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July 25, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
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RE: Docket No. 01P-0560(CP/1)

COMMENTS AND OBJECTIONS TO THE CITIZEN PETITION

Pursuant to 21 C.F.R. § 10.30(d), the undersigned submits the following comments on behalf of Purdue Pharma LP in opposition to the citizen petition (Docket No. 01P-0560(CP/1)) filed by Hogan & Hartson L.L.P. on December 11, 2001, and supplemental information filed by the same firm on April 10, 2002.

The citizen petition fails to state a reasoned basis for requesting that approval of buprenorphine be delayed pending a review before the appropriate FDA advisory committee and/or until buprenorphine is rescheduled to a "much stricter control under the CSA."¹ It is particularly troubling that, although the petitioner identifies the real party in

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¹ Citizen petition at 2.

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interest as “a leading provider of opiate addiction treatment services,”² the effect of the petition, if granted, would be to protect the economic and financial interests of current providers of opiate addiction treatment by imposing medically unwarranted obstacles to treatment. The petition does not address the potential harm to patients in need of addiction treatment by the continued delay in approval of buprenorphine and displays an inadequate understanding of more than 20 years of scientific research on buprenorphine.

For the reasons discussed below, the Food and Drug Administration (FDA) should reject the citizen petition and move forward immediately to make both Subutex and Suboxone available for the office-based treatment of addiction as contemplated under the Drug Addiction and Treatment Act of 2000 (DATA). Pub.L. No. 106-310, 21 U.S.C. § 823(g).

I. The Petition Presents No New Information to Support the Contention that an Advisory Committee Meeting is Necessary to Obtain Public Comment on the Efficacy And Safety of Buprenorphine.

A. Subutex And Suboxone have been Developed in an Extraordinarily Public Process.

The original human abuse liability studies of buprenorphine were published by Jasinski in 1978. As of July 2002, over 720 NIDA research grants were listed in the Computer Retrieval of Information on Scientific Projects (CRISP) database as discussing “buprenorphine” and 1782 publications were identified searching for “buprenorphine” in Medline. There is no doubt that buprenorphine has been extensively studied and such information has been widely available to the public. Moreover, there has been ample opportunity for public comment and the public has had access to the necessary scientific information to allow any interested party to provide meaningful comment on the development of buprenorphine for the treatment of addiction.

The citizen petition requests “advisory committee” review of buprenorphine. However, the Drug Abuse Advisory Committee (DAAC) has reviewed the control of buprenorphine on two occasions at which the issue of abuse of buprenorphine was extensively debated. In both of these meetings, NIDA’s interest in buprenorphine as a treatment for addiction was clear.

²

Citizen petition at 1.

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In addition to offering comments at an advisory committee meeting, members of the public have had opportunity to comment on these developments to both NIDA and SAMSHA. For example, NIDA requested public comments on its May 12, 1993 announcement to enter into a CRADA with Reckitt and Colman (now Reckitt Benckiser) published specifically as a "Notice of intent to award a cooperative research and development agreement and request for comment" in the Federal Register. 58 Fed. Reg. 28031. Further, the public has also been provided the opportunity to participate in the ongoing meetings of NIDA's National Advisory Council on Drug Abuse and SAMSHA's National Advisory Council.

Congress extensively debated the availability of buprenorphine under the DATA. Comments were solicited from many experts in the scientific and medical community. The public actively participated in the process and there was overwhelming support for ensuring the availability of buprenorphine in treatment of addiction in office-based treatment.³ The benefits and risks of buprenorphine for the treatment of addiction have been subject to extensive public debate. Thus, the contention of the citizen petition that the marketing of buprenorphine "raises important scientific, medical and policy issues that should be vetted before a public advisory committee" is simply without merit.⁴ Arguably, few products in the history of drug development have been subject to such extraordinary and sustained scrutiny prior to approval as Subutex and Suboxone.

³ See, e.g., Statement of Dr. Charles O'Brien, Professor and Vice Chair of Psychiatry at the University of Pennsylvania, before the Senate Caucus on International Narcotics Control, May 9, 2000. 146 Cong. Rec. D440. Dr. O'Brien stated that: "[t]he safety and efficacy of buprenorphine is such that it should be made available to all physicians to treat patients with opiate problems in their offices. This would be a major benefit to patients who are unable and unwilling to come to specialized methadone programs. It would be available not just to heroin addicts, but to anyone with an opiate problem, including many citizens who would not ordinarily be associated with the term addiction. The availability of buprenorphine would enable physicians to control the opiate abuse problems of many Americans who are now being inadequately treated or not treated at all." Quoted in 146 Cong. Rec. S9094, 9113 (Sept. 22, 2000).

