4/8/85

BEFORE THE
DRUG ENFORCEMENT ADMINISTRATION
DEPARTMENT OF JUSTICE

IN THE MATTER OF MDMA SCHEDULING	Docket No. 84-48

First Memorandum of Law Submitted on Behalf of
Doctors Grinspoon and Greer, Professors Bakalar and Roberts

I. Introduction and Summary

This memorandum addresses the following question:

> Assuming that a substance has a potential for abuse and has no currently accepted medical use in treatment in the United States, can the substance be placed in any Schedule other than in Schedule I?

Our answer to this question is "yes." In summary, scheduling decisions under the Controlled Substances Act must be made on the basis of a consideration of all the factors listed in Sections 811 and 812 of the Controlled Substances Act. In general, these factors make clear that the seriousness of the potential for abuse is to be a critical consideration in scheduling decisions and that scientific and medical considerations are to be given substantial weight. The Secretary of Health and Human Services has the authority to veto the scheduling of a substance, and has the binding authority to advise the DEA on medical and scientific matters. However, it is absolutely clear that the DEA

may not treat the single issue of whether a drug does or does not have an accepted medical use as the single controlling factor in deciding in what Schedule to place it.

It is our position that a substance with no currently accepted medical use in treatment in the United States may only be placed in Schedule I if it has a high potential for abuse. It is our further position that substances with either a moderate potential for abuse or a low potential for abuse which have no currently accepted medical use in treatment in the United States may properly be placed in Schedules III, IV, or V under the Controlled Substances Act.

These conclusions are based on (1) the statutory provisions of the Controlled Substances Act; (2) the legislative history indicating the intent of the Congress in enacting those provisions; and (3) legislative enactments by the Congress itself placing substances with no medical use in Schedules other than Schedule I.

But most importantly, we believe the question at issue here has been definitively and authoritatively resolved by decisions of two U.S. Courts of Appeals (the D.C. Circuit and the Eighth Circuit) and by a decision of a three-judge court of the United States District Court for the District of Columbia. It is our position that these three decisions totally foreclose the issue as far as the current proceeding is concerned.

In this memorandum we discuss in detail each of the bases for our conclusions.

II. The Statutory Language of the Controlled Substance Act

Section 811 and 812 of Title 21 of the United States Code establish the criteria on which scheduling decision under the Controlled Substances Act are to be made. Section 811(c) requires that the Attorney General (and hence DEA) "shall consider" eight enumerated factors whenever "any finding" with respect to scheduling is to be made. Specifically, Section 811(c) requires DEA to "consider the following factors with respect to each drug or other substance proposed to be controlled":

> (1) its actual or relative potential for abuse.
>
> (2) scientific evidence of its pharmacological effect, if known.
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> (3) the state of current scientific knowledge regarding the drug or other substance.
>
> (4) its history and current pattern of abuse.
>
> (5) the scope, the duration, and significance of abuse.
>
> (6) what, if any, risk there is to the public health.
>
> (7) its psychic or physiological dependence liability.
>
> (8) whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. § 811(c).

Then, section 812 lists three criteria for each of the five Schedules on the basis of which a scheduling decision is to be made. These criteria essentially set up a continuum in which drugs having the highest potential for abuse and requiring the most stringent controls are to be placed Schedule I, drugs with the lowest potential for abuse and requiring the least stringent controls are to be placed in Schedule V, and drugs with an intermediate abuse potential and an intermediate need for controls are to be placed, as appropriate, in Schedules II, III, and IV.

The nature of the continuum created by the statute may be seen by summarizing the requirements for each schedule:

- Schedule I is generally for substances with a high potential for abuse and no medical use;
- Schedule II is generally for substances with a high potential for abuse which do have accepted medical use;
- Schedule III is generally for drugs with a potential for abuse less than a high potential but which may lead to moderate or low physical dependence or high psychological dependence;
- Schedule IV is generally for drugs with a lesser potential for abuse relative to drugs to drugs in Schedule III where use of the drug may lead to limited physical or psychological dependence relative to substances in Schedule III; and
- Schedule V is generally for drugs with a lesser potential for abuse relative to substances in Schedule IV and where abuse of the drug made to

> limited or physical or psychological dependence relative to drugs in Schedule IV.

