to the meat industry.

"Whether it's intentional or not, USDA gives the impression of being a wholly owned subsidiary of America's cattlemen," said Carol Tucker Foreman, director of the Consumer Federation of America's Food Policy Institute. She served as a USDA assistant secretary in the Carter White House. "Their interests rather than the public interests predominate in USDA policy."

When he came to the USDA, Lambert signed an agreement stating that in his first year he would "not participate personally and substantially in any particular matter involving specific parties in which (Cattlemen's) is a party or represents a party, unless I am authorized to participate."

During that period he met at least 12 times with current or former members of Cattlemen's and its affiliates, an office calendar obtained by The Denver Post shows.

Lambert said that at any meeting where policy was discussed, he acted only as a facilitator and that another USDA person was present. The calendar shows meetings where other USDA people were present, although it is not always clear what was discussed.

The rest of those meetings were at social settings, he said.

"You're not required to sever all personal and past relationships ... when you come to federal employment," Lambert said in an interview.

ENVIRONMENT

Jeffrey Holmstead

The EPA official, a lawyer, formerly worked for a firm that represents utility companies, which are among the biggest air polluters.

When the Environmental Protection Agency issued proposed changes to air pollution rules Jan. 30, the wording troubled Martha Keating, a scientist with environmental advocacy group Clear the Air.

"It struck me that I had seen this before," Keating said.

At least 12 paragraphs were identical to or closely resembled a Sept. 4, 2003, proposal given to the Bush administration by Latham & Watkins, a law firm that represents utility companies.

The EPA official overseeing the proposed changes is Jeffrey Holmstead, who until he joined the EPA in October 2001 had worked as a lawyer at Latham & Watkins. His clients included a chemical company and a trade group for utility companies. Power plants are among the biggest air polluters.

Holmstead oversees the EPA division that governs air pollution.

Environmental groups say the rewrite poses a health threat because it slows the reduction of mercury emissions by as much as 11 years. Those emissions can end up in water where they contaminate fish. Forty-three states have issued advisories about fish consumption because of mercury pollution, the U.S. Public Interest Research Group said.

One effect of the proposal would be that 168 of 236 Western- based plants, including those in Colorado, would not be required to reduce those emissions at all, Keating said.

Lobbyists commonly suggest wording for legislation. But even EPA Administrator Mike Leavitt objects to how this language was lifted.

"To take something from a source without noting it doesn't seem to be the normal course of business, and it shouldn't have been done," EPA spokeswoman Cynthia Bergman said, speaking for Leavitt.

Holmstead declined to comment.

Six Democratic senators are asking for an investigation. Ten attorneys general and 45 senators - including three Republicans - have asked Leavitt to void the proposed rule because of undue industry influence.

The inspector general hasn't decided whether to investigate. Bergman said the final pollution rule is still under development.

LAND USE

J. Steven Griles

The tenure of the veteran energy lobbyist at the Interior Department was labeled an "ethical quagmire" by the agency's inspector general.

At the U.S. Department of the Interior, which oversees some 507 million

acres of national parks, refuges and rangeland, top officials weigh the competing merits of resource conservation and development.

Bush named J. Steven Griles, a veteran energy industry lobbyist, as the department's second-highest official in June 2001.

Griles earned $585,000 a year as a lobbyist, representing an array of oil, gas and other energy interests. As Interior's deputy secretary, he continues to receive $284,000 a year for four years to pay him for the value he had created for the firm by bringing in clients.

Upon entering the government, Griles had pledged to remove himself from deliberations that affected his former clients.

This year, the department's inspector general called Griles' tenure an "ethical quagmire."

"Mr. Griles' lax understanding of his ethics agreement and attendant recusals, combined with the lax dispensation of ethics advice given to him, resulted in lax constraint over matters in which the deputy secretary involved himself," the inspector general concluded.

That report or a subsequent review by the U.S. Office of Government Ethics found other issues:

A former business partner of Griles' hosted a party for Griles and top Interior officials for land and mining.

Also, a former Griles client, Advanced Power Technologies Inc., won some $2 million in no-bid contracts from his department after two people Griles supervised pressed APTI's case.

And Griles urged the EPA not to press concerns over a plan to open 8 million acres in Wyoming and Montana to gas drilling by companies including six of his former clients. The project is proceeding while a task force studies the matter.

The investigations of Griles found no illegalities. Secretary of the Interior Gale Norton announced that her right-hand man had been "cleared."

Review of ethics guidelines

Neither the Bush administration nor Congress has called for a systematic review of government's ethics guidelines.

They should, says Stuart Gilman, president of the Ethics Resource Center, a nonprofit group in Washington that works with companies and government

groups.

"The question is, are we dealing with the problems we're currently confronting in government?" Gilman said.

Complaints about ethical breaches within government in some cases can be politically motivated, said Gilman, who also worked in the Office of Government Ethics under Presidents George H.W. Bush and Clinton.

At the same time, Gilman said, governmental leaders have a responsibility to eliminate both real and perceived conflicts of interest.

"For government to function, government must have the confidence of people," Gilman said. "If people don't believe the government is acting fairly, it encourages everyone to cheat."

- Denver Post staff writers John Aloysius Farrell and Mike Soraghan and researchers Tamania Davis, Barbara Hudson and Regina Avila contributed to this report.

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