⁴ Citizen petition at 1.

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B. Both NDAs have already been Reviewed by the Agency and Found to be Approvable.

The petition states that on or about June 1997 Reckitt Benckiser submitted an NDA for Subutex and that in June 1999 an NDA was submitted for Suboxone. It also states that on June 30, 1998 an approvable letter was issued for Subutex, with a second approvable letter issued for the same NDA in January of 2000. Finally, the petition notes that an approvable letter was issued for Suboxone in December of 1999—a mere six months after the reported submission.⁵

The issuance of an approvable letter is described in 21 C.F.R. § 314.110, in part as follows:

“(a) In selected circumstances, it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application or abbreviated application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed....”

⁵ The chronology of the issuance of approvable letters reported by the petition was confirmed by Charles O’Keeffe, President of Reckitt Benckiser, in a presentation at the College on Problems of Drug Dependence June 2002 annual meeting in Quebec Canada. He also reported receiving two additional approvable letters in January of 2001.

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The fact that approvable letters have been issued for Subutex and Suboxone demonstrates that these applications "substantially meet the requirements for approval." The issuance of approvable letters for both applications clearly indicates that FDA has determined that further public comment is unnecessary. This position is supported by the fact that extensive scientific and medical information is available and there have been many opportunities for public input during the development of these products.

The citizen petition advocates that despite such extensive study and a demonstrated need, approval of Subutex and Suboxone should be delayed. Such a request is contrary to the public health and safety.

C. The Petition Presents No New Scientific Data that would Justify Setting Aside the Agency's Determination that the New Drug Applications for Subutex and Suboxone are Approvable.

The scientific information cited by the petition as the grounds on which FDA should seek advisory committee input includes only facts that are already known to the agency and to the public, such as: 1) that the proposed dose of buprenorphine for use in treatment of narcotic addiction is higher than the recommended dose contained in the Buprenex® formulation; 2) that buprenorphine is derived from thebaine; and 3) that buprenorphine-associated deaths have been reported from France following the introduction of Subutex in that country in 1996.⁶ There is little doubt that the FDA was well aware of the first two of these facts prior to the initiation of development efforts under the CRADA between NIDA and Reckitt Benckiser (these facts and others cited by the petition are attributed to the labeling for Buprenex). The Subutex-associated deaths reported by Reynaud and others⁷ were published well before the FDA issued the most recent approvable letters for these products. The agency had sufficient time to consider this information and to plan and conduct all advisory committee meetings it considered necessary prior to the issuance of approvable letters for these products.

⁶ Reynaud M, Petit G, Potard D, Courty P. Six deaths linked to concomitant use of buprenorphine and benzodiazepines. *Addiction*. 1998 Sep;93(9):1385-92. Cited in Citizen Petition at 3.

⁷ See, for example, Tracqui A., Kintz P, Ludes B., "Buprenorphine-related deaths among drug addicts in France: a report on 20 fatalities", *J. Anal Toxicol*. 1998 Oct: 22(6):430-4.

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The supplemental filing to the citizen petition purports to present new data on this issue, but in reality fails to do so. For example, the situation described in the supplement to the petition (hereinafter "supplemental filing") with respect to abuse of buprenorphine in India is well known.⁸ The report from Singh⁹ may be new information to the petitioner, but it is certainly not new information to the FDA. The report by Kintz¹⁰ could reasonably be anticipated based on prior reports by Reynaud and Traqui and thus is not new information that would warrant setting aside the agency's determination that these applications are approvable.

D. The Participation of NIDA and NIDA-Funded Investigators in the Development of Subutex And Suboxone does not Create the Potential for Conflicts of Interest that the Petition Claims would Justify an Advisory Committee Meeting.

The petition claims that an advisory committee is necessary because NIDA has been involved in the development of Subutex and Suboxone and has made a number of public statements concerning the safety and efficacy of these products "long before FDA has had a chance to consider the data."¹¹ It is unclear exactly what public statements the petition is referring to and the petition cites no evidence in support of these claims beyond the fact that both NIDA and FDA are agencies of the Department of Health and Human Services (DHHS). The petition cites the joint letter issued by FDA, DEA and SAMSHA clarifying that buprenorphine is not approved for addiction treatment. There is nothing in this letter that even remotely suggests improper public statements by NIDA in regard to buprenorphine. In fact the letter refers practitioners and the public to NIDA for information about buprenorphine.

⁸ Supplemental filing at 2.

