

March 21, 2005

Ms. Karen P. Tandy, Administrator
Drug Enforcement Administration (DEA)
Mailstop: AXS
2401 Jefferson Davis Highway
Alexandria, VA 22301

Re: DOCKET NO. DEA-261N (Commenting on Interim Policy Statement, “Dispensing of Controlled Substances for the Treatment of Pain;” Docket No. DEA-258S)

Dear Administrator Tandy:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, and the American Academy of Child and Adolescent Psychiatry (AACAP), composed of over 7,200 child and adolescent psychiatrists, appreciate the opportunity to submit these comments concerning DEA’s interim policy statement, filed November 12, 2004. This statement was published in the Federal Register on November 16, 2004, with the title, “Dispensing of Controlled Substances for the Treatment of Pain.”¹ DEA then solicited comments on this interim policy statement through its Notice, published in the Federal Register on January 18, 2005.² By promoting this as an interim policy statement, in anticipation of a final policy statement, DEA is wisely leaving the door open to discussion and review. This way, DEA can consider input from the medical community, prior to modifying and further clarifying its approach to any aspect of Schedule II prescribing that it wishes to address in its final policy statement.

Any views expressed within the following comments are designed to fully comport with the legislative intent and goals of controlled substance laws. That is, to control certain medications from being diverted from accepted medical pathways of distribution, hence, preventing their abuse. Ultimately, the goal is to safeguard public health. The APA and AACAP wholeheartedly support this goal, and do not condone any activities designed to circumvent or thwart lawful distribution systems for controlled substances.

In the following comments, the APA and AACAP will address DEA’s interim policy statement, including undue burdens it imposes upon psychiatrists and their patients. The APA and AACAP will detail how the prescribing context and risk of abuse

¹ DEA Interim Policy Statement: “Dispensing of Controlled Substances for the Treatment of Pain,” FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; pp. 67170-67172.

² DEA Notice: “Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain,” FR Doc 05-906 [Federal Register: January 18, 2005 (Volume 70, Number 11)].

or diversion differs between Schedule II substances used for pain treatment, compared with psychiatric treatment. APA and AACAP will then provide their recommendations for a prescribing policy that balances the interests of the psychiatric community and DEA's goal of decreasing substance abuse.

DEA's interim policy statement is confined to the issue of dispensing Schedule II medications for the treatment of pain

DEA filed its interim policy statement, published November 16, 2004, in order to explain why an earlier DEA FAQ was withdrawn from its website.³ The FAQ had been published on DEA's website in August of 2004, though it had not been formally published in the Federal Register. The FAQ was entitled, "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel."

DEA's interim policy statement was clearly limited, by its title and language, to the issue of dispensing Schedule II controlled substances used to treat pain.⁴ It did not address the use of Schedule II substances for therapeutic purposes other than pain alleviation, nor did it refer to the use of such substances within psychiatric treatment settings. It also refrained from dealing with the issue of cross-over or multi-purpose drugs that may be used simultaneously to relieve pain and to improve psychiatric symptoms.

DEA's FAQ on writing multiple prescriptions comports with applicable law

This interim policy contravened one notable part of the FAQ, per the following excerpt. This had been on DEA's website for three months, from August to November 2004, prior to its withdrawal. In that time, the prescribing method articulated in the FAQ, as acceptable to DEA, had influenced the medical community. Moreover, the method of preparing multiple prescriptions described in the FAQ comports with applicable law; it is not prohibited or contravened by law in any way:

"Refills of schedule II prescriptions—

*The August 2004 FAQ stated: 'Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates' (Italics added.)"*⁵

³ In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (August 2004 FAQ; <http://www.deadiversion.usdoj.gov>)

⁴ DEA Interim Policy Statement: "Dispensing of Controlled Substances for the Treatment of Pain," FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; pp. 67170-67172.

⁵ DEA Interim Policy Statement: "Dispensing of Controlled Substances for the Treatment of Pain," FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; p. 67171.

