

**General Principles
for the Use of
Pharmacological
Agents to Treat Individuals
with Co-Occurring Mental
and Substance Use Disorders**



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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration

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Centers for Substance Abuse Treatment and Mental Health Services (CSAT and CMHS), SAMHSA
1 Choke Cherry Road
Rockville, MD 20857

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Individuals with co-occurring mental and substance use disorders (COD) are common in behavioral and primary health settings (Grant et al., 2004; Hasin et al., 2007; Kessler, Chiu, et al., 2005; Kessler, Nelson, et al., 1996). These individuals frequently benefit from pharmacologic interventions, whether for mental disorders, substance use disorders, or both conditions.

While some research is available on prescribing pharmacologic agents to individuals diagnosed with COD, this information is not available in a brief, easy-to-use format that provides guidance to both frontline practitioners, as well as to system or program policymakers. This document provides general principles to assist in the planning, delivery, and evaluation of pharmacologic approaches to support the recovery of individuals with COD.

Development of the General Principles

The Pharmacotherapy Principles were assembled by a task order work group, which included federal Substance Abuse and Mental Health Services Administration (SAMHSA) staff and contractors. These principles are drawn from a number of reputable resources and edited to be applicable. Each of the principles is supported by an evidence base—a reference list accompanies each.

The principles were reviewed and rated (i.e., on a 5-point scale, “How much do you agree or disagree that each statement should be included in the final principles document?”) by an expert Consensus Panel. The role of the Consensus Panel was to provide guidance based on up-to-date research, their experiences, and expertise. The panel was made up of 33 individuals who are identified as experts in psychiatry, pharmacotherapy, COD, mental health, addictions, health center administration, and health reform. All panelists were nominated by national professional organizations or SAMHSA federal staff.

The Consensus Panel process is discussed in more detail in a separate summary report.

Definition of COD

A diagnosis of COD requires that individuals have one or more disorders relating to the use of alcohol and/or other

drugs of abuse, as well as one or more mental disorders. A diagnosis of COD can be made when at least one disorder of each type can be established independent of the other, and is not simply a cluster of symptoms resulting from one disorder (Substance Abuse and Mental Health Services Administration, 2005b). COD may include alcohol, other drugs, and non-substance related DSM-IV-TR Axis I & II mental disorders.

Target Audience

The primary target audience for these principles is providers who prescribe medication for adults with COD. This includes psychiatrists, primary care physicians, nurse practitioners and other nurse prescribers, physician assistants, and other licensed prescribers. In the document, the term “prescribers” is used to describe this audience.

The secondary target audience is individuals who work in administrative and leadership roles at the program, agency, or system level. This may include medical directors, clinical directors, executives, quality managers, and regulators. These principles provide guidance for the design of policies and protocols to support best practice pharmacologic interventions for individuals with COD in all settings. They are intended to support the attainment of valued recovery outcomes and the more efficient and effective use of resources for individuals with complex challenges.

Structure of the Document

The principles are organized in the sequence in which a prescriber will likely meet, engage, and intervene with an individual with COD. This sequence begins with welcoming and engagement, proceeds through screening and assessment, followed by treatment planning that includes pharmacologic interventions, and continuation of care and collaboration with the individual and other team members. The principles are tied together with attention to continuous quality improvement processes.

Introduction

Pharmacotherapy alone is not an adequate treatment plan for individuals with COD (Power et al., 2005; Substance Abuse and Mental Health Services Administration, 2005b, 2008). Pharmacotherapy for individuals with COD is optimally delivered by prescribers in a context of a broad range of treatment and services to address the needs of individuals with multiple types of issues and priorities in a system of care. These may include a range of specific types of services such as health, housing, employment, childcare, eldercare, and parenting, as well as a range of program types, provider networks, and funding streams (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Minkoff & Cline, 2004; Rosenthal & Ries, 2009; Substance Abuse and Mental Health Services Administration, 2004, 2005b, 2008). It is generally recognized that untreated COD complicates and reduces the effectiveness of treatment of either disorder (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005a,b, 2008).