⁹ Sing RA, Matto SK, Malhora A, Varma VK. Cases of buprenorphine abuse in India. *Acta Psychiatr Scand* 1992; 86:46-8.

¹⁰ Supplemental filing at 2; See Kintz P., "Related Articles Deaths Involving Buprenorphine; a compendium of French cases. *Forensic Sci. Int.* 2001 Sep. 15;121(1-2) 65-9.

¹¹ Citizen petition at 8.

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The implication in the citizen petition that either NIDA or its investigator grantees are somehow tainted by their efforts to develop Subutex and Suboxone in collaboration with Reckitt Benckiser is unfounded. Applicant institutions for NIH research grants must comply with obligations for assuring objectivity in research set forth under 42 C.F.R. Part 50. These regulations require institutions to address financial conflicts of interest on the part of investigators. This is similar to an advisory committee where members are subject to financial disclosure requirements applicable to Special Government Employees.¹² In particular, disclosure by advisory committee members of participation in drug development efforts involving the drug under consideration (as well as disclosure of investigations involving competing products such as methadone and LAAM) is required, but it need not result in disqualification of an individual from participation on an advisory committee.¹³

Indeed, NIH grantees often participate in drug development and are valuable members of FDA advisory committees, precisely because they have exactly the experience that the FDA requires to render meaningful advice. If participation in investigations involving buprenorphine, methadone or LAAM precluded service on an advisory committee, it would be impossible to convene the meeting that the petition is requesting.

E. The Agency has had Ample Time to Consider the Evidence of Safety and Efficacy Presented by the Sponsor.

Any U.S. studies conducted as part of the CRADA between Reckitt Benckiser and NIDA as well as any U.S. studies by NIDA investigators that may be included in the NDAs for Subutex and Suboxone were conducted under an Investigational New Drug Exemption. The protocols for these studies were submitted for FDA review at the time they were initiated, and results would have been reported to FDA, even for those studies that may not have been published. On the basis of this information, FDA clearly had many opportunities to assess the appropriateness of the proposed clinical development plan for these products. Were any of the proposed protocols considered to involve unreasonable and significant risk of illness or injury or were any of the proposed phase 2 and 3 protocols considered to be so

¹² 67 Fed. Reg. 6545 (Feb. 12, 2002).

¹³ See US Food and Drug Administration, Draft Guidance On Disclosure Of Conflicts Of Interest For Special Government Employees Participating In FDA Product Specific Advisory Committees, U.S. Department of Health and Human Services, Food and Drug Administration, January 2002.

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clearly deficient in design to meet its stated objectives, FDA had the opportunity to place the offending protocols on clinical hold pending resolution of these issues.¹⁴ The FDA could have taken any issues identified to an advisory committee for resolution before it ever received either NDA. Finally, FDA during its reviews of these two NDAs had ample opportunity to surface any safety or efficacy concerns that might have resulted from the trials conducted as part of these development efforts.

F. FDA has had Ample Time to Consider the Data that would be Required to Develop Appropriate Labeling for Buprenorphine as a Treatment for Addiction in Office-Based Practice and to Assure that Such Data is included in the NDA.

As noted above, FDA has been aware of NIDA's interest in developing buprenorphine as a treatment for addiction for many years. Reckitt Benckiser as well as the Federal Government have previously contemplated the possibility of using buprenorphine outside of the confines of traditional methadone maintenance programs. This was also well known to FDA. The required changes to the CSA were enacted by the DATA in 2000. Although this law does not mention buprenorphine specifically, such use of buprenorphine was clearly contemplated. Congress recognized the Act would make buprenorphine available for treatment and noted that "[b]uprenorphine is not addictive like methadone so that the likelihood of diversion is small."¹⁵ Congress also noted that then Secretary Shalala had sent a letter of support for DATA commenting that "[b]uprenorphine and [b]uprenorphine/naloxone products are expected to have low diversion potential."¹⁶

The petition presents no medical or scientific evidence for FDA to find these approvable applications to be deficient.

¹⁴ See 21 C.F.R. § 312.42

¹⁵ 146 Cong. Rec. S 9094, 9112 (Sep. 22, 2000).

¹⁶ Id.

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G. The Petition Requests that the Advisory Committee Consider Issues that are not Relevant to the Approval of Subutex or Suboxone

1. The efficacy standard for the approval of Subutex or Suboxone is whether these products are effective, not how they compare to methadone, LAAM or to each other.

