FDA approves Mifepristone for the termination of early pregnancy

The Food and Drug Administration approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.

Under the approved treatment regimen, a woman first takes 600 milligrams of mifepristone (three 200 milligram pills) by mouth. Two days later, she takes 400 micrograms (two 200-microgram pills) of misoprostol, a prostaglandin. Women will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated.

Because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side effects can occur. "The approval of mifepristone is the result of the FDA's careful evaluation of the scientific evidence related to the safe and effective use of this drug," said Jane E. Henney, M.D., Commissioner of Food and Drugs. "The FDA's review and approval of this drug has adhered strictly to our legal mandate and mission as a science-based public health regulatory agency."

FDA based its approval of mifepristone on data from clinical trials in the United States and France.

The labeling for mifepristone emphasizes that most women using the product will experience some side effects, primarily cramping and bleeding. Bleeding and spotting typically last for between 9 and 16 days. In about one of 100 women, bleeding can be so heavy that a surgical procedure will be required to stop the bleeding.

The drug's labeling also warns that it should not be used in women with the following conditions:

- Confirmed or suspected ectopic ("tubal") pregnancies
- Intrauterine device (IUD) in place
- Chronic failure of the adrenal glands
- Current long-term therapy with corticosteroids
- History of allergy to mifepristone, misoprostol or other prostaglandins
- Bleeding disorders or current anticoagulant (blood-thinning) therapy.

Under the terms of the approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding—or they must have made plans in advance to provide such care through others.

To gather additional data about the use of mifepristone, the Population Council (sponsor of the product) has made a commitment to conduct postmarketing studies. These include a study comparing patient outcomes among physicians who refer their patients needing surgical intervention, compared to those who perform surgical procedures themselves; an audit of prescribers that will examine whether patients and their physicians are signing the patient agreement and placing it in the patient's medical record, as required; and a system for surveillance, reporting and tracking rare ongoing pregnancies after treatment with mifepristone in the U.S.

Mifepristone, which was developed by a French pharmaceutical firm, was first approved for use in France in 1988. Since then, more than 620,000 European women have taken mifepristone in combination with a prostaglandin to terminate pregnancy. The drug has also been approved in the United Kingdom, Sweden, and other countries.

Mifepristone will be distributed in the U.S. by Danco Laboratories, LLC, New York, N.Y.

More detailed information about this product is available on FDA's website at www.fda.gov/cder/drug/infopage/mifepristone/. This site also features questions and answers about Mifepristone, patient agreement form and prescriber's agreement form. ■

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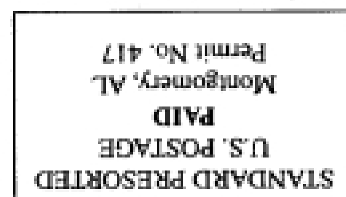
Larry Dixon, Executive Director, P.O. Box 946, Montgomery, AL 36102-0946 or call (334) 242-4116 or fax (334) 242-4155. Please visit our web site: **www.albme.org.**



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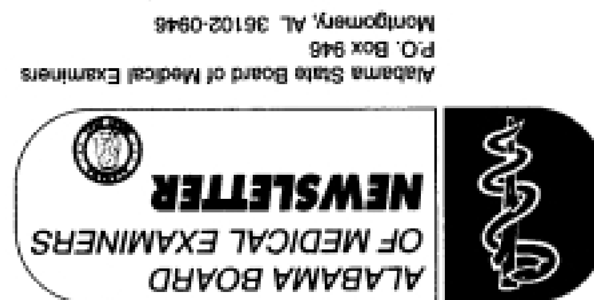

ALABAMA BOARD OF MEDICAL EXAMINERS
NEWSLETTER

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Addiction . . . . A disease??

By Gregory E. Skipper, MD, FASAM
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The debate continues regarding whether or not addiction to alcohol or drugs is a disease. At the real heart of this debate are questions regarding the individual's responsibility for the disorder and understanding of the pathophysiology of the brain.

