

Medroxyprogesterone Treatment for Paraphiliacs

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This study addresses the following questions: (1) what are the essential components of a medroxyprogesterone acetate (MPA) pretreatment evaluation?; (2) do paraphilic men treated with MPA (Depo-Provera) report a lowering of both deviant and nondeviant sexual drive and activities?; (3) is behavioral improvement associated with testosterone level reductions?; and (4) what significant side effects are associated with MPA treatment? A total of 29 paraphilic men who underwent a comprehensive psychiatric, medical, and legal evaluation and were eligible for treatment with MPA were followed naturalistically while receiving concurrent MPA and group therapy. The principal outcome measures were data obtained from a weekly self-reported psychosexual inventory that quantified five dimensions of deviant and nondeviant sexual activities and testosterone levels that were drawn pretreatment and after three and six months of MPA. Self-reported data were analyzed by nonparametric methods. Because MPA's effectiveness is evident early in treatment, we report on data from the first six months. Subjects reported a differential rate of suppression of sexual activities, a median of up to two weeks for deviant and 2 to 10 weeks for nondeviant behaviors ($p \leq .01$ for each of the five dimensions). Testosterone levels suppressed to less than 0.5 ng per milliliter for all but two subjects at three months and for all at six months. Recidivism was reported for one subject. Except for one subject who developed pulmonary emboli, no major medical problems were encountered. MPA safely and effectively reduced sex drive, controlled deviant sexual impulses and behavior, and lowered the testosterone levels of these paraphilic men during the first six months of treatment. However, the relative rapidity and completeness of the response raises questions regarding possible distortions in self-reported sexual activities. This should alert the practicing clinician to consider the use of collateral sources of information in interpreting treatment outcome for patients with paraphilic behaviors. Also, longer follow-up periods are required for monitoring treatment efficacy.

Men who molest children, expose themselves, and commit other sex offenses are

increasingly being ordered to undergo psychiatric evaluation and treatment.^{1, 2} The prevalence of sex offense in the general population has been reported to be very high, ranging from 3 percent to 62 percent.³⁻⁷ Lest deviant sexual interests and behavior be considered rare activities perpetrated largely by socially disadvantaged men, Briere and Runtz,⁸ surveying male college students, provided data suggesting that self-reported sexual

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responses to children are relatively common. Five percent of their nonincarcerated and nonclinical sample reported masturbating to fantasies about sex with a child at least once and seven percent of the sample indicated at least some likelihood of having sex with a child if detection and punishment could be avoided. Abel^{9, 10} published research indicating that the average paraphiliac usually engages in more than one type of paraphilic behavior with numerous victims per type of behavior. Studies of recidivism among sex offenders indicate a high rate of re-offending, up to 40 percent even in treated samples.^{11, 12} Recently, we have begun to gain a better understanding of the full impact of sexual abuse on the victims.¹³ Therefore, given the scope of the growing problem, research into the efficacy of different treatment modalities for paraphilic patients has become increasingly important.

Numerous nonhormonal treatment interventions for paraphilic patients have been implemented with some degree of success.¹⁴⁻¹⁶ These include behavior therapies, such as aversion therapy, covert sensitization, shame therapy, biofeedback, orgasmic reconditioning, masturbatory satiation, systematic desensitization, and social skills and assertiveness training, as well as psychoanalytic, cognitive, and insight-oriented therapies. However, a combination of hormonal treatment with behavioral techniques and counseling has been considered the treatment of choice.¹⁷

Hormonal treatment of sex offenders has included the use of medroxyprogesterone acetate (MPA).^{1, 18-20} MPA has

been described as influencing androgen production, activity, and clearance at numerous levels.^{1, 21} These include testosterone synthesis by the testes, testosterone reductase activity in the liver, and displacement of testosterone from sex steroid-binding protein. In addition, it has been hypothesized that MPA may act on brain cells that may be associated with sexual behavior.^{22, 23}

Numerous studies in non-sex offender samples have demonstrated a relationship between testosterone levels and self-report of sexual fantasy and initiation of sexual activity.²⁴⁻²⁶ In studies of the effects of MPA in sex offenders, reduced testosterone levels along with decreased self-reported deviant sexual drive, fantasy, and behavior were observed consistently.^{1, 21, 27-42} However, more empirical research is needed to confirm the suspected relationship between MPA's physiologic effects on testosterone and its observed effectiveness for sex-offending behavior.