Because not all programs will have the capacity to prescribe medications for mental and/or substance use

disorders to individuals with COD who may benefit from such medication, prescribers should develop opportunities for routine and consistent partnerships with such programs to facilitate timely access to necessary pharmacologic interventions so that individuals in need can more easily receive these essential treatments (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Substance Abuse and Mental Health Services Administration, 2005b, 2008).

Given the evolving empirical evidence for COD pharmacotherapy effectiveness, prescribers should be engaged in continuous learning as new information emerges (Khalsa & Elkashef, 2009; Litten et al., 2005; McCance-Katz et al., 2009). The objective is to determine the best pharmacologic strategy in a context of ongoing psychosocial, behavioral, cognitive, and other interventions, including peer support, to help the individual address mental health and/or substance use disorders to achieve his or her recovery goals (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005a,b).

Principles

1 *Engagement*

As part of usual practice, prescribers should be prepared to:

- welcome and engage individuals with COD;
- anticipate the need to screen, assess, and diagnose COD;
- promote access to medications and other psychosocial, behavioral, and cognitive interventions; and
- provide medication and treatment education for individuals with COD (American Psychiatric Association, 2004; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Power et al., 2005; Substance Abuse and Mental Health Services Administration, 2005b, 2007c, 2008).

2 *Relationship Building*

Successful pharmacologic interventions for individuals with COD are most likely to occur in the context of a relationship in which the prescriber positions himself or herself as a collaborator in the recovery process, with the goal of helping the individual achieve his or her life goals. The relationship should be empathetic, hopeful, and strength-based, and the prescribing clinician should be prepared to work with the individual in a continuing process of assessment and reassessment (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Power et al., 2005; Substance Abuse and Mental Health Services Administration, 2005b, 2007c, 2008).

3 Shared Decision-Making

Shared decision-making between the prescriber and individuals receiving services (and, where appropriate, their families or other support individuals of their choosing) should be incorporated into standard treatment practice (unless the individual is deemed to lack capacity). Prescribers should:

- communicate likely outcomes of various treatment options (including pharmacologic strategies) for both mental and substance use disorders;
- ascertain the individual's understanding of the information being conveyed;
- work in partnership with the individual to consider risks and benefits for each option in relation to the individual's personal recovery goals;
- decide collaboratively on a course of treatment within this partnership, based on discussion between the prescriber and the individual;
- request individual consent to obtain prior medical records (review again with the individual if consent is initially refused); and
- document the individual's participation in the shared decision-making process (Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005b, 2006b, 2008).

4 Screening & Assessment

Individuals presenting for service in any behavioral or primary health setting should be screened for both mental and substance use disorders, as well as physical conditions that may present as behavioral health conditions (e.g., brain tumor, subdural hematoma). There should be no requirements related to blood alcohol levels, length of abstinence from psychoactive substances, or length of medication adherence as a precondition for access to evaluations and appropriate acute care (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005b). Ongoing alcohol and/or drug use, however, warrants increased caution when prescribing medications. Medication adherence should be assessed initially and monitored on an ongoing basis as poor adherence might increase the risks associated with medications and undermine treatment success. Prescribers should recognize the need to screen, assess, and treat an intoxicated individual, but appreciate that an accurate diagnosis cannot be made, and non-urgent interventions should be delayed until the person is not intoxicated and is capable of understanding and participating in decision making regarding treatment options (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005b, 2007a). Laboratory studies, drug screening, electrocardiography (EKG), and imaging studies should all be considered as part of the assessment. Positive screenings should lead to further integrated assessment and treatment planning (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Power et al., 2005; Substance Abuse and Mental Health Services Administration, 2005b, 2007a, 2008).

