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EVALUATING THE PROPRIETY AND ADEQUACY OF THE OXYCONTIN CRIMINAL SETTLEMENT

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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EVALUATING THE PROPRIETY AND ADEQUACY OF THE OXYCONTIN CRIMINAL SETTLEMENT

TUESDAY, JULY 31, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 2:36 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Cardin, Specter, Sessions, and Coburn.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good afternoon, Dr. Coburn. We are just a minute or two late because we were all at our various caucuses, but I had scheduled this hearing at the request of the distinguished senior Senator from Pennsylvania. Senator Specter has long expressed an interest in criminal liability for the introduction of dangerous or defective products into the marketplace. I agree with him that this is a very important issue and one where further congressional action may be warranted.

The hearing will examine the recent plea agreement between the makers of OxyContin and the Federal Government. Last month, this Committee held a hearing addressing the role of rogue online pharmacies in our Nation's growing prescription drug abuse problem. Among young people, prescription drugs have become the second most abused illegal drug, behind marijuana. In fact, if you exclude marijuana, more adults and teens report abusing prescription drugs than all other illicit drugs combined. I noted then that Purdue's admitted misrepresentations about the addictiveness and abuse potential of their product was very troubling.

The criminal conduct involved in the marketing of OxyContin has been one of the most tragic examples in recent memory of a company favoring the bottom line over the health of our Nation's citizens. The tragic irony is that the dangerous product they were talking about purported to help people manage pain. And I know that for many it has been effective. But for many others, this drug, and its diversion due to widespread distribution, has caused terrible harm—from addiction to in many instances death. Purdue made billions of dollars marketing OxyContin as a less addictive alternative to painkillers. Today, we will hear about what punish-

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ment the Justice Department found appropriate for this criminal conduct.

I look forward to discussing today with the witnesses how best to prevent this type of dangerous corporate decisionmaking from ever occurring again. Americans should not have their lives reduced to a mere factor in an actuarial table. While the makers of OxyContin have been prosecuted, have pled guilty, and are paying a multi-million dollar fine, no one from the company is going to jail. Frankly, I felt in my days as a prosecutor and I am sure others, like Senator Specter, who had the privilege of serving as prosecutors know that nothing focuses the mind as much as thinking you are going to be behind bars. Fines can sometimes become simply a cost of doing business. When you sit behind bars, you think far more about whether you did the right thing.

I believe it is fair to ask, in light of Purdue's profits of approximately $2.8 billion between 1996 and 2001, whether the $680 million in penalties they received in this plea agreement will serve as a deterrent to similar future conduct or just simply become part of the cost of doing business.

We will hear testimony today about the way Purdue's conduct has affected the lives of those who have lost loved ones as a result of taking OxyContin. Many are asking why the three executives who pled guilty were not given jail time. As I said before, nothing makes corporate executives think twice about malfeasance more than the prospect of the iron bars slamming shut.

The judge who presided over the plea agreement stated at the sentencing hearing: "I do not doubt that many of our fellow citizens...will deem it inappropriate that no jail time is imposed. It bothers me, too." I would say to the judge it certainly bothers me.

The United States Attorney who prosecuted the case will testify today about why he did not insist that the responsible corporate officials pay a similar price as the individuals who sell OxyContin on the street. I look forward to hearing from these witnesses.

[The prepared statement of Senator Leahy appears as a submission for the record.]

Senator Specter?

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman, for scheduling this hearing.

The criminal charge involves a matter where there was a plea to a felony offense, including an intent to mislead. According to the DEA, in just 2000 and 2001, there were 146 deaths in which OxyContin was determined to be the direct "cause of" or "a contributing factor to" the deaths and an additional 318 deaths that were "most likely" caused by OxyContin. In seeing the reports on this matter, with very substantial profits involved and a fine, albeit substantial, it has a very ominous overtone of insufficient prosecution efforts. Where someone places a dangerous instrumentality in commerce with reason to believe that a death may occur and a death does occur, that constitutes malice and supports prosecution for murder in the second degree.

I have long expressed my concern about such products in the marketplace, and that is why I suggested to Chairman Leahy that a hearing would be useful.

I believe that as a generalization—and I base this on substantial experience on this Committee—that there is insufficient oversight by the Committee on what happens in the Department of Justice and what happens in the criminal prosecutions.

I have since been contacted by attorneys representing the defendant company who contend that there is a gross misstatement of what the underlying facts are. Well, I am prepared to listen. This Committee is prepared to listen. But Senator Leahy puts his finger on the issue, that is, if there is reason to believe that it is a dangerous instrumentality and that deaths will occur and deaths do occur, that supports a homicide prosecution. And it is not deterred by a fine.

I see fines with some frequency and think that they are expensive licenses for criminal misconduct. I do not know whether that applies in this case, but a jail sentence is a deterrent and a fine is not—not a corporate fine in the context of the kind of profits which are involved here.

Since this hearing was scheduled, we have a very heavy commitment this afternoon to the Director of National Intelligence. We have been called upon to revise the FISA law, so at least speaking for myself, I am going to have to conclude my participation by 4 o'clock. I do not control the gavel, but the Chairman—

Chairman LEAHY. If you would yield on that, you will control the gavel, because I am going to be leaving before that.

Senator SPECTER. If I control the gavel, the hearing will be over by 4 o'clock.

Chairman LEAHY. And I am going to turn the gavel over to you.

Senator SPECTER. Well, we have the time limits of 5 minutes, and if I have the gavel, I would request—in fact, even if I did not have the gavel, I would request the witnesses stay within the time limits to give the maximum time for dialog. But we have enough time to give this a thorough hearing.

I had a call from Senator Coburn, who is concerned about the adequacy of the witness list, and I immediately said the witnesses he wanted to add I thought were fine. And we have an expert here—we have a couple of experts: one in the medical field and one in the legal field. So we will see how it goes.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you.

Mr. Brownlee, would you please stand and raise your right hand? Do you solemnly swear that the testimony you will give in this matter will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. BROWNLEE. Yes, sir.

Chairman LEAHY. Thank you.

Senator COBURN. Mr. Chairman, might I have the privilege of having an opening statement?

Chairman LEAHY. Certainly.

STATEMENT OF HON. TOM COBURN, A U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator COBURN. First of all, what has happened with OxyContin in terms of how it has been abused represents some of the greatest problems we have in this country with poly drug abuse. As a practicing physician, as a cancer survivor, as somebody who has prescribed this medicine, I am somewhat concerned with the direction we are taking, and the question I would ask of the Chairman and the Ranking Member is: Where is our study on Lortab and the drug and poly drug abuse with Lortab? Where is our study and our hearing on Coumadin and the people that die every year from Coumadin? The facts are that 98 percent of the people who died using this drug are poly drug abusers.

Now, whether there was intent to distribute outside of there—but I think it is really important that everybody recognizes what a Class II drug is. It is a highly addictive drug. And where is the question and the culpability on the medical community in this country who wrote the prescriptions for this drug? They read the PDR. They read the approved statement, which fully outlines the dangerousness of this drug when used in an inappropriate manner.

The thing that concerns me, never was it alleged that this drug was designed to be ground up and used in an illegal fashion and that there was a motivation to do that. And yet we are coming after a drug manufacturer who may or may not—according to the plea, has pled guilty to something, but we are turning a blind eye to all the other areas.

The problem in this country is poly drug abuse. Ninety-eight percent of the people who have died with this on autopsy are found to have multiple other drugs.

Look at the other side of it. Look at somebody who has bone pain from metastatic bone cancer and say, Do we not want them to have this wonderful drug that makes life bearable instead of unbearable? We are not considering this in a balanced fashion, and I believe as a physician, No. 1, I ought to challenge my own profession. They created this problem by not following their own ethical standards and by writing prescriptions for drugs that they never should have written. And the same thing is going on with Lortab right now.

Final point. We need to be careful that we do not act as the FDA. This was an approved drug under Schedule II that everybody in the medical community understands the addictive potential and the danger of. And to hold no culpability for the physician community I think would be seriously in error.

And I thank the Chairman for allowing me an opening statement.

Chairman LEAHY. Thank you.

Mr. Brownlee, I expect that you are aware that your name appeared on at least one termination list of U.S. Attorneys. The Washington Post reported this list was prepared November 2006 by Mike Elston, who was the chief of staff of then outgoing Deputy Attorney General McNulty. Why do you think Mr. Elston put you on that list?

Mr. BROWNLEE. Well, Mr. Chairman, first of all, thank you for allowing me to be here today and to testify.

Chairman LEAHY. I am glad you are here, because as I told you before we started, as a prosecutor you have probably the best job in America. Go ahead.

Mr. BROWNLEE. Thank you, sir. I do not have specific knowledge of exactly why Mr. Elston placed me on that list. No one has come forward and told me. However, when I learned that I had been placed on the list—Mr. Elston is the one who informed me on March 14th of this year—I became concerned enough that I reported that event to the Justice Department that very evening. And so although I do not have any conclusive information as to why I was targeted for termination, I certainly had concerns about it and reported that.

Chairman LEAHY. Did you discuss it with Deputy Attorney General McNulty?

Mr. BROWNLEE. I spoke to Mr. McNulty the following day, on March 15th. I told him that my name had appeared on this list by Mr. Elston in an e-mail dated November 1, 2006, that I was concerned about it. And I outlined him the facts that I knew concerning that. He assured me that Mr. Elston was a good man. I had my own views of that.

Chairman LEAHY. Had you ever been given any negative evaluations by Mr. Elston or by anybody at the Department?

Mr. BROWNLEE. No, sir.

Chairman LEAHY. I find this interesting because you have such an interesting background that I was surprised you were on there. I realize I overlooked giving you time for an opening statement, which I will. I was just going to ask you two other questions, and I will stop with that.

In your written testimony, you say you began your investigation of Purdue's activities surrounding OxyContin in the fall of 2001.

Mr. BROWNLEE. That is correct.

Chairman LEAHY. You then spoke with officials at Main Justice, including Mr. Comey, about the charges you were considering. Were you given any direction or criticism or pressure from anyone in the Justice Department with regard to your investigation or your plea negotiations?

Mr. BROWNLEE. If I may split that into two answers, I spoke to Mr. Comey in 2005 concerning an issue regarding our application of the Thompson memo, which was in effect at the time that we were investigating this case. Mr. Comey had received information from defense counsel that the Western District was not applying that pursuant to DOJ policy. So Mr. Comey inquired. I felt the inquiry was serious enough that I actually grabbed one of my—not grabbed, but one of my prosecutors and I drove up to Washington from Roanoke and sat down with Mr. Comey and laid out for him exactly what we had done pursuant to Thompson, our methods for trying to acquire the necessary records to do this investigation.

Once Mr. Comey heard my explanation, he said, "Brownlee, you are fine. Go back to Virginia and do your case." And we did, and I never spoke to him about the matter—

Chairman LEAHY. Did you ever get any pressure from anybody else even after Mr. Comey left?

Mr. BROWNLEE. The only thing that ever occurred was from Mr. Elston himself. On October 24, I believe, 2006, that is the day that

this plea was to expire. We had provided counsel for the company on October 19th, I believe, the final Government offer to settle this case or they would face other things. And so that evening—we had received earlier that day authority from the Justice Department to go ahead and either accept the plea or charge the company. Mr. Elston, who I had only met on one prior occasion, on August 3rd—so I had only known him less than 90 days—contacted me and was inquiring about the case. He told me he had received a phone call from one of the defense lawyers about the case and that that counsel had once again said that we were moving too quickly, that they needed more time, those kinds of things. And through his questioning of me, I sensed that he was inquiring almost on their behalf.

I asked him if he was calling on behalf of the Deputy Attorney General, and I was at home at this time. He told me he was not. Once I learned that he was not speaking on behalf of Mr. McNulty, based on the fact he had never attended any substantive briefings and he was one that I did not feel understood the case, I simply just kind of dismissed him and told him that I had authority from Mrs. Fisher to proceed forward and we were going to do just that and he needed to back out of the way of the case. Ultimately, he complied with that, and the company accepted the plea that evening.

Chairman LEAHY. Thank you. And please feel free to go ahead and give your opening statement. I apologize. Sometimes I forget the procedure here, being new in this job.

Go ahead and give your opening statement, Mr. Brownlee.

STATEMENT OF JOHN L. BROWNLEE, UNITED STATES ATTORNEY, WESTERN DISTRICT OF VIRGINIA, ROANOKE, VIRGINIA

Mr. BROWNLEE. Chairman Leahy, Senator Specter, and members of the Committee, thank you for holding this hearing and allowing me the opportunity to testify.

During the past 5 years, I led a team of career prosecutors from my office and the Department of Justice, as well as State and Federal investigators that conducted a sweeping investigation of the manufacturer and distributor of the painkiller OxyContin. Bringing this company and its executives to justice was a difficult and important challenge, and I am grateful for the hard work of the law enforcement professionals upon whom these convictions rest. They represent the very best of our Nation's law enforcement, and I am honored to serve with them.

According to the evidence, Purdue began using focus groups of primary care physicians in 1995 to determine whether such physicians would be willing to prescribe OxyContin for patients with non-cancer pain. These focus groups showed that what doctors wanted was a long-lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue set out to do.

Despite knowing that OxyContin had an abuse potential similar to that of morphine and was at least as addictive as other pain medications on the market, in January 1996, Purdue began mar-

keting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

Due in part to Purdue's aggressive and misleading marketing campaign, prescriptions for OxyContin skyrocketed, increasing from approximately 300,000 in 1996 to nearly 6 million in 2001. As OxyContin became more available, its abuse and diversion increased, and this increase had a devastating effect on many communities throughout Virginia and America.

On May 10, 2007, Purdue pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and agreed to pay $600 million, an amount that represented approximately 90 percent of the profits for the sale of OxyContin during the time period of the offense. Purdue also was required to subject itself to independent monitoring.

In addition, Purdue's President Michael Friedman General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenheim pled guilty to a misdemeanor charge of misbranding OxyContin. These defendants were placed on supervised probation for 3 years, ordered to perform 400 hours of community service, and collectively pay $34.5 million in criminal fines.

Like other high-profile prosecutions, this case has not been free of controversy. It has been suggested that my office attempted to demonize OxyContin and that our decision to charge the executives was "a regrettable choice of prosecutorial discretion." On the other hand, our decision not to seek active incarceration also has been questioned.

After studying this case and the evidence carefully, I am confident that the facts and law compelled our decision to prosecute and sentence this company and its executives in precisely the manner in which we did. The three executives pled guilty to a strict liability misdemeanor offense based on the fact that they were the responsible corporate officers of this pharmaceutical company. This misdemeanor charge required no proof of intent or actual knowledge of the violations to establish their guilt.

The intent of the statute is to impose the highest standard of care on certain corporate officials. The three defendants had no prior criminal records, and the Sentencing Guideline range for each defendant was 0 to 6 months. Under these circumstances, I decided, and the court has agreed, that prison sentences were not necessary to adequately punish these defendants.

Convictions of the corporate officials will have significant consequences. Each defendant will bear the stigma of being a convicted criminal. These convictions also will send a strong warning to executives of other pharmaceutical companies that they, too, will be expected to exercise the highest standard of care.

During the last several years, I have spoken to many people who have been harmed or who have had a loved one harmed by OxyContin—people like Marianne Skolek, whose daughter Jill died from OxyContin and whose grandson, Brian, will now grow up without his Mom. My belief is that these convictions have advanced the cause of justice and I hope offer some measure of closure for those who have suffered. These convictions have confirmed what

many believed for a long time: that Purdue's marketing of OxyContin was deceptive and criminal.

It is important to note that most of the people never claimed that Purdue was solely responsible for their loved one's death. They just wanted Purdue to tell the truth about the drug. The investigators and prosecutors who built this case have brought that truth to light.

On April 1, 1940, Attorney General Robert Jackson spoke to a group of United States Attorneys who had assembled in the Great Hall at Main Justice. The future Supreme Court Justice reminded those Federal prosecutors of their ethical and legal duties in pursuing justice, and I quote: "What every prosecutor is practically required to do is to select the cases for prosecution and to select those in which the offense is the most flagrant, the public harm the greatest, and the proof the most certain."

I am confident that our prosecution of Purdue and its executives and the sanctions imposed are consistent with Department policies and Robert Jackson's mandate for justice.

I thank the Committee for allowing me to appear before you today, and I would be pleased to answer your questions. Thank you, sir.

[The prepared statement of Mr. Brownlee appears as a submission for the record.]

Chairman LEAHY. Well, thank you very much, Mr. Brownlee, and I must state that I am very pleased to have you here, as I said to you not only publicly but privately before.

I also should note I appreciate your duties in the Judge Advocates Corps in the Army Reserve.

Mr. BROWNLEE. Thank you, sir.

Chairman LEAHY. it is probably a little bit different than your days as a paratrooper.

Mr. BROWNLEE. Yes, sir.

Chairman LEAHY. And some days that may look like it is more enjoyable.

Mr. BROWNLEE. Some days jumping out of the plane looks pretty good, Senator. Thank you.

Chairman LEAHY. I have done it once with the Golden Knights, and I would do it again in a second. And I hope my wife did not hear me say that because there would be probably a vote on that.

I turn the gavel over to Senator Specter.

Senator SPECTER. [Presiding.] Thank you very much, Mr. Chairman.

Mr. Brownlee, the company pled to a felony offense, including an intent to mislead.

Mr. BROWNLEE. That is correct.

Senator SPECTER. Chief Judge Jones said, "In the absence of legal proof by the Government that the individual defendants had knowledge of the wrongdoing charged or participated in it, I do not think prison appropriate."

Didn't the Government establish the underlying facts of the guilty plea that there was intent to mislead known to the individual defendants?

Mr. BROWNLEE. The answer is no, sir. The way we built this case was through—in December of 2002, we served an administrative

health care subpoena on the company, a multi- page document requesting records concerning the marketing of OxyContin. Once we got those records, conducted hundreds of interviews—these were millions of documents. We put them in a data base, and the investigators and prosecutors, through word search programs, went through those records and built a case against the company.

It was almost putting together a puzzle. It was a piece from a training manual. It was a piece from a call note.

Senator SPECTER. You ended up with an indictment that the corporation and the individual defendants—a corporation does not act by itself. A corporation acts through individuals, who become individual defendants—that they had an intent to mislead.

Mr. BROWNLEE. That is correct.

Senator SPECTER. And that resulted in, caused a great many deaths.

Mr. BROWNLEE. Yes, sir.

Senator SPECTER. Well, that being so, wasn't there legal proof that the individual defendants knew, since they intended to mislead, knew what they were doing?

Mr. BROWNLEE. Well, the evidence that we submitted to the court under the Agreed Statement of Facts did not include that, and I want to be very careful, Senator Specter, on how I speak concerning facts. All of these—much of these facts are protected under Rule 6(e). This was a grand jury—

Senator SPECTER. It was not presented to the court. Does that mean you did not have the facts? You did make a charge of intent to mislead?

Mr. BROWNLEE. We did as to the corporate entity. This was a corporate culture put together by many people.

Senator SPECTER. Well, I understand that. But the corporation does not act by itself. It is inanimate. It acts through people. So are you saying you could not identify the people?

Mr. BROWNLEE. I think it is fair to say that when we looked at the proof as to the corporate entity and we looked at the proof as to particular individuals, that proof tested out differently. As you well know, a corporation can be held criminally responsible for the acts of its agents. For instance, if a sales representative in another—

Senator SPECTER. I understand that. It could only be held liable for the acts of its agents. That is the way it is liable. And it can only be held liable for intent to mislead if its agents intended to mislead.

Mr. BROWNLEE. Yes, sir.

Senator SPECTER. But once you have agents who intend to mislead, you have the requisite proof to charge them with wrongdoing.

Mr. BROWNLEE. Right.

Senator SPECTER. Which the judge said he did not have. There is a total disconnect. Either you have a basis for saying that there is an intent to mislead or you do not. And if you have a basis for saying there is an intent to mislead, it is because individuals acted in a way which led you to that conclusion. And that being so, I do not see how you can have a conclusion that the individuals were not wrongdoers who deserved jail.

Mr. BROWNLEE. Well, Senator Specter, I think that the way it boils down is that—I mean, the premise, I believe, is correct, but when prosecutors and investigators look at particular evidence as to a particular individual, the outcome may very well be different.

For instance, in the example, let's say that that sales rep did go to a physician and provide misleading information about the product. There may be a sense, well, maybe you can prosecute that particular individual based on that statement. But then you look behind it and the defense would be, well, wait a minute, I was trained that way and look at the training manual. It has a graph in there that tells me this. And then you—

Senator SPECTER. If they were trained that way, they did not intend to mislead. Unless they knew that they were misleading, they did not intend to mislead.

Mr. BROWNLEE. Exactly.

Senator SPECTER. Once you have them intending to mislead, you have them engaged in conduct which merits jail.

Mr. BROWNLEE. Well, I think that the Senator is correct in the sense that under that scenario, that individual would not—we could not prove that that individual had the intent to mislead. But as a corporate entity—

Senator SPECTER. Well, could you prove that any individual had the intent to mislead?

Mr. BROWNLEE. We did not charge any individuals with the intent to mislead.

Senator SPECTER. I understand you did not charge them. That was not my question.

Mr. BROWNLEE. Yes, sir.

Senator SPECTER. My question was: Couldn't you prove that some individual had an intent to mislead?

Mr. BROWNLEE. The evidence in this case was reviewed by career prosecutors and investigators, and it was their judgment—and I agree with them—that under the evidence in this case, that the charging decisions, the felony for the company and the strict liability misdemeanors for the executives, were the appropriate charging decisions.

I must tell you, this case, no one wanted to bring these defendants to justice more than the Western District of Virginia. We initiated this in 2001. We spent 4 years going through millions of records, conducting hundreds of interviews. And this is the evidence of the case. And the career prosecutors who have gone through this have asked themselves—we asked ourselves the very questions you are asking me practically every day for years about this case. We are bound by the policies of the Department. The Ashcroft memo says you must charge the most serious, readily provable charge that the prosecutor has a good-faith belief that he or she can prevail at court, which means a lawyer would have to stand up and prove beyond a reasonable doubt to a unanimous verdict that a particular individual had the specific intent to mislead. And after reviewing this evidence, the charges that we came up with were the appropriate charges under this evidence, with this evidence.

Senator SPECTER. Well, the red light went on in our last exchange, and I believe in observing the time limits meticulously be-

cause I am asking everybody else to. But I do not agree with you. The memo, the famous Thompson memo, Deputy Attorney General Larry Thompson, "Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation." And where you have a basis for saying that there was an intent to mislead by an individual, that is enough.

I respect your professionalism and I respect your judgment, but speaking from an oversight capacity, I disagree.

Mr. BROWNLEE. Yes, sir.

Senator SPECTER. Senator Cardin?

Senator CARDIN. Thank you very much, Mr. Chairman.

Mr. Brownlee, welcome to the Committee.

Mr. BROWNLEE. Thank you, Senator.

Senator CARDIN. You are in a difficult position. It does not look like you can win on either side on this issue. But I first want to compliment you for bringing this case, for challenging the corporate structure and doing a professional investigation, which was extremely difficult to establish a case of criminal conduct and then presenting it in a way that you could succeed in court. It is challenging, and there are a lot easier cases that you could have worked on, but you chose an extremely difficult case. And I think it will have a major impact on corporate conduct in our country.

Mr. BROWNLEE. Yes, sir.

Senator CARDIN. Now, having said that, I think the point that Senator Specter is raising is a legitimate point. When we saw corporate greed hurt shareholders and employees, the Congress changed its laws. Sarbanes-Oxley was passed. And we changed the attitude that it is all right for corporations and businesses to do whatever they wanted to do, that Congress would take a more aggressive role.

I am just wondering whether we have a similar problem here. I think the point that Senator Specter raised about a company that is guilty of intentional conduct, misrepresenting information that leads to consumers being put at risk and losing their lives, that type of criminal conduct is actionable by more than just fines. And, yes, it is extremely difficult to be able to prove the actions of the agents, but somebody in this company is responsible for intentionally taking action to put the public at risk and cost people their lives.

So I am just wondering whether there is a need for change of law or other types of tools that can be made available, because I do think there are dual standards in America in our criminal justice system, that if you happen to be guilty of traditional type crimes, we would not think twice about letting you ought of jail. You are going to go to jail. But if you have a sophisticated network in which people are killed, you can avoid jail time. To me, that is something that is unacceptable in our system, and we need to look for how we change policy.

I want to thank Senator Coburn for his point because I think there is responsibility beyond just the pharmaceutical company here. People in the medical community who perhaps look for easy ways to deal with a problem and do not supervise properly or find out the medical history of an individual in prescribing certain

medications are also at least negligent, if not further than negligent.

So I think this case brings up the need for further review by perhaps Congress and by prosecutors as to whether we cannot have a more effective way to get the message out that our system of justice is going to be equally applied, and people who intentionally bring harm to other people are going to pay the consequences and not just the fine.

Mr. BROWNLEE. Thank you, Senator.

Senator CARDIN. That is more of a statement, I guess, than a question, but I really do want to come back to the point that this was not an easy case, and I admire your willingness to take this on. And I hope that the questioning you hear today is not interpreted as challenging the manner in which you proceeded, but we need to learn from this experience to make sure that those that are responsible for criminal conduct are held accountable in our system.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Cardin.

Senator Coburn?

Senator COBURN. Thank you.

Mr. Brownlee, I too want to compliment you for your service, one. It is extremely frustrating to be a physician in this country today and see all the problems we have in terms of access to care, lack of availability of drugs, drugs being used inappropriately. So looking at the problem that you had, I do not find any fault with what you did. But I have some questions that I would just like to have answered for me.

As you looked at all this documentation, did you see a systematic marketing plan in all areas of the country that was designed to oversell this product and underrepresent it, its risks?

Mr. BROWNLEE. I believe the evidence that was submitted to the court established the fact that the company as a corporate entity made a judgment that they were going to market this drug in a way that—and told doctors essentially that the basic premise is addicts would not like it. There was a graph that they used.

Senator COBURN. But that was throughout the country? You did not see different areas throughout—different areas of the country where you saw more penetration and less penetration where you saw somebody doing this to a greater extent than other areas? And the question I asked you was: Was there a marketing plan that you actually saw that said that this was an intent to do this?

Mr. BROWNLEE. Again, I think the evidence that was submitted certainly indicated that the company intentionally marketed the drug that it would be less addictive, less subject to abuse and diversion, and that was the evidence that has been submitted to the court.

As far as all parts of the country, I mean, it was a company that certainly marketed the drug in all areas of the country, and so, yes, that marketing was for everyone.

Now, some sales reps push harder than others. Some sales reps said different things. But you had a training manual that had these graphs in it, and I believe that—and some of other pieces of marketing that was company-wide. And so—

Senator COBURN. Well, if that is the case and these executives were responsible for that marketing plan, why are they not culpable along the lines that Senator Specter asked you?

Mr. BROWNLEE. Well, I would say, first of all, that they have been held accountable.

Senator COBURN. But in light of his question, in other words, you did not feel like you had the proof to convince a jury 100 percent that that was the case.

Mr. BROWNLEE. That is correct. We looked at this evidence very carefully for a long period of time. It was our judgment that the charges that we brought—the felony for the corporate entity, the strict liability misdemeanor for the executives—was sufficient—well, was appropriate under the evidence that we had.

Senator COBURN. So let me ask you another question. Why were the guys that were out doing this and violating what they knew this said, which is the label, why weren't they prosecuted?

Mr. BROWNLEE. I would answer that in two ways. First of all, the proof as to a particular individual, as we reviewed it, was difficult to establish beyond a reasonable doubt. As I gave the example to Senator Specter, there were some good defenses that because the corporation had training manuals, they had marketing materials, they had videos in which they were trained this way—

Senator COBURN. But, Mr. Brownlee, these are professional sales representatives. The one thing they are taught everywhere in the country is the label is what counts and you cannot go beyond the label. They all know that. So whether they were trained to do it or not, they are also trained you cannot go beyond the label. So the question comes, if you do not have proof that the individual sales reps were actually doing it and you do not have proof that will convince a jury that the executives were, how do you know they were?

Mr. BROWNLEE. Well, I think—

Senator COBURN. And I am not disputing your case. I have said that. But how do you know they were?

Mr. BROWNLEE. Well, in this case they pled guilty so they told us they were. So in that sense, they have admitted it. But it is a valid question. How could we have established at trial that this company committed a felony? It is my judgment if you look at all the pieces of that puzzle and you put it together, I would feel comfortable as a litigator standing in front of a jury and making the point this was a corporate culture, this was a company, look at the training manual, look at these call notes, look at these statements here, and you put it together. It may not equal individual culpability as to a particular person, but as a whole, I felt comfortable arguing before a jury that we had sufficient evidence to convict the corporate entity.

This was a case where there was not that smoking gun, there was not that "Aha" moment where we found the e-mail that had the grand admission. It just was not that kind of case. It was kind of a deliberate process. It is one of the reasons why it took so long to build that kind of case.

Senator COBURN. You have become pretty familiar with this drug, right?

Mr. BROWNLEE. I have never taken it, but I—

Senator COBURN. No, no. I am not accusing you of that.

[Laughter.]

Senator COBURN. Hopefully you will not ever have to take it.

Mr. BROWNLEE. Yes, sir.

Senator COBURN. When taken properly, it is a very good drug. The question I have for you is: If you had significant pain problems today and your doctor offered you OxyContin because that is the best way to treat it, would you be afraid to take this drug?

Mr. BROWNLEE. Senator, it is hard to say what I would personally do.

Senator COBURN. Well, let me rephrase it a different way then. If I offered you three Lortab instead of an OxyContin 10, would you take that?

Mr. BROWNLEE. Again, Senator, I have been very blessed, and I am not sure what a Lortab does either.

Senator COBURN. It is oxycodone except it is not slow release. So here is the point I am trying to make, is we are talking about a drug that I personally have experience with as a physician and hundreds of thousands of other physicians do, too, that shows that it does a very good job. The problem is the abuse potential of it.

One point I want to make clear in here is there is a great value to this medicine for me as a practitioner and thousands and thousands of other doctors.

Senator SPECTER. Senator Coburn, how much more time will you need?

Senator COBURN. I will stop with that if we are coming back again. Are we coming back again? I guess the point I want to make is this is not about the drug. This is about the actions. And I want to make sure we keep it separate because if we do to all the other abuse potential drugs, all the other Class II drugs, if, in fact, there is anything out there in terms of the marketing what we have done here, I may be without the kind of drugs that I need for patients in the future. So we need to separate the issue.

Mr. BROWNLEE. Yes, sir.

Senator COBURN. This has value in terms of this drug does have great value. It is also a very dangerous drug, and all narcotics are highly susceptible to abuse.

Mr. BROWNLEE. If I may respond just on one issue, you are absolutely correct, and we were very careful to build this criminal case about the specific facts of the misrepresentation, the misbranding, and that is what is in the Agreed Statement of Facts, and that is what provides the factual basis for the plea.

But I also believe, as I talked about in my press release and press statement, and the court talked about in his order, that there was significant harm caused by the misbranding of the drug. So much of it got out there that it gave addicts and those dependent and others the opportunity to abuse it.

And so you are absolutely right, sir, that when we are in the courtroom conducting a Rule 11 colloquy, it is the facts that support the plea. But as Chief Judge Jones noted in his order, there was harm caused by this, and a lot of folks suffered. And it is one of the reasons why we pursued it as we did because of that harm.

Senator COBURN. Well, my only concern is we should have been pursuing every physician who was writing a scrip for it when it was not needed, and that is the defect on the side of the Justice

Department and the DEA. Doctors make millions of dollars writing this drug when they should not be doing it, and we are not putting them in jail, and they need to be in jail for that because they are just as guilty as anybody in that company who might have marketed it wrong.

Mr. BROWNLEE. I will say that my office—and I cannot speak for the entire Department, but—and we have 23 Federal prosecutors, so we are a pretty small shop. But we have taken an aggressive stance against physicians as well. We have prosecuted physicians. We recently convicted a physician out in Nevada who was—I think he was an OB/GYN—who was prescribing OxyContin to folks from southwest Virginia. They were actually driving to Nevada and getting the scrips and coming back and then selling them and taking them. So we reached out to Nevada and convicted him.

Senator SPECTER. Thank you, Senator Coburn.

Senator Sessions?

Senator SESSIONS. Thank you. I don't know why I thought about a case I prosecuted. It was a Fortune 500 case, a defendant from a Fortune 500 company, and it was so complicated. I had one of the best prosecutors in America involved in it and had one of the best defense lawyers, several great defense lawyers. And so we finally got a misdemeanor charge on one of the guys, and he was a professional lawyer. He said, well, we will tell you what you really want to know. Large amounts of money going through a foreign consulate and all kinds of things. It was of great interest to us. And he pled and testified, and we convicted the top guys for perjury and that sort of thing.

