



AMERICAN PSYCHIATRIC ASSOCIATION

166TH ANNUAL MEETING

MAY 18-22, 2013 • SAN FRANCISCO, CA

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DAILY BULLETIN

PURSUING WELLNESS ACROSS THE LIFESPAN



The Road to San Francisco: Developing DSM-5

The long and winding road that was the DSM-5 development process culminates this week at the APA Annual Meeting in San Francisco — approximately 2,800 miles and almost a decade and a half from where it began — with the official unveiling of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

The first step in the DSM-5 journey was taken in 1999, at the National Institute of Mental Health in Bethesda, when a discussion between Steven Hyman, MD, (then-director of the NIMH), Steven M. Mirin, MD (then-medical director of the APA), and David J. Kupfer, MD, (then-chair of the APA Committee on Psychiatric Diagnosis and Assessment) put the wheels in motion to begin the DSM-5 development process.

“The publication of DSM-5

is the culmination of a nearly 14-year process that began with the decision by APA to move forward with a DSM-5 revision that would reflect current advances and facilitate both clinical practice and research,” said David J. Kupfer, MD, Chair of the DSM-5 Task Force.

Darrel Regier, MD, MPH, Director of the APA Division of Research and Executive Director of the American Psychiatric Institute for Research and Education (APIRE) is Vice-Chair of the DSM-5 Task Force, serving jointly with Task Force Chair, the aforementioned

Dr. Kupfer, who is the Thomas Detre Professor of Psychiatry and

Professor of Neuroscience and Clinical and Translational Science at the University of Pittsburgh School of Medicine.

Prior to the formation of the Task Force, preliminary work on DSM-5 began with three planning conferences held by

the APA and NIMH in 1999 and 2000, which included psychiatrists, psychologists, other mental health professionals, and research experts. These meetings set the stage for the development process with the formation of several groups of national and international experts who worked to compile a series of white papers, published together as “A Research Agenda for DSM-5,” in 2002.

The next stage of development was supported by a \$1.1 million cooperative agreement from the National Institutes of Health (U13 MH067855), including the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, to coordinate a series of additional conferences to identify research advances and major

Developing DSM-5, continued on page 22



Darrel A. Regier, MD, MPH



David J. Kupfer, MD

Addiction Performance Project Returns for Encore Performance

National Institute on Drug Abuse Track

The APA Annual Meeting program once

again includes a special educational track sponsored by the National Institute on Drug Abuse, featuring a wide range of symposia and lectures designed to update attendees on areas critical to psychiatric practice. Among the highlights of the NIDA Track, and returning for a repeat of last year's popular performance, is the Addiction Performance Project — a unique educational event featuring a dramatic reading from the Eugene O'Neill play “Long Day's Journey into Night” by Emmy Award-winning actress Mare Winningham and other actors. Although the play was published more than a half-century ago and is set in the early 1900s, the issues and themes it addresses make it powerful and relevant still today.

“At its core, it is a story of how addiction is both an individual and a family disease. It is the story of any family that has been torn apart by addiction,” said NIDA Director

Nora D. Volkow, MD. “This play also speaks to how stigma and shame keep people that are addicted from getting the help they need from the medical establishment. As true today as it was over a hundred years ago.”

The Addiction Performance Project includes a panel and audience discussion after the reading. Joining Dr. Volkow on this year's panel are Congressman

Patrick Kennedy, Dr. Roger Weiss, Professor of Psychiatry at Harvard

Medical School and Chief of the Division of Alcohol and Drug Abuse at McLean Hospital in Belmont, Massachusetts; and Dr. Steven Batki, Professor in the UCSF Department of Psychiatry, Chief of the SFVAMC Substance Abuse Programs, and Director of the SFVAMC Addiction Research Program. The Addiction Performance Project takes place on Sunday, beginning at 2 p.m., in Room 130/131 of the Moscone Convention Center.



Nora D. Volkow, MD

Frontiers of Science

Dr. Volkow will also deliver a Frontiers of Science Lecture on Monday at 11 a.m. in the Gateway Ballroom 102/103 of the Moscone Convention Center. In her lecture — “Substance Use Disorders: New Scientific Findings and Therapeutic Opportunities” — Dr. Volkow will discuss a range of findings in the area of addiction science, such as what researchers are learning about genetic vulnerability and resilience for drug abuse and effects of drug exposure on gene expression and on brain development.

“In the past few years our understanding of the biological, developmental, and environmental factors involved in drug abuse and addiction has grown enormously, and it is paving the way for exciting new treatment approaches,” Dr. Volkow said. “Translational research is also paving the way for the use of new imaging tools as biomarkers, which will both help predict the effectiveness of prevention interventions and assess and monitor addiction treatment strategies.”

She will also talk about new addiction

NIDA TRACK, continued on page 3

Annual Meeting Highlights

SATURDAY

Registration Hours

7:30 a.m. – 5 p.m.

Resident Competition Poster Sessions

9 a.m. – 10:30 a.m. and 11:30 a.m. – 1 p.m.
Exhibit Hall, Moscone Convention Center

International Poster Session

2 p.m. – 4 p.m.
Exhibit Hall, Moscone Convention Center

DSM-5 Exclusive Event

4 p.m. – 5 p.m.
Meet the Task Force chairs, purchase DSM-5, and get a free gift with purchase.

Opening Session

4:30 p.m. – 6:30 p.m.
Opening ceremonies will be followed by a conversation between APA President Dilip Jeste, MD, and Elyn Saks, JD, PhD
Hall D, Moscone Convention Center

APP Bookstore (see page 22)

Exhibit Hall, Moscone Convention Center

American Psychiatric Foundation Benefit

7 p.m. – 10 p.m.
City Club of San Francisco

SUNDAY

New Research Poster Session

8:30 a.m. – 10 a.m.
Exhibit Hall, Moscone Convention Center

Young Investigator Poster Session

10:30 a.m. – 12 p.m.
Exhibit Hall, Moscone Convention Center

Exhibits

10 a.m. – 4 p.m.
Exhibit Hall, Moscone Convention Center

NIDA Addiction Performance Project

2 p.m. – 4 p.m.
Room 130/131, Moscone Convention Center

Challenges and Opportunities in Schizophrenia Treatment

Sunday, May 19, 2013

1:00 PM – 2:00 PM

Lunch will be served

Please Join Sunovion Pharmaceuticals Inc. at
Moscone Convention Center
Exhibit Halls A-C, Exhibit Level
for a Product Theater presentation given by

Stephen M. Stahl, MD, PhD

Adjunct Professor of Psychiatry

University of California, San Diego School of Medicine

Honorary Visiting Senior Fellow

University of Cambridge, UK

Editor-in-Chief, *CNS Spectrums*

Director of Psychopharmacology Services

California Department of State Hospitals

Consultant of Sunovion Pharmaceuticals Inc.

This promotional non-CME program is only intended for those healthcare professional involved in the treatment of adult patients with schizophrenia.

The content and the views expressed therein are those of Sunovion Pharmaceuticals Inc. and not of the American Psychiatric Association (APA). Continuing Medical Education (CME) credit for this event is not offered by APA or Sunovion Pharmaceuticals Inc.

This program is not intended or eligible for continuing education credits and does not meet guidelines governing continuing education.

INDICATIONS AND USAGE for Latuda® (lurasidone HCl)

LATUDA is an atypical antipsychotic indicated for the treatment of adult patients with schizophrenia. Efficacy was established in five 6-week controlled studies of adult patients with schizophrenia. The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

IMPORTANT SAFETY INFORMATION FOR LATUDA

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- LATUDA is not approved for the treatment of patients with dementia-related psychosis.

Please see additional Important Safety Information, including **Boxed Warning**, and full Prescribing Information available at Booth 1632 or www.LatudaHCP.com.



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www.LatudaHCP.com

**Actors subject to change*

FACTS ABOUT THE ANNUAL MEETING

Each year many questions are asked

about the Annual Meeting. This fact sheet has been prepared to answer the most commonly asked questions and to provide basic information about the APA meeting.

Did you know?

- The Annual Meeting is booked at least ten years in advance to obtain the necessary meeting space and sleeping rooms. Dates are held through 2027 now.
- APA strives for a geographical rotation based on adequate accommodations and availability.
- Approximately 7,000 hotel sleeping rooms are needed on peak night to house meeting attendees, exhibitors, and staff.
- The commercial/educational exhibits, APA Member Center, APP Bookstore, and the registration area require a minimum of 275,000 gross square feet of space. Over 200 10x10 booths are used for the exhibit program.
- Approximately, 100-135 concurrent meeting rooms are used for scientific sessions, courses, allied and committee activities, and operational office space.
- Approximately 50 temporary personnel are employed to assist with registration, course monitoring, etc.
- During peak hours about 50 motor coaches are in use.

Facts About CME

CME credit is earned on an hour-for-hour basis by attending scientific sessions. Signing into sessions is not necessary, nor is having your attendance verified by the APA. The APA does not keep records of registrants' attendance at individual sessions; **physicians are responsible for maintaining their own records.** A Log Sheet for recording the individual sessions you attend is located in the Program Book. There are two ways for a physician to receive a CME Certificate:

- Complete the General Evaluation at the Convention Center, available Saturday-Wednesday;
- Or, complete the online General Evaluation at, www.psych.org/annualmeetingcme during or after the meeting until mid-August. This evaluation is identical to the evaluation available at the CME Certificate of Attendance booth.

ANSWERS TO COMMONLY ASKED QUESTIONS

Can my spouse/guest attend scientific sessions without a badge?
No

Can my spouse/guest go through the exhibits without a badge?

You can purchase a guest pass for \$25 per day. This pass is only good to tour the exhibits for one day, and may be purchased in the registration area by a registered attendee.

Where can I leave messages?

At one of the two message centers, located in the registration area and in the south lobby.

How can I get a copy of Dr. X's paper?

Copies of session abstracts can be obtained in the syllabus and proceedings book provided on a CD-ROM to each registered meeting attendee or post meeting on our website by visiting the APA Melvin Sabshin library and archives.

I just got here how do I get a hotel room? How can I change my hotel?

Go to the housing desk in the south lobby of the convention center.

Where can I change my currency into U.S. dollars?

Check with your hotel for the nearest major bank. The airport and most hotels also offer foreign currency exchange.

Where can I get information on the 2014 Annual Meeting submission process, the 2013 APA Institute on Psychiatric Services, or Certificates of Attendance?

At the APA Member Center in the exhibit hall at the convention center.

Where can I find information on exhibits?

In the exhibits section of the Guide to the Annual Meeting, distributed at registration.

How can I find out where and when my committee is meeting, and where the reception is for residents and fellows?

Refer to the APA Committee, Allied Organizations, and Sponsored Scientific Sessions Booklet, available in the registration area.

What is the difference between the books in my registration packet?

Days-at-a-Glance is a pocket-size booklet outlining the meeting by day and time, with formats listed alphabetically. Use for ease in finding sessions.

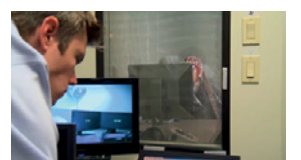
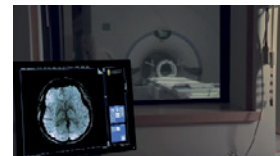
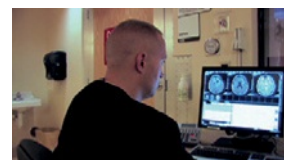
Annual Meeting Guide contains:

- A detailed listing of each session, including all presenters, listed by day, start time, then alphabetically by format, with locations.
- General information about the meeting, presenter disclosures, and a topic index, participant index, and floor plans.
- New Research Program listing all posters presented at the meeting
- Exhibits Section listing all exhibitors and exhibit floor plan.

Syllabus & Proceedings Book is available as a PDF file on the CD-ROM in your registration materials and contains the title, educational objectives, presenter names, degrees and abstracts for scientific sessions. The CD also includes the Lecturer Brochure, Course Brochure, Research Track Highlights and other promotional materials related to the Annual Meeting program content.

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CAPTURING ISSUES
• AUDIENCES

health



APA TV returns for the 3rd year!

Welcome to San Francisco, host to the APA 166th Annual Meeting and APA TV - your conference television channel dedicated to news and views from the conference.

Whether it's a workshop, debate or speech APA TV is here to cover all the important issues, raise the visibility of the APA and highlight the current emerging trends in psychiatry.

You will be able to watch exclusive reports, produced especially for the conference from medical centers, hospitals and universities.

Tune In!

We will be screening a new episode each day of the conference. Watch the program around the conference venue, in the rooms of selected hotels, and online at:

www.websedge.com/videos/health

www.youtube.com/WebsEdgeHealth

Twitter: @WebsEdge_Health and the conference #APAAM13

Be on TV - APA TV!

You will see our camera team touring throughout the Convention Center. Please say hello and share with us your comments on the speakers and sessions you attended.

The APA TV team welcomes all feedback and would like to hear what you think of your new conference TV show, as well as your views on the various issues raised at the conference.

We hope you enjoy the meeting and APA TV 2013!

APA TV is part of WebsEdge/Health - our group of products and services for health organizations, connecting issues and audiences through the power of television.

For up to date information and news, follow us on Twitter: @websedge_health and the conference on #APAAM13

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MEET AND SHARE IDEAS WITH INCOMING
APA PRESIDENT, **JEFFREY LIEBERMAN, M.D.**
AT OUR BOOTH ON MAY 21ST, 11 AM – 12 PM



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Corporate Leaders Discuss Return To Work

Today's workplace confronts people with increasingly high levels of uncertainty and stress. More workers are absent from work because of stress and anxiety than because of physical illness or injury. Effective psychiatric treatment requires understanding the impact of stress on the entire person, both physiologically and psychologically. Who is the champion for the employed psychiatric patient? Is it the psychiatrist? Is it the employer? Or can it be both?

APA leaders, along with employers DuPont and JPMorgan Chase, will present the symposium, "Return to Work: the Most Underutilized 'Pill' in the Psychiatrist's Formulary" on Wednesday, May 22 from 2 p.m. – 5 p.m. in room 306 at the Moscone Center.

The symposium is being presented by the Partnership for Workplace Mental Health, a program of the American Psychiatric Foundation, dedicated to collaborating with employers to advance quality mental health care. Presentations will highlight real-world employer approaches to mental health.

Hear innovative employer mental health strategies and explore how psychiatry can be a partner in efforts to reduce employee stress and the amount of time away from work.