Empirical studies of the outcome of treatment of paraphilic men with MPA can be criticized on two grounds. First, self-reported data have been described in a vague or global manner. It is unclear, for example, whether reduction in sexual drive for sex offenders is equivalent across different types of sexual activities, both deviant and nondeviant. It is also unclear in most of the MPA studies whether drive reduction has been associated predominantly with lower self-report of sexual thoughts, fantasies, and urges; masturbation and frequency of erection; or sexual acting out. Although many of these studies report significant lowering of de-

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viant sexual activity, they do so in a general manner with little reference to limitations of self-reported data.

A second basis for criticism of previous studies of MPA has been on the grounds that there are only a few controlled studies with MPA.⁴³⁻⁴⁵ The reason for few controlled studies may be due to complex ethical, medical, and legal issues.^{17,46} Offenders receiving a placebo control may be at even higher risk for recidivism. Recidivism could have dire consequences on the victim (traumatization), the offender (incarceration), and the treatment facility (litigation). Given these obstacles to controlled studies, greater importance should be given to empirical data from clinical trials.

An important concern in treating these sex offenders is swift suppression of their deviant behavior. Therefore, we principally focus herein on the pretreatment evaluation, early dose titration, and monitoring efficacy and safety. Because treatment response and testosterone suppression tend to occur rather rapidly, within a few weeks,^{28,29} in the current study, we report on subjects' responses during the first six months of treatment. This also is the duration for which Walker *et al.*^{21,46} recommend maintaining the initial dosage before lowering it if deviant behavior has been suppressed. We address the following questions:

(1) What are the essential components of a MPA pretreatment evaluation?

(2) Do paraphilic patients treated with MPA report a lowering of both deviant and nondeviant sexual drive and activity?

(3) Is behavioral improvement associated with concurrently reduced testosterone levels?

(4) What are the significant side effects associated with MPA treatment?

Methods

Subjects The 29 men who are the subject of this article were treated with intramuscular MPA (Depo-Provera; Upjohn Co., Kalamazoo, MI), and they completed self-rating questionnaires on their deviant and nondeviant sexual thoughts, fantasies, urges, and behaviors before and during treatment. These subjects initiated treatment with MPA in a sexual behaviors clinic (SBC) in a large urban area from 1986 through 1992 and are part of a larger series of studies of male sex offenders who have been evaluated and treated for paraphilic disorders in the SBC over the past decade.^{1,47-51}

This study was approved by the medical center's human investigation committee, and written informed consent for this open-label treatment was obtained after a full explanation, including a discussion of possible side effects. The consent sheet included the statement "[Y]ou do not have to accept this treatment as part of your probation or parole requirements, or as mandated by court order."¹ Despite this wording, the authors acknowledge that those who were court-ordered to our facility may not have consented in the true spirit of the term "voluntary." This ethical issue has been considered elsewhere.^{21,46}

Evaluation Protocol. *Initial Evaluation* Sex offenders who are referred to this program undergo an intensive screening evaluation, including a psychiatric interview, psychological testing, and record review (psychiatric, medical, and legal). Corroborative interviews also are

conducted. A comprehensive battery of sexual inventories and questionnaires are completed. Twenty-seven subjects underwent pretreatment penile plethysmography to assess arousal to deviant sexual stimuli. Two subjects objected to plethysmography on religious grounds and so did not have this pretreatment assessment. Data from the pretreatment and six-month follow-up plethysmography evaluations will be presented in a subsequent communication.⁵²

For patients diagnosed with a primary paraphilia by the evaluating psychiatrist, a decision whether to recommend MPA treatment is made. A paraphilia diagnosis is the major clinical indication for MPA use. Psychiatric judgment involving diverse clinical elements, including intensity of sex drive and capacity for impulse control; denial, lack of empathy, and commitment to treatment and compliance also played a significant role in the decision to recommend MPA treatment.

