



Regulatory Review

June 13, 2011

Important FDA MedWatch Safety Alerts Announced

The FDA alerted health professionals to the following recently identified concerns related to drugs in the 5-ARI class, including finasteride and dutasteride, which are marketed under the brand-names Proscar, Propecia, Avodart, and Jalyn.

FDA notified healthcare professionals that the Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs has been revised to include new safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer).

Prior to initiating therapy with 5-ARIs, perform appropriate evaluation to rule out other urological conditions, including prostate cancer, that might mimic benign prostatic hyperplasia (BPH). See Drug Safety Communication for a Data Summary and additional information.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258529.htm>

The FDA also alerted health professionals to a recall of the Oridion Medical and Philips Healthcare Microstream CO2 Filterline.

The Microstream CO2 Filterline is a medical device used by emergency medical services, hospitals, and other health care providers to measure exhaled carbon dioxide (CO2) during ventilation of newborn and infant patients. See the recall notice for affected models and lots.

Philips instructed users to immediately identify all products from affected lots, remove them from inventory and dispose in accordance with local regulations.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258133.htm>.

NeHC Webinar Features ONC Speaker

On **Monday, June 13, 2011 at 1 p.m. ET**, the National eHealth Collaborative (NeHC), in collaboration with the Office of the National Coordinator for Health Information Technology (ONC), will host a webinar featuring ONC's Director of the Office of Policy and Planning, Jodi

Daniel, who will provide updates on ONC advisory committees and workgroups. Register at <http://www.nationalehealth.org/Events.aspx?id=36>.

New AHRQ Reports on Future Research Needs

AHRQ's Effective Health Care (EHC) Program posted four new reports, all of which are open for comment until July 8, 2011. The reports are as follows:

- [Engaging Stakeholders To Identify and Prioritize Future Research Needs](#).
- [Assessing the Impact of AHRQ Evidence-based Practice Center \(EPC\) Reports on Future Research](#).
- [Evaluating the Potential Use of Modeling and Value-of-Information Analysis for Future Research Prioritization Within the Evidence-based Practice Center Program](#).
- [Defining an Optimal Format for Presenting Research Needs](#).

AHRQ Brief Highlights Patient-Centered Medical Home

AHRQ's latest brief, *The Patient-Centered Medical Home: Strategies to Put Patients at the Center of Primary Care*, provides a clear and concise definition of the patient-centered medical home and outlines 6 strategies that can be used to support primary care practices in their efforts to engage patients and families. More information on the patient-centered medical home (PCMH) can be found at www.pcmh.ahrq.gov.

CMS Final Rule on Medicaid Payment Adjustment for Provider-Preventable Conditions

Last week, CMS issued a final rule on payment adjustments for provider-preventable conditions, which include health care-acquired conditions (HCACs), in the Medicaid program. The [final rule](#) implements section 2702 of the Affordable Care Act (ACA), which prohibits federal payments for States for any amounts expended for providing medical assistance for certain health care-acquired conditions and provider-preventable conditions. The rule is effective on July 1, 2011.

Opportunities to Submit Nominations

AHRQ is [soliciting nominations](#) of seven new members to the National Advisory Council for Healthcare Research and Quality (the Council). Submit nominations to Karen Brooks at karen.brooks@ahrq.hhs.gov.

AHRQ is soliciting nominations of 15 experts on pediatric quality measures for the Children's Health Insurance Program Reauthorization Act (CHIPRA) Pediatric Quality Measures Program. Nominations should be e-mailed to chipra@AHRQ.hhs.gov by June 30, 2011.

Opportunities to Submit Proposals & Requests for Information

[Medicare Program; Solicitation for Proposals for the Medicare Community-Based Care Transitions Program](#); Contact Juliana Tionson at (410) 786-0342 or by e-mail at CareTransitions@cms.hhs.gov for more information.

[Analgesic Clinical Trials Innovation, Opportunities, and Networks \(ACTION\) Initiative](#); Important dates are as follows:

- The application due date is June 8, 2011.
- The anticipated start date is July 14, 2011.
- The opening date is April 22, 2011.
- The expiration date is June 9, 2011.

Visit the [FDA website](#) for details.

[Request for Input To Inform a Possible Surgeon General Action on Prescription Drug Abuse in Youth](#): Submit comments on/or before June 2, 2011 to comments4sg@nih.gov.

Upcoming Federal Regulatory Meetings

Agency for Healthcare Research and Quality (AHRQ)

AHRQ announced that the **Guidelines International Network (G-I-N) Conference 2011** will be held August 28-31, 2011 in Seoul, Korea. [Register online](#) now.

AHRQ announced that its 2011 Annual Conference, [Leading Through Innovation and Collaboration](#), will be held on September 18-21 at the Bethesda North Marriott Convention Center in Bethesda, MD.

AHRQ announced that it will host a free Web-based teleconference, [Medication Management Using Health IT for the Care of Elderly](#), on Tuesday, June 21, 2011, from 11:30 a.m. until 1:00 p.m.

