

PURDUE

Purdue Pharma L.P.

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February 13, 2004

Hon. Richard Blumenthal
Attorney General
State of Connecticut
55 Elm Street
P.O. Box 120
Hartford, CT 06141-0120

Dear Mr. Blumenthal:

This responds to your January 23, 2004 letter providing a redacted version of your Citizen Petition and requesting that Purdue Pharma L.P. ("Purdue") waive confidentiality as to the documents designated as confidential in the January 7, 2004 version of your Petition.

As we have indicated in meetings with you and your staff, Purdue disagrees with the scientific conclusions which you have reached and the concerns you have raised regarding the practice of prescribing OxyContin at intervals more frequent than a 12 hour dosing schedule. We do agree that the Food and Drug Administration is the appropriate arbiter of this disagreement and stand ready to provide to the agency any information it requires concerning this issue.

We appreciate that you have respected the confidentiality of Purdue's data and information by preparing a redacted version of your Petition which omits direct reference to Purdue's proprietary information. However, because this version still makes indirect reference to the redacted information and cannot be fully understood or addressed without reference to the deleted material and to other confidential data and information which are also proprietary to Purdue, we do not believe that a Citizen Petition provides an appropriate forum for the agency to consider these issues.

Therefore, while we understand the basis for your request that Purdue waive confidentiality, we do not believe that such a waiver is necessary or appropriate, particularly in light of the fact that there are alternate means by which FDA can have access to all of the necessary information without such a waiver. We have determined, however, that we have no claim of confidentiality over some of the information. We have attached Exhibit A which is a listing of those items.

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While the confidential nature of much of the relevant information does not allow this issue to be addressed properly in a Citizen Petition proceeding, we emphasize that it will not prevent FDA from considering the issues raised in the Petition and taking any action it considers appropriate. As stated above, Purdue will cooperate with any agency consideration of these issues and provide any information requested by the agency to the best of its ability, in a manner which preserves the confidentiality of the information under applicable statutory and regulatory safeguards.

On a related matter, Purdue has recently contacted Dr. Paul Kramer who, as a consultant to your office on this matter, met with Purdue's clinical and pharmacology experts on November 17th, 2003 to attempt to understand better the scientific basis, if any, for the concerns expressed in your petition. When contacted, Dr. Kramer indicated that he considered this matter to be confidential with your office and that he therefore could not discuss it further with Purdue. Since Dr. Kramer's views are not cited in your Petition, we request that you consider waiving any confidentiality restrictions you may have imposed on Dr. Kramer and tell him that he may discuss this matter with Purdue and with the FDA, as a constructive step toward resolving the issues involved.

Please let us know if you have any further questions or wish to discuss this further.

Yours truly,



Howard R. Udell
Executive Vice President,
Chief Legal Officer
Purdue Pharma L.P.

cc: Dockets Management Branch ✓
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Office of Criminal Investigation
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Exhibit A

Documents not deemed Confidential by Purdue Pharma L.P.

- Adams, Bhakta Study Abstract “Retrospective Assessment of Frequency of Dosing of Sustained Release Opiate Preparations in Chronic Pain Patients”
- LA County Dept. of Coroner Report (2001)
- “Aggressive Pharmacologic Treatment of Pain,” Pain Management in the Rheumatic Diseases (February 1999)
- “Considerations for Acute Pain Management in Ambulatory Orthopedic Surgery” Orthopedic Special Edition
- “New Strategies In Opioid Therapy for Cancer Pain,” The Journal of Oncology Management (Jan/Feb 2000)
- “Opioid formulations: tailoring to the needs in chronic pain” European Journal of Pain
- Tab 7: “Relationship between Dosing Regimen and Oxycodone Concentrations” and pages from Applied Biopharmaceutics and Pharmacokinetics, Sec. ed., L. Shargel, and A. Yu