And we got to court, and the judge chewed me out. He thought we had given too sweet a deal to the guy who pled guilty to get the other guys. And we never would have had a case. I mean, you have to work cases in difficult ways. It was an intense effort.

But, first of all, with 24 assistants, you have a number of those on civil matters, a number of those on training matters, a number of those—so you do not have that many line prosecutors, do you? It is a fairly small office compared to the several hundred some of the big offices have.

Mr. BROWNLEE. We are fairly small. Of those 23, four are civil, 19 handle criminal work over three staffed offices, and then the U.S. Attorney.

Senator SESSIONS. You have three different offices.

Mr. BROWNLEE. Yes, Senator.

Senator SESSIONS. Well, were you personally involved in this case? Did you work it?

Mr. BROWNLEE. From the very beginning to the end.

Senator SESSIONS. Well, that is unusual. A lot of the prosecutors just sit upstairs and let the assistants do all the work. So I congratulate you on that.

Are you aware of any U.S. Attorney in recent years that has got a $600 million fine against a company?

Mr. BROWNLEE. Gosh, Senator, I am sure someone out there has done better than me, but, again, I am not aware of that this year.

Senator SESSIONS. That is one of the biggest fines I have observed, and I think first I just want to say that to you.

Mr. BROWNLEE. Thank you, Senator.

Senator SESSIONS. First of all, you personally led this case. It could have been prosecuted in any district in America, I suppose. You stepped up, you led the fight, you really crushed their defense ultimately, and I am sure with this much at stake, they had some of the best lawyers in America involved in defending the case. And you got pleas on two of the top CEOs and a $600 million fine on the corporation. And 90 percent of the profit off this drug—Senator Coburn makes a valid point. It dawned on me a lot of this drug was legitimately sold. It is not in and of itself inherently an evil drug. So you got 90 percent of the profit. That means you got far more than the abused sales that occurred. I want to make that point.

Second, we created, Congress did at some point in its history, a strict liability statute, and that means—I will summarize it and see if it is correct—that you simply proved that they ran the red light, that they violated the standards, and you do not have to show any criminal intent. You are just guilty. Is that correct?

Mr. BROWNLEE. That is correct. We just have to establish that they were the responsible corporate officers of a particular company that delivers products under the Food, Drug, and Cosmetic Act.

Senator SESSIONS. But to convict them of a felony, you have to have a specific criminal intent, and you had to prove it as to each one of the persons you would individually charge. Is that correct?

Mr. BROWNLEE. That is correct, Senator.

Senator SESSIONS. Now, with regard to prosecuting a corporation, you can aggregate knowledge, can you not? In other words, you can prove this officer knew this, this one knew that, this one knew this, and as a whole the corporation was acting unlawfully, and you can sue the corporation. It is not an entity. It does not have the same constitutional rights that individuals have.

Mr. BROWNLEE. That is correct. It would obviously have a trial, if it went there, and have all its rights in many ways, although I am not so sure they actually have grand jury protection. I think that is still a debatable issue. But you do aggregate or you do look at the actions of all the players, all its agents, when assessing corporate liability. And that is what we have done.

Senator SESSIONS. And whereas it may not be enough to prove personal criminal intent, felony knowledge on an individual, that information can be aggregated as proof that the corporation as a whole had knowledge and the corporation can be held liable.

Mr. BROWNLEE. That is correct.

Senator SESSIONS. And that is what you did on the corporation.

Mr. BROWNLEE. That is what we have done on the corporation.

Senator SESSIONS. Now, to convict the officers of a felony—and we have got civil libertarians on this Committee that think you cannot prosecute terrorists, you know. They want to give them every right in the world. But anybody that is a—I should not say that. Let me withdraw that.

[Laughter.]

Senator SESSIONS. That is not a fair statement. We do have a great deal of interest in seeing that even terrorists have a fair shake and the law is properly applied.

But I guess what I am saying with regard now to those individuals defendants, you have to prove to charge them with a felony

that they had specific knowledge of the standards that were expected of them and that these standards were not being adhered to and that they authorized them in some fashion. Is that correct?

Mr. BROWNLEE. The Government would have had to establish beyond a reasonable doubt that whichever particular individual you charged had the intent, showed the intent to defraud or mislead.

Senator SPECTER. Senator Sessions, how much more time will you require?

Senator SESSIONS. I am about through.

So you felt you did not have that knowledge, that proof?

Mr. BROWNLEE. This prosecution team reviewed, as I stated, millions of records, conducted hundreds of interviews, and the charges that we brought were the charges we felt we could establish and were the proper charges under DOJ policy.

Senator SESSIONS. Now, the judge in sentencing—

Senator SPECTER. Senator Sessions, how much more time do you—

Senator SESSIONS. One minute. The judge in sentencing did give more probation than you asked for, but he could have given custody. All you could do was make a recommendation. If the judge had felt a custody sentence was appropriate, he had every right to impose the full 6 months in jail, did he not?

Mr. BROWNLEE. This was conducted under Rule 11 (c)(1)(C), and the Government agreed not to seek active incarceration. The judge could have rejected the plea agreement if he felt that these sentences and the plea itself was inappropriate.

Senator SESSIONS. But he found that he did not think, based on the facts there, that prison was appropriate.

Mr. Chairman, I do not dismiss your concerns, and maybe we need to review the law also to see if it needs to be tightened up. But I just feel like this fine young United States Attorney committed several years of his life to this case and did something nobody else had done: put an end to this OxyContin abuse, which is an absolute national problem.

I thank you for having the hearing.

Senator COBURN. Mr. Chairman, I would just ask unanimous consent—he is our Chairman today—that the full opinion of Judge Jones and the court order be placed in the record.

Senator SPECTER. Without objection, it will be included.

Senator COBURN. And I would also note that there was no pleading of guilty to knowing by the executives of this company misbranding with intent to mislead.

Senator SPECTER. Mr. Brownlee, thank you very much for your service.

Mr. BROWNLEE. Thank you.

Senator SPECTER. It is a tough job, but it is a very rewarding job, and we appreciate what you are doing.

Mr. BROWNLEE. It is a honor. Thank you, Senator.

Senator SPECTER. I call the second panel now. Will you step forward? Will you, ladies and gentlemen, stand please and raise your right hands? Do you solemnly swear that the testimony you will give before the Senate Judiciary Committee will be the truth, the whole truth, and nothing but the truth, so help you God?

Ms. SKOLEK. I do.

Mr. KHANNA. I do.
Dr. WOLFE. I do.
Ms. PAGANO. I do.
Mr. MCCLOSKEY. I do.
Dr. CAMPBELL. I do.
Senator SPECTER. You may be seated.

We have a very limited amount of time, so I am going to ask all of you to stay right within the time limits, and we begin with Ms. Marianne Skolek, who began looking into Purdue Pharma after the death of her daughter, who took OxyContin. Thank you for joining us, Ms. Skolek, and the floor is yours.

STATEMENT OF MARIANNE SKOLEK, LPN, MYRTLE BEACH, SOUTH CAROLINA

Ms. SKOLEK. Thank you, Senator Specter. My name is Marianne Skolek. I had a beautiful 29-year-old daughter named Jill. She had the misfortune of being prescribed OxyContin in January 2002 and was killed on April 29, 2002. Jill left behind her son, Brian, who was 6 years old at the time of his mom's death. Brian is with me in the Senate today.

Why did a $9 billion privately held pharmaceutical corporation take the life of my precious daughter? My work against Purdue Pharma for the past 5 years initially focused on J. David Haddox, dentist turned psychiatrist and senior medical director of Purdue Pharma. I also focused on Robin Hogen, former public relations spokesman for Purdue Pharma.

In 1996, the American Academy of Pain Medicine and the American Pain Society issued a set of guidelines for the use of opiates in the treatment of chronic pain. These guidelines are referred to as a "consensus statement." The statement leaning toward a more liberal use of opiates was adopted just as the marketing push for OxyContin began. This consensus statement was produced by a task force, which was headed by J. David Haddox, former president of the American Academy of Pain Medicine, who was senior medical advisor for Purdue Pharma, the maker of OxyContin. Haddox was quoted as saying that "the point was to gather consensus. If you are going to do this, this is how it should be done." There was question as to whether it was ethical for Haddox to be associated with a pharmaceutical manufacturer to guide the formation of a document that would play a key role in promoting the use of products made by the company Purdue Pharma.

When OxyContin was introduced on the market, it was intended for the treatment of cancer patients, and they were losing the patent on MS Contin. At one point, in the greed and sheer evil of Purdue Pharma, they intended to market OxyContin to OB/GYN patients. I flooded the country with e-mails and faxes to Attorney Generals and the media reporting that we had had enough devastation in the country without addicting infants to OxyContin. This marketing ploy was terminated by Purdue Pharma.

Pain patients from various pain societies will speak of the merits of OxyContin and their quality of life being restored because of the drug. These pain societies throughout the country are funded by Purdue Pharma. Let the pain patients not a part of any funded pain society of Purdue Pharma speak about the quality of life they

have after becoming addicted to OxyContin—and when their physicians refuse to renew prescriptions for the drug and they go on the street to buy the drug because they can't kick the habit of this less addictive drug. Ask the FDA and the DEA why OxyContin is in such plentiful supply on the streets all over the country.

Jill and thousands of victims of an out-of-control, greedy pharmaceutical company headed by three convicted criminals marketed OxyContin as less likely to be addictive and abused. There are assertions that the only victims in the criminal activities of Purdue Pharma were the physicians who were misled by Purdue Pharma's sales representatives. The physicians, who were used as pawns by Purdue Pharma, were not ingesting a powerful narcotic that was being marketed as less likely to be addictive or abused. The patients were ingesting OxyContin and were becoming addicted and dying. If patients aren't victims of Purdue Pharma's criminal activities, tell me what they should be called.

The addiction and loss of lives because of OxyContin continue to impact every State in the country every single day. The far-reaching consequences of the criminal activity of Purdue Pharma did not end in 2001 or 2002 as they would like it to be believed. No one can turn the clock back. This has been allowed to become a national crisis because there was no conscience in the marketing of OxyContin; there was only greed.

We all hear on the news every day about individuals who work for Government agencies or private industry who embezzle funds. Purdue Pharma has been found criminally responsible for marketing OxyContin which resulted in death and addiction. Is it justice to have these convicted criminals—these monsters—fined an amount of money that is very well afforded by them? Or will the Senate send a message that because of the magnitude of the crime committed, they deserve to be further investigated by the Senate?

Anything that is imposed against these convicted criminals will not give us back Jill, but I will guarantee that Purdue Pharma will never forget the name Jill Skolek. When I began my work at exposing these three convicted criminals and Haddox and Hogen, I told Hogen that you messed with the wrong mother. And they did because my work is not over.

I want to know why the FDA allowed OxyContin to cause such destruction to the lives of scores of innocent victims. I want to know why 12 warning letters were sent by the FDA to Purdue Pharma about their marketing of OxyContin and to this day they are not required to put "highly addictive" or "addictive" on the label of the drug. I want to know why the FDA deleted so many of my e-mails about the marketing of OxyContin until this last month. I want to know why Curtis Wright while employed by the FDA played an intricate part—

Senator SPECTER. How much more time will you need?

Ms. SKOLEK. One more minute. In the approval of OxyContin and then was hired by Purdue Pharma. I want to know why Attorney General Blumenthal of Connecticut's Citizen Petition which requests strengthened warnings for OxyContin is still sitting at the FDA—without any action—since January 2004. I want to know how Rudy Giuliani could be the "big star" hired by Purdue Pharma to play down the abuse and diversion of OxyContin and then get

paid by the DEA for work performed for them. I want to know why the Sackler family has not been held accountable for their involvement.

Eventually Purdue Pharma will introduce another blockbuster drug similar to OxyContin, as they did with Palladone. Palladone was removed from the market after a couple of months. My advice to Purdue Pharma is when you are ready to introduce another drug such as OxyContin or Palladone, look behind you, because I will be right there.

I will be working at having Howard Udell disbarred for his criminal activities and Paul Goldenheim's medical license revoked for what amounts to white-collar drug trafficking. I will accomplish this—hopefully with the help of Attorney General Blumenthal. Do not doubt me at not being successful at achieving this.

Her name was Jill Carol Skolek. She did not deserve to be prescribed OxyContin and die because of the criminal activities of individuals of Purdue Pharma. Please give my family justice and investigate the criminal activity of Purdue Pharma.

Thank you, Senators, for giving me the opportunity to speak for thousands of victims of an out-of-control pharmaceutical corporation.

[The prepared statement of Ms. Skolek appears as a submission for the record.]

Senator SPECTER. Thank you very much for your testimony, Ms. Skolek. I am very sorry about your daughter.

Ms. SKOLEK. Thank you very much.

Senator SPECTER. This Committee and the Senate has no authority, no power, once the case is concluded. It is what we call res judicata, double jeopardy. But there are important principles, which is the reason we are proceeding with this hearing. Thank you.

Ms. SKOLEK. Thank you.

Senator SPECTER. We now turn to Professor Khanna, S.J.D., from Harvard Law School, Professor of Law at the University of Michigan.

Thank you for joining us, Professor Khanna, and the next 5 minutes are yours.

STATEMENT OF VIKRAMADITYA KHANNA, PROFESSOR OF LAW, UNIVERSITY OF MICHIGAN LAW SCHOOL, ANN ARBOR, MICHIGAN

Mr. KHANNA. Thank you, Chairman Specter, and thank you very much for inviting me to testify today. I will focus my comments today on basically two questions.

The first is: Are criminal sanctions on executives something we should consider when executives knowingly introduce defective and dangerous products into the market? And my short response to that question is yes, with the qualification that we should try to exhaust the deterrent effect of civil penalties first.

The second question I will address briefly is: If we do decide to go forward with criminal sanctions on executives, then what safeguards should we begin to think about putting in place to help reduce the cost of criminal—

Senator SPECTER. Professor Khanna, pull the microphone a little closer to you.

Mr. KHANNA. Sorry. What sort of safeguards should we bring into place to help reduce the cost of criminal liability on executives? And my response here is that a well-defined and -implemented mental state requirement, such as a knowledge requirement, would be ideal with good examples of what satisfies this particular mental state requirement. Also, I would suggest some adjustments to the liability that corporations bear that I will hopefully be able to discuss in the next few moments.

Turning to the first point, whether a case can be made for imposing criminal liability on executives, I would say that yes, there can be a case made for that, but before doing so, one should try to exhaust the deterrent effect of civil penalties. The reason I sort of mention this is that in this area we frequently rely more on corporate civil liability rather than direct liability on executives. The reason for this usually is that executives do not have the assets to pay for the large amounts of harm that might be caused through the corporate products they are selling. If they do not have the assets to pay for it, their incentives to sort of take appropriate care are somewhat less.

The corporation, of course, has more assets, and it can also monitor its employees, so in some respects we deputize the corporation to monitor what its employees are doing to prevent them from engaging in harmful activity.

Of course, there are some kinds of harms that are so large, such as drugs that induce death or serious injury, that sanctions on the corporation will not be sufficient. They may not also have the assets to pay for all the harm caused. In those cases, we may go one step further and decide to impose liability on executives, for example, criminal sanctions.

Senator SPECTER. Were the sanctions sufficient in this case?

Mr. KHANNA. Well, clearly, when the harm caused is death and serious injury, it is quite likely that most corporate assets will not be sufficient to pay for the harm caused, especially given the numbers that are suggested here. I am not familiar with all the people who have been injured and died from using OxyContin, but if the numbers are as suggested in the news reports, then we are in that range.

Moving sort of quickly on to talking a little bit about safeguards, if we decide to go forward with criminal liability, my primary concerns with imposing criminal liability are largely the effects they are likely to have on who decide to become executives at firms that produce these sort of high-risk products. I can imagine a lot of good people, good, conscientious, careful people, who might become a little reluctant to take on the position of an executive at a firm that is producing high-risk products because of the fear of criminal liability. The primary concern that comes to me from that is that if the good, conscientious, and careful people refuse to be executives of these firms, then who do become the executives of these firms? Perhaps people not so careful, not so conscientious may be a little bit more tolerant of risk. That might lead to more dangerous products being marketed and in commerce in the U.S.

One way to address that particular concern, of course, is to have a high mental state requirement; that is, to only target liability to

those people who were knowingly involved in marketing dangerous products or defective products to the U.S. public.

Of course, if you have a nice high mental state requirement like knowledge, one additional concern is raised, which is, if it is very hard to prove or difficult to prove that executives knew about a particular product's defectiveness or dangerousness, then many executives might find it in their interest not to learn much about what are the safety risks of their products. It may prove to them, at least in their mind, to be a safer course to follow to not know much; that is, to have their head in the sand, essentially.

Senator SPECTER. A corporate executive deliberately decides not to know much, does that expose him to some liability for failing to do his duty?

Mr. KHANNA. It does under the willful blindness standard. The only difficulty is that that is a rather difficult standard to prove.

Senator SPECTER. They are all hard to prove.

Mr. KHANNA. They are all hard to prove. That is true. But it raises the same similar concern that if you have a mental state requirement that is uncertain and difficult to prove, then the careful people will probably be a little bit reluctant to take on a position that exposes them to that kind of uncertainty, especially when the consequences are spending time in jail.

But there are ways to address the—

Senator SPECTER. How much more time will you need?

Mr. KHANNA. Probably about 1 minute, if that is OK.

Very briefly, there is a way to address the concern that executives may stick their heads in the sand, which is to impose liability directly on the corporation in addition to liability on the executive. And that may induce a corporation to put in place measures to gather information about product risk. Once the corporation has measures in place, it is very difficult for executives to claim that they did not know what was going on when reports are passing by their table on a regular basis about product risk.

With that, I will conclude my testimony, and I thank the Committee for allowing me to testify here today. Thank you.

[The prepared statement of Mr. Khanna appears as a submission for the record.]

Senator SPECTER. Thank you very much, Professor Khanna.

We now turn to Dr. Sidney Wolf, Director of Public Citizen's Health Research, adjunct professor of medicine at Case Western Reserve University. Thank you very much for joining us today, Dr. Wolfe, and we look forward to your testimony.

STATEMENT OF SIDNEY M. WOLFE, M.D., DIRECTOR, HEALTH RESEARCH GROUP OF PUBLIC CITIZEN, WASHINGTON, D.C.

Dr. WOLFE. Thank you, Senator Specter. I will discuss three issues that have arisen from the highly touted prosecution by the Justice Department of the Purdue Frederick Corporation for "misbranding Oxycontin with the intent to defraud and mislead the public." The issues highlight the double standard in this country for prosecuting corporations and individual corporate officials whose intentional activities result in hundreds of deaths, versus the much more stringent penalties imposed on non-corporate individuals who serve long jail sentences for activities resulting in a

tiny fraction of the damage done by such corporate criminal activity.

The first issue is the prosecution of Purdue and subsequent financial penalties that were inexplicably and unacceptably limited to a time period—1996 to 2001—ending well before the company ceased engaging in illegally misbranding Oxycontin. The evidence for this is that on January 17, 2003, the FDA sent Purdue a warning letter concerning clearly illegal promotion of OxyContin during late 2002, almost a year after the curtain dropped on the period for which they were prosecuted. And the nature of the violations then—again, after December 31, 2001—was almost exactly the same as those in the earlier periods of time.

The beginning of the letter, which was, interestingly, to one of the three company officials who were convicted of misdemeanors—Michael Friedman—is reproduced here, and I will just read a couple sentences from it.

First, it states that this is clearly a violation of the Food, Drug, and Cosmetic Act. "Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisement to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of the risk. In addition, your journal advertisements fail to present in the body of the advertisement critical information regarding limitations on indicated use, thereby promoting OxyContin for a much broader range of patients," and so on.

In addition to this, under the first point about the limited period of time of the prosecutions, the ending period of prosecution, there was a nonprosecution agreement signed by the three individual corporate criminals and the company itself and agreed to by the Justice Department that prevents any further prosecution of the company or the three guilty officials for any activities before May 10, 2007—and, implicitly, after December 31, 2001, including the one illegal activity I just cited. This nonprosecution agreement includes the promise not to seek additional criminal penalties or forfeiture actions during this period of time. And I include in the testimony from their own statements the nature of this nonprosecution agreement.

The second point is the criminal penalties paid by the company, said to be 90 percent of their profits on Oxycontin, were apparently limited to the 1996 to 2001 interval even though much of the subsequent 2002 to 2006 sales and profits were unequivocally derivative of the earlier—and subsequent—illegal promotional activities.

I include a chart in here of the sales. The Justice Department has stated the financial penalties of $634 million that they were assessed was 90 percent of the profits, which would mean that the profits during the interval ending in 2001 December were about $700 million. Aside from the obvious, continuing impact of the illegal pre-December 2001 promotional activities, as evidenced by the massive continued prescribing, the peak years of sales were 2002, 2003, and 2004, after the end of this period. The further illegal activity that the FDA caught them at adds to the need for their having gone farther.

In an affidavit in this case signed by the IRS, they themselves said that going up through September 2004, there were $2.67 billion in profits, and there are more since then. The standard for the Government forcing a company to disgorge profits is that the money was obtained through illegal means. The illegal promotional activities of Purdue in 2002 were clearly successful in continuing the earlier illegal activities, as evidenced by the peak year of sales being 2003. The subsequent sharp decrease in sales, with 2006 sales being only 37 percent of the peak sales year in 2003, confirms that once, belatedly, illegal promotion was finally stopped, the ill-gotten sales and profits dropped significantly.

And the final point, no company official is going to jail—and this is what you have focused on, Senator Specter—because there was no felony conviction of any company person, just of the corporation itself, which cannot go to jail. U.S. Attorney Brownlee has said that the many prosecutors "spent years culling through millions of documents, looking for the evidence. And what they did is they were able to piece together a corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."

Senator SPECTER. Dr. Wolfe, how much more time will you need?

Dr. WOLFE. A minute, at the most. Why was it that there were no individual humans who carried out the deadly missions of the "corporate culture" such as the admitted activities—and I quote from their own statement: "Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences..." and so on. They had caught people doing illegal kinds of things, and yet these people were never criminally prosecuted and put in jail. This is from their own press statement.

Why is it that no individual who had engaged in "misbranding OxyContin with the intent to defraud and mislead the public" could be found and sent to jail? In 2002, a physician who recklessly dispensed prescriptions for OxyContin was convicted and subsequent sentenced for his crime. James Graves, M.D., former naval flight surgeon, was sentenced to 63 years in jail for manslaughter for patients overdosed on OxyContin. He was imprisoned in Santa Rosa County Jail in Milton, Florida, pending appeal. Other non-physicians who illegally sold OxyContin have also received jail sentences.

Employees of Purdue orchestrated an illegal scheme to promote the same drug—OxyContin—as being safer, more effective, and less subject to abuse than it actually was, and pushed—

Senator SPECTER. Dr. Wolfe, we are going to have to move on now. Very limited time.

Dr. WOLFE. Just 10 more seconds, really. Two more sentences to go. And pushed hundreds of millions of prescriptions for the drug based on the false pretenses of their promotional campaigns.

Why are there no manslaughter charges, no jail sentences, and such relatively low amounts of financial penalties? Is it perhaps because Purdue has the money to hire Rudy Giuliani and the best white-collar criminal defense lawyers to minimize the damage to itself and its executives? If this does not represent a double standard of justice, what does?

Thank you.

[The prepared statement of Dr. Wolfe appears as a submission for the record.]

Senator SPECTER. Thank you very much, Dr. Wolfe.

Our next witness is Police Officer Virginia Pagano from the 26th Police District in Philadelphia, DEA certificate for outstanding contribution in the field of drug law enforcement.

Thank you for joining us, Officer Pagano, and we look forward to your testimony.

STATEMENT OF VIRGINIA PAGANO, POLICE OFFICER, PHILADELPHIA POLICE DEPARTMENT, NARCOTICS BUREAU, PHILADELPHIA, PENNSYLVANIA

Ms. PAGANO. Thank you, Senator. Good afternoon to the Senate Committee. I am honored to be here today to speak to you on behalf of the Philadelphia Police Department. I will speak to you today on the devastation caused by OxyContin on family, friends, and the communities that we serve.

I have been a police officer in the city of Philadelphia for 20 years, and my current assignment is with the Philadelphia Police Department, Narcotics Bureau's Drug Education Program entitled "H.E.A.D.S.–U.P." The Heads-up Program has joined together law enforcement, family members, unfortunately, who have lost loved ones, and the recovery community. The response to this program has been overwhelming.

Since its inception, the Heads-up Program has been viewed by approximately 449,000 people at 3,032 different locations. We have been across the State of Pennsylvania, New Jersey, Delaware, Massachusetts, and Connecticut. The program for the past 6 years has exposed me to a completely different aspect of law enforcement: the education side. It is of the utmost importance to educate not only the law enforcement officers that I work with, but the general public so that they can better understand the devastation that is caused by drug addiction.

The abuse of OxyContin is a problem that we cannot arrest our way out of. It will primarily require education, along with treatment and enforcement. We must educate every child before they pick up that first drug because after that, we are just simply playing catch-up.

I am inspired every day to continue the Heads-up Program, and I often listen to story after story of how addictive OxyContin is. The story seems to stay the same, but the faces continue to change. Whether black, white, Hispanic, or Asian, no matter what religion or political party, OxyContin has crossed all boundaries.

It seems to me that among our young people, "prescription drugs"—namely, OxyContin, which is one of the most commonly abused by our teens—just sounds safe, and yet the progression from Oxy to heroin is a very common one.

One young lady's story always comes to mind, and I tell these stories day in and day out. She stated to me that she started using Percocet at the age of 13. She couldn't get Percocet one night, and someone suggested Oxy. Then one night she didn't have enough money to get OxyContin, so she tried heroin, and as she says, that is when her life changed forever. At 18 years old, this young lady

is now in treatment because of one little pill. But so many more are not as fortunate.

The abuse numbers are chilling. OxyContin addiction has increased dramatically over the past 10 years, by 300 percent in the United States alone.

In 2006, this past year's abuse of OxyContin among eight graders drastically doubled—increasing 100 percent over the last 4 years. Fifty-six percent of our teens agreed that prescription drugs are now easier to get than any illegal drug on the street.

I could spend the next 5 hours talking about statistics—300 percent, 100 percent, 56 percent. But today I would like to concentrate on the number "one." Over the past 6½ years I have met countless families who have lost a son, a daughter, a husband, or a mother, and what I know is 300 percent, 100 percent, 56 percent means nothing. The only thing that matters is that "one"—the "one" who is and will always be missing from that family from OxyContin addiction or overdose.

Because of these addictions, we continue to meet family after family who live every day thinking about what it would be like if their loved ones were still here, always asking themselves, "Who would they be today?"

The "cost" I believe you will never be able to measure. The son who died from Oxy might have held the cure for cancer; the daughter will never be able to walk down the aisle with her father. A father who was selling OxyContin is sitting in prison, and the mother who was originally prescribed the drug because of her pain from a car accident is now addicted and can no longer care for her children.

Too many people realize too late that OxyContin abuse could lead to incredible losses—lost families, lost friends, lost jobs, lost opportunities, and lost lives either to the lifelong addictions or overdose.

The $634.5 million in fines and three executives who pled guilty for "misbranding" the drug as a "low-risk" painkiller will never equal the "one" who has been lost to these addictions or overdoses. For that "one" who has been lost will affect a whole family, a whole community, a whole generation.

There are many, many faces that have been entrusted to us with the Heads-up Program, and my only hope is that somehow "one" story, "one" face will somehow save another—

Senator SPECTER. Officer Pagano, how much more time will you need?

Ms. PAGANO. Ten seconds.—from the pain and never-ending heartache that comes with addiction, because dead is dead whether it comes at the hands of illegal drugs or prescription drugs like OxyContin.

When I hit the street tomorrow, I will tell you honestly, the abuse is not over from Oxy, as the Senator said.

Thank you.

[The prepared statement of Ms. Pagano appears as a submission for the record.]

Senator SPECTER. Thank you very much, Officer Pagano.

We now turn to Attorney Jay McCloskey, a very distinguished record in the U.S. Attorney's Office in Maine, held the position as Assistant for 13 years and then was the U.S. Attorney for 8 years.

Thank you for coming in from Portland, where you now practice law, to join us here. The floor is yours.

STATEMENT OF JAY P. MCCLOSKEY, FORMER UNITED STATES ATTORNEY, DISTRICT OF MAINE, MCCLOSKEY, MINA, CUNNIFF & DILWORTH, LLC, PORTLAND, MAINE

Mr. MCCLOSKEY. Thank you very much, Senator, and thank you for allowing me to testify today. I served as the United States Attorney, as you said, 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. I was an active drug prosecutor and prosecuted literally dozens upon dozens of cases and individuals as an Assistant United States Attorney.

In late 1999 and early 2000, I became aware of a growing problem in Maine of prescription drug abuse that included, but was not limited to, OxyContin. That prompted me in February 2000 to send a letter to all Maine practicing physicians warning them about the abuse. Shortly thereafter, in March 2000, I received a call from Purdue's medical director, asking me to meet and discuss the problem, but I deferred his request.

At the time, law enforcement officials were just discovering the extent of the opiate abuse problem, and I didn't see what the manufacturer could provide in the way of helping law enforcement.

However, as I got into the problem, I came to realize that traditional law enforcement was not going to solve this problem and really was not going to even make a dent. I also came to realize that Purdue Pharma could actually help law enforcement reach health care providers to whom law enforcement generally did not have access.

In September of 2000 I organized a meeting attended by Federal, State and local enforcement, and Purdue executives. Rather than sending lower-level executives, Michael Friedman, the company's CEO; Howard Udell, the chief legal officer; and the Purdue medical director attended this meeting and pledged to do whatever they could to help. Howard Udell specifically said to me—and I remember this very distinctly—"We want to do what is right." That is what he said to me directly as a United States Attorney, and I remember those words. But I did not give them much moment at that point. But as I watched what Purdue did and what they tried to do, I recalled those words later on.

I worked with Purdue Pharma as the United States Attorney because I saw that the company wanted to stop the abuse and diversion of drugs, and it was able to help law enforcement do that. They allowed me and others in my office to make unrestricted presentations to doctors about the dangers of overprescribing. That was sort of the chief problem at the time. It was doctors overprescribing, not realizing that there were drug seekers in the office, and the only way to reach large numbers was at these medical seminars.

Purdue offered to provide, at no cost, tamper-resistant prescription pads. This was very helpful, and they helped develop those, and they helped distribute those. They developed brochures to send out to all Maine doctors, and I think across the Nation, about the dangers of drug abuse. And they showed me those brochures as

United States Attorney and gave me an opportunity to change some of the information in there as I saw fit in terms of making doctors and pharmacists aware of the problems. These were the sort of steps that Purdue took while I was United States Attorney.

In April 2001, I told Purdue executives that drug agents in Maine had discovered that OxyContin 160's were being sold on the street. I told them that if OxyContin 160 was abused, it could result in death almost immediately.

A couple of weeks later, one of the executives called me and, without any prompting from me, said, "We are going to take that product off the market." I can tell you, Senator, at the time—this was the early stages of the OxyContin problem—that was very impressive, that a company offered to take a legitimate product off the market. And there were people who did not want that to happen, especially in the cancer community.

After I left the Government in 2001, I continued to work with Purdue as a consultant, and I counseled them and worked with them to implement continuing programs to try to prevent the abuse and diversion of OxyContin. In each and every occasion, they took my recommendations. The executives saw that it was carried out. And I was persuaded many, many times that these executives wanted to do the right thing, as the chief legal officer said. They wanted to stop the abuse and diversion of OxyContin, and everything they did established that to my satisfaction. They marked the drugs for law enforcement so they could tell where they were coming from. They stopped the distribution in Mexico when there was a problem with diversion in Mexico. Everything you could ask a company to do in terms of trying to stop illegal diversion, they did.

Now, I do not condone any of the misstatements by the sales representatives of any of the marketing problems. But it clearly did not reach to the higher levels of the organization. I was involved for a couple of years in very much detail and heard nothing about the marketing—

Senator SPECTER. Mr. McCloskey, how much more time will you—

Mr. MCCLOSKEY. Another minute, Senator. The marketing problems that have resulted in the criminal plea.

So I believe that this company did what any law enforcement officer would hope that a company would do whose product was being abused and diverted.

Thank you.

[The prepared statement of Mr. McCloskey appears as a submission for the record.]

Senator SPECTER. Thank you very much, Mr. McCloskey.

Our final witness is Dr. James Campbell, Professor of Neurosurgery at Johns Hopkins.

Thank you very much for coming down today, Dr. Campbell, and we look forward to your testimony.

STATEMENT OF JAMES N. CAMPBELL, M.D., PROFESSOR OF NEUROSURGERY, SCHOOL OF MEDICINE, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MARYLAND

Dr. CAMPBELL. Thank you, Senator Specter. I am Professor of Neurosurgery at the School of Medicine at the Johns Hopkins Uni-

versity. I have dedicated my career, spanning 30 years, to the mission of decreasing the suffering associated with pain.