From reviewing the statutory criteria it is clear that the continuum established by Schedules I, II, III, IV and V focuses on the potential a particular drug or substance has to be abused and the extent of the psychological or physical dependence that it may create.

The other notable conclusion that follows from examining the criteria for each of the schedules is that it is clear that the scheduling criteria in section 812(b) cannot be literally applied unless the Act is to exclude from regulation entire categories of substances with abuse potential. In United States v. Maiden, 355 F. Supp. 743, 748-49 n.4 (D.Conn. 1973), the Court recognized that the statutory criteria for each schedule can not be literally applied:

> Section 202 of the Act in establishing the three findings for each of the five schedules, does not in turn specify whether the findings are cumulative * * * in fact they cannot be read as cumulative in all situations. For example finding (B) for Schedule I requires that "the drug or other substance has no currently accepted medical use in treatment in the United States." Finding (B) for the other four schedules specifies that the drug has a currently accepted medical use. At the same time, finding (A) requires the drug has a "high potential for abuse" for placement in Schedule I, but a "potential for abuse less than the drugs or other substances in Schedules I and II" for placement in Schedule III. If the findings are really cumulative, where would one place a drug which has no accepted medical use but also has potential for abuse less

> than the drugs in Schedules I and II? According to finding (A) for Schedule III it belongs in Schedule III, but finding (B) for that schedule precludes Schedule III; according to finding (B) for Schedule I it belongs in Schedule I, but finding (A) for that schedule appears to preclude Schedule I.

In this regard, it seems elementary that the DEA has only one of two choices in seeking to interpret the statutory language. It can take the literalist approach. The literalist approach would insist that each of the three criteria listed for each schedule must always be met for every substance placed in every schedule. Plainly, that would require that every substance placed in Schedule I have no accepted medical use. Similarly, it would require that no drug which does not have an accepted medical use could be put in Schedules II - V.

However, the literalist approach would obviously not be free to adopt a more flexible approach to other criteria. Therefore, only substances with a high potential for abuse could be put in Schedules I and II, and only substances with less than a high potential for abuse could be put in Schedules III, IV, and V. As Judge Newman pointed out, such a literalist approach to the criteria in section 812(b) would mean that a drug that has no accepted medical use and a potential for abuse less then the drugs in Schedule I and Schedule II simply could not be scheduled at all.

Given the obvious plan embodied in the Controlled Substances Act to provide a comprehensive regulatory scheme for substances which have a potential for abuse, adopting

such a literalist approach to the statute would not appear to be consistent with the very statute being interpreted.

Even more importantly, section 811(c) sets out a broad list of factors which the Attorney General is required to consider in making every finding with respect to a scheduling decision. These factors are obviously much broader than the three criteria listed for each schedule. Thus the statutory language of section 811(c) strongly suggests that the criteria of section 812 were not intended to be construed as the exclusive determinants for scheduling decisions.

In sum, we submit that the statutory language in section 811 and section 812 demonstrate that a literalist approach to the three criteria set out for each of the schedules in section 812 is indefensible. First, Congress intended to enact a comprehensive scheme. A literalist approach to interpreting the criteria in section 812 would exclude several categories of substances which Congress obviously intended the statute to cover. Second, a literalist approach to the criteria in section 812 would require ignoring the broad scope of the factors laid out by the Congress in section 811(c) which were to be considered in coming to conclusions with respect to the criteria in section 812. Therefore, for both these reasons, we submit that the statutory language itself makes clear the criteria in section 812 cannot be interpreted literally to mean that all

drugs with no currently accepted medical use in the United States should automatically be placed in Schedule I.

To the contrary, the statutory language strongly suggests that the continuum set up from Schedule I and II (high potential for abuse) through Schedule V (low potential for abuse and limited physical or psychological dependence) focuses primarily on the abuse potential of a drug. It is obvious that the statutory language intended to create a scheme under which a balancing analysis could be undertaken and the strictness of the regulation under the Controlled Substance Act could be keyed to the seriousness of the abuse potential, the extent of the abuse, the extent of the risk of public health, and the drug's usefulness and importance in medicine. It is, therefore, clear from the statutory language that no one criterion alone was to determine a drug's placement in the Scheduling scheme established by the Act.

