Testimony of

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STATEMENT OF JAY P. McCLOSKEY
For the Hearing Before the Committee on the Judiciary
United States Senate
on
"Evaluating the Propriety and Adequacy of the
OxyContin Criminal Settlement"
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MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I thank you for allowing me to testify in connection with this Hearing. I served as the United States Attorney for the District of Maine from 1993 to 2001 and, prior to that, as an Assistant United States Attorney in that office from 1980 to 1993. During the course of my career as a prosecutor, I handled many drug cases as an Assistant United States Attorney and I continued to take a very active role in drug prosecutions as United States Attorney. In late 1999 and early 2000, I became aware of a growing problem in Maine involving the abuse of prescription drugs that included, but was not limited to, OxyContin. I was deeply concerned with this disturbing development. So, in February 2000, I sent a letter to all of Maine's practicing physicians warning them about increasing problems with the illegal diversion and abuse of OxyContin and other opiate-based prescription medications. Shortly thereafter, in March 2000, I received a call from Purdue Pharma's Medical Director, who asked me about the level of OxyContin abuse in Maine. He asked whether I would be willing to meet with him and other Purdue Pharma executives in order to discuss and better understand the problem, but I deferred his request.

Purdue Pharma's initial contact with me occurred at a time when Maine law enforcement officials were just discovering the extent of the opiate abuse problem, and I found it difficult to envision how the manufacturer could help stop the illegal diversion and abuse of OxyContin. As I became more knowledgeable about the nature and extent of the problem, I realized that traditional law enforcement techniques alone would have very little impact on the fast-growing abuse of prescription opiates. As a consequence, my office began to develop a broad-based public education initiative to combat prescription drug abuse as a supplement to the more traditional law enforcement response. I also began to give more thought to the possibility that Purdue Pharma could help me and other law enforcement officials reach an audience of health care providers to whom law enforcement generally did not have access.

As a consequence, in September 2000 I organized a meeting attended by federal prosecutors, state and federal drug enforcement agents, local police chiefs and their investigators, and Purdue Pharma executives. Rather than sending lower level executives, Michael Friedman, then Chief Operating Officer, Howard Udell, the Chief Legal Officer, and the company's Medical Director attended this meeting themselves. The Purdue Pharma executives expressed surprise at the extent of the diversion of OxyContin in Maine. They said that Purdue Pharma had a similar product, MS Contin, on the market for some years and they had not experienced any significant diversion problems with that product. However, once I explained the basis for our knowledge about OxyContin abuse, which included both numerous undercover purchases of OxyContin and other information about the availability of OxyContin "on the street" that was derived from informant debriefings, the Purdue Pharma executives responded positively. They pledged that they would do whatever they could to assist the efforts of law enforcement officials to address the illegal diversion of OxyContin. Howard Udell specifically said to me, "We want to do what is right." I remember these words very distinctly, and although I did not give any special weight to them at the time, I later recalled them on several occasions as I observed all that Purdue Pharma later did, and offered to do, in an effort to reduce OxyContin abuse.

Let me provide some examples of the extraordinary programs and assistance provided.
?? Purdue Pharma allowed law enforcement to make unrestricted presentations - Purdue had no input or control over the content of the presentations - at Purdue Pharma-sponsored medical seminars to describe the nature and extent of the illegal diversion of opiates. This approach gave law enforcement officials access to the medical community in a way that otherwise would not have been possible.
?? Purdue Pharma offered to provide, at no cost to prescribers, tamper-resistant prescription pads, because the alteration of prescriptions was a significant source of illegal diversion. In fact, Purdue Pharma paid for the development of tamper-resistant prescription pads, and then distributed them to healthcare professionals free of charge.
?? Purdue Pharma sent informational brochures to doctors and pharmacists that provided warnings about the dangers of prescription drug abuse and how to spot drug seekers. Prior to sending the brochures, Purdue Pharma willingly adopted suggestions that I made for changes to the brochures.
?? When I told Purdue Pharma executives that appropriate educational materials for middle-school students did not exist, Purdue spent months and millions of dollars developing educational materials and making them available to schools at no cost. I received substantial feedback from Maine school officials indicating that students viewed these materials as informative and effective. Reaching youths and educating them about the dangers of prescription drug abuse is absolutely essential if we want to succeed in reducing the level of opiate abuse.

