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INSIDE

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Naltrexone in the Treatment of Alcohol Dependence and Craving for Alcohol

Donald R. Wesson, MD

An addiction medicine specialist would have had to be on another planet not to know that the FDA recently approved naltrexone for the treatment of alcohol dependence. The media hype and the clamoring of patients to get the "new cure" have been phenomenal. The background and a thoughtful analysis of some of the issues raised by the clinical availability of naltrexone for treatment of alcohol dependence have been slower in coming. This article provides some of the background and focuses on one of the current "hot" issues of interest to clinicians: whether the effectiveness is the same in the abstinent person as it is in the person who continues to drink.

On December 30, 1994, the Food and Drug Administration approved DuPont Merck's New Drug Application to add alcohol dependence as an indication for naltrexone. The trade name of naltrexone (Trexan) was changed to ReVia (pronounced rehVEE uh) to prevent possible confusion with Tranxene, a benzodiazepine made by Abbott Laboratories. ReVia is manufactured by the DuPont Merck Pharmaceutical Company and marketed by DuPont Pharma, which has marketed Trexan since 1984. (DuPont Merck is a partnership formed in 1991 between the DuPont Pharmaceutical Company and Merck and Company. DuPont Pharma is a separate company which conducts the sales and marketing functions.)

On January 17, 1995, DuPont Merck launched ReVia with a press conference at the Hotel Macklowe in New York. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) also listed a press release for the same date. Many of the subsequent popular media reports were based, in some part, on the press releases of DuPont Merck and NIAAA.

The efficacy of naltrexone in treatment of alcohol dependence is supported by two NIAAA-funded clinical studies (Volpicelli et al 1992; O'Malley et al 1992). Supplemental safety data were available from a three-month, open-label "usage," or "label validation," study sponsored by DuPont Merck.The study involved 570 subjects treated with naltrexone and 295 subjects, in a non-randomized reference group, who did not receive naltrexone. In the primary study protocol, subjects were treated with naltrexone for up to three months. Under two sequential extension protocols (the first for three months and the second for six months), some subjects could continue taking naltrexone for up to one year. Some subjects are still participating in the extension proto-

cols. The results of the label validation study have not yet been published. The NIAAA press release indicated that NIAAA is supporting nine additional clinical trials to determine the "patient type, dose, therapy combinations, and treatment duration with which naltrexone works best."

Much of today's media focus has been on naltrexone's effect on alcohol craving, leading some patients who are taking disulfiram (Antabuse) to want to take naltrexone also because they believe from what they have read in the media that naltrexone will decrease their craving for alcohol. Therefore, it is important to know whether or not naltrexone decreases craving in patients *who are alcohol abstinent*. It is instructive to compare what was reported on this question in the two published studies (O'Malley 1992; Volpicelli 1992) and what was claimed in the press releases of DuPont and NIAAA.

From the NIAAA Media Advisory:[1]

> Naltrexone appears to reduce craving in abstinent patients and block the reinforcing effects of alcohol in patients who drink. The latter effect lessens the likelihood that patients who drink a small amount of alcohol will return to heavy drinking. NIAAA is continuing neuroscience research to delineate the specific brain mechanisms involved in the reward and reinforcement associated with alcohol. (NIAAA, p. 2)

From the DuPont press releases:[2]

> "Alcoholism treatment specialists now have a novel medical approach available that significantly increases abstinence rates and seems to reduce alcohol craving when used as part of a comprehensive treatment program," said Joseph R. Volpicelli, MD, PhD, assistant professor of psychiatry and director of the Penn/VA Treatment Research Center at the University of Pennsylvania. (DuPont, p. 1)
>
> . . . patients in comprehensive treatment programs who were treated with naltrexone reported a decrease in craving. (DuPont, p. 2)
>
> Research indicates that brain chemistry may play a part in craving and impaired control over drinking. Alcohol's effects on behavior are the consequences of its interactions with brain neurotransmitter systems. Among neurotransmitters believed to play a role in drinking behavior are dopamine, serotonin, gamma-aminobutyric acid (or GABA) and opioids.
>
> "Changes in the activity of these four neurotransmitters may be responsible for the hallmark features of alcohol dependence, including craving for alcohol in its absence," said Richard K. Fuller, MD, Director of the Division of Clinical and Prevention Research, NIAAA. (DuPont, p. 4)

The press was supplied with the above authoritative conclusions. While it appears that the studies showed an overall statistically significant decrease in craving between treatment placebo and naltrexone-treated subjects, it does not necessarily follow that naltrexone reduces craving *among abstinent alcoholics*. Alcohol use was higher in the placebo treatment subjects. For an alcoholic, alcohol use itself may be a potent stimulus for craving, a point acknowledged in the report by Volpicelli et al., 1992. "Naltrexone may help break the vicious cycle where one drink stimulates the desire for the next." (p. 880)

What do the available data actually show? The data from the study by Volpicelli et al. are easier to analyze because the design was a straightforward two group, randomized trial. (The study by O'Malley et al. is not as easy to analyze because they compared two different forms of psychotherapy in addition to placebo and naltrexone.) An understanding requires a knowledge of how craving was measured and how the data were analyzed.