"Employers increasingly recognize that untreated mental illness increases absenteeism, saps

productivity, and drives up health care and disability costs. More than that, we see the impact of stress and emotional health on our employees every day," said panelist Paul Heck, MEd, LPC, Global Manager for Employee Assistance and WorkLife Services

for DuPont and Advisor to the Partnership for Workplace Mental Health. "Let's talk about how employers and psychiatry can partner in reaching our shared goals of people receiving quality treatment that

"Employers increasingly recognize that untreated mental illness increases absenteeism, saps productivity, and drives up health care and disability costs. More than that, we see the impact of stress and emotional health on our employees every day,"

– Paul Heck, MEd, LPC

avoids the need to miss work or that minimizes time away from work."

Support a coordinated return-to-work strategy. The idea of "functional impairments" will be highlighted in conjunction with DSM-IV diagnoses to present a model of how psychiatry can better partner with workplaces to restore patient functioning. The session will present a pathway to understand disability and identify various roles mental health professionals can play to enhance return to work planning.

"A widespread culture of stigma continues to surround mental health, often preventing individuals from reaching out for help they need when they need it most," said panelist Paul Pendler, PsyD, Vice President for Employee Assistance & WorkLife Program at JPMorgan Chase. "Employers are implementing

strategies that enable help-seeking behavior and psychiatry needs to be at the table as part of an overall wellness and health promotion strategy."

Partner with employer coalitions. The panel will explore how employers collaborate through business coalitions to make a positive impact on mental health care delivery and financing.

"Beyond learning how employers are addressing stress and mental health with their employees, I believe that attendees of this symposium will discover firsthand how, in many ways, the goals of business and psychiatry are in fact aligned, and that employers can be a valuable ally to psychiatry," said symposium chair Alan Axelson, MD and co-chair of the Partnership for Workplace Mental Health's Advisory Council. ●

Return to Work: the Most Underutilized 'Pill' in the Psychiatrist's Formulary

Wednesday, May 22
2 p.m. – 5 p.m.
Room 306, Moscone Center



For more information, please contact:
American Psychiatric Association
1000 Wilson Blvd., Suite 1825
Arlington, VA 22209-3901
Phone: 1.888.35.PSYCH or 703.907.7300
Fax: 703.907.1090
E-mail: apa@psych.org
www.psychiatry.org/ips

CEU accreditation pending with:



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Behavioral Healthcare Education

TRANSFORMING PSYCHIATRIC PRACTICE, REFORMING HEALTH CARE DELIVERY

Save the date now to attend the American Psychiatric Association's 65th Institute on Psychiatric Services, APA's leading educational conference on clinical issues and community mental health to meet the service needs of people with severe mental illness.

This four-day event will feature more than 100 expertly led educational sessions on a variety of topics, popular networking events, and exhibits that complement the educational program. Further information can be found on the Web at: www.psychiatry.org/ips

Who Should Attend?

- All APA members, including early career psychiatrists and psychiatric residents (advance registration begins June 3)
- International psychiatrists
- Primary Care physicians
- Mental health professionals from all disciplines

Why Should You Attend?

- To earn CME credit (CEUs have also been applied for)
- To improve patient care
- To learn about clinically-focused topics that offer specific skill sets

- To network with colleagues and obtain solutions for the challenges you face
- Because your return on investment will reap both personal and professional rewards

The IPS Has Gone "GREEN"

The Preliminary Program, which will include registration, housing, travel, and detailed program information, will be available later this spring, online only.

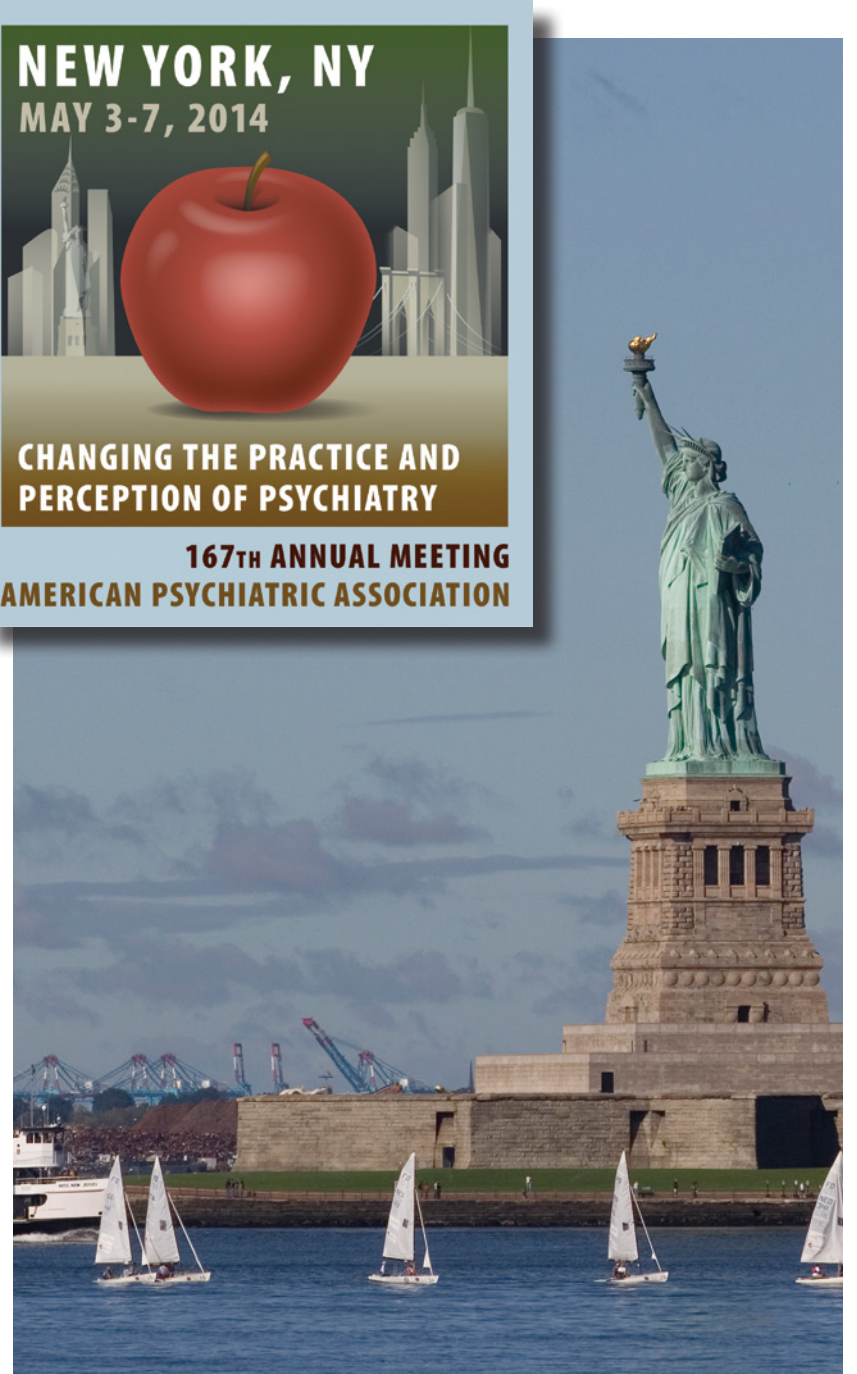
The American Psychiatric Association is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.



NEW YORK, NY
MAY 3-7, 2014

CHANGING THE PRACTICE AND
PERCEPTION OF PSYCHIATRY

167TH ANNUAL MEETING
AMERICAN PSYCHIATRIC ASSOCIATION





Resident Track

APA Program Offers a Comprehensive Schedule and a Place to Call ‘Home’ for MITs

This year's Annual Meeting features a full schedule of educational sessions, networking opportunities and social events for psychiatry residents and fellows, offering more chances than ever for members-in-training to meet and socialize with one another, ask questions, share information and learn more about their profession.

“The Resident's Track that has been put together for the meeting here in San Francisco is going to be very exciting,” said Erik Vanderlip, MD, APA Member-in-Training Trustee-Elect. “One new thing I think everyone will appreciate is the MIT Center, which will serve as ‘home base’ for MITs throughout the meeting.”

The MIT Center, located in room 110 of the Moscone Convention Center, will house MIT-specific educational programming as well as live mentoring opportunities with leaders across all sub-specialties. The MIT Center will have all the real-time updated information on ongoing activities and events for residents and fellows.

Among the highlights of the 2013 Resident Track is a special workshop on Saturday, “DSM-5 for the Member-in-Training,” designed to introduce residents and fellows to the new manual, orient them to the DSM scientific process and familiarize them with significant updates across the disorders. The workshop begins at 9 a.m. in the MIT Center.

“The DSM-5 for the MIT presentation will include background information

on the development process of the DSM-5 and some of the history of the document,” said Dr. Vanderlip, who will co-chair the workshop with Alik Widge, MD, APA Member-in-Training Trustee. “It will also explore challenges in criterion formation for DSM-5 diagnoses, and we will have a discussion on the tensions in developing a consensus for the current criterion set.”

Another “must-attend” workshop — “What Happens Now That I've Graduated? Pearls, Pitfalls, Strategies For Negotiating Your First Job, And Other Transitions After Residency” — will be held on Monday at 1:30 p.m. in the MIT Center. Chaired by Sarah Johnson, MD, MSc, this workshop will include tips and tricks from early career psychiatrists on how to “survive” the transition from residency into early careers.

Other highlights of the 2013 Resident Track include the “Meet the Experts Breakfast,” beginning at 7 a.m. Monday in Nob Hill Room A-D at the Marriott Marquis; the MIT Caucus Meeting Sunday evening at 7:30 p.m., California Pizza Kitchen (53rd Street, 2 blocks from Moscone, across from the Westin); and the always popular Mind Games competition, which will be held on Tuesday at 5:30 p.m. Moscone, room 135.

“All in all, our goal is to make the MIT program at the Annual Meeting current and comprehensive for the residents and fellows attending the meeting, and make it flexible and adaptable to their interests and availability,” Dr. Vanderlip said. ●

Saturday, May 18

9 a.m. – 10:30 a.m.

Resident Poster Competition Session #1

Small Interactive Session (S1): The Future of Psychiatry

Workshop (W3): Medical Conditions Mimicking Psychiatric Disorders vs Psychiatric Disorders Mimicking Medical Conditions (Council on Psychosomatic Medicine)

Workshop (W4): DSM-5 for the Member-in-Training

11 a.m. – 12:30 p.m.

Workshop (W10): Resilience and Risk: How Women Psychiatrists Balance Life-Work Issues Across the Life Span

11:30 a.m. – 1 p.m.

Resident Poster Competition Session #2

1:30 p.m. – 3 p.m.

Small Interactive Session (S03): The Art of Being a Geriatric Psychiatrist: Integrating Clinical Research Findings Into Patient Care

3:30 p.m. – 5 p.m.

Workshop (W26) Part 1: Making the Most of Your Chief Year: Chief Residents' Forum

Sunday, May 19, 2013

8 a.m. – 9:30 a.m.

Workshop (W33) Part 2: Making the Most of Your Chief Year: Chief Residents' Forum

8 a.m. – 12 p.m.

Seminar (S9): How to Give a More Effective Lecture

8 a.m. – 5 p.m.

APA's Chief Resident Leadership Conference (Separate Registration Required)

10 a.m. – 11:30 a.m.

Workshop (W37): Transition to Practice and Transitions in Practice

1 p.m. – 4 pm

Symposium (S40): The Sixth Vital Sign: Assessing Cognitive Impairment in HIV-Infected Patients

2:30 p.m. – 4 p.m.

Workshop (W56): Developing a Career in Child and Adolescent Psychiatry

7 p.m. – 10 p.m.

Media Workshop (MW6): We Were Here: A Documentary About Surviving the AIDS Epidemic in San Francisco (AACAP)

7:30 p.m. – 8:30 p.m.

Resident Event: MIT Caucus Meeting (all residents) Chair: Alik Widge, MD

Monday, May 20, 2013

7 a.m. – 8:30 a.m.

Resident Mentoring Event: Meet the Experts: Sunny Side Up Breakfast

7:30 a.m. – 9:30 a.m.

Resident Mentoring Event: Women's Mentoring Breakfast

11 a.m. – 12:30 p.m.

Small Interactive Session (SI14): Seeking Fulfillment & Balance in Your Professional & Personal Life

Workshop (W66): Making Your Presentation More Interactive: The Better Way

1:30 p.m. – 3 p.m.

Workshop (W75): What Happens Now That I've Graduated? Pearls, Pitfalls, & Strategies for Negotiating Your First Job & Other Transitions After Residency

3:30 p.m. – 5 p.m.

Small Interactive Session (SI7): Psychiatry, the AMA, and Medicine: The Next Chapter

Workshop (W85): Professionalism in Social Networking: What Shouldn't Be Tweeted, Blogged, or Posted

Tuesday, May 21, 2013

7 a.m. – 8:30 a.m.

Resident Mentoring Event : Early Research Career Breakfast

9 a.m. – 10:30 a.m.

Forum (F6): Psychiatric Residents and the Creative Process

Small Interactive Session (SI18): Psychodynamic Psychotherapy in the Era of the Internet

Small Interactive Session (SI19): Professionalism and the Professional Society

Workshop (W94): Research Literacy in Psychiatry: Part 1

9 a.m. – 4 p.m.

Master Course (MC06): 2013 Psychiatry Review

11 a.m. – 12:30 p.m.

Workshop (W100): To Be or Not To Be Out: Gay and Transgender Psychiatrists Discuss Implications for Faculty, Trainees, and Patients

Workshop (W101): Research Literacy in Psychiatry: Part 2

1:30 p.m. – 3 p.m.

Forum (F9): (FOR RESIDENTS ONLY) A Resident's Guide to Borderline Personality Disorder From the Experts: Part 1

3:30 p.m. – 5 p.m.

Forum (F10): (FOR RESIDENTS ONLY) A Resident's Guide to Borderline Personality Disorder From the Experts: Part 2

5:30 p.m. – 6:30 p.m.

Mind Games Final Resident Competition



APA Annual Meeting ON DEMAND

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APA Annual Meeting on Demand is a digital library of presentations of the 2013 American Psychiatric Association Annual Meeting.

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South Lobby (street level)
Exhibit Halls A – C, near Registration



More than 500,000 U.S. participants in the Middle East conflicts may suffer from Post-Traumatic Stress Disorder.

Meet one of them.

Retired Lieutenant Colonel John O'Brien served four tours as a Special Operations officer in the Middle East. He received a Purple Heart and a Bronze Star for service to his country. The nightmares of war can leave the body and the mind ravaged. But there's a real stigma associated with PTSD. John says that some of his fellow soldiers believe that the need to go to psychotherapy means you're "weak," and that it's something only "crazy" people do.

John participated in a PTSD clinical trial at NewYork-Presbyterian, where both medical and virtual therapy treatments are being pioneered. He says, "My treatment at NewYork-Presbyterian has brought me to a point in my life where I can really start to move on and do the things I want to do."