Dorland's Medical Dictionary defines disease as "a definite morbid process having a characteristic train of symptoms; it may affect the whole body or any of its parts, and its etiology, pathology, and prognosis may be known or unknown." At first blush addiction certainly seems to satisfy this definition. The Jellnick curve graphically portrays the inexorable morbid progression of symptoms from surreptitious use, to compulsive use, to use despite adverse consequences and eventual isolation and loss of family, health, occupation and eventual incarceration or death.

Most people have an erroneous view of disease as something that invades or attacks your good health; an innocent victim attacked by a "perpetrator" over whom he or she has no control. In addiction, the person participates in or causes many of their own problems by their behavior.

In fact, most diseases are self-imposed by behavior, at least in part. If someone smokes cigarettes and eats fatty foods and then gets coronary artery disease, they have largely caused their own problem. They are a "victim" of their own unhealthy behavior. It's not that they wanted to have heart disease but rather in the pursuit of their chosen lifestyle they inadvertently chose behaviors that have undesirable consequences. Likewise, when someone drinks it is never their goal to become addicted; (people usually drink or use drugs because of peer pressure, curiosity, escape, recreation, teenage rebellion, etc.) however, they have caused their own problem, in part, and often largely in ignorance, by their behavior.

The exact pathophysiology of addiction is not known. Theories regarding possible causes include abnormal or different receptors for neurotransmitters such as dopamine or serotonin, different neuroanatomical connections, or different chemical responses to addictive drugs. If the exact defect were known the acceptance of addiction as a disease would be much easier.

Hester and Miller have described numerous conceptual models for understanding addiction. Including the dispositional disease model, they also list moral, temperance, spiritual, educational, social, characterologic, biologic, conditioning, sociocultural, general systems, and public health models. All of these models have merit and point out differing aspects of the complex problem of addiction.

Again addiction in this regard is like other illnesses. For example, there are differing models for understanding coronary artery disease. With coronary disease much has been said regarding personality type A and B as contributing or preventing the disease. There are also educational socioeconomic factors with heart disease. Heredity and diet are important factors as are issues of lifestyle, exercise, and self care. There is a genetic and also a biological perspective. The exact cause of coronary disease is also not known. (See Table 1)

(see Addiction page two)

Table 1 Conceptual Models of Addiction and Coronary Artery Disease

Model	Causal Factors in Addiction	Causal Factors in Coronary Dz
Moral	Personal Responsibility, self control	Gluttony, cigarette smoking
Temperance	Alcohol	Cholesterol
Spiritual	Spiritual deficit	Stress, Lack of serenity
Dispositional Disease	Genetic abnormality	Genetic predisposition
Educational	Lack of knowledge	Lack of knowledge
Characterological	Personality traits, defenses	Personality traits, Type A/B
Conditioning	Classical or operant conditioning	NA
Social Learning	Modeling, skill deficit	Diet, exercise, behavior
Cognitive	Beliefs, expectancies	NA
Sociocultural	Environmental, cultural norms	Cultural norms
General Systems	Boundaries and rules, family dysfunction	Stress in family systems
Biological	Heredity, Brain physiology	Heredity, Vascular physiology, Biochemistry
Public Health	Agent, Host, Environment	Agent, Host, Environment

Addiction *continued*

None of these other models detract from the fact that addiction is a disease. It occurs in approximately 15% of Americans during their life. Addiction to alcohol and/or drugs appears to affect physicians at the same rate as it does the general population. There appears to be a hereditary genetic component. What is inherited is the potential for addiction and not the disease. There are various degrees of severity and complexity. Treatment can be very effective, especially if long-term follow-up is performed.

One way addiction is unlike most other diseases is with regards the fact that addicts in the course of their illness do bad things. They lie, steal, cheat, and are unreliable. The compulsion to use eventually supersedes moral constraints. The compulsion to use supersedes values. The compulsion to use is so strong it exceeds most other drives. Addicts do bad things and they should be responsible and deserve consequences. However, this still does not mean addiction is not a disease. The fact that AIDS patients have been known to steal to buy medicine does not mean AIDS is not a disease. The fact that promiscuity leads to sexually transmitted diseases does not mean syphilis is not a disease.