Pretreatment Evaluation After informed consent for this treatment, a pre-MPA medical and laboratory work-up is initiated. This pretreatment evaluation involves a complete physical examination, five-hour glucose tolerance test, urinalysis, electrocardiogram, chest x-ray, rapid plasma reagin test (RPR), serum testosterone level, complete blood count, and blood chemistries including liver enzymes, cholesterol, and triglyceride levels. If necessary, subjects are referred for a comprehensive medical evaluation that includes diagnostic testing (one subject was referred for a computed tomography brain scan and another for an electroencephalogram).

Treatment Monitoring Follow-up included monitoring of testosterone levels, blood glucose, and liver enzymes, usually at three-month intervals during treatment. Blood pressure and weight were measured monthly. Subjects were asked questions regarding possible medication-related side effects, alcohol use, and non-drug-related medical problems weekly. Questions regarding sexual activity will be described in "Procedure" below.

Procedure All but one subject received MPA intramuscular injections weekly. One subject received an injection every other week. Treatment with MPA was usually begun at 300 mg per week (modal dose for 18 of 29; range, 300 to 900 mg) intramuscularly in the deltoid or gluteal muscles. Higher doses (more than 400 to 500 mg) may be given in two or three weekly divided doses, especially if at the beginning of treatment there was evidence of heightened intensity of sex drive or poor impulse control. Mean weekly doses averaged 547 ± 238 (SD) mg per week (range, 148 to 1009 mg/week). The Upjohn Company provided medication and covered the costs of some of the laboratory tests (e.g., testosterone and lipid levels).

Twenty-six subjects also participated in group therapy, which focused on cognitive distortions, minimization, denial, lack of empathy, sex education, and self-awareness. Three subjects were not in group therapy: one Spanish-speaking subject did not speak English well; one subject had hearing problems and a trial of therapy was unsuccessful; and one subject lived too far from the treatment center

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(and ultimately transferred to a program in another state).

Subjects completed a weekly psychosexual inventory to assess the presence and extent of deviant and nondeviant sexual activities. This inventory surveys five areas: (1) sexual thoughts/fantasies, (2) erections and (3) masturbation to deviant and nondeviant stimuli, (4) urges to engage in sexual activities, and (5) engagement in deviant and nondeviant sexual behavior. The data from the psychosexual inventory comprise some of the major outcome variables for this communication. Although subjects were asked to quantify their weekly activities, because of potential recall biases in remembering specific numbers (subject logs were not required), these data were coded as present or absent. The criterion for improvement was a complete suppression of all deviant thoughts and behaviors. We defined "complete suppression" in sexual activity as the subject giving no further report of sexual activities on a given dimension for the remainder of the six months of the study. For example, if a subject reports absence of sexual activity the first four weeks of treatment and then reports an activity during week 5, followed by absence of sexual activity on the same dimension for the remainder of the study, this person would be coded "6" (i.e., week 6). This conservative categorical estimate of deviant behavior was adopted because of the tendency of these subjects to either exaggerate or minimize problems and symptoms.^{47-49, 51, 53} Six subjects missed at least one week of treatment, and, for these subjects, the self-report rating for the subsequent week was used.

Recidivism was defined as either (1) an arrest for a sexual offense committed subsequent to starting treatment or (2) a self-report made to a member of the treatment team that the patient was reoffending.

Data Analyses Data were analyzed using SPSS/PC+ software (version 4.01).⁵⁴ Categorical data were analyzed with non-parametric tests. To determine the effect of MPA on self-reports of deviant and nondeviant sexual activities, we calculated the number of weeks for subjects to report a complete suppression in each of the five areas of sexual activities. From this tabulation, a median score was calculated for each variable separately for both self-reported deviant and self-reported nondeviant sexual activities. The number of weeks from the start of treatment until the cessation of deviant and nondeviant sexual activities were analyzed with the Wilcoxon matched-pairs, signed-ranks test because they were nonnormally distributed data. Repeated-measures ANOVA was used for examining continuous variables measured on several occasions, including testosterone levels, blood pressure, and weight. Significant differences were tested further with *post hoc* paired *t* tests.