Visit NewYork-Presbyterian's Booth #713, and at nyp.org/psychiatry.

 **NewYork-Presbyterian**

**AMAZING
THINGS
ARE
HAPPENING
HERE**

Minority, Underrepresented Groups Share Concerns Through Caucuses

Psychiatrists who identify with any of APA's recognized minority and underrepresented (M/UR) groups are urged to join that group's caucus and attend its meeting during the APA 2013 Annual Meeting in San Francisco. The minority and underrepresented group caucuses were established to provide a networking opportunity and foster communication among members who share a special interest.

There are caucuses for the following groups: American Indian/Alaska Native/Native Hawaiians; Asian Americans; Blacks; Hispanics; Lesbians, Gays, and Bisexuals; International Medical Graduates; and Women.

Participation in a caucus is a pathway to the following:

- Exploring concerns about professional growth and advancement.
- Identifying, supporting, and electing top-notch M/URs for leadership posts.
- Networking with members with shared backgrounds.
- Advocating for minority patient populations.
- Talking about key issues facing APA.
- Initiating mentoring relationships.
- Bringing concerns to APA leadership.
- Assuming leadership roles in APA.

To join a caucus, at www.psychiatry.org, click on:

- "Join & Participate" then
- "My Account" then
- Log into your account then
- "Member Profile" section 3Fa and select the appropriate caucus(es).

College Mental Health Caucus to Meet

APA members with a special interest in college mental health issues are invited to participate in a meeting of APA's College Mental Health Caucus at this year's Annual Meeting in San Francisco. Participants will have an opportunity to discuss issues, raise concerns, and share information. The meeting will be held Tuesday, May 21, from 9:30 a.m. – 11:30 a.m. at the San Francisco Marriott Marquis, Sierra Suite C, Fifth Floor. ●

Sunday, May 19

2 p.m. – 3:30 p.m.

Caucus of Hispanic Psychiatrists

Sierra Conference Suite F, 5th Floor, San Francisco Marriott Marquis

3 p.m. – 4:30 p.m.

Caucus of Gay, Lesbian, and Bisexual Psychiatrists and Association of Gay and Lesbian Psychiatrists (Joint Meeting)

Howard Room, 5th floor, Intercontinental San Francisco

Monday, May 20

4 p.m. – 5 p.m.

Caucus of International Medical Graduate Psychiatrists

Laurel Room Upper B2 Level, San Francisco Marriott Marquis

6:45 p.m. – 7:45 p.m.

Caucus of Black Psychiatrists

Golden Gate Hall, Salon C3, Level B2, San Francisco Marriott Marquis

6:45 p.m. – 8 p.m.

Caucus of Asian-American Psychiatrists

Pacific Suite E, 4th Floor, San Francisco Marriott Marquis

6:45 p.m. – 8:30 p.m.

Caucus of American Indian, Alaska Native, and Native Hawaiian Psychiatrists

Laurel Room Upper B2 Level, San Francisco Marriott Marquis

Tuesday, May 21

5:30 p.m. – 7:30 p.m.

Caucus of Women Psychiatrists and the Association of Women Psychiatrists (Joint Meeting)

Pacific Suite 1, 4th Floor, San Francisco Marriott Marquis

Psychiatric Care During Pregnancy To Be Focus of *AJP* Forum

by Leslie Sinclair

Clinical treatment decisions during pregnancy require careful balancing of risk and benefit. Authors of studies recently published in *AJP* will give clinical guidance for such decisions.

"The American Journal of Psychiatry (*AJP*) will host a forum titled "Treatment of the Pregnant Woman and Her Child," chaired by Robert Freedman, MD, editor in chief of *AJP*, on Monday, May 20, at 11 a.m.

We strive to make the journal's cutting-edge research germane to today's practicing clinician," Freedman told *Psychiatric News*, "and we particularly target clinical situations in which even the most experienced psychiatrists are the most careful in their approach. The care of the psychiatrically ill pregnant woman and her fetus is an area in which all clinicians want to be informed about the latest research that investigates the risk and benefit of treatment." He added that the forum "will bring together authors of four recently published articles to discuss their research, all of which informs current care and will affect future treatment development."

But first, Harita Raja, MD, a psychiatry resident at Medstar Georgetown University Hospital in Washington, D.C., will begin the symposium with a case presentation. She is the author of a recent review article on treatment of maternal depression in the *Residents' Journal*, an online publication of the *American Journal of Psychiatry*.

The first speaker will be Katherine Wisner, MD, a professor of psychiatry; obstetrics; gynecology; and reproductive sciences and epidemiology at the University of Pittsburgh School of Medicine. Wisner has meticulously characterized the effects of depression

and medication treatment for it on the growth and development of the fetus and found independent effects of each, but little evidence that antidepressants cause additional harm to the fetus.

Mallay Occhiogrosso, MD, an assistant professor of psychiatry at Weill Cornell Medical College, and her colleagues made similar findings about newborn pulmonary hypertension, once thought to be an adverse effect of SSRI treatment during pregnancy (*Psychiatric News*, May 4, 2012). Their extensive epidemiologic investigations revealed that the effect is small and as likely to be caused by depression itself as by the medications.

Veerle Bergink, MD, a psychiatrist at the Erasmus Medical Center in Rotterdam, the Netherlands, will present a study of the approach preferred by her clinic for pregnant women with a history of bipolar disorder or postpartum psychosis (*Psychiatric News*, May 4, 2012). Her clinic's prophylactic treatment diminishes some but not all risk for subsequent illness during or after pregnancy.

The final speaker, Randal Ross, MD, a professor in the Department of Psychiatry at the University of Colorado School of Medicine, has developed a physiological indicator of the newborn's brain development. With this technique, he finds that antidepressant treatment frequently prevents the otherwise deleterious effect of a maternal anxiety disorder and that the nutrient choline may prevent the development of pathological brain dysfunction associated with later mental disorders in the child. ●

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EDUCATIONAL PROGRAM INCLUDING:
Interactive Interview with a Caregiver and Patient

Addressing the Major Unmet Needs in Schizophrenia:

Physician, Patient and Caregiver Perspectives

Saturday, May 18, 2013

**San Francisco Marriott Marquis
Yerba Buena Ballroom 9 • Lower Level B2**

6:30 PM – 7:00 PM Registration & Dinner
7:00 PM – 9:00 PM Educational Program

Overview Statement

Schizophrenia has a substantial impact on everyday functioning, being one of the top five causes of disability in individuals under the age of 25. In most cases, individuals who develop schizophrenia manifest behavioral and cognitive changes prior to the formal diagnosis of the condition. Clinicians face challenges in diagnosing this disorder, as well as designing treatment plans that will reduce negative symptoms, maximize adherence and reduce side effects. This program will feature a patient and caretaker interview, while world renowned experts will discuss pathobiology, as well as current and future therapies designed to improve cognitive function in addition to alleviating symptoms, improving the quality of life for patients and their caregivers.

Target Audience

This activity is designed for psychiatrists and other healthcare professionals involved in the treatment of patients with schizophrenia.

Learning Objectives

Upon successful completion of the live non-certified activity, participants will be able to:

- Review the recent neuroscience advances that shed light on the neurobiology of schizophrenia.
- Discuss the clinical features of the “prodrome” in schizophrenia and how specific symptoms and deficits emerge before the conversion to psychosis.
- Recognize the various measurement tools used to assess the severity of clinical symptoms and cognitive dysfunction in schizophrenia.
- Evaluate therapeutic strategies utilized to treat specific symptoms and deficits in schizophrenia to address the major unmet needs associated with this disabling neuropsychiatric syndrome.



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Pre-registration is encouraged but not required. Seating to be based on arrival order; early arrival is recommended.

Course Chair

Henry A. Nasrallah, MD

Professor and Vice Chair,
Department of Psychiatry
Director, Schizophrenia Program
University of Cincinnati
College of Medicine
Cincinnati, OH

Faculty

Leslie Citrome, MD, MPH

Clinical Professor of Psychiatry
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New York Medical College
Valhalla, NY

Diana O. Perkins, MD, MPH

Professor, Department of Psychiatry
University of North Carolina
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Chapel Hill, NC

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This live activity is not
approved for **AMA PRA**
Category 1 Credit™

This activity will be held in conjunction with the APA Annual Meeting. It is not considered part of the official scientific program of APA and is not for CME credit.

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For your patients with schizophrenia who need improvement in symptom control— **FANAPT MAY HELP**

INDICATION

FANAPT is an atypical antipsychotic agent indicated for the treatment of schizophrenia in adults. In choosing among treatments, prescribers should consider the ability of FANAPT to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate FANAPT slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analysis of seventeen placebo-controlled trials (modal duration 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. FANAPT is not approved for the treatment of patients with dementia-related psychosis.

*Please see additional Important Safety Information and brief summary of Prescribing Information, including **Boxed WARNING**, on adjacent pages.*

FANAPT FACTS

Efficacy

- FANAPT significantly improved overall symptoms in 2 clinical trials, as measured by the Positive and Negative Syndrome Scale (PANSS; 4-week trial) and the Brief Psychiatric Rating Scale (BPRS; 6-week trial)¹

Akathisia/EPS*

- Incidence of akathisia and EPS was similar to placebo^{1†}

Metabolics

- Mean change in weight from baseline at end point for FANAPT patients was 2.1 kg across all short-term and long-term trials^{1‡}
- The majority of patients taking FANAPT 24 mg/day did not experience a shift from normal to high in fasting lipid measurements in a 4-week study^{1§}

Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics. Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Tolerability

- Discontinuation rates due to adverse events were similar for FANAPT (5%) and placebo (5%)^{1†}
- The most common adverse reactions were dizziness, dry mouth, fatigue, nasal congestion, somnolence, tachycardia, orthostatic hypotension, and weight increase.^{1†}

TRIAL SAVINGS OFFER

Receive savings on up to 34 days (68 tablets) of FANAPT.
Visit www.FANAPT.com to learn more.

*Extrapyramidal symptoms.

†Based on pooled data from 4 placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies.

‡Pooled data from 4 placebo-controlled, fixed- or flexible-dose studies show a change from baseline in body weight of 2.0 kg with FANAPT 10-16 mg/day (n=481), 2.7 kg with FANAPT 20-24 mg/day (n=391), and -0.1 kg with placebo (n=576).

§3.6% of patients taking FANAPT 24 mg/day experienced a shift from normal (<200 mg/dL) to high (≥240 mg/dL) in fasting total cholesterol versus 1.4% of patients taking placebo. 10.1% of patients taking FANAPT 24 mg/day experienced a shift from normal (<150 mg/dL) to high (≥200 mg/dL) in fasting triglycerides versus 8.3% of patients taking placebo.

IMPORTANT SAFETY INFORMATION

Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all atypical antipsychotic drugs have been shown to produce some metabolic changes, each drug in the class has its own specific risk profile.

FANAPT® is a registered trademark of Vanda Pharmaceuticals Inc. and is used by Novartis Pharmaceuticals Corporation under license. FANAPT® is licensed by Novartis Pharmaceuticals Corporation from Titan Pharmaceuticals, Inc.

Reference: 1. FANAPT [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; January 2013.



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Receive a Rebate by Becoming a Member at the Annual Meeting

Psychiatrists who are eligible for APA General Membership may qualify for a \$585 rebate equal to the difference between the nonmember and member Annual Meeting registration fees if they join at the meeting. The rebate will be applied toward 2013 national and local membership dues, and any balance will be applied toward future years' dues.

To qualify, you must be a psychiatrist residing in the United States or Canada and be eligible for APA General Membership status and have paid the full nonmember registration rate to attend the meeting. To apply, submit your General Member application at one of the Membership Desks located in the meeting registration area or in the Member Center, both located in the Exhibit Hall. You will also need to submit proof of ACGME-AOA or RCPS(C) - approved psychiatry residency training and valid medical licensure to APA no later than June 30. ●

Join Us at the APA International Discussion Groups

The International Discussion Groups at the APA Annual Meeting afford psychiatrists the opportunity to meet and discuss relevant medical and mental health issues pertinent to the world. These groups are open to all Annual Meeting attendees and chaired by APA members.

- Sunday, May 19**
7:30 a.m. – 9 a.m.
Europe Discussion Group
Marriott Marquis, Laurel Room, Upper B2

2:30 p.m. – 4:30 p.m.
Africa Discussion Group
Marriott Marquis, Willow Room, Upper B2
- Monday, May 20**
2 p.m. – 4 p.m.
South Asia Discussion Group
Marriott Marquis, Willow Room, Upper B2

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analysis of seventeen placebo-controlled trials (modal duration 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. FANAPT is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: FANAPT is contraindicated in individuals with a known hypersensitivity reaction to the product. Reactions have included pruritus and urticaria.

Cerebrovascular Adverse Events, Including Stroke: In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly patients with dementia, there was a higher incidence of cerebrovascular adverse events (cerebrovascular accidents and transient ischemic attacks) including fatalities compared to placebo-treated patients. FANAPT is not approved for treatment of patients with dementia-related psychosis.

QT Prolongation: FANAPT was associated with QTc prolongation of 9 msec at an iloperidone dose of 12 mg twice daily. The effect of FANAPT on the QT interval was augmented by the presence of CYP450 2D6 or 3A4 metabolic inhibition (e.g., paroxetine 20 mg once daily and ketoconazole 200 mg twice daily, respectively). Under conditions of metabolic inhibition for both 2D6 and 3A4, FANAPT 12 mg twice daily was associated with a mean QTcF increase from baseline of about 19 msec. No cases of torsades de pointes or other severe cardiac arrhythmias were observed during the premarketing clinical program. FANAPT should be avoided in combination with other drugs that are known to prolong QTc. FANAPT should also be avoided in patients with congenital long QT syndrome and in patients with history of cardiac arrhythmias, and in circumstances that may increase risk of torsades de pointes and/or sudden death in association with use of drugs that prolong the QTc interval. Use caution and consider dose modification. Patients being considered for FANAPT treatment who are at risk for significant electrolyte disturbances should have baseline serum potassium and magnesium measurements with periodic monitoring. FANAPT should be discontinued in patients who are found to have persistent QTc measurements >500 msec.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported in association with administration of antipsychotic drugs, including FANAPT. NMS can cause hyperpyrexia, muscle rigidity, altered mental status, irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysarrhythmia. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management should include immediate discontinuation of the antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and medical monitoring, and treatment of any concomitant serious medical problems. If antipsychotic treatment is required after recovery from NMS, reintroduction should be carefully considered and patient should be carefully monitored.

Tardive Dyskinesia (TD): Risk of developing tardive dyskinesia, and the likelihood that it will become irreversible, may increase as the duration of treatment and the total cumulative dose increases. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. If signs and symptoms appear, drug discontinuation should be considered.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all atypical antipsychotic drugs have been shown to produce some metabolic changes, each drug in the class has its own specific risk profile.