Addiction is a disease. Patients and family benefit from understanding this fact. This understanding helps the patient to have less shame and guilt and to begin a process of accepting help. The family benefits by decreasing their anger and frustration and they begin to support healthy rehabilitative activities and support for the patient and themselves. ■

Alabama Board of Medical Examiners
PUBLIC ACTION REPORT
October - December 2000

On October 1, 2000, Nathan B. Collier, M. D., license number 7913, Gadsden AL, entered into voluntary restrictions on his certificate of qualification and license to practice medicine in Alabama, including a restriction to prescribing controlled substances in Schedules IV and V only.

On October 4, 2000, Richard Thomas Lowe, M. D., license number 2449, Haleyville AL, voluntarily surrendered his certificate of qualification and license to practice medicine in Alabama while under investigation for alleged violations of Ala. Code §34-24-360 (1997). Dr. Lowe is no longer authorized to practice medicine in Alabama, which includes no authority to prescribe controlled substances or legend drugs.

On October 16, 2000, Ralph D'Auria, M. D., license number 11921, Decatur GA, voluntarily requested and consented to certain restrictions being placed on his certificate of qualification for a license to practice medicine in Alabama, including, if he should engage in the practice of medicine in Alabama, a restriction to the practice of physical and rehabilitation medicine.

On November 10, 2000, Dick Owens, M. D., license number 7870, Haleyville AL, voluntarily requested and consented to certain restrictions being placed on his certificate of qualification for a license to practice medicine in Alabama, including monitoring provisions.

On November 15, 2000, the Board entered an Order removing the voluntary restrictions previously attached to the certificate of qualification and license to practice medicine in Alabama of John W. Scarborough, M. D., license number 9992, Florence AL. Dr. Scarborough's Alabama license has been reinstated to full, unrestricted status.

On November 22, 2000, the Board entered an Order removing the voluntary restrictions previously attached to the certificate of qualification and license to practice medicine in Alabama of Keith L. Fuller, D. O., license number DO-350, Opelika AL. Dr. Fuller's license has been reinstated to full, unrestricted status.

On December 20, 2000, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of G. Jan Hinnen, M. D., license number 8409, Dadeville AL, after the filing of an Administrative Complaint by the Board and the issuance of a summary suspension Order by the Medical Licensure Commission on October 24, 2000. As of October 24, 2000, Dr. Hinnen is no longer authorized to practice medicine in Alabama.

On December 20, 2000, the Board of Medical Examiners accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of Victoria Lochiel Woods, M. D. a/k/a Victoria Lochiel Anderson, M. D., license number 14888, Mobile AL, after the filing of an Administrative Complaint by the Board and the issuance of a summary suspension Order by the Medical Licensure Commission on November 22, 2000. As of November 22, 2000, Dr. Woods a/k/a Dr. Anderson is no longer authorized to practice medicine in the state of Alabama.

On December 20, 2000, the Board of Medical Examiners accepted the voluntary surrender of the Alabama Controlled Substances Certificate of Joseph Ayer Beckwin, M. D., license number 12480, Fairfield AL, while under investigation for alleged violations of Ala. Code §34-24-360 (1997). Dr. Beckwin is no longer authorized to prescribe controlled substances in Alabama.

On December 20, 2000, the Board of Medical Examiners voted to remove the voluntary restrictions previously entered against the certificate of qualification and license to practice medicine in Alabama of Milton R. Raines, license number 5465, Gulfport MS. Dr. Raines' Alabama medical license has been reinstated to full, unrestricted status. ■

RETRACTION/ERROR NOTICE

It was mistakenly reported in the Fall 2000 Board of Medical Examiners newsletter that Joseph W. Johnson, M. D., license number 2806, Andalusia AL, entered into a Stipulation and Consent Order wherein Dr. Johnson must obtain additional CME and obtain written authorization from the Board prior to returning to the practice of medicine. This report was made in error and is hereby retracted. ■

The physician's obligation to report impaired drivers

Alabama law permits physicians to submit a confidential report to the Department of Public Safety concerning any patient whose medical condition may impair their ability to safely operate a motor vehicle.

These reports are reviewed by the Department which can require drivers to submit to an independent medical assessment which provides the basis for a decision on the issuance of a driver's license.