Volpicelli et al. describe their craving measure as follows. "Craving for alcohol was assessed simply by asking subjects to rate their craving from 0 to 9, where 0 was equivalent to no craving and 9 was craving so severe that the subject was unable to resist a drink if it was available." (p. 877) The time frame was not specified. They analyzed craving using "endpoint analysis techniques," i.e., "the status of the dependent variable at either week 12 or at the last data point." There was a difference in baseline craving scores between the naltrexone and placebo treatment groups; therefore, an analysis of covariance was conducted using baseline craving scores as a covariate. Mean craving during the 12 weeks of the study was significantly lower for the naltrexone treatment group.

The paper did not report the relevant comparison: the mean craving scores in subjects while they were abstinent vs. the mean craving scores in subjects who were drinking. The focus on overall group differences does not fully address the question of whether or not naltrexone reduces craving in abstinent alcoholics. There is some suggestion in their data that naltrexone may reduce craving. Twenty (57%) of the placebo-treated patients sampled alcohol, whereas 16 (46%) of the naltrexone-treatment patients sampled alcohol. While patients may "sample" alcohol for reasons other than craving (e.g., curiosity about whether the medication works), the trend is at least in the right direction.

Conclusion

The NIAAA Media Advisory notwithstanding, the published studies do not clearly support the assertion that naltrexone reduces craving for alcohol among abstinent alcoholics. It well may do so, but the fact cannot be established by the two pivotal studies. While the overstatement of naltrexone's curative powers in the popular press can be traced in part to the NIAAA press release and in part to the creativity of the press, the two studies do provide strong evidence that naltrexone exerts a pharmacological effect that somehow decreases relapse to alcohol abuse among abstinent alcoholics. □

Notes and Reference List

1. NIAAA Media Advisory, "Naltrexone approved for alcoholism treatment," January 17, 1995.

2. DuPont Press Release, "DuPont Merck introduces a new medication for the treatment of alcohol dependence," January 17, 1995.

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Naltrexone in the Treatment of Alcohol Dependence: Frequently Asked Questions

Q: Can patients with elevated liver function tests be treated with naltrexone?

A: Many patients who have been drinking heavily have elevations of SGOT (AST), several times the upper limit of normal. If the elevation of liver function is the result of heavy alcohol consumption, the tests will usually return to normal after several weeks. Such patients can be begun on naltrexone after alcohol detoxification is complete. Liver tests should be repeated every few weeks. If they are returning toward normal, naltrexone can be continued. If the liver function values increase, naltrexone should be stopped.

Q: Can an alcoholic patient who is taking codeine or other opiate analgesia regularly for chronic pain be started on naltrexone?

A: Naltrexone is a potent opiate antagonist and blocks the analgesic effects of all opiates. In addition, naltrexone could precipitate opiate withdrawal in patients who had developed dependence to the opiate in their body. The patient should be off all opiates for 7-10 days before beginning naltrexone.

Q: If a patient were injured while taking naltrexone, wouldn't the effect of opiate analgesics be blocked?

A: For 24-48 hours after the last 50 mg dose of naltrexone, usual doses of opiate analgesics would probably not provide adequate pain relief. With injuries to the arms and legs, a nerve block could be used to provide pain relief. For injuries to the face, chest and abdomen, every effort should be made to provide pain relief without opiates, e.g., intravenous ketorolac tromethamine (Toradol). As a last resort, the patient could be given doses of opiates incrementally until enough has been given to override the blocking effect of the naltrexone while being closely monitored in an intensive care unit. □

— DRW

The Efficacy Studies

A review of the efficacy studies by O'Malley and Volpicelli appeared in a previous issue, along with a bibliography of 25 references. The following is quoted from "Naltrexone Treatment of Alcohol Dependence," CSAM NEWS, Spring 1993, Vol 20, No 1.

The first study was conducted by Joseph Volpicelli. Seventy newly admitted alcohol dependent men receiving outpatient rehabilitation treatment at the Substance Abuse Treatment Unit of the Philadelphia Veterans Affairs Medical Center were subjects in the study. For the first week, all subjects received placebo. They were then randomly assigned to receive either naltrexone 50 mg/day or identical-appearing placebo tablets. Subjects self-administered their medication for 12 weeks. The men treated with naltrexone reported significantly less craving for alcohol and significantly fewer relapsed. (The investigators defined relapse as reporting drinking on 5 or more days within 1 week, reporting 5 or more drinks per drinking occasion, or coming to the treatment appointment with a blood alcohol concentration above 100 mg/dl.) Twenty-three percent of the naltrexone subjects relapsed compared to 54 percent of the placebo-treated subjects (Volpicelli et al. 1992).