The citizen petition implies that the relevant approval standard for Subutex and Suboxone is the comparison of these treatments to methadone.¹⁷ While such information is important to allow physicians to determine whether Subutex, Suboxone, methadone or LAAM may be best for a particular patient, such comparative information is not required for approval. For purposes of approval under the FD&C Act the intended relevant efficacy standard is substantial evidence, generally based on a comparison to placebo, not another active drug with the same or similar indication.¹⁸

The broad application of the standard proposed by the citizen petition would deter the development of many important new drugs besides Subutex and Suboxone. For example, by this standard, fluoxetine might be the only SSRI approved and propranolol the only beta blocker. Or if the petition's logic were accepted, perhaps no SSRI's would be approved, even though these drugs offer significant advantages over tricyclic antidepressants.

¹⁷ Citizen petition at 7.

¹⁸ See for example, S. Rep. No. 1744, 87th Cong., 2d Sess. 16 (1962), reprinted in 1963 U.S.C.C.A.N. 2892; see also Hearings Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary (pursuant to S. Res. 52 and S. 1552), 87th Cong., 1st Sess. pt. I, at 417 (1961) ("I want to make clear . . . it was only intended that the manufacturer satisfy the Food and Drug Administration that it (a drug) was efficacious for the use intended and claimed by the manufacturer, not trying to say it is better than some other drug or poorer than some other drug.") (statement of Sen. Estes Kefauver).

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2. The standard for approving Subutex is whether the product is safe and effective for use under the conditions recommended in the proposed labeling and is unrelated to the existence of Suboxone.

The petition implies that the safety standard for approval is somehow different for Subutex, if Subutex and Suboxone are equally effective.¹⁹ However, the standard of safety in approving an NDA is whether the drug is safe for use under the conditions recommended in the labeling. 21 U.S.C. § 355(d). The standard for the approval of Subutex is not changed by either the existence or possible existence of a different product merely because the product is expected to be safer in a drug abusing population.

There is no legitimate medical reason to deny the approval of either Subutex or Suboxone, or to impose restrictions on their use beyond those that would be imposed by the DATA. Restrictions on Subutex, for example, would have the effect of denying office-based treatment with buprenorphine to pregnant patients, patients entering treatment, patients who may be unable to tolerate Suboxone, and any other patients for whom the reasonable judgment of the treating physician might indicate that Subutex would be the appropriate option.

The agency is well aware of scientific data demonstrating the ceiling effect of buprenorphine compared to methadone.²⁰ The result of this ceiling effect is seen in data from France showing that, even when Subutex is used by general practitioners (who do not benefit from the special training required by the DATA) while methadone is used in specialized centers, methadone is far more likely to result in fatal overdose than buprenorphine.²¹ The agency is also well aware that the French have seen a dramatic drop

¹⁹ "What is the rationale for approving Subutex, if the combination product, Suboxone, is equally effective?" Citizen petition at 7.

²⁰ For example, the FDA recommendation to reschedule buprenorphine to schedule III of the CSA cites: Walsh SL, Preston KL, Stitzer ML, Cone EJ, Bigelow GE. Clinical pharmacology of buprenorphine: ceiling effects at high doses. *Clin Pharmacol Ther.* 1994 May;55(5):569-80.

²¹ Auriacombe M, Franques P, Tignol J. Deaths attributable to methadone vs buprenorphine in France. *JAMA.* 2001 Jan 3;285(1):45.

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in heroin overdose deaths since the introduction of Subutex.²² This, together with French data showing that deaths due to Subutex overdose alone are unusual, clearly supports both the safety and efficacy of buprenorphine (alone) in office-based treatment. These observations do not, as the petitioner suggests, cast doubt on the approvability of either treatment.

Were the agency to accept the citizen petition's argument not to approve Subutex or to approve either product with special restrictions on its use beyond those required by the CSA and DATA, it would find itself in the difficult position of having to explain why it is imposing restrictions on buprenorphine but not imposing additional restrictions on the use of methadone, which despite clear evidence of efficacy has an additional safety burden in this population. The unwarranted controversy that would result should the approval of Subutex and Suboxone fail to clearly reflect the established relative safety of buprenorphine versus methadone would only serve to delay communities in need of addiction treatment services from making any substitution treatment available to patients who need it.

