

# Fellowship Program in Medical Communications at MedVal & PharmaWrite



PharmaWrite®

# What Is Medical Communications?

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- Medical communications professionals
  - Blend science, research, writing, and art in order to educate healthcare professionals about up-to-date treatment options and help improve patient care
- Medical communications companies
  - Collaborate with pharmaceutical/biotech companies to facilitate the development and dissemination of disease state and treatment information to healthcare professionals and patients

# What Is Medical Communications?

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- Medical communications companies
  - Oftentimes are driven by pharmacists, PhDs, and physicians
  - Activities include a broad range of print, electronic, online, and onsite educational initiatives
  - Projects follow data across all phases of a product lifecycle, from study reports to first abstract/poster presentations to completed clinical manuscripts
  - May be accredited providers of continuing education or unaccredited joint sponsors of CE

*Pharmacists have the appropriate scientific and clinical foundation for working in this arena*

# About MedVal & PharmaWrite

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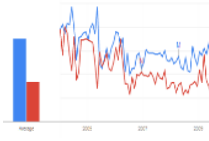
- Sister medical communication companies in the Princeton, NJ area
- Provide pharma/bio/device clients with scientific and strategic expertise
- Employ a number of pharmacists
- Use diverse scientific teams of professionals with advanced degrees, including medical writers, scientific managers, medical editors, medical librarians, meeting planners, graphic designers, IT & web specialists, and speaker bureau program coordinators

# MedVal & PharmaWrite: Core Activities

## CORE DEVELOPMENT



Scientific Platforms



Landscape/Gap Analyses



Publication Planning



Medical Writing



Regulatory Writing



Strategic Communications



KOL Identification & Development

## MEETING ACTIVITIES



Advisory Boards



Surveillance



Investigator Meetings



Roundtables



Speaker Training



Speakers Bureau

## INTERACTIVE & DIGITAL



Digital Posters



Mobile Devices & Apps



Social Media Monitoring



Websites



eFeedback

## ENDURING MATERIALS



Abstracts & Posters



Publications



Slide Decks



Response Letters



AMCP Dossier/Monograph



Newsletters

# MedVal & PharmaWrite: Core Activities

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- Publication Planning
  - Market surveillance
  - Abstracts and posters
  - Clinical trial papers/manuscripts
  - Case reports
  - Reviews
  - Monographs and formulary kits
  - Journal supplements
  - Letters
- Advocacy Development
  - Advisory boards/roundtables
  - Consultant meetings
  - Satellite meetings
  - Expert investigator websites
  - Newsletters
- Special Event Planning
  - Investigator meetings
  - Consultant meetings
  - Resident/Fellow training seminars
  - International congresses
- Speakers Bureau Management
  - Promotional speakers bureaus
  - Speaker training
  - Speaker websites
  - Webcasts
- Other
  - Drug information materials
  - Decision tree analyses
  - Comparison guides
  - PharmQD

# Experience in a Wide Array of Therapeutic Areas

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- Addiction medicine
- Alzheimer's dementia
- Anesthesiology
- Antifungals
- Bone and joint health
- Cardiovascular disease
- Collagen disorders
- Dyslipidemia
- Diabetes
- Emergency medicine
- Endocrine diseases
- Enzyme replacement
- Epilepsy and seizure disorders
- Gastrointestinal diseases
- Geriatrics
- Growth disorders
- Hepatitis C
- HIV/AIDS
- Hypertension
- Immunology
- Infectious diseases
- Migraine
- Men's health
- Monoclonal antibodies
- Multiple sclerosis
- Nephrology
- Oncology/hematology
- Osteoporosis
- Pain management
- Parkinson's disease
- Pharmacology/ pharmacokinetics
- Psoriasis
- Psychiatry
- Pulmonology
- Rare diseases
- Rheumatoid diseases
- Schizophrenia
- Supportive care
- Urology
- Women's health