In the second study, conducted at the outpatient Alcohol Treatment Unit of the Connecticut Mental Health Center in New Haven, 97 subjects who met DSM-III-R criteria for alcohol dependence and who had at least 7 days of abstinence were randomly assigned to either naltrexone 50 mg/day or placebo. Subjects in this double-blind study were given the doses for 12 weeks and were randomly assigned to either coping skill therapy or supportive therapy. Relapse was defined for men as drinking 5 or more drinks on an occasion and for women as drinking 4 or more drinks. Almost all the subjects on placebo in both the skill training and supportive therapy relapsed compared to 34% of the subjects in the naltrexone/support therapy group and 43% in the naltrexone/coping skills group (O'Malley et al. 1992).

Evaluating Adolescent Substance Abuse Treatment Programs

Arthur Bolter, MD, FAAP, FASM

When parents consult with the addiction medicine specialist regarding substance abuse in their children, it is important for the specialist to be familiar with adolescent treatment programs in the area and to evaluate them carefully before making referrals.

The critical components of a good program include evaluation, treatment and aftercare.

Evaluation

When an adolescent is referred to a treatment program, the evaluation should assess the extent of the drug use and differentiate between substance abuse and dependence. Ideally the program will have different levels of care so initial treatment can take place in an inpatient or outpatient setting, depending on the outcome of a careful evaluation. If an adolescent continues to use drugs despite serious adverse consequences, he or she must be treated initially as an inpatient. If, however, the young person is using drugs experimentally, an outpatient program can be appropriate. The length of time as an inpatient should be individualized depending upon the availability of several levels of acuity, i.e., inpatient, day treatment and varying types of outpatient groups.

An adolescent treatment program should be highly structured. There should be little free time available.

In a good program, an Addiction Medicine specialist experienced in the treatment of adolescents will be available for consultation. This physician should make the final decision as to the level of care appropriate for each patient. A complete history and physical examination should be done on admission and necessary laboratory work should be readily available. Any ongoing medical problems can be addressed at this time.

There should be an educational evaluation, as well, and it should be conducted by the appropriate experts. The evaluation should assess the level of educational achievement and the presence or absence of any learning problems. The elements of the treatment program can then be individualized to the academic level of the patient. In addition, a psychological screening should be done to evaluate for any psychosis and/or Attention Deficit Disorder with or without hyperactivity.

An assessment focused on the strengths and weaknesses of the family can help determine how much, if any, family therapy is indicated. Also, an evaluation of the drug and alcohol use by the parents or other household members should be done to help in discharge planning. Other living arrangements may be recommended if there is continued use of drugs and/or alcohol in the family.

Treatment

It is essential that an adolescent chemical dependency treatment program be highly structured. There should be little free time available. The program must have either an inhouse school or a school program provided by the local school district. The school program should be set up to provide ongoing school credits approved by the local school district. There should be a consistent recreation program in order to provide maintenance of good physical fitness.

The chemical dependency portion of the program should include drug education, process groups and 12-Step study groups and presentations. It is important to remember that when an adolescent gets involved in substance abuse, he or she slows down or stops his or her emotional development. Careful attention should be paid to developing the necessary social skills to cope with abstinence as a lifestyle. Relapse prevention must be a major element in treatment as the adolescent will have to return to his or her using environment (usually school). There must be education about perils and pitfalls of risk-taking behavior. AIDS and STD prevention should be thoroughly discussed. It is sometimes helpful to have separate male and female groups to discuss these issues.

In a good quality program there will be levels of status or privilege, and patients will be rewarded with increased privileges as they progress through treatment. Giving different levels of privileges in return for certain levels of accomplishment is a behavioral modification approach with proven efficacy.

An adolescent involved in substance abuse slows down or stops his or her emotional development. Treatment programs should pay careful attention to developing the necessary social skills to cope with abstinence as a lifestyle.

It is my feeling that a good quality adolescent substance abuse treatment program should be smoke-free. Too often smoking privileges are given as a reward in the behavioral modification program. It is certainly hypocritical to

allow the use of a serious addictive substance in a drug treatment program.

Aftercare

The aftercare program is crucial to maintenance of a clean and sober lifestyle. Slips and relapses are common and must be used as learning experiences. They do not necessarily indicate a need for inpatient treatment. The longer the patient maintains contact with the program through aftercare, the more solid his or her recovery becomes.

A good aftercare program will involve the family in both individual and multi-family sessions for approximately six to eight weeks. The number of visits can gradually decrease as the family learns to cope with the behavior of the adolescent. Careful attention must be paid to whether there is use of alcohol and/or other chemicals by family members and if so, what impact it has on the adolescent.

Close coordination must be maintained between the program and the school.

