

NIH Proposes Rules to Revise Research Funding Regulations

The National Institutes of Health (NIH) is inviting comments on proposed rules to amend its regulations on financial ties and conflicts of interest among clinical investigators who apply for or receive research funding from the U.S. Public Health Service. The rules aim to expand and add transparency to researchers' disclosures of financial interests and to enhance regulatory compliance and oversight by institutions, according to a notice of proposed rulemaking in the May 21, 2010, *Federal Register*. Proposed changes would lower monetary thresholds of "significant financial interests" required to disclose from \$10,000 to \$5,000; modify interests excluded from the financial interests definition, broaden regulations on small business applications; and create or revise other definitions for clarity and consistency. Interested parties may comment on the proposed rules through July 20, 2010. The rules will be finalized later this year. For more information, visit <http://www.aafp.org/news-now/clinical-care-research/20100608nihfundingrule.html> and <http://www.gpo.gov/fdsys/pkg/FR-2010-05-21/pdf/2010-11885.pdf>.

Study Finds That High Percentage of Physicians Use FOBT Inappropriately

Many primary care physicians who order or perform fecal occult blood tests (FOBTs) for colorectal cancer screening fail to follow recommended screening guidelines, according to a study in the April 10, 2010, *Journal of General Internal Medicine*. The study used data from surveys of more than 1,100 primary care physicians. Of those participants, 25 percent reported using in-office FOBTs exclusively to screen for colorectal cancer, more than 50 percent reported using both in-office and home tests, only 22 percent primarily used home-based FOBT exclusively, and less than one half of those who used home tests had reminder systems to ensure that patients completed and returned the tests. The study's authors said the data show no evidence of a shift away from the use of in-office tests, despite published evidence of low accuracy of in-office FOBT and a change in Current Procedural Terminology codes that was intended to reinforce appropriate use of FOBT. For nearly a decade, The American Cancer Society has recommended the use of serial home-based FOBTs rather than a single in-office FOBT. For more information, visit <http://www.aafp.org/news-now/clinical-care-research/20100525fobt-study.html> and <http://www.springerlink.com/content/p7q4n4114510574t/fulltext.pdf>.

AAFP Calls for Senate Approval of Berwick Nomination to Head CMS

The American Academy of Family Physicians (AAFP) has reaffirmed its support for Donald Berwick, MD, as the new administrator of the Centers for Medicare and Medicaid Services (CMS) by signing two widely circulated letters calling on the Senate to rapidly approve Berwick's nomination. The first letter is being circulated by First Focus, a bipartisan family and children's advocacy organization. The second letter is being circulated by the Patient-Centered Primary Care Collaborative. As CMS administrator, Berwick would serve as a key player in overhauling the nation's health care system by overseeing tasks associated with the new health care reform law, such as expanding Medicaid coverage, writing new rules and regulations, and establishing pilot projects to test different models of care and payment policies. Berwick is a Harvard University professor and the president and CEO of the Institute for Healthcare Improvement, a non-profit organization in Cambridge, Mass., that advances concepts to improve patient care. The Senate Finance Committee is preparing to hold hearings on the Berwick nomination ahead of a vote by the full Senate. For more information, visit <http://www.aafp.org/news-now/government-medicine/20100608berwicknomltrs.html>.

FDA Seeks Input on Public Disclosure Proposals from Transparency Initiative

The U.S. Food and Drug Administration (FDA) is seeking public comment through July 20, 2010, on draft proposals related to its public disclosure policies, including a proposal that would provide more data about the safety and effectiveness of medical products with pending applications. The proposals were published May 21, 2010, in the *Federal Register*. If the proposals are adopted, the FDA could disclose when a drug or medical device is being studied and for what indication, when an application for a new product has been submitted or withdrawn, whether there were safety concerns associated with a product that led to withdrawal of an application, and why they did not approve an application. The FDA's transparency task force will review comments and decide which proposals to recommend to FDA Commissioner Margaret Hamburg, MD. For more information, visit <http://www.aafp.org/news-now/health-of-the-public/20100609fdadisclosureproposals.html> and <http://www.fda.gov/downloads/AboutFDA/WhatWeDo/FDATransparencyTaskForce/TransparencyReport/GlossaryofAcronymsandAbbreviations/UCM212110.pdf>.