Results

Subject Demographics and Offense Characteristics The 29 men who comprised the current sample ranged in age from 18 to 77 years (38.5 ± 15.5 [1 SD]). Of the 29 men, 16 were single, 8 were married, and 5 were divorced or separated. Ethnic distribution includes 25 Caucasians, 2 African-Americans, and 2 Hispanics. Eighteen were employed at the

time of their evaluation. Educationally, all but four had at least a four-year high school education, and nine had at least 16 years of formal education. Only one had less than a grammar-school education (third grade); data were missing for four. The Shipley Institute of Living Scale IQ estimate⁵⁵ was 107.2 ± 16.2 (range, 80 to 132; $N = 22$), consistent with published data for normal control subjects (114 ± 9.1 , range, 87 to 131).⁵⁶ Five subjects had Shipley IQ estimates of 80 to 86.

Subjects were referred primarily through the legal system; 18 were court-ordered, and four were pretrial. Seven voluntarily initiated evaluation for treatment. Of the 29, 15 had been arrested previously, 11 for sex-related offenses, two for nonsexual offenses, and two for both. Of the 29 men, 23 admitted to the current allegations, whereas six denied the allegations. When they were in treatment, 52 percent ($N = 15$) admitted to having a problem and 48 percent ($N = 14$) denied having any sexual behavior disorder.

All 29 subjects in this sample were diagnosed with paraphilic disorders. The primary deviant behavior in which subjects engaged is described in Table 1. Seventy-six percent of the sample ($N = 22$) were primarily child molesters. Four of the child molesters were exclusively incestuous. Twenty-one percent ($N = 6$) of the subjects engaged primarily in exhibitionism, and one subject's primary deviant behavior was frottage. Twelve subjects had a reported history of multiple deviant sexual behaviors.

The median number of victims admitted by the 22 men whose primary offense was child molestation was 13 (range, 1

Table 1
Primary Paraphilic Behavior (N = 29)

Behavior	N (percent)
Child molestation	22 (76%)
Non-incest	18
Same sex	14
Opposite sex	1
Mixed	3
Incest	4
Same sex	1
Opposite sex	3
Exhibitionism	6 (21%)
Frottage	1 (3%)

to 200), and the median age of their youngest victim was 9 years (range, 2 to 16). Table 2 shows the distribution of the number of victims reported by the child molesters. The age range distributions of the youngest victims of these 22 subjects are presented in Table 3.

As expected by the nature of the behavior, subjects who primarily engaged in exhibitionism had the largest number of victims; all six reported at least 100 (also, they all admitted to the charges against them). The subject whose primary deviant behavior was frottage reported 25 victims. Three of the exhibitionists reported the age of their youngest victim to be at least 16 years old and three reported that their youngest victims were 7 to 10 years old.

Table 2
Number of Victims for Child Molesters (N = 22)

Number of Victims	N
1	2
2-5	5
6-10	2
11-20	6
21-50	3
51-100	2
>100	2

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Table 3
Age of Youngest Victim for Child Molesters
(N = 22)

Age (years)	N
2-5	6
6-9	8
10-13	6
14-16	2

Treatment Response—Effectiveness.
Testosterone Level Baseline testosterone levels averaged 4.61 ± 2.11 ng per milliliter (range, 2.02 to 10.5 ng/ml; normal = 3 to 12 ng/ml). Interestingly, six had baseline levels of less than 3 ng per milliliter. Adequate suppression was evident at three and six month follow-up ($0.31 \pm$

0.24 ng/ml and 0.29 ± 0.26 ng/ml, respectively). All levels were suppressed below 1.00 ng per milliliter at three months. Only two subjects had levels exceeding 0.50 ng per milliliter at three months, and none at six months. This drop was highly significant ($F = 39.15$; $df = 2, 21$; $p < .0005$), and primarily was accounted for by the change from pre-treatment to three months ($t = 10.96$; $df = 27$; $p < .0005$) (month 3 versus month 6: $t = 1.91$; $df = 22$; $p = .07$).