Relapse prevention must be a major element in treatment as the adolescent will have to return to his or her using environment (usually school).

In my experience, an independent study program is not appropriate for an adolescent returning from an inpatient program because it allows too much unstructured time and can set off relapse.

If the program has been operating for enough time to have graduated a significant number of young people, there should be a group of recovering teens that can act as a support system for the returning individual.

Table 1: American Academy of Pediatrics Guidelines for Selecting an Adolescent Treatment Program

- ☐ Does the program require that the patient become totally abstinent?
- ☐ Is the program focused on drug abuse? Are appropriate professionals and therapeutic or educational activities provided?
- ☐ Does the program emphasize the importance of family involvement and family therapy?
- ☐ Does the program emphasize follow-up outpatient care? Does it acknowledge substance abuse as a chronic problem?

American Academy of Pediatrics, 1990. Provisional Committee on Substance Abuse. Selection of substance abuse treatment programs. *Pediatrics*, 86:139-140. Quoted in Comerci, GD, *Principles of Addiction Medicine*. Chevy Chase, MD: ASAM, 1994.

Unfortunately, resources and facilities for adolescent substance abuse treatment are often very limited, particularly for inpatient treatment. However, most communities have some outpatient counseling services available. The American Academy of Pediatrics has suggested guidelines for selecting an adolescent treatment program (see Table 1) which can be used as minimum criteria for selection of a treatment resource. Inpatient treatment may have to be done in a distant community and the patient followed up at a local outpatient counseling center.

It is very important to evaluate adolescent substance abuse treatment programs before referring families for care. I hope that the above described guidelines can be of help in that process. ☐

Reading List

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The Doctor-Patient Relationship and Addiction Medicine

Timmen L. Cermak, MD

In a recent *JAMA* article, "Preserving the Physician-Patient Relationship in the Era of Managed Care," Ezekiel Emanuel and Nancy Dubler raise issues of intense relevance to addiction medicine, but I fear the article missed the heart (or, perhaps, the soul) of the issue.

Their conclusion is unarguable: "The physician-patient relationship is the cornerstone for achieving, maintaining, and improving health. The structure of financing and regulation should be designed to foster and support an ideal relationship between the physician and the patient."

Emanuel and Dubler formulate the fundamental elements of the "ideal physician-patient relationship" in six C's: choice, competence, communication, compassion, continuity and (no) conflict of interest. Trust, which many people would also identify as being an aspect of the ideal physician-patient relationship, is viewed as the culmination of realizing these six elements.

He makes a sharp distinction between the *role* of the physician and the person who attempts to fill that role.

As any reader could predict, managed care is seen as having far greater potential to interfere with each of these six elements than having much potential for improving them. The primary forces described as affecting physician-patient relationships are the environment of competition and financial pressures created by managed care.

An interesting alternative perspective on these authors' "ideal" can be found in Jacob Needleman's book, *The Way of the Physician*. From the point of view of Needleman's ideas, it appears that the core of the physician-patient relationship is missing from Emanuel and Dubler's definition. In essence, these authors have fallen into the managed care view of doctors as "health care providers," while Needleman speaks of "medical virtue" and the capacity of the role of the physician to strengthen the patient's will to become healthy.

Needleman is a philosopher, not a physician — a fact that cuts two ways. On the one hand, he is not self-serving in his recognition of the sacred element in medicine. On the other hand, he can be criticized for his naively romanticised view of doctors. In the end, I find his arguments credible because he makes a sharp distinction between the *role* of the physician and the person who attempts to fill that role. It is the role that is sacred, and we practitioners are called upon to find the humility and humanity that permits the role to envelope and direct both our practice and our lives.

What makes the role of the physician one of the last surviving traces of the sacred in our world? Needleman argues that such profundity arises from the fact that physicians spend a life standing "at the gate of the reality of that one experience which can bring every man and woman in front of the question of Being — namely the experience of death and the mortal body." While we gaze into the mysteries of life and death, we remain steadily focused on how to bring science to the aid of the living. The world wants this of us. Society creates the mantle we wear. As long as we are physicians, we cannot escape that mantle, for it does not belong to us. Try as we might, deliberately or otherwise, to shed that mantle we cannot, for it is not of our own creation.

Needleman views the "role of the physician" as though it were a necessary life form within the strictly human "ecosystem." This means that the role emanates from within the psyche of our patients. It arises in mythological forms (especially in times of crisis) — an archetype which we are uniquely called upon to fulfill for others (and which we share the same need for in our own times of illness).

Once we enter the role of physician, it begins to change us. It brings us experiences and a degree of inner power that we find difficult to understand or appreciate. This power can corrupt us, especially when we believe we have created it. It can overwhelm us, and we may shy away from it. We may deny its reality and denigrate patients who call upon us to exercise it in their behalf.

Once we enter the role of physician, it begins to change us.