MEDWATCH Blacksmith Recalls PediaCare Products, Claris Recalls IV Medications

Blacksmith Brands Inc. announced May 28, 2010, that it is voluntarily recalling all lots of four over-the-counter (OTC) products in its PediaCare line as a precautionary measure because they were manufactured at McNeil Consumer Healthcare's plant in Fort Washington, Pa. The FDA issued a highly critical report of the plant on April 30, 2010, at which time McNeil closed the facility and recalled several of its brand-name OTC pediatric liquid medications manufactured there. The four PediaCare items involved in the Blacksmith recall are PediaCare Multi-Symptom Cold, PediaCare Long-Acting Cough, PediaCare Decongestant, and PediaCare Allergy & Cold. Additionally, the FDA is advising physicians not to use intravenous bags of certain antibiotics and an antiemetic manufactured by Claris Lifesciences Ltd. in Ahmedabad, India, because of potential mold contamination. As a precautionary measure, Claris is recalling its intravenous products sold under the following labels: Claris (metronidazole, ciprofloxacin, ondansetron); Pfizer Inc. (metronidazole, ciprofloxacin, ondansetron); Sagent Pharmaceuticals Inc. (metronidazole, ondansetron); and West-Ward Pharmaceutical Corp. (metronidazole, ondansetron). For more information, visit <http://www.aafp.org/news-now/health-of-the-public/20100604pediacare.html> and <http://www.aafp.org/news-now/health-of-the-public/20100608clarisrecall.html>.

MEDWATCH FDA Issues Warning About PPIs, Also Updates Orlistat Label Information

The FDA recently issued a warning about a possible increased risk of hip, wrist, and spine fractures with high doses or long-term use of proton pump inhibitors (PPIs), based on an FDA review of seven studies. The labeling on OTC and prescription PPIs will be changed to describe these risks. The FDA advised physicians to consider lower dosages or shorter durations of PPI therapy, when possible. The FDA also approved a revised label for the prescription version of the weight-loss medication orlistat (Xenical) and a new label warning for the OTC version of orlistat (Alli). In a May 26, 2010, safety announcement, the FDA said it identified 12 foreign reports of severe liver injury with Xenical and one domestic report of severe liver injury with Alli. Of these reports, two patients died from liver failure and three patients required liver transplants. The FDA added information about the reported cases to the product labels to educate consumers about the signs and symptoms of liver injury and the need to see a physician promptly should they occur. For more information, visit <http://www.aafp.org/news-now/clinical-care-research/20100601ppifracture.html> and <http://www.aafp.org/news-now/health-of-the-public/20100604orlistatlabel.html>.

IOM Recommends FDA Heighten Its Scrutiny of Food and Supplement Claims

A new report from the Institute of Medicine (IOM) recommends the FDA apply the same rigor to evaluating the science behind the health claims of foods and nutritional supplements as it does to assessing new drug applications. Food and nutritional supplement marketers often make health claims based on how individual ingredients in their products affect biomarkers such as cholesterol or glucose levels. John Ball, MD, chair of the IOM committee that produced the report and EVP of the American Society for Clinical Pathology, said in a news release that without changes in the way biomarkers are used and assessed, health care providers, regulators, and consumers cannot reliably collect or judge information about such claims. In 2008, the FDA's Center for Food Safety and Applied Nutrition asked the IOM to recommend a framework for the evaluation of biomarkers. The IOM's proposed biomarker evaluation process consists of three steps: validating that a biomarker can be accurately measured, ensuring that it is associated with the clinical outcome of concern, and confirming that it is appropriate for the proposed use. For additional information, visit <http://www.aafp.org/news-now/health-of-the-public/20100609fdabiomarkers.html> and <http://www.iom.edu/Reports/2010/Evaluation-of-Biomarkers-and-Surrogate-Endpoints-in-Chronic-Disease.aspx>.

Four-Year Residency Would Improve Practice of Family Medicine, Educator Says

In an article from the March/April 2010 issue of the *Journal of the American Board of Family Medicine*, Perry Pugno, MD, MPH, director of the AAFP's Division of Medical Education, said that family medicine residencies should be expanded to four years to teach physicians-in-training more clinical skills, allow them time to concentrate on areas of particular interest, and provide additional practice management education. Trainees also should have longitudinal experience in continuity of care with a patient population in a community practice setting and be able to customize their residency experience with a "value-added" component, such as a focus on preventive medicine or geriatrics. The major barriers to implementing a four-year residency, according to Pugno, are time and money. For more information, visit <http://www.aafp.org/news-now/resident-student-focus/20100609fouryearresidency.html> and <http://www.jabfm.org/cgi/content/full/23/Supplement/S23>.

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