Hyperglycemia and Diabetes: Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including FANAPT. Patients with an established diagnosis of, or with risk factors for, diabetes mellitus who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the antipsychotic.

Dyslipidemia: Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Seizures: As with other antipsychotics, FANAPT should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold, e.g., Alzheimer's dementia.

Orthostatic Hypotension and Syncope: FANAPT must be titrated from a low starting dose to avoid orthostatic hypotension. FANAPT can induce orthostatic hypotension associated with dizziness, tachycardia, and syncope. Therefore FANAPT must be titrated as directed. Dose increases to reach the target range of 6-12 mg twice daily (12-24 mg/day) may be made with daily dosage adjustments not to exceed 2 mg twice daily (4 mg/day). The maximum recommended dose is 12 mg twice daily (24 mg/day). Control of symptoms may be delayed during the first 1 to 2 weeks of treatment. FANAPT should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that predispose the patient to hypotension. Monitoring of orthostatic vital signs should be considered in patients who are vulnerable to hypotension.

Leukopenia, Neutropenia, and Agranulocytosis: In clinical trial and postmarketing experience with antipsychotic agents, events of leukopenia/neutropenia have been reported temporally. Agranulocytosis (including death) has also been reported. Patients with a preexisting low white blood cell count or a history of drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue FANAPT at the first sign of a decline in WBC in the absence of other causative factors.

Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, FANAPT elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds.

Body Temperature Regulation: Appropriate care is advised when prescribing FANAPT for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. FANAPT and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia.

Suicide: The possibility of a suicide attempt is inherent in psychotic illness, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for FANAPT should be written for the smallest quantity of tablets in order to reduce the risk of overdose.

Priapism: Three cases of priapism have been reported in the premarketing FANAPT program. Severe priapism may require surgical intervention.

Cognitive and Motor Impairment: FANAPT, like other antipsychotics, has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with FANAPT does not affect them adversely.

Commonly observed adverse events: Commonly observed adverse reactions (incidence ≥5% and twofold greater than placebo) were: dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increase.

Specific Populations

Pregnancy: FANAPT is Pregnancy Category C.

Hepatic Impairment: FANAPT is not recommended for patients with hepatic impairment.

Drug Interactions: Given the primary CNS effects of FANAPT, caution should be used when it is taken in combination with other centrally acting drugs and alcohol. FANAPT has the potential to enhance the effect of certain antihypertensive agents. Coadministration of FANAPT with potential CYP2D6 inhibitors (e.g., fluoxetine, paroxetine) and potential CYP3A4 inhibitors (e.g., ketoconazole) should be done with caution. FANAPT dose should be reduced by one-half. Cautiously approach coadministration of drugs mainly eliminated via CYP3A4 with FANAPT.



Women Psychiatrists: Join us in the Women's Center

Stop by the APA Women's Center, where you can meet up with other women colleagues, catch your breath, enjoy lively conversation, informative sessions, and more. A schedule of Center activities will be included in the Daily Bulletin and will be available at the Center.

The Women's Center is located in Pacific Suite C, 4th floor of the Marriott Marquis Hotel. Hours of operation are Saturday, Monday, Tuesday and Wednesday, 8 a.m. – 5 p.m.; and Sunday, 8 a.m. – 4:30 p.m.

Women's Center Featured Sessions

Saturday, May 18

9 a.m. – 11 a.m.
International Women Psychiatrists' Meet and Greet with the Association of Women Psychiatrists

11 a.m. – 1 p.m.
Unique Issues for Lesbian, Bisexual and Transgender Women: Ellen Haller, MD

1 p.m. – 3 p.m.
Making Choices Without Guilt: Leah Dickstein, MD, MA

3 p.m. – 4 p.m.
Psychodynamic Psychiatry in the Era of Managed Care: Silvia W. Olarte, MD

Sunday, May 19

9 a.m. – 11 a.m.
Gender Disparities in Mental Health: Chigo Okoye, MD

11 a.m. – 1 p.m.
Negotiating Salary and Leadership Opportunities for Women: Christina Mangurian, MD

1 p.m. – 3 p.m.
How to Organize a Women's Group at Your District Branch: Sheila Judge, MD

3 p.m. – 5 p.m.
Wraparound and Community Child and Adolescent Psychiatry - Creative Solutions: Gabrielle L. Shapiro, MD

Questions are encouraged. Don't limit presenter interactions to just these listed topics. Expand on and engage with presenters and attendees on subjects of interest to you and other women. We look forward to meeting you at the APA Women's Center!

Women's Mentoring Breakfast

Women residents and early career psychiatrists are invited to attend the Women's Mentoring Breakfast to meet and interact with experienced women psychiatrists. The Women's Mentoring Breakfast is on Monday, May 20, 7:30 a.m. – 9:30 a.m., Marriott Marquis hotel, Sierra Suite C, 5th floor, and is hosted by the APA Office of Minority and National Affairs, APA Women's Caucus, and the Association of Women Psychiatrists. Interested mentors are invited as well. Mentoring is an ideal way for mid-level and senior women psychiatrists to give back to the profession by nurturing and enhancing the professional lives of their young colleagues.

FANAPT® (iloperidone) tablets
Initial U.S. Approval: 2009
BRIEF SUMMARY: Please see package insert for full prescribing information.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analysis of seventeen placebo-controlled trials (modal duration 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. FANAPT is not approved for the treatment of patients with Dementia-Related Psychosis. [see Warnings and Precautions (5.1)]

1 INDICATIONS AND USAGE
FANAPT® tablets are indicated for the treatment of adults with schizophrenia. Efficacy was established in two short-term (4- and 6-week) placebo- and active-controlled studies of adult patients with schizophrenia [see Clinical Studies (14) in the full prescribing information].
When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that FANAPT is associated with prolongation of the QTc interval [see Warnings and Precautions (5.2)]. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether FANAPT will cause torsade de pointes or increase the rate of sudden death is not yet known.
Patients must be titrated to an effective dose of FANAPT. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia [see Dosage and Administration (2.1) and Clinical Studies (14) in the full prescribing information].
The effectiveness of FANAPT in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use FANAPT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient [see Dosage and Administration (2.3)].

2 DOSAGE AND ADMINISTRATION
2.1 Usual Dose
FANAPT must be titrated slowly from a low starting dose to avoid orthostatic hypotension due to its alpha-adrenergic blocking properties. The recommended starting dose for FANAPT tablets is 1 mg twice daily. Dose increases to reach the target range of 6-12 mg twice daily (12-24 mg/day) may be made with daily dosage adjustments not to exceed 2 mg twice daily (4 mg/day). The maximum recommended dose is 12 mg twice daily (24 mg/day). FANAPT doses above 24 mg/day have not been systematically evaluated in the clinical trials. Efficacy was demonstrated with FANAPT in a dose range of 6 to 12 mg twice daily. Prescribers should be mindful of the fact that patients need to be titrated to an effective dose of FANAPT. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require similar titration. Prescribers should also be aware that some adverse effects associated with FANAPT use are dose related.
FANAPT can be administered without regard to meals.
2.2 Dosage in Special Populations
Dosage adjustments are not routinely indicated on the basis of age, gender, race, or renal impairment status [see Use in Specific Populations (8.6, 8.7)].
Dosage adjustment for patients taking FANAPT concomitantly with potential CYP2D6 inhibitors: FANAPT dose should be reduced by one-half when administered concomitantly with strong CYP2D6 inhibitors such as fluoxetine or paroxetine. When the CYP2D6 inhibitor is withdrawn from the combination therapy, FANAPT dose should then be increased to where it was before [see Drug Interactions (7.1)].
Dosage adjustment for patients taking FANAPT concomitantly with potential CYP3A4 inhibitors: FANAPT dose should be reduced by one-half when administered concomitantly with strong CYP3A4 inhibitors such as ketoconazole or clarithromycin. When the CYP3A4 inhibitor is withdrawn from the combination therapy, FANAPT dose should be increased to where it was before [see Drug Interactions (7.1)].

Dosage adjustment for patients taking FANAPT who are poor metabolizers of CYP2D6: FANAPT dose should be reduced by one-half for poor metabolizers of CYP2D6 [see Pharmacokinetics (12.3) in the full prescribing information].

Hepatic Impairment: FANAPT is not recommended for patients with hepatic impairment.
2.3 Maintenance Treatment
Although there is no body of evidence available to answer the question of how long the patient treated with FANAPT should be maintained, it is generally recommended that responding patients be continued beyond the acute response. Patients should be periodically reassessed to determine the need for maintenance treatment.
2.4 Reinitiation of Treatment in Patients Previously Discontinued
Although there are no data to specifically address re-initiation of treatment, it is recommended that the initiation titration schedule be followed whenever patients have had an interval off FANAPT of more than 3 days.
2.5 Switching from Other Antipsychotics
There are no specific data to address how patients with schizophrenia can be switched from other antipsychotics to FANAPT or how FANAPT can be used concomitantly with other antipsychotics. Although immediate discontinuation of the previous antipsychotic treatment may be acceptable for some patients with schizophrenia, more gradual discontinuation may be most appropriate for others. In all cases, the period of overlapping antipsychotic administration should be minimized.

4 CONTRAINDICATIONS
FANAPT is contraindicated in individuals with a known hypersensitivity reaction to the product. Reactions have included pruritus and urticaria.
5 WARNINGS AND PRECAUTIONS
5.1 Increased Risks in Elderly Patients with Dementia-Related Psychosis Increased Mortality
Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. FANAPT is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning].
Cerebrovascular Adverse Events, Including Stroke
In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly patients with dementia, there was a higher incidence of cerebrovascular adverse events (cerebrovascular accidents and transient ischemic attacks) including fatalities compared to placebo-treated patients. FANAPT is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning].
5.2 QT Prolongation
In an open-label QTc study in patients with schizophrenia or schizoaffective disorder (n=160), FANAPT was associated with QTc prolongation of 9 msec at an iloperidone dose of 12 mg twice daily. The effect of FANAPT on the QT interval was augmented by the presence of CYP450 2D6 or 3A4 metabolic inhibition (paroxetine 20 mg once daily and ketoconazole 200 mg twice daily, respectively). Under conditions of metabolic inhibition for both 2D6 and 3A4, FANAPT 12 mg twice daily was associated with a mean QTcF increase from baseline of about 19 msec.

No cases of torsade de pointes or other severe cardiac arrhythmias were observed during the pre-marketing clinical program.
The use of FANAPT should be avoided in combination with other drugs that are known to prolong QTc including Class 1A (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, antipsychotic medications (e.g., chlorpromazine, thioridazine), antibiotics (e.g., gatifloxacin, moxifloxacin), or any other class of medications known to prolong the QTc interval (e.g., pentamidine, levomethadyl acetate, methadone). FANAPT should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.
Certain circumstances may increase the risk of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QTc interval; and (4) presence of congenital prolongation of the QT interval; (5) recent acute myocardial infarction; and/or (6) uncompensated heart failure.
Caution is warranted when prescribing FANAPT with drugs that inhibit FANAPT metabolism [see Drug Interactions (7.1)], and in patients with reduced activity of CYP2D6 [see Clinical Pharmacology (12.3) in the full prescribing information].
It is recommended that patients being considered for FANAPT treatment who are at risk for significant electrolyte disturbances have baseline serum potassium and magnesium measurements with periodic monitoring. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. FANAPT should be avoided in patients with histories of significant cardiovascular illness, e.g., QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. FANAPT should be discontinued in patients who are found to have persistent QTc measurements >500 ms.
If patients taking FANAPT experience symptoms that could indicate the occurrence of cardiac arrhythmias, e.g., dizziness, palpitations, or syncope, the prescriber should initiate further evaluation, including cardiac monitoring.

Apply to Become an APA Fellow

Are you ready to take the next step in your professional career? Being a Fellow of the APA is an honorary designation to recognize early-career members who have demonstrated allegiance to their profession and commitment to the ongoing work of the APA. Members who pursue Fellow status perceive it as one of the first steps to enhancement of their professional credentials.

Members who apply and are approved this year for Fellow status will be invited to participate in the Convocation of Fellows and

Distinguished Fellows during the 2014 APA Annual Meeting.

Eligibility Criteria:

• **Certification by the ABPN, RCPS(C), or AOA**

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5.3 Neuroleptic Malignant Syndrome (NMS)

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs, including FANAPT. Clinical manifestations include hyperpyrexia, muscle rigidity, altered mental status (including catatonic signs) and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases in which the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system (CNS) pathology.

The management of this syndrome should include: (1) immediate discontinuation of the antipsychotic drugs and other drugs not essential to concurrent therapy, (2) intensive symptomatic treatment and medical monitoring, and (3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

5.4 Tardive Dyskinesia

Tardive dyskinesia is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, which may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely on prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic administered increases. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, FANAPT should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on FANAPT, drug discontinuation should be considered. However, some patients may require treatment with FANAPT despite the presence of the syndrome.

5.5 Metabolic Changes

Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain [see Patient Counseling Information (17.3) in the full prescribing information]. While all atypical antipsychotic drugs have been shown to produce some metabolic changes, each drug in the class has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including FANAPT. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics included in these studies. Because FANAPT was not marketed at the time these studies were performed, it is not known if FANAPT is associated with this increased risk.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity,

family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Data from a 4-week, fixed-dose study in adult subjects with schizophrenia, in which fasting blood samples were drawn, are presented in Table 1.

Table 1: Change in Fasting Glucose

	Placebo n=114	FANAPT® 24 mg/day n=228
Mean Change from Baseline (mg/dL)		
Serum Glucose Change from Baseline	-0.5	6.6
Serum Glucose Normal to High (<100 mg/dL to ≥126 mg/dL)	2.5% (2/80)	10.7% (18/169)

Pooled analyses of glucose data from clinical studies including longer term trials are shown in Table 2.

Table 2: Change in Glucose

	Mean Change from Baseline (mg/dL)		
	3-6 months	6-12 months	>12 months
FANAPT 10-16 mg/day	1.8 (N=773)	5.4 (N=723)	5.4 (N=425)
FANAPT 20-24 mg/day	-3.6 (N=34)	-9.0 (N=31)	-18.0 (N=20)

Dyslipidemia

Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

Data from a placebo-controlled, 4-week, fixed-dose study, in which fasting blood samples were drawn, in adult subjects with schizophrenia are presented in Table 3.