Beyond educating healthcare professionals and law enforcement and disseminating important tools to address the problems of abuse and diversion, Purdue Pharma also took steps that negatively affected their commercial interests. In April of 2001, I told Purdue Pharma executives that drug agents in Maine had made an undercover "street" purchase of a 160-milligram OxyContin tablet that could be very dangerous if abused. I told Purdue Pharma that I was worried that this high strength could present an overdose danger to a teenager who made the mistake of abusing OxyContin on even one occasion. Approximately two weeks later, a Purdue Pharma executive told me that the company would voluntarily take the 160-milligram OxyContin product off the market in an effort to prevent the health risks that might come from abuse of that particular strength. Many pain advocates criticized Purdue Pharma for taking this legitimate product off the market. In my opinion, Purdue Pharma's decision to do this was an extraordinary example of corporate responsibility.

It should not be forgotten that these efforts by Purdue Pharma occurred in 2000, 2001 and 2002. This is significant because in those years we, meaning law enforcement officials, were all first grappling with the evolving problem of increasing prescription drug abuse that was first noted in Maine and shortly thereafter in southern Virginia, West Virginia and eastern Kentucky. I further point out that what might seem to be an obvious example of "corporate responsibility" today was not so clear when the OxyContin abuse problem initially emerged. It is important to note the time frame because Purdue took the steps that I described long before it became aware of the investigation in the Western District of Virginia in December 2002.

After I left the government and entered private law practice in 2001, Purdue Pharma consulted with me about its continuing efforts to reduce the diversion and abuse of OxyContin. In my capacity as a consultant, I worked on several projects to combat OxyContin abuse in close conjunction with Purdue Pharma executives from approximately July 2001 through early 2004. In the interest of full disclosure, I was paid for the consulting services that I provided to Purdue Pharma during this period. Except for travel expenses, I am not being compensated for my testimony here today. During that time, I worked closely with several Purdue Pharma executives, and I came to know them and to understand the company's corporate culture. I was deeply impressed by the unmistakable interest in the public welfare that emanated from the executives with whom I worked. In every instance, Purdue Pharma executives not only fully supported my public interest-oriented recommendations, but they also ensured that they were implemented in a thorough and meaningful fashion. They did so even when the recommended initiatives ran counter to the company's economic interests and when the programs exposed Purdue Pharma to potential criticism from the pharmaceutical industry or from the pain patient advocate community.

Let me provide a few examples. Contrary to the pharmaceutical industry's position at the time, as well as that of some leading physician and patient advocacy groups, Purdue Pharma championed the adoption of Prescription Monitoring Programs ("PMPs"). In that connection, Purdue Pharma released a document in October 2001 outlining the attributes of an appropriately designed state electronic PMP, and announced its support of such programs. Purdue then became involved in the legislative debate concerning such programs, meeting with state legislators and state healthcare professional associations to convince them that a prescription monitoring program was consistent with the

public interest. By November 2006, 33 states had enacted legislation establishing prescription monitoring programs. Purdue also supported congressional legislation designed to authorize federal funding for states that would implement prescription monitoring programs. Purdue Pharma's support for the passage of these statutes was praised by several elected leaders.

In the summer and fall of 2002, before Purdue Pharma was aware of any criminal investigation of its activities, Purdue Pharma developed and implemented a procedure to advise law enforcement and state medical boards concerning suspicious OxyContin prescribing practices by medical professionals. In that connection, Purdue Pharma required its sales force to report to the company's Office of General Counsel any unusual prescribing activity or troubling observations made in connection with their sales calls. In those circumstances, Purdue Pharma's policy foreclosed sales personnel from having further contact with the suspicious prescriber until the General Counsel's Office had reviewed the situation. When appropriate, the General Counsel's Office forwarded relevant information to government officials. In establishing this program, Purdue Pharma sought my advice as to what might constitute suspicious activity in a physician's office so that this information could be passed on to its sales representative in the form of a Standard Operating Procedure. After this program had been in operation for some time, Purdue Pharma called on me to review the company's files and decisions as to whether or not the observed conduct should be reported to law enforcement or medical licensure authorities. As part of that process, I met with members of Purdue Pharma's Office of General Counsel who were working on this anti-diversion program, and we spent hours together reviewing these files. Purdue Pharma wanted a law enforcement perspective on whether its lawyers were appropriately evaluating the data that they received after implementing the suspicious prescribing practice program. This experience underscored my view that Purdue Pharma was undertaking these programs with sincere commitment and for the best of motives. I am aware of no other pharmaceutical company that has undertaken such extraordinary efforts.

