News from
Attorney General
Richard Blumenthal

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For Immediate Release

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ATTORNEY GENERAL CALLS FOR MAJOR CHANGES IN THE MARKETING AND DISTRIBUTION OF OXYCONTIN

Attorney General Richard Blumenthal today announced that he is calling on Purdue Pharma, the Stamford, CT-based manufacturer of OxyContin, to completely overhaul and reform its marketing and distribution of the powerful prescription painkiller. Blumenthal also urged the company to devote a specified percentage of its profits to treatment and rehabilitation of OxyContin addiction, resulting from both legitimate and illicit use.

In a letter to Dr. Richard Sackler, president of Purdue Pharma, Blumenthal also recommended several reforms aimed at restricting the availability of OxyContin and educating physicians about the proper use of the drug. [SEE ATTACHED LETTER]

"This extraordinarily powerful medicine promises tremendous benefits to people who suffer from severe chronic pain, but it also has led to widespread misuse, diversion, criminal wrongdoing, and related problems. Addiction is a real, present and growing danger," wrote Blumenthal. "While Purdue Pharma seems sincere in seeking to address the problems, no comprehensive effective solutions have been offered. Very bluntly, initiatives must move beyond cosmetic and symbolic steps to deal directly with alarming and growing diversion, abuse, fraud, robbery and other law breaking spawned by the present system of distribution. Purdue Pharma must overhaul and reform its marketing practices, eliminating the videos and other promotional materials aimed at persuading patients to pressure doctors into prescribing the prescription drug."

Blumenthal is asking Purdue Pharma to immediately act on several different fronts to address the problems of OxyContin, including:

- Devoting resources to treatment and rehabilitation programs, particularly among population groups most affected. According to Blumenthal, the company has a "responsibility, legal and moral, to individuals who are addicted, whether they acquired the drug legitimately or illicitly;"

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- Distributing OxyContin through designated pharmacies to stem diversion and stop the spread of armed robberies of drug stores. The proposal, originally suggested by the Drug Enforcement Authority, would help identify individuals engaging in "doctor shopping" and allow better and more frequent surveillance to help deter robberies. This should not impede access for individuals who legitimately need the drug, so long as the dispensing pharmacies are wisely chosen;

- Limiting the distribution of OxyContin only to physicians who have extensive experience or training in pain management, such as those physicians who regularly treat patients for chronic or severe pain. While OxyContin was initially prescribed to cancer patients, it is now made widely available for many other conditions involving pain. Of the 6.5 million OxyContin prescriptions last year, oncologists accounted for only three percent of prescribers, while family physicians accounted for 21 percent;

- Instituting a physician certification program whereby doctors are trained in the proper use of Oxycontin and its attendant dangers and benefits. Purdue Pharma could then require such certification prior to selling the pharmaceutical to any physician; and,

- Adopting a plan that incorporates a multi-disciplinary approach to pain management, where Schedule II opioids such as OxyContin are the treatment of last resort for chronic pain, and requiring physicians to accept such a "contract."

"OxyContin has been described as a great medical boon when prescribed responsibly for those who need it. Recognizing its perils as well as promise, Purdue Pharma has a moral, ethical, and legal responsibility to take effective, meaningful steps to rectify the problems," Blumenthal wrote. " Whether or not the company should or could have readily foreseen how the time released formulation of OxyContin could be so easily compromised, the danger is now undeniable, and raises an unquestionable ethical and legal obligation. In short, it is time for Purdue Pharma to change its practices, not just its public relations."

Blumenthal spoke last week with officials at Purdue Pharma and plans to meet with company executives in the near future to discuss his recommendations.

END

EDITOR'S NOTE: A COPY OF ATTORNEY GENERAL BLUMENTHAL'S LETTER TO PURDUE PHARMA CAN BE FOUND AT http://www.cslib.org/attygenl

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State of Connecticut

RICHARD BLUMENTHAL
ATTORNEY GENERAL

Hartford

July 31, 2001

Richard Sackler, M.D.
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Dear Dr. Sackler:

I have been increasingly dismayed and alarmed about the problems and escalating abuse of OxyContin.

As I have discussed with you and other Purdue officials, this extraordinarily powerful medicine promises tremendous benefits to people who suffer from severe chronic pain, but it also has led to widespread misuse, diversion, criminal wrongdoing, and related problems. As you observed in your July 18 precautionary letter, OxyContin is a synthetic narcotic "with an abuse liability similar to morphine." Addiction is a real, present and growing danger.

Once confined largely to a few eastern states and the Appalachian region, such problems have now spread across the country. Once limited to rural areas, abuse has migrated to the cities. It is the drug of choice for the middle class and middle aged, along with teenagers and young adults.