Centers for Disease Control and Prevention (CDC)

The CDC announced the establishment of the [World Trade Center \(WTC\) Health Program Scientific/Technical Advisory Committee](#). No meetings of this have been announced at this time.

The CDC [Ethics Subcommittee of the Advisory Committee to the Director \(ACD\)](#) will meet from 1 p.m. - 5 p.m., June 16, 2011 and from 8:30 a.m.-12:30 p.m., June 17, 2011 at the Thomas R. Harkin Global Communications Center, Distance Learning Auditorium, 1600 Clifton Road, NE., Atlanta, Georgia 30333. This meeting is also available by teleconference. Please dial (877) 928-1204 and enter code 4305992.

The CDC [Healthcare Infection Control Practices Advisory Committee \(HICPAC\)](http://www.cdc.gov/hicpac) will meet from 9 a.m.-5 p.m., June 16, 2011 and 9 a.m.-12 p.m., June 17, 2011 at the CDC Global Communications Center, Building 19, Auditorium B3, 1600 Clifton Road, NE., Atlanta, Georgia, 30333. You must register for this meeting at <http://www.cdc.gov/hicpac>.

The CDC [Advisory Committee on Immunization Practices \(ACIP\)](http://www.cdc.gov/acip) will meet from 8 a.m.-6 p.m., June 22, 2011 and from 8 a.m.-4 p.m., June 23, 2011 at the Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ``Oz" Nelson Auditorium, Atlanta, Georgia 30333.

Centers for Medicare and Medicaid Services (CMS)

The CMS announced the following Special Open Door Forums and Listening Sessions:

- ***Special Open Door Forum: The Advance Payment Initiative:*** Tuesday, June 14, 2011 2 pm-3:30 pm ET. To participate, dial 1-866-501-5502 Conference ID 71725238.
- ***Physician, Nurses and Allied Health Professionals Open Door Forum:*** Tuesday, June 28, 2011 from 2pm-3pm ET. To participate, dial 1-800-837-1935 Conference ID 59680265.
- ***Hospital Quality Open Door Forum:*** Wednesday, July 13, 2011 from 2pm-3pm ET. To participate, dial 1-800-837-1935 Conference ID 68627432.

The CMS announced its [Accelerated Development Sessions for Accountable Care Organizations](https://acoregister.rti.org)--June 20, 21, and 22, 2011. The first ADS will be held at the Doubletree by Hilton, Minneapolis-Park Place, 1500 Park Place Boulevard, Minneapolis, MN 55416. Register at <https://acoregister.rti.org>.

Food and Drug Administration (FDA)

The FDA [Dermatologic and Ophthalmic Drugs Advisory Committee](http://www.fda.gov/oc/ohrt) will meet on June 17, 2011, from 8 a.m. to 4:30 p.m. at the Marriott Inn and Conference Center, University of Maryland University College (UMUC), 3501 University Blvd. East, Adelphi, MD.

An FDA public "industry exchange" workshop entitled "[The Future of Medical Products Regulation: Ensuring Safety and Integrity in a Global Market](http://www.fda.gov/oc/ohrt)," will be held on June 20 and 21, 2011, from 8 a.m. to 5 p.m. at the Marriott Dallas/Plano at Legacy Town Center, Plano, Texas, 7120 Dallas Pkwy., Plano, Texas 75024.

The FDA [Pulmonary-Allergy Drugs Advisory Committee](http://www.fda.gov/oc/ohrt) will meet on June 23, 2011, from 8:30 a.m. to 5 p.m at the Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910.

The FDA will hold a [hearing](http://www.fda.gov/oc/ohrt) on its **proposal to withdraw approval of the breast cancer indication for bevacizumab (Avastin)** on June 28 and 29 from 8 AM ET to 5 PM ET at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg 31, Rm. 1503 (Great Room), Silver Spring, MD 20993.

The FDA [Cellular, Tissue and Gene Therapies Advisory Committee](http://www.fda.gov/oc/ohrt) will meet on June 29, 2011, from 8 a.m. to 5 p.m. at the Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD, 20910.

The FDA [Gastrointestinal Drugs Advisory Committee](#) will meet on July 21, 2011, from 8 a.m. to 4 p.m. at the Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910.

Health Resources and Services Administration (HRSA)

The HRSA [National Advisory Committee on Rural Health and Human Services](#) will meet on June 15, 2011, 9 a.m.-4:45 p.m., June 16, 2011, 9 a.m.-4:45 p.m., June 17, 2011, 8:45 a.m.-10:30 a.m. (all times are ET) at the Park Place Hotel, 300 East State Street, Traverse City, MI 49684.

The HRSA [Council on Graduate Medical Education](#) will meet on June 14, 2011, 1 p.m.-4 p.m. ET and June 15, 2011, 9 a.m.-Noon ET via webinar. Visit <http://www.cogme.gov> to participate in the meeting.