# MedVal and PharmaWrite Clients

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- Amgen
- Arbor
- Auxilium
- CareFusion
- Cephalon
- Corcept
- Cubist
- Dara
- Lipocine
- Dendreon
- Eisai
- GI Dynamics
- GlaxoSmithKline
- Lipocine
- Mallinckroct
- Mesoblast
- Mylan
- NAMSA
- Novo Nordisk
- Nuvo Research
- Proximagen
- Sobi
- Solvay
- Sunesis
- Teva
- Upsher-Smith
- Zogenix

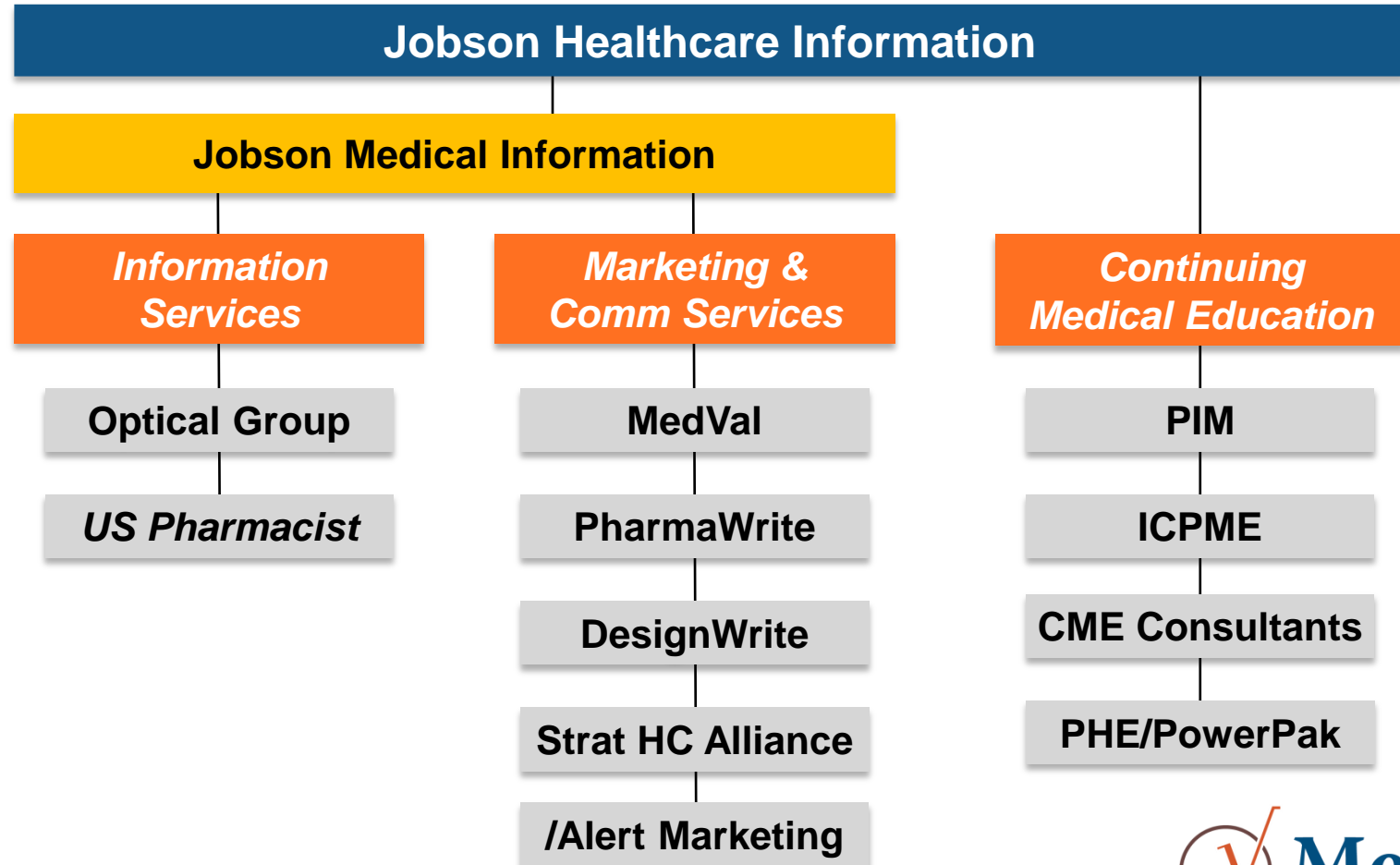


# Ethical Guidelines for Professional Medical Writing

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- AMWA: American Medical Writers Association
- CONSORT: Consolidated Standards of Reporting Trials
- COPE: Committee on Publication Ethics
- EMWA: European Medical Writers Association
- ICMJE: International Committee of Medical Journal Editors
- Institute of Medicine
- ISMPP: International Society for Medical Publication Professionals (GPP2)
- PRISMA: Preferred Reporting Items for Systematic Reviews & Meta-Analyses
- SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
- TIPPA: The International Publication Planning Association
- WAME: World Association of Medical Editors
- WMA: World Medical Association Declaration of Helsinki (2008)
- Individual journal requirements

# Jobson Medical Information Holdings, LLC



# Overview of the Fellowship Program

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- MedVal Scientific Information Services and PharmaWrite Medical Communications are offering a 1-year, postdoctoral fellowship
  - Begins July 1, 2015
  - Affiliated with the Philadelphia College of Pharmacy at the University of the Sciences (USciences) in Philadelphia, PA
    - Offers teaching experience as an Adjunct Clinical Instructor
    - Includes an opportunity to acquire a teaching certificate
- The fellow will divide his or her time between MedVal, PharmaWrite, and USciences

# Fellowship Program Goals

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- Primary goal
  - To provide a foundation for a career in medical communications through training and exposure to various aspects of the industry
