

Daily Briefing

“Nation’s news in five minutes”

News for Health Care Executives • Thursday, March 27, 2008

SPOTLIGHT

FDA’s drug-review deadlines associated with safety problems

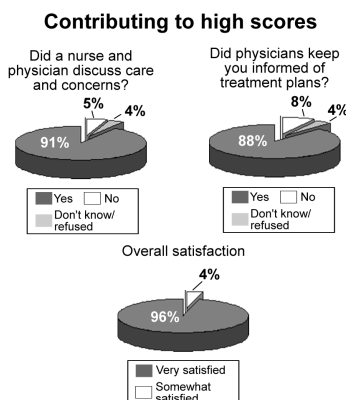
Drugs approved by the FDA in the last two months before review deadlines are more likely to later be withdrawn for safety reasons, carry subsequent black-box warning labels, and have one or more dosage forms voluntarily discontinued by the manufacturer compared with drugs approved at other times, according to a study in today’s *NEJM*.

See story #1

RESEARCH HIGHLIGHT

Patient assessments reinforce benefits of care briefings

Patient care briefings—mandatory collaborative care conferences involving the patient, physician, primary nurse, and family members—are an effective means of improving communication between patients and caregivers, as well as overall patient comfort and satisfaction. In addition, physicians appreciate a formal system to ensure that nurses, patients, and families understand the plan of care. To learn more, please see the Health Care Advisory Board’s *Service Amidst Shortage* study.



Source: Health Care Advisory Board interviews

THIS DAY IN BRIEF

FDA issues draft guidelines for stent testing, development

The FDA yesterday proposed more rigorous guidelines for testing drug-eluting stents, saying that longer studies are needed before and after device makers apply for the agency’s approval, the *Wall Street Journal* reports.

See story #2

Cigarette maker paid for landmark lung cancer study, *N.Y. Times* reveals

A highly publicized *NEJM* lung cancer screening study published in 2006 was financed in part by a tobacco company, a discovery that some prominent cancer researchers say has tainted the research and could undercut early detection lung cancer screening efforts underway since the study’s release, according to the *New York Times*.

See story #3

USA Today finds PCI procedures declining amid safety, efficacy concerns

An analysis commissioned by *USA Today* reveals that the number of percutaneous coronary intervention procedures performed annually appears to have declined by 10% to 15% across the past two years, suggesting “the meteoric rise of [PCI] during the past