Table 3: Change in Fasting Lipids

	Placebo n= 114	FANAPT® 24 mg/day n=228
Mean Change from Baseline (mg/dL)		
Cholesterol	-2.17	8.18
Change from baseline		
LDL	-1.09	2.17
Change from baseline		
HDL	-1.41	9.03
Change from baseline		
Triglycerides	-3.35	0.55
Change from baseline		
	16.47	-0.83
Proportion of Patients with Shifts		
Cholesterol		
Normal to High (<200 mg/dL to ≥240 mg/dL)	1.4% (1/72)	3.6% (5/141)
LDL		
Normal to High (<100 mg/dL to ≥160 mg/dL)	2.4% (1/42)	1.1% (1/90)
HDL		
Normal to Low (≥40 mg/dL to <40 mg/dL)	23.8% (19/80)	12.1% (20/166)
Triglycerides		
Normal to High (<150 mg/dL to ≥200 mg/dL)	8.3% (6/72)	10.1% (15/148)

Pooled analyses of cholesterol and triglyceride data from clinical studies including longer term trials are shown in Tables 4 and 5.

Table 4: Change in Cholesterol

	Mean Change from Baseline (mg/dL)		
	3-6 months	6-12 months	>12 months
FANAPT 10-16 mg/day	-3.9 (N=783)	-3.9 (N=726)	-7.7 (N=428)
FANAPT 20-24 mg/day	-19.4 (N=34)	-23.2 (N=31)	-19.4 (N=20)

Table 5: Change in Triglycerides

	Mean Change from Baseline (mg/dL)		
	3-6 months	6-12 months	>12 months
FANAPT 10-16 mg/day	-8.9 (N=783)	-8.9 (N=726)	-17.7 (N=428)
FANAPT 20-24 mg/day	-26.6 (N=34)	-35.4 (N=31)	-17.7 (N=20)

Events Explore the Intersection Between Work, Mental Health and Cultural Diversity

The APA Office of Minority and National Affairs (OMNA) and the American Psychiatric Foundation’s Partnership for Workplace Mental Health are teaming up during the APA Annual Meeting to focus on the intersection between work, mental health, and race and culture.

The symposium, “Work, Mental Health and Cultural Diversity: A Dynamic Triad,” takes place on Sunday, May 19, 8 a.m. – 11 a.m. at

the Moscone Center in room 3022. The symposium will look at how discrimination in the workplace — be it racial, ethnic, cultural, or sexual orientation — affects one’s mental health, and how it can be addressed in clinical practice. This symposium will discuss the important role of employment in recovery and will examine the reality of discrimination and its impact in the workplace.

While many companies articulate a commitment to diversity, successfully

putting it into practice is a much more difficult reality. A corporate policy alone cannot prevent employees from experiencing the effects of discrimination that exists in society at large. This symposium will address the effects of such discrimination and the disconnect between corporate policies related to diversity and the reality of everyday life at work. Attendees will learn how to help patients succeed at work in the face of overt discrimination or subtle micro-aggressions.

Expert speakers for the symposium include Price Cobbs, MD, Keris Myrick, MBA, MS, PhD, Donald Williams, MD, and Amani Nuru-Jeter, PhD, MPH.

The symposium is part of the OMNA on Tour program, which is a series of community meetings around the nation addressing the significance and impact of mental health disparities and serves as a catalyst for collaboration to improve societal health and well-being. ●

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Across all short- and long-term studies, the overall mean change from baseline at endpoint was 2.1 kg.

Changes in body weight (kg) and the proportion of subjects with ≥7% gain in body weight from four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies in adult subjects are presented in Table 6.

Table 6: Change in Body Weight

	Placebo n=576	FANAPT 10-16 mg/day n=481	FANAPT 20-24 mg/day n=391
Weight (kg) Change from Baseline	-0.1	2.0	2.7
Weight Gain ≥7% increase from Baseline	4%	12%	18%

5.6 Seizures

In short-term placebo-controlled trials (4- to 6-weeks), seizures occurred in 0.1% (1/1344) of patients treated with FANAPT compared to 0.3% (2/587) on placebo. As with other antipsychotics, FANAPT should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer’s dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older.

5.7 Orthostatic Hypotension and Syncope

FANAPT can induce orthostatic hypotension associated with dizziness, tachycardia, and syncope. This reflects its alpha1-adrenergic antagonist properties. In double-blind placebo-controlled short-term studies, where the dose was increased slowly, as recommended above, syncope was reported in 0.4% (5/1344) of patients treated with FANAPT, compared with 0.2% (1/587) on placebo. Orthostatic hypotension was reported in 5% of patients given 20-24 mg/day, 3% of patients given 10-16 mg/day, and 1% of patients given placebo. More rapid titration would be expected to increase the rate of orthostatic hypotension and syncope.

FANAPT should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction, ischemia, or conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in patients who are vulnerable to hypotension.

5.8 Leukopenia, Neutropenia and Agranulocytosis

In clinical trial and postmarketing experience, events of leukopenia/neutropenia have been reported temporally related to antipsychotic agents. Agranulocytosis (including fatal cases) has also been reported.

Possible risk factors for leukopenia/neutropenia include preexisting low white blood cell count (WBC) and history of drug induced leukopenia/neutropenia. Patients with a pre-existing low WBC or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue FANAPT at the first sign of a decline in WBC in the absence of other causative factors.

Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm³) should discontinue FANAPT and have their WBC followed until recovery.

5.9 Hyperprolactinemia

As with other drugs that antagonize dopamine D2 receptors, FANAPT elevates prolactin levels.

Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadalsteroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male patients.

Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin-dependent *in vitro*, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Mammary gland proliferative changes and increases in serum prolactin were seen in mice and rats treated with FANAPT [see *Nonclinical Toxicology (13.1) in the full prescribing information*]. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time.

In a short-term placebo-controlled trial (4-weeks), the mean change from baseline to endpoint in plasma prolactin levels for the FANAPT 24 mg/day-treated group was an increase of 2.6 ng/mL compared to a decrease of 6.3 ng/mL in the placebo-group. In this trial, elevated plasma prolactin levels were observed in 26% of adults treated with FANAPT compared to 12%

in the placebo group. In the short-term trials, FANAPT was associated with modest levels of prolactin elevation compared to greater prolactin elevations observed with some other antipsychotic agents. In pooled analysis from clinical studies including longer term trials, in 3210 adults treated with iloperidone, gynecomastia was reported in 2 male subjects (0.1%) compared to 0% in placebo-treated patients, and galactorrhea was reported in 8 female subjects (0.2%) compared to 3 female subjects (0.5%) in placebo-treated patients.

5.10 Body Temperature Regulation

Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing FANAPT for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

5.11 Dysphagia

Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer’s dementia. FANAPT and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia [see *Boxed Warning*].

5.12 Suicide

The possibility of a suicide attempt is inherent in psychotic illness, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for FANAPT should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

5.13 Priapism

Three cases of priapism were reported in the pre-marketing FANAPT program. Drugs with alpha-adrenergic blocking effects have been reported to induce priapism. FANAPT shares this pharmacologic activity. Severe priapism may require surgical intervention.

5.14 Potential for Cognitive and Motor Impairment

FANAPT, like other antipsychotics, has the potential to impair judgment, thinking or motor skills. In short-term, placebo-controlled trials, somnolence (including sedation) was reported in 11.9% (104/874) of adult patients treated with FANAPT at doses of 10 mg/day or greater versus 5.3% (31/587) treated with placebo. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with FANAPT does not affect them adversely.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The information below is derived from a clinical trial database for FANAPT consisting of 2070 patients exposed to FANAPT at doses of 10 mg/day or greater, for the treatment of schizophrenia. Of these, 806 received FANAPT for at least 6 months, with 463 exposed to FANAPT for at least 12 months. All of these patients who received FANAPT were participating in multiple-dose clinical trials. The conditions and duration of treatment with FANAPT varied greatly and included (in overlapping categories), open-label and double-blind phases of studies, inpatients and outpatients, fixed-dose and flexible-dose studies, and short-term and longer-term exposure.

Adverse reactions during exposure were obtained by general inquiry and recorded by clinical investigators using their own terminology. Consequently, to provide a meaningful estimate of the proportion of individuals experiencing adverse reactions, reactions were grouped in standardized categories using MedDRA terminology.

The stated frequencies of adverse reactions represent the proportions of individuals who experienced a treatment-emergent adverse reaction of the type listed. A reaction was considered treatment emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation.

The information presented in these sections was derived from pooled data from four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies in patients who received FANAPT at daily doses within a range of 10 to 24 mg (n=874).

Adverse Reactions Occurring at an Incidence of 2% or More among FANAPT-Treated Patients and More Frequent than Placebo

Table 7 enumerates the pooled incidences of treatment-emergent adverse reactions that were spontaneously reported in four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies, listing those reactions that occurred in 2% or more of patients treated with FANAPT in any of the dose groups, and for which the incidence in FANAPT-treated patients in any dose group was greater than the incidence in patients treated with placebo.

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APA Introduces Fellow Membership Category for International Psychiatrists

The APA has created a new International Fellow membership category for international psychiatrists. International Fellow status is an honor that reflects dedication to the work of the APA and signifies allegiance to the psychiatric profession. International Fellows are recognized by their colleagues in the APA as members of a very select group and are publicly recognized at the Convocation of Fellows and Distinguished Fellows during APA’s Annual Meeting. Membership dues for APA International Members and Fellows are the same.

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Eligibility requirements:

- Eligibility for International Membership (i.e., licensed physicians who have completed an acceptable program of training in psychiatry)
- Three (3) years of either APA membership or membership in the applicant’s national or local psychiatric organization, if one exists
- Letter of verification that the applicant is a member in good standing of the national or local psychiatric organization (letter must be written on organization’s letterhead)
- Board certification or equivalent, if certification exists in applicant’s country
- Approval by the Membership Committee
- Approval by the Board of Trustees

The deadline for submitting an application is August 1. Stop by an APA Membership Booth in the Exhibit Hall for an application or go online at www.psychiatry.org and select the link for **Join & Participate / International Psychiatrists**.

Table 7: Treatment-Emergent Adverse Reactions in Short-Term, Fixed- or Flexible-Dose, Placebo-Controlled Trials in Adult Patients*

Body System or Organ Class Dictionary-derived Term	Percentage of Patients Reporting Reaction Placebo (N=587)	FANAPT 10-16 mg/day (N=483)	FANAPT 20-24 mg/day (N=391)
Body as a Whole			
Arthralgia	2	3	3
Fatigue	3	4	6
Musculoskeletal Stiffness	1	1	3
Weight Increased	1	1	9
Cardiac Disorders			
Tachycardia	1	3	12
Eye Disorders			
Vision Blurred	2	3	1
Gastrointestinal Disorders			
Nausea	8	7	10
Dry Mouth	1	8	10
Diarrhea	4	5	7
Abdominal Discomfort	1	1	3
Infections			
Nasopharyngitis	3	4	3
Upper Respiratory Tract Infection	1	2	3
Nervous System Disorders			
Dizziness	7	10	20
Somnolence	5	9	15
Extrapyramidal Disorder	4	5	4
Tremor	2	3	3
Lethargy	1	3	1
Reproductive System			
Ejaculation Failure	<1	2	2
Respiratory			
Nasal Congestion	2	5	8
Dyspnea	<1	2	2
Skin			
Rash	2	3	2
Vascular Disorders			
Orthostatic Hypotension	1	3	5
Hypotension	<1	<1	3

*Table includes adverse reactions that were reported in 2% or more of patients in any of the FANAPT dose groups and which occurred at greater incidence than in the placebo group. Figures rounded to the nearest integer.

Dose-Related Adverse Reactions in Clinical Trials

Based on the pooled data from four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies, adverse reactions that occurred with a greater than 2% incidence in the patients treated with FANAPT, and for which the incidence in patients treated with FANAPT 20-24 mg/day were twice than the incidence in patients treated with FANAPT 10-16 mg/day were: abdominal discomfort, dizziness, hypotension, musculoskeletal stiffness, tachycardia, and weight increased.

Common and Drug-Related Adverse Reactions in Clinical Trials

Based on the pooled data from four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies, the following adverse reactions occurred in ≥5% incidence in the patients treated with FANAPT and at least twice the placebo rate for at least one dose: dizziness, dry mouth, fatigue, nasal congestion, somnolence, tachycardia, orthostatic hypotension, and weight increased. Dizziness, tachycardia, and weight increased were at least twice as common on 20-24 mg/day as on 10-16 mg/day.

Extrapyramidal Symptoms (EPS) in Clinical Trials

Pooled data from the four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies provided information regarding treatment-emergent EPS. Adverse event data collected from those trials showed the following rates of EPS-related adverse events as shown in Table 8.

Table 8: Percentage of EPS Compared to Placebo

Adverse Event Term	Placebo (%) (N=587)	FANAPT 10-16 mg/day (%) (N=483)	FANAPT 20-24 mg/day (%) (N=391)
All EPS events	11.6	13.5	15.1
Akathisia	2.7	1.7	2.3
Bradykinesia	0	0.6	0.5
Dyskinesia	1.5	1.7	1.0
Dystonia	0.7	1.0	0.8
Parkinsonism	0	0.2	0.3
Tremor	1.9	2.5	3.1

Adverse Reactions Associated with Discontinuation of Treatment in Clinical Trials

Based on the pooled data from four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies, there was no difference in the incidence of discontinuation due to adverse events between FANAPT-treated (5%) and placebo-treated (5%) patients. The types of adverse events that led to discontinuation were similar for the FANAPT- and placebo-treated patients.

Demographic Differences in Adverse Reactions in Clinical Trials

An examination of population subgroups in the four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies did not reveal any evidence of differences in safety on the basis of age, gender or race [see Warnings and Precautions (5.1)].

Laboratory Test Abnormalities in Clinical Trials

There were no differences between FANAPT and placebo in the incidence of discontinuation due to changes in hematology, urinalysis, or serum chemistry.

In short-term placebo-controlled trials (4- to 6-weeks), there were 1.0% (13/1342) iloperidone-treated patients with hematocrit at least one time below the extended normal range during post-randomization treatment, compared to 0.3% (2/585) on placebo. The extended normal range for low-ered hematocrit was defined in each of these trials as the value 15% below the normal range for the centralized laboratory that was used in the trial.

Other Reactions During the Pre-marketing Evaluation of FANAPT

The following is a list of MedDRA terms that reflect treatment-emergent adverse reactions in patients treated with FANAPT at multiple doses ≥ 4 mg/day during any phase of a trial with the database of 3210 FANAPT-treated patients. All reported reactions are included except those already listed in Table 7, or other parts of the Adverse Reactions (6) section, those considered in the Warnings and Precautions (5), those reaction terms which were so general as to be uninformative, reactions reported in fewer than 3 patients and which were neither serious nor life-threatening, reactions that are otherwise common as background reactions, and reactions considered unlikely to be drug related. It is important to emphasize that, although the reactions reported occurred during treatment with FANAPT, they were not necessarily caused by it.