My perspective also arises from my work with the American Pain Foundation. The APF is the Nation's leading nonprofit organization devoted exclusively to serving the needs of people with pain. Purdue has contributed generously during the 10 years that the APF has been in existence.

Let me begin by just indicating once again that chronic pain is a serious health problem that afflicts more than 50 million Americans. Untreated pain has serious consequences. This is not a benign condition. It interferes with sleep, work, family relations, and induces depression and anxiety. Patients with chronic pain become demoralized, and some even commit suicide.

OxyContin is an opioid, and it is important to know that opioids continue to be the most effective class of medications there is for treatment of serious pain.

OxyContin is a form of oxycodone, prepared in such a way that release into the bloodstream occurs in a steady manner over a 12-hour period of time. The FDA was correct when they originally, in 1996, approved the statement in the OxyContin package insert—that is, the label—which said, and I quote from the package inset approved by the FDA: "Delayed absorption as provided by OxyContin tablets is believed to reduce the abuse liability of the drug."

The popularity of OxyContin among addicts stems from one simple fact: When the addict crushes an OxyContin pill, more oxycodone is available than when the addict crushes a typical immediate-release oxycodone pill. That this simple difference could be associated with a problem of enhanced abuse was not anticipated when the drug came out. No one in industry, no one in academia, and no one at the FDA anticipated the problems with OxyContin.

OxyContin, as Senator Coburn pointed out in his comments, was always designated as a Schedule II medication. This is the strictest label for prescribed drugs. The Schedule II designation means that the drug has significant addiction and abuse risk. Every doctor knows this. I find it very unlikely that any competent doctor would not understand this simple fact. Whatever a sales representative might or might not say to a doctor, the doctor is obligated to know what he is prescribing.

The numbers of prescriptions of OxyContin, unlike what Dr. Wolfe indicated, continue to climb, regardless of the adverse publicity associated with this drug and regardless of what clearly now are responsible marketing efforts. If criminal misconduct and reckless promotion were the sole drivers of OxyContin use, why would sales continue to increase after these alleged practices stopped? The answer is that OxyContin is a good pain drug. The drug sells itself because pain is in large part an unmet medical problem in America, and Americans are desperate to get relief of their pain.

My heart, Senator Specter, goes out to those who have had family members that have suffered complications of OxyContin therapy or, for that matter, any drug therapy. I would like to point out that last year over 10,000 Americans lost their lives because of problems with NSAIDs, that is, drugs like aspirin and ibuprofen. I wish we had perfect drugs, and I hope for the day when we can offer relief

of pain with greater safety and efficacy. It is important to note, however, that the risk of OxyContin arises in large part from a deliberate and intentional misuse of the drug. When taken as directed by the physician, the risk of OxyContin is no greater than with any other opioid.

I think you should know also that when the abuse problems with OxyContin became clearly apparent, Purdue undertook many programs to combat addiction. I identify in my written statement six programs initiated by Purdue. I know of no other company that sells opioids that has instituted as aggressive a program to fight abuse and addiction.

In conclusion, we here should all acknowledge that many thousands, if not millions, of patients have benefited and continue to benefit from use of OxyContin. The majority of patients and doctors use this medication responsibly. Abuse is a major problem as well. Making the executives at Purdue out to be criminals does not engage us in a proactive fight against abuse; rather, casting Purdue and its leadership as criminals sends a chilling message to industry: "Develop drugs at your own peril. If problems develop with the drugs you develop, you may end up in jail."

I think we can do better, Senator Specter. I think we can send a proactive message, and that is that both pain treatment and drug abuse are major problems in our society, and we need academia, industry, and Government to work together to address these critical problems.

Thank you.

[The prepared statement of Dr. Campbell appears as a submission for the record.]

Senator SPECTER. Thank you very much, Dr. Campbell.

Well, I think there is a fair amount to be learned from the hearing which we have had today. I cannot quite agree with you, Dr. Campbell, about the lack of complicity of the manufacturers. There at least appears to be substantial evidence of misleading conduct on their part. They certainly have defended the case. I understand the risks of litigation, but there are serious, serious problems.

Senator Coburn may well be right when he talks about doctors' culpability, and I would not let anybody off the hook, and this need not be the last hearing on this subject with respect to doctors who have not prescribed the proper recourse. But there have been a lot of deaths, and to the extent that you have misuse of the drugs, the manufacturer cannot prevent that. There is no doubt about that. But there has to be an evenhanded approach by the Department of Justice, and the U.S. Attorney who appeared here is obviously an able man who approached this in very good faith and in a very professional way. So I believe that this kind of oversight is very important, and we have the benefit of Dr. Coburn's medical expertise to provide an extra dimension, which he does on quite a number of subjects.

Again, our regrets to you, Ms. Skolek.

As I said, I am past due on excusing myself, and Senator Coburn is left in charge to keep the last questioning Senator in tow.

Senator COBURN. I will. Thank you, Mr. Chairman.

First of all, I would like unanimous consent to put some things in the record from the National Survey on Drug Use and Health,

which directly contradicts some of the testimony we have heard today. OxyContin accounts for less than 7 percent in 2005 and less than 4 percent in 2006 of the opioid abuse.

Senator SPECTER. Senator Coburn, you are going to have to persuade the substitute Chairman to give you consent on that because I am leaving.

Senator COBURN. Well, I am the substitute Chairman so I will grant such a thing.

I will also ask unanimous consent that the breakdown of drugs of abuse from the National Survey on Drug Use and Health be placed in the record.

Senator SPECTER. Senator Coburn, thank you for taking over the balance of the hearing.

Senator COBURN. [Presiding.] I will be happy to. It will be the first it has happened from the far right.

[Laughter.]

Senator SPECTER. I refer to you most often as the "far correct."

Senator COBURN. "Far correct," well, thank you. That is a nice compliment.

I want to thank each of you for your testimony. You know, what we have in front of us is we are struggling with problems in our society. Lortab is a far greater problem out there than OxyContin, and I think you would probably agree. You see it a whole lot more. It is abused more. The problem is you cannot kill yourself as easy with it. That is the problem.

We are struggling in our Nation and we are looking for things, and oftentimes I have the feeling that maybe somebody might have done something wrong, but maybe they did not. What if there was no intent on this case? You know, we had testimony there was not an organized marketing plan that was intended to violate the standard. There was nothing from the FDA that ever said they—there is no change in the label. The question is: Are we going to, regardless of what happened, continue to have medicines available for people that solve tons of problems? As noted by Dr. Campbell, we did have over 40,000 people die last year just from Motrin and Advil and aspirin and Aleve, complications of it.

Every death is a tragedy, but we should not confuse good medicines that are abused and ruin what can be great success for individuals with serious pain. And my hope is with all the people that are suffering grief from the consequences of this, for all the doctors who have written a prescription when they should not, for those of us who assume that chronic pain is not as big a problem as it is—which we do every day. We fail to listen properly to those people who are having that. To our law enforcement who are struggling to try to control this thing, to the real absence of the problem—and here is the real problem. We do not have great drug treatment in this country, and instead, we incarcerate people rather than put them into a drug treatment center where we know two-thirds to three-quarters of them will come out of that and never use drugs again, but yet we incarcerate them.

We need to change the channel on how we do that. We need to offer a helping hand to life back on people who are drug addicted. And we know it will work if we will invest in it.

So to all of you that testified, I want to thank you for making an effort to put forth your views. I would affirm that I think this is a valuable drug in our armamentarium to help people in this country, and until you can get us something better, we ought to continue to use it.

I also agree with Senator Specter that we ought to look at the responsibility of physicians in this country on Class II drugs and do we need to change that. Do we need to restrict—as a physician, I hate that word, "restricting" my ability to practice medicine. But if my peers are not going to be responsible in distributing and writing prescriptions for these medicines, maybe we need to make them more responsible.

The drugs that are on the street, somebody wrote a prescription for. They did not just get out there. They did get them out of the warehouse. Somebody wrote a prescription.

I also am going to enter into the record a statement of Howard Shapiro evaluating the propriety and adequacy of the OxyContin criminal statement. That is at the request of an absent Senator, and I thank each of you for being here, and the hearing is adjourned.

[Whereupon, at 4:16 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

January 25, 2008

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of United States Attorney John Brownlee before the Committee on July 31, 2007, at a hearing entitled "Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General

Cc: The Honorable Arlen Specter
Ranking Member

40884.001

"Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement"

July 31, 2007

Questions for the Hearing Record
for
John L. Brownlee
United States Attorney
Western District of Virginia
United States Department of Justice

QUESTIONS FROM CHAIRMAN LEAHY

1. **You testified that Mike Elston, Chief of Staff to Deputy Attorney General Paul McNulty, called you at home, on your mobile phone, and asked you to delay the deadline that Purdue had to agree to the plea agreement you proffered to them.**

   A. **Was the plea agreement that was in place at the time Mr. Elston contacted you the same plea agreement that you ended up filing with the court eight months later?**

RESPONSE:

The terms of the plea agreements in this case did not change as a result of Mr. Elston's telephone call. Mr. Elston had no impact on the plea agreements.

   B. **Did this initial draft plea agreement allow the Purdue company to continue selling OxyContin? How else was it different?**

RESPONSE:

Yes, the general terms discussed prior to Elston's contact allowed Purdue to continue selling OxyContin. The terms of the plea agreements in this case did not change as a result of Mr. Elston's telephone call. Mr. Elston had no impact on the plea agreements.

2. **In the plea agreement between the Government and Purdue, the criminal acts subject to the agreement were limited to acts that occurred between 1996 and 2001. Dr. Wolfe, who also testified at the hearing, pointed to an additional illegal act, which occurred in 2002. The conduct to which Dr. Wolfe referred was explained in a warning letter, sent to Purdue from the Department of Health and Human Services ("HHS") on January 17, 2003.**

   In its letter to Purdue, HHS stated that Purdue's conduct, involving marketing materials distributed by Purdue, were "in violation of the Federal Food, Drug, and

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Cosmetic Act (Act), 21 U.S.C. §§ 331(a) and (b), 352 (n), and its implementing regulations." This apparent illegal conduct by Purdue was publicly known by the time you were negotiating this plea agreement. As a part of the plea agreement entered into with Purdue, the Government provided Purdue with a non-prosecution agreement. The agreement promised that so long as Purdue complied with the requirements of its plea agreement, the Government would not institute any legal action against the company or its related and associated entities for conduct prior to May 10, 2007.

A. Why did you decide to limit the illegal acts that were the subject of your criminal charges to those occurring before December 31, 2001 when there was evidence at the time you negotiated the plea agreement that illegal conduct had occurred in 2002, and was communicated by HHS to Purdue in 2003?

RESPONSE:

In July 2001, FDA informed Purdue that the Agency believed a "black box warning," the strongest type of warning for an FDA-approved drug, should be added to the OxyContin labeling. This warning was intended to change prescription practices and increase physicians' focus on the potential for abuse, misuse, and diversion of OxyContin. After Purdue added the black box warning, the widespread nature of the misbranding that was the focus of our criminal investigation began to subside. Accordingly, government counsel believed it was appropriate to use June 30, 2001 as the ending date of the crime to which the defendants pled guilty.

The conduct outlined by FDA in its January 17, 2003, Warning Letter pertained to the omission of information from the black box warning regarding the potentially fatal risks associated with the use of OxyContin and the abuse liability of the drug, as well as the unsubstantiated efficacy claims promoting the use of OxyContin for pain relief, in the body of two medical journal advertisements published in October and November 2002. In response to the Warning Letter, Purdue published remedial corrective advertisements in the same medical journals that had run the initial misleading advertisements. The conduct covered by the Warning Letter was addressed by the remedial corrective action taken by Purdue and was distinct from the false or misleading statements that were described in the Agreed Statement of Facts underlying the guilty pleas.

B. Did the version of the plea agreement that Mr. Elston contacted you about contain a later end date, such that it would have covered known illegal conduct relating to OxyContin beyond December 31, 2001?

RESPONSE:

No, the general terms of the proposed plea agreements discussed with Purdue prior to Elston's contact did not include a different end date than the one set forth in the final plea

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agreement. The terms of the plea agreements in this case did not change as a result of Mr. Elston's telephone call. Mr. Elston had no impact on the plea agreements.

QUESTIONS FROM SENATOR SPECTER

1. **You pursued a felony charge and $600 million in fines against Purdue Frederick Company, yet sought a misdemeanor charge, no prison time, and lesser fines against the executives who ran the company.**

   A. **How do you square the charges in this case with the directive of the Department of Justice's Principles of Federal Prosecution of Business Organization (at the time – the "Thompson Memorandum") that "[p]rosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation"?**

RESPONSE:

The plea agreements reached in this case are consistent with Department of Justice policies. In determining whether charges should be brought against Purdue and its executives, the prosecutors weighed all of the factors normally considered in the sound exercise of prosecutorial judgment: the sufficiency of the evidence; the likelihood of success at trial; the probable deterrent, rehabilitative, and other consequences of conviction; and the adequacy of noncriminal approaches. *See* 162 Criminal Resource Manual (CRM) Section III(A).

The Purdue Frederick Company, Inc., and the Purdue executives were charged with and plead guilty to the most serious, readily provable offenses that were supported by the facts of the case. The prosecutors made the determination regarding what charges to bring based on "an assessment of the extent to which particular charges fit the specific circumstances of the case, [were] consistent with the purposes of the federal criminal code, and maximized the impact of federal resources on crime." *See* 162 CRM Section XIII(B). Also, "a charge is not 'readily provable' if the prosecutor has a good faith doubt, for legal or evidentiary reasons, as to the Government's ability to prove a charge at trial." Department Policy Concerning Charging Criminal Offenses, Disposition of Charges, and Sentencing (Sept. 22, 2003) ("Ashcroft Memorandum"). "[C]harges should not be filed simply to exert leverage to induce a plea." *Id.*

It is important to note that corporations are vicariously liable for the acts of employees acting within the scope of their employment for the benefit of the corporation or partnership. A conviction of The Purdue Frederick Company, Inc. on a felony charge of misbranding could be sustained so long as the United States was able to prove that any employee or combination of employees, acting within the scope of their employment, misbranded OxyContin with the intent to defraud or mislead. *See United States v. Bank of New England, N.A.*, 821 F.2d 844, 855 (1st Cir. 1987)("[Y]ou have to look at the bank as an institution. As such, its knowledge is the sum of the knowledge of all of the employees. That is, the bank's knowledge is the totality of what all of the employees know within the scope of their employment.")

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In contrast, corporate executives are not vicariously liable for the felonious conduct of employees within the corporation. Therefore, a conviction of a Purdue executive for feloniously misbranding OxyContin would require proof beyond a reasonable doubt that the executive had personal knowledge of the felonious misbranding activity *and directed that criminal conduct.* Congress *has recognized for fifty years* that in large organizations, such as Purdue, it will be very difficult to prove, beyond a reasonable doubt, that high level executives had knowledge of the misbranding activity of their inferiors. Accordingly, Congress enacted a law, 21 U.S.C. § 333(a)(1), that provides that responsible corporate officers can be found guilty of the misdemeanor crime of misbranding without any showing by the government that the executives had knowledge of *or participated in* the misbranding activity.

Also, in accord with the principles set forth in Federal Prosecution of Business Organizations, the collateral consequences were considered. Purdue Pharma L.P. entered into a comprehensive Corporate Integrity Agreement with the Department of Health and Human Services. *See* 162 CRM Section X. In addition, Purdue Frederick agreed to place a detailed Statement of Facts into the public record to establish Purdue's guilt. *See* 162 CRM Section XIII(B).

2. Although you charged the company and its executives with misbranding under the Food, Drug and Cosmetics Act (21 U.S.C. 333), you make a much broader claim about the seriousness of the offense in your press release, stating that "[i]n the process" of the misbranding "scores died as a result of Oxycontin abuse and an even greater number of people became addicted to Oxycontin[.]"

A. Do you believe that "scores died" as a result of the misbranding?

RESPONSE:

Purdue's crimes of misbranding OxyContin contributed to increased prescribing of the drug. This led to a higher number of OxyContin pills being available for illegal use and diversion. The abuse and diversion of OxyContin resulted in many deaths and much suffering.

According to the DEA, the number of oxycodone-related deaths increased significantly between 1996 and 2001. During that same time period, the annual number of prescriptions for OxyContin increased from approximately 300,000 to more than 7 million. (Actual prescription numbers are: 1996 - 316,789; 2000 - 5,932,981; and 2001 - 7,183,327). The DEA reviewed numerous Medical Examiner reports relating to oxycodone-related deaths in an effort to determine the extent of diversion and abuse of oxycodone products. Of the 949 complete ME reports received by DEA, 146 deaths were categorized as "OxyContin® verified" deaths; 318 deaths were re-categorized as "OxyContin® likely". The remainder were categorized as undetermined deaths (i.e., DEA was not able to determine whether or not OxyContin® was involved in the deaths).

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B. If you don't believe or couldn't prove that the scores of deaths were tied to the misbranding – to the case at issue – why were you making such a claim in your press release?

RESPONSE:

Not applicable.

C. Conversely, if you do believe or had evidence to suggest that scores of deaths were tied to the criminal conduct at issue, why didn't you charge a more serious offense?

RESPONSE:

The United States brought the most serious, readily provable charges against the Company and the executives that were supported by the facts of the case.

1. Are the claims in your press release at variance with the facts of your case?

RESPONSE:

No. The U.S. Attorney statement and press release are accurate and consistent with the Agreed Statement of Facts. There are four important sets of documents for this case: (1) Criminal Information, Plea Agreements, and Corporate Integrity Agreement, (2) Agreed Statement of Facts, (3) U.S. Attorney statement and press release, and (4) Court's Order dated July 23, 2007. Each of those sets of documents provided the Court and public with important and accurate information related to the investigation and prosecution of Purdue and its executives. The first set of documents, Criminal Information, Plea Agreements, and Corporate Integrity Agreement, provided the Court and public with the specific charges filed against the company, the admissions of guilt, and an explanation of the defendants' obligations and penalties. The Agreed Statement of Facts provided the Court and public with a factual basis for the plea agreements as to the elements of the charged crimes. It is important to note that the nature of the harm that was caused by the defendants' crimes was not an element of the charges contained in the Information. The U.S. Attorney statement and press release provided the public with an explanation of the charges and plea agreements as well as a brief history of the investigation and the harm caused by the defendants' criminal conduct. Finally, the Court's Order, like the U.S. Attorney statement and press release, explained the facts of the case, the basis for the Court's acceptance of the plea agreements, and the nature of the harm caused by the defendants' criminal conduct. The Court held that "[t]he potential damage by the misbranding disclosed in this case was substantial and I do not minimize the danger to the public from this crime."

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1a. What you describe is more akin to felony murder or involuntary manslaughter. Is such a description fair?

RESPONSE:

No. The United States brought the most serious, readily provable charges against the Company and the executives that were supported by the facts of the case. Since 1996, Purdue marketed OxyContin in all 50 states, and our prosecution has not and does not restrict any state, other than Virginia, from pursuing criminal charges against Purdue. To date, however, no other jurisdiction has brought criminal charges against Purdue or its executives.

2. The U.S. Attorneys' Manual states at 1-7401(A) that "Prudence and caution should be exercised in the conduct of any press conference or other media contact." Do you think you exercised the requisite amount of prudence and caution here? In the interest of fairness, are you willing to revisit your press statement?

RESPONSE:

The United States Attorney exercised prudence and caution in the preparation and conduct of his press conference. There has been no effort or request to revisit the press statement.

3. Your prosecution has received criticism from all sides. Some have criticized your prosecution in this case for being overly aggressive, relying on demands of attorney-client privilege waiver, strict criminal liability to prosecute executives, and corporate criminal liability. Others have criticized your prosecution as too lenient, especially as to the Purdue executives who received no prison time and face what is an economic sanction.

A. Given your knowledge of the facts in this case, and given the widespread effects of Oxycontin abuse, do you think you would have sought prison time for the executives if the law or facts supported it?

RESPONSE:

We entered into a plea agreement that was supported by the law and facts of the case and was in the best interest of the people of the United States.

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B. Might criminal prosecutions such as this one deter individuals from taking positions as corporate officers, and might such prosecutions deter corporations from making or researching new products or drugs?

RESPONSE:

This prosecution should only deter criminal conduct. Corporate executives in the industries subject to the Food, Drug, and Cosmetic Act have known for more than 50 years that they could face criminal prosecution if they failed to meet their responsibilities under the statute. None of those industries has had a problem finding highly qualified individuals to take positions as corporate officers.

As the Supreme Court said, in *United States v. Park*, 421 U.S. 658 (1975):

> [the statute] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

The individual defendants in this case did not implement measures to ensure that violations would not occur and, as a result, widespread violations were committed by individuals within the company. OxyContin was, by far, the most important product that Purdue sold. This relatively small drug manufacturer was operated under the combined leadership of the charged defendants. A responsible corporate officer who implements the appropriate measures to prevent such violations should have no fear of criminal prosecution. Those who do not implement appropriate measures should expect to be criminally prosecuted.

This prosecution should not deter corporations from making or researching new products or drugs. OxyContin is merely an extended release, highly potent form of oxycodone, a drug substance that has been available for medicinal purposes for approximately 100 years. This was a corporate fraud prosecution in which the company made false statements in an attempt to portray OxyContin as something that it was not (i.e., less subject to addiction, abuse and withdrawal than other pain medications.) *These charges dealt with the false and misleading marketing of Oxycontin, which is an approved drug. The charges were not connected to research and development of Oxycontin . There should be no impact on making or researching new products or drugs as the result of this prosecution.*

4. In your criminal Information and press releases, you state that "certain PURDUE supervisors and employees, with the intent to defraud and mislead, marketed and

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promoted Oxycontin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," and that they gave misleading training and information to sales representatives.

A. Why weren't any of these "certain PURDUE supervisors and employees" charged in this case?

RESPONSE:

The United States charged the most serious, readily provable offenses for the company and its executives that were supported by the facts of the case. The conviction of the corporation as set forth in the plea agreement is supported by evidence that some individual or individuals, for the benefit of the corporation, with the intent to defraud and mislead, marketed and promoted Oxycontin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. To obtain a conviction of an individual, the United States would be required to prove, beyond a reasonable doubt, that a specific named individual had the requisite intent to commit the crime.

B. Is it fair to hold the executives accountable for strict liability crimes when the Department of Justice elects not to prosecute individuals alleged to have an "intent to defraud and mislead?"

RESPONSE:

Yes. Each of the three executives voluntarily accepted positions of responsibility, and the lucrative pay attendant to such positions, in an industry widely known to be subject to strict regulatory scrutiny and in which the responsible corporate agent doctrine had existed for years. Although well aware of their heightened responsibilities, these three executives failed to exercise the due diligence and oversight over their subordinates that would have enabled them to use their authority to implement measures to discover, prevent, and remediate the violations described in the Information and Agreed Statement of Facts.

C. How does this charging approach square with the Department of Justice's requirement that you charge the most serious, readily provable offense?

RESPONSE:

The government's charging decisions comported with all DOJ policies.

5. In "The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA"[1], the authors state that "it makes much less sense today than it did in 1938

[1] Article by Brent Gurney, Howard Shapiro and Robert Mays (of WilmerHale LLP) was released at the American Bar Association's 17th Annual National Institute on Health Care Fraud held May 16-17, 2007.

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to indulge in the fiction that executives – in pharmaceuticals or any other industry – can personally carry [the] burden" of perfect compliance with the Food, Drug, and Cosmetic Act.

A. In bringing criminal charges against Michael Friedman, Howard Udell, and Paul Goldenheim, did you consider whether, as a practical matter, they could have prevented the misleading statements about Oxycontin by trainers or sales representatives within the Purdue corporation?

RESPONSE:

The United States reviewed and considered all relevant evidence in determining the appropriateness of guilty pleas by the individual defendants. This evidence indicated that records documenting the misleading statements about OxyContin by trainers and/or sales representatives within Purdue were readily accessible to the executives. *The Agreed Statement of Facts accompanying the plea agreements sets forth the problems with this marketing approach.* Had these executives exercised due diligence and oversight of the activities of their subordinates they could have discovered, prevented, and remedied these false or misleading statements. Instead, due to this lack of due diligence and oversight the misrepresentations were widespread and continued for years.

B. Are you at all concerned that the strict liability crime you pursued in this case will discourage good people from taking on executive positions in companies?

RESPONSE:

No. *See answer to question 3B.*

1. The "responsible corporate agent" doctrine used by the Supreme Court in the *Park* and *Dotterweich* cases makes clear that corporate executives should not be held criminally liable merely for their position, but only where the executive's position is such that he/she is placed in responsible relation to the violation of the act. If you determined the three executives had a responsible relation to the violation of this law, what specific evidence supported this determination?

RESPONSE:

In the Agreed Statement of Facts, the executives agreed that they were responsible corporate officers, as defined by law, and that "[a] responsible corporate officer for these purposes was one who had responsibility and authority either to prevent in the first instance or to

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promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce." Agreed Statement of Facts ¶¶ 11, 45.

An individual may be guilty of violating the FDCA's less punitive misdemeanor misbranding provision by "a finding . . . that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." *United States v. Park*, 421 U.S. 658, 673-74 (1975).

In *Park*, the United States Supreme Court upheld a jury verdict finding the chief executive officer of a national food chain guilty of an FDCA misbranding violation where the company had caused interstate food shipments being held in their Baltimore warehouse to be exposed to rodent contamination. The Court held that the law provided for criminal liability where the defendant had a responsible relation to the violation, even though he may not have participated personally and even if he did not consciously do wrong. *Id.*, at 665 fn. 9. The trial court's instruction provided that "[t]hough he need not have personally participated in the situation, he must have had a responsible relationship to the issue." *Id.; accord, United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (Food and Drugs Act of 1938 dispenses with the conventional requirement for criminal conduct of awareness of some wrongdoing putting the burden of acting on a person otherwise innocent but standing in responsible relation to a public danger); *United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) (misdemeanor provision of FDCA's misbranding statute imposes liability without any conscious fraud at all, thus creating a form of strict criminal liability); *United States v. Jorgensen*, 144 F.3d 550, 560 (8th Cir. 1998) (corporate officer in responsible relationship to an activity within a company that violates provisions of federal food laws can be held criminally responsible even though that officer did not personally engage in that activity).

The Agreed Statement of Facts accompanying the plea agreement sets forth the fact that Purdue knew that OxyContin was being abused in different communities. Notwithstanding that knowledge, Purdue continued to use labeling that included misleading language.

In *Park*, the Supreme Court held that criminal liability was appropriate for corporate officers who have the authority to prevent or correct the prohibited condition but fail to exercise such authority. A defendant can raise the defense that he was "powerless" to prevent or correct the violation. The evidence in this case established that these three executives were the final decision makers for Purdue's marketing activity. The three defendants admitted that they had the authority to prevent or correct the misbranding activity, and none of the three defendants asserted that they were "powerless" to prevent or correct the violations.

6. In an article in the New York Times on July 31, 2007, Barry Meier cites unnamed sources to suggest that your superiors "appeared initially to favor a less aggressive approach to the case against" Purdue.

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A. Was your prosecution in this case influenced by a disagreement with officials at the Justice Department?

RESPONSE:

The plea agreements reached in this case are consistent with Department of Justice policies. In determining whether charges should be brought against Purdue and its executives, the prosecutors weighed all of the factors normally considered in the sound exercise of prosecutorial judgment: the sufficiency of the evidence; the likelihood of success at trial; the probable deterrent, rehabilitative, and other consequences of conviction; and the adequacy of noncriminal approaches. *See* 162 Criminal Resource Manual (CRM) Section III(A).

Additionally, because the corporate and individual defendants in this case requested an agreement that was binding on all federal prosecutors throughout the United States – what commonly is referred to as a "global agreement" – the U.S. Attorney was required by Department policy to ensure that none of the other U.S. Attorneys nor the Criminal Division had an objection to the "global agreements" before consummating them. In that regard, Section 9-27.641 of the U.S. Attorneys' Manual provides that "[n]o district or division shall make any agreement, including any agreement not to prosecute, which purports to bind any other district(s) or division without the express written approval of the United States Attorney(s) in each affected district and/or the Assistant Attorney General of the Criminal Division."

7. Your prepared testimony refers to subpoenas and "a difficult struggle between Purdue's counsel and the government for the necessary information we needed to conduct our review. Purdue's counsel fought hard and did the very best to protect the requested information and records." Was this struggle over attorney-client privilege claims or other claims?

RESPONSE:

Some of the struggle involved attorney-client privilege claims. For example, Purdue's counsel, for years, refused to turn over many documents, including documents which Purdue's counsel classified as "potentially privileged." After the government finally obtained access to such documents it was clear that a large number of such documents were not privileged.

A. Did you condition the charging decision as to Purdue Frederick, in whole or in part, on the company's failure to provide a blanket waiver of attorney-client privilege?

RESPONSE:

No.

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B. Did you factor this legal struggle over privilege claims into your decision to charge Purdue Frederick with a felony charge?

RESPONSE:

No.

8. You have told my staff and suggested in pleadings that you did not have evidence that senior management within Purdue intended to mislead through misbranding. Did you consider this lack of evidence of management involvement as a factor under the "Principles of Federal Prosecution of Business Organization" guidelines, which state that "Of these factors, the most important is the role of management."?

RESPONSE:

As noted in the Agreed Statement of Facts, there was ample evidence that the misbranding activity was widespread within the company, and that, for the time period of the offense, there were insufficient controls in place to prevent the misbranding conduct.

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James Campbell, M.D. - Questions

1. You stated several times in your testimony that OxyContin is a very effective treatment for chronic pain and has less potential for abuse than other comparable pain medications ***if used as prescribed and directed by a physician.*** You also indicated that you believe it is wrong to hold Purdue Pharma executives criminally responsible for OxyContin abuses. In light of the fact that Purdue Pharma was aware of both the potential for abuse and of actual widespread abuse –
   a. To what extent should Purdue be held responsible when doctors either fail to adequately warn their patients of the risks that accompany a drug like OxyContin, or when doctors overprescribe the drug?

Pharmaceutical companies are held to strict standards with regard to how they promote drugs. Law mandates adherence to these standards. It is illogical to hold a company responsible for the behavior of the prescribing physicians, as physicians understand that a significant addiction liability exists whenever they prescribe a Schedule II drug (OxyContin is Schedule II). I do not believe that a company should be held responsible for a prescriber's failure to evaluate and discuss the risks of a particular therapy with a patient. Neither do I feel that it is appropriate to hold a company responsible for aberrant behavior or errors in judgment on the part of healthcare professionals.

Physicians have a responsibility to select the most appropriate therapy for their patients. It is incumbent upon the prescriber to evaluate the benefits and risks of the medication for each patient and, when warranted, to advise the patient of those risks.

Purdue's prescribing information for OxyContin has always contained warnings regarding potential side effects, and serious adverse events. Furthermore, the company has sought to educate healthcare

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professionals through its sales force and its medical education programs on the proper selection and assessment of patient candidates for opioid therapy based on third-party medical guidelines.

b. To what extent should Purdue be held responsible when its own employees or sales representatives misrepresent or fail to correct misperceptions about OxyContin or its drug base oxycodone?

I believe that a pharmaceutical company has the responsibility to train and monitor its sales representatives' activities to ensure that their representations to healthcare professionals about a product are consistent with that product's prescribing information. It is my understanding that the misstatements in this case were made by employees six or more years ago without the knowledge of the company's senior management and were a violation of company written policies regarding promotion of its products. Based on my understanding of the recent settlement agreement with the federal government, Purdue has accepted responsibility for the actions of its employees, paid a fine, and taken steps to prevent a recurrence of the problem in the future.

2. In your testimony you discussed some of the steps Purdue Pharma took both to warn the prescribing physician of the potential for abuse and to respond to the increased incidence of abuse. In light of the fact that OxyContin abuse is often purposeful and does not occur as a result of taking the medication as directed by a physician, are there other ways to combat OxyContin abuse beyond those already employed by Purdue Pharma?

OxyContin is only one of many medications that are subject to abuse. Currently, efforts to reduce diversion and abuse, such as the programs offered by Purdue, can only be effective through the participation and cooperation of the medical community, law enforcement, our educational and

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social institutions and regulatory entities. There needs to be a greater level of participation between each of these entities in collaborative efforts to prevent diversion and abuse of medications.

Medical students, practicing physicians, and other health care professionals, need more extensive training in pain medicine and addiction medicine so that they understand how to choose the best pain management therapy and manage patients at risk for substance abuse. It may be useful for states to follow the example of California, which requires physicians to complete a continuing education course in pain management as a condition of renewal of their medical license.