After Purdue Pharma became aware that there were concerns about international diversion of OxyContin, Purdue Pharma created unique markings for OxyContin tablets in order to assist law enforcement in determining whether tablets that were seized "on the street" originated from the company's facilities in the United States, Canada or Mexico. After concerns surfaced about diversion from its manufacturing facility in Mexico, Purdue Pharma stopped the manufacturing of OxyContin in Mexico at great cost to the company, and despite severe criticism from the Mexican distributor, who, incidentally, later sued Purdue Pharma after the company took this anti-diversion action.

Some individuals have criticized Purdue Pharma's efforts as nothing more than public relations. I think that this sort of commentary is extremely unfair. I am convinced that Purdue Pharma made real contributions to suppress the abuse of OxyContin, and I believe that the company went well beyond what any pharmaceutical company, even others that market scheduled opioids, has ever done. In my opinion, Purdue Pharma is a company that tried very hard to make a difference. It is clear that drug abuse and related prescription medication diversion are daunting problems. With billions of dollars in financing, the Drug Enforcement Administration and other law enforcement agencies have strived for decades to have a meaningful impact on the widespread problem of drug abuse. Yet, when law enforcement suppresses the availability of an abused drug, another quickly takes its place as the drug of choice amongst substance abusers. Purdue Pharma executives were not hanging window-dressing. They embraced each of the company's anti-diversion initiatives, and many others I have not detailed today, without any hesitation whatsoever. Purdue Pharma executives tried to treat the public welfare as their first priority at every step without hurting legitimate pain patients. I can think of no better way to measure a corporate culture.

Since September of 2000, I have had an opportunity to observe Purdue Pharma and its executives in a variety of different contexts: as United States Attorney, in meetings with dozens of attorneys who were handling OxyContin civil litigation, at Congressional hearings, at meetings with DEA officials and in private. In all of my dealings, I do not recall even one instance in which a Purdue Pharma executive favored the company's business interests over efforts to curb OxyContin diversion and abuse. In fact, just the opposite is true, which is obvious from what I have already described. Although Purdue Pharma executives are advocates for legitimate pain patients not being denied access to OxyContin, they have spent considerable personal and professional time in a genuine effort to reduce OxyContin diversion and abuse.

Although I do not in any way condone the misstatements by sales representatives that formed the basis for Purdue Pharma's plea to misbranding, I can state unequivocally that I never observed any instance in which such activity was approved. Further, I have never heard any suggestion made by a Purdue Pharma executive, or any other Purdue

Pharma employee for that matter, that OxyContin was less addictive, less subject to diversion and abuse, or less likely to cause tolerance or withdrawal than other opiates. I have no doubt that the Purdue Pharma executives would have stopped any Purdue Pharma employee from making these improper claims had they known about them.

Because the executives pleaded guilty to a strict liability offense, knowledge or criminal intent was not at issue. Indeed, Judge Jones found that the government had not presented any evidence that the accused executives had knowledge of the wrongdoing in the case, and I understand that there was no such evidence. In my experience, bringing a criminal case in these circumstances against individuals is highly unusual. While, by definition, strict liability offenses do not require knowledge or intent, to the best of my knowledge in every other case where the government has brought this charge, the individuals actually knew of or had been warned about the misconduct that was the subject of the prosecution in those cases. Indeed, the government's use of the statute in the circumstances surrounding the prosecution of Purdue Pharma and its top executives is strikingly contrary to the position that the United States took before the Supreme Court in the seminal case on this issue, United States v. Park.1 In the Park case, government prosecutors assured the United States Supreme Court that corporate officials who are technically deemed by statute to be "responsible corporate agents" would ordinarily not be prosecuted without some further evidence of culpability. This element was lacking in the Purdue Pharma case. For that reason, the criminal prosecution of the executives in this case, was, in my opinion, unprecedented and a regrettable choice of prosecutorial discretion.

In conclusion, I want to thank the Committee for hearing my statement and I will be happy to answer any questions the Committee may have.

1 United States v. Park, 421 U.S. 658 (1975).