II. Legislative History of the Controlled Substances Act

The conclusions based on an analysis of the Act's language are confirmed by the Act's Legislative history. From the beginning of the legislative process to its conclusion when the Controlled Substances Act was enacted into law, it was clear that the Congress was creating a scheduling scheme that was to involve a balancing of a variety of factors. A few selected quotations from the relevant legislative history will make this point. Section 812 had its origins in the bill ultimately proposed by the Nixon Admin-

istration in 1970. John Ingersoll, Director of the Bureau of Narcotics and Dangerous Drugs (the predecessor agency of the Drug Enforcement Administration), testified on the provision in the Administration's bill as follows:

> . . . before undertaking to bring a drug under control . . . the Attorney General must first consider the advice of the Secretary of Health, Education, and Welfare, . . . As well as providing for the necessary scientific and medical input into the Attorney General's determination to control a drug, nine criteria are set forth which he must consider before bringing any substance under control. Drugs subject to control under the Controlled Dangerous Substances Act are listed in the one of the four schedules. Each schedule has its own set of additional criteria which must also be met before a drug can be included within the particular schedule. Drugs are to be scheduled according to their relative hazard, potential for abuse, and therapeutic utility and safety. [emphasis added]
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> * * *
>
> In discussions with the Subcommittee on Public Health and Welfare we have been working to clearly distinguish the input of the Secretary of Health, Education, and Welfare from that of the Attorney General. We recognize that the Secretary must make the necessary medical and scientific determinations which shall be determinative on the Attorney General in terms of keeping a drug from being brought under control. However, the converse is not true. An affirmative decision to control involves more than medical and scientific determinations. It has important policy, legal and enforcement implications, as well. It is the responsibility of the Attorney General to determine whether or not all the facts and data support a conclusion that a given drug should be brought under control. [Emphasis in original.]

Prepared Statements Presented by Administration Witnesses at Hearings on Legislation to Regulate Controlled Dangerous Substances and on H.R. 17463, House Committee on Ways and Means, Committee Print (July 21, 1970), at pp. 11-12, 13-14.

Thus, it is clear that the Administration's intent in drafting and introducing the bill -- as expressed to the Congress -- was to establish a regulatory scheme that required consideration of an extensive number of factors and that did not permit scheduling decisions to be determined by a single factor taken out of context.

The Congressional consideration of the bill indicates that the Congress contemplated precisely the same balancing approach. The language that ultimately became section 812 of Title 21, U.S.C. came from the House bill. The House Report on the House bill devoted three and one-half pages to discussing the nature of the scheduling decision. Those pages are reproduced in Appendix A to this memorandum.

It is crystal clear from the House Committee's discussion that the Scheduling decision was to be based on a variety of factors including <u>both</u> medical and nonmedical factors. Thus, the House Report discusses at length the obligation of the Attorney General to seek the advice of the Secretary of Health, Education, and Welfare with respect to scientific and medical evaluations. The Report also makes clear that the Secretary's advice and recommendation on these matters is to be determinative. But, the report also

emphasizes that the Attorney General must consider all the evidence, including the advice of the Secretary, in making the scheduling decision:

> After receiving the recommendation of the Secretary, the Attorney General shall consider it and all other relevant data to ascertain whether there is substantial evidence of a potential of abuse such as to warrant the initiation of a control proceeding. In making this determination, the Attorney General is to consider the same criteria as the Secretary considers in making his evaluations and recommendations, subject, of course, to the above-mentioned requirements as to the effect to be given the Secretary's recommendations. If the Attorney General finds that all the relevant data constitutes substantial evidence of a potential for abuse, he may proceed under the rulemaking procedures of the Administrative Procedure Act to control the substance.

Report of the House Committee on Interstate and Foreign Commerce on H.R. 18583, H.Rpt. No. 91-1444 (Part 1), 91st Cong., 2d Sess., at 33-34 (Sept. 10, 1970).

The Committee Report emphasizes that,

> a key criterion for controlling a substance, and the one which will be used most often, is the substance's potential for abuse.

Id., at 34. The House Report then goes on to emphasize further that the Attorney General must consider all the factors set out in section 811(c) in making his scheduling decisions:

> Aside from the criterion of actual or relative potential for abuse, subsection (c) of section 201 lists seven other criteria, already referred to above, which must be considered in determining whether a substance meets the

> specific requirements specified in section 202(b) for inclusion in particular schedules and accordingly should be designated a controlled substance under a given schedule. . . .