Several states like Ohio, Virginia, Kentucky and Nevada have implemented prescription monitoring programs to track the prescribing and dispensing of controlled substances. When properly designed to meet certain standards, these programs can help healthcare professionals and state regulators detect unusual patterns of prescribing and deter potentially unlawful efforts to obtain prescriptions from multiple physicians (e.g., doctor shopping) and pharmacies. There is a need to support the implementation of well designed monitoring programs in all states and to allow and enable the state agencies managing these programs to share access to the data with neighboring states so that physicians, pharmacists and regulators are better prepared to detect and prevent efforts to divert controlled substances for non medical use.

The FDA is working currently with manufacturers to develop risk management plans for specific products, including OxyContin. However these programs are voluntary and there is no standard or minimum requirements defining what constitutes an effective risk management program. Legislation giving the

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FDA the authority to require manufacturers to develop risk management programs that meet a minimum standard may help bring more industry resources to bear on this problem.

For example, one approach to more effective risk management might be to require manufacturers to implement or participate in existing surveillance programs (such as Denver Health Foundation's RADARS System), that identify emerging trends of abuse, diversion and addiction in a timely fashion. If companies and drug regulators can gain a better understanding of the nature of the drug abuse problem in a given area of the country, they can implement targeted interventions (such as outreach to and education of local healthcare professionals and law enforcement personnel) in local communities where an emerging drug problem has been identified.

Finally, the growth of use of opioids for pain control speaks to the fact that pain treatment is largely an unmet medical need. Opioids quite often have significant side effect issues, and patients are forced to choose between these side effects and pain control. Though pain is one of the major health care problems in America, relatively little NIH research money is dedicated to pain research. NSAIDs (aspirin like drugs) also have significant liabilities in terms of health risks (by some estimates there are over 10,000 deaths per year from NSAIDs). In addition the effect of NSAIDs on pain in many patients is often quite limited. The conclusion is that we need better solutions, and to find these solutions requires a major investment into research. The National Pain Care Policy Act of 2007 (H.R. 2994) to be introduced to Congress contains many provisions to address the pain care crisis in America. This Act deserves your full support.

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3. You state in your testimony that it is wrong to describe OxyContin as a "defective product" because it underwent extensive study and examination before it was released on the market, and the FDA approved Purdue's New Drug application for OxyContin, which included the results of numerous clinical trials.
   a. Given widespread abuse, scores of deaths, and some physicians' apparent misunderstanding about OxyContin and oxycodone, how would you describe it?

OxyContin is a safe and effective medication when used as directed. Its active ingredient, oxycodone, is used in numerous other widely prescribed medications, such as Percocet and Tylox. *When used as directed* the abuse liability of OxyContin may in fact be lower than that for the immediate-release preparations of oxycodone. The abuse liability of OxyContin arises from one simple fact, and that is that the dose of oxycodone is higher than with other oxycodone preparations because of the time-release feature.

Abuse and addiction are important and complex problems in America. We need more effective approaches to solving these problems. It is my understanding from published medical literature that the majority of overdose deaths involving oxycodone are in fact caused by the ingestion of multiple substances, including alcohol, illicit drugs and other medications. Clearly there is a need for greater resources to prevent and treat substance abuse. However, these efforts should not restrict the legitimate medical use of medications like OxyContin in appropriately selected patients.

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Prof. Vikramaditya Khanna – Questions

1. In your 2003 article "Should the Behavior of Top Management Matter", published in the Georgetown Law Journal, you said: "the corporation is the better risk-bearer for unintentional wrongdoing, but the corporation is not the better risk-bearer for the intentional or knowing misdeeds of top management." 91 Geo. L.J. 1215, 1254 (2003).
    a. Given what you have heard of the OxyContin case, in your opinion, does the misbranding of OxyContin seem like the type of "intentional or knowing misdeeds of top management" for which you would be in favor of criminal penalties against executives?
    b. In your opinion, generally what kinds of materials would typically and realistically be used to show "intentional or knowing misdeeds of top management"?

Response to Q1.a:

If there were proof beyond a reasonable doubt that executives knowingly or intentionally engaged in an activity (e.g., misbranding a product) that led to very high levels of harm (e.g., serious injuries or deaths) then that would urge me towards suggesting criminal penalties for those executives (assuming civil sanctions had been exhausted). However, I would need more facts on OxyContin to come to a more definitive conclusion on the specific facts of that case.

Response to Q1.b:

There are many types of evidence that might be useful in proving an executive's intent or knowledge. Examples could include a memo or email suggesting what the executive(s) knew or were planning. Another would be testimony from others who observed the behavior of executives (from which one might make certain inferences). Additionally, one might rely on certifications that executives have signed (similar to those that they sign under Sarbanes-

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Oxley) suggesting they are aware of the product risks (or other relevant activities) associated with their firm's products. If an executive signs this it becomes more difficult to argue that the executive did not know of the risks.

Another type of evidence that might be indicative is documentation and information from the compliance department of the firm. If the compliance department were to send information about product risk to executives and there were a meeting about it, which included the executive, then that would provide some proof of what executives probably knew. Documentation from compliance departments has been increasing over the years and there may be meetings revolving around the issues raised by this documentation. As corporations may perceive business and legal benefits from effective compliance programs (e.g., one that informs decision-makers/executives of product risks) then it may be in the corporation's interest to ensure that its executives are made aware of product risks and take some measures to reduce them. If such a system is in place, then it becomes more difficult for executives to say they did not know about these risks.

2. In your prepared testimony you said that you would prefer criminal liability for executives where civil liability against the corporation would not be a sufficient deterrent, and yet you also said that you would prefer a very high knowledge standard for those executives.
   a. Would such a course of action have a truly deterrent effect without the existence of a proverbial smoking gun?

Response to Q.2.a:

One could obtain evidence on the executive's knowledge indirectly and directly (as noted in my response to Q.1.b), but there is the prospect that there may not be sufficient evidence to meet the knowledge requirement. This, however, is also an issue for all crimes to a degree.

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However, it may be worth noting that if we do not require some kind of mental state requirement then we risk frightening away many good people from serving as executives. This may lead to more dangerous products being produced (i.e. less deterrence) as less careful people manage these firms. Moreover, if the costs of such liability are broad enough people may have a disincentive to produce new products (e.g., pharmaceuticals).

3. What tools should Congress employ in crafting legislation to provide a major deterrence to corporate executives from introducing defective products into the stream of commerce – products that cause serious bodily injury or even death – while still preserving the certainty and consistency that corporations need to progress?

Response to Q.3:

I think exhausting civil options is generally the best course of action first. Thus, increasing civil sanctions on executives and corporations would be the first step. If this proved insufficient to obtain the desired level of deterrence then opting for criminal sanctions on executives would be worth considering.

Adding certainty and consistency might be achieved through many means including prosecutorial discretion and legislation. For example, one could narrow the range of acts for which criminal liability was available by requiring, as part of the *actus reus* of the criminal offense, proof of very serious harm (e.g., serious bodily injury or death). Another step might be to place in legislation the requirement that civil penalties be exhausted first. A simple rule may be that if the appropriate sanction is beyond the financial capacity of the firm, its executives, and insurance policies then criminal sanctions against executives may be warranted upon proof of high levels of harm caused and the mental state requirement. One could also begin to specify what is meant by "knowledge" with examples either in legislation or in an enforcement guideline. One further step

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would be to consider enacting safe harbors in certain areas (as we do under Federal Securities Laws) that might provide some certainty to business people about whether their activities are likely to violate the law. All of these legislative steps could be accompanied by greater certainty and consistency in prosecutorial guidelines (e.g., a requirement in enforcement guidelines that criminal prosecution only be initiated if a Senior U.S. Attorney states that civil sanctions are insufficient).

Such rules may not always be easy to enforce or follow, but they provide some level of certainty. In the end, some consistency and certainty in prosecutorial practices and clearer legislation could be beneficial.

4. Does your position on criminal liability for individual corporate officers change where, as in the market for drugs, there are others such as doctors who determine whether a consumer will receive a product?

Response to Q.4:

The presence of intermediaries (e.g., doctors) could influence how one assesses whether the executives had the requisite mental state to be held criminally liable. For example, if the executive knows that the product has harmful effects that are not disclosed to the intermediary or the final consumer then the presence of the intermediary would not influence the executive's liability. However, if the executive knows of the harmful effects and they are accurately disclosed to intermediaries and final consumers then that would tend to suggest that executives should not be held criminally liable. Further, if the executive knew of these effects and they were disclosed to the intermediaries and those intermediaries failed to disclose (and explain) these risks, or distorted these risks, to consumers then the liability of executives would turn to a large degree on whether the executives knew the intermediaries were distorting or not disclosing these risks to consumers. The

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intermediaries may well be liable for some wrongdoing in such a situation.

The presence and behavior of intermediaries goes toward the factual question of assessing the mental state of the executives rather than obviating the need for a mental state requirement. Whether the intermediary should be held liable may turn on what the intermediary knew or could be expected to know.

5. If Congress was interested in addressing cases like the OxyContin case – one in which hundreds of people have died - what actions should Congress refrain from taking? What standards or sanctions against corporate executives do you envision to be counterproductive?

Response to Q.5:

I think criminal sanctions are an option, but they must be carefully crafted and enforced. First, they should have a mental state requirement (such as knowledge) and prosecutors in the US Attorneys Office should be encouraged to rely on them only when civil options have been exhausted (as suggested above). Consequently, criminal sanctions with a minimum knowledge requirement seem important. Moreover, a prosecutorial understanding or legislative requirement that criminal sanctions only be sought if both: (1) the level of harm is very high and (2) civil options have been exhausted seems a useful supplement to the mental state requirement. Without providing some mental state requirement and requiring civil sanctions to be exhausted first we risk deterring the production of many potentially valuable products as well as potentially increasing the risks of some products if less careful people become executives.

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Questions for the Record for Senator Tom Coburn, M.D.
"Evaluating the Propriety and Adequacy of the Oxycontin Criminal Settlement"

Question for Jay McCloskey.

1) In his testimony, Dr. Sidney Wolfe stated: "The subsequent sharp decrease in sales – with 2006 sales being only 37% of the peak sales year in 2003 – confirms that once, belatedly, illegal promotion was finally stopped, the ill-gotten sales and profits dropped significantly." Do you agree or disagree?

I disagree. This statement and its underlying assumption are not supported by the facts. The decline in sales of OxyContin after 2003 is because of generic competition to OxyContin, which began in April 2004. Prior to April 2004, OxyContin comprised 100 percent of the long-acting oxycodone market. By December 2006, generic competition had reduced OxyContin's share of that market to 18 percent. During that time, as the attached graph furnished to me by Purdue demonstrates, overall prescriptions for long-acting oxycodone remained relatively constant while prescriptions for long-acting oxycodone dispensed with OxyContin fell dramatically. Under the laws of many states and the practices of many health care plans, once an FDA-approved generic is available, a prescription written for the branded product must ordinarily be filled with the generic, even if the physician writes the name of the branded product on the prescription. OxyContin's sharp decrease in market share due to generic competition (rather than what Dr. Wolfe suggests) is what caused the sharp decrease in sales of OxyContin after 2003.

Attachment: Prescriptions Dispensed for Long-Acting Oxycodone
(January 1996 - December 2006)

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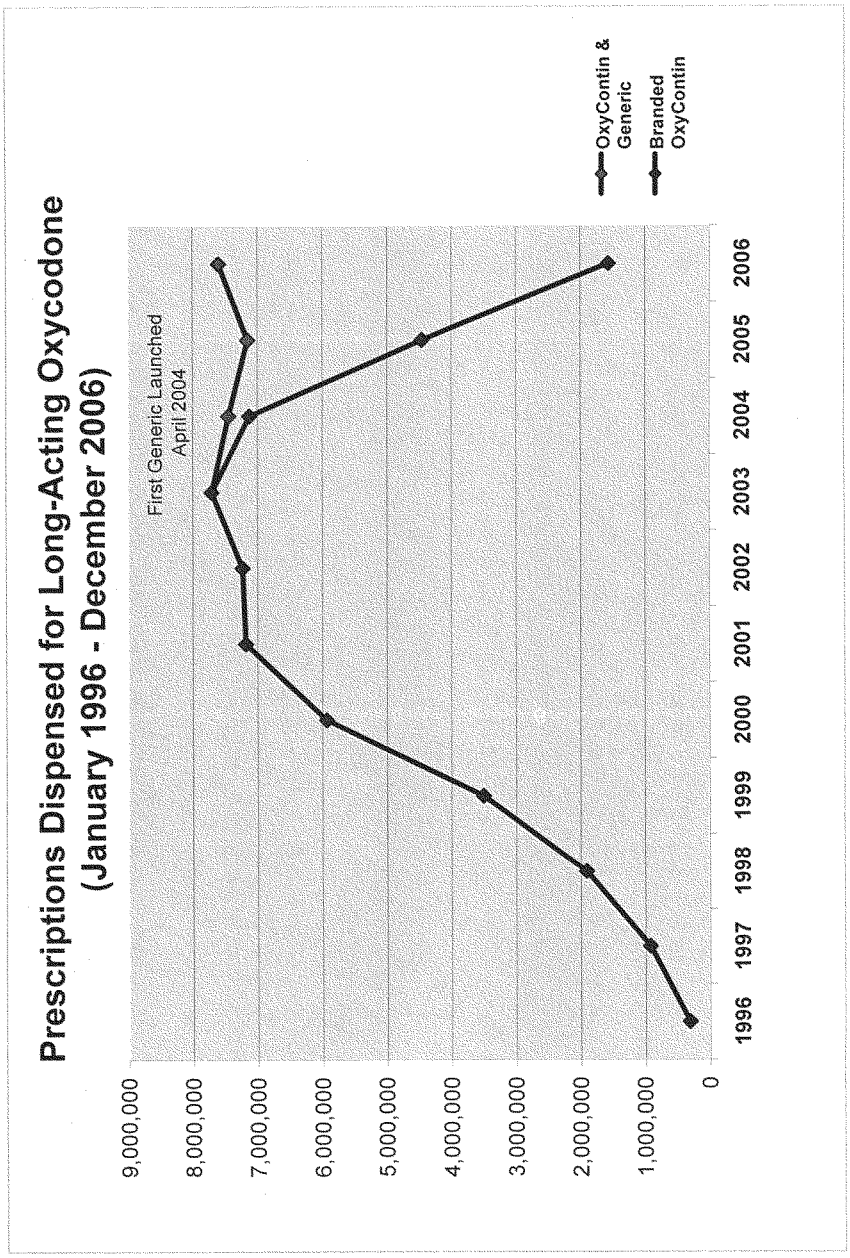
Prescriptions Dispensed for Long-Acting Oxycodone
(January 1996 - December 2006)
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First Generic Launched
April 2004
OxyContin & Generic
Branded OxyContin

Jay P. McCloskey - Questions

1. Although your testimony shows that Purdue appeared to take steps to limit illegal access to Oxycontin beginning with their contact with your office in March 2000, the misbranding conduct covered by the plea agreements takes place from December 1995 through about June 30, 2001.
   a. What, if any, actions are you aware of that Purdue took before March 2000 to make sure Oxycontin was not being illegally diverted?

      Since OxyContin was first approved by the FDA, the product's prescribing information, which is distributed by Purdue Pharma to healthcare professionals, has always identified the medication as an "opioid with an abuse liability similar to morphine" and "a Schedule II controlled substance." The prescribing information also states that oxycodone products are targets for diversion and abuse. In fact, Dr. Kathy Foley, who ran the Pain Service at Memorial Sloan Kettering Hospitals and who I understand to be one of the leading pain experts in the world, wrote to the judge who presided over the Purdue case: "[T]he package insert at the time that it was first published was viewed as providing even more information on the risks and benefits of opioids and their potential for abuse than package inserts for the comparable available strong opioid drugs."

      Purdue Pharma regularly provides healthcare professionals with important information about the proper prescribing of opioid analgesics. Since 1998, Purdue's representatives have distributed more than one million copies of medical guidelines on the proper use of controlled substances published by the Federation of State Medical Boards, the American Pain Society, and numerous federal and state health agencies. These materials emphasize the need to properly evaluate patients, help teach physicians about proper documentation, and alert healthcare professionals to the possibilities of abuse and diversion.

      Since March 1997, the company has also distributed hundreds of thousands of Opioid Therapy Documentation Kits that provide physicians with tools to select and evaluate which of their patients may benefit from opioid therapy and to properly assess and document the patients' pain. I have learned from doctors and experts in the field that proper patient selection and monitoring of therapy – that is, making sure that patients with a legitimate medical need are receiving and ingesting the proper amounts of medication – are important factors in reducing abuse, diversion and addiction.

   b. You state in your submitted testimony that Purdue officials "expressed surprise at the extent of the diversion of Oxycontin in Maine" when they met with you in September 2000. Were you

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yourself surprised that they were unaware of the extent of abuse of their product, which was a strong painkiller that had, at that time, been on the market for over four years?

I was not surprised that Purdue Pharma was unaware of the extent of abuse of their product in early 2000, since neither the United States Drug Enforcement Administration (DEA) nor apparently the United States Food and Drug Administration (FDA) were aware of the problem at that time either.

As I stated in my initial testimony to the committee, the company contacted me soon after I sent a letter to physicians in Maine in February 2000 expressing my concern about the growing abuse of OxyContin. The company requested a meeting with me to learn more about the nature of the problem and offer their assistance. As I indicated in my previous testimony, I arranged a meeting with the company and local law enforcement officials in September 2000 in order to determine if the company could in fact support our local efforts to address the problem.

In early 2000, I called the Special Agent-in-Charge of DEA for New England, located in DEA's Boston Office,,to alert him to the growing problem of OxyContin abuse and to request additional diversion agents to help address OxyContin diversion and abuse in Maine. It became clear during that conversation that the DEA personnel responsible for monitoring and combating drug diversion in the region were unaware of the nature and scope of the problem at that time. I was told not to be concerned about the issue and that the fastest growing drug abuse problem in New England involved Ecstasy.

The DEA's dismissal of my concerns should not be understood as a criticism of either the agency or the Special Agent-in-Charge with whom I spoke. This was a problem that was just emerging at the time and law enforcement was unaware of its scope.

The FDA may also not have been aware of the extent of the problem. FDA officials stated in testimony before the United States Senate Committee on Health, Education, Labor & Pensions in February 12, 2002, that the agency "did not foresee the widespread abuse, and misuse of OxyContin that has been reported in the past few years."

In retrospect this, too, is not surprising, since the national drug surveillance data available at that time did not reflect reports of what was happening on the ground in Maine.

The federal Drug Abuse Warning Network (DAWN), which tracks hospital Emergency Department (ED) visits involving reports of drug abuse, did not

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show a significant increase in ER visits involving sustained-release oxycodone until 2001 and that data was not publicly available until July 2002. Therefore, DAWN, while a useful surveillance tool, did not provide an early warning system to help identify drug abuse trends as they were occurring. Furthermore, the National Household Survey on Drug Abuse, which asked individuals if they had ever used a particular drug for non-medical purposes in their lifetime, did not begin asking about non-medical use of OxyContin until 1999, and did not show a significant increase in reports of non-medical use of the product until 2001.

c. It appears that many of Purdue's voluntary measures involved preventing illegal *diversion* of Oxycontin. What measures, other than taking the 160-milligram tablet off the market, did Purdue voluntarily take to conceivably prevent *abuse and addiction*? What measures does Purdue take today?

It is my belief that there is a direct relationship between reducing diversion and reducing and preventing abuse and addiction. Furthermore, based on my work with the company, I know that many of their medical education and public education programs are indeed aimed at preventing abuse and the potential for addiction that can stem from abuse. Some patients who receive a medically necessary prescription for OxyContin may take the medicine improperly despite the advice of their physician and the warnings contained in the product's FDA-approved patient information. However, virtually all of the medicine that is diverted outside of lawful supply channels is intended for illegal sale to recreational drug users and individuals with substance abuse disorders. Therefore, almost on a pill-for-pill basis, prevention of diversion also protects against abuse and – because abuse increases the risk of addiction – addiction itself.

I have attached a document provided to me by Purdue Pharma entitled "Key Purdue Initiatives to Combat Prescription Medicine Diversion and Abuse" that summarizes some of their efforts to combat abuse and addiction as well as diversion.

2. You state in your written testimony that when you first became aware of the OxyContin problem, your 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. Can you briefly describe this initiative? In your opinion, was this initiative effective?

In a six month period, from February to July 2000, my office with the help of drug agents, police officers, physicians and other experts and volunteers implemented a variety of programs including:

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a. A prevention education program was developed and presented to approximately forty high schools in eastern Maine.
b. An awareness program was developed for doctors, pharmacists and others in the health care community since much of the diversion was occurring through "doctor shopping" or the forging or altering of prescriptions.
c. A outline of a model substance abuse treatment program for young opiate abusers was developed.
d. Community coalitions were organized in the three Maine counties where opiate abuse seemed to be growing most rapidly.
e. A media campaign was organized which produced radio and television ads by the author Steven King and others, warning of the dangers of opiate and heroin abuse.
f. A committee composed of doctors, pharmacists, drug agents, pharmacy inspectors, the State medical and pharmacy licensing boards was formed to work on prescription writing issues and the electronic transmission of prescriptions.
g. As stated, a traditional law enforcement effort involving multiple agencies was also organized and implemented.
h. Educational programs related to appropriate prescribing of opioids. For example, I participated in two CME programs in Maine which were jointly sponsored by Tufts University School of Medicine and the Maine Medical Association and were funded with an unrestricted educational grant from Purdue.

I believe the multi-level campaign was effective in reducing the growth of prescription drug abuse while it lasted. I received many letters from high school principals praising the effectiveness of the program. Law enforcement statistics also reflected a decrease in prescription drug cases in 2001 and 2002. Unfortunately, shortly after I left office as United States Attorney, the program was abandoned.

3. You note that Purdue Pharma developed and implemented procedures to advise law enforcement and state medical boards regarding suspicious OxyContin prescribing practices by medical professionals.

   a. To your knowledge, how effective were these programs? What type of information was reported?

   To my knowledge, Purdue is the only pharmaceutical company that has implemented a program aimed at screening for potentially aberrant prescribing activity. I consulted with the company on the creation of this program and its subsequent implementation. Furthermore, Purdue has provided me with some additional details of the program which I summarize below. Since the inception of the program in 2002, Purdue has initiated referrals to law enforcement or

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regulatory authorities (such as medical boards) in approximately 57 instances. In dozens of additional instances, Purdue has provided assistance where investigations of potential misprescribing were already pending.

In the cases in which Purdue initiated a referral, it has provided the state medical boards or law enforcement authorities with the pertinent information giving rise to the concern about the particular healthcare professional as well as relevant identifying information. I know from my experiences in law enforcement that this kind of information can often be critical to efforts to identify and stop inappropriate practices.

I understand that these efforts were considered quite effective. To my knowledge, Purdue analyzed prescribing data in an effort to ascertain whether information about potentially aberrant prescribing practices could be derived from these data. Although analysis of the prescribing data is useful to spot potential problems, after months of study by internal and external experts, it was determined that Purdue's internal program was more predictive of potentially problematic prescribing than an analysis based solely on prescribing data.

b. To the best of your knowledge, did Purdue Pharma respond in any way to the reports or was the information strictly relayed to law enforcement and state medical board personnel?

Purdue reviewed and considered each report that was made concerning potentially aberrant prescribing. In hundreds of those cases, even where it determined that a referral to law enforcement or regulatory authorities was not warranted, Purdue decided that it would no longer promote its products to a particular healthcare professional. In many additional instances, Purdue provided educational materials to the healthcare professional or referred healthcare professionals to educational meetings or seminars in the area to assist in educating the professional about appropriate prescribing practices. In instances where a report raised a concern about potential misconduct and there was no information to suggest that an investigation was already pending regarding that professional, Purdue initiated a referral as referenced above.

c. Have these procedures lead to prosecution of any medical personnel reported as engaging in abusive prescribing practices?

When Purdue initiates a referral to law enforcement and/or regulatory authorities, the details of the subsequent investigation related to the healthcare professional are confidential. Purdue is aware, however, that in many instances authorities have taken official action based upon their finding of wrongful conduct against a healthcare professional where a referral was initiated by Purdue.

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d. Have the medical boards taken action against any personnel reported as engaging in abusive prescribing practices?

Yes, as set forth above, Purdue is aware that in many instances authorities have taken official action against healthcare professionals where Purdue initiated a referral to the authorities.

Attachment: Key Purdue Initiatives to Combat Prescription Medicine Diversion and Abuse

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Key Purdue Initiatives to Combat Prescription Medicine Diversion and Abuse

- **September 2000:** Michael Friedman, President and CEO, and Howard Udell, Executive Vice President and Chief Legal Officer, traveled to Maine to meet with the US Attorney there after reports of OxyContin® (oxycodone HCl controlled-release) Tablets abuse appeared in the Portland press.
- **February 2001:** Purdue began its national "Protect Your Practice" campaign involving direct mailings to 395,000 prescribers and 65,000 pharmacists and follow-up visits with sales representatives to heighten awareness among healthcare professionals about diversion and abuse risks.
- **March 2001:** Purdue launched its tamper-resistant prescription pads program, which involved providing such pads at no cost to healthcare professionals in Virginia to help curb prescription fraud. The program was subsequently expanded and, to date, more than 16,000 prescribers in 33 states and the District of Columbia have ordered these pads.
- **March 2001:** Purdue endorsed appropriately designed state prescription monitoring programs to reduce "doctor shopping" by diverters who unlawfully obtain prescriptions for controlled substances from multiple prescribers. To date, 31 states have enacted legislation to implement a prescription monitoring program. Twelve additional states are considering such legislation in 2007.
- **April 2001:** Purdue voluntarily ceased distribution of 160 mg tablets after reports of concern about potential misuse of the 160 mg tablet.
- **April-May 2001:** Purdue launched its "100 Counties Program" under which Purdue management directed its sales representatives in at-risk counties to focus discussions with healthcare professionals on reducing abuse and diversion.
- **June 2001:** Purdue established RADARS® System (Researched Abuse, Diversion, and Addiction-Related Surveillance), the first national surveillance program to detect and investigate abuse of specific pharmaceuticals with geographic specificity.
- **July 2001:** Purdue voluntarily added amplified warnings about abuse and diversion to OxyContin product labeling and trained sales representatives to call healthcare professionals' attention to these warnings.
- **July 2001:** Purdue sent 800,000 letters to healthcare professionals alerting them to the amplified warnings in the OxyContin labeling.
- **November 2001:** Purdue launched Painfully Obvious®, an awareness program designed to educate pre-teens, parents and teachers about the dangers of prescription drug abuse.

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- **November 2001:** Purdue established its Law Enforcement Liaison and Education (LELE) program to assist law enforcement in detecting and apprehending criminal diverters and to counsel practitioners on how to protect their practices from criminal diverters. To date, more than 400 educational programs have been conducted, reaching more than 13,500 law enforcement professionals.
- **August 2002:** Purdue hired a drug diversion expert and former agent for the DEA and FDA as its Vice President of Corporate Security to head overall security operations and to work with law enforcement to reduce theft and illegal trafficking in Purdue products.
- **June 2003:** Purdue established RxPatrol®, the first national clearinghouse of data to be used to deter and solve pharmacy crimes.
- **October 2003**: Purdue completed initial development, refinement and introduction of Controlled Substance-Patterns of Utilization Requiring Evaluation (CS-PURE®) software to managed care customers. CS-PURE is an approach to identify, for further evaluation, potential members with controlled substance misuse or mismanagement, using software queries applied to administrative health claims data.
- **March 2004:** Purdue endorsed federal legislation to provide grants to states for conforming Prescription Monitoring Programs that could interact with other states' PMPs.
- **March 2004:** Purdue endorsed federal legislation to place restrictions on internet sales of controlled substances.
- **November 2004:** Purdue began use of RFID (radio frequency identification) tags integrated into labels on 100-tablet bottles of OxyContin to protect against counterfeiting and diversion.
- **April 2005:** Purdue created a partnership with Crime Stoppers USA SM to publicize descriptions of suspects and offer rewards for information leading to the arrest of pharmacy robbers. Since inception, 27 arrests have been made based on information provided through this program.

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The professional product labeling for OxyContin® Tablets contains the following **boxed warning:**

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Full prescribing information for OxyContin is available at http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf.

# # #

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Virginia Pagano - Answers to Senate Questions

1. I truly believe that most people who hear 'Oxycontin' immediately think "doctors", "prescription drug", "legal", "safe", and "controllable". I believe this, in and of itself, contributes to how susceptible some people are to this drug at the onset of use. (i.e. As long as they are not using heroin, crack, cocaine, meth, etc., they think they are okay. We have to remember the stigma attached to "illegal drugs", and so as long they are not using "illegal drugs" they believe they are not addicts.) Many people become addicted after being prescribed this medication for very real pain. Many others self-medicate and again, they think "prescription drug" and "manageable". Their mind-set is "it's just a pill", and "how could I get addicted?", or "it's never going to happen to me".

2. a) One word – "AVAILABLE": Example: If one person in a household is prescribed Oxycontin for a real medical reason, any other person looking to experiment (or who is already using) has easy access either for selling to make money to support their own addiction, or using the Oxycontin because of their addiction. You never have to approach a "drug dealer" and buy it, and Oxycontin even today does not have the same stigma attached to it. This, of course, is only one theory. According to the Philadelphia Medical Examiner's Office, since 2000 there has been a 64% increase in decedents with oxycodone in their systems (refer to Philadelphia/Camden HIDTA 2008 Threat Assessment).

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b) As their tolerance to the drug increases, people need more and more Oxycontin to maintain their high. Oxycontin is very expensive as a street drug (roughly $1.00 per mg. i.e. 10 mg. pill = $10.00, 20 mg pill = $20.00 and so on). As the price of their addiction increases, more often than not, they switch to heroin which is cheaper, and at that point the stigma of using an illegal drug no longer matters to them. No addict I have met will use $60.00 for one 60 mg pill of Oxycontin when they can get approximately six bags of heroin for the same amount of money and get the same high. As I say in the HEADS-UP Program in reference to Oxycontin and heroin:

"SAME HIGH"

"SAME ADDICTION"

"SAME WITHDRAWAL"

3. The most common methods of pharmaceutical diversion in the region are theft (i.e. from homes where someone has been legally prescribed Oxycontin, drug stores, nursing homes, etc.) fraud, patients selling prescribed medicines, health care professionals prescribing medicines to people with no legitimate medical need, prescription forgery, "doctor shopping schemes", rogue internet pharmacies, and the list goes on.

4. a) The HEADS-UP Program reached its' seven year anniversary on April 10, 2008. HEADS-UP was established to attack drug and violence problems from a preventive standpoint. The Philadelphia Police Department (Office of Violence Prevention and Victim Services) realizes the importance of this type of program. The program presents a very real outlook on the damage and

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destruction that drugs and violence are causing young and old alike. This program is so important that every effort must be made to present it to as many people as possible. The program itself is presented in power-point and is narrated by police officers from the Philadelphia Police Department. Other key components are the volunteers from the recovery community and, most importantly, family members who have lost loved ones to drugs and violence. The volunteers speak from the heart to convey their stories. Together they have devoted their time and energy to educate children and adults in order to prevent their involvement in drugs and, hopefully, give them the tools to build solid character.

b) Preventive.

The goal of the program was, and still is, to educate as many people as possible. The number of people who have seen the program continues to grow every year.

We pride ourselves on the fact that we have never turned down anyone who has called to schedule a program or asked for help with treatment.

We will continue our quest to reach as many people as possible, hopefully inspiring and motivating them into making better choices concerning their lives. Our ultimate goal is to not have another family experience the heartache that comes from drugs and violence.

c) I strongly believe it would be very beneficial if the HEADS-UP Program would be made mandatory within the schools. I believe that everyone who

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has had the opportunity to view the HEADS-UP Program has benefited in some way.

For more information on the HEADS-UP Program you can go to our website, www.ppdonline.org and look for the Prevention tab. Click on Prevention and you will find the HEADS-UP Program on the left.

P/O Virginia Pagano
267-235-5492 (cell)

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Marianne Skolek – Questions

1. Ms. Skolek, I know this may be painful for you, but could describe your daughter's involvement with OxyContin? That is, could you describe how she came to be prescribed the product in January 2002, her battle with her addiction to the product, and her attempts to stop using it?

Marianne Skolek response 8/8/07 -- Jill was prescribed OxyContin by an orthopedic surgeon in January 2002 for a herniated disc. When she questioned the physician about the drug, he assured her there was little risk of addiction and it was a "miracle" drug. She did not attempt to stop using it, but used it for 4 months up to 4/29/02 when she died. I suspect she came to be addicted to OxyContin, but did not "battle her addiction" because she had been prescribed the drug by a physician she trusted when he told her the drug was not addictive.

a. Do you know if Jill was informed about the risks of using OxyContin by her doctor?

Marianne Skolek's response 8/8/07 - I was not with Jill when she talked with her physician so I do not know if he explained the risks of the drug, or even knew there were risks associated with the drug.