What DEA originally promoted in the FAQ is an eminently practical prescribing method that minimizes extraneous patient visits and allows the patient to have a steady stream of prescription medication at hand for a prolonged period. At the same time, it does not allow excessive amounts of the drug into the stream of distribution at any one point in time. The real effect of this drug-dispensing process is no different than if the patient receives multiple, successive prescriptions, one at a time, over the same time period. This assessment assumes that all factors in the prescriptions are equivalent as to drug type, dosage, and quantity. Comparing these methods on a matrix of two factors: 1) intensity of available drug quantities; and 2) a time span, both prescribing methods pose an equal, yet minimal risk of abuse or diversion of a specific drug quantity at any given time point.

The rationale for withdrawing the FAQ published on DEA's website was that it "was not published in the **Federal Register** and was not an official statement of the agency."⁶ DEA also withdrew the FAQ because "it contained misstatements."⁷ DEA's FAQ had been on DEA's website for three months by then, influencing the prescribing habits of many physicians, including psychiatrists. DEA's interim policy statement was exclusively focused on drugs used for pain, many of which are narcotics that are highly subject to abuse and diversion. However well-intentioned, this interim policy poses significant practical difficulties for psychiatrists who prescribe controlled substances, by restricting their prescribing options.

DEA's stated purpose of this interim policy, as articulated within it, is solely to support its mandate to enforce existing, relevant law on prescribing Schedule II substances, per 21 U.S.C. § 829(a) and 21 C.F.R. §§ 1306.01-1306.27. As DEA stated, "(T)his document provides the public with DEA's policy for ensuring that the law administered by the agency relating to the subject matter of this document is faithfully executed."⁸ Of course, DEA's inarguable role is to enforce applicable law. However, this quote does show DEA's emphasis on its intent to restrict the interim policy to the subject matter therein, which is solely that of dispensing controlled substances for treatment of pain.

DEA's interpretation as to procedures that constitute prohibited "refilling" of a prescription are not based on applicable law

DEA's interim policy statement as to the more specific subject of Schedule II prescription refills for pain treatment is not supported by law. This was purportedly based on the decision in a single, federal appeals case, *United States v. Rosen*, 582 F.2d 1032 (5th Cir., 1978). That case involved the conviction of a physician for dispensing

⁶ DEA Interim Policy Statement: "Dispensing of Controlled Substances for the Treatment of Pain," FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; p. 67170.

⁷ DEA Interim Policy Statement: "Dispensing of Controlled Substances for the Treatment of Pain," FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; p. 67170.

⁸ DEA Interim Policy Statement: "Dispensing of Controlled Substances for the Treatment of Pain," FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; p. 67172.

controlled substances for other than a legitimate medical purpose. That factual situation is highly distinguishable from and completely irrelevant to the scenario of a psychiatrist, or any physician, who prescribes medications to patients for a legitimate medical purpose. DEA quotes from the decision, which articulates a constellation of nine obvious signals to indicate that a physician is illegally prescribing controlled substances. These indicators apparently were culled from other cases. DEA quotes the court as stating that,

“one can glean from the reported cases in which physicians have been convicted of dispensing controlled substances for other than legitimate medical purpose ‘certain recurring concomitance of condemned behavior,’ such as the following:

- (1) An inordinately large quantity of controlled substances was prescribed.
- (2) Large numbers of prescriptions were issued.
- (3) No physical examination was given.
- (4) The physician warned the patient to fill prescriptions at different drug stores.
- (5) The physician issued prescriptions to a patient known to be delivering the drugs to others.
- (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
- (7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
- (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
- (9) The physician wrote more than one prescription on occasions in order to spread them out.

United States v. Rosen, 582 F.2d, 1032, 1035–1036 (5th Cir. 1978) (citations omitted).”⁹

All of these indicators are robustly inconsistent with legitimate medical diagnostic, treatment, and prescribing practices. Among the nine indicators, only two dealt with numbers of prescriptions written. None of these indicators equates to a legal interpretation that it is unlawful to write multiple prescriptions for a legitimate medical purpose on the same day with instructions to fill them on different dates, nor can they be so construed. DEA presumably left out the *Rosen* court’s citations to cases from which it had gleaned these indicators. DEA did not otherwise quote from *Rosen* to demonstrate that the court made any such legal interpretation as to prescribing methods. Indeed, DEA did not quote or cite to any interpretive statements at all in this case, as to what constitutes the permissible or prohibited “refilling” of a prescription, under applicable law. Despite this lack of legal support for its statement, DEA referenced these indicators, then crafted its own interpretation as to what ostensibly constitutes prohibited prescription refills:

“For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a). Indeed, as the factors quoted above from the *Rosen* case indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes. Under

⁹ DEA Interim Policy Statement: “Dispensing of Controlled Substances for the Treatment of Pain,” FR Doc. 04-25469 [Federal Register: November 16, 2004 (Volume 69, Number 220)]; p. 67171, quoting from *United States v. Rosen*, 582 F.2d 1032 (5th Cir., 1978), at 1035-1036.

no circumstances may a physician dispense controlled substances with the knowledge that they will be used for a nonmedical purpose or that they will be resold by the patient.” *United States v. Rosen*, 582 F.2d 1032 (5th Cir., 1978), at 1035-1036.

It is noteworthy that DEA’s interpretation as to what constitutes a prohibited prescription refill, under 21 U.S.C. 829(a) or its implementing regulation, 21 C.F.R. 1306.12, is merely an opinion issuing from DEA alone. This opinion is not a recitation of a legal principle or construct from the referenced *Rosen* case, any other case law, state or federal statute, regulation or common law. In fact, DEA does not quote any supporting law for this narrow interpretation. This DEA opinion not only misinterprets *Rosen*, we believe it lacks any legal force or effect. Unfortunately, many people misconstrue policy as law. Even some DEA agents working at the state level are misinterpreting this interim policy statement as federal law, causing undue complications for the medical community.

This assessment is echoed by William T. Winsley, M.S., R.P.h., Executive Director of the Ohio Board of Pharmacy. In his letter of December 16, 2004, to the DEA Administrator, he protested issuance of DEA’s legal interpretation,

“Please note that the prohibition against refilling a Schedule II prescription is confirmed in this opinion by the citation of 21 USC 829(a). This is clearly stated in federal law and no one is disputing it. However, the opinion regarding the second part of the original statement from the August 2004 FAQ (a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates) is not based on either federal law or regulations (you will note that none are cited), but is merely an opinion that is now being conveyed by DEA diversion officers in Ohio as federal law. This is not merely an incorrect interpretation of federal law; it is an attempt by someone within DEA to promulgate new laws without bothering to consult with Congress. To put it as mildly as I can: trying to promulgate new law this way is inappropriate.”¹⁰

The legal role of DEA policy statements

As DEA itself points out, its interim policy statement is not legally binding. Its final policy statement will, likewise, not be binding. However, it *does* provide a degree of guidance to the medical community. This is true as to general or specific statements related to prescription refills. DEA’s statements can, at most, serve only as policy.

DEA’s policy can provide the most value as guidance when it is crafted to specifically target its goals of abuse and diversion prevention. In that respect, the interim policy that focused on curbing substance abuse and diversion from pain medications in the medical setting is excessively restrictive for psychotropics in the psychiatric setting.

Because of the potential reaction by practitioners, dispensers, and state law enforcement agencies, DEA, as any agency, should be careful to reconcile an overarching goal (i.e., diminishing diversion and abuse of pain medication) with unintended consequences for other medications on the same schedule. We believe that the impact of the interim policy fails to balance one with the other, and thus needlessly creates added

¹⁰ Letter of December 16, 2004, from William T. Winsley, M.S., R.P.h., Executive Director of the Ohio Board of Pharmacy, to Ms. Karen P. Tandy, Administrator of DEA, p. 2.

barriers to medically necessary treatment with medicine commonly used to treat disorders such as Attention Deficit Hyperactivity Disorder (ADHD).

DEA can craft policy that accounts for the uniqueness of prescribing psychotherapeutics

The statute and regulation, respectively, 21 U.S.C. 829(a) and 21 C.F.R. 1306.12, that prohibit refilling of prescriptions for Schedule II substances, apply universally to all substances within that schedule.^{11, 12} However, as it did with the interim policy on pain medications, DEA can carve out a special policy for the subclass of Schedule II substances that are used as psychotherapeutics, based on their relatively low risks of abuse and diversion inherent in the prescribing pathway.