  - Educational and promotional programs/activities
- Academic component
  - Adjunct Clinical Instructor
  - Develop teaching skills through formal educational instruction of PharmD students

# Academic Component

## Philadelphia College of Pharmacy/USciences in Philadelphia

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- Opportunity to acquire a teaching certificate
- Academic opportunities
  - Prepare and deliver lectures to students on drug information resources, applied literature evaluation, and/or disease states
  - Participate in Drug Information recitation
  - Serve as preceptor for USciences P4 students
  - Lead a student discussion of a journal club article
  - Participate during in-class activities or workshops
  - Utilize and understand methods to teach effectively
  - Create and deliver a CE program for pharmacists
  - Develop a dynamic teaching portfolio

# Additional Opportunities

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- Optional rotation
  - Optional offsite rotation in an area of interest to the fellow
    - Drug information
    - Health Economic Outcomes Research
    - *US Pharmacist*-pharmacy journalism
    - Clinical Research Organization
- Attendance at national meetings
  - In addition to ASHP Midyear, MedVal and PharmaWrite will sponsor attendance of one national meeting of Fellow's choice
- Serve as a guest blogger on PharmQD

# Candidate Requirements and Application Deadline

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- Fellow candidate qualifications:
  - PharmD or advanced academic degree
  - Must become licensed in NJ and the Commonwealth of PA (if Fellow chooses to participate in direct patient care rotation at USciences) by the end of the second quarter
  - Possess good interpersonal and communication skills
- Application materials and deadline
  - Letter of intent
  - Official transcript
  - 3 letters of reference
  - Updated curriculum vitae