2. Ms. Skolek, how do you respond to Dr. Campbell's written testimony that claims, "[w]hat I believe is often lost in the discussion of OxyContin is that the abuse problem itself arises almost entirely from intentional abuse rather than from use according to proper prescribing[?]"
Marianne Skolek's response 8/8/07 - the proper prescribing of the drug was tainted by the marketing of OxyContin as less likely to be addictive or abused and what Purdue Pharma and Friedman, Udell and Goldenheim pled guilty to and were convicted criminally of. Intentional abuse was not the issue here, physicians put the lives of their patients at risk because of exactly what Purdue Pharma and Friedman, Udell and Goldenheim pled guilty to -- that the drug was less likely to be addictive or abused. The abuse problem is in epidemic proportion throughout the country because OxyContin is in such plentiful supply on the streets in every state in the country.

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a. To your knowledge, your daughter did not take Oxycontin before being prescribed it by a doctor, did she?

Marianne Skolek's response 8/8/07 -- Jill did not take OxyContin before being prescribed by a physician who was misled by Purdue Pharma into thinking the drug was less likely to be addictive or abused and which Purdue and Friedman, Udell and Goldenheim pled guilty to and were convicted of criminally.

3. In your opinion, what would the FDA and the DEA say in response to the question you pose in your written testimony, "why is OxyContin in such plentiful supply on the streets across America?"

Marianne Skolek's response 8/8/07 -- OxyContin has found its way onto the streets in every state in the country and there is an epidemic of unbridled proportion because it is mass manufactured by the same pharmaceutical corporation that was criminally convicted of misleading physicians and patients as less likely to be addictive or abused which resulted in thousands of addictions and deaths throughout each state.

4. As a nurse, what appropriate role do you see for doctors and health professionals in screening out potentially dangerous drugs for their patients? Do they or should they bear some responsibility if they rely on misleading statements by aggressive sales representatives?

Marianne Skolek's response 8/8/07 -- In Purdue Pharma's case, it was not the aggressive statements of their sales representatives. Sales representatives represent their product and in this case a drug by what they have been instructed to tell the customer by the pharmaceutical company's management team. Sales representatives promoted OxyContin as less likely to be addictive or abused because this is how they were told to market it to physicians which resulted in thousands of addictions and deaths throughout the country. This was also what Purdue Pharma and Friedman, Udell and Goldenheim were criminally charged with and pled guilty to. Sales representatives are not the convicted criminals here.

5. In your opinion, is there a benefit to the continued availability of Oxycontin? Do pain societies have a legitimate interest in the

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access to strong painkillers that have the potential for addiction as well as other side effects?

Marianne Skolek's response 8/8/07 -- OxyContin was intended for terminally ill cancer patients who could not become addicted to the drug because their life expectancy was short. When Purdue Pharma reaped the rewards the first year of marketing OxyContin beyond what they expected, they off labeled marketed OxyContin which has resulted in a modern day epidemic in the country of addiction and death. At one point, Purdue Pharma began a marketing campaign to market OxyContin to OB/GYN patients. I flooded the country with emails and faxes to every Attorney General and the media in an effort to prevent further destruction of lives. Purdue Pharma shortly thereafter withdrew their marketing campaign to market to OB/GYN patients. Pain societies throughout the country are funded by Purdue Pharma whose revenues are now approximately $9 billion. No pain society would be willing to risk losing that funding from Purdue Pharma.

As an addendum to these questions, I have a bill which Congressman Michael Ferguson of New Jersey has in his possession which is entitled the Jill Carol Skolek Bill which in part calls for prison time for any pharmaceutical corporation and its executives being charged with criminally marketing a dangerous drug which jeopardizes the health and safety of the American people. I will keep you informed as to the status of the bill. Please feel free to contact Congressman Ferguson at 908-757-7835. He has been very responsive to me and the safety of not only the citizens of New Jersey, but every state in the country.

Thank you Senators for giving me the opportunity to being the voice for all victims of Purdue Pharma and Friedman, Udell and Goldenheim criminal activity. I will be available to you further in an effort to bring justice to these victims. Marianne Skolek

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Sidney M. Wolfe, M.D. Questions

1. You mentioned in your interview on May 11, 2007, on the PBS on-line NewsHour that "the papers that were produced yesterday clearly show that somebody in the company intended to defraud and mislead."
    a. Although it could not be substantiated with the three Purdue executives, do you believe that there are Purdue employees who should be criminally prosecuted under felony charges and serving time? Do you have any idea who those persons are? With what do you believe these individuals should be charged?

Since the standard for felony is "intent to defraud and mislead", the following activities by Purdue employees involved in marketing the drug, agreed upon by both parties as statements of fact, clearly qualify as felonies (all are taken from the material released by the U.S. Attorney's Office on May 10 when they announced the prosecution):

"....certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted Oxycontin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:" [1]

(The following are descriptions of these intentionally fraudulent or misleading activities as summarized in the press statement of U.S. Attorney Brownlee on May 10, 2007) [2]

"A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote Oxycontin.

B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.

C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed

[1] Page 5 of attachment B of May 10, 2007 plea agreement entitled "Agreed Statement of Facts"
[2] Pages 5 and 6 of U.S. Attorney Brownlee's press release of May 10, 2007.

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that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to **falsely teach Purdue sales supervisors** (emphasis supplied) that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids."

Unless there is a mystical belief that those above-described supervisors and employees who committed these felonious acts do not exist as individuals but are merely, as suggested by U.S. Attorney Brownlee, part of the "corporate culture", why were they not criminally prosecuted for the felonies that are agreed upon as statements of facts?

2. Despite the fact that you believe that individuals within Purdue Pharma should be held serving prison time for their actions, do you think that the $600 million in fines to the company and over $35 million personally to the Purdue executives convicted executives makes a bold statement regarding society's intolerance for this type of conduct? Do you think it will act as a deterrent to other similarly positioned companies?

If, as stated by U.S. Attorney Brownlee, Purdue had been forced to disgorge 90% of its profits, this might have sent a stronger message to other companies contemplating criminal activity as a way of selling more drugs. As stated in my testimony, however, the actual profits from Oxycontin were well over $2 billion and thus the $600 million in fines constitutes a much smaller portion of the profits. It was clearly stated by Senator Leahy during the hearing that "nothing focuses the mind as much as thinking you are going to be behind bars. Fines can sometimes become simply the cost of doing business." Senator Specter added that "I see fines with some frequency and think that they are expensive licenses for criminal conduct."

Thus, the paying of criminal penalties, even the larger more appropriate ones that should have been imposed, is not remotely as effective deterrent to subsequent corporate criminal activity such as this as going to jail would have been.

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3. Mr. Jay McCloskey, former U.S. Attorney for the District of Maine, noted in his submitted testimony that he witnessed Purdue Pharma undertaking extraordinary measures to help prevent illegal diversion of OxyContin.
   a. Do you believe Purdue's actions at that time were effective and adequate?

   Mr. McCloskey described meetings he had with the company as early as 2000 concerning the serious problems with Oxycontin. The illegal activities of the company, continuing through but extending well beyond the December 31, 2001 ending date of the period of prosecution, give lie to the notion that Purdue's actions were effective and adequate except to the end of selling more and more Oxycontin each year, with sales in 2002, 2003 and 2004 all well above the sales in any previous years.

4. To determine which criminal sentences to impose on individual Purdue Pharma officials, one must look to their intent in misbranding.
   a. Would you also propose taking into account evidence of Purdue's good faith efforts, including whether the company assisted law enforcement or informed health care providers?

   As in evaluating the benefits and risks of a drug, the company's good faith efforts, including any assist to law enforcement or informing health care providers were outweighed by the damage they did in criminally, but successfully, promoting the drug. As late as the end of 2002, they were caught by the FDA with misleading advertising of Oxycontin strikingly similar to the earlier distortions of its dangers that formed the basis for the criminal prosecution. I would not think that many law enforcement officials in the country, especially from areas that had massive amounts of Oxycontin use and abuse, would look upon the company as assisting law enforcement.

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SUBMISSIONS FOR THE RECORD

RICHARD BLUMENTHAL
ATTORNEY GENERAL

55 Elm Street
P.O. Box 120
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Office of The Attorney General
State of Connecticut

TESTIMONY OF
ATTORNEY GENERAL RICHARD BLUMENTHAL
BEFORE THE SENATE COMMITTEE ON THE JUDICIARY
JULY 31, 2007

I appreciate the opportunity to submit testimony on OxyContin and other defective products that cause death or serious injury. I commend the committee for holding a hearing on this important issue and Senator Specter for his continuing concern about the need for greater criminal penalties to deter knowing distribution of dangerously defective products

OxyContin is the latest grim example of corporate greed and arrogance causing death and serious injury. More than one hundred years ago, a similar corporate mindset led to many federal and state consumer protection and employee rights laws. The question we must ask is whether these laws offer sufficient deterrence -- and the answer clearly is no

Purdue Pharma conducted focus groups and determined that physicians would be reluctant to prescribe OxyContin because its main ingredient, oxycodone, is so addictive. Purdue Pharma also determined that physicians were looking for effective pain medication with low risk of addiction. Although Purdue Pharma knew that OxyContin was highly addictive, it instituted a comprehensive marketing campaign that continuously marketed OxyContin to health care providers as a pain management drug with low risk for addiction

While Purdue Pharma made hundreds of millions of dollars in profits, more than 300 people died as a result of overdoses of OxyContin

I urge Congress to consider several initiatives to toughen our criminal sanctions and strengthen our oversight agencies to prevent a recurrence of the tragedy of OxyContin:

- Classify as a federal felony any knowing distribution of a product that is defective and causes serious injury or death
- Require mandatory prison terms for any individual convicted of such felony.
- Require the Food and Drug Administration to make a final ruling on Citizen's Petitions within six months of submission unless extended through agreement with the petitioner.

Corporate officials who knowingly and willfully distribute a defective product where the defect directly causes death or serious injury should be held to the same standard as an individual who kills or injures another person

Many victim families are understandably disappointed in the plea agreement between Purdue Pharma executives and the United States Attorneys office because it failed to require any prison terms for the individuals who knowingly allowed a false marketing campaign Payment of hundreds of millions of dollars in fines and forfeitures may be appropriate and commendable, but significant deterrence usually depends on prison terms

Individuals who engage in illegal actions that cause significant financial harm are imprisoned. Why not corporate officials who engage in illegal actions causing death and serious injury?

Federal law must mandate minimum prison terms for individuals whose illegal corporate activities cause death or serious injury.

While strengthening federal deterrence is important, Congress should also consider making federal oversight agencies more effective in preventing such tragedies.

The Food and Drug Administration (FDA) is charged with ensuring that prescription drugs are safe and effective, and properly marketed Yet, the FDA turned its back on its serious responsibility with regard to OxyContin. Despite all the evidence available to the FDA -- through public media reports and private government channels -- the FDA never even required Purdue Pharma to add a black box warning or implement a Risk Management Plan until 2001, five years after the drug was launched

On January 23, 2004, after a year-long investigation of Purdue Pharma and after uncovering alarming evidence that the company knew the drug was being mis-prescribed by physicians but not taking appropriate action to warn them, I filed a detailed Citizen's Petition with the FDA. The petition requested the FDA require Purdue Pharma to expressly warn prescribers of the increased occurrence of side effects or potentially serious adverse reactions resulting from prescribing OxyContin at dosing intervals less than the manufacturer's recommended 12 hours. The petition suggested strengthening the drug's black box warning statement, supplementing the labeling with additional bolder warnings and initiating a "Dear Healthcare Professional" letter.

More than 3 years have passed and the FDA has yet to rule on -- or even substantively answer -- the petition While federal law establishes a Citizen's Petition process, there is no deadline within which the agency is required to make a final ruling. I have enclosed my recent letter to the FDA expressing my concern and frustration with the lack of response

Early and aggressive FDA action on this petition may have saved lives. The FDA's glaring and galling failure to act demonstrates the need for wide-ranging reform of the agency

I urge Congress to consider legislation to require the FDA to rule on citizen's petitions within 6 months of the filing of such petition unless the petitioner agrees to extend such period. Congress should also initiate oversight hearings into the FDA's role in the OxyContin issue. These proceedings will hold the FDA accountable and responsible

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RICHARD BLUMENTHAL
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Office of The Attorney General
State of Connecticut

July 27, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Connecticut Citizens Petition - 2004P - 0043

Dear Dr. von Eschenbach:

I am writing to urge you to issue a decision on a Citizen Petition ("Petition") I filed with the Food and Drug Administration ("FDA" or "agency") more than three years ago. In that Petition, I requested that the FDA require Purdue Pharma L.P. ("Purdue") to revise the labeling of OxyContin® Tablets ("OxyContin") to expressly warn prescribers of the increased occurrence of side effects or potentially serious adverse reactions resulting from prescribing OxyContin off-label at dosing intervals less than the manufacturer's recommended every 12 hours. The recent conviction of Purdue and several of its present and former executives on charges that they misled prescribers and the public about OxyContin's risk of addiction underscores the need for the labeling changes requested in my Petition.

The Petition was filed on January 23, 2004, initially in redacted form due to documents supporting the Petition that had been designated "confidential" by Purdue. On July 21, 2004, the FDA sent my Office an interim response indicating that the agency was unable at the time to reach a decision "because the petition raises significant and complex issues requiring extensive review and analysis ..."

On March 16, 2005, this Office supplemented the original redacted Petition with the entire unredacted version of the Petition to ensure that the full weight of the evidence supporting the Petition would be available for consideration by the FDA prior to its rendering a final decision on the critical public health interests raised therein.

On September 28, 2006, having received no further response, I wrote to the FDA requesting the status of the FDA's review of the Petition and asking when we might expect your ruling on the important issues raised in the Petition, To date, I have received no response to the letter or a substantive response to the Petition

As I am sure you are aware, there have been several recent developments on the legal front related to OxyContin and Purdue that underscore the urgency of the issues raised in the Petition. First, on May 8, 2007, my Office, in collaboration with 25 other states and the District of Columbia, entered into a $19 5 million dollar settlement with Purdue That settlement was prompted by Purdue's failure adequately to disclose abuse and diversion risks associated with OxyContin, and the company's failure to take sufficient action or provide adequate warnings to prevent the potential harm that occurs from the off-label dosing regimen of less then every 12 hours

Second, on May 10, 2007, Purdue and three of its senior executives pleaded guilty in federal court to charges of misbranding OxyContin Among the charges in the criminal Information are that Purdue supervisors and employees misled prescribers by marketing OxyContin and claiming that the drug resulted in less euphoria and less potential for abuse [1] The conduct at the heart of both the Attorneys General settlement and the U.S. Attorney's investigation includes some of the very same information detailed in the Petition, which underlies the actions I have requested the agency to take to remedy these public and patient safety concerns Just last week, the federal court ordered Purdue and its three executives to pay fines totaling $634.5 million for misleading the public about OxyContin's risk of addiction.

It has now been three and a half years since the FDA received my initial Petition and close to two and a half years since the agency received the additional information supplementing the Petition To date, other then the "interim response" that more time was needed to evaluate the issues raised, we have received no other information, much less a final decision on our requests.

Given the serious risks to the public safety and health, I ask that the FDA issue its formal decision on the Petition and order the label warnings as quickly as possible. In the meantime, I ask that you provide information regarding (1) the status of the FDA's review and when we might expect a ruling; (2) whether any preliminary decisions or conclusions have been reached regarding the Petition; and (3) whether any additional information could be provided by my Office to the FDA to assist it in coming to a resolution on this issue

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1 Purdue has agreed that the facts alleged in the federal government's criminal Information are true *U S v The Purdue Frederick Co , Inc et al*, No 1:07CR00029, 2007 U S Dist LEXIS 53042, at *3 (WD VA July 23, 2007)

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In light of the relevance of the Petition to the Senate Committee on the Judiciary's upcoming hearing on July 31, 2007 entitled *"Ensuring that Death and Serious Injury are More than a Business Cost OxyContin and Defective Products "*, I am sending copies of this letter and the Petition to the Chairs of the committee.

I look forward to your prompt response.

Very truly yours,

RICHARD BLUMENTHAL

Cc: Sen , Patrick J. Leahy (w/enclosure) Sen. Arlen Specter (w/enclosure)
U S. Senate Committee on the Judiciary

Howard Udell, Esq (w/o enclosure) Purdue Pharma, L.P.

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STATEMENT

OF

JOHN L. BROWNLEE
UNITED STATES ATTORNEY
FOR THE WESTERN DISTRICT OF VIRGINIA
UNITED STATES DEPARTMENT OF JUSTICE

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

CONCERNING

"ENSURING THAT DEATH AND SERIOUS INJURY ARE MORE THAN A BUSINESS COST: OXYCONTIN AND DEFECTIVE PRODUCTS"

PRESENTED ON

JULY 31, 2007, AT 2:30 PM
ROOM 226 OF THE SENATE DIRKSEN OFFICE BUILDING

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STATEMENT
JOHN L. BROWNLEE
UNITED STATES ATTORNEY
FOR THE WESTERN DISTRICT OF VIRGINIA
UNITED STATES DEPARTMENT OF JUSTICE
BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

Introduction

Chairman Leahy, Senator Specter, and members of the committee, thank you for convening this important hearing to discuss the prosecution and conviction of the manufacturer and distributor of the painkiller OxyContin and the company's top three executives. Professional career prosecutors from my office and the Department of Justice and dedicated State and Federal investigators spent over 5 years investigating Purdue and its executives. Convicting these defendants and bringing them to justice was a difficult and challenging endeavor, and I am grateful for the hard work and outstanding accomplishments of these members of law enforcement. They, in my judgment, represent the very best of the Department of Justice. Thank you for inviting me to be here, and I deeply appreciate the opportunity to appear before you today to offer my perspective on the investigation and convictions.

July 20, 2007 Plea Agreement

On July 20, 2007, in a Federal courthouse located in Abingdon, Virginia, the Honorable James P. Jones, Chief U.S. District Judge for the Western District of Virginia, accepted the guilty pleas of The Purdue Frederick Company, Inc., the manufacturer and distributor of OxyContin, and its top three executives.

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Purdue pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. Purdue agreed to pay $600 million in criminal fines, forfeitures and civil recoveries. While the total settlement was based on the assessment of legally relevant factors and not on profits realized by Purdue, it should be noted that this figure reflects 90 percent of the company's profit on the sale of OxyContin during the time period of the offense. Purdue also was required to acknowledge that it illegally marketed and promoted OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support those claims. An affiliated company, Purdue Pharma, which will continue to market Oxycontin, will operate for five years under a corporate integrity agreement with the Department of Health and Human Services. This agreement requires extensive compliance measures and independent reviews. In addition, Purdue's former President and Chief Executive Officer Michael Friedman, General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenheim pleaded guilty to a misdemeanor charge of misbranding OxyContin. These defendants were placed on supervised probation for 3 years, ordered to perform 400 hours of community service related to the prevention and treatment of prescription drug abuse, and collectively paid $34.5 million in criminal fines.

Purdue Frederick Company

The defendant, The Purdue Frederick Company, a New York corporation headquartered in Connecticut, was created in 1892 and purchased by its current owners in 1952. Defendant Michael Friedman joined Purdue in 1985 and later was appointed President and Chief Executive

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Officer. Mr. Friedman left Purdue two months ago. Defendant Howard Udell joined Purdue in 1977 and is presently Purdue's Executive Vice President and Chief Legal Officer. Defendant Dr. Paul Goldenheim joined Purdue in 1985 as its Medical Director. Dr. Goldenheim left Purdue in 2004.

OxyContin - Food and Drug Administration Approval and Marketing Practices by Purdue Frederick

In 1996, the Food and Drug Administration (FDA) approved Oxycontin controlled-release tablets for the treatment of moderate to severe, ongoing pain. Oxycontin contains oxycodone HCL, a narcotic with an addiction potential similar to that of morphine. Accordingly, OxyContin is a controlled substance and subject to regulation by the Drug Enforcement Agency. Oxycontin remains an approved prescription drug.

Backed by an aggressive marketing campaign, Purdue's OxyContin became a promising pain medication for many doctors and patients. Purdue claimed it had created a new, low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse than other pain medications.

But OxyContin was not what Purdue claimed it was. Purdue's assertions that OxyContin was less addictive and less subject to abuse and diversion were false – and the company knew its claims were false. Purdue's misrepresentations contributed to a serious national problem in terms of abuse of this prescription drug. Purdue's OxyContin did not offer a low risk way of reducing pain, as promised.

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Due, in part, to Purdue's aggressive and misleading marketing campaign, prescriptions for OxyContin increased from approximately 300,000 in 1996 to nearly 6 million in 2001. As OxyContin became more available, its abuse and diversion increased, and that increased availability had, in my judgment, a devastating effect on many communities throughout Virginia and the United States, as documented by the DEA and local law enforcement.

Early Legal Action

In response to the effects of OxyContin abuse and diversion, government officials and private citizens began focusing on Purdue and OxyContin. Product liability litigation began in Ohio in April, 2001. In 2000, the former U.S. Attorney for the District of Maine announced his awareness of the growing problem of OxyContin abuse in his state. In February 2000, he sent a letter to all of Maine's practicing physicians warning them about increasing problems with the illegal diversion and abuse of OxyContin. Also, the former U.S. Attorney for the Eastern District of Kentucky, in February 2001, launched Operation OxyFest arresting more than 200 OxyContin users and dealers. That U.S. Attorney, according to news accounts, called OxyContin abuse "an epidemic like some sort of locust plague rolling through southeastern Kentucky." There were also numerous reports from around the nation that OxyContin was being abused and diverted. In July 2001, FDA approved a new warning on Oxycontin's labeling concerning the drug's potential for abuse and issued a letter to healthcare professionals urging them to be alert to the potential for Oxycontin misuse, abuse, and diversion.

Chronology of Western District of Virginia's Investigation and Prosecution of Purdue

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In the fall of 2001, just weeks after I was appointed U.S. Attorney in Virginia, we began our preparations for an investigation of Purdue, in conjunction with FDA's Office of Criminal Investigations. The Office of Inspector General of the Department of Health and Human Services and other investigative agencies later joined the investigation. The Western District of Virginia has 19 criminal prosecutors and 4 civil attorneys located in 4 staffed offices to cover the entire district of 52 counties and an approximate population of 2.2 million. Our Abingdon office, where this case was investigated and prosecuted, has three Assistant U.S. Attorneys and two support staff. In order to prepare for the investigation, we had to shift cases to our other attorneys, including myself, and recruit State prosecutors to help with our other criminal investigations.

On December 3, 2002, prosecutors from my office served an administrative health care subpoena on Purdue demanding corporate records related to the manufacturing, marketing and distribution of OxyContin. That subpoena, and the nearly 600 that followed over the next several years, represented the beginning of a difficult struggle between Purdue's counsel and the government for the necessary information we needed to conduct our review. Purdue's counsel fought hard and did the very best to protect the requested information and records. Once we began to receive the corporate records, every document was scanned into a computer database and reviewed. In addition to reviewing several million records, we also conducted nearly 300 interviews of individuals who had some connection to Purdue or OxyContin marketing and distribution. To say the least, this was a time consuming and challenging process.

In the beginning of 2006, prosecutors began preparing a detailed prosecution memorandum and charging document. This was an effort to determine whether there was

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sufficient evidence to charge the company or any individuals. Although much of the evidence is protected under Federal Rule of Criminal Procedure 6(e), and I am therefore prohibited from divulging it, I think it is important to discuss for a moment that portion of the factual record that is not protected by 6(e), in order to give you a better understanding of the nature of the evidence in this case.

The Agreed Statement of Facts

According to the Government's evidence submitted to the Court in an Agreed Statement of Facts, Purdue's actions began in early 1995, when Purdue used focus groups of primary care physicians and surgeons to determine whether such physicians would be willing to prescribe OxyContin for patients with non-cancer pain. According to Purdue's research, many of these physicians had great reservations about prescribing OxyContin because of the drug's addictive potential and side effect profile, and its abuse potential. It was clear from these focus groups that physicians were concerned about the safety and risks of OxyContin.

Purdue also learned from these focus groups that physicians wanted a long lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue tried to do.

Purdue's Unlawful Marketing and Promotion of OxyContin

Despite knowing that OxyContin contained high concentrations of oxycodone HCL, had an abuse potential similar to that of morphine, and was at least as addictive as other pain

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medications on the market, Purdue, beginning in January 1996, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Purdue did so in the following ways:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68 percent of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer opportunities for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids, resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients taking 60 mg or less could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug at lower doses.

And fifth, Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-

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release opioids, and could be used to "weed out" addicts and drug seekers. Purdue later amended the statement to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Response to the July 20, 2007 Convictions

Since these convictions were announced, there has been criticism of my decision to prosecute these cases. For example, on May 15, 2007, in an editorial published in the *Wall Street Journal*, Dr. Sally Satel, a resident scholar at the American Enterprise Institute, wrote that "the real public-health damage here comes from the pitched campaign conducted by zealous prosecutors and public-interest advocates to demonize [OxyContin] itself." Dr. Satel claimed that this prosecution and convictions will only make it harder for pain patients to get treatment and that "this newest injection of malignant hype is the last thing they need." Also, in a paper presented to the American Bar Association, defense attorneys wrote that requiring executives to plead guilty to misdemeanor offenses was unfair and suggested that Congress should consider removing the provision from the statute that holds executives and owners strictly liable for the criminal acts of their companies. In addition, a former U.S. Attorney from the District of Maine wrote a letter to Chief Judge Jones and called our prosecution of the executives "a case of unusual, if not unprecedented, use of prosecutorial discretion." Despite these criticisms, I am confident that the facts and law compelled a decision to proceed against this company and its executives, contrary to the positions taken by some.

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Legal Basis for July 20, 2007 Convictions

Some have raised important questions regarding why we did not demand incarceration of the three executives. I would like to take a few moments to explain the government's reasoning for that decision. Michael Friedman, Paul Goldenheim, and Howard Udell pled guilty to strict liability misdemeanor offenses based on the fact that they were responsible corporate officials at the time these offenses occurred. The statute which formed the basis for the guilty pleas requires no proof of intent or actual knowledge of the violations by the corporate officials to establish their guilt for the misdemeanor offense. The intent of the statute, as explained in the United States Supreme Court's decision in *United States v. Park*, 421 U.S. 658, 676 (1975), is to impose the highest standard of care on certain corporate officials having authority over business organizations involved in activities regulated by the Federal Food, Drug, and Cosmetic Act. Under the *United States Sentencing Guidelines*, the guideline range for these defendants was 0–6 months. While we believe corporate officials must be held accountable for the actions of the company, a sentence of incarceration based on a strict liability offense for defendants with no prior criminal history would be unusual.

The Impact of the Convictions on Future Corporate Misconduct

It is our judgment that even without a sentence of incarceration, conviction of the corporate officials will have significant consequences. Each corporate official will bear the stigma of being a convicted criminal, and the Court has imposed a term of probation of 3 years and ordered each defendant to perform 400 hours of community service and pay significant monetary fines. During the time period of probation, each defendant will live with the

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knowledge that any violation of probation can result in a sentence of imprisonment. Also, these unique guilty pleas by the company's three top executives are likely to have a significant positive impact on the pharmaceutical industry by emphasizing the high standard of care that the law recognizes for those with authority over the activities of business organizations. While the strict liability misdemeanor for misbranding has been in effect for a great number of years, it has rarely been used against company executives for misbranding a pharmaceutical product. I believe that the plea agreements and the resulting finding of guilt against the corporate officials will serve as a strong warning to executives of other pharmaceutical companies that they, too, will be expected to exercise the highest standard of care and diligence in the supervision and management of company activities and the actions of their subordinates to avoid the potential for appearance in a Federal courtroom to face criminal charges. In addition, the contemplated non-incarcerative sentences are part of an overall negotiated resolution of a criminal investigation that will accomplish the objective of holding accountable a company and its executives for criminal conduct that had previously not been addressed.

Victims of OxyContin and the Impact of the Convictions

Finally, I would like to address the human element to this case. I have spoken to many people who have been harmed or who have had a loved one harmed by OxyContin. People like Marianne Skolek, whose daughter Jill died from OxyContin on April 29, 2002, and whose little boy Brian will now have to grow up without his mom. Although there are complex legal questions about the relationship between Purdue's crimes and the events that have led to such harm, the stories of those who have lost a loved one are heartbreaking. As a prosecutor I have

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seen the aftermath of terrible crimes and witnessed much sadness, but that doesn't make it any easier to hear about the death and separation caused by OxyContin. As a parent of two small children, I cannot imagine the pain that these people have suffered, and I pray that they can find some peace. I also recognize that the convictions of Purdue and its executives, although important, offer little comfort to people like Marianne and Brian.

My hope is these convictions can serve some purpose for these individuals, however. Many people, especially Ms. Skolek, have been raising concerns about Purdue and its conduct for years. And most of these people weren't saying that Purdue was solely responsible for their loved one's deaths – they just wanted Purdue to tell the truth about the drug. This case has exposed that truth. This prosecution also has given them a forum to publicly face the top three executives of Purdue and express their true feelings. It has confirmed what they believed for a very long time – that the marketing of OxyContin was deceptive and criminal. By convicting this company and its executives and imposing serious sanctions, perhaps these individuals can find some relief and a measure of closure. These individuals have stood up for truth and the Federal prosecution proved to these individuals and the world that Purdue and its executives committed Federal crimes for which they were held accountable. The Federal prosecution demonstrated that Purdue is a company that was guilty of false and misleading statements to maximize its profits.

Again, I thank the Committee for allowing me to speak today.

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
	)	Case No. 1:07CR00029
v.	)	
	)	**OPINION AND ORDER**
THE PURDUE FREDERICK	)	
COMPANY, INC., ET AL.,	)	By: James P. Jones
	)	Chief United States District Judge
Defendants.	)	
	)	

John L. Brownlee, United States Attorney, Rick A. Mountcastle and Randy Ramseyer, Assistant United States Attorneys, Roanoke, Virginia, for United States; Howard M. Shapiro and Kimberly A. Parker, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C., for The Purdue Frederick Company, Inc.; Mark F. Pomerantz, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, N.Y,, for Michael Freidman; Mary Jo White, Debevoise & Plimpton LLP, New York, N.Y., for Howard R. Udell; and Andrew Good, Good & Cormier, Boston, Massachusetts, for Paul D. Goldenheim.

The issue before the court is whether or not to accept the plea agreements in this case.[1]

The Purdue Frederick Company, Inc. ("Purdue") has pleaded guilty to misbranding OxyContin, a prescription opiod pain medication, with the intent to defraud or mislead, a felony under the federal Food, Drug, and Cosmetic Act. 21 U.S.C.A. §§ 331(a), 333(a)(2) (West 1999). The individual defendants, Michael

[1] This Opinion elaborates on the court's oral opinion.

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Friedman, Howard R. Udell, and Paul D. Goldenheim, have pleaded guilty to the misdemeanor charge of misbranding, solely as responsible corporate officers.[2] 21 U.S.C.A. § 333(a)(1) (West 1999); *see United States v. Park*, 421 U.S. 658, 676 (1975). The individual defendants are not charged with personal knowledge of the misbranding or with any personal intent to defraud.

The Information in this case charges, among other things, that

> [b]eginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:
>
> a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;
>
> b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
>
> c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level

[2] Friedman is the former president and CEO of Purdue, Udell is the executive vice president and chief legal officer, and Goldenheim is the former chief scientific officer.

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effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

(Information ¶ 19.) Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas. (Agreed Statement of Facts ¶ 46.)

The plea agreements have been submitted pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), which allows the parties to agree to a specific sentence to be imposed. The court is not bound by the plea agreements, and may reject them. If a plea agreement is rejected, that defendant must be given an opportunity to withdraw the guilty plea. Fed. R. Crim. P. 11(c)(5)(B). The government has agreed in this case that if the court rejects any of the plea agreements, the government will dismiss the Information filed in the case, without prejudice to the government's right to later

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indict the defendants or any other entity or individual on any charge. (Plea Agreements ¶ 2.) Accordingly, if the court rejects any of the plea agreements, the present case may end, and it will be up to the government to decide whether to re-prosecute the defendants, or any of them.

In addition to a lengthy hearing on the present issue, the parties were required to submit extensive written material, including financial information, for the court's consideration.

The Supreme Court has held that defendants have "no absolute right to have a guilty plea accepted." *Santobello v. New York*, 404 U.S. 257, 262 (1971). The Court stated, "A court may reject a plea in exercise of sound judicial discretion." *Id.* "[I]t is not only permitted but expected that the court will take an active role in evaluating the agreement." *United States v. Kraus*, 137 F.3d 447, 452 (7th Cir. 1998). But as the Sixth Circuit stated, "By leaving the decision whether to accept or reject a plea to the exercise of sound judicial discretion, the Supreme Court did not intend to allow district courts to reject pleas on an arbitrary basis." *United States v. Moore*, 916 F.2d 1131, 1136 (6th Cir. 1990) (internal quotations and citation omitted).