5 *Assessment of Co-Occurring Disorders*

Symptoms of mental disorders can be either temporary or permanent, and continuing re-evaluation in partnership with the individual receiving care is required (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005a,b). Psychiatric syndromes diagnosable as mental disorders that originate during periods of active substance use may persist once substance use is discontinued and may require ongoing intervention. Assessment of individuals with COD should occur over time (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005b, 2008) and should:

- include a review of chronologic history, including time frames for onset and continuation of both mental and substance use disorders;
- differentiate between substance-induced disorders that resolve when substance use stops and independent, co-occurring mental disorders that require ongoing intervention (American Psychiatric Association, 2004; McCance-Katz, 2009; Rosenthal & Ries, 2009; Substance Abuse and Mental Health Services Administration, 2004);
- include a review of current and previous pharmacotherapy for behavioral disorders effectiveness and problems encountered; and
- include a review of family history of both mental and substance use disorders.

6 *Integrated Interventions*

When a determination has been made that both a mental and substance use disorder are present, the prescriber should consider both disorders to be “primary.” Treatment plans should integrate best practice interventions—including both psychosocial interventions and pharmacotherapy—to address each of the CODs (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Power et al., 2005; Rosenthal & Ries, 2009; Substance Abuse and Mental Health Services Administration, 2005b, 2008).

7 *Treatment Readiness*

In keeping with the Stages of Change Model (Substance Abuse and Mental Health Services Administration, 2005b), the individual may be less motivated to address one of the disorders, and may benefit from other interventions to facilitate treatment readiness (e.g., Motivational Interviewing) (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Power et al., 2005; Substance Abuse and Mental Health Services Administration, 2004, 2005a, 2005b, 2008). Prescribers should monitor individuals for ongoing alcohol or drug use due to the risks involved.

8 *Interdisciplinary Communication*

Prescribers may provide non-pharmacologic interventions, such as Motivational Interviewing, in the context of the pharmacologic relationship and/or work in collaboration with a treatment team that provides ongoing psychosocial, behavioral, cognitive, and other interventions. Improved outcomes occur through regular communication and coordination of care. It is important for the individual to receive an integrated and consistent message from all providers. (Arias & Kranzler, 2008; National Institutes of Health, 1997; Substance Abuse and Mental Health Services Administration, 2005b, 2006b, 2007b, 2008).

9 *Integrated Treatment*

Individualized treatment plans that include pharmacologic strategies should be developed through a person-centered planning process and should integrate interventions to respond to multiple factors identified in the assessment, including:

- immediate risk and safety
- recovery goals
- cognitive functioning
- social and physical functioning and disability
- other medical conditions and medications prescribed to treat them
- strengths, skills, and periods of success
- history of treatment response
- motivation and stage of change
- phase/stage of treatment
- age and gender
- culture and background (Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Rosenthal & Ries, 2009; Substance Abuse and Mental Health Services Administration, 2004, 2005b, 2008).

10 *Pharmacologic Strategies & Drug Interaction/ Toxicity*

Prescribers should be familiar with the full range of pharmacologic strategies available for both the mental and substance use disorders. Prescribers should not be limited to a single model, approach, category, or formulation of medications. In populations with COD, additional consideration should be given to the potential for abuse of prescribed medication (American Psychiatric Association, 2004; Blanco et al., 2010; Brady et al., 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004; Substance Abuse and Mental Health Services Administration, 2005b, 2008). Side effects should be monitored carefully and differentiated from the effect of ongoing alcohol and/or drug use. Prescribers must also consider potential toxicities and drug interactions that may occur between medications prescribed, medications being considered, and tobacco, alcohol, and/or drug use to treat individuals with COD (e.g., the combination of opiates and benzodiazepines carries a particularly high risk, and tobacco can lower antipsychotics blood levels) (Blanco et al., 2010; Brady et al., 2010; Khalsa & Elkashef, 2009; Lintzeris & Nielsen, 2009; McCance-Katz et al., 2009; Substance Abuse and Mental Health Services Administration, 2004, 2005b).