Id., at 35.

The discussions on the floor of the House further reinforced the fact that scheduling was to be based on a balancing decision. Representative Springer, a sponsor of the bill and one of the bill's floor managers, described the scheduling decision as follows:

> So the Attorney General is given authority to classify substances for purposes of control. He first asks HEW for a scientific opinion. If that opinion is negative, that ends it. If scientific information indicates that a substance can be abused, the Attorney General looks around to see if there is evidence that it is. He must consider all possible facets of the problem to make sure that control is necessary. The bill gives him many pointers on the kinds of things to look for. If ultimately a drug is tagged for control, it must be placed in one of the five categories created.

116 Cong. Rec. H-33300 (Sept. 23, 1970). Rep. Hastings, another member of the subcommittee that drafted the bill, emphasized the overall flexibility inherent in the scheme established by the statute:

> By tying the regulatory scheme into the drug classification scheme, thereby making the degree of regulatory control dependent on the schedule in which a substance is classified, considerable flexibility is achieved. This flexibility will enable the Attorney General to meet the demands of changing conditions in that he can tailor the regulatory controls imposed over any particular

> drug to fit the degree of abuse potential posed by it.

116 Cong. Rec. H-33309 (Sept. 23, 1970).

In sum, an examination of the legislative history of the provisions of the Controlled Substances Act that govern the scheduling of drugs and substances can produce no conclusion other than the one reached by the United States Court of Appeals for the District of Columbia Circuit:

> The legislative history of the CSA indicates that medical use is but one factor to be considered [in scheduling decisions], and by no means the most important one.

National Organization for Reform, Etc. v. DEA, 559 F.2d 735, 748 (D.C. Cir. 1977).

IV. Subsequent Congressional Action Demonstrates That Lack of Accepted Medical Use Does Not Preclude The Placement of a Substance in Schedule III, Schedule IV, or Schedule V.

The Congress itself has taken action on two occasions which underlines the fact that lack of accepted medical use does not preclude placement of a substance in a Schedule other than Schedule I.

First, in enacting the Controlled Substances Act, the Congress placed poppy straw in Schedule II. Poppy straw has no accepted medical use in treatment in the U.S.

Second, in 1978, the Congress enacted the Psychotropic Substances Act of 1978. P.L. 95-633, 92 Stat. 3768. The purpose of this Act was to permit the United States to comply with the provisions of the international Convention on Psychotropic Substances. Two substances had been sched-

uled under the Convention which were not then controlled in the United States. Section 102 of the Act directed the Attorney General to place the two psychotropic substances (pipradrol and SPA) into Schedule IV under the Controlled Substances Act. Congress specifically directed that this action should be taken without regard to the procedures established by sections 811 and 812 of Title 21 of the United States Code. Instead Congress itself determined the appropriate scheduling.

The final Act draws primarily on language from the House bill. The House Report explains the Congressional intent behind placing pipradrol and SPA into Schedule IV even though the drugs did not have a current medical use in the United States. The House Report stated as follows:

> There are two drugs controlled under the Convention which are not currently controlled under the Controlled Substances Act. These drugs, pipradrol and SPA, are stimulants controlled in Schedule IV of the Convention. These drugs do not have current medical uses in the United States and are not manufactured domestically. Although the Committee is unaware of plans of any domestic producer to manufacture these drugs, the Committee's proposal contains a provision which would require the Attorney General to issue an order controlling these drugs in Schedule IV of the Controlled Substances Act. Schedule IV was selected as an appropriate schedule to assure that, with respect to these drugs, the minimum control requirements under the Convention would be met. The usual findings and procedures required under Section 201 of the Controlled Substances Act would be waived to avoid delay in the scheduling of these drugs.

Report of the House Interstate and Foreign Commerce Committee to accompany H.R. 12008, H. Rpt. No. 95-1193, 95th Cong., 2d Sess., at p. 9 (May 15, 1978), reprinted in [1978] U.S. Code Congressional and Administrative News, at 9496, 9504.