While the court's decision must not be arbitrary, "Rule 11 does not limit the reasons for which the district court may reject a proposed plea agreement." *United States v. Skidmore*, 998 F. 2d. 372, 376 (6th Cir. 1993). "The authority to exercise

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judicial discretion implies the responsibility to consider all relevant factors and rationally construct a decision." *Moore*, 916 F.2d at 1136. Rule 11 explicitly states that a court cannot accept a plea if it is not supported by the factual record or if the court believes that that the plea is not voluntary. Fed. R. Crim. P. 11(b)(2),(3). But Rule 11 also allows a district judge to reject a plea agreement if it is too lenient or too harsh. *Skidmore*, 998 F.2d at 376.

In determining the proper criminal sentence, the court must consider certain factors set forth by statute. I must consider "the nature and circumstances of the offense and the history and characteristics of the defendant," as well as

> the need for the sentence imposed—(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C.A. § 3553(a) (West 2000 & Supp. 2004). The court's obligation is to impose "a sentence sufficient, but not greater than necessary, to comply with" these purposes. *Id.*

Under the law, Purdue is subject to a penalty of five years probation and a fine of up to $500,000. In its plea agreement, Purdue has agreed to substantial additional

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monetary sanctions totaling $600 million, reported to be one of the largest in the history of the pharmaceutical industry. The amount includes the following:

1. $100,615,797.25 payable to federal government health care agencies under a Civil Settlement Agreement;

2. $59,384,202.75 in escrow for those states that elect to settle their claims against Purdue. These civil settlements to the federal and state government total $160 million, of which the federal government is receiving sixty percent;

4. $3,471,220.68 to Medicaid programs for improperly calculated rebates;

5. $500,000 fine to the United States;

6. $20 million in trust to the Commonwealth of Virginia for operating the Virginia Prescription Monitoring Program;

7. $5.3 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund;

8. $276.1 million forfeiture to the United States;

9. $130 million to settle private civil claims related to OxyContin; and

10. $4,628,779.32 to be expended by Purdue for monitoring costs in connection with a Corporate Integrity Agreement with the U.S. Department of Health and Human Services.

The individual defendants are subject to a punishment of twelve months imprisonment and a fine of up to $100,000. In their plea agreements, they have agreed to pay a total of $34.5 million to the Virginia Medicaid Fraud Unit's Program

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Income Fund.[3] In return, the government has agreed to sentences for them without any imprisonment.

There have been several reasons suggested why the court should reject the plea agreements.

Lack of Restitution. The plea agreements preclude restitution other than as set forth in the agreements and a number of alleged victims object to this provision, contending that the amounts allocated to private parties are insufficient, compared to the recovery by governmental victims. BlueCross BlueShield of Tennessee has filed a Request for Notice, an Opportunity to be Heard at Sentencing, and an Order of Restitution. Other third-party health care payors have joined in this motion. In addition, an individual who considers herself a victim because of her addiction to OxyContin has objected to the plea agreements and has filed a formal Motion to Assert Victim's Rights, in which she complains about restitution, as well as other matters.

These parties have received notice of this present proceedings and the court has allow them an opportunity to speak.[4]

---

[3] Defendant Friedman has agreed to pay $19 million, whereas defendants Udell and Goldenheim have agreed to pay $8 million and $7.5 million, respectively.

[4] It is argued that the Crime Victims Rights Act, 18 U.S.C.A. § 3771(a)(2) (West Supp. 2007), has not been complied with in this case because general notice to potential

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The government and the defendants, in agreeing to preclude other restitution, rely on the Victim and Witness Protection Act of 1982 ("VWPA"), which states in relevant part as follows:

> To the extent that the court determines that the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution under this section outweighs the need to provide restitution to any victims, the court may decline to make such an order.

18 U.S.C.A. § 3663 (a)(1)(B)(ii) (West 2000 & Supp. 2007).[5]

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victims has been insufficent. In fact, there has been extensive national publicity about the case, *see, e.g.,* Barry Meier, *Narcotic Maker Guilty of Deceit Over Marketing*, N.Y. Times, May 11, 2007, at A1, with widespread comment by victims rights blogs and Web sites. Notice of the sentencing and of the right of victims to attend and speak was published on the court's Web site, and all of the pleadings and other documents filed in the case have been available for viewing without charge on that site. The court received numerous letters and e-mails from interested members of the public concening the scheduled sentencing. Any person known to be a possible victim was given individual notice of the hearing and of the right to speak, and over twenty people accepted this opportunity. The main courtroom was full, and a second courtroom equipped with an audio and video feed was used for the overflow. I find that notice to potential victims was adequate.

[5] The plea agreements cite to this provision of the VWPA. The Mandatory Victims Restitution Act of 1986 ("MVRA") has nearly identical language:

> This section shall not apply in the case of an offense described in paragraph (1)(A)(ii) if the court finds, from facts on the record, that—
>
> (A) the number of identifiable victims is so large as to make restitution impracticable; or
>
> (B) determining complex issues of fact related to the cause or amount of the victim's losses would

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In order to award an alleged victim restitution under either the VWPA or the MVRA, the court would have to determine whether that person was "directly and proximately" harmed by the misbranding offense that was the subject of the plea agreements. The Fourth Circuit has held that to be considered "directly and proximately harmed" under either the VWPA or the MVRA, a person must show that the harm resulted from "conduct underlying an element of the offense of conviction." *United States v. Blake*, 81 F.3d 498, 506 (4th Cir. 1996) (construing the phrase "directly and proximately harmed" under the VWPA); *see also United States v. Davenport*, 445 F.3d 366, 374 (4th Cir. 2006) (citing to *Blake* but interpreting the phrase "directly and proximately harmed" as used in the MVRA).

Purdue argues that third-party payors cannot show that they were directly and proximately harmed by Purdue's misbranding, unless they can prove the following:

1. That a Purdue sales representative misstated to a specific prescribing physician that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance or withdrawal than other pain medications;

> complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

18 U.S.C.A. § 3663A (c)(3) (West 2000 & Supp. 2007). The Crime Victims Rights Act confirms the general right of victims to "full and timely restitution as provided in law." 18 U.S.C.A. § 3771(a)(6) (West Supp. 2007).

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2. That specific prescribing physician relied upon that misstatement by that Purdue sales representative and, in reliance on that misstatement, prescribed OxyContin rather than an alternative pain medication (e.g. Percocet) for one of the private third-party payor's insured individuals;

3. That the physician prescribed OxyContin for the insured because of the misstatement and not because of the other attributes of OxyContin (e.g., twelve-hour dosing or the absence of acetaminophen, which risks liver toxicity);

4. That the private third-party payor paid for that prescription of OxyContin; and

5. That the private third-party payor paid more for the OxyContin prescription than the particular alternative pain medication that the prescribing physician would have prescribed if he or she had not relied on the misstatement and prescribed OxyContin.

(Purdue's Resp. July 9, 2007, at 9-10.)

Purdue further argues that the chain of causation between the harm alleged and the misbranding offense could have been broken by any intervening act on behalf of the insured patient or the prescribing health care professional. For example, if patients obtained OxyContin improperly by deceiving their physicians or by altering an otherwise proper prescription, the third-party payors would not be entitled to restitution for those prescriptions since the misbranding did not directly and proximately caused any financial loss to the third-party payor. Or if a physician negligently prescribed OxyContin, the third-party payor that paid for that prescription

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is also not entitled to restitution because the misbranding once again did not directly and proximately cause the third-party payor's financial loss.

Even if third-party payors can show that they were directly harmed by Purdue's misbranding, Purdue claims that each payor would have to present to this court the facts of every instance of overpayment in order for the Court to determine the proper amount of restitution for each third-party payor.

As to any individuals injured by the use of OxyContin, the difficulties of establishing causation are demonstrated by the numerous civil suits that have been filed by such persons against Purdue, including two before this court, *McCauley v. Purdue Pharma, L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004), and *Ewing v. Purdue Pharma, L.P.*, No. 2:02CV00150, 2004 WL 1856002 (W.D. Va. Aug. 19, 2004). Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding proximately caused their injuries. *See, e.g., Bodie v. Purdue Pharma Co.*, No. 05-13834, 2007 WL 1577964, at *3 (11th Cir. June 1, 2007) (affirming the district court's conclusion that the plaintiff's claims failed because he could not show that he was proximately harmed by Purdue's allegedly inadequate warnings); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 556 (N.D. Tex. 2006) ("Because plaintiffs have failed to show that an adequate warning would have changed [the physician]'s decision to prescribe OxyContin, and

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because [the physician] testified that he would not have changed his decision, the Court finds that Plaintiffs have failed to raise a genuine fact issue."); *Timmons v. Purdue Pharma Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at *4 (M.D. Fla. Feb. 2, 2006) ("Even if OxyContin were considered unreasonably dangerous, which it has not been deemed so, Plaintiff has failed to show any evidence of causation."); *McCauley*, 331 F. Supp. 2d at 465 (granting Purdue's motion for summary judgment and stating "[t]he plaintiffs' burden is greater than merely showing a temporal link between their use of OxyContin and any injuries they sustained. Instead, it is evidence of the causal link between OxyContin and their injuries that the plaintiffs lack."); *Foister v. Purdue Pharma, L.P.*, No. 01-268-JBC, 2001 U.S. Dist. LEXIS 23765, at *27 (E.D. Ky. Dec. 27, 2001) (denying the plaintiffs' motion for injunctive relief and noting that the "plaintiffs have failed to produce any evidence showing that the defendant's marketing, promotional, or distribution practices have ever caused even one table of OxyContin to be inappropriately prescribed or diverted.").

It is argued that restitution might be handled in this case as with a civil class action claim, but class certification has been generally denied in OxyContin claims because of the variety of causation issues. *See, e.g., Hurtado v. Purdue Pharma Co.*, No. 12648/03, 2005 WL 192351, at *1(N.Y. Sup. Ct. Jan. 24, 2005) (denying class

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certification "because of the different reasons and methods by which the drug was prescribed and used.").

It is true that the governmental health care providers have been allotted a portion of Purdue's payment in settlement of their civil claims for the misbranding of OxyContin ($160 million) that is greater than the portion to be used by Purdue to settle private claims ($130 million). However, Purdue's liability for private claims is not capped by the plea agreements. Purdue agrees to pay at least $130 million to settle private claims, but no maximum limit is imposed. I do not find that the plea agreements are inherently unfair in this regard.

Accordingly, in spite of the arguments by putative victims, I agree that the restitution process would unduly complicate and prolong the sentencing process. In order to prove causation, litigation over many months, if not years, would be required before final judgment in this case could be entered. Such delay would be contrary to the basic principles of our criminal justice system.

I would have preferred that the plea agreements had allocated some amount of the money for the education of those at risk from the improper use of prescription drugs, and the treatment of those who have succumbed to such use. Prescription drug abuse is rampant in all areas of our country, particularly among young people,

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causing untold misery and harm. The White House drug policy office estimates that such abuse rose seventeen percent from 2001 to 2005. That office reports that currently there are more new abusers of prescription drugs than new users of any illicit drugs. As recently reported, "Young people mistakenly believe prescription drugs are safer than street drugs . . . but accidental prescription drug deaths are rising and students who abuse pills are more likely to drive fast, binge-drink and engage in other dangerous behaviors." Carla K. Johnson, *Arrest Puts Spotlight on Prescription Drug Abuse*, The Roanoke Times, July 6, 2007, at 4A. It has been estimated that there are more than 6.4 million prescription drug abusers in the United States.

On the other hand, I am forbidden by law to participate in plea discussions, Fed. R. Crim. P. 11(c)(1), and I will not reject these agreements simply because they do not contain provisions that I would have preferred. The government has represented that it did not demand inclusion of a treatment provision in the plea agreements because national drug policy has been placed by Congress in the Substance Abuse and Mental Health Service Administration, an agency of the U.S. Department of Health and Human Services. The government prosecutors were reluctant to direct treatment funds in a manner beyond their expertise and possibly contrary to national policy. I will not second-guess their decision in this regard.

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Political Interference. It has been suggested that Purdue may have received a favorable deal from the government solely because of politics.

I completely reject this claim. I have had long experience with the United States Attorney for this district, and I am convinced that neither he nor the career prosecutors who handled this case would have permitted any political interference. In fact, I am sure that they would have refused to accept a plea agreement that they did not sincerely feel was in the best interests of justice.

Lack of Incarceration. The plea agreements provide for no incarceration for the individual defendants. The government points out that a sentence of incarceration under the federal sentencing guidelines would be unusual based on the facts of the case. The government is also convinced that the nature of the convictions of the individual defendants— based on strict liability for misbranding—will send a strong deterrent message to the pharmaceutical industry. The defendants point to their lack of prior criminal record, their strong commitment to civic and charitable endeavors, as well as their other positive personal attributes. On the other hand, the potential damage by the misbranding disclosed in this case was substantial and I do not minimize the danger to the public from this crime. The defendants voluntarily accepted responsibility over this business enterprise, for which they were generously rewarded. However, while the question is a close one, I find that in the absence of

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government proof of knowledge by the individual defendants of the wrongdoing, prison sentences are not appropriate.

Summary. In summary, I find that the plea agreements are supported by the facts and the law and impose adequate punishment on the defendants and I accept them. Moreover, for the reasons stated, I will deny the third party motions. (Dtk. Nos. 35, 42, 43, 44, 48, 49 and 65.)

It is so **ORDERED**.

ENTER: July 23, 2007

/s/ JAMES P. JONES
Chief United States District Judge

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STATEMENT OF DR. JAMES N. CAMPBELL

Professor of Neurosurgery
School of Medicine, Johns Hopkins University
Director of the Blaustein Pain Treatment Center of the
Johns Hopkins Hospital
Chairman of the Board of the American Pain Foundation

FOR THE HEARING ON

"Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement"

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

JULY 31, 2007

Introduction

Chairman Leahy and Members of the Committee, thank you for the invitation to testify today. I am Professor of Neurosurgery at the School of Medicine at the Johns Hopkins University. I am also the Director the Blaustein Pain Treatment Program at the Johns Hopkins Hospital, as well as Chairman of the Board at the American Pain Foundation and past president of the American Pain Society. I have dedicated my career, spanning 30 years, to the mission of decreasing the suffering associated with pain. I do research on pain funded by the NIH, see patients, and engage in a number of pro bono activities pursuant to this mission. I come before this hearing because of my concern for patients who have pain and their access to care.

I have a perspective on the problem of pain in America because I am in the trenches battling with the issue of how to help individual patients who are devastated by the problem of chronic pain. My perspective also arises from my work with the American Pain Foundation. The APF is the nation's leading nonprofit organization devoted exclusively to serving the needs of people with pain. The APF works toward its mission by providing information, education, and advocacy. I founded the APF with the help of several colleagues including Dr. Kathleen Foley, who served for fifteen years as head of the Pain and Palliative Care Services at Memorial Sloan Kettering Hospital, and Dr. Charles Cleeland, Director of the Pain Research Group at M.D. Anderson Cancer Center. We recognized that there was a need for a national grassroots organization that was dedicated to furthering research, providing education, and raising awareness about the problem of chronic and acute pain in America. Purdue Pharma has contributed generously during the ten years that the APF has been in existence.

I am testifying before you today because I believe the adverse publicity and the prosecution of several Purdue Pharma executives in relation to OxyContin risk the welfare of patients in pain. Access to treatment is a major problem affecting millions of patients who suffer with pain. This hearing has the potential to clarify many misunderstood facts about OxyContin and it is in this spirit that I appear before you today.

Chronic Pain is Under-treated in the United States

Let me begin by pointing out that chronic pain is a serious public health problem and numerous surveys report that more than 50 million Americans live with chronic pain. The National Center for Health Statistics of the Centers for Disease Control and Prevention estimate that, including all types and duration of pain, there are 76.2 million persons afflicted, more than the total number suffering from diabetes mellitus (20.8 million), coronary heart disease and stroke (18.7 million) and cancer (1.4 million) combined. Yet, pain is arguably the most untreated, under-treated, and mistreated serious health problem in the United States. For instance, a recent study in the Journal of the American Medical Association of nursing home patients with cancer found that 24% of patients with significant pain received nothing stronger than aspirin. Another study showed that an estimated 70% of those with cancer experience significant pain, yet fewer than half of these individuals received adequate treatment for their pain.

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Pain Exacts A Heavy Toll

People who endure chronic, unrelieved pain are more likely to suffer depression and anxiety. They have trouble sleeping, have other physical ailments, and take longer to recover from these ailments. They lose time at work, lose their jobs, and have other financial problems. They have more difficulty caring for children and other dependents, and suffer deteriorated relationships with family and friends. There is evidence that chronic pain adversely affects the immune system. Patients with back pain may even suffer brain damage. Pain is a serious problem and treatment has to be considered an essential function of medical care.

Furthermore, the Drug Enforcement Administration, together with two independent groups, issued a document in 2004 stating that uncontrolled pain accounts for "many tens of billions of dollars of needed health care and lost productivity" and the National Institutes of Health have stated that pain costs "the American public more than $100 billion each year."

I have treated thousands of patients who suffer with severe significant pain. I have treated patients who contemplated suicide – and know of patients who have committed suicide – some of this is due simply to the problem of under treatment. OxyContin, and other powerful opioids, are the smart, safe and sometimes the only effective choice for many of these patients.

Opioids Are Effective Medications

Drug abuse and addiction are major problems in America. Prescription drug abuse is part of that problem, though tobacco and alcohol use remain the biggest abuse problems. Regardless of this, still in this year, 2007, I think remarkably, opioids remain the most effective class of drugs for treatment of moderate and severe pain. In every study I know where opioids have been compared to other medications, opioids have proven to be the more effective drug. Unlike other pain medications, such as aspirin and Tylenol, opioids are not associated with enduring drug toxicities. Opioids such as OxyContin do not cause liver damage, kidney damage, or hemorrhage from the stomach. While addiction and abuse are concerns, in my experience, these problems are rare events in patients with serious chronic pain and no history of substance abuse. This is not to say opioids are a panacea for pain. Patients are often inadequately relieved of pain and they complain of other side effects of opioids including the problem of constipation. While all patients on opioids have a *physical dependence*, meaning that they will have a physiological withdrawal problem if they stop the medication abruptly, few develop addiction. This is worth restating: *addiction is a rare problem in patients who take opioid medications as prescribed for serious pain.*

Development of OxyContin

OxyContin is an extended release preparation of oxycodone, one of the most commonly used opioids in the world. Two benefits of OxyContin are:

- Abuse is related to the kinetics of drug delivery to the brain. Rapid delivery is correlated with a higher abuse potential. OxyContin was developed to have

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slower drug delivery kinetics. The fact is that the more gradual rise in oxycodone blood levels with an extended release formulation, such as OxyContin, is very likely to have less abuse potential when taken as instructed, than the same medication provided in an immediate release preparation such as what is present in medications such as Tylox, Vicodin, and Percocet.

- A second advantage of OxyContin is that it provided a medication that provides more steady blood levels of oxycodone with less frequent dosing. This strategy is likely to improve the so-called therapeutic window, which refers to the ratio of benefit to adverse effects.

When taken as instructed, OxyContin almost certainly achieves both objectives. Thus, OxyContin when introduced in 1995 was considered a major advance in pain treatment. The only other extended release opioids at the time were controlled release morphine products, which many patients did not tolerate well.

Why is OxyContin Abused?

Frequently overlooked in the media hype about OxyContin is an understanding of the pharmacological facts about this drug. OxyContin is nothing more than an extended release form of the common pain reliever, oxycodone. What was not clear to anyone when OxyContin was first introduced, was that the larger amounts of oxycodone provided in the OxyContin pills would become an attraction to drug abusers. Drug abusers learned that the pills could be modified (for example, crushed) such that oxycodone could be extracted in relatively large amounts. The typical oxycodone pills contain 5 to 10 mg of oxycodone. OxyContin pills vary in dose and may contain anywhere from 10 to 80 mg of oxycodone. OxyContin is a very effective medication for patients with pain. The success and popularity of the drug meant that the medication became widely available. Thus, abuse became an increasing issue in particular, for reasons still not understood, in rural areas of the country. No one I know in 1995 in the drug industry, at the FDA, or in the academic community foresaw what would later become a major problem with regard to OxyContin abuse. What I saw in my practice were patients who often got effective pain relief with OxyContin where nothing else would work.

What I believe is often lost in the discussion of OxyContin is that the abuse problem itself arises almost entirely from intentional abuse rather than from use according to proper prescribing. Taking the medication as directed with all of the precautions outlined in the packaging insert approved by the FDA and used by Purdue Pharma simply does not lead to abuse problems. As with a wide variety of chemicals available freely in our society, there are ways to misuse OxyContin, but this abuse problem arises because the abuser deliberately subverts the slow delivery mechanism in order to use the drug for non-medical purposes.

Role of Purdue Pharma in the Promotion of OxyContin

It is a fact that when OxyContin was launched, its package insert was recognized to include even more information about the risks and benefits of opioids and their potential for abuse than did the package inserts for other comparable opioid drugs. And when it became

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apparent that there was a problem with the abuse and diversion of the drug in 2000 - 2001, Purdue and its executives took what I consider to be Herculean steps to combat this abuse.

I cannot attest one way or the other as to the alleged hyperbolic promotion of OxyContin by certain employees of Purdue Pharma. My understanding of the facts is that upper management did not in fact promote any illegal sales practices by their employees. The criminal prosecution of senior executives at Purdue Pharma may play to certain popular sentiments, but sends a chilling message to those who dare to develop high-risk drugs for important diseases.

The use of opioids, any opioid, for treatment of pain is a serious undertaking and all physicians know this. We have learned more about drug abuse in recent years, but identifying the abuser and preventing diversion of prescription medications remains a very challenging task for physicians, concerned with the compassionate care of patients and the protection of their welfare. I in no way condone the misbranding of any drug. In this case I understand that some employees made statements to some doctors either overstating the benefits, or understating the risks of OxyContin. That is wrong. But I also must state that I believe all physicians understand what a schedule II narcotic is. This is how OxyContin was labeled and every physician recognizes that every narcotic is the potential target of diversion, abuse, and misuse.

It must also be recognized that OxyContin underwent extensive study and examination before it was put on the market. At the end of 1994, Purdue submitted a New Drug Application for OxyContin to the FDA. This application included detailed information on numerous clinical trials of the drug, in which thousands of individuals participated. The FDA approved the application a year later and found that the drug was safe and effective when administered in accordance with its label. It is simply wrong to say that OxyContin is a defective product. This would be like saying that medicines containing morphine and hydrocodone are defective products. It remains not only plausible but likely that when taken as directed that OxyContin in fact does have less abuse potential than other immediate release medications.

Did Purdue Pharma Responsibly Warn of Abuse Liabilities?

I note again that abuse largely depends on the deliberate extraction of oxycodone from the pill for purposes of injecting or snorting the drug. Purdue warned of abuse issues from the beginning. The original OxyContin package insert warned the prescribing physician that:

- "OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance."
- "Oxycodone products are "common targets for both drug abusers and drug addicts."
- "Drug seeking" behavior is very common to addicts.
- The top line of the package insert bore the "CII" symbol, immediately telling doctors that OxyContin is a Schedule II drug.
- The section of the package insert entitled "Information for Patients/Caregivers" also warned that OxyContin is a "potential drug of abuse" and that patients should guard their medication from theft.

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The package insert then was subsequently revised as new information about abuse became available including the addition of a boxed warning in July 2001, the strongest warning the FDA issues for an approved drug product.

The abuse problem has occurred, almost exclusively, outside of the realm in which Purdue marketed the medication. Purdue never advertised OxyContin directly to consumers. Purdue markets OxyContin for the use in legitimate pain patients under the careful supervision of physicians. The OxyContin label warns in bold capital letters against crushing, breaking or chewing the tablets. That, however, is what abusers do, transforming it into a different product, and one that can be very dangerous and addictive. In stark contrast, the scientific evidence suggests that addiction to opioids by legitimate chronic pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug. For example, in several states where formulary programs have substituted methadone for OxyContin, methadone overdoses have risen and even eclipsed OxyContin abuse, despite the fact that no pharmaceutical company actively markets methadone for the treatment of pain.

Purdue Responded to the Increased Incidence of Abuse with Initiatives Aimed at Combating Abuse

When OxyContin abuse was identified as an unexpectedly significant problem, Purdue developed an extensive series of initiatives to combat prescription drug abuse. In fact, these initiatives have helped to build for risk management for all opioids. Examples of a few of the programs Purdue has participated in, initiated, or funded follows:

- Disseminating tamper resistant prescription pads to physicians.
- Educating physicians and pharmacists about how to protect their practice from abuse.
- Developing and funding the heralded research-based initiative ("RADARS"), which gathers quantitative and qualitative data on abuse trends.
- Researching abuse-resistant formulations of OxyContin.
- Funding community-based programs to prevent and drug abuse and addiction.
- Developing public service campaigns that educate the public about the dangers of prescription drug abuse.

These programs and initiatives have helped educate medical professionals and law enforcement about how to combat and deal with prescription abuse. These programs have also attempted to educate the public about the risks inherent in using these medications other than as prescribed and outside the supervision of a physician. These programs have worked to promote the safe use of all opioids, and represent Purdue's leadership in the area of abuse prevention. Many of them have become models in the field. I know of no pharmaceutical company that has taken the problem of abuse and diversion more seriously than Purdue and that has done more to help healthcare professionals attempt to combat the problem.

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Conclusion

OxyContin stands as one of the effective choices to treat serious pain in patients. Despite the stigma associated with this drug, many physicians recognize that OxyContin (and I might add other competing extended release preparations of oxycodone) is an important part of the pain treatment arsenal. Purdue Pharma in my opinion is to be lauded for pioneering the use of extended release opioid preparations for treatment of pain. Many thousands if not millions of patients have benefited. Abuse is a major problem as well. We do a disservice to attack the problem of abuse by limiting the treatment choices of patients with pain. This august committee might make note that our ultimate goal is to develop better choices for patients through research conducted via the funding from the NIH, and the pharmaceutical industry. Our goal should be to encourage industry and academia to find drugs that have no abuse liability and yet relieve pain safely and effectively. While it does appear that some sales representatives at Purdue may have understated the inherent risks of using opioid therapy, it is in my view reckless to say that because of this, senior executives are criminally responsible. Purdue has helped fill a void in pain treatment. Many thousands of patients have benefited. I believe Purdue and its management deserve recognition for their contribution to the welfare of these many patients.

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July 30, 2007

The Hon. Patrick Leahy
Chairman
United States Senate Committee on the Judiciary
Washington, D.C. 20510

Dear Senator Leahy:

I understand that your Committee will hold a hearing on July 31, 2007, to evaluate the propriety and adequacy of the disposition of the government's indictment against The Purdue Frederick Company and three of its executives. As explained below, my experience as former Chief Counsel of the Food and Drug Administration may be relevant to your deliberations, and I request that this letter be made part of the record. (A brief curriculum vitae is attached.)

At the outset, in the interest of full disclosure, I note that my law firm represents Purdue in various matters, but I have not personally been involved in any of those matters. When Purdue asked if I would share my experience and views with the Committee, I agreed to do so.

The judge in the Purdue case accepted guilty pleas from Michael Friedman, Howard Udell, and Dr. Paul Goldenheim to a single misdemeanor count of a misbranding violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In this statute, Congress imposed unique "strict criminal liability." Under the FD&C Act, criminal liability attaches without the classic common law elements of criminal law -- *a mens rea* (guilty mind) and an *actus reus* (guilty act). Two Supreme Court decisions have upheld this interpretation of the FD&C Act -- United States v. Dotterweich, 320 U.S. 277 (1943) and United States v. Park, 421 U.S. 658 (1975). I was Chief Counsel for the Food and Drug Administration during the time that the Park case was brought, through the ultimate Supreme Court decision. I participated in the drafting of the government's brief in the Supreme Court and signed that brief. It was my responsibility to assure that FDA policy was accurately represented before the Supreme Court in that case.

Under the Supreme Court's interpretation of the FD&C Act, it is exceedingly difficult for any high-level executive to successfully defend against a strict liability charge with respect to violations committed by company employees. Both FDA and the Department of

Justice emphasized in the government's brief in the Park case that the two agencies resorted to the strict criminal liability provision of the statute only in appropriate circumstances, i.e., that prosecutorial discretion was used wisely. I am attaching to this letter a two-page excerpt from the third edition of the casebook on Food and Drug Law authored by myself, Professor Richard A. Merrill (who followed me as Chief Counsel for FDA and then served as Dean of the University of Virginia Law School), and Professor Lewis A. Grossman (who teaches Food and Drug Law at American University Law School). Like the first and second editions, this third edition (published only a month ago) quotes from the government's brief in Park at pages 1319-1320. That brief assured the Supreme Court that corporate officials who satisfy the Dotterweich standard of "responsibility in the business process resulting in unlawful distribution" would not be prosecuted without some further evidence of culpability:

> "Officials . . . who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action. Even if investigation discloses the elements of liability, and indicates that an official bears a responsible relationship to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations."

Thus, the Supreme Court was informed by the government that strict criminal liability would be used sparingly and only when executives were aware of the violations of the FD&C Act and failed to correct them.

In the Purdue case, nothing in the Agreed Statement of Facts suggests that the three executives had knowledge of the facts constituting misbranding by others at the time it occurred. Nor were any of them given a warning and an opportunity to correct the problem before they were prosecuted, unlike Mr. Park and unlike the representations made by the government to the Supreme Court in its brief in the Park case.

Prosecutions under the strict criminal liability criteria as established in Dotterweich and Park have been exceedingly rare. I assume that this has been the case because others in the position to make these prosecutorial decisions have chosen, as I did in Park, to reserve prosecutions under this statute for cases where the executive was aware of the violation and failed to correct it, notwithstanding the fact that the statute does not require such knowledge. In the Purdue case the Government does not appear to have followed that policy.

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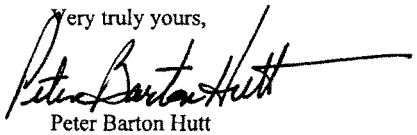
I bring these matters to your attention because I believe that are relevant to the issues you are considering at the July 31 hearing. If I can be of any further assistance to the Committee, please do not hesitate to contact me.

Very truly yours,



Peter Barton Hutt

Attachments

cc: The Hon. Arlen Specter

Written Statement of
Professor Vikramaditya Khanna
University of Michigan Law School
Before the
Committee on the Judiciary
United States Senate
Hearing on Evaluating the Propriety and Adequacy of the
OxyContin Criminal Settlement

Tuesday, July 31, 2007

1. Introduction

Chairman Leahy, Senator Specter, and distinguished Members of the Committee, thank you very much for inviting me to testify today regarding the prospect of criminal liability for executives who knowingly introduce defective and dangerous products into the market.

My remarks will primarily focus on the circumstances in which it might be desirable to impose criminal sanctions on executives as a supplement (or complement) to monetary sanctions on corporations. I will also discuss methods for ameliorating concerns raised by the possibility of such sanctions. My discussion is largely based on the analyses in a series of my articles over the last decade or so on liability regimes for corporate wrongdoing.[1]

My overall conclusions are that a case can, in theory, be made for the imposition of criminal liability on executives for knowingly introducing defective products into the market which, due to the defect, can cause death and serious injury. However, before that course is chosen we should first exhaust other options for deterring corporate wrongdoing (e.g., increasing civil liability for corporations, increasing civil liability for executives). If these civil options have indeed been exhausted then a case can be made for criminal sanctions. Moreover, if we are proceeding with criminal liability then we must carefully draft and apply it to assuage concerns that the proposed criminal liability may lead to even worse results than those it was designed to address.

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[1] *See* V.S. Khanna, *Corporate Criminal Liability: What Purpose Does It Serve?* 109 HARV. L. REV. 1477 (1996) [hereinafter *Corporate Criminal Liability*]; V.S. Khanna, *Is The Notion Of Corporate Fault A Faulty Notion?: The Case of Corporate Mens Rea,* 79 B.U.L. REV. 355 (1999)[hereinafter *Corporate Fault*]; V.S. Khanna, *Corporate Liability Standards: When Should Corporations Be Held Criminally Liable?* 37 AM. CRIM. L. REV. 1239 (2001)[hereinafter *When Corporations*]; Vikramaditya S. Khanna, *Should the Behavior of Top Management Matter?,* 91 GEO. L.J. 1215 (2003)[hereinafter *Top Management*]; Vikramaditya S. Khanna, *Politics and Corporate Crime Legislation,* 27 REGULATION 30 (2004)[hereinafter *Politics*]; Vikramaditya S. Khanna, *Corporate Defendants and the Protections of Criminal Procedure: An Economic Analysis,* DISCUSSION PAPER NO. 2004-015, JOHN M. OLIN CENTER FOR LAW & ECONOMICS, UNIVERSITY OF MICHIGAN LAW SCHOOL, 2004[hereinafter *Corporate Defendants*].