Nor are cancer patients now the main recipients of such opioid painkillers. Of the six and one-half million OxyContin prescriptions last year -- a staggering number -- oncologists accounted for only three percent. As *The New York Times* reported last Sunday, "The largest single group of OxyContin prescribers is now family physicians who accounted for 21 percent of the total." Physicians in that group tend to have little or no special training or skill-set in prescribing such drugs.

Connecticut, unfortunately, has not been spared problems relating to improper use and criminal diversion of the prescription drug. As you are well aware, at least one overdose death this month -- a teenager in Clinton -- has been linked to OxyContin, and law enforcement is investigating its role in other fatalities as part of the rave drug scene. (The state's Chief Medical Examiner has reported increasing numbers of deaths in Connecticut related to oxycondone: 16 reported in 1999, 26 in 2000, and an even higher number projected for this year.) Recent events -- including the Bridgeport physician arrest -- highlight the increased incidence of OxyContin-related criminal activity.

The serious, almost epidemic dimensions of these problems are reflected in:

- Overdose deaths attributed, in whole or in part, to OxyContin;
- Pharmacy robberies and other criminal wrongdoing related to the prescription drug; and
- Growing addiction to OxyContin, whether acquired illegally or prescribed.

I have initiated an investigation of OxyContin abuse, involving cooperative and joint action with other state and federal law enforcement and regulatory authorities. One factor prompting our heightened interest is the astonishing growth in state funding for OxyContin prescriptions -- doubling this year, for example, to a projected $7.4 million from $3.7 million last year, and far less the year before. I am advocating legislation to establish a state electronic prescription monitoring program, and I have personally met twice with representatives from Purdue Pharma so that I have now heard and read your company's side of the story. While Purdue Pharma seems sincere in seeking to address the problems, no comprehensive effective solutions have yet been offered.

A number of supposed anti abuse steps have been publicly touted in recent weeks -- tamperproof prescription pads, for example, or educational programs for children about general prescription drug dangers. These programs fail to address the fundamental and serious risks inherent in the drug itself, particularly its extraordinary potency and exploding availability. Each addresses only a small source of the abuse problem. The educational effort, for instance, deals generally with a broad array of prescription drugs, and only the very youngest age group, ignoring the steep pitfalls of addiction and misuse among adults. Similarly, I am encouraged and impressed by the strengthened warnings in labeling or letters to health care professionals -- recently required by the U.S. Food and Drug Administration (FDA). There is no assurance that such steps will stem (let alone stop) much of the illicit market or misuse. Very bluntly, initiatives must move beyond cosmetic and symbolic steps to deal directly with alarming and growing diversion, abuse, fraud, robbery, and other law breaking spawned by the present system of distribution. Purdue Pharma must overhaul and reform its marketing practices, eliminating the videos and other promotional materials aimed at persuading patients to pressure doctors into prescribing the prescription drug. Real reform will signal that the company is sincere, as it seems to be.

OxyContin is not the only powerful prescription drug that may be abused, or pose other dangers. But OxyContin is different. It offers extraordinarily potent relief, but also raises special health care pitfalls and policy obligations. It is more powerful, more addictive, more widely sold, more illicitly available, and more publicized, than almost any other painkiller. These problems are different in magnitude and scope, if not in kind. Such problems provide an opportunity -- to create a model for dealing effectively with similar dangers that inevitably accompany other powerful and useful pharmaceutical drugs. It is, indeed, an historic opportunity and a challenge. An important first step, which I commend, is indeed the announcement made in conjunction with the FDA to

strengthen warnings on your labeling that improper use of OxyContin can lead to addiction or death. Your vision and courage as a company could help lead the industry as well as save countless lives and social costs. Unfair as you may feel the public attention has been -- both to OxyContin and your company -- it may magnify all the more the impact of your actions.

To that end I have some specific requests for immediate action which I feel will help address the problems while your company works to reformulate the drug, which may take three years to accomplish.

1. Centralized Pharmacies

Limiting availability of OxyContin to centralized pharmacies, initially suggested by the Drug Enforcement Administration, is a viable concept to stop the spread of armed robberies of drug stores. Reducing the number of pharmacies that carry OxyContin would facilitate preventive patrols and help deter such robberies. Restricting the number of pharmacies would also help identify individuals who engage in "doctor shopping." It should not impede access for individuals who legitimately need it, so long as the dispensing pharmacies are wisely chosen.

An alternative is that you work with your distributors and larger customers to reduce the amount of OxyContin available at each pharmacy and consolidate supplies at select locations within each state. Such an alternative, although not as effective as a centralized pharmacy, will still help to prevent robberies. Independently, I plan to approach the large pharmaceutical chains in our state and make such a request.