Self-reported Sexual Activities To test for differences in the median number of weeks until complete suppression of self-reports of deviant versus nondeviant sex-

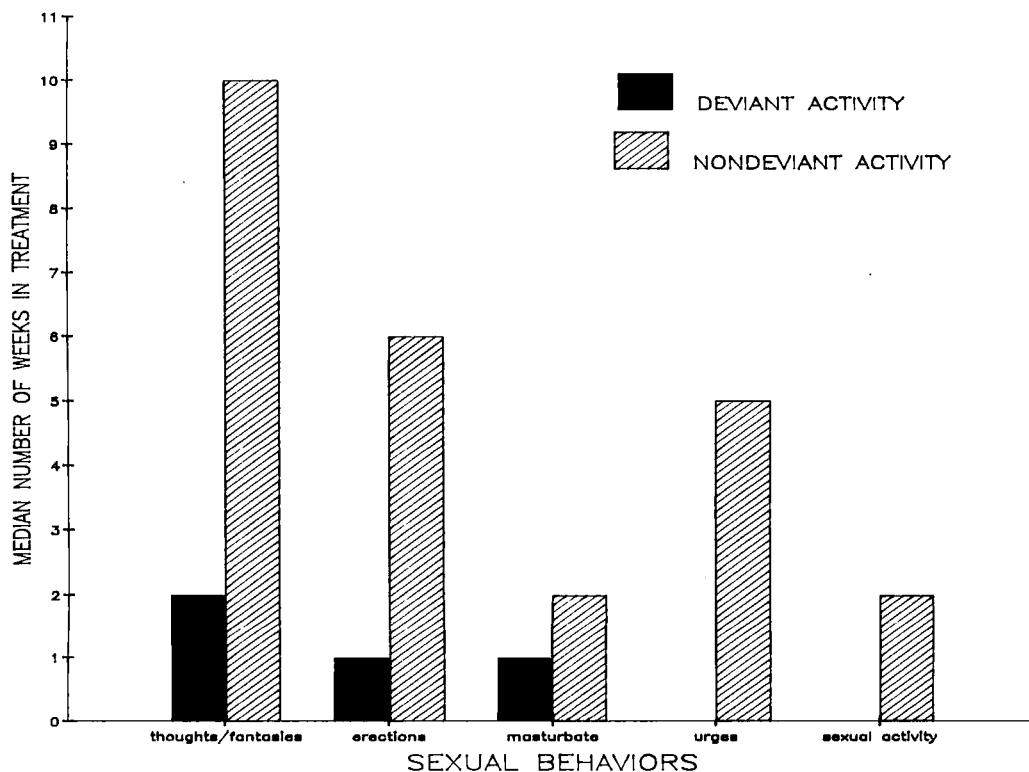


Figure 1. Median number of weeks in treatment before total reduction in self-report of deviant and nondeviant sexual activities. Solid bars = deviant activity; hatched bars = nondeviant activity. Thoughts and fantasies: deviant = 2, nondeviant = 10; erections: deviant = 1, nondeviant = 6; masturbation: deviant = 1, nondeviant = 2; urges: deviant = 0, nondeviant = 5; engaged in sexual activity: deviant = 0, nondeviant = 2.

ual activities, we conducted a Wilcoxon matched-pairs signed-ranks test for each of the five sexual activity variables. The results in Figure 1 indicate that subjects reported a significantly shorter period of time before experiencing complete suppression in deviant sexual activities than nondeviant sexual activities for all five variables, which included thoughts and fantasies ($Z = 2.47, p < .01$); erection ($Z = 3.05, p < .003$); masturbation ($Z = 3.42, p < .001$); urges ($Z = 3.44, p < .001$); and engagement in sexual activities, ($Z = 3.27, p < .002$).

The results shown in Figure 1 indicate that it took a median time of two weeks for subjects to report complete suppression in deviant sexual thoughts and fantasies and a median time of one week to report a complete suppression in self-report of erection to deviant sexual activities. It took a median of one week of treatment for subjects to report a complete suppression in masturbation to deviant sexual activities. Sixteen subjects reported they had no urges to engage in deviant sexual activity the week before treatment or during treatment and therefore had a median score of zero weeks. Eighteen subjects reported they did not engage in deviant sexual activity the week before beginning treatment or during treatment, and therefore had a median score of zero weeks.