11 *Medications & Crossover Benefits*

In general, the most appropriate medication for addressing an individual's mental disorder is likely to be the same medication for addressing these symptoms when the individual is diagnosed with a co-occurring substance use disorder. Likewise, the most appropriate medication for addressing an individual's substance use disorder is likely to be the same one when they are diagnosed with a co-occurring mental disorder (Blanco et al., 2010; Brady et al., 2010; Substance Abuse and Mental Health Services Administration, 2004, 2005a, 2005b). Be aware that certain medications that are effective for one condition may have a crossover benefit for the other co-occurring condition (e.g., Valproate for the treatment of bipolar disorder may also benefit a co-occurring substance use disorder [Green et al., 2007; Salloum et al., 2005]).

12 *Risk/Benefit Assessment*

Within the shared decision-making partnership, the selection of pharmacologic interventions should move from low risk to higher risk strategies, dependent on clinical response. The use of medications with the potential for abuse is risky in individuals with COD, and requires careful risk/benefit assessment within a prescribing relationship prior to initiation. However, these categories of medication should not be arbitrarily denied to individuals who have substance use disorders if the medications may be medically beneficial or indicated. In such cases, the risks involved with using substances while on medications should be reviewed with the individual and close monitoring is required (Minkoff & Ajilore, 1998; Minkoff & Cline, 2004).

13 *Coordinated Treatment Approach*

It is essential that prescribers, with client consent, routinely communicate with other providers regarding an individual's medical conditions, test results, and prescribed medications (Manubay & Horton, 2010). Individuals with COD are at high risk for concurrent medical problems due to substance toxicities, lifestyle factors (e.g., injection drug use and homelessness), lack of regular medical attention, and medication side effects. There is also concern that commonly used medications can interfere with the metabolism of substance abuse and psychiatric medication, and vice versa, and may cause increased or decreased drug levels and potency (e.g., fluoxetine and fluvoxamine decreases the metabolism of methadone and buprenorphine; methadone decreases the metabolism of zidovudine) (Khalsa & Elkashef, 2009; McCance-Katz et al., 2009). Coordinated treatment of COD and concurrent medical conditions benefits overall recovery (Manubay & Horton, 2010).

14 *Relapse Prevention*

An essential component of relapse prevention and relapse management is close monitoring of individuals for signs of relapse, with the goals of:

- identification of the relapse signs,
- identification of the causes of relapse, and
- assisting individuals to anticipate early warning signs of relapse and developing strategies to interrupt the relapse process (Substance Abuse and Mental Health Services Administration, 2005b).

15 *Continuity
of Treatment*

Medications that are used for symptom management and stabilization of known mental disorders or medical conditions should generally be maintained even when the individual continues to abuse substances. Individuals should be closely monitored and discontinuation of treatment should only occur when the risk of prescribing outweighs the benefits of continued therapy (Blanco et al., 2010; Manubay & Horton, 2010; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004).

16 *Quality
Improvement*

Prescribers should develop a quality improvement approach to address the needs of individuals with COD. This involves monitoring the effect of treatment decisions and keeping up to date on new medications, research on drug use, and revised standards of practice (Khalsa & Elkashef, 2009; Litten et al., 2005; McCance-Katz et al., 2009; Minkoff & Ajilore, 1998; Minkoff & Cline, 2004).

Glossary

Assessment – The process of gathering information and engaging with a client to establish (or rule out) the existence of a co-occurring disorder or service need, determine the client’s readiness for change, identify the client’s strengths and problem areas that may affect treatment and recovery, and work with the client to develop a treatment and service plan (Substance Abuse and Mental Health Services Administration, 2005b).

Behavioral interventions – A therapeutic approach that targets changes in behavior without necessarily exploring the cognitive/thinking processes that underlie feelings or behavior (Substance Abuse and Mental Health Services Administration, 2006a).

Cognitive-behavioral interventions – A therapeutic approach that targets both thought and behavior change (i.e., thinking differently about substance abuse and coping in ways that do not involve substance use) (Substance Abuse and Mental Health Services Administration, 2005b).