Risks of abuse, addiction and diversion differ within subcategories of Schedule II substances, notably between those typically used for pain relief and psychotherapy. DEA policies that impact and intend to restrict prescribing practices for Schedule II substances should not be “one-size-fits-all.” Policy designed for medical settings creates undue, overbearing restrictions on the uniquely situated class of physicians who are psychiatrists. Instead, policies should be tailored as closely as possible to their goal of reducing the relative risks for drug abuse and diversion. To do so, they should accommodate current practice situations that are specific to psychiatrists.

Ideally, policies should also be prospectively applicable to Schedule II substances that are likely to be available in new delivery systems that further minimize risks of abuse and misdistribution. If not, it may be necessary to periodically issue multiple, piecemeal policies that will add further complexity and interpretative confusion for both the medical and the legal communities.

Sound public policy demands solid integration between requirements of the law and its practical application within the real-life realm of medical and psychiatric practices. The APA and AACAP maintain that there are specific prescribing practices that psychiatrists use for psychotherapeutic medications that fall squarely within the

¹¹ 21 U.S.C. Sec. 829. “Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act (21 U.S.C. 353(b)). Prescriptions shall be retained in conformity with the requirements of section [827](#) of this title. No prescription for a controlled substance in schedule II may be refilled.”

¹² 21 C.F.R. Sec. 1306.12 “Refilling prescriptions. The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.”

intent and purpose of applicable laws and regulations. Some of these were previously mentioned. The flexibility that such practices afford general psychiatrists, child and adolescent psychiatrists, and their patients needs to be preserved, not squelched, by any DEA policy that is issued.

We are highly concerned that some psychiatrists and state pharmacy boards have already been interpreting this interim policy statement, as though it is legally binding. They have been using it to define what they believe are legally permissible prescribing procedures for psychotherapeutic medications. Unfortunately, what appears to be a quick turn-around in DEA's approach to prescribing methods has been causing confusion and a lack of standardization in prescribing practices among psychiatrists. They are attempting to balance the therapeutic and practical needs of their patients with their perceptions of what they think the law requires. This is further complicated by state pharmacy boards that are attempting to provide guidance on permissible prescribing procedures to physicians in all specialties.

We urge DEA to consider the following concerns and articulate a final policy statement that takes into account both the law and the best interests of psychiatrists and their patients. This could conceivably be an expansion of the interim policy statement on pain medications, to incorporate potentially permissible prescribing methods for psychotherapeutic medications. Alternatively, it could be a stand-alone policy statement directed solely toward the prescribing of psychotherapeutic medications for psychiatric disorders. Any interpretations of law within the policy statement should derive solely and directly from sources acceptable within the legal system, such as statutes, regulations and case decisions with legal precedent, rather than an agency's own *sua sponte* interpretation of statutes, regulations or case law.

Policy must take into account differences in the risk of abuse and diversion between medications used for pain and psychotherapeutics

Despite some crossover in the use of Schedule II medications for pain and psychotherapy, there are considerable differences between these categories of drugs and factors in the typical medical and psychiatric practice settings. Some distinguishing characteristics that influence the risk of abuse and diversion, making them relatively lower for psychotherapeutics, are:

- Bioactivity of the drugs: effect and side effects at therapeutic and higher doses (a potential for enjoyable effects influences the attractiveness for abuse)
- Synergistic effects when taken with alcohol or other drugs
- Formulation: capsules, tablets, gel, liquid, dosage
- Delivery systems and tamper resistance: i.e., Concerta is provided in a crush-resistant capsule and releases the drug slowly over a 12-hour period. Tampering with the capsule renders the product unusable.
- Quantity of drug prescribed over a given time period
- Ability of a physician or psychiatrist to recognize and forestall drug-seeking/abusing patient behavior

- Patient age, demographics, medical and psychological status
- Patient's length or continuity of relationship with physician
- Patient's compliance ability, i.e., losing, misplacing drugs
- Psychological or physical addictive potential
- Patient's relationship with parents and/or guardian or teacher

DEA inherently recognized distinctions in abuse and diversion potential of various drugs by focusing its interim policy statement on medications used to treat pain, rather than addressing Schedule II drugs collectively.