The sacred art of medicine bridges two worlds. Physicians care for "the physical body while attending to the inner man!" in Needleman's words. We are both scientists, awestruck at the simultaneous complexity and simplicity of the DNA code, and priests, ministering to those who confront insanity and death. Called on to straddle these two worlds in order to be of practical service to others, we are permanently changed.

The uniqueness of our role does not mean that we are unique as individuals. Needleman is clear that "the qualities of the good physician are inseparable from the qualities that make up the being of a real and authentic human being — namely, impartiality; impersonal love; inner freedom from opinion, fear and tension; and the instinctive sensing of the

manner in which nature actually operates in [both] the body and the mind of man...."

The uniqueness of our role lies in the way we approach people in crisis and permit them to be patients. We sit with them and stare into the face of death, at the same time that we intelligently administer medications, deftly wield knives and thread, and dispassionately speak the truth about what our observations and tests reveal. No longer interchangeable "health care providers," we are descendants from the priests and shamans who gave rise in antiquity to both science and medicine. Our lineage goes back to the Great Physicians who first fixed their gaze on the confluence of the infinite and the finite within each person.

Our patients grant authority to us to focus attention on the truths in their lives, both physical and existential. A person who can bring us to the truth mobilizes our energy and facilitates healing. A person who does this is a healer. When that person is also given permission to touch every part of the

Our addicted patients have lived in two worlds, believing that manipulations on one level (the physical/brain) could achieve lasting changes on the other level (the mind/heart).

body and to minister to it in line with the laws of nature that govern it, that healer is also a physician. We all need a physician.

Our addicted patients have as the unique aspect of their illness a massive experience with the relationship between matter and the mind. They have lived in two worlds, believing that manipulations on one level (the physical/brain) could achieve lasting changes on the other level (the mind/heart). The fact that their manipulations often achieve strikingly accurate *simulations* of the desired changes, at least in a transitory way, leads them to chase harder after the altered state of mind they desire. The additional fact that biochemical systems governing compulsion/craving are activated by their alcohol and other drug usage makes this chase especially difficult to abandon.

The addictionist, with "impartiality; impersonal love; inner freedom from opinion, fear and tension; and the instinctive sensing of the manner in which nature actually operates in [both] the body and mind of man..." alleviates the suffering of withdrawal. We stare with our patients into the mini-deaths of intoxication and speak to the existential side of their experience. We attend to them with concern. We do not judge. We feel a sense of wonder at the miraculous connection between mind and brain that has captivated them for years. Our attention to their suffering evokes a vision of the truth too often obscured by denial.

Our role in healing wounds is to keep them clean (remove denial), open to air (entering into community), to rest and feed the whole of the body well, and to trust in the underlying powers of nature (spirituality) to heal them.

We fix our gaze on the possibilities of sobriety, and, by the authority they grant to us, we evoke in our patients a state of mind consistent with these possibilities. This is spiritual, in the sense that it involves greater connection with the world around the addict. In connecting with that world, they experience what is simultaneously objective and compassionate. In this way, our presence embodies enough recovery to stimulate their sense of awe.

If all of this appears to be a romanticized notion, so be it. Most of what I am describing goes on outside our awareness, just as most of the healing occurring in a laceration goes on outside our awareness, without our direction. Our role in healing wounds is to keep them clean (remove denial), open to air (entering into community), to rest and feed the whole of the body well, and to trust in the underlying powers of nature (spirituality) to heal our wounds.

We should never forget that the ideal physician-patient relationship is sacred. Our patients require it, whether they are aware of this need or not. The sanctity of our role is endowed to it from without, and only our humility at accepting it begins to make us worthy of it.

There will always be a role for the physician, because there will always be a need. The physician-patient relationship remains one of the strongest (and for many people, the very strongest) means available to help the sick. We are more than health care providers. We are physicians. Jacob Needleman reminds us of the difference. □

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CMA Speaks Out on Physicians' Ability to Prescribe Narcotics for Addiction Treatment

In March, the House of Delegates of the California Medical Association voted to support the development of mechanisms by which physicians may prescribe maintenance medications to individuals already known to be addicted to illegal substances and to support development of appropriate safeguards for such prescribing.

The Resolution (#703-95) was prepared by Harvey Rose, MD, and CSAM member John J. McCarthy, MD, both of Sacramento. Doctor McCarthy is Medical Director of Bi-Valley Medical Clinic, a methadone maintenance treatment program. In advocating for the resolution, he pointed out that maintenance medications for treatment of opioid dependence can be used only in programs which are highly regulated by both Federal and State regulation, and that these programs can meet the needs of less than 10% of those who need this treatment. The number of programs is kept small by the restrictive nature of the regulations governing their operation. There are not enough programs or enough "treatment slots" in the existing programs to meet the need. Furthermore, the regulations make the programs "user-unfriendly," in Doctor McCarthy's term. The combination of restrictions often means that the working patient, or the disabled patient, cannot comply and thus cannot take advantage of this treatment modality, even if it is the clinically appropriate match.