II. An Advisory Committee Meeting is Unnecessary on the Issue of Abuse of Buprenorphine

The citizen petition expresses concern about "recent reports of serious adverse events associated with buprenorphine, particularly in countries where the drug is marketed as an addiction therapy" and notes the buprenorphine-associated deaths reported from France.²³ However, this information was considered by both HHS when it conducted the eight-factor analysis and the DEA when it proposed moving buprenorphine from schedule V to schedule III of the CSA.²⁴ The petition cites the DEA review document wherein DEA expresses concern about the potential for serious overdose incidents.²⁵ The petition does not contend that the proposed rescheduling of buprenorphine is incorrect, nor does it

²² See, Drug use and drug trafficking in France: 1998 annual statistics [in French]. Paris, France: Ministry of the Interior, Director's Office of the National Police, Central Directorate of the Judicial Police, Central Office Against Illicit Drug Trafficking; March 1999; p. 8.

²³ Supplemental filing at 1.

²⁴ The data reported by Kintz is discussed extensively by both FDA and DEA.

²⁵ Supplemental filing at 1.

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provide substantive new data concerning abuse of buprenorphine. The petition's concern notwithstanding, no facts are presented that would warrant convening an advisory committee meeting.

Neither the CSA nor the FD&C Act require that an advisory committee meeting is necessary to make a scheduling finding under the CSA. Although in some cases the DAAC has assisted the FDA in the past, such consultation is not required and could reasonably be considered redundant in the case of buprenorphine. In this case, both FDA and DEA had available over 20 years of studies on buprenorphine use and transcripts of two prior advisory committee meetings. Moreover, the CSA and DEA regulations provide adequate notice and comment rulemaking for the public to comment on a proposed scheduling action. The petitioner and other interested parties took full advantage of this opportunity and submitted comments to the DEA. An advisory committee meeting would not provide any additional information to the FDA at this point in the scheduling process.

III. The Risk Management Measures outlined in DATA are adequate to Assure the Safe Use of Subutex and Suboxone.

The petition argues that it might not be possible for FDA to approve buprenorphine without additional restrictions beyond those contemplated by DATA.²⁶ However, the petition presents no data in support of this contention, and there is no reason to believe that such additional restrictions are necessary. The U.S. system of narcotic addiction treatment is based on a specific set of regulations established under the CSA and FD&C Act. In an analogous way, use of Subutex and Suboxone in substitution treatment are governed by the DATA, the petition's assertions to the contrary notwithstanding.

The DATA specifically restricts use of buprenorphine to trained and certified physicians who have "the capacity to refer the patients for appropriate counseling and other appropriate ancillary services." 21 U.S.C. § 823(g). These provisions are, in effect, the same as the restrictions permitted under 21 C.F.R. § 314.520 which contemplate restriction based on physician training and on the performance of specified medical procedures. In addition, both the Secretary of HHS and the Attorney General have responsibilities under

²⁶ Supplemental filing at 5. ("Thus, the types of strategies FDA generally employees for new drug products are fully available for buprenorphine. If they are not then it is even more *unlikely* that FDA will be able to conclude that buprenorphine is safe and effective.")

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DATA to assure that the law is functioning as intended and that the benefits contemplated from Subutex and Suboxone are realized.

Considering the prior failings of the regulation of methadone treatment,²⁷ the safety of Subutex compared to methadone as observed in France, and the requirements of the DATA for both regulation and evaluation of this new treatment approach, the petition's assertion that additional regulation of buprenorphine treatment is necessary is entirely without merit.

IV. Conclusion

The citizen petition's request that FDA delay approval of buprenorphine products is not supported by the scientific or medical evidence. The proposed rescheduling of buprenorphine and buprenorphine-containing products from schedule V to schedule III of the CSA already reflects a conservative interpretation of current data. Another advisory committee meeting or eight-factor analysis is unnecessary and will not provide any further data other than that already known to HHS, DEA and the public. The petition also provides no data that marketing of buprenorphine is of "great public concern" or that "abuse and diversion is likely to have a significant impact on the communities where the drug may be used," or that the provisions of the DATA are inadequate as a means of appropriately regulating buprenorphine for use as an addiction treatment. On the contrary, the safe and effective use of buprenorphine is likely to improve significantly the availability and quality of treatment for drug addiction to patients who continue to be seriously underserved medically.

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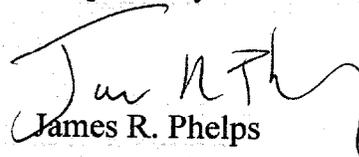
See, for example: United States General Accounting Office. Report to the Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives METHADONE MAINTENANCE Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed, 1990. Although the regulations have been revised since this report, methadone treatment still does not offer the same level of access to care that office-based treatment with buprenorphine will provide.

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FDA should deny the citizen petition in its entirety and move rapidly to make both Subutex and Suboxone available for office-based addictions treatment as contemplated under DATA.

Respectfully submitted,


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