It is crystal clear from the House Report that the Congress recognized that neither pipradrol nor SPA had recognized medical uses in the United States at the time that the Congress directed they be placed in Schedule IV. Notwithstanding that fact, the Congress declared Schedule IV was the "appropriate schedule" to meet the minimum control requirements under the international Convention. The House Report specifically declared that the reason that it was directing that these two drugs be placed in Schedule IV as a matter of statute rather than allowing the normal procedures to go forward under the Controlled Substances Act was solely "to avoid delay in the scheduling of these drugs." The House Report specifically took note that the drugs specifically did not have current medical uses in the United States, yet did not make any statement suggesting that there was any problem in terms of the criteria for control or the criteria for placing materials in Schedule IV with directing that pipradrol and SPA be placed in that schedule.

In short, the Congress acted to place these two drugs into Schedule IV as the most appropriate place for them to be placed based on an assessment of their abuse potential and did not see any problem with doing so even

though one criterion for Schedule IV is that there be "accepted medical use" for all drugs placed into that schedule.

Moreover, the House Report specifically declared that,

> In providing for the scheduling of these drugs in Schedule IV, it is not intended that the Attorney General and the Secretary of Health, Education and Welfare be proscribed from subsequently initiating proceedings to transfer these drugs to another schedule. . . .

Id., at 9.

The DEA has taken no action to reschedule pipradrol and SPA into Schedule I on the ground that these two substances do not meet the criteria of Schedule IV. To the contrary, DEA has been content to leave them in Schedule IV. Similarly, DEA has taken no action to reschedule poppy straw.

In sum, we submit that the action of the Congress itself--as well as the subsequent inaction by the DEA--with respect to pipradrol, SPA, and poppy straw demonstrate that it is wholly consistent with the statutory scheme, in appropriate cases, to schedule a drug which has no accepted medical use in the United States in schedules other than Schedule I.

V. The Decisions of Two Circuit Courts of Appeals and a Three Judge District Court in The District of Columbia Have Established the Flexible Nature of the Controlled Substances Act

The conclusions set out above with respect to the appropriate interpretation of the provisions of the Controlled Substances Act have been authoritatively confirmed

by decisions of the United States Court of Appeals for the District of Columbia Circuit and of the United States Court of Appeals for the Eight Circuit. In addition, a three-judge court of the United States District Court for the District of Columbia has also reached the same conclusion.

In National Organization for Reform, Etc. v. DEA, 559 F.2d 735 (D.C. Cir. 1977), the D.C. Circuit considered the proper interpretation of Section 202(b) of the Controlled Substances Act, 21 U.S.C. § 812(b). The court explicitly came to the conclusion that the fact that a substance had no currently accepted medical use did not require that it be placed in Schedule I:

> . . . Section 202(b), 21 U.S.C. § 812(b), which sets forth the criteria for placement in each of the five CSA schedules, established medical use as the factor that distinguishes substances in Schedule II from those in Schedule I. However, placement in Schedule I does not appear to flow inevitably from lack of a currently accepted medical use. Like that of Section 201(c), the structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence. To treat medical use as the controlling factor in classification decisions is to render irrelevant the other "findings" required by Section 202(b). The legislative history of the CSA indicates that medical use is but one factor to be considered, and by no means the most important one.
>
> Moreover, DEA's own scheduling practices support the conclusion that substances lacking medical usefulness need not always be placed in Schedule I. At the hearing before ALJ Parker DEA's Chief Counsel, Donald Miller, testified that several substances listed in CSA

> Schedule II, including poppy straw, have no currently accepted medical use. Tr. at 473-474, 488. He further acknowledged that marijuana could be rescheduled to Schedule II without a currently accepted medical use. Tr. at 487-488. Neither party offered any contrary evidence.

559 F.2d, at 748 (footnotes omitted).

The United States Court of Appeals for the Eighth Circuit came to the same conclusion as the D.C. Circuit about the appropriate interpretation of the criteria in 21 U.S.C. § 812(b) in the case of United States v. Fogarty, 692 F.2d 542 (8th Cir. 1982). In Fogarty, the Eighth Circuit concluded that the criteria set out for each schedule in the Controlled Substances Act constituted "guides" and that no single criterion could be regarded as determinative of a scheduling decision. Thus, in considering the scheduling of marijuana in Schedule 1, the Eighth Circuit wrote as follows:

> . . . the three statutory criteria for Schedule I classification set out in § 812(b)(1) -- high potential for abuse, no medically accepted use, and no safe use even under medical supervision -- should not be read as being either cumulative or exclusive. Thus, even assuming, arguendo, that marijuana has some currently accepted medical uses, the Schedule I classification may nevertheless be rational in view of countervailing factors such as the current pattern, scope, and significance of marijuana abuse and the risk it poses to public health. See 21 U.S.C. § 811(c)(1)(8).