**DEADLINE: December 16, 2014**

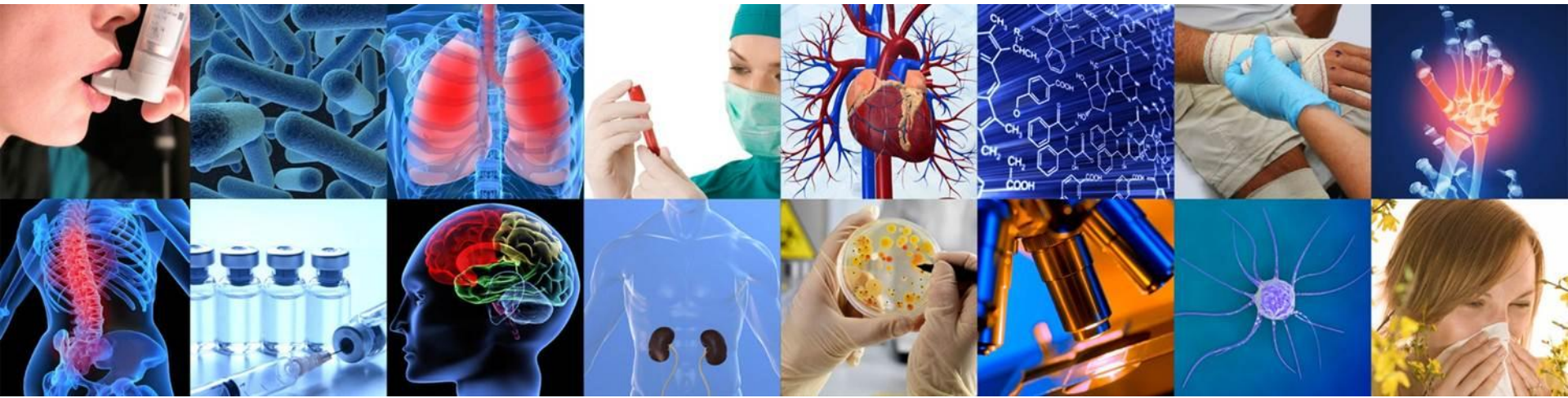
# Benefits

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- Comprehensive benefits and health care package
  - Annual stipend of \$43,000
  - Medical, dental, vision, and life insurance package
- Certification of completion of fellowship
- Optional teaching certificate



# Examples of Our Work...



**SCIENCE WELL TOLD**

# Extensive Experience in Publishing Message-Driven...

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- Primary papers
- Secondary papers
- Reviews
- Abstracts and posters
- Case reports
- Short communications
- Letters to the editor
- Journal supplements
- Symposium reports
- Newsletters
- In-house publications
- Poster books
- Monographs





# High-Tier Publications

**JAMA**  
The Journal of the American Medical Association

May 22/29, 2002

## Effect of Lower Doses of Conjugated Equine Estrogens With and Without Medroxyprogesterone Acetate on Bone in Early Postmenopausal Women

Robert Lindsay, MD, PhD, FRCP  
Christopher Gallagher, MD  
Michael Akerman, MD  
James R. Pickar, MD

**Context** Lower than commonly prescribed doses of conjugated equine estrogens (CEE) with and without medroxyprogesterone acetate (MPA) improve osteoporosis and prevent fractures. The lower-dose therapy's protection against loss of bone mineral density (BMD) associated with menopause has not been thoroughly tested.

**Objective** To determine the effects of lower doses of CEE with or without MPA on bone turnover, bone mineral density (BMD), and bone mass in early postmenopausal women.

**Design and Setting** Two-year randomized, double-blind, placebo-controlled study of the Women's Health Initiative, Osteoporosis, Prevention, and Fracture Trial, conducted between August 1996 and October 2000.

**Participants** Eight hundred twenty-two healthy postmenopausal women aged 50 to 64 years who were either 4 years or less from their last menstrual period.

**Interventions** Patients were randomly assigned to receive CEE 0.625 mg daily with MPA 3.75 mg daily, CEE 0.40 mg daily with MPA 2.5 mg daily, or placebo. All patients received calcium at 600 mg daily.

**Main Outcome Measures** Changes from baseline in spine and total hip bone mineral density (BMD) and biochemical markers of bone turnover (urinary excretion of deoxypyridinoline [D-PIDP] and urinary excretion of hydroxyproline [OH-PIDP]) were measured at 6-month intervals during treatment groups with a double-blind, randomized, placebo-controlled trial.