The excessive burden upon psychiatrists, their patients and caregivers

Psychiatrists and their patients experience heavier burdens than medical patients, with respect to constraints placed on prescribing options. When overly restrictive policies impede psychiatrists from scheduling visits and using prescribing methods that most suit their patients, there are several results. Treatment effectiveness can be compromised, leading to suboptimal patient outcomes. More administrative time is expended on handling prescription issues. Lost revenue from the extra time is either absorbed as a loss to the psychiatrist or is passed along in some form as charges to patients and/or their insurers. This raises the overall cost of psychiatric treatment. An appropriate policy consideration is the potential cost-savings for mental health insurers and governmental programs through efficient prescribing procedures.

Patients who have become stabilized on medications, such Ritalin or other stimulants used to treat ADHD, generally do not require personal visits with a psychiatrist as often as they need prescriptions filled. While regular contact with a physician is certainly appropriate, we believe that it is unduly costly for the healthcare system to require such patients to have extra visits just to obtain a prescription, when otherwise not medically indicated. It also wastes the effect of the limited number of visits for which they may have coverage, under managed care insurance or governmental programs. Especially for such patients, who do not require monthly monitoring, the most streamlined system of obtaining psychotherapeutic drugs at optimal, appropriate intervals would save time and stress for them and for their psychiatrists. The treating psychiatrist should retain discretion as to when a personal visit should be scheduled, in order to maximize the patient's treatment.

There is certainly widespread concern about balancing legal compliance with the practical constraints of psychiatric practice and patients' life situations. It bears emphasis that treatment access and compliance with prescription medications can be a serious issue for some psychiatric patients in ways that they are not for other medical patients. It may be more difficult for them to make or keep appointments, obtain prescriptions and fill them in a timely way to comply with a treatment regimen. More importantly, with every unnecessary visit required to obtain prescriptions, there is a potential for disruption and added stress that is antithetical to their treatment goal.

There is also the effect upon caregivers for psychiatric patients, who may be parents of minors or friends or relatives of adult patients. These caregivers help patients to make and keep appointments, get medication and deal with coverage issues. For them, the lost work time and energy to deal with this becomes another burden.

The APA and the AACAP are concerned that this policy may be creating an access barrier to child and adolescent patients, in particular. According to data from the 1999 Surgeon General's report, the New Freedom Commission on Mental Health, and other sources, most children and adolescents with mental illnesses are not receiving treatment. The current barriers to treatment include the inability to afford treatment, stigma, and the shortage of child and adolescent psychiatrists, along with other children's mental health specialists.

Patients and parents or guardians of minor patients often face physical and geographical barriers to accessing child and adolescent psychiatrists, since there are so few of these specialists. They find it very burdensome to have more visits to psychiatrists and pharmacies than absolutely necessary. We are concerned that the necessity for parents of minor patients of making additional office visits in order to obtain prescriptions for needed medications will create an extreme hardship on these already overburdened families. Also affected in this way are the elderly and their caregivers, patients with physical challenges and or multiple morbidities, AIDS patients, rural patients far from psychiatrists, inner city patients without adequate transportation and parents of minor patients.

Some of the problems stemming from DEA's interim policy statement were set forth in a letter from the Executive Director of the Ohio Pharmacy Board. These practical issues and solutions in handling prescriptions, among others, have been reported to APA by members and state pharmacy boards.

“Writing multiple prescriptions was a procedure initially suggested by this Board to physicians in Ohio who were trying to deal with ADHD children who were stabilized on their stimulant therapy and needed to be seen only once every six months. In order to meet the requirement of a written prescription for these products, physicians were mandating that the parents come to the office every month, they were mailing a new prescription every month, or they were writing for large quantities at one time. Obviously, there were problems with each of these practices: patients sometimes lived long distances away from the specialist; many prescriptions were lost in the mail; patients or their parents could not afford to buy large amounts at one time or were prohibited by their insurance plans from coverage of more than a month's supply at once. From the Board's perspective, another concern, of course, involved the issuance of a large number of dosage units at one time to those individuals who were trafficking or abusing the drugs. **Consequently, we suggested that the prescriber sign and date the prescription on the date issued, as mandated by 21 CFR 1306.05(a), but that there should be an indication to the pharmacist within the directions for use that the prescription should not be dispensed until a certain date. This method eliminates most of the above mentioned problems.** Once we suggested that physicians and pharmacists consider this, DEA tried to force Meijer, Inc. to stop accepting these prescriptions. After discussions between this Board and DEA, a letter was issued to Meijer indicating that DEA indeed found this to be an acceptable practice. Now we have reverted to the beginning again because some DEA employees don't know that

their jobs are to enforce federal laws and regulations rather than make them.”¹³ (*Phrases emboldened.*)