Methadone maintenance is one of the modalities studied in the outcome study conducted for the State of California's Department of Alcohol and Drug Programs by the National Opinion Research Center. Findings were that treatment-related ecomonic savings outweighed costs by at least 4 to 1.

FDA's approval of LAAM (levo-alpha-acetylmethadol) for use as an alternative to methadone has the potential to make the restrictions less rigid. Because its effects develop slowly and are prolonged, patients can be successfully maintained with doses of LAAM three times a week, rather than daily. But LAAM will also be available only in highly restricted treatment programs. Physicians will not be able to prescribe it. Doctor McCarthy asserts that access should be broadened to include individual physicians. He said, "Preventing physicians from using the proper medical treatment for narcotic addiction contributes to the spread of AIDS and other infectious diseases among drug users and their sexual partners."

CSAM endorsed the development of additional mechanisms to provide maintenance medications in the treatment of addiction, with the understanding that the mechanisms would be developed to incorporate appropriate safeguards for the patient, the prescriber and the public. □

— GBJ

CSAM Activities

The **Committee on Education** is developing "Essential Elements of an Addiction Medicine Clerkship" focused on the elective clerkship for fourth-year medical students. The document is intended for the reference of both the medical school faculty coordinators of clerkships and those who are responsible for training at the clinical sites. A desired outcome will be an increase in the number of clerkship opportunities which are providing training of appropriate content and quality. ***If you would like to contribute to this project, contact the CSAM office or Donald Gragg.***

The **Committee on Membership** is preparing its outreach to potential new members and to those who have not yet paid 1995 dues. Invitations will be extended along lines of common interest; for example, physicians in training will contact physicians in training; those interested in adolescent issues will contact others with a similar interest. ***If you would like to contribute to this project, contact the CSAM office or Diane Hambrick, Joseph Galletta or Bill Shaw.***

The **Committee on Physician Impairment**, at the request of the CMA/CSAM/MBC Liaison Committee to the Diversion Program for Physicians, is designing a quality assurance/quality improvement study of the role and function of the Case Consultant. Each physician in Diverison is assigned to one member of the Diversion Evaluation Committee who serves as that participant's Case Consultant.

CSAM frequently takes on assignments for the Liaison Committee for the QA/QI function for the Diversion Program. ***If you would like to contribute to this project, contact the CSAM office or Lyman Boynton or William Brostoff.***

The **Committee on Physician Impairment** is also preparing a workshop for hospital medical staff committees on the well-being of physicians, to be given in San Francisco in the fall. ***If you would like to contribute to this project, contact the CSAM office or Michael Parr or Glenhall Taylor.*** □

California Enacts Landmark Managed Care Law

California legislators have passed landmark legislation to standardize the processes health plans use to authorize or deny medical services. Senate Bill 1832 requires HMOs and other managed care plans to comply with a number of rules regarding prior authorization.

- ☐ Reimburse providers for emergency services and care rendered without prior authorization in specified circumstances (generally involving medical emergencies);
- ☐ Follow procedures for resolving disagreements about the discharge of patients who have received emergency care;
- ☐ Disclose to the Commissioner of Corporations and to contract providers (as well as to enrollees who request it) the processes used to determine whether to authorize a service as a covered benefit;
- ☐ Establish an appeals process for contested claims that involves the plan's medical director or other appropriately licensed health care professional; and
- ☐ Notify enrollees of the termination and — in certain circumstances, the reasons for terminating — a contract with a provider selected by those enrollees.

The law also forbids HMOs and other managed care plans from rescinding or modifying an authorization for a specific episode of treatment after the treatment has been given, and prohibits the release of any information to the employer of an enrollee, except with the enrollee's permission.

How the new requirement will affect the accessibility of treatment for alcoholism and other drug dependencies remains to be seen.

The California Medical Association sponsored the bill in the wake of numerous reports of patient suffering as a result of HMO decision to delay or deny treatment. On the other side, the California Association of HMOs, which vigorously opposed the bill, rejected as inaccurate the charge that health plans use untrained medical clerks to review claims.

Not surprisingly, the California legislation — and the controversy surrounding it — has stirred interest in other states and at the national level. A model "Patient Protection Act" based on SB 1832, drafted by the American Medical Association, has been introduced in Indiana, Oklahoma, Mississippi and Rhode Island. There also is discussion of attempting federal enactment of the Patient Protection Act sometime in 1995. ☐

How the new requirement will affect the accessibility of treatment for alcoholism and other drug dependencies remains to be seen.

— Bonnie Wilford

Bonnie Wilford is on the research staff of the Intergovernmental Health Policy Project at George Washington University.