In contrast, subjects reported a higher median number of weeks before complete suppression in nondeviant sexual activities. Subjects reported a median of 10 weeks before total suppression in nondeviant sexual thoughts and fantasies and a median of six weeks before complete suppression of erection to nondeviant sexual

activities. Subjects reported a complete suppression of masturbation to nondeviant sexual activities after two weeks and a median of five weeks before complete suppression of urges to engage in nondeviant sexual activity. It took a median of two weeks for subjects to report a complete suppression in engagement in nondeviant sexual activities.

Six-Month Outcome An important measure of outcome for these subjects is relapse while in treatment. Consistent with their self-reports of reduced sexual urges and behavior, only one subject, an exhibitionist, admitted to recidivistic behavior during the first six months of treatment. No subjects were rearrested for new offenses during this period.

Seven subjects did not complete six months of MPA treatment. Two subjects were incarcerated on charges predating entry into the treatment program. One subject transferred to another program out of state. One subject was hospitalized for pulmonary emboli and was withdrawn from the MPA program. One subject improved and was tapered off MPA while continuing to be monitored; he did not relapse during these six months. One subject's treatment was interrupted by hepatitis unrelated to MPA treatment; he later resumed treatment. One subject continued on MPA but had not been in the program for six months.

Treatment Response—Safety The most commonly reported side effects were muscle cramps ($N = 12$), weight gain and headaches ($N = 10$ each), fatigue ($N = 7$), lethargy ($N = 1$), drowsiness ($N = 5$), and sleepiness ($N = 3$). Four subjects reported depression, anxi-

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ety, and/or irritability. Genital symptoms (burning at the tip of the penis with masturbation/ejaculation, testicular pain, impotence, and diminished heterosexual function) also were experienced by four subjects. Most side effects did not persist.

Average weight gain was statistically ($F = 10.92, df = 2, 19, p = .001$), but not clinically, significant (baseline = 189.5 ± 27.8 pounds; three months = 192.0 ± 30.7 pounds; six months = 194.3 ± 31.4 pounds). All *post hoc* paired *t* tests were significant at the $p < .02$ level. Blood pressure changes (baseline = $132 (\pm 16)/85 (\pm 10)$; three months = $138 (\pm 18)/85 (\pm 11)$; six months = $134 (\pm 16)/81 (\pm 10)$), although statistically significant ($F = 4.05, df = 4, 19, p = .015$), generally were not clinically significant.

The most serious medical event observed during this six-month treatment period was the development of pulmonary emboli in one subject. His history of leg phlebothrombosis was not deemed an absolute contraindication to initiating treatment, and the potential benefits of treatment were considered as outweighing the potential risks. Because he had a past history of phlebothrombosis, it could not be determined with certainty that MPA was directly related to this event. However, because pulmonary emboli can potentially cause death, MPA treatment was not resumed postrecovery.

One subject developed viral hepatitis after one month of treatment and was taken off MPA. (This infection occurred during incarceration and was not related to MPA administration.) MPA treatment was resumed after his liver function tests

normalized, and he had no further hepatic dysfunction.

One subject fathered a healthy child while on treatment, despite being cautioned not to risk impregnating his wife while he was on MPA. Communication with The Upjohn Company regarding the question of conception during MPA treatment revealed that only a single report in their worldwide voluntary medical event database (spontaneous reporting system) specified that the patient receiving MPA was male, and a normal child was delivered by cesarean section (personal communication, The Upjohn Company, June 6, 1990).

Other medications in addition to ongoing MPA treatment, and which may have been temporally related to its use, include antihypertensive treatment (two subjects), antidepressants (three subjects), and a quinine preparation to suppress leg cramps, which were believed to be side effects of MPA (two subjects).

Discussion

In this study we described a comprehensive assessment protocol for treatment with MPA and analyzed the influence of MPA on testosterone level and self-reported sexual activity for 29 treated male paraphilic patients. The data show that subjects treated with MPA report both lowering of sex drive and greater control over deviant sexual impulses and behavior during the first six months of treatment. To a lesser extent, self-reporting of nondeviant sexual activity also was reduced. The effect was rather immediate, and adequate hormonal (testosterone) suppression was reliably achieved. Our results are consis-

tent with previous research indicating that testosterone levels and self-reporting of deviant sexual activity are dramatically reduced in a short period of time.^{28, 29}

These results would seem to suggest that MPA, as part of a multimodal therapeutic approach to paraphilic patients, may quickly suppress and prevent the recurrence/recrudescence of sexually deviant behavioral activity. But it is not clear from the current data whether the lowering of self-reported sexual thoughts and activities was due to the physiologic effects of MPA, the psychotherapy, other factors not directly related to treatment, or a combination of these possibilities. For these and a number of other reasons to be discussed, the data should be interpreted with caution.