2. Restricting Sales to Physicians with a Specialized Need and Expertise to Prescribe the Drug

According to your representatives, many medical schools fail to adequately teach their students about pain management. If so, the company should voluntarily limit the distribution of OxyContin only to physicians who have extensive experience or training in pain management, such as those physicians who regularly treat patients for chronic or severe pain.

3. Instituting a Physician Certification Program

A company sponsored training program to teach physicians about the proper use of OxyContin, including its attendant dangers and benefits, would help provide expertise. I am not advocating more seminars in Florida or Arizona to encourage more OxyContin prescriptions, but rather local workshops to train these physicians about the limited circumstances where such prescriptions are appropriate. Following this training, the company could issue a certificate to the physician that attests to attendance at the training and acknowledgment of OxyContin's risks. Purdue Pharma could require such certification prior to selling the pharmaceutical to any physician.

4. The Use of Physician Risk Management Plans

Pain management experts advocate a multi-disciplinary approach to effectively treat pain. Schedule II opioids like OxyContin are a legitimate and necessary part of that approach, but the general consensus among experts is that these powerful drugs should be the treatment of last resort for chronic pain. As you well know, pain management is more than simply prescribing a pill. Purdue Pharma should adopt a plan that incorporates this approach to pain management and require a physician's acceptance of such a "contract."

5. Treatment and Rehabilitation Programs

Recognizing the powerful addiction dangers of OxyContin, the company must devote resources to treatment and rehabilitation programs, particularly among population groups most affected. The company has a responsibility, legal and moral, to individuals who are addicted, whether they acquired the drug legitimately or illicitly. Regardless of the source of the drug, they and their families must now cope with the addiction, and their communities must provide for their care. Addiction risks affect patients with legitimate prescriptions as well as illegal users. Eventually reformulation may reduce the risks, but the drug now does great harm as well as good. To diminish the damage, programs treating addiction are now essential. They also would serve to educate and emphasize to the general public that OxyContin's benefits may exact a great price. Such efforts would be more appropriate and effective than entrepreneurial or other general community programs currently sponsored by the company.

I ask your company to devote a specific, set percentage of its OxyContin profits to fight addiction through such rehabilitation and treatment programs. The commitment could be implemented initially in areas hardest hit by addiction, but eventually in every state, since none has been completely spared such problems. While the details may depend on additional study and discussion, an immediate commitment will demonstrate your conviction and resolve to reach the right result and combat addiction.

Finally, three other points: First, I know that Purdue Pharma has offered to provide tamper proof prescription pads to physicians. This step is welcome, but prescription forgeries are only a very small part of the overall problem. Second, while I must accept that your company does not market OxyContin directly to consumers, I take strong exception with the message conveyed in the "Patient Bill of Rights for Pain Management" on the Internet site "Partners Against Pain," which is financed by your company. Specifically, I am disturbed by the site's statement that addiction from prescribed opioids is "rare in patients without a history of drug/alcohol abuse" if prescribed under a physician's care. This statement is simply not true, and I have received letters and phone calls from patients attesting to the fact that they or family members became addicted to OxyContin after it was prescribed by their physician. It must be changed. Third, as important as anything said so far, none of these proposed remedies is meant to minimize the state and federal governments' responsibility to

enforce existing laws prohibiting illegal distribution or sale of controlled substance such as OxyContin, or seek stronger civil and criminal measures. We will continue to review current laws and advocate better ones.

I recognize that Purdue Pharma's adoption of one or more of these proposals will affect the company's sales of OxyContin. I feel strongly that some decrease in sales of this very profitable prescription drug is a short term consequence Purdue Pharma must accept. OxyContin has been described as a great medical boon when prescribed responsibly for those who need it. Recognizing its perils as well as promise, Purdue Pharma has a moral, ethical and legal responsibility to take effective meaningful steps to rectify the problems. Whether or not the company should or could have readily foreseen how the time released formulation of OxyContin could be so easily compromised, the danger is now undeniable, and raises an unquestionable ethical and legal obligation. In short, it is time for Purdue Pharma to change it practices, not just its public relations strategy.

I would be open to further discussion on any of these strategies or on any other concrete proposals you may have to address the issues. If you disagree that they are viable short-term solutions, I would like to know why. My hope is that you will implement immediately a comprehensive affirmative and material plan of action to address these issues. While I cannot speak for all of the Attorneys General involved in our task force, I am confident that there would be a positive response to significant and effective measures dealing with distribution such as the ones I have suggested. In the meantime, this office will continue to identify and evaluate all of its options to remedy the problem.

Sincerely,

RICHARD BLUMENTHAL

RB:jb

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