Letter to the Editors:

Re: MROs and SAPs

Reading the last issue of our newsletter ("Substance Abuse Professionals Do More Than MROs," CSAM *NEWS*, Winter 1994, 21(3):1-3), I see that the Medical Review Officer is now joined by the Substance Abuse Professional with lower rank and the Blood Alcohol Technician who collects breath with machines — a further expansion of the Hobbesian "social contract" of authority over the individual. All of this is inconsistent with Constitutional guarantees — irrespective of the current Supreme Court's failure to uphold those guarantees (Skinner *v* Railway Labor Executives Association, 1989; National Treasury Employees Union *v* von Raab, 1989). The creation of the drug testing industry is not unlike a corporate version of the temple Pharisees spun out of control by profits from government-mandated testing. Elaborate specimen-handling protocols that rival rituals of high religious ceremony guarantee rectitude and purity but have absolutely nothing to do with fitness for duty. The chief inquisitor would be the first to admit. It was the physician's responsibility to see that this evil wasn't more stupidly executed, and that became the rationalization for participation in this immoral exercise. The venture has been so successful that others want a cut of the action.

Re: Spirituality and Addiction Medicine

Another aspect of fragmented and compartmentalized unselfconscious blurring of the separation of the church and state is the entry into the spiritual realm ("Why Spirituality?," and "Spiritual Health," CSAM *NEWS*, Winter 1994, 21(3)). The definition of spirit or spiritual is problematic in itself. The functional definition as depicted by example is ludicrous. The example of speaking forthrightly hardly bespeaks spirituality but basic character.

Raised as a Quaker, I find that these issues warrant continuing contemplation. Medical school did nothing toward my spiritual education to qualify me as an authority, unless the powerlessness and servitude of the experience convey acolyte status in the secular priesthood of being a physician. I object to another physician setting him or herself up to be an authority on the subject and I regard this as a detraction rather than an enhancement to the practice of medicine. The use of spirituality in medical models would appear to attenuate and confuse the role of the physician — or is it the minister?

As a minister in the Universal Life Church since April 11, 1969 (certificate number 53205) with thousands of hours in silent meetings and individual contemplation, meditation, cerebration, discussion, peregrination, I definitely qualify for the newly created dual certification of physician-spiritual leader. Actually, I can lay claim to being a certified addiction specialist and certified medical review officer. That should be worth numerous badges, ribbons, and stripes to

I volunteer to chair discussions on medical ethics....

decorate my ceremonial costumes. Spirituality? No, not spirituality — hubris and abuse of process.

Where are the boundaries between church, government, workplace, and the citizen? As a physician and psychiatrist I find myself frequently facing the need to protect my patients from the harm caused by the "system." These "systems" need critical examination from the perspective of medical ethics and not blind facilitation — let alone creation of spiritual political social psychological biological pharmacological problems.

I volunteer to chair discussions on medical ethics and individual privacy and confidentiality vs. authority and public safety in addiction medicine; physician-patient roles, responsibilities and expectations in addiction medicine; abstinence vs. harm reduction; medicine and spirituality: boundaries and commonalities.

Tod Mikuriya, MD
Berkeley
January 9, 1995

State of the Art in Addiction Medicine — 1995

November 2-4, 1995
Ritz-Carlton Hotel, Marina del Rey
Los Angeles

Clarification of Policies for California's Diversion Program for Physicians

Senate Bill 779 (Lewis) will clarify the extent to which physicians may be "diverted" from discipline in the Diversion Program of the Medical Board of California.

Changes in 1993 had eliminated the ability of the 15-year-old Diversion Program to function in lieu of discipline. The CMA/CSAM/MBC Liaison Committee to Diversion received several expressions of concern indicating that those changes were keeping physicians from entering Diversion and were thus having a paradoxical effect, undermining the ability of the Diversion Program to contribute to protection of the public by getting a physician into Diversion quickly, easily and early.

The CSAM Committee on Physician Impairment and the California Medical Association Committee on the Well-Being of Physicians and the Committee on the Medical Board worked cooperatively with Medical Board Staff and the Attorney General's Office to find a solution. The result is a compromise acceptable to the Medical Board's Enforcement arm as well as to the clinicians.

The compromise is to put into law authorization that the Diversion Program will divert physicians from discipline for certain specific violations of the Medical Practice Act if they enter the program and comply with its requirements. The following quotes from the proposed legislation specify the violations:

> ... the self-administration of drugs or alcohol under Section 2239 (of the Business and Professions Code), or the illegal possession, prescription, or non-violent procurement of drugs for self-administration, that does not involve actual harm to the public or patients.

Neither acceptance into nor participation in the diversion program shall preclude the MBC Division of Medical Quality from taking disciplinary action or continuing to take disciplinary action against any licensee for any unprofessional conduct committed before, during or after participation in the diversion program, **except for that conduct which resulted in the licensee's referral to the diversion program.**

Any licensee who successfully completes the diversion program shall not be prosecuted for any alleged violation of law that resulted in referral to diversion.