**Results** At 24 months, women assigned to all of the active treatment groups had significantly higher BMD in the spine and total hip than those in the placebo group. The lowest doses of CEE with MPA (0.40 mg CEE and 2.5 mg MPA) were associated with the greatest increase in BMD. The increase in BMD was significantly greater in the 0.40 mg CEE with 2.5 mg MPA group than in the 0.625 mg CEE with 3.75 mg MPA group. The increase in BMD was significantly greater in the 0.40 mg CEE with 2.5 mg MPA group than in the 0.625 mg CEE with 3.75 mg MPA group. The increase in BMD was significantly greater in the 0.40 mg CEE with 2.5 mg MPA group than in the 0.625 mg CEE with 3.75 mg MPA group.

**Conclusions** Lower doses of CEE with MPA have beneficial effects on bone mass and BMD in early postmenopausal women.

## Tramadol and Acetaminophen Combination Tablets in the Treatment of Fibromyalgia Pain: A Double-Blind, Randomized, Placebo-Controlled Study

Robert M. Bennett, MD, Marc Kamin, MD, Ronald Karim, PhD, Norman Rimmthal, MD

**Purpose** To evaluate the efficacy and safety of a combination analgesic tablet (50 mg tramadol/325 mg acetaminophen) for the treatment of fibromyalgia pain.

**Methods** This 41-day multicenter, double-blind, randomized, placebo-controlled study compared tramadol/acetaminophen combination tablets with placebo. The primary outcome measure was the mean change in pain score (Visual Analog Scale) from baseline to the end of the study.

**Results** The mean change in pain score from baseline to the end of the study was significantly greater in the tramadol/acetaminophen group than in the placebo group.

**Conclusions** Tramadol/acetaminophen combination tablets are effective for the treatment of fibromyalgia pain.

Tramadol/acetaminophen combination tablets were significantly more effective than placebo in the treatment of fibromyalgia pain. The primary outcome measure was the mean change in pain score (Visual Analog Scale) from baseline to the end of the study.

The mean change in pain score from baseline to the end of the study was significantly greater in the tramadol/acetaminophen group than in the placebo group.

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## Double-blind randomized trial of tramadol for the treatment of the pain of diabetic neuropathy

E. Havel, MD, C. Gomb, MD, M. Stevermann, MD, S. Edelstein, MD, D. Grewin, MD, P. Baskin, MD, P. Dandekar, MD, D. Corfield, MD, B. Schwab, MD, C.O. Sio, PhD, and M. Kamin, MD

**Objective**—The objective of this study was to evaluate the efficacy and safety of tramadol in treating the pain of diabetic neuropathy. **Background**—The pain of diabetic neuropathy is a major cause of morbidity among the diabetic population, and treatment, with either small-dose neuropathic or other analgesics, is often unsatisfactory. Tramadol is a centrally acting analgesic for use in treating moderate to moderately severe pain. **Methods** This multicenter, outpatient, randomized, double-blind, placebo-controlled, parallel-group study consisted of a 4-week screening phase, during which all study patients were treated with tramadol (n = 60) or placebo (n = 60) for 14 days. A total of 120 patients with painful diabetic neuropathy were treated with tramadol (n = 60) or placebo (n = 60) for 14 days. The primary efficacy analysis compared the mean pain intensity score at baseline and at the end of the study or at the time of discontinuation. Secondary efficacy assessments were the mean change in pain score and a quality of life evaluation based on daily activities and sleep characteristics. **Results**—The mean change in pain intensity score from baseline to the end of the study was significantly greater in the tramadol group than in the placebo group. The mean change in pain intensity score from baseline to the end of the study was significantly greater in the tramadol group than in the placebo group. The mean change in pain intensity score from baseline to the end of the study was significantly greater in the tramadol group than in the placebo group. **Conclusions**—The results of this placebo-controlled trial showed that tramadol is effective for the treatment of the pain of diabetic neuropathy.