Reporting by physicians is voluntary and state law (Ala. Code §32-6-45) provides immunity from civil liability for physicians who make reports in good faith.

The Drivers License Medical Advisory Board, composed of physicians nominated by the Medical Association of the State of Alabama, advises the Director of Department of Public Safety on the medical aspects of driver licensure: Reports should be submitted to: *Medical Unit, Department of Public Safety, Post Office Box 1471, Montgomery, AL 36102-1471, Telephone: 334-242-4239*

In June, 2000 the American Medical Association Council on Ethical and Judicial Affairs issued an opinion which discusses a physician's obligation to report impaired drivers and offers guidelines for reporting. The opinion is set out below:

E-2.24 Impaired Drivers and Their Physicians

The purpose of this Opinion is to articulate physicians' responsibility to recognize impairments in patients' driving ability that pose a strong threat to public safety and which ultimately may need to be reported to the Department of Motor Vehicles. It does not address the reporting of medical information for the purpose of punishment or criminal prosecution.

Physicians should assess patients' physical or mental impairments that might adversely affect driving abilities. Each case must be evaluated individually since not all impairments may give rise to an obligation on the part of the physician. Nor may all physicians be in a position to evaluate the extent or the effect of an impairment (e.g., physicians who treat patients on a short-term basis). In making evaluations, physicians should consider the following factors: (a) the physician must be able to identify and document physical or mental impairments that clearly relate to the ability to drive; and (b) the driver must pose a clear risk to public safety.

Before reporting, there are a number of initial steps physicians should take. A tactful but candid discussion with the patient and family about the risks of driving is of primary importance. Depending on the patient's medical condition, the physician may suggest to the patient that he or she seek further treatment, such as substance abuse treatment or occupational therapy. Physicians also may encourage the patient and the family to decide on a restricted driving schedule. Efforts made by physicians to inform patients and their families, advise them of their options, and negotiate a workable plan may render reporting unnecessary.

Physicians should use their best judgement when determining when to report impairments that could limit a patient's ability to drive safely. In situations where clear evidence of substantial driving impairment implies a strong threat to patient and public safety, and where the physician's advice to discontinue driving privileges is ignored, it is desirable and ethical to notify the Department of Motor Vehicles.

The physician's role is to report medical conditions that would impair safe driving as dictated by his or her state's mandatory reporting laws and standards of medical practice. The determination of the inability to drive safely should be made by the state's Department of Motor Vehicles.

Physicians should disclose and explain to their patients this responsibility to report.
Physicians should protect patient confidentiality by ensuring that only the minimal amount of information is reported and that reasonable security measures are used in handling that information.

Physicians should work with their state medical societies to create statutes that uphold the best interests of patients and community, and that safeguard physicians from liability when reporting in good faith. (III, IV, VII) Issued June 2000 based on the report "Impaired Drivers and Their Physicians," adopted December 1999. ■

Medical Licensure Commission
PUBLIC ACTION REPORT
October through December 2000

On October 24, 2000, the Medical Licensure Commission entered an Order which temporarily suspended the medical license of Gerhard Jan Hinnen, M.D., license number 8409.

On October 25, 2000, the Medical Licensure Commission entered a Stipulation and Consent Order which issued to Dr. John Clarence Simmons, license number16795, a reprimand, assessed and administrative fine and placed Dr. Simmons' medical license on probation subject to the terms contained in the Consent Order.

On November 1, 2000, the Medical Licensure Commission entered an Order which revoked the medical license of William J. Lupinacci, M.D., license number 10601.

On November 1, 2000, the Medical Licensure Commission entered an Order which revoked the medical license of Nival Rizk Miller, M.D., license number 21444.

On November 22, 2000, the Medical Licensure Commission entered an Order which temporarily suspended the medical license of Michael Roy Whittle, M.D., license number 9247.

On November 22, 2000, the Medical Licensure Commission entered an Order which temporarily suspended the medical license of Victoria Lochiel Anderson Woods, license number 14888.

On November 30, 2000, the Medical Licensure Commission entered an Order which issued to Dr. Dan Stephen Hollis a reprimand and assessed an administrative fine in the amount of $1,000. Dr. Hollis' Alabama license number is 8278. ■