SB 779 will clarify the extent to which physicians may be "diverted" from discipline by the Diversion Program

Getting agreement on this approach and getting the bill introduced into the California Legislature are only the first steps. The bill must now proceed through the legislature where it is subject to amendment (or defeat). The first hearing was before the Senate Business and Professions Committee on March 27. For a copy of SB779, contact the CSAM office. □

— GBJ

NEWS ABOUT MEMBERS

Michael Stulberg was appointed to a Diversion Evaluation Committee in March. He now serves on the Northern California DEC II for the Diversion Program for Physicians of the Medical Board of California.

Glen Taylor is the Chief of the new Alcohol and Drug Abuse Program (ADAP) at Kaiser in Stockton. He continues as Consultant to Child Psychiatry there.

Merritt Smith took office in January as the President of the John Hale Medical Society, the Northern California component of the Golden State Medical Association and the National Medical Association.

David Smith is the Interim Medical Director of the State Department of Alcohol and Drug Programs.

Four hundred fifty-three members are listed in CSAM's 1995 Directory. Two hundred three of them became members automatically on January 1, 1995, because they were members of ASAM residing in California. Following is a brief profile of the newly combined membership.

Most members report their specialty as psychiatry (30%), internal medicine (22%), family practice (19%), or addiction medicine (9%). All other specialties account for the remaining twenty percent.

Sixty-three percent of the 453 members are certified by the American Society of Addiction Medicine. Twenty two (or 16%) of the 136 psychiatrists have a Certificate of Additional Qualifications in Addiction Psychiatry. □

Continuing Medical Education

ASAM's 26th Annual Medical-Scientific Conference

April 27-30, 1995
Marriott Hotel, Downtown Chicago
Sponsored by the American Society of Addiction Medicine
Symposium topics and speakers were listed in the last issue of CSAM *NEWS*.
Courses are presentations of clinical material that complement the scientifically oriented symposia.
Course topics and speakers include Structure and Techniques of Group Work for Facilitators of Health Professionals Recovery Groups: Peter Mezciems, Graeme Cunningham; Perinatal Addiction: Sidney Schnoll; Addiction Treatment in Psychiatric Patients: Richard Ries, Marc Wallen, Norman Miller; For the Addictionist: HIV Testing, Counseling, Confidentiality and Support: Barbara Chaffee, Melvin Pohl; Integration of Pharmacotherapy into Mainstream Medicine: Walter Ling, Norman Miller, Richard Rawson, David Smith, Donald Wesson.
Distinguished Scientist Lecture: Harold Kalant, MD, PhD, Professor Emeritus, Department of Pharmacology, University of Toronto. "Experimental Studies on Tolerance: What Can They Teach Us About Alcoholism in Humans?"
Fees: $425 for ASAM members for three days; $150 for one day
Credit: Up to 21 hours of Category 1 credit
For information, contact ASAM, 4601 North Park Avenue, Suite 101, Chevy Chase, MD 20815, 800/844-8948.

7th Annual Conference for Hospital Personnel

CMA Guidelines for Physician Well-Being Committees

Wednesday, May 10, 1995
Sponsored by the Riverside County Medical Association, CSAM and CMA
Fees: $300 per hospital registers four persons from that hospital. $50 for each additional person. Individual registration, $125.
Speakers include John Lanier, John Chappel, Max Schneider, Donald Gragg, Garrett O'Connor, Chet Pelton, and Kim Davenport, CMA Legal Counsel
For information: contact Nancy Barker, Riverside County Medical Association, 909/686-3342.

ASAM MRO Course

The Basics of Being an MRO — Friday morning, 8:00 am to noon

The Latest on the Science, Rules and Art of Medical Review — Friday, 1:00 pm to Sunday, 11:45 am

July 7-9 in Washington, DC; November 17-19 in New Orleans
Sponsored by American Society of Addiction Medicine
Credit: 4 hours for "The Basics"; 14.5 hours for "The Latest"
Fees: For "The Basics," $75 for ASAM members, $100 for non-members. For "The Latest," $450 for ASAM members, $525 for non-members.
For information: contact ASAM, 800/844-8948
Certification: The Medical Review Officer Certification Council (MROCC) will offer the MROCC Certification Exam immediately following the course in both locations. A separate application/eligibility form must be requested from MROCC, 55 West Seegers Road, Arlington Heights, IL 60005, 708/228-7476.

46th Annual IDAA Meeting

The Seasons Resort, Great Gorge, NJ
Wednesday, August 2 to Sunday, August 6, 1995
Fees: IDAA members, $300; spouse/guest, $200; resident/medical student, $175
For information: International Doctors in Alcoholics Anonymous, POB 199, Augusta, MO 63332, 314/482-4548.