I will be focusing on deterrence based arguments for liability rather than other types of arguments that may be used to support liability.

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2. Corporate Wrongdoing & Corporate Liability Regimes: When are Criminal Sanctions on Executives Desirable?[2]

Imposing civil monetary sanctions on corporations is an important tool for deterring corporate wrongdoing. However, it is only one tool, amongst many, that we have at our disposal. Others include civil monetary sanctions on executives (or employees);[3] criminal sanctions on corporations; criminal sanctions on executives; sanctions of various kinds on associated third parties; and combinations of these regimes. In light of all these options a natural question is which liability tool is best to use and when?

As a general matter, I would recommend relying on civil monetary sanctions against corporations as the primary means of deterring corporate wrongdoing. This is for a number of reasons. First, if we relied solely on sanctions against employees there may be many employees who would be judgment proof – that is, not have enough assets to pay for the harm caused. Such employees would not have appropriate incentives to exercise care in their activities to avoid harm.[4] This would lead to riskier products and more of these types of products being made and sold.[5] Imposing corporate liability addresses these problems to the degree that the combined assets of the corporation and employee can pay for the harm caused (i.e., that the corporation and employee together are less likely to be judgment proof than the employee alone).

Second, corporate liability can often deter as effectively as direct monetary liability against employees. This is because monetary sanctions on the corporation will motivate shareholders to prevent or deter employees from engaging in harmful acts. This may manifest itself in closer monitoring of employees and modifications to employment contracts providing employees with appropriate incentives. This, in effect, deputizes the corporation to monitor employees, whereas direct liability requires the government (or private litigants) to monitor employees' activities. This suggests an advantage of corporate liability. The corporation may be a better monitor of its employees' behavior than the government or private litigants because the corporation is closer to its employees and is probably already monitoring them to some extent (e.g., to ensure they are performing their primary tasks and for promotion purposes).

Third, corporate liability may address risk bearing costs better than executive liability. The reason is that executives are more risk averse than shareholders (or the corporation). The risk of liability can be diversified better by shareholders (who can invest in many corporations to spread their risk) rather than executives who cannot work at nearly as many

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[2] The discussion in this section relies on Khanna, *Corporate Criminal Liability*, *supra* note 1; Reinier H. Kraakman, *Corporate Liability Strategies and the Costs of Legal Controls*, 93 YALE L.J. 857 (1984); A. Mitchell Polinsky & Steven Shavell, *Should Employees Be Subject to Fines and Imprisonment Given the Existence of Corporate Liability?*, 13 INT'L REV. L. & ECON. 239 (1993).

[3] I will use the terms employees and executives interchangeably for purposes of this testimony.

[4] A numerical example would be as follows. Assume exercising care costs employees $20 in time and effort, the harm avoided is $100, and the employee's assets are only $5. In this scenario, the employee would be inclined not to spend $20 in time and effort when the most he or she can lose is $5. Society would want care exercised for $20 because it avoids $100 of harm.

[5] If only employees are liable and employees are judgment proof then the firm can avoid including the full cost of the harm into the price of its products and too much of the product will be sold. *See* Steven Shavell, *Strict Liability Versus Negligence*, 9 J. LEGAL STUD. 1 (1980).

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corporations to spread their risk. The greater risk aversion of executives could reveal itself in attempts to over-comply with the law. Executives may exercise too much caution in approving projects, may take too long to make decisions and may become reluctant to take a position as an executive if liability risks are very large. Corporate liability helps to reduce this by placing liability on shareholders, who are better able to diversify risk and thereby are less risk averse.[6]

Although this provides a number of reasons for preferring corporate liability, it also implicitly suggests when direct liability on employees or executives would be a desirable supplement. For example, if the corporation itself might be judgment proof with respect to the harm caused then it will be under-deterred. The corporation would not have appropriate incentives to monitor its employees. In addition to this, if the maximum sanctions the corporation can impose on employees (e.g., denial of salary, future pay and pensions) are not sufficient to obtain the desired level of deterrence then the corporation's ability to effectively deter its employees is hampered. In these situations direct liability on executives may be desirable.[7]

For example, we might consider imposing additional civil monetary sanctions or criminal sanctions (e.g., prison) on executives. Generally, we prefer to first rely on civil sanctions before criminal ones. The reason for this is that criminal sanctions are more costly than civil sanctions (e.g., criminal sanctions have the costs of maintaining prisons). Consequently, if we can obtain the desired level of deterrence with the cheaper civil sanctions then we should prefer to rely on them first. For example, we might increase civil penalties on executives or deny them insurance coverage for certain wrongs.

However, sometimes even these higher civil sanctions on executives would not obtain the desired level of deterrence. For example, if the harm caused exceeds the combined assets of the corporation and the executive then one might need to consider imposing criminal sanctions. This seems most likely for activities that cause very high levels of harm (e.g., a sizeable risk of death or serious injury to a number of people from defective products). For such cases the assets of the corporation and executives may prove to be insufficient to pay for the harm and a case can be made for the imposition of criminal sanctions on executives.[8]

However, this presumes that the deterrence potential of civil sanctions on corporations and executives has been exhausted. Only after then would criminal sanctions be worth considering. However, assuming for the moment that the civil alternatives have been exhausted, and that there is still a need for greater deterrence, then we need to examine how criminal sanctions might be drafted and used.

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[6] Corporations may also over-comply (e.g., when there are very large penalties under uncertain legal standards). *See* Richard Craswell & John E. Calfee, *Deterrence and Uncertain Legal Standards*, 2 J.L. ECON. & ORGANIZATION 279 (1986). But that point may come later for corporations than executives given that executives are generally thought to be more risk averse than corporations.

[7] After all, corporations cannot send their employees to jail without state intervention and they cannot tap employees' savings that easily.

[8] I do not discuss the potential for increasing criminal sanctions on corporations because I do not think that will generally be very helpful. *See* Khanna, *Corporate Criminal Liability*, *supra* note 1; Khanna, *Politics*, *supra* note 1.

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3. Costs of Criminal Liability and Potential Ways to Reduce Those Costs[9]

Criminal sanctions are a powerful tool. However, this power comes at considerable cost. There are, of course, the direct costs of operating and maintaining prisons, but there are important indirect costs as well. One that merits particular attention is how the threat of criminal sanctions may lead executives to exercise too much caution and potentially lead to even more wrongdoing.

Because criminal sanctions are severe the risk of bearing them is likely to motivate risk averse executives to become too cautious and spend too much time and effort on monitoring employees. What is more troubling, however, is if executives become too scared to take on positions of importance at firms that face a greater risk of criminal liability (e.g., pharmaceutical firms whose products can cause the kinds of serious consequences being considered at this hearing). It is not difficult to imagine good people who would refuse to become executives of such firms due to the fear of facing criminal liability if things went wrong.[10] If this happened then these positions would be taken by people who are perhaps not so careful and more tolerant of high risk activities. However, having more risk-tolerant people in charge of corporations that produce highly dangerous products does not seem like a way to *reduce* harm or wrongdoing. Indeed, it may lead to more harm or wrongdoing depending on the circumstances.

There may, however, be ways to address this concern in some measure. If we could avoid imposing liability on executives who attempted to do a good job or those who tried their best to prevent the harm, then the risk of scaring away good people would be reduced. One way to do this would be to premise criminal liability on a showing that the executive knew of the large risks associated with the product and its defects.

Although, in theory, this seems a desirable solution, in practice it may flounder. If there is legal error in applying the knowledge requirement (or perceived error in applying it or uncertainty amongst executives about what it means) then there will still be concerns about frightening away (or "chilling") good people from taking positions of importance in these firms. Thus, if one is considering criminal sanctions on executives it would seem critical to lay out in considerable detail, and without too much room for error, how and when executives would be held liable. A high mental state requirement might help in this direction with clear examples of criminal behavior provided either by legislation or enforcement agency policy.

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[9] The discussion in this section relies on Khanna, *Corporate Fault, supra* note 1; Khanna, *When Corporations, supra* note 1; Polinsky & Shavell, *supra* note 2; Jennifer Arlen, *The Potentially Perverse Effects of Corporate Criminal Liability*, 23 J. LEGAL STUD. 833 (1994); Jennifer Arlen & Reinier H. Kraakman, *Controlling Corporate Misconduct: An Analysis of Corporate Liability Regimes*, 72 N.Y.U. L. Rev. 687 (1997); Steven Shavell, *Liability and the Incentive to Obtain Information About Risk*, 21 J. LEGAL STUD. 259 (1992).

[10] This is especially true of executives who have excellent reputations. Those reputations would have taken time to build and can be seriously injured with one corporation's harmful activities.

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If this can be achieved then these concerns are somewhat reduced. However, other concerns would be generated. For example, if we premise criminal sanctions on how much executives knew (or how much information they had) then some executives may find that knowing very little is a good way to avoid criminal liability. Indeed, if executives do not bother to gather information then they cannot be found to have "knowledge" and thereby they could avoid liability. If this were common practice then there is a potential for more harmful products to be introduced in the market. Of course, one could try to make "willful blindness" a potential mental state that would trigger liability, but this adds yet more uncertainty in the process (e.g., when is "willful blindness" met) and is likely to push in the direction of scaring executives away. Thus, it appears that however we draft the mental state requirement we will face a trade off between executives being unwilling to serve on corporate boards for fear of liability or allowing too many executives to escape liability by not gathering information about product risk.

There is no simple solution to this problem and perhaps the best one can hope for is to try to minimize the costs associated with scaring away executives and providing executives an escape route. However, I will attempt to provide a more hopeful outcome in the next few paragraphs.

One method of addressing the concern of executives' not gathering information is to make *corporations* strictly liable for the harm caused or make gathering information about product risk a matter that reduces or eliminates *corporate* liability. Under either alternative (strict liability or reducing liability), the corporation has an incentive to set up a system of gathering information about product risk. Under strict liability this is because corporations will bear the costs of harm and will want to reduce those costs by avoiding the sale of dangerous products. This means they will need a system in place to ferret out which products are indeed dangerous. Under the reducing or eliminating corporate sanctions alternative the firm would probably have a system for gathering information about product risk because its presence would help to reduce the liability the firm would face.[11]

Once such a system is set up it becomes more difficult for executives to avoid being aware of information or gathering information. As this information is gathered, distributed and used in making decisions it will become more difficult to avoid. Surely, some executives will find ways to avoid gathering information, but that number will be less than when corporations do not set up such a system.

Thus, these options, although not perfect, could address some concerns of imposing criminal sanctions on executives. [12] Nonetheless, the foregoing discussion highlights the kinds of trade offs that would need to be considered if we were to follow the path of increasing criminal sanctions on executives.

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[11] I do not discuss whether strict liability or the reducing or eliminating corporate sanctions option is better in my testimony today, but it is a matter worthy of much fuller discussion.

[12] Other methods of ameliorating these concerns could be considered (e.g., requiring executives to certify certain matters), but I do not discuss those here.

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4. Other Concerns.

Before concluding, I want to offer a few thoughts on coordinating sanctions and the continuing importance of prosecutorial discretion. First, coordinating the sanctions imposed on executives and corporations in civil and criminal proceedings is something that needs to be explored in greater depth to ensure that we are obtaining the appropriate level of deterrence. Absent coordination we may in some cases over-deter and in other cases under-deter the relevant actors.[13] I will not address methods for achieving coordination in the context of today's testimony, but will be happy to provide my thoughts on it should that be of interest.

Second, prosecutorial discretion remains important even with well drafted legislation. The prosecutor's decisions to charge, indict and pursue a prosecution are all important in determining the likely deterrent effect of the law. Greater guidance on how this discretion may be exercised would be helpful in assessing the likely benefits of a law imposing criminal sanctions on executives. For example, it may be helpful to have clear enforcement policy (or legislative) guidelines suggesting that criminal sanctions on executives should be pursued when alternative civil sanctions cannot pay for the harm caused and when proof of mental state is fairly clear.

5. Concluding Remarks

Corporate wrongdoing can lead to grievous harms. However, the kinds of liability regimes we put in place to deter or prevent such wrongdoing requires careful thought to avoid creating a situation where the cure is worse than the disease. In my testimony I have tried to highlight when criminal sanctions for executives may prove desirable. This is generally when the harm caused is so large that civil sanctions on corporations and executives prove to be insufficient in terms of deterring harmful behavior. If so then criminal sanctions on executives are worth considering. Defective products that cause serious injury or death to many people appear to be this kind of large harm, but before adopting criminal sanctions we would need to first exhaust the deterrent effects of civil sanctions.

If it appeared that criminal sanctions were indeed warranted, then considerable care is needed in drafting them to ensure that we do not scare away good people from becoming executives and also that we provide adequate incentives for corporations to gather information about product risk. Keeping these two features in mind one might be inclined to have a high mental state requirement (e.g., knowledge or more) with clear examples of what is meant by it, accompanied by either strict liability or some kind of liability reduction for corporations that have appropriate information gathering systems in place.

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[13] This point also relates more generally to examining the kinds of sanctions that seem appropriate in the context of corporate wrongdoing. For general discussion see Khanna *Top Management*, *supra* note 1; Vikramaditya Khanna & Timothy L. Dickinson, *The Corporate Monitor: The New Corporate Czar?*, 105 MICH. L. REV. 1713 (2007).

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Statement of Senator Patrick Leahy
Chairman, Senate Judiciary Committee
Hearing on "Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement"
July 31, 2007

I scheduled today's hearing at the request of the distinguished Ranking Member. The Senior Senator from Pennsylvania has long expressed an interest in criminal liability for the introduction of dangerous or defective products into the marketplace. I agree with him that this is an important issue and one where further congressional action may be warranted.

This hearing will examine the recent plea agreement between the makers of OxyContin and the Federal government. Last month, this Committee held a hearing addressing the role of rogue online pharmacies in our Nation's growing prescription drug abuse problem. Among young people, prescription drugs have become the second most abused illegal drug, behind marijuana. In fact, if you exclude marijuana, more adults and teens report abusing prescription drugs than all other illicit drugs combined. I noted then that Purdue's admitted misrepresentations about the addictiveness and abuse-potential of their product was very troubling.

The criminal conduct involved in the marketing of OxyContin has been one of the most tragic examples in recent memory of a company favoring the bottom line over the health of our Nation's citizens. The tragic irony is that the dangerous product here purported to help people manage pain. And I know that for many it has been effective. But for many others, this drug, and its diversion due to widespread distribution, has caused terrible harm -- from addiction to death. Purdue made billions of dollars marketing OxyContin as a less-addictive alternative to other painkillers. Today, we will hear about what punishment the Justice Department found appropriate for this criminal conduct.

I look forward to discussing today with the witnesses how best to prevent this type of dangerous corporate decision-making from occurring again. Americans should not have their lives reduced to a mere factor in an actuarial table. While the makers of OxyContin have been prosecuted, have pleaded guilty, and are paying a multi-million dollar fine, no one from the company is going to jail. I believe it is fair to ask in light of Purdue's profits from OxyContin of approximately $2.8 billion between 1996 and 2001, whether the $680 million in penalties they received in this plea agreement will serve as a deterrent to similar future conduct or just another cost of doing business as usual.

We will hear testimony today about the way Purdue's conduct has affected the lives of those who have lost loved ones as a result of taking OxyContin. Many are asking why the three executives who pleaded guilty were not given jail time. Certainly nothing makes corporate executives think twice about malfeasance more than the prospect of the iron bars slamming shut. The Judge who presided over the plea agreement stated at the sentencing hearing: "I do not doubt that many of our fellow citizens . . . will deem it

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inappropriate that no jail time is imposed. It bothers me, too." The United States Attorney who prosecuted the case will testify today about why he did not insist that the responsible corporate officials pay a similar price as the individuals who sell OxyContin on the street. I look forward to hearing from the witnesses and thank them for joining us this afternoon.

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Michael H. Levy, MD, PhD
Vice-Chair

July 30, 2007

The Honorable Arlen Specter
711 Hart Building
Washington, DC 20510

RE: Senate Judiciary Committee Hearing 7/31/07

Dear Senator Spector,

I am writing you this letter as my Senator to describe the privilege that I have had working with the Purdue Pharma Company over the past 23 years and to emphatically emphatically disagree with the notion that OxyContin is a defective product. Over the years I have been very impressed with the honesty, integrity, and high ethical standards of the Purdue Pharma Company and its leadership. I have prescribed OxyContin for hundreds of patients who have come to Fox Chase Cancer Center and recently needed to rely on it to help me recover from major abdominal surgery.

After seeing the benefit of Purdue Pharma's British, sister company's controlled-release opioid analgesic, MST Continus, in 1981 while I was training at St. Christopher's Hospice in London, I sought out Purdue Pharma when I heard that they were bringing this analgesic to the United States as MS Contin. In 1984, I presented an update on cancer pain management to their medical and marketing staff, parts of which became a resource for the training of their sales force. I was a member of their Speaker's Bureau and presented lectures, symposia, and workshops in 47 states and 7 countries. Every employee with whom I interacted displayed corporate-driven expertise and advocacy in our combined battle to overcome the prevalent undertreatment of cancer pain at that time. Due to the quality of their sales training, most of the sales representatives with whom I worked knew more about opioid therapy than the physicians that they were detailing. At no time did I hear or see marketing that was unethical or outside of FDA package insert guidelines. My interactions over the years with Purdue Pharma's medical staff, including Dr. Paul Goldenheim, have always been highly professional, evidence-based, and medically sound. Similarly, I had the opportunity to work with their Corporate Counsel,

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Howard Udell, on FDA package label approval and on his meticulous screening of any educational material that I had prepared for corporate sponsored educational presentations and enduring materials. He too was cautious and prudent and displayed the highest ethical and legal standards.

I participated in Purdue Pharma's Train-the-Trainer symposia to increase the army of teachers which was needed to overcome long existing myths and barriers to adequate pain management. As a Board Member of the National Hospice and Palliative Care Organization in the 1980's and the American Academy of Hospice and Palliative Medicine in the 90's, I facilitated bringing Purdue Pharma's earnest support of the academic and clinical mission of these organizations who were providing pain and symptom management services to thousands of patients and their families every year. When OxyContin was introduced in 1996, I was one of the thought leaders who began comparing it to MS Contin in search of any relevant differences that might help our patients despite the research data that did not show any difference in safety or efficacy. In our patients with advanced cancer and a narrow therapeutic window for adverse side effects from opioid analgesics, we did see advantages that were truly valuable to patients and their loved ones. Again, at no time did anyone from Purdue Pharma promote any attributes of OxyContin outside of the FDA package insert. I presented a paper on OxyContin pharmacology and clinical advantages at the European Association of Palliative Care Annual Meeting in Geneva in 2000 which was published in the European Journal of Cancer in 2001. At our Pain Management Center, we were very pleased with the comfort and function that we were able to provide for our patients with OxyContin and did not find that it was any more likely to be abused or diverted than any other opioid we had prescribed for our patients.

You can understand how upset I felt when people with the disease of addiction in this country began abusing OxyContin by disobeying package insert guidelines and crushing, snorting, melting, and injecting it into their veins. OxyContin abuse grew rapidly due to its efficacy, alterability, and availability in even rural community pharmacies. Deviant addicts and drug pushers duped pharmacists and physicians for inappropriate prescriptions or obtained OxyContin through actual theft and burglary. Unethical pharmacists and physicians began to profiteer from the high street price of OxyContin and further accelerated this tragic diversion of an opioid analgesic that, to this day, remains a cornerstone of safe and effective pain management. At no time was I ever asked to recommend OxyContin for non-approved uses. In my practice and in my local educational efforts, I constantly corrected physicians, pharmacists, and patients not to crush, cut, or chew OxyContin tablets.

Once it became apparent to Purdue Pharma that OxyContin was being diverted and abuse due to its potency when crushed, snorted, or injected, they immediately launched a campaign to educate health care providers about the this issue and about the effective screening of patients who were at high risk for diversion or abuse. They worked with major pain societies and sent out informational mailings and brochures to clinicians to help protect their practice and community. I personally testified at a Commonwealth of Pennsylvania hearing in Philadelphia about the dangers of OxyContin. In the face of

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distressed parents whose children died from chewing OxyContin and politicians who were using the hearing for a pre-election photo opportunity, several of us spoke to the safety and efficacy of OxyContin. It was clear to me that Purdue Pharma was being scapegoated for all of limitations of our regulatory and mental health system to manage the disease of addiction in our country. One of the parents admitted that his 17-year old son was also found to have alcohol and alprazolam in his blood stream, both illegally consumed. As this father overcame his acute grief about his loss, he changed his initial website from "oxycontinkills.com" to "oxycontinabusekills.com" and set out to work with community agencies to help educated and counsel his son's friends and peers. I next testified at a federal hearing in Bucks County, PA, where an unscrupulous physician was arrested for selling OxyContin prescriptions. At that hearing, I had the opportunity to work with Purdue Pharma's CEO, Michael Freedman. Like Paul and Howard, I found him to be sincere, honest, and truly concerned about the inappropriate use of the product they had worked hard to develop to help legitimate patients with moderate to severe, chronic pain. Similar to his colleagues, Michael had not foreseen and never intended for OxyContin to become anything but a legitimate analgesic.

On an even more personal note, I am just now recovering from emergency bowel surgery for an acute obstruction. Once I was able to tolerate oral intake, I found that OxyContin was less sedating than intravenous hydromorphone. My OxyContin allowed be to return home, learn how to take care of ileostomy, and begin my physical therapy with a clear head and a pain that averaged 2-3 out of 10. Over the past four weeks, I have been able to taper my OxyContin use to zero, without any signs or symptoms of physical or psychological withdrawal. I have already advised my surgeon that I plan to use OxyContin again following my planned reconnection surgery the end of August. It was a superb opioid analgesic for me and has been one for thousands of my patients. The district attorney's exaggerated comments and the media coverage's demonic portrayal of OxyContin, Purdue Pharma, and it officers has caused many of our patients unnecessary suffering due to their fear that they would be harmed by the OxyContin that had been helping them cope with their cancer pain over the past months and years. After receiving our pain center staff's diligent counseling and education, our patients are doing well again, on doses OxyContin from 10 mg q 12h to 1120 mg q 12h.

In closing, I fully support the judge's recent acceptance of Purdue Pharma's plea settlement. I would ask that you consider the noble and pioneering work that Purdue Pharma and its officers have done over the past 20 years and that you accept the propriety and adequacy of that plea settlement agreement to bring this ordeal to a close. In their Statement of Fact, Purdue Pharma's leadership admitted that improper things occured on their watch by some of their employees. From my close collaboration with them over the past 23 years, I can unquestionably swear that it was never their intent to promote or permit these wrongs. I strongly disagree with District Attorney Brownlee's overarching statement that Purdue Pharma has a poor corporate culture. What happened in this matter was done by employees in the field despite the excellent corporate culture that I have described above. I am saddened by what has occurred and look forward to Purdue Pharma's speedy recovery as a true advocate for the millions of patients in this country that suffer from inadequate control of their chronic pain. Finally, I am appalled the

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implication that OxyContin is a defective product. When used as directed, it is safe and effective and no more toxic or addictive than any other opioid. Only when it was used outside of package insert directions, does OxyContin cause harm. Only when it is used illicitly and illegally and then chewed, crushed, snorted, or injected is it harmful. It is the persons who use OxyContin inappropriately or illegally and our healthcare and regulatory system that has not provided adequate care to the 6 – 10 % of our population with the disease of addiction that are defective! Intravenous abuse of crushed and melted hydromorphone (Dilaudid) tablets remains all too common, but that does not make Dilaudid a defective product. Recent examples of defective product include Vioxx, Bextra, and now possibly Avandia, which when taken as directed cause toxic side effects. I am very concerned about the impact of OxyContin being labeled as defective on the patients in our Pain Management Center and others like it who might stop taking their OxyContin out of fear or inaccessibility. They could develop accelerated pain or symptoms of physical withdrawal. They might have to take an alternative opioid for their moderate to severe pain that might not give them the same comfort and function as OxyContin.

I would welcome the opportunity to speak with you or members of your committee directly, if that would help you better understand the value of OxyContin and Purdue Pharma to those of us who have committed our careers to reducing the suffering of patients and families dealing with chronic pain. Thank you for this opportunity to write this letter of support.

Sincerely,

Michael H. Levy, MD, PhD

Michael H. Levy, MD, PhD
Vice-Chair, Department of Medical Oncology
Director, Pain Management Center
Fox Chase Cancer Center
Associate Professor of Medicine
Temple University School of Medicine
Past-President, American Academy of Hospice
and Palliative Medicine

CC: The Honorary Patrick Leahy

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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"

July 31, 2007

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

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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

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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

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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

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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

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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

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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

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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.

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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

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

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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.

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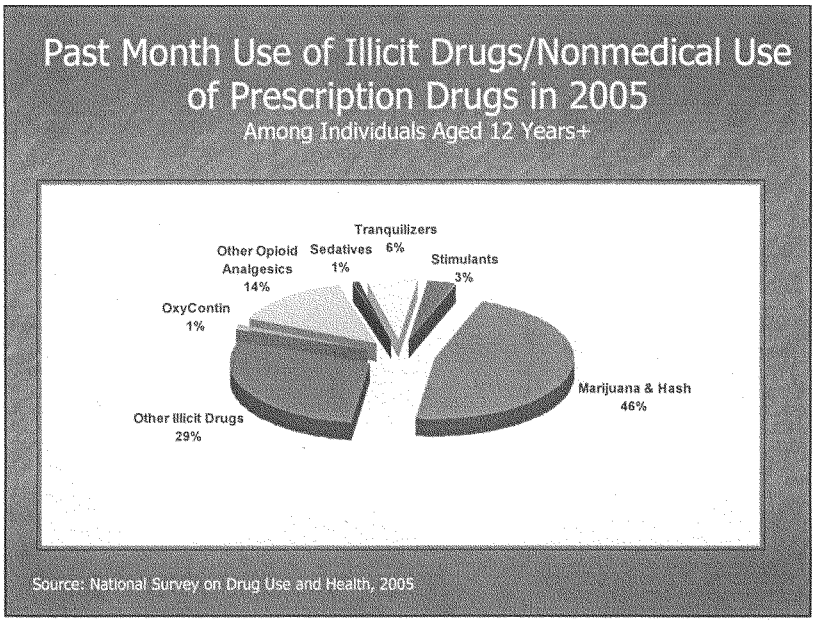
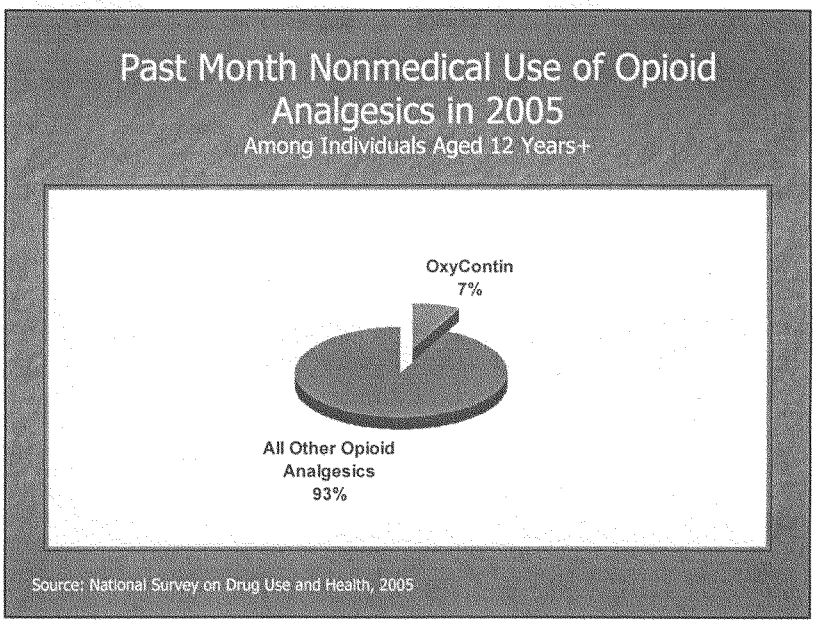

Past Month Use of Illicit Drugs/Nonmedical Use of Prescription Drugs in 2005
Among Individuals Aged 12 Years+
Tranquilizers 6%
Other Opioid Analgesics 14%
Sedatives 1%
Stimulants 3%
OxyContin 1%
Marijuana & Hash 46%
Other Illicit Drugs 29%
Source: National Survey on Drug Use and Health, 2005


Past Month Nonmedical Use of Opioid Analgesics in 2005
Among Individuals Aged 12 Years+
OxyContin 7%
All Other Opioid Analgesics 93%
Source: National Survey on Drug Use and Health, 2005

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"ENSURING THE DEATH AND SERIOUS INJURY ARE MORE THAN A BUSINESS COST: OXYCONTIN AND DEFECTIVE PRODUCTS"

RESPONSE BY POLICE OFFICE VIRGINIA PAGANO #2161
PHILADELPHIA POLICE DEPARTMENT, NARCOTICS BUREAU

Good afternoon Chairman Leahy and members of the Senate Committee. I am honored to be here today to speak to you on behalf of the Philadelphia Police Department. I will speak to you on the devastation caused by OxyContin on family, friends and our communities.

My current assignment is with the Philadelphia Police Department, Narcotics Bureau's Drug Education Program entitled, "H.E.A.D.S.-U.P." (Heroin, Education and Dangerous Substance Understanding Program). The Heads-up Program has joined together law enforcement, family members, who have lost their loved ones, and the recovering community.

Since its inception, the Heads-up Programs has been viewed by approximately 449,000 people at 3,032 locations, and has been shown across Pennsylvania, New Jersey, Delaware, Massachusetts

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and Connecticut. The program has for the past six and a half (6 1/2) years exposed me to a completely different aspect of law enforcement, the education side; the education, of not only law enforcement officers but of the general public so they can better understand the devastation that is caused by drug addiction, is of the utmost importance.

Abuse of OxyContin is a problem that we (as Police Officers) cannot arrest our way out of. It will require primarily education, along with treatment and enforcement. We must educate the children before they pick up that drug because after that, we're just simply playing catch up.

I am inspired every day to continue the Heads-up Program. I often listen to story after story of how addictive OxyContin is. The story seems to stay the same but the faces continue to change. Whether black, white, Hispanic or Asian, no matter what religion or political party, OxyContin has crossed all boundaries.

It seems that among our young people, "Prescription Drugs" namely, OxyContin, which is one of the most commonly abused by teens, just sounds safe and yet the progression from OxyContin to Heroin is a very common one.

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One young lady's story always comes to mind. She stated that she started using Percocet at the age of 13, she couldn't get Percocet one night and someone suggested OxyContin. Then one night she didn't have enough money to get OxyContin, so she tried Heroin, and as she says, "That's when her life changed forever". At 18 years of age she is now in treatment because of one little pill. But so many more are not as fortunate.

The abuse numbers are chilling – OxyContin addiction has increased dramatically over the past ten (10) years by 300 % in the United States alone.

In 2006, this past year's abuse of OxyContin among 8th graders exactly doubled – increasing 100 % over the last four (4) years (MTF 2006 – From 1.3 % in 2002 to 2.6 % in 2006). Fifty-six percent (56%) of teens agreed that prescription drugs are easier to get than illegal drugs.

I could spend the next five (5) hours talking about statistics, 300 %, 100 %, 56 %, etc. But today I would like to concentrate on the number "One". Over the past 6 ½ years I have met countless families who have lost a son, a daughter, a husband or a mother,

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and what I know is 300 %, 100 %, 56 % means nothing. The only thing that matters is that "One". The "One" who is and will always be missing from that family due to OxyContin addiction or overdose.

Because of these addictions, we continue to meet family after family who live everyday thinking about what it would be like if their loved ones were still here; always asking, "Who would they be today?"

The "cost" I believe you'll never be able to measure. The son who died from the OxyContin overdose might have held the cure for cancer; the daughter will never be able to walk down the aisle with her father. A father, who was selling OxyContin is sitting in prison, and the mother who was originally prescribed OxyContin because of her pain from a car accident, is now addicted and can no longer care for her own children.

Too many people realize too late that OxyContin abuse could lead to incredible losses. Lost family, lost friends, lost jobs, lost opportunities, and lost lives either to a life-long addiction or overdose.

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The 634.5 million in fines and three (3) executives who have pled guilty for "Misbranding" the drug as a "low-risk" painkiller will never equal the "One" who has been lost to these addictions or the overdoses. For that "One", who is lost has affected a whole family, a whole community, a whole generation.

There are many faces and stories that have been entrusted to the "Heads-up" Program. The only hope is that somehow "One" story, or "One" face will somehow save another from the pain and the never-ending heartache that comes with addiction; because **DEAD** is **DEAD** whether it comes at the hands of Illegal drugs or Prescription drugs like OxyContin.

I hope my testimony today has somehow helped. It was truly an honor to appear before this committee.

Thank you for your attention and I will be available to answer any follow-up questions.