First, the medication trial was conducted open label. Controlled, double-blind studies involving MPA-treated and untreated subject groups have not been done because of the medicolegal and ethical concerns regarding the withholding of safe and effective treatment from persons with these paraphilias.^{17, 57} Kiersch⁴⁵ conducted a double-blind within-subjects trial in which eight subjects, each serving as his own control, received MPA or sterile saline in four alternating blocks of 16 weeks over a 64-week period. Unexpectedly, favorable results were obtained with both injected substances. MPA and placebo both were associated with self-reported decrements in deviant fantasies, but the subjects' reports were not substantiated consistently by penile plethysmography responses.

Second, subjects seemed to improve almost too rapidly to attribute the response

to the medication effect. Also, MPA has been reported to produce nondifferential effects on sexual behaviors,¹⁸ diminishing both deviant and nondeviant thoughts, fantasies, drives, and activities. We found differences in the median time until full reduction of self-reported deviant and nondeviant sexual thoughts and activities. Our results indicated that deviant sexual activities were totally reduced in a short period of time, zero to two weeks. In contrast, nondeviant sexual activities took 2 to 10 weeks before being reported as totally reduced. Kafka and Prentky⁵⁸ found a similar differential effect on "conventional" versus "nonconventional" sexual behaviors during treatment with a serotonin reuptake inhibiting drug.

A third reason for interpreting our results with caution is that, because the MPA therapy and group therapy were offered concurrently, it is not possible to distinguish medication from psychotherapy effects nor to determine the unique contribution from either treatment. This initial decrement in self-reported deviant and nondeviant sexual activity may have been related, at least in part, to psychotherapeutic intervention and social acceptability. In therapy, deviant sexual activities were discouraged, whereas nondeviant sexual activities were given positive reinforcement. Also, just being in treatment and being monitored can have an inhibiting effect on acting-out behavior. Hence, the subsequent lowering of deviant sexual drives and activities may be due to a supportive environment and group therapy effects.

An alternative explanation is that, although these deviant behaviors and

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thoughts remained suppressed throughout treatment, serious consideration should be given to the possibility of distortion in self-reports of deviant and nondeviant sexual activities. In fact, reliance on these subjects' self-reports of the impact of treatment on their behavior is a limitation of this study design. Sex offenders are known to deny and minimize problems and psychopathology.^{47-49, 51, 53} Subjects may have learned in therapy which questionnaire responses would bring the least difficulty to their sessions. Hence, subjects could have deliberately lied about sexual activities. A learned response pattern cannot be ruled out as having influenced self-reports of decreased sexual activities. Answering in a socially desirable manner would make it easier for patients to avoid dealing with their problems with their therapists or with themselves. Therefore, the validity of self-reports may be questioned. Including collateral information from significant others, parole officers, etc., would strengthen the validity of our findings. Penile plethysmography may be a useful objective measurement for validating self-reports.^{52, 59}

Fourth, although MPA may help decrease initial relapse rates, our data do not address its long-term effectiveness. Our six-month recidivism rate was quite low. Recidivism (but not rearrest) was observed in one subject in the first six months of treatment. Meyer *et al.*⁵⁷ reported (based on self-admission and arrest records) a 13 percent reoffense rate among 23 treated pedophiles and a 20 percent reoffense rate among 10 treated exhibitionists. However, they did not clarify when in the course of treat-

ment these reoffenses occurred. Nevertheless, six months is not a sufficient period of time to adequately assess long-term recidivism.^{11, 12} Long-term follow-up extending at least a decade, with monitoring of both treated and untreated offenders, has been recommended because of the extremely low reporting rate for sex offenses and the lifelong potential for reoffense.^{11, 12}

Another factor may contribute to our low recidivism rate. A large percentage of subjects were referred into treatment through the criminal justice system because of child molestation. The mandatory reporting law requires that a reoffense is reported; not to do so would be in violation of this law. Because this report can have serious ramifications, including revocation of parole and/or incarceration, subjects may be reluctant to report recidivism. This also may explain, at least in part, why many subjects reported no deviant thoughts or behaviors before treatment was implemented.