This is an eminently practical solution with a low risk of abuse. APA and AACAP recommend this approach to DEA.

Coverage issues

We note that most public and private insurance imposes discriminatory limits on coverage and cost-sharing for treatment of psychiatric illness. This means that out-of-pocket costs for visits associated with routine prescribing of medications commonly used to treat ADHD places a disproportionate cost on patients and their families. Prior policy alleviated at least some of the discriminatory cost burden, but the amended policy needlessly shifts still more costs onto patients.

Limitations in visits and reimbursements, under healthcare insurance and governmental programs, make it imperative that psychiatrists schedule patient visits to maximize treatment effectiveness and positive patient outcomes. In an attempt to avoid prescription refilling prohibitions, some psychiatrists reported to APA that they schedule sub-optimally close intervals for patient visits, when they write successive prescriptions. They also expend significant amounts of time to track and write multiple prescriptions. These “workarounds” are unnecessarily burdensome and raise the ultimate social cost of psychiatric treatment. Worse, this adverse effect is not balanced by any significant enhancement in the control of Schedule II medications from diversion. Psychiatrists would prefer to have the option to write prescriptions in a manner, such as the Ohio Pharmacy Board suggested, that could provide medications for the patient over a more prolonged time period.

Of all physician specialists, psychiatrists are uniquely trained to assess patients for signs of potential substance abuse and in ways to forestall drug-seeking and drug-abusing behaviors. Policies on prescribing practices that are designed to curb abuse and diversion should be appropriately tailored to the true risks of these events within the prescribing pathways for psychiatrists. In addition, such policies must take into account the realistic constraints of psychiatric patients, who have special access and compliance issues that psychologically well medical patients do not share.

GAO finds little evidence of significant abuse

With children and adolescents on stimulant medications to treat attention disorders, a September 2001 GAO Report on drugs used to treat attention disorders found few incidents of diversion or abuse in schools. According to GAO, “Most principals did not perceive the diversion or abuse of prescribed attention deficit drugs to be a major

¹³ Letter of December 16, 2004, from William T. Winsley, M.S., R.P.h., Executive Director of the Ohio Board of Pharmacy, to Ms. Karen P. Tandy, Administrator of DEA, p. 2.

problem at their school. An estimated 89 percent reported that it was less of a problem than other illicit drug use, excluding alcohol and marijuana."¹⁴

While we restate our view that all medications, including those used to treat ADHD, should be used for their intended purpose, the GAO findings suggest that education (and, perhaps, additional treatment, where appropriate) would be an effective means of addressing the problem. This is echoed by the conclusion that the GAO does "not believe that the diversion or abuse of attention deficit disorder is a major problem at middle or high schools . . ." ¹⁵ These findings underscore our view that DEA should be more flexible in seeking a solution to the pain-medication abuse problem without unduly burdening patients and physicians who prescribe other Schedule II medications, such as stimulants used to treat ADHD.

Technology's impact on prescription controls

Technological controls built into the prescribing process and the delivery systems of prescription medications to prevent abuse and diversion make it less necessary to restrict other aspects of prescribing that reduce flexibility for psychiatrists. Tamper-resistant technologies enhance controls for prescriptions, such as California's prescription forms used by institutions. They are pre-printed with names of the facility and prescriber, use batch/lot numbers, thermochromic ink and have chemical voiding protection. These can only be printed on special security printers.¹⁶

Conclusion

We believe that psychiatrists should retain flexibility in their prescribing practices within conformity to applicable law. It is imperative that they maintain the maximum level of authority to make prescribing decisions in the best interests of their patients. Psychiatrists must be able to respect the constraints of their patients and work toward maximum clinical effectiveness. It is only then that they can most strongly influence their patients' movement toward optimal mental health and use resources most effectively. The effective, efficient use of mental health resources in turn produces the best possible patient outcome. When patients can reach their psychological health potential, there is a societal effect that is incalculably beneficial. Of course, it also relates to cost-savings across various dimensions.