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Testimony of Siobhan Reynolds
Founder and President Pain Relief Network
By Submission To The Chairman
Of The Senate Committee on The Judiciary
Senator Patrick Leahy of Vermont

Hearing before the Senate Judiciary Committee
"Evaluating the Propriety and Adequacy
of the Oxycontin Criminal Settlement"

Tuesday, July 31, 2007
Dirksen Senate Office
Building Room 226 2:30 p.m.

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Mr. Chairman and Senators:

Thank you for taking my testimony on the propriety of the criminal settlement between the United States Department of Justice and Purdue Pharmaceuticals. Pain Relief Network has opposed the United States Department of Justice crackdown on the pain treatment community and has had ample opportunity to witness the actions of both the Department of Justice and Purdue Pharmaceuticals. Our conclusion is not flattering to the Department of Justice and forms the basis for our formal request, hereby submitted, that this Committee convene hearings into the Justice Department's campaign against medical pain management. We take no position as to whether or not Purdue's executives have committed any crimes and maintain that we could not know the truth under current circumstances. The plea deal in question is, indeed, a criminal settlement.

Purdue Pharma was coerced, under threat of destruction by the U.S. Department of Justice (USDOJ), into pleading guilty to charges that their drug, Oxycontin, was "more addictive" than they had claimed, the government alleging that the company failed to inform both doctors and the public of this information when it came available.

The problem for Americans in pain, and for the country in general, is that this private deal creates, if you will, a "fact" on the public record that is not factual, a "fact" that severely prejudices the interests of patients in pain.

Whether Purdue is in reality guilty of misinforming the public as to the "abusablity" of the medicine is not in serious dispute. Indeed, they seem to have promoted Oxycontin as though it were less abusable than other opioid medicines, even when they had evidence that recreational users had figured out how to defeat the time release mechanism. This attempt to distinguish Oxycontin from other opioid pain medicines was certainly ill-advised-foolish really-because, all opioid drugs are abusable.

The lawlessness that we should be concerned about, however, is not Purdue's. Rather, we should all be gravely troubled by the actions of the USDOJ, whose institutional character in many respects determines whether the American people are actually a free people or not. Most unfortunately, the USDOJ appears to have lost all respect for the sanctity of our court system and for the rule of law itself. While enjoying a conviction rate of over 97 percent and happily availing itself of its power to compel testimony from so-called "cooperating witnesses", this is a department that has taken to securing convictions in order to send political messages, rather than restricting itself to enforcing the law.

Over the last five or so years, US DOJ has engaged in a brutal and systematic campaign to intimidate medical practitioners out of prescribing supposedly legal opioid pain medications. They have imprisoned many skilled and compassionate physicians on trumped up charges, for sentences amounting to three decades or more, (See the New York Times Magazine Cover article, When Is A Pain Doctor a Drug Pusher, June 17, 2007....) and have caused thousands more physicians to stop treating their patients' serious pain.

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This effort has caused a society-wide breach of the duty of care owed patients by physicians and represents a wholesale attack on the doctor/patient relationship. In short, the Department's actions have destroyed the due process rights-and sometimes the lives-of Americans in pain.

One only need look at what happened to the Arthur Andersen corporation in 2005 to understand the overwhelming force exerted by the USDOJ and why millionaire executives of a company as large as Purdue might plead guilty to crimes they may not have actually committed. For when the US DOJ seeks to get its way, the law be damned, and with it all of the political freedoms our country was supposed to further and protect. What's worse, no one at the legislative branch appears to have been minding the store.

While Arthur Andersen maintained its innocence and was ultimately exonerated by a unanimous ruling of the United States Supreme Court, Arthur Anderson was, nevertheless, destroyed as an institution. The point that seems to have been missed there, and the one that must be remembered now, if we are to analyze Purdue's situation correctly, is that in the Arthur Anderson case, the US DOJ was caught and exposed for procuring a criminal conviction without any showing of mens rea, and nothing was done about it. As a result, a message has been sent by the USDOJ to all defendants, and it is coming through loud and clear: you may fight for your innocence and even ultimately prevail, but we will bring you down, nevertheless.

Purdue would have faced the same fate as Arthur Anderson if they'd taken the government on, whether they were guilty or not. Just as every Federal defendant is ultimately obliged to do, one way or another, Purdue was put into a position to let the United States Department of Justice characterize the nature of their enterprise, or lose the company entirely. Under such astonishing coercive power, the truth could not possibly come out. What's worse, under this scenario, the Justice Department is attempting to use the Senate Judiciary Committee as a platform upon which government attorneys can proudly parade their victory before the public. So, Members of the Committee, we counsel you not to assume that a guilty plea by Purdue executives signifies any actual guilt. In fact, one can only fairly deduce from the existence of such an agreement, that the defendants primarily wish to survive their encounter with our USDOJ.

Many people in severe pain, especially those with high dose requirements, have been maimed or killed as a result of this department's campaign against pain management. But we haven't, as of yet, seen Senate Judiciary Committee hearings about that ongoing atrocity. Instead, we watch raptly as a mother blames this company for the death of her daughter, a death that, no matter how genuinely heartbreaking, resulted-if not accidentally- at most from medical negligence. I fail to see why a story of medical malpractice is properly before the Senate Judiciary Committee. What possible value could it have to this committee except to prejudice the committee against this company?

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Government lawyers and their supporters are attempting to influence the Committee just like they do Federal judges and juries, such that if the issue is drugs, then the protective rules of evidence are turned on their heads. As is true in courtrooms throughout the land-whenever drugs are at issue-if the testimony offered by the government is irrelevant and prejudicial, it comes in. It is unfortunate that these perverse tactics are not only employed in Federal courtrooms by Federal prosecutors, but in testimony to the Senate Judiciary Committee as well. Prosecutors are leading this country around by the nose and they are doing so through shameless emotional manipulation.

Bad as this is, and it is bad indeed, what is even more troubling is the bedlam hidden from view by these cheap theatrics. Many Americans continue to lose their lives, their jobs, their very ability to get out of bed, all of this and more, as a result of the USDOJ's campaign against pain treatment. Today, the USDOJ sends yet another deadly message, this time not to physicians, but to the pharmaceutical industry: stay away from the manufacturing and marketing of opioids-or else. But this time, sadly, the USDOJ does it with the tacit, and, we hope, unintentional approval of the United States Senate.

In coercing this plea deal, the US government effectively dissuades pharmaceutical companies from manufacturing better opioid pain drugs, drugs that are badly needed by the estimated 10 million Americans suffering in out-of-control pain.
Patients in pain are dying unnecessarily in droves. In addition to being driven to suicide, these patients develop deadly conditions secondary to the stress of ceaseless pain, often dying of conditions such as heart disease and stroke arising as a result of abnormally high blood pressure and the sedentary life style imposed on them by their untreated pain. Hundreds of thousands of pain patients have been damaged or killed by non-controlled drugs like Vioxx or Celebrex, drugs which unlike Oxycontin did their damage when taken as directed. And we have no idea how many law abiding citizens are forced to go to the street to buy "controlled" pain medicines, making ill Americans vulnerable to accusations of criminality because this is the only way for them to survive and to continue to provide for their families.

Opioid medications have been a Godsend to man for over two thousand years. But now, in America under the Bush Administration, American men and women, children, babies, and veterans are unable to access dosages that provide relief. The overarching goal of the government's campaign appears to be the maintenance of the widespread and highly prejudicial (to patients in pain) confusion over the addictiveness of these medications. For while opioid addiction is a terrible problem for those rare people who suffer its ravages, it is indeed a rare affliction and is not caused by exposure to opioid pain medicines.

This was proven definitively by studies done by the US Government itself on data compiled on soldiers returning from Vietnam. The U.S. Army found by testing urine specimens that more than 250,000 American soldiers had used heroin, and that of these, some 80,000 could be classified as addicts (in that they used it every day for long periods and suffered withdrawal symptoms). Yet, more than 90 percent of these users and addicts were able voluntarily to withdraw from the use of heroin without any medical assistance

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or without any permanent aftereffects. Follow-up studies showed that less than 1 percent of the total number-and less than 6 percent of the addicts-used heroin again in a two-year period after they were discharged from the Army. Doctors and scientists studying this massive data were compelled to conclude that heroin use did not necessarily lead to addiction, and that addiction was not necessarily irreversible. Indeed, the Vietnam data suggested that in large part addiction resulted from problems in adjusting to a dangerous environment (i.e., the war in Vietnam) rather than from the chemical effects of the drug itself. The rarity of addiction following opioid exposure has since been confirmed by a wealth of data on patients in pain who were given opioids for extreme pain such as severe burns. Still, as you see from the testimony brought to you by the Department of Justice, they seek to enflame public fears about opioids, fears that should have been laid to rest 35 years ago.

Because the Federal imperative to manifest a "drug free America," has fueled the explosive growth of both the Federal law enforcement apparatus and the addiction treatment industry, the simple, scientific truth that opioids are remarkably safe, effective, and lack inherent 'addictiveness' poses a grave threat to the Federal bureaucracy.

Hence, the Justice Department uses the Federal court system to coerce agreements out of individuals and companies, imprisoning those who resist, for terms whose lengths are unheard of in any other part of the world. It is by these methods that they generate false evidence of a large drug addiction problem, evidence they then bring to you and other members of Congress in their never-ending plea for greater funding and expanded powers. The attorneys at the US DOJ ultimately responsible for the pain crisis are using their power to suppress science, and are destroying the public health in the process.

We at the Pain Relief Network abhor this outrageous misuse of public trust, public moneys and goodwill, and denounce it in the strongest possible terms. We ask, therefore, that the Senate Committee on the Judiciary hold hearings into the real tragedy the American people have suffered under this government suppression of the truth, and we ask that the Senate hold those responsible, accountable for their actions.

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STATEMENT OF

HOWARD M. SHAPIRO

PARTNER

WILMER CUTLER PICKERING HALE AND DORR LLP

COUNSEL TO THE PURDUE FREDERICK COMPANY INC.

FOR THE HEARING ON

"Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement"

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

JULY 31, 2007

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Chairman Leahy and Members of the Committee:

My name is Howard M. Shapiro and I am a partner in the firm of Wilmer Cutler Pickering Hale and Dorr LLP. I represented The Purdue Frederick Company Inc. in the matter that is the subject of today's hearing. Before entering private practice, I served as the General Counsel of the Federal Bureau of Investigation from 1993 to 1997, and I was an Assistant United States Attorney in the Southern District of New York from 1987 to 1992.

As you know, on July 20, 2007, Chief Judge James P. Jones of the United States District Court for the Western District of Virginia accepted a plea that had been entered on May 10, 2007 by The Purdue Frederick Company Inc., resolving an investigation by the government that spanned more than four years. With the plea, the Company accepted responsibility for the acts of some of its supervisors and employees, all of which took place more than six years ago. The plea required Purdue to pay $600 million in fines, forfeiture, restitution, and the settling of civil claims.

As set forth in the Agreed Statement of Facts -- which the government and the Company filed jointly and which forms the sole factual basis for the plea – prior to July 2001, certain Purdue employees made, or told others to make, statements about OxyContin to some healthcare professionals that were inconsistent with the prescribing information for OxyContin that had been approved by the Food and Drug Administration ("FDA") and the express warnings the OxyContin label contained about risks associated with the medicine. Specifically, these misstatements were that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. These misstatements were far from pervasive. They were not the way the Company intended to market its product

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and, indeed, they violated written Company policies requiring adherence to the FDA-approved prescribing information. But these misstatements did occur, and they were wrong.

Purdue is deeply troubled by this misconduct and believes that it has taken significant steps over the past six years to prevent it from recurring. During that time, Purdue has implemented substantial changes to its training, compliance, and monitoring systems. In July 2001, working with the FDA, Purdue added amplified warnings to the prescribing information for OxyContin and communicated those warnings to healthcare professionals. Purdue has enhanced its compliance infrastructure, increased its training, and developed a risk management program that has been acknowledged to be a model for the industry. These efforts seek to ensure that the misconduct that led to this plea does not occur again.

Purdue's plea has occasioned significant public attention, culminating in the hearing before this Committee today. Much of that attention has understandably focused on the individuals who have suffered personal tragedies and terrible losses related to OxyContin. One would be less than human not to respect the grief and pain of these families. There is no question that OxyContin abuse and misuse has ravaged a number of communities across the country in recent years. And, like virtually any medication, even the proper use of OxyContin can, on occasion, be associated with serious side effects, as is reflected in the FDA-approved label.

But it is also important to be precise and accurate about the plea The Purdue Frederick Company entered in this case. That plea does not establish that any act by Purdue caused, or even contributed to, abuse or misuse of OxyContin. There is nothing in the Agreed Statement of Facts or in any other evidence of which I am aware that suggests that the acts of misbranding that forms the basis for Purdue's plea are in any way connected to, let alone, responsible for,

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OxyContin abuse and diversion. I understand that some have argued that Purdue's misbranding caused more OxyContin to be prescribed and thus available for misuse. But, as the government conceded in court, there is no proof that a single OxyContin prescription was written as a result of any act of misbranding and there is no evidence that links any promotional act by Purdue to illegal diversion or abuse. Purdue marketed OxyContin only to trained physicians, who are well aware of the risks of opioid abuse, and never directly to consumers. It has never been shown that pharmaceutical marketing practices cause illegal abuse. Indeed, some of the most abused drugs in the nation – such as Vicodin and methadone – are not actively marketed by any company.

I do not minimize the very real harm that many have suffered as a result of OxyContin misuse. Prescription drug abuse is a serious problem with often tragic consequences, whether it involves OxyContin or any other medicine. The personal and societal consequences that have resulted from the abuse and misuse of OxyContin cannot be denied. And yet, that is only one part of the story of Purdue and OxyContin, and not the larger part.

The rest of the story involves the lives that have been dramatically improved by access to OxyContin, a medication that is indisputably safe and effective when taken as directed. Indeed, millions of people suffering from debilitating chronic pain, and not just those battling cancer or life-ending conditions, have found effective pain relief from OxyContin. In many, many instances, this relief of chronic pain has repaired families, renewed hope, and restored lives.

Despite all of the negative publicity, the genuine fears of abuse and diversion and, indeed, the risk that law enforcement will scrutinize and challenge a prescribing doctor's medical judgments, OxyContin continues to have wide support among medical professionals. This is for the simple reason that it works to alleviate the tragic suffering of pain patients and it works well; because day after day, and patient after patient, these professionals make the same judgment that

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the FDA has repeatedly made – that the enormous benefits of OxyContin far outweigh its risks, even taking into account its harm to those who abuse it. In evaluating the propriety and adequacy of the criminal settlement as you are with this hearing, it is important not to lose sight of this central fact: OxyContin and the Company and the individuals who oversaw its development and brought it to physicians and patients, have done vastly more good than harm.

To say that Purdue's acts did not cause OxyContin abuse and diversion is not to say that the Company has been heedless to the abuse that has occurred. All Schedule II products, by definition, have a high risk of abuse. Purdue was attentive to that expected potential abuse and took steps to try to prevent it. From the time of launch, the OxyContin package insert had extensive written warnings about abuse and diversion, including warnings against crushing or chewing the tablets. Dr. Kathy Foley, who served for fifteen years as the Chief of the Pain Service of Memorial Sloan Kettering and is one of the leading pain experts in the world, wrote Judge Jones that "the package insert at the time that it was first published was viewed as providing even more information on the risks and benefits of opioids and their potential for abuse than package inserts for the comparable available strong opioid drugs." Since 1996, Purdue has spent in excess of $325 million attempting to develop a number of different opioid formulations that would be resistant to abuse. In December 1998 – at its own initiative and expense – Purdue started distributing to physicians hundreds of thousands of copies of guidelines created by the Federation of State Medical Boards which explained how properly to use opioid-based pain medications and how to avoid dispensing them to abusers. Over the years, Purdue has handed out more of these materials than the Federation itself.

Despite these efforts, as is now well known, Purdue recognized that OxyContin had become part of a trend of increasing prescription drug abuse in the United States and stepped up

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its anti-abuse activities. Through research, grants to and partnerships with law enforcement agencies, and community and public education initiatives, Purdue has dedicated extraordinary and unprecedented resources to combating this problem. Purdue has spent more than $68 million to aid law enforcement in fighting abuse and diversion of prescription drugs. These efforts have included distributing more than 270,000 tamper-resistant prescription pads in 34 states to combat prescription forgery and counterfeiting, a commonly used method to obtain medications illegally. Purdue has provided OxyContin placebo tablets to law enforcement, which have contributed to dozens of arrests of illegal drug diverters. Purdue developed RxPATROL, the nation's first and only Web-based information clearinghouse to collect, analyze and disseminate pharmacy theft information. Since its inception, RxPATROL has collected and disseminated information on thousands of incidents of pharmacy robbery, burglary, fraud, and forgery, leading to arrests. Purdue has funded community-based organizations that provide drug abuse prevention, education, recovery, and employment services. Purdue has also developed innovative programs to discourage prescription drug abuse, especially among vulnerable teens.

Some have argued that these programs are nothing more than public relations. That label denigrates programs that have made a real impact. In fact, these efforts, along with many others that I have not described, have dwarfed those of every other company, including others that also market Scheduled opioids. They have also received widespread recognition from law enforcement officials. For example, former Attorney General Mark Earley said on March 1, 2001, that when Purdue learned of the problem of abuse and diversion, "it jumped in with both feet" to solve it.

Dr. Michael Brennan, an experienced pain physician, aptly stated in a letter submitted to Judge Jones in connection with the sentencing: "OxyContin has been misused. No one of

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probity would argue with that. On the other hand, the appropriate use by physicians has enabled thousands of patients to regain some part of their lives otherwise lost to pain. The education of physicians that has been sponsored by Purdue has greatly improved the community's understanding for better pain control." That is the rest of the story that must, in fairness, be taken into account as this Committee evaluates Purdue's plea and the Court's sentence.

The Committee is also considering the propriety of the strict liability misdemeanor pleas entered in this case by Michael Friedman, Howard Udell, and Paul Goldenheim, each current or former senior Purdue executives. This unique statutory provision applicable to pharmaceutical executives does away with the criminal law's usual intent requirement and instead provides that an individual can be held criminally liable without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding committed by others. In this case, the individual defendants had no intent to violate the law and no knowledge of the violations committed by others. As Judge Jones noted in his Opinion and Order accepting the pleas, there was an "absence of government proof of knowledge by the individual defendants of the wrongdoing." In fact, these individuals led Purdue's extensive efforts to combat abuse and diversion.

The government has acknowledged that charging individuals in these circumstances is unprecedented. One of the Assistant United States Attorneys who prosecuted this case said in court at the sentencing hearing that, to his knowledge, "never before have pharmaceutical corporate executives been held liable for this type of conduct." In each of the prior cases in which this strict liability misdemeanor provision has been used, the individuals charged had been warned about or had knowledge of the wrongdoing.

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Thus, far from reflecting lenient treatment as some have argued, the prosecution of these individuals represents an extremely aggressive application of this statute. It is an application that will have profound public policy consequences as senior pharmaceutical executives fear punishment for wrongdoing committed by even low-level employees.

These pleas reflect Purdue's willingness to accept responsibility for the inappropriate actions of some of its supervisors and employees. Purdue now hopes to move forward with a renewed focus on its mission of alleviating the suffering of millions with chronic pain, on its affirmative efforts to prevent abuse and diversion of its products, and on ensuring that the acts that lead to its plea do not recur.

Thank you.

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The professional product labeling for OxyContin® Tablets contains the following **boxed warning:**

WARNING:
OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.
Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.
OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.
OxyContin Tablets are NOT intended for use as a prn analgesic.
OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.
OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Full prescribing information for OxyContin is available at http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf.

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Prepared Statement of Marianne Skolek

My name is Marianne Skolek. I had a beautiful 29 year old daughter named Jill. She had the misfortune of being prescribed OxyContin in January 2002 and was killed on April 29, 2002. Jill left behind her son Brian who was 6 years old at the time of his mom's death. Brian is with me in the Senate today.

Why did a $9 billion privately held pharmaceutical corporation take the life of my precious daughter? My work against Purdue Pharma for the past 5 years initially focused on J. David Haddox, dentist turned psychiatrist and Senior Medical Director of Purdue Pharma. I also focused on Robin Hogen, former Public Relations spokesman for Purdue Pharma.

In 1996, the American Academy of Pain Medicine and the American Pain Society issued a set of guidelines for the use of opiates in the treatment of chronic pain. These guidelines are referred to as a "consensus statement." The statement leaning toward a more liberal use of opiates was adopted just as the marketing push for OxyContin began. This consensus statement was produced by a task force, which was headed by J. David Haddox, former president of the American Academy of Pain Medicine, who was senior medical advisor for Purdue Pharma – the maker of OxyContin. Haddox was quoted as saying that "the point was to gather consensus. If you are going to do this, this is how it should be done." There was question as to whether it was ethical for Haddox to be associated with a pharmaceutical manufacturer to guide the formation of a document that would play a key role in promoting the use of products made by the company – Purdue Pharma.

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When OxyContin was introduced on the market, it was intended for the treatment of cancer patients and they were losing the patent on MS Contin. At one point, in the greed and sheer evil of Purdue Pharma, they intended to market OxyContin to OB/GYN patients. I flooded the country with emails and faxes to Attorney Generals and the media reporting that we had enough devastation in the country without addicting infants to OxyContin. This marketing ploy was terminated by Purdue Pharma.

Pain patients from various pain societies will speak of the merits of OxyContin and their quality of life being restored because of the drug. These pain societies throughout the country – are funded by Purdue Pharma. Let the pain patients not a part of any funded pain society of Purdue Pharma speak about the quality of life they have after becoming addicted to OxyContin – and when their physicians refuse to renew prescriptions for the drug – and they go on the street to buy the drug because they can't kick the habit of this less addictive drug. Ask the FDA and the DEA why OxyContin is in such plentiful supply on the streets all over the country.

Jill and thousands of victims of an out of control, greedy pharmaceutical company headed by three convicted criminals marketed OxyContin as less likely to be addictive and abused. There are assertions that the only victims in the criminal activities of Purdue Pharma were the physicians who were misled by Purdue Pharma's sales representatives. The physicians, who were used as pawns by Purdue Pharma, were not ingesting a powerful narcotic that was being marketed as less likely to be addictive or abused – the patients were ingesting OxyContin and

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were becoming addicted and dying. If patients aren't victims of Purdue Pharma's criminal activities, tell me what they should be called.

The addictions and loss of lives because of OxyContin continue to impact every state in the country every single day. The far reaching consequences of the criminal activity of Purdue Pharma did not end in 2001 or 2002 as they would like it to be believed – no one can turn the clock back. This has been allowed to become a national crisis because there was no conscience in the marketing of OxyContin – there was only greed.

We all hear on the news every day about individuals who work for government agencies or private industry who embezzle funds. Purdue Pharma has been found criminally responsible for marketing OxyContin which resulted in death and addiction. Is it justice to have these convicted criminals – these monsters – fined an amount of money that is very well afforded by them, or will the Senate send a message that because of the magnitude of the crime committed, they deserve to be further investigated by the Senate.

Anything that is imposed against these convicted criminals will not give us back Jill, but I will guarantee that Purdue Pharma will never forget the name Jill Skolek. When I began my work at exposing these three convicted criminals and Haddox and Hogen, I told Hogen that you messed with the wrong mother – and they did because my work is not over.

I want to know why the FDA allowed OxyContin to cause such destruction to the lives of scores of innocent victims. I want to know why 12 warning letters were sent by the FDA to Purdue

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Pharma about their marketing of OxyContin and to this day, they are not required to put "highly addictive" or "addictive" on the label of the drug. I want to know why the FDA deleted without reading so many of my emails about the marketing of OxyContin until this last month. I want to know why Curtis Wright while employed by the FDA played an intricate part in the approval of OxyContin and then was hired by Purdue Pharma. I want to know why Attorney General Blumenthal of Connecticut's Citizen Petition which requests strengthened warnings for OxyContin as a result of information they uncovered in their investigation against Purdue Pharma has been sitting at the FDA – without any action – since January 2004. I want to know how Rudy Guliani could be the "big star" hired by Purdue Pharma to play down the abuse and diversion of OxyContin and also get paid by the DEA for work performed for them. I want to know why the Sackler family has not been held accountable for their involvement with Purdue Pharma and the mass marketing of OxyContin.

Eventually Purdue Pharma will introduce another blockbuster drug similar to OxyContin and as they did with another devastating drug called Palladone. Palladone was removed from the market after a couple of months. I like to think that my faxes and emails all over the country played an intricate part in having it removed. My advice to Purdue Pharma is when you are ready to introduce another drug such as OxyContin or Palladone, look behind you, because I will be right there.

I will be working at having Howard Udell disbarred for his criminal activities and Paul Goldenheim's medical license revoked for what amounts to white collar drug trafficking. I will be actively working at Friedman, Udell and Goldenheim never being able to work in the

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pharmaceutical industry again because they are convicted criminals who criminally marketed OxyContin. I will accomplish this – hopefully with the help of Attorney General Blumenthal -- do not doubt me at not being successful at achieving this.

Her name was Jill Carol Skolek. She did not deserve to be prescribed OxyContin and die because of the criminal activities of individuals of Purdue Pharma . Please give my family justice and investigate the criminal activity of Purdue Pharma .

Thank you Senators for giving me the opportunity to speak for thousands of victims of an out of control pharmaceutical corporation.

Marianne Skolek
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Testimony of Sidney M. Wolfe MD
Health Research Group of Public Citizen
Senate Judiciary Committee Hearing
Oxycontin and the Prosecution of Purdue
July 31, 2007

I will discuss three issues that have arisen from the highly-touted prosecution by the Justice Department of the Purdue Frederick Corporation for "misbranding Oxycontin with the intent to defraud and mislead the public." The issues highlight the double standard in this country for prosecuting corporations and individual corporate officials whose intentional activities result in hundreds of deaths vs. the much more stringent penalties imposed on non-corporate individuals who serve long jail sentences for activities resulting in a tiny fraction of the damage done by such corporate criminal activity.

The three issues are as follows:

1/ **The prosecution of Purdue and subsequent financial penalties were inexplicably and unacceptably limited to a time period (1996-2001) ending well before the company ceased engaging in illegally misbranding Oxycontin.**

On January 17 2003, the FDA sent Purdue a warning letter concerning clearly illegal promotion of Oxycontin during late 2002, almost a year after the end of the period for which the Justice Department prosecuted Purdue's illegal activities.[1]

The nature of the violations is almost exactly the same as those earlier ones for which the Justice Department prosecuted the company and extracted financial retribution.

The beginning of the letter, to one of the three company officials who were convicted of misdemeanors (Michael Friedman, COO and Executive Vice President of the company) is reproduced on the next page:

[1] FDA Warning Letter to Purdue, January 17, 2003.
http://www.fda.gov/cder/warn/2003/oxycontin11400.pdf

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WARNING LETTER

Dear Mr. Friedman:

This Warning Letter (revised) concerns the dissemination of promotional materials for the marketing of OxyContin® (oxycodone HCl controlled-release) Tablets by Purdue Pharma L.P. ("Purdue"). Specifically, we refer to two journal advertisements for OxyContin that recently appeared in the *Journal of the American Medical Association* (JAMA), one in the October 2, 2002 issue (A7038) (the "October Ad") and one in the November 13, 2002 issue (A7087) (the "November Ad"). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these advertisements and has concluded that they are in violation of th Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C.§§ 331(a) and (b), 352 (n), and its implementing regulations.

Your journal advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective. Specifically, your journal advertisements fail to present in the body of the advertisements <u>any</u> information from the boxed warning in the approved product labeling (PI) for OxyContin regarding the potentially fatal risks associated with the use of OxyContin and the abuse liability of OxyContin, which is a Schedule II controlled substance, and make unsubstantiated efficacy claims promoting the use of OxyContin for pain relief. Your journal advertisements also understate the minimal safety information that is presented.

Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements

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critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use, is especially egregious and alarming in its potential impact on the public health.

In addition, there was a non-prosecution agreement signed by the three individual corporate criminals and the company itself and agreed to by the Justice Department that prevents any further prosecution of the company or the three guilty company officials for any activities before May 10, 2007. (and, implicitly, after December 31, 2001). This includes the promise not to seek additional criminal penalties (forfeiture actions) for actions between 12/31/01 and May 10, 2007.

Three company criminals signed following agreement:

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

The company itself also signs a non-prosecution agreement with the US attorney

11. COMPLETION OF PROSECUTION

PURDUE understands that except as provided for in this Plea Agreement and the Non-Prosecution Agreement (attached as Attachment C), so long as PURDUE complies with all of its obligations under the Plea Agreement, and all entities set forth in the Non-Prosecution Agreement comply with their obligations therein, there will be no further criminal prosecution or forfeiture action by the United States for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement, against the following, or any property owned by any of the following: PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A); and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts.

Plea Agreement
United States v. The Purdue Frederick Company, Inc. Page 9 of 12 *Authorized Corporate Officer's Initials:* Plea

2/ The criminal penalties paid by the company, said to be 90% of their profits on Oxycontin, were apparently limited to the 1996-2001 interval, even though much of the subsequent (2002-2006) sales and profits were unequivocally derivative of the earlier (and subsequent) illegal promotional activities.

The Justice Department has stated that the financial penalty of $634 million the company was assessed was 90% of the profits on Oxycontin during that interval (1996-2001) which would have amounted to about $700 million. Aside from the obvious, continuing impact of the illegal pre-December 2001 promotional activities---as evidenced by massive continued prescribing of Oxycontin for several years after then---the illegal 2002 activities discussed above directly document why several years of the post December 2001 period should also have been the subject of prosecution and a much larger disgorgement of profits.

In an affidavit in this case from the IRS, it was disclosed that the company had made $2.85 billion in profits from 1995 through September 30, 2004, 90% of which ($2.57 billion) were said to be from Oxycontin. Thus, in those 2 ¾ years

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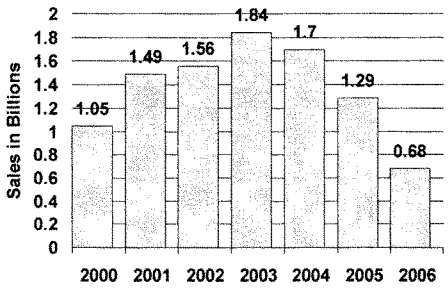
following the end of the period of the prosecution, the company appears to have made an additional $1.8+ billion in profits. ($2.57 billion minus $700 million). U.S. retail sales of Oxycontin in 2002, 2003 and ¾ of 2004 were approximately $4.7 billion alone. As can be seen in the chart below, the three biggest sales years for Oxycontin were 2002-2004, after the period during which the prosecution of illegal activities and "retribution" were done. There is little question that the company should have been forced to disgorge much more of its ill-gained profits than the $634 billion that was settled upon, possibly has much as $2 billion or more.

The standard for the government forcing a company to disgorge profits is that the money was obtained through illegal means. The illegal promotional activities of Purdue in 2002 were clearly successful in continuing the earlier illegal activities as evidenced by the peak year of sales being 2003. The subsequent sharp decrease in sales, with 2006 sales being only 37% of the peak sales year in 2003, confirms that once---belatedly---illegal promotion was finally stopped, the ill-gotten sales and profits dropped significantly.

Annual U.S. Retail Sales of Oxycontin
(2002-2006) in Billions



Source: Drug Topics Magazine

3/ No company official is going to jail because there was no felony conviction of any company person, just of the corporation itself which can not go to jail.

U.S. Attorney Brownlee has said that the many prosecutors "spent years culling through millions of documents, looking for the evidence. And what they did is they were able to piece together a corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."

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Why was it that there were no individual humans who carried out the deadly missions of the "corporate culture" such as the admitted activities of:

Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

(The above is from page 4 of the press the statement issued by the Justice Department on May 10th of this year announcing the prosecution).

Why is it that no individual who had engaged in "misbranding Oxycontin with the intent to defraud and mislead the public" could be found and sent to jail?

In 2002, a physician who recklessly dispensed prescriptions for Oxycontin was convicted and subsequently sentenced for his crime. James Graves, M.D., former Navy flight surgeon, was sentenced to 63 years for manslaughter (4 patients overdosed on OxyContin). He was imprisoned in the Santa Rosa County Jail in Milton, FL, pending appeal. Others, non-physicians, who illegally sold Oxycontin, have also received jail sentences.

Employees of Purdue orchestrated an illegal scheme to promote the same drug,Oxycontin, as being safer, more effective and less subject to abuse than it actually was and pushed hundreds of millions of prescriptions for the drug based on the false pretenses of their promotional campaigns. Many of the hundreds of deaths attributed to Oxycontin could have been avoided if these illegal activities had not occurred.

Why are there no manslaughter charges, no jail sentences and such relatively low amounts of financial penalties? Is it perhaps because Purdue has the money to hire Rudy Giuliani and the best white collar criminal defense lawyers to minimize the damage to itself and its executives? If this does not represent a double standard of justice, what does?

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