Although not a major problem in the first six months of our treatment assessment, a high percentage of patients discontinued MPA.^{17, 27, 46} Preventing attrition is the clinician's challenge. Treatment may be terminated because of MPA-related side effects, the inconvenience of intramuscular injections, or other factors associated with recidivism. Although the optimal MPA dose has not been established,⁶⁰ the clinician must titrate the dose to achieve a balance between side effects serious enough to lead to discontinuance and successful reduction in urges to commit deviant behavior. The higher initial doses usually must be continued for at

least six months; indefinite use may be necessary.^{1, 46, 60} Therefore, clinicians must be cautioned to continue monitoring for side effects during MPA treatment.

Our low treatment drop-out rate also may be due in part to our selection process. Expressed commitment to treatment and the expectation for compliance were important considerations in accepting patients into our program. Also, for patients on probation, the risk for legal sanctions may have enhanced compliance. In addition, although MPA and some of the laboratory testing were available at no cost, some suitable candidates who could not afford the cost of the required therapy sessions and other laboratory tests were excluded from treatment.

Overall, MPA was well tolerated by our subjects. Although no major adverse effects could be directly attributed to MPA during the first six months of treatment, one person developed pulmonary emboli. Because pulmonary emboli can have grave consequences, the risk for this infrequent adverse event should always be considered. Reversible side effects similar to those found in previous MPA research were observed in the present study.^{18, 27, 29, 60} The most common of these side effects were leg muscle cramps, headache, fatigue and drowsiness, and weight gain. Blood pressure changes also were observed. Most side effects did not persist.

One subject fathered a normal child while receiving MPA. Meyer *et al.*⁶¹ reported on three pregnancies in wives of their sex offender subjects. Two underwent elective abortion and the third delivered a normal female infant. None resulted in chromosome abnormalities; all

three fetuses had XX karyotype with normal banding. Although we are aware of no published data showing that chromosomal abnormalities result from high MPA doses given to men over prolonged periods, patients should be counseled not to father children while on this drug.

Other side effects to be aware of include nausea, insomnia, loss of body hair, hot and cold flashes, depression, nervousness, and changes in quality and frequency of ejaculation. Medical disorders such as epilepsy, asthma, migraines, and cardiac impairment have been reported to be exacerbated by MPA.¹ Glucose intolerance, cholelithiasis, and elevated blood pressure (which is not necessarily related to weight gain) may develop.⁶¹ More serious but rare side effects include pulmonary emboli, which can cause death. Previously cited relative medical contraindications to the use of MPA include the presence of a disease affecting testosterone production, such as renal failure, cirrhosis, protein malnutrition, hypothalamic-pituitary dysfunction, and cancer chemotherapy.¹

Finally, Meyer *et al.*⁶¹ have recommended additional measurements, including penile length and testicular volume, sperm analysis, luteinizing hormone and follicle-stimulating hormone levels, ultrasound of the gall bladder, and monitoring of MPA levels. Except for the ultrasound,⁶² these tests may provide data of more theoretical relevance relating to MPA's effect on sexual behavior and function. Our protocol has permitted us to effectively work-up and monitor the patients in our SBC program, and the yield from these additional tests would not likely offset the extra cost.

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Although psychotherapy and MPA together may be an effective combination for lowering deviant sexual drive, future controlled trials (although difficult to conduct) are required to distinguish the unique therapeutic benefits of MPA and psychotherapy in the treatment of paraphilic disorders. Future study should address issues such as the relationship of testosterone suppression to behavioral change and reliable measurement/assessment of behavioral change in deviant thoughts, fantasies, and urges. Multiple types of outcome measures should be assessed longitudinally, including self-reported, psychophysiological, and hormonal data.

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