APA and AACAP strongly urge DEA to adopt as its final policy the same approach originally articulated in its FAQ, directed specifically to the use of

¹⁴ GAO Report, "Attention Disorder Drugs, Few Incidents of Diversion or Abuse Identified by Schools;" (GAO-01-1011, Sep. 2001) p. 9.

¹⁵ GAO Report, "Attention Disorder Drugs, Few Incidents of Diversion or Abuse Identified by Schools;" (GAO-01-1011, Sep. 2001) p. 19.

¹⁶ California State Board of Pharmacy website, retrieved March 7, 2005:
http://www.pharmacy.ca.gov/publications/rxform_look.pdf

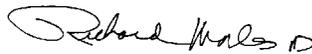
psychotherapeutic drugs prescribed by psychiatrists. Specifically, APA and AACAP's joint recommendation is that DEA support psychiatrists in retaining the option to write multiple Schedule II prescriptions on a single date, with instructions in each prescription for these to be filled on successive dates. This prescribing approach is completely supported by applicable law.

This prescribing option for psychiatrists will streamline the prescribing process, eliminate the need for extra or unproductive visits, and maximize the patient's opportunity to stay in compliance with their drug regimen. In turn, this approach eliminates the undue burden on psychiatrists, their patients, and caregivers. It also promotes optimal mental health for patients and cost-savings for mental health programs.

Thank you for your consideration of these comments.



James H. Scully, Jr., M.D.
Medical Director, American Psychiatric Association



Richard Sarles, M.D.
President, American Academy of Child and Adolescent Psychiatry

APPENDIX I

Table 5.1B Substance Dependence for Specific Substances in the Past Year, by Age Group: Percentages, 2002 and 2003

Past Year Dependence	Total		AGE GROUP (Years)					
			12–17		18–25		26 or Older	
	2002	2003	2002	2003	2002	2003	2002	2003
ANY ILLICIT DRUG¹	2.0	1.8	3.2	2.8	5.5	5.2	1.2	1.1
Marijuana and Hashish	1.1	1.1	2.5 ^b	2.0	3.9	4.0	0.4	0.4
Cocaine	0.4	0.4	0.2	0.2	0.8	0.7	0.4	0.4
Heroin	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1
Hallucinogens	0.1	0.1	0.2	0.2	0.3	0.2	0.0	0.0
Inhalants	0.0	0.0	0.1	0.1	0.0	0.0	*	*
Nonmedical Use of Any Psychotherapeutic ²	0.5	0.5	0.8	0.9	1.2	1.0	0.4	0.4
Pain Relievers	0.4	0.4	0.5	0.7	0.8	0.7	0.3	0.3
Tranquilizers	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1
Stimulants	0.1	0.1	0.2	0.2	0.3	0.3	0.1	0.1
Sedatives	0.1	0.0	0.1	0.1	0.1	0.0	0.1	0.0
ALCOHOL	3.5	3.2	2.1	2.0	7.0	6.7	3.1	2.7
ANY ILLICIT DRUG OR ALCOHOL¹	4.9	4.6	4.4	4.2	11.0	10.6	3.9	3.6
BOTH ANY ILLICIT DRUG AND ALCOHOL¹	0.6 ^a	0.4	0.8	0.7	1.5	1.4	0.4	0.3

*Low precision; no estimate reported.

NOTE: Dependence is based on the definition found in the 4th edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV).

^aDifference between estimate and 2003 estimate is statistically significant at the 0.05 level.

^bDifference between estimate and 2003 estimate is statistically significant at the 0.01 level.

¹ Any Illicit Drug includes marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or any prescription-type psychotherapeutic used nonmedically.

² Nonmedical use of any prescription-type pain reliever, tranquilizer, stimulant, or sedative; does not include over-the-counter drugs.

Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002 and 2003.