Co-occurring disorders – A diagnosis of co-occurring disorders requires that clients have one or more disorders relating to the use of alcohol and/or other drugs of abuse as well as one or more mental health disorders. A diagnosis of co-occurring disorders can be made when at least one disorder of each type can be established independent of the other and is not simply a cluster of symptoms resulting from one disorder. Co-occurring disorders may include alcohol, other drugs, and non-substance related DSM-IV Axis I & II mental health disorders (Substance Abuse and Mental Health Services Administration, 2005b).

DSM-IV-TR – Diagnostic and Statistical Manual of Mental Disorders, 4th edition (revised). The DSM-IV-TR organizes mental health disorders into five dimensions (axes). Those germane to these Principles include:

- **Axis I:** Clinical disorders and conditions that need clinical attention;
- **Axis II:** Personality disorders and intellectual disabilities; and
- **Axis IV:** Psychosocial and environmental problems (American Psychiatric Association, 2000).

Motivational interviewing – A therapeutic approach that helps clients enhance their motivation to reduce substance use or to become abstinent in order to reach their personal goals. The approach fosters change by helping clients explore and clarify their goals, and then make the commitment to change in order to reach their desired goals (Substance Abuse and Mental Health Services Administration, 2005b, 2008).

Psychosocial interventions – A therapeutic approach that helps clients with concerns such as housing, entitlements, vocational assistance, legal services, and access to food, clothing, and medication (Substance Abuse and Mental Health Services Administration, 2005b).

Recovery from Mental Disorders and Substance Use Disorders – A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential (<http://www.samhsa.gov/recovery/>).

Relapse – The return to active substance use in a person with a diagnosed substance use disorder or the return of disabling psychiatric symptoms after a period of remission related to a non-addictive mental health disorder (Substance Abuse and Mental Health Services Administration, 2006a).

Screening – The process to determine the likelihood that a person has a co-occurring disorder and whether there is a need to conduct an in-depth assessment (Substance Abuse and Mental Health Services Administration, 2006a).

Shared decision making – An approach where prescribers and the client discuss together the making of decisions regarding medications and treatments, where the client is supported in considering the best attributes and options, to arrive at informed preferences regarding care (Gafni & Whelan, 1997).

Stages of change – A six-stage model that assesses an individual’s readiness to act on new healthier behavior, and provides strategies, or processes of change to guide the individual through the stages to action, maintenance, and recovery (Substance Abuse and Mental Health Services Administration, 2005b).

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PLANNING COMMITTEE MEMBERS

H. Westley Clark, M.D., J.D., M.P.H., C.A.S., F.A.S.A.M.

Director of the Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Dulari Gandhi

Co-Occurring Disorders Integration and
Innovation (CODI) Research Assistant
Westat
Rockville, Maryland

Shoma Ghose, Ph.D.

Co-Occurring Disorders Integration and
Innovation (CODI) Task Lead
Westat
Appleton, WI

Nina Hamburg, M.B.A.

Project Manager, Co-Occurring Disorders
Integration and Innovation (CODI)
Westat
Rockville, Maryland

Charlene Le Fauve, Ph.D.

Chief, Co-Occurring and Homeless Activities Branch
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Robert Lubran, M.S., M.P.A.

Director, Division of Community Programs
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Mary Anne Myers, Ph.D.

Project Director, Co-Occurring Disorders
Integration and Innovation (CODI)
Westat
Rockville, Maryland

Fred Osher, M.D.

Director, Health Systems and Services Policy
Council of State Governments Justice Center
Johns Island, South Carolina

Dr. Lawrence D. Rickards

Consultant to Westat
Washington, DC

Onaje Salim, M.A., L.P.C.

Public Health Advisor
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Deborah Stone, Ph.D.

Social Science Analyst
Center for Mental Health Services
SAMHSA
Rockville, Maryland

SAMHSA'S PHARMACOTHERAPY EXPERT CONSENSUS PANEL MEMBERS

J. Craig Allen, M.D.

Chief Medical Officer
National Council of Community Behavioral Healthcare
Rushford Center, Inc.
Meriden, Connecticut

John Paul Allen, Ph.D., M.P.A.