National Institutes of Health (NIH)

The NIH [National Advisory Council on Minority Health and Health Disparities](#) will meet on June 14, 2011 from 9:30 a.m. to 5 p.m. at the Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

The NIH [National Arthritis and Musculoskeletal and Skin Diseases Advisory Council](#) will meet on June 14, 2011, with an open public session from 8:30 a.m. to 12 p.m. ET at the National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

The NIH [National Institute on Aging Board of Scientific Counselors](#) will hold several open sessions during its upcoming meeting on June 14-15, 2011 at the National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

The NIH [National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Kidney, Urologic and Hematologic Diseases D Subcommittee](#) will meet on June 21-23, 2011, with an open public session on June 21, 2011, 4 p.m. to 4:30 p.m. ET at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

The NIH [National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Digestive Diseases and Nutrition C Subcommittee](#) will meet on June 27-28, 2011, at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814. The open public session will be held on June 27, 2011, 8 a.m. to 8:30 a.m.

The NIH [Council of Councils](#) will meet on June 29, 2011, with an open public session from 8:30 a.m. to 12:30 p.m. ET and 2:20 p.m. to 5:30 p.m. ET at the National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

The NIH [National Advisory Allergy and Infectious Diseases Council](#) and related subcommittees will hold a series of meetings on September 19, 2011 at the National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Office of the National Coordinator (ONC)

The [Office of the National Coordinator for Health Information Technology \(ONC\) HIT Standards & Policy Committee and related workgroups](#) meet almost daily on various topics. Visit the ONC web site for the full schedule. Most meetings are held both in-person and via webcast.

Other HHS Meetings

The [National Committee on Vital and Health Statistics \(NCVHS\) Full Committee](#), will meet on June 15, 2011 9 a.m.-2:30 p.m., June 16, 2011 10 a.m.-3 p.m., and June 17, 2011 9 a.m.-5 p.m. at the Double Tree Hotel, 300 Army Navy Drive, Arlington, VA 22202, (703) 416-4100.

A meeting of the [Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020](#) has been announced for June 30, 2011, from Noon to 2 p.m. It will be held on the Internet via WebEx software. Visit the [dedicated web page](#) to register.

Opportunities for Public Comment

Federal Regulations

[Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates; Proposed Rule](#): Comments due on June 20, 2011

[Public Health Information Network \(PHIN\) Messaging Guide for Syndromic Surveillance](#): Comments due on June 20, 2011

[Periodic Review of Existing Regulations; Retrospective Review Under E.O. 13563](#): Comments due on June 27, 2011

[Examination of Online Direct-to-Consumer Prescription Drug Promotion](#): Comments due on June 27, 2011

[Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Disclosures of Ownership and Additional Disclosable Parties Information; Proposed Rule](#): Comments due on June 27, 2011

[Reducing Regulatory Burden; Retrospective Review Under Executive Order 13563](#): Comments due on June 30, 2011

[Medicaid Program; Methods for Assuring Access to Covered Medicaid Services](#): Comments due on July 5, 2011

[Medicare Program; Hospice Wage Index for Fiscal Year 2012](#): Comments due on July 8, 2011

[Disqualification of a Clinical Investigator](#): Comments due by July 12, 2011

[Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program](#): Comments due on July 19, 2011.

[Medicare Program; Proposed Changes to the Electronic Prescribing \(eRx\) Incentive Program](#): Comments due on July 25, 2011.

[Medicare Program; Five Year Review of Work Relative Value Units Under the Physician Fee Schedule](#): July 25, 2011.

[HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act](#): Comments due on August 1, 2011.

[Medicare Program; Availability of Medicare Data for Performance Measurement; Proposed Rule](#): Comments due on August 8, 2011.

FDA Guidance Documents

[Guidance for Industry and Investigators on Enforcement of Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies](#): Comments accepted at any time.

[Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act](#): Submit comments by July 12, 2011.

[Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators](#): Submit comments by July 25, 2011.

[Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](#): Submit comments by August 1, 2011.

[Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia Trachomatis and/or Neisseria Gonorrhoeae: Screening and Diagnostic Testing](#): Submit comments by August 9, 2011.

[Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus Species Detection](#): Submit comments by August 16, 2011.

[Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions](#): Submit comments by August 30, 2011.

Other

The CDC has [extended the public comment period](#) for its [Draft Action Plan--A Public Health Action Plan to Combat Antimicrobial Resistance](#) by 60 days to June 14, 2011.

The FDA has reopened its comment period following its workshop entitled “[Determination of System Attributes for the Tracking and Tracing of Prescription Drugs](#).” Comments are now due on June 22, 2011.

The CMS issued a [request for information on opportunities for alignment under Medicaid and Medicare](#). Respond to this request as outlined in the notice by July 11, 2011.

The FDA has [extended the public comment period](#) for its notice of public meeting on generic drug user fees. Comments are now due by August 1, 2011.

The CMS issued a request for applications for Pioneer ACOs. Letters of intent must be submitted by June 30, 2011 as described on the Innovation Center Web site <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco>. Applications must be received on or before August 19, 2011.