Reactions are further categorized by MedDRA system organ class and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring in at least 1/100 patients (only those not listed in Table 7 appear in this listing); infrequent adverse reactions are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.

Blood and Lymphatic Disorders: *Infrequent* – anemia, iron deficiency anemia; *Rare* – leukopenia

Cardiac Disorders: *Frequent* – palpitations; *Rare* – arrhythmia, atrioventricular block first degree, cardiac failure (including congestive and acute)

Ear and Labyrinth Disorders: *Infrequent* – vertigo, tinnitus

Endocrine Disorders: *Infrequent* – hypothyroidism

Eye Disorders: *Frequent* – conjunctivitis (including allergic); *Infrequent* – dry eye, blepharitis, eyelid edema, eye swelling, lenticular opacities, cataract, hyperemia (including conjunctival)

Gastrointestinal Disorders: *Infrequent* – gastritis, salivary hypersecretion, fecal incontinence, mouth ulceration; *Rare* – aphthous stomatitis, duodenal ulcer, hiatus hernia, hyperchlorhydria, lip ulceration, reflux esophagitis, stomatitis

General Disorders and Administrative Site Conditions: *Infrequent* – edema (general, pitting, due to cardiac disease), difficulty in walking, thirst; *Rare* – hyperthermia

Hepatobiliary Disorders: *Infrequent* – cholelithiasis

Investigations: *Frequent:* weight decreased; *Infrequent* – hemoglobin decreased, neutrophil count increased, hematocrit decreased

Metabolism and Nutrition Disorders: *Infrequent* – increased appetite, dehydration, hypokalemia, fluid retention

Musculoskeletal and Connective Tissue Disorders: *Frequent* – myalgia, muscle spasms; *Rare* – torticollis

Nervous System Disorders: *Infrequent* – paresthesia, psychomotor hyperactivity, restlessness, amnesia, nystagmus; *Rare* – restless legs syndrome

Psychiatric Disorders: *Frequent* – restlessness, aggression, delusion; *Infrequent* – hostility, libido decreased, paranoia, anorgasmia, confusional state, mania, catatonia, mood swings, panic attack, obsessive-compulsive disorder, bulimia nervosa, delirium, polydipsia psychogenic, impulse-control disorder, major depression

Renal and Urinary Disorders: *Frequent* – urinary incontinence; *Infrequent* – dysuria, pollakiuria, enuresis, nephrolithiasis; *Rare* – urinary retention, renal failure acute

Reproductive System and Breast Disorders: *Frequent* – erectile dysfunction; *Infrequent* – testicular pain, amenorrhea, breast pain; *Rare* – menstruation irregular, gynecomastia, menorrhagia, metrorrhagia, postmenopausal hemorrhage, prostatitis.

Respiratory, Thoracic and Mediastinal Disorders: *Infrequent* – epistaxis, asthma, rhinorrhea, sinus congestion, nasal dryness; *Rare* – dry throat, sleep apnea syndrome, dyspnea exertional

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of Fanapt: retrograde ejaculation. Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.



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APA 2013

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7 DRUG INTERACTIONS

Given the primary CNS effects of FANAPT, caution should be used when it is taken in combination with other centrally acting drugs and alcohol. Due to its α 1-adrenergic receptor antagonism, FANAPT has the potential to enhance the effect of certain antihypertensive agents.

7.1 Potential for Other Drugs to Affect FANAPT

Iloperidone is not a substrate for CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP2E1 enzymes. This suggests that an interaction of iloperidone with inhibitors or inducers of these enzymes, or other factors, like smoking, is unlikely.

Both CYP3A4 and CYP2D6 are responsible for iloperidone metabolism. Inhibitors of CYP3A4 (e.g., ketoconazole) or CYP2D6 (e.g., fluoxetine, paroxetine) can inhibit iloperidone elimination and cause increased blood levels.

Ketoconazole: Co-administration of ketoconazole (200 mg twice daily for 4 days), a potent inhibitor of CYP3A4, with a 3 mg single dose of iloperidone to 19 healthy volunteers, ages 18-45, increased the AUC of iloperidone and its metabolites P88 and P95 by 57%, 55% and 35%, respectively. Iloperidone doses should be reduced by about one-half when administered with ketoconazole or other strong inhibitors of CYP3A4 (e.g., itraconazole). Weaker inhibitors (e.g., erythromycin, grapefruit juice) have not been studied. When the CYP3A4 inhibitor is withdrawn from the combination therapy, the iloperidone dose should be returned to the previous level.

Fluoxetine: Co-administration of fluoxetine (20 mg twice daily for 21 days), a potent inhibitor of CYP2D6, with a single 3 mg dose of iloperidone to 23 healthy volunteers, ages 29-44, who were classified as CYP2D6 extensive metabolizers, increased the AUC of iloperidone and its metabolite P88, by about 2-3 fold, and decreased the AUC of its metabolite P95 by one-half. Iloperidone doses should be reduced by one-half when administered with fluoxetine. When fluoxetine is withdrawn from the combination therapy, the iloperidone dose should be returned to the previous level. Other strong inhibitors of CYP2D6 would be expected to have similar effects and would need appropriate dose reductions. When the CYP2D6 inhibitor is withdrawn from the combination therapy, iloperidone dose could then be increased to the previous level.

Paroxetine: Co-administration of paroxetine (20 mg/day for 5-8 days), a potent inhibitor of CYP2D6, with multiple doses of iloperidone (8 or 12 mg twice daily) to patients with schizophrenia ages 18-65 resulted in increased mean steady-state peak concentrations of iloperidone and its metabolite P88, by about 1.6 fold, and decreased mean steady-state peak concentrations of its metabolite P95 by one-half. Iloperidone doses should be reduced by one-half when administered with paroxetine. When paroxetine is withdrawn from the combination therapy, the iloperidone dose should be returned to the previous level. Other strong inhibitors of CYP2D6 would be expected to have similar effects and would need appropriate dose reductions. When the CYP2D6 inhibitor is withdrawn from the combination therapy, iloperidone dose could then be increased to previous levels.

Paroxetine and Ketoconazole: Co-administration of paroxetine (20 mg once daily for 10 days), a CYP2D6 inhibitor, and ketoconazole (200 mg twice daily) with multiple doses of iloperidone (8 or 12 mg twice daily) to patients with schizophrenia ages 18-65 resulted in a 1.4 fold increase in steady-state concentrations of iloperidone and its metabolite P88 and a 1.4 fold decrease in the P95 in the presence of paroxetine. So giving iloperidone with inhibitors of both of its metabolic pathways did not add to the effect of either inhibitor given alone. Iloperidone doses should therefore be reduced by about one-half if administered concomitantly with both a CYP2D6 and CYP3A4 inhibitor.

7.2 Potential for FANAPT to Affect Other Drugs

In vitro studies in human liver microsomes showed that iloperidone does not substantially inhibit the metabolism of drugs metabolized by the following cytochrome P450 isozymes: CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, or CYP2E1. Based on *in vitro* studies, iloperidone is a time-dependent inhibitor of CYP3A at therapeutic exposure levels. Co-administration of iloperidone may lead to an increase in plasma levels of drugs that are predominantly eliminated by CYP3A4. Furthermore, *in vitro* studies in human liver microsomes showed that iloperidone does not have enzyme inducing properties, specifically for the following cytochrome P450 isozymes: CYP1A2, CYP2C8, CYP2C9, CYP2C19, CYP3A4 and CYP3A5.

Dextromethorphan: A study in healthy volunteers showed that changes in the pharmacokinetics of dextromethorphan (80 mg dose) when a 3 mg dose of iloperidone was co-administered resulted in a 17% increase in total exposure and a 26% increase in C_{max} of dextromethorphan. Thus, an interaction between iloperidone and other CYP2D6 substrates is unlikely.

Fluoxetine: A single 3 mg dose of iloperidone had no effect on the pharmacokinetics of fluoxetine (20 mg twice daily).

7.3 Drugs that Prolong the QT Interval

FANAPT should not be used with any other drugs that prolong the QT interval [see *Warnings and Precautions* (5.2)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

FANAPT caused developmental toxicity, but was not teratogenic, in rats and rabbits.

In an embryo-fetal development study, pregnant rats were given 4, 16, or 64 mg/kg/day (1.6, 6.5, and 26 times the maximum recommended human dose [MRHD] of 24 mg/day on a mg/m² basis) of iloperidone orally during the period of organogenesis. The highest dose caused increased early intrauterine deaths, decreased fetal weight and length, decreased fetal skeletal ossification, and an increased incidence of minor fetal skeletal anomalies and variations; this dose also caused decreased maternal food consumption and weight gain.

In an embryo-fetal development study, pregnant rabbits were given 4, 10, or 25 mg/kg/day (3, 8, and 20 times the MRHD on a mg/m² basis) of iloperidone during the period of organogenesis. The highest dose caused increased early intrauterine deaths and decreased fetal viability at term; this dose also caused maternal toxicity.

In additional studies in which rats were given iloperidone at doses similar to the above beginning from either pre-conception or from day 17 of gestation and continuing through weaning, adverse reproductive effects included prolonged pregnancy and parturition, increased stillbirth rates, increased incidence of fetal visceral variations, decreased fetal and pup weights, and decreased post-partum pup survival. There were no drug effects on the neurobehavioral or reproductive development of the surviving pups. No-effect doses ranged from 4 to 12 mg/kg except for the increase in stillbirth rates which occurred at the lowest dose tested of 4 mg/kg, which is 1.6 times the MRHD on a mg/m² basis. Maternal toxicity was seen at the higher doses in these studies.

The iloperidone metabolite P95, which is a major circulating metabolite of iloperidone in humans but is not present in significant amounts in rats, was given to pregnant rats during the period of organogenesis at oral doses of 20, 80, or 200 mg/kg/day. No teratogenic effects were seen. Delayed skeletal ossification occurred at all doses. No significant maternal toxicity was produced. Plasma levels of P95 (AUC) at the highest dose tested were 2 times those in humans receiving the MRHD of iloperidone.

There are no adequate and well-controlled studies in pregnant women.

Non-Teratogenic Effects

Neonates exposed to antipsychotic drugs, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

FANAPT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.2 Labor and Delivery

The effect of FANAPT on labor and delivery in humans is unknown.

8.3 Nursing Mothers

FANAPT was excreted in milk of rats during lactation. It is not known whether FANAPT or its metabolites are excreted in human milk. It is recommended that women receiving FANAPT should not breast feed.

8.4 Pediatric Use

Safety and effectiveness in pediatric and adolescent patients have not been established.

8.5 Geriatric Use

Clinical Studies of FANAPT in the treatment of schizophrenia did not include sufficient numbers of patients aged 65 years and over to determine whether or not they respond differently than younger adult patients. Of the 3210 patients treated with FANAPT in pre-marketing trials, 25 (0.5%) were ≥65 years old and there were no patients ≥75 years old.

Studies of elderly patients with psychosis associated with Alzheimer's disease have suggested that there may be a different tolerability profile (i.e., increased risk in mortality and cerebrovascular events including stroke) in this population compared to younger patients with schizophrenia [see *Boxed Warning and Warnings and Precautions* (5.1)]. The safety and efficacy of FANAPT in the treatment of patients with psychosis associated with Alzheimer's disease has not been established. If the prescriber elects to treat such patients with FANAPT, vigilance should be exercised.

8.6 Renal Impairment

Because FANAPT is highly metabolized, with less than 1% of the drug excreted unchanged, renal impairment alone is unlikely to have a significant impact on the pharmacokinetics of FANAPT. Renal impairment (creatinine clearance <30 mL/min) had minimal effect on maximum plasma concentrations (C_{max}) of iloperidone (given in a single dose of 3 mg) and its metabolites P88 and P95 in any of the three analytes measured. AUC_{0-∞} was increased by 24%, decreased by 6%, and increased by 52% for iloperidone, P88 and P95, respectively, in subjects with renal impairment.


8.7 Hepatic Impairment

A study in mild and moderate liver impairment has not been conducted. FANAPT is not recommended for patients with hepatic impairment.

8.8 Smoking Status

Based on *in vitro* studies utilizing human liver enzymes, FANAPT is not a substrate for CYP1A2; smoking should therefore not have an effect on the pharmacokinetics of FANAPT.

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DAILY BULLETIN

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Ethics Track

Is Social Media Challenging the Boundaries in Psychiatry?

The evolution of the Internet and the explosion of user-generated content have undeniably altered our society's basic notions of privacy, connectivity and communication. As more and more people are interacting and sharing more information in the Internet, one notable consequence has been the blurring of boundaries between social and professional spheres — and psychiatrists have not been immune from these trends.

"With more psychiatrists blogging, posting on social media websites, and uploading personal videos onto the Internet, distinctions between personal and professional realms have become blurred," said Paul Appelbaum, MD, Director of the Division of Law, Ethics, and Psychiatry at Columbia University.

Dr. Appelbaum will address the challenges to traditional notions of psychiatrist-patient boundaries that result from the exponential growth of social media in the workshop, "Social Media & the Internet: New Challenges to Boundaries in Psychiatry," beginning at 1:30 p.m. on Monday in Room 122 of the Moscone Convention Center. The workshop is part of the APA Annual Meeting Ethics Track.

Whether as users of data posted by others or creators of information that others can access, psychiatrists are full participants in the social media revolution,

Dr. Appelbaum notes, which creates a complex set of practical and ethical challenges for psychiatric practice. He points to several inherent conflicts that speak directly to the nature of the practice of psychiatry versus the nature of social media use.

"Whereas psychiatry emphasizes the privacy of the therapeutic relationship, for example, social media encourages open sharing of personal and private information, often leading to what is known as the disinhibition effect," Dr. Appelbaum said. "In a professional setting, there are defined boundaries within which psychiatrists and their patients interact. Social media, on the other hand, erase boundaries by blurring the distinction between personal and public information."

During the workshop, Dr. Appelbaum will share case examples of psychiatrists' involvement in social media, and outline approaches that psychiatrists can use to avoid compromising their professional roles.

"The bottom line is physicians don't have to shun social media, so long as they use it prudently, which includes using appropriate privacy settings, avoiding unprofessional content and learning to manage their digital footprint," Dr. Applebaum said. "Above all, keep in mind that behaving badly online can have severe consequences in the real world." ●

- Saturday, May 18
- 9 a.m. – 12 p.m.
Update on the Status of Psychiatry in the Arab World
- 11 a.m. – 12:30 p.m.
Disruptive Behavior in the Workplace: Dealing With the Distressed and Disruptive Physician
- 1:30 p.m. – 3 p.m.
The Risks and Responsible Roles for Psychiatrists Who Interact With the Media
- 3:30 p.m. – 5 p.m.
United Kingdom Critical Psychiatry Network: Implications for APA and Global Psychiatry
- Sunday, May 19
- 9 a.m. – 4 p.m.
Sex, Drugs, and Social Media: Professionalism and Ethics Put to the Test
- 10 a.m. – 11:30 a.m.
Overview of Conscientious Objection With Special Attention to Quaker Conscientious Objectors in World War II: Unlikely Heroes of Psychiatric Reform
- 12:30 p.m. – 2 p.m.
Brain Imaging and Psychiatric Diagnosis: Scientific and Societal Issues
- Rejuvenating Empathy Through Reflective Writing: A Workshop for Clinicians
- 1 p.m. – 4 p.m.
Attention Deficit Hyperactivity Disorder and Driving Safety
- 2:30 p.m. – 4 p.m.
The Internet and Electronic Communication

- When the Pursuit of Wellness in One Domain Leads to Disability in Another Domain: Implications of Evidence for Health Care and Health Policy
- Monday, May 20
- 9 a.m. – 10:30 a.m.
"Crisis Junkies": Stereotypes Affecting the Treatment of Patients With Borderline Personality Disorder
- Ethical Issues In Geriatric Psychiatry
- 9 a.m. – 10:30 a.m.
When Patients Can't Decide: A Case Discussion of Good Clinical Practice, Ethics, Law and the Boundaries of Self- Determination
- 9 a.m. – 12: p.m.
Ethical Waves of the Silver Tsunami: Focus on Capacity, Decision Making, and End-of-Life Issues
- 11 a.m. – 12:30 p.m.
Deciding Who Decides: Surrogate Decision-Making Policies Across the United States
- 1:30 p.m. – 3 p.m.
Mental Health, Involuntary Treatment, And Due Process Of Law
- Social Media And The Internet: New Challenges To Boundaries In Psychiatry
- 3:30 p.m. – 5 p.m.
You Can't Call My Mom: Balancing Privacy Versus Potential Negligence In Emergency Psychiatric Assessment
- Professionalism In Social Networking: What Shouldn't Be Tweeted, Blogged Or Posted



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DSM-5, continued from page 1

gaps in knowledge for the full range of mental disorder diagnostic areas. These conferences, co-sponsored by the World Health Organization, took place between 2003 and 2008.

“At that time, the World Health Organization was developing the 11th edition of the International Classification of Diseases, so it made sense to work in tandem with them to develop a research base for both the DSM and the ICD,” Dr. Regier said. “We held a total of 13 conferences around the world, involving nearly 400 clinicians and scientists. A series of monographs was published, based on the findings and recommendations that came out of those conferences.”

In 2006, then-APA President Dr. Steven Sharfstein announced the formation of the DSM-5 Task Force and the appointments of Drs. Kupfer and Regier as chair and vice-chair. They, along with other leaders at the APA, nominated additional members to the Task Force to serve as chairs of 13 Work Groups to focus on different diagnostic categories.

Over the next two years, additional Task Force and Work Group members were recruited based on their expertise and leadership in their respective fields. In all, more than 160 researchers and clinicians with expertise in mental disorders, neuroscience, biology, genetics, statistics, epidemiology, and public health would serve on the DSM-5 Task Force and Work Groups — and included psychiatrists, psychologists, social workers, psychiatric nurses, pediatricians, and neurologists. In addition, Study Groups were created and assigned to review important aspects of diagnosis relevant to all of the diagnostic categories, such as gender, age and cross-cultural issues; assessment of impairment and disability; and development of dimensional scales and ratings to better characterize patients’ symptoms, inform treatment planning, and track treatment response.

“The volunteer Task Force and Work Group members reviewed the findings and recommendations developed from the conferences with an eye towards drafting proposals for DSM-5 criteria and revisions that might be supported by this earlier work,” said Dilip Jeste, MD, President of APA and a former member of the DSM-5 Task Force. “They began by analyzing the strengths and the weaknesses in the current DSM-IV, which led to the development of the research questions and the hypotheses that would set the agenda for the revision process.”

Based on comprehensive reviews of scientific advancements, targeted research analyses, and clinical expertise, the Work Groups developed the first draft of the DSM-5 diagnostic criteria, which was posted online for public comment in February 2010.

“Also in 2010, APA launched a series of field trials of approximately 30 disorders that were either new disorders or ones that had significant changes. We also included some that had very few changes so we’d have a basis of comparison,” Dr. Regier said. “To conduct the trials, we selected four child-oriented centers and seven adult-oriented centers. We then launched a very sophisticated field trial protocol in these 11 centers to look at selected disorders in both child and adolescent populations and in adult populations.”

After reviewing and deliberating the public feedback and preliminary data from the field trials, the Work Groups and Task Force further revised the DSM-5 criteria and posted them for a second open-comment period in 2011. Following a similar review and deliberation process, proposed criteria were posted for a third and final public comment period in May 2012.

The final Work Group proposals were then evaluated by the Task Force, and two panels convened specifically to evaluate the proposals — a Scientific Review Committee and a Clinical and Public Health Committee. Additionally, there was a forensic review by members of the APA Council on Psychiatry and Law. After final Task Force approval, recommendations were reviewed by the DSM-5 Summit Group. The criteria were then put before the APA Assembly for review and approval. The APA Board of Trustees’ review was the last step in the process.

“The Board of Trustees review was completed in the first week of December 2012, finally and officially bringing to close the development process of DSM-5 with the Board’s approval,” Dr. Jeste said. “As part of the DSM-5 launch here in San Francisco, we’ll be offering a number of courses, events, and workshops to introduce members to the new manual. It’s going to be a very comprehensive and exciting roll-out for DSM-5.”

2013 APA Annual Meeting: DSM-5 Track Schedule of Sessions

Saturday, May 18		11 a.m. – 12:30 p.m. Feeding and Eating Disorders: New Issues for DSM-5 (workshop)
9 a.m. – 10:30 a.m. Substance Use Disorders in DSM-5 (workshop)		1:30 p.m. – 3 p.m. Understanding and Operationalizing the Somatic Symptom Disorders (workshop)
9 a.m. – 12 p.m. Symptoms and Disability Measures in DSM-5 DSM-5 Psychosis Chapter		2 p.m. – 5 p.m. Obsessive-Compulsive and Related Disorders in DSM-5 DSM-5 Bipolar Disorders: Update on Revised Criteria and Their Clinical Implications Eating Disorders Update Looking Towards DSM-5.1: The Utility of Assessing Personality Functioning and Traits in Personality Disorder Diagnosis
9 a.m. – 4 p.m. DSM-5: What You Need to Know (master course)		
2 p.m. – 5 p.m. Substance Use Disorders in DSM-5 Anxiety Disorders in DSM-5		
Sunday, May 19		
1 p.m. – 4 p.m. The DSM-5 Cultural Formulation Interview: A Standardized Cultural Assessment DSM-5 and Major Depression		
Monday, May 20		
9 a.m. – 12 p.m. DSM-5 Intellectual Disability (Intellectual Developmental Disorder): New Criteria, Co-Occurring Psychiatric Conditions, and Forensic Implications Sleep-Wake Disorders in Psychiatric Practice: Guidance From DSM-5 Trauma and Stress-Related and Dissociative Disorders in DSM-5		
Tuesday, May 21		
9 a.m. – 12 p.m. Sexual Disorders and Sexual Health in the ICD-11: Parallels and Contrasts with DSM-5		
2 p.m. – 5 p.m. Autism and Social Communication in DSM-5 Culture and DSM-5: Changes to Disorder Criteria and Text		
Wednesday, May 22		
9 a.m. – 12 p.m. Report from the DSM-5 Sexual and Gender Identity Disorders Work Group		



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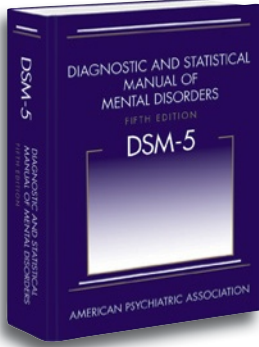
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Saturday, May 18	Drs. Glen O. Gabbard and Otto F. Kernberg to Sign Books in APP Bookstore
11:00am – 12:00pm	Glen O. Gabbard, M.D. <i>Textbook of Psychoanalysis</i> , Second Edition <i>Professionalism in Psychiatry</i>
11:00am – 12:00pm	Otto F. Kernberg, M.D. <i>The Inseparable Nature of Love and Aggression</i>
Sunday, May 19	Drs. Anthony W. Bateman, Peter Fonagy, and Mantosh Dewan to Sign Books in APP Bookstore
11:00am – 12:00pm	Anthony W. Bateman, M.A., F.R.C.Psych. <i>Handbook of Mentalizing in Mental Health Practice</i>
11:00am – 12:00pm	Peter Fonagy, Ph.D., F.B.A. <i>Handbook of Mentalizing in Mental Health Practice</i>
11:00am – 12:00pm	Mantosh Dewan, M.D. <i>The Art and Science of Brief Psychotherapies</i> , Second Edition
11:00am – 12:00pm	Abraham Nussbaum, M.D. <i>The Pocket Guide to the DSM-5 Diagnostic Exam</i>

Annual Meeting Program Changes

Disclosures

- Nathan J. Claes, PhD, has nothing to disclose.
- Melissa Hirt, MA, has nothing to disclose.
- Dilesh Doshi, PhD, discloses that he is an employee of Johnson and Johnson.
- Brady Bradshaw, MD, has nothing to disclose.
- Donna Zubek has disclosed that she is an employee of Otsuka America Pharmaceuticals, Inc.
- Sudhakar Kateel Shenoy, MBBS has nothing to disclose.
- Carol Koplan, MD has nothing to disclose.
- Stefana Borovska has nothing to disclose.
- Susan Swedo, MD has nothing to disclose.
- Jeri Davis, MBA has nothing to disclose.

Saturday, May 18

Courses Sold Out

- Master Course 7, Course 1 Course 13, Course 17, Course 28, Course 38, Course 40
- Course 05- Robert Atkins, MD, MPH will not be in attendance and will be replaced by Jeri Davis, MBA.

Cancellations/Withdrawals

- NR3-99 has been withdrawn
- NR3-19 has been withdrawn
- NR1-073 WITHDRAWN
- NR2-44 WITHDRAWN
- NR2-78 WITHDRAWN

Participant Changes

- Master Course 07 DSM- Faculty Susan Swedo, MD, Andrew Skodol, MD and Ronald Petersen, MD have been added as presenters to this course.
- Symposium 9 – Janet E. Kemp, PhD, will be replaced by Nathan J. Claes, PhD.
- NR2-54 Lee Robinson will not be presenting. Poster will be presented by Alan Hsu.
- NR2-21 Hulegar Abhishek, MBBS will not be presenting. Poster will be presented by Sudhakar Kateel Shenoy, MBBS.
- NR2-25 Adam Hunzeker will not be presenting. Poster will be presented by William Rumbaugh, MD.
- NR3-20 Carmen T Pitti, PhD will not be presenting. Poster will be presented by Pedro Barreiro Marin, MD.
- NR3-21 Anusha Manjegowda, MBBS, will not be presenting. Poster will be presented by Sudhakar Kateel Shenoy, MBBS.
- NR3-22 Beatriz Comenge Acosta, BD will not be presenting. Poster will be presented by Pedro Barreiro Marin, MD.
- NR3-30 Richard Brook, MBA, MS, will not be presenting. Poster will be presented by Andrei Pikalov, MD, PhD.
- Small Interactive Session 02: Robert I. Simon, MD will not be presenting, has had to withdraw from this session.
- Symposium 02 – Thomas Spencer, MD will not be presenting and will be replaced by Joseph Biederman, MD.

Corrections/Miscellaneous Changes

- NR2-52 title has changed to Assessment of Military Cultural Competency: A Pilot Study
- NR3-73 Presenters name is incorrectly spelt, it should be Sung-yun Sohn
- NR1-089 has moved to NR2-080

Sunday, May 19

Cancellations/Withdrawals

- Poster NR5-01 WITHDRAWN
- Workshop 32 has been canceled.

Participant Changes

- NR5-08 presented by David Bickford – has moved to poster NR7-85 and will be presented by Melissa Hirt, MA.
- NR5-19 Rachel Neuhut, MD will not present. Poster will be presented by Brady L. Bradshaw, MD.
- NR7-60 moved from Monday to NR5-94 to be presented today by Dovie Watson, BA.
- SCR9-3 will not be presented by Bryna Siegel, MD it will be presented by Olivia Song Park as Dr. Siegel will not be in attendance.
- Presidential Symposium #5 – Kevin Sevarino, MD will not be in attendance and will be replaced by Steven Batki, MD.
- Symposium 39- Fred Goodwin, MD will not be in attendance as discussant.
- Symposium 46- Dr. Salima Jiwani has been added as co-author on paper titled A Cultural Perspective on the Management of Depression in Women.
- Workshop 38- Francis Lu, MD will not be in attendance and will be replaced by Neil Aggarwal, MD.
- Forum 3- Addiction Performance Program Actress Mare Winningham will be in attendance.

Courses Sold Out

- Course 13, Course 17

Corrections/Miscellaneous Changes

- NR4-27 has moved to NR6-45 Medical Comorbidities in an Acute Inpatient Setting presented by Jessy Warner-Cohen, PhD, MPH.

Monday, May 20

Cancellations/Withdrawals

- Small Interactive Session 17 - WITHDRAWN
- Poster NR7-45 has been WITHDRAWN
- Poster NR8-14 has been WITHDRAWN
- Poster NR9-53 has been WITHDRAWN

Participant Changes

- NR9-20 Manisha Madhoo, MD will not be presenting. Poster will be presented by Anita Clayton, MD.
- NR9-47 Carmen T. Pitt, PhD will not be presenting. Poster will be presented by Pedro Barreiro Marin, MD.

Courses Sold Out

- Course 17, Course28

Corrections/Miscellaneous Changes

- NR8-52 presented by Dr. Richard Jackson, MD, moved to this session from NR10-03 on Tuesday.

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The recommended starting dose of NUDEXTA (20 mg dextromethorphan hydrobromide and 10 mg quinidine sulfate) is one capsule daily by mouth for the initial seven days of therapy. On the eighth day of therapy and thereafter, the daily dose should be a total of two capsules a day, given as one capsule every 12 hours. The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients.

CONTRAINDICATIONS

Quinidine and related drugs: NUDEXTA contains quinidine, and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine. **Hypersensitivity:** NUDEXTA is contraindicated in patients with a history of NUDEXTA, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome; also in patients with known hypersensitivity to dextromethorphan *[see Warnings and Precautions (5.1 in full PI)]*. **MAOIs:** NUDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome. Allow at least 14 days after stopping NUDEXTA before starting an MAOI *[see Drug Interactions (7.1 in full PI)]*. **Cardiovascular:** NUDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and in patients with heart failure *[see Warnings and Precautions (5.3 in full PI)]*. NUDEXTA is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimoziide), as effects on QT interval may be increased *[see Drug Interactions (7.2 in full PI)]*. NUDEXTA is contraindicated in patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block.

WARNINGS AND PRECAUTIONS

Thrombocytopenia and Other Hypersensitivity Reactions: Quinidine can cause immune-mediated thrombocytopenia that can be severe or fatal. Non-specific symptoms, such as lightheadedness, chills, fever, nausea, and vomiting, can precede or occur with thrombocytopenia. NUDEXTA should be discontinued immediately if thrombocytopenia occurs, unless the thrombocytopenia is not drug-related, as continued use increases the risk for fatal hemorrhage. Likewise, NUDEXTA should not be restarted in sensitized patients, because of the risk of more rapid and more severe thrombocytopenia. NUDEXTA should not be used if immune-mediated thrombocytopenia from structurally related drugs including quinine and mefloquine is suspected, as cross-sensitivity can occur. Quinidine-associated thrombocytopenia usually resolves within a few days of discontinuation of the sensitizing drug. Quinidine has also been associated with a lupus-like syndrome involving polyarthritis, sometimes with a positive ANA. Other associations include rash, bronchospasm, adenopathy, hemolytic anemia, vasculitis, uveitis, angioedema, agranulocytosis, the sicca syndrome, myalgia, elevated serum levels of skeletal muscle enzymes, and pneumonitis. **Hepatotoxicity:** Hepatitis has been reported in patients receiving quinidine, generally during the first few weeks of therapy. **Cardiac Effects:** NUDEXTA causes dose-dependent QTc prolongation *[see Clinical Pharmacology (12.2 in full PI)]*. QT prolongation can cause torsades de pointes-type ventricular tachycardia, with the risk increasing as prolongation increases. When initiating NUDEXTA in at risk patients, ECG evaluation of QT interval should be done at baseline and 3-4 hours after the first dose. This includes patients concomitantly taking drugs that prolong the QT interval or that are strong or moderate CYP3A4 inhibitors, and patients with left ventricular hypertrophy (LVH) or left ventricular dysfunction (LVD). LVH and LVD are more likely to be present in patients with chronic hypertension, known coronary artery disease, or history of stroke. LVH and LVD can be diagnosed utilizing echocardiography or another suitable cardiac imaging modality. Reevaluate ECG if risk factors for arrhythmia change during the course of treatment. Risk factors include concomitant use of drugs associated with QT prolongation, electrolyte abnormality (hypokalemia, hypomagnesemia), bradycardia, and family history of QT abnormality. Hypokalemia and hypomagnesemia should be corrected prior to initiation of therapy with NUDEXTA, and should be monitored during treatment. If patients experience symptoms that could indicate cardiac arrhythmias, e.g., syncope or palpitations, NUDEXTA should be discontinued and the patient further evaluated. **Concomitant use of CYP2D6 Substrates:** The quinidine in NUDEXTA inhibits CYP2D6 in patients in whom CYP2D6 is not otherwise genetically absent or its activity otherwise pharmacologically inhibited *[see CYP2D6 Poor Metabolizers (5.8 in full PI), Pharmacokinetics (12.3 in full PI), Pharmacogenomics (12.5 in full PI)]*. Because of this effect on CYP2D6, accumulation of parent drug and/or failure of active metabolite formation may decrease the safety and/or the efficacy of drugs used concomitantly with NUDEXTA that are metabolized by CYP2D6 *[see Drug Interactions (7.5 in full PI)]*. **Dizziness:** In a controlled trial of NUDEXTA, 10% of patients on NUDEXTA and 5% on placebo experienced dizziness. **Serotonin Syndrome:** When used with SSRIs or tricyclic antidepressants, NUDEXTA may cause serotonin syndrome, including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor *[see Drug Interactions (7.4 in full PI), Overdosage (10 in full PI)]*. **Anticholinergic Effects of Quinidine:** Monitor for worsening clinical condition in diseases that may be adversely affected by anticholinergic effects. **CYP2D6 Poor Metabolizers:** The quinidine component of NUDEXTA is intended to inhibit CYP2D6 so that higher exposure to dextromethorphan can be achieved compared to when dextromethorphan is given alone *[see Concomitant use of CYP2D6 substrates (5.4 in full PI), Pharmacokinetics (12.3 in full PI), Pharmacogenomics (12.5 in full PI)]*. Approximately 7-10% of Caucasians and 3-8% of African Americans are poor metabolizers (PMs) lacking capacity to metabolize CYP2D6. In patients who may be at risk of significant toxicity due to quinidine, consider genotyping to determine if they are PMs prior to treating with NUDEXTA.

Tuesday, May 21

Cancellations/Withdrawals

- Workshop 106 – WITHDRAWN (title: The DSM-5: Do Values Really Undermine Objectivity in Disease Classification?)
- Poster 10-32 WITHDRAWN

Participant Changes

- NR10-02 and NR10-51 changed to NR10-57 and NR10-58 and will both be presented by Leslie Citrome, MD.
- Symposium 53 – Thomas Spencer, MD will not be presenting and will be replaced by Joseph Biederman, MD.
- Symposium 118 – Carol Koplan, MD will be an additional speaker on presentation title Suicide Prevention with Frederick Langheim, MD, PhD.
- Symposium 110 – Dan G. Blazer, MD, PhD will not be in attendance and will be replaced by Andrew Newberg, MD.
- NR10-28 Mike Durkin is not presenting - poster will be presented by Dilesh Doshi, PhD.
- NR10-34 – Jennifer Kern Silwa, PhD, is not presenting - poster will be presented by Cyndi Bossie, PhD.
- NR11-38 – Mark Nobel is not presenting-poster will be presented by L. Danielle Chukumah, MD.

ADVERSE REACTIONS

A total of 946 patients participated in four Phase 3 controlled and uncontrolled PBA studies and received at least one dose of the combination product of dextromethorphan hydrobromide/quinidine sulfate in various strengths at the recommended or higher than the recommended dose. In a 12-week, placebo-controlled study (N=326), the most commonly reported adverse reactions (incidence ≥ 2% and greater than placebo) that led to discontinuation were muscle spasticity (3%), respiratory failure (1%), abdominal pain (2%), asthenia (2%), dizziness (2%), fall (1%), and muscle spasms (2%). The most common adverse reactions (≥ 3% and ≥ 2X placebo) were diarrhea (13%), dizziness (10%), cough (5%), vomiting (5%), asthenia (5%), edema (5%), urinary tract infection (4%), influenza (4%), flatulence (3%) and increased GGT (3%). Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. **Safety Experience of Individual Components:** *Dextromethorphan:* Drowsiness, dizziness, nervousness or restlessness, nausea, vomiting, and stomach pain. *Quinidine:* Cinchonism (nausea, vomiting, diarrhea, headache, tinnitus, hearing loss, vertigo, blurred vision, diplopia, photophobia, confusion, and delirium) is most often a sign of chronic quinidine toxicity, but it may appear in sensitive patients after a single moderate dose of several hundred milligrams. Other adverse reactions occasionally reported with quinidine therapy include depression, mydriasis, disturbed color perception, night blindness, scotomata, optic neuritis, visual field loss, photosensitivity, keratopathy, and abnormalities of skin pigmentation.

DRUG INTERACTIONS

MAOIs: Do not use NUDEXTA with monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days *[see Contraindications (4.3 in full PI)]*. **Drugs that Prolong QT and are Metabolized by CYP2D6:** Do not use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimoziide) *[see Contraindications (4.4 in full PI)]*. **Drugs that Prolong QT and Concomitant CYP3A4 Inhibitors:** Recommend ECG in these patients who are taking NUDEXTA *[see Warnings and Precautions (5.3 in full PI)]*. **SSRIs and Tricyclic Antidepressants:** Use of NUDEXTA with SSRIs or tricyclic antidepressants increases the risk of serotonin syndrome *[see Warnings and Precautions (5.6 in full PI)]*. **CYP2D6 Substrate:** The co-administration of NUDEXTA with drugs that undergo extensive CYP2D6 metabolism may result in altered drug effects *[see Warnings and Precautions (5.4 in full PI)]*. **Desipramine (CYP2D6 substrate):** This tricyclic antidepressant is metabolized primarily by CYP2D6. A drug interaction study was conducted between a higher combination dose of dextromethorphan (dextromethorphan hydrobromide 30 mg/quinidine sulfate 30 mg) and desipramine 25 mg. This dose increased steady state desipramine levels approximately 8-fold. If NUDEXTA and desipramine are prescribed concomitantly, the initial dose of desipramine should be markedly reduced. The dose of desipramine can then be adjusted based on response, but a dose above 40 mg/day is not recommended. **Paroxetine (CYP2D6 inhibitor and substrate):** When the combination dose of dextromethorphan hydrobromide 30 mg/quinidine sulfate 30 mg was added to paroxetine at steady state, paroxetine exposure (AUC₀₋₂₄) increased by 1.7 fold and C_{max} increased by 1.5 fold. Consider initiating treatment with a lower dose of paroxetine if given with NUDEXTA. The dose of paroxetine can then be adjusted based on response, but dosage above 35 mg/ day is not recommended. **Digoxin:** Quinidine is an inhibitor of P-glycoprotein. Prescribing quinidine with digoxin, a P-glycoprotein substrate, results in serum digoxin levels that may be as much as doubled. **Alcohol:** As with any other CNS drug, caution should be used when NUDEXTA is taken in combination with other centrally acting drugs and alcohol.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C: There are no adequate studies of NUDEXTA in pregnant women. **Labor and Delivery:** The effects of NUDEXTA on labor and delivery are unknown. **Nursing Mothers:** It is not known whether dextromethorphan and/or quinidine are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NUDEXTA is given to a nursing mother. **Pediatric and Geriatric Use:** The safety and effectiveness of NUDEXTA in these populations has not been determined. **Renal and Hepatic Impairment:** Dose adjustment of NUDEXTA is not required in patients with mild to moderate renal or hepatic impairment. Increases in dextromethorphan and/or quinidine levels are likely to be observed in patients with severe renal or hepatic impairment.

DRUG ABUSE AND DEPENDENCE

NUDEXTA contains dextromethorphan, and dextromethorphan abuse has been reported, predominately in adolescents. These observations were not systematic and it is not possible to predict on the basis of this experience the extent to which NUDEXTA will be misused once marketed. Therefore, patients with a history of drug abuse should be observed closely.

OVERDOSAGE

Evaluation and treatment of NUDEXTA overdose is based on experience with the individual components. Treatment of dextromethorphan overdosage should be directed at symptomatic and supportive measures. Treatment of quinidine overdosage requires monitoring the QTc interval and should involve a healthcare provider experienced in cardiac arrhythmia prevention and treatment and α-blockade-induced hypotension. Because of the theoretical possibility of QT prolongation that might be additive to those of quinidine, antiarrhythmics with Class I (procainamide) or Class III activities should (if possible) be avoided.

PATIENT COUNSELING INFORMATION

Physicians should discuss the following topics with patients when prescribing NUDEXTA: **Hypersensitivity:** *[see Contraindications (4.2 in full PI), Warnings and Precautions (5.1 in full PI)]*. **Cardiac effects:** Consult their healthcare provider immediately if they feel faint or lose consciousness. Inform their healthcare provider if they have any personal or family history of QTc prolongation *[see Contraindications (4.4 in full PI), Warnings and Precautions (5.3 in full PI) Drug Interactions (7 in full PI)]*. **Dizziness:** *[see Warnings and Precautions (5.5 in full PI), Adverse Reactions (6.1 in full PI)]*. **Drug Interactions:** *[see Drug Interactions (7 in full PI)]*. **Dosing:** Instruct patients to take NUDEXTA exactly as prescribed, not to take more than 2 capsules in a 24-hour period, to be sure that there is an approximate 12-hour interval between doses, and not to take a double dose after a missed dose. **General:** Contact their healthcare provider if their PBA symptoms persist or worsen. Advise patients to keep this and all medications out of reach of children and pets.

Marketed by Avanir Pharmaceuticals, Inc., Aliso Viejo, CA 92656
1-855-4NUDEX (468-3339)
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NUE-0421-ADV-0413



Encourage neurologic patients to open up about PBA by asking,
“Do you ever cry or laugh for no reason?”



82%
reduction in PBA episodes
at 12 weeks¹

- NUEDEXTA® may offer rapid relief from pseudobulbar affect (PBA) episodes within the first week of treatment¹
- Efficacy was sustained over the course of 12 weeks¹
- Reduction in PBA episodes for placebo was 45% at 12 weeks¹

NUEDEXTA is the only FDA-approved treatment for PBA

NUEDEXTA Important Safety Information

NUEDEXTA is indicated for treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurological conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state.

Studies to support the effectiveness of NUEDEXTA were performed in patients with amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). NUEDEXTA has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias.

NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) 20/10 mg capsules can interact with other medications causing significant changes in blood levels of those medications and/or NUEDEXTA which may lead to serious side effects. Adjust dose or use alternate treatment of the other medication when clinically indicated.

NUEDEXTA is contraindicated in patients concomitantly taking: QT-prolonging drugs metabolized by CYP2D6 (eg, thioridazine and pimozide); monoamine oxidase inhibitors (MAOIs) within the preceding or following 14 days; other drugs containing quinidine, quinine, or mefloquine and in patients with a known hypersensitivity to these drugs or any of NUEDEXTA's components.

Discontinue use of NUEDEXTA if hepatitis, thrombocytopenia, serotonin syndrome or a hypersensitivity reaction occurs.

NUEDEXTA is contraindicated in patients with certain risk factors for arrhythmia: Prolonged QT interval; congenital long QT syndrome, history suggestive of torsades de pointes; heart failure; complete atrioventricular (AV) block or risk of AV block without an implanted pacemaker.

NUEDEXTA causes dose-dependent QTc prolongation. When initiating NUEDEXTA in patients at risk for QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation should be conducted at baseline and 3-4 hours after the first dose. Risk factors include left ventricular hypertrophy or dystrophy or concomitant use of drugs that prolong QT interval or certain CYP3A4 inhibitors.

The most common adverse reactions are diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence. NUEDEXTA may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls.

These are not all the risks from use of NUEDEXTA. Please refer to the adjacent page for the Brief Summary of the Prescribing Information or see full Prescribing Information at www.NUEDEXTA.com.

Visit NUEDEXTA.com or call 1-855-4NUEDEX (468-3339).

Reference: 1. Data on file, Avanir Pharmaceuticals, Inc.



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NUEDEXTA[®]
(dextromethorphan HBr and
quinidine sulfate) Capsules

20mg/10mg