**JAMA**  
The Journal of the American Medical Association

February 25, 2004

## Topiramate for Migraine Prevention: A Randomized Controlled Trial

Jon Lewis Swanson, MD  
Dorcas M. D'Amico, MD  
E. Condit, MD, PhD  
Michael W. Lewis, MD  
William Schmitt, MD  
Peter Neta, MD  
Julian Schwab, MD  
David Swanson, MD  
for the MACE (M) Study Group

**Context** Small open-label and controlled trials suggest that the antiepileptic drug topiramate is effective for migraine prevention.

**Objective** To assess the efficacy and safety of topiramate for migraine prevention in a large controlled trial.

**Design, Setting, and Patients** A 26-week, randomized, double-blind, placebo-controlled study was conducted during outpatient treatment of 52 female migraineurs. Patients were aged 12 to 45 years and had a 6-month history of migraine (International Headache Society criteria) and 3 to 12 migraine attacks per month (more than 15 headache days a month during a 26-day prospective baseline period).

**Interventions** After a washout period, patients receiving either topiramate (n = 26) or placebo (n = 26) for 26 weeks. Topiramate was titrated to 150, 200, or 300 mg daily or placebo. Topiramate was titrated to 150, 200, or 300 mg daily or placebo. Topiramate was titrated to 150, 200, or 300 mg daily or placebo. Topiramate was titrated to 150, 200, or 300 mg daily or placebo.

**Main Outcome Measures** The primary efficacy measure was change in mean monthly migraine frequency. Secondary efficacy measures included headache severity, reduction in mean number of monthly migraine days, severity, and patients continued receiving that dose for 18 weeks.

**Results** Of 683 patients randomized, 488 provided at least 1 postbaseline data point and completed the study on their assigned treatment. Mean monthly migraine frequency decreased significantly for patients receiving topiramate (1.7, 1.5, 1.2, and 1.0 migraine days per month for 150, 200, 250, and 300 mg, respectively) compared with placebo (2.0 migraine days per month). The difference in mean monthly migraine frequency between topiramate and placebo was significantly greater for the 150-mg (P = .000) and 200-mg (P = .000) groups. The difference in mean monthly migraine frequency between topiramate and placebo was significantly greater for the 150-mg (P = .000) and 200-mg (P = .000) groups. The difference in mean monthly migraine frequency between topiramate and placebo was significantly greater for the 150-mg (P = .000) and 200-mg (P = .000) groups.

**Conclusions** Topiramate showed significant efficacy in migraine prevention. Topiramate showed significant efficacy in migraine prevention. Topiramate showed significant efficacy in migraine prevention. Topiramate showed significant efficacy in migraine prevention.

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Strength 

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**PharmNews**

Featured News

 **First Generic Olanzapine Approved to Treat Schizophrenia, Bipolar Disorder** - 10.24.2011

The U.S. Food and Drug Administration today approved the first generic versions of Zyprexa (olanzapine tablets) and Zyprexa Zydus (olanzapine orally disintegrating tablets) to treat schizophrenia and bipolar disorder.

Schizophrenia is a chronic, severe, and disabling brain disorder. About 1 percent of

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# Competitive Surveillance

## Monthly report on competitive activity in



**Scientific Literature**



**Meetings**



**Media/Internet**

## Databases searched for information

- PubMed/Medline
- EMBASE
- BIOSIS
- CRISP
- Factiva
- Mediconf
- Pharmaceutical/  
product databases

# Is This Fellowship for You?

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- Do you have a strong interest in writing?
- Do you have an interest in doing something nontraditional?
- Do you have an interest in advancing patient care by delivering high quality information to HCPs?
- Do you have an interest in teaching?

*Consider Becoming a Medical Communications Fellow!*



# Thank you on behalf of MedVal, PharmaWrite, and USciences

*We look forward to  
meeting with you*



PharmaWrite®