National Mental Health Director, Addictive Disorders
Office of Mental Health Services
Veterans Health Administration
Washington, DC

Michael H. Allen, M.D.

Trustee and Past President
American Association of Emergency Psychiatry
Director of Research
University of Colorado Depression Center
Aurora, Colorado

Tony B. Campbell, R.Ph., D.O.

Medical Officer, Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Jason Carter, Pharm.D.

Chief Pharmacist, Tennessee Department
of Mental Health and Developmental Disabilities
State Opioid Treatment Authority
Associate Professor, Clinical Pharmacy
University of Tennessee College of Pharmacy
Nashville, Tennessee

Anthony Dekker, D.O., F.A.O.A.A.M.

Hospital Vice President for Medical Affairs
and Chief Medical Officer Brighton Hospital
Brighton, Michigan

Walter Ginter, C.M.A.

Project Director, Medication Assisted
Recovery Support (MARS) Project
Port Morris Wellness Center
Bronx, New York

Janice Kauffman, R.N., M.P.H., C.A.S.

Vice President, Addiction Treatment Services
North Charles Foundation, Inc.
Somerville, Massachusetts

Jeffrey A. Kelman, M.D., M.M.Sc.

Chief Medical Officer, Center for Beneficiary Choices
Centers for Medicare and Medicaid Services
Baltimore, Maryland

Jag H. Khalsa, Ph.D.

Chief, Medical Consequences of Drug Abuse
and Co-Occurring Infections Branch
Division of Pharmacotherapies and Medical
Consequences of Drug Abuse
National Institute on Drug Abuse, NIH
Bethesda, Maryland

R. Gregory Lande, D.O., F.A.C.N.

Clinical Consultant, Department of Psychiatry
Walter Reed Army Medical Center
Army Substance Abuse Program
Washington, DC

Raye Z. Litten, Ph.D.

Associate Director, Division of Treatment
and Recovery Research
National Institute on Alcohol Abuse and Alcoholism
Bethesda, Maryland

SAMHSA'S PHARMACOTHERAPY EXPERT CONSENSUS PANEL MEMBERS (cont.)

Elinore McCance-Katz, M.D., Ph.D.

Director, Addiction Medicine Research
San Francisco General Hospital
Adjunct Professor, Psychiatry
University of California, San Francisco
San Francisco, California

Laura McNicholas, M.D., Ph.D.

American Psychiatric Association
Philadelphia, Pennsylvania

Fran Randolph, Dr.PH.

Director of the Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Bob Rappaport, M.D.

Director, Division of Anesthesia and Analgesia Products
Food And Drug Administration
Silver Spring, Maryland

Nicholas Reuter, M.PH.

Senior Public Health Analyst, Division
of Pharmacologic Therapy
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Deidra Roach, M.D.

Medical Director, Division of Treatment
and Recovery Research
National Institute on Alcohol Abuse and Alcoholism
Bethesda, Maryland

Richard N. Rosenthal, M.D.

Senior Associate Dean
Arthur J. Antenucci Professor of Clinical Psychiatry
Columbia University College of Physicians and Surgeons
Chairman, Department of Psychiatry
St. Luke's Roosevelt Hospital Center
New York, New York

Matthew Rudorfer, M.D.

Associate Director for Treatment and Research
Division of Services and Intervention Research
National Institute of Mental Health
Bethesda, Maryland

Steven Samra, M.P.A.

Recovery Specialist
Center for Social Innovation
Newton Center, Massachusetts

Tison Thomas, M.S.W.

Public Health Advisor
Center for Substance Abuse Treatment
SAMHSA
Rockville, Maryland

Douglas Ziedonis, M.D., M.PH.

Professor and Chairman of the Department of Psychiatry
University of Massachusetts Medical School and
University of Massachusetts Memorial Health Care
Worcester, Massachusetts

Penelope P. Ziegler, M.D., F.A.S.A.M.

Medical Director, Virginia Health Practitioners
American Society of Addiction Medicine
Richmond, Virginia

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