692 F.2d, at 548 (footnotes omitted).

Finally, in perhaps the most definitive consideration of this question, Judge Tamm wrote an extensive and careful opinion in which his central conclusion was that "[t]he statutory criteria of Section 812(b)(1) are guides in determining the schedule to which a drug belongs, but they are not dispositive." NORML v. Bell, 488 F. Supp. 123, 140 (D.D.C. 1980) (three-judge court) (emphasis added). Judge Tamm's discussion is sufficiently authoritative and complete that it is worth reproducing in full:

> The statutory criteria of section 812(b)(1) are guides in determining the schedule to which a drug belongs, but they are not dispositive. Indeed, the classification at times cannot be followed consistently, and some conflict exists as to the main factor in classifying a drug -- potential for abuse or possible medical use. The district court in United States v. Maiden, 355 F.Supp. 743 (D. Conn. 1973), discussed this problem in rejecting the identical claim raised here by NORML:
>
> > "[The statutory classifications] cannot logically be read as cumulative in all situations. For example finding (B) for Schedule I requires that "The drug or other substance has no currently accepted medical use in treatment in the United States." Finding (B) for the other four schedules specifies that the drug has a currently accepted medical use. At the same time, finding (A) requires that the drug has a "high potential for abuse" for placement in Schedule I, but a "potential for abuse less than the drugs or other substances in Schedules I and II" for placement in Schedule III. If the findings are really cumulative, where would one place a drug that has no accepted medical use but also has a potential for abuse less than the drugs in Schedules I and II? According to finding (A) for Schedule III it belongs in Schedule III, but

> finding (B) for that schedule precludes Schedule III; according to finding (B) for Schedule I it belongs in Schedule I, but finding (A) for that schedule appears to preclude Schedule I."
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> Id. at 749 n. 4.
>
> The legislative history also indicates the statutory criteria are not intended to be exclusive. The House report states that "[a]side from the criterion of actual or relative potential for abuse, subsection (c) of section 201 [21 U.S.C. § 811(c)] lists seven other criteria . . . which must be considered in determining whether a substance meets the specific requirements specified in section 202(b) [21 U.S.C. § 812(b)] for inclusion in particular schedules . . . ." 1970 House Report, supra at 35, reprinted in [1970] U.S. Code Cong. & Admin. News at 4602. The criteria listed in section 811(c) include the state of current knowledge, the current pattern of abuse, the risk to public health, and the significance of abuse. These more subjective factors significantly broaden the scope of issues to be considered in classifying a drug.

488 F. Supp., at 140-41.

We submit that these three cases definitively resolve the question of DEA's regulatory authority. The Drug Enforcement Administration sits in the District of Columbia. We submit that when both the United States Court of Appeals for the District of Columbia Circuit and a three-judge panel of the United States District Court for the District of Columbia have authoritatively and independently reached similar conclusions about the nature of the regulatory scheme of the Controlled Substances Act, the DEA no longer has the legal authority to take a contrary position.

VI. Conclusion

For the reasons set out above, we believe it is clear that substances which have a potential for abuse but which have no accepted medical use may be classified in schedules other than Schedule 1. In making scheduling decisions, we believe the Controlled Substances Act requires the DEA to consider the statutory criteria listed in both Section 811(c) and 812(b). Based on its overall consideration of these criteria, the DEA must then schedule a substance in the most appropriate schedule based on all the evidence before it. What is clear from the statutory scheme, from the legislative history of the statute, and from the authoritative decisions of the courts, however, is that the agency may not elevate a single criterion to controlling force. We submit that no answer other than "yes" is possible as a response to the question posed at the beginning of this memorandum.

Respectfully submitted,

Richard Cotton
DEWEY, BALLANTINE, BUSHBY,
PALMER & WOOD
1775 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
(202) 862-1000

Attorney for Drs. Grinspoon and Greer,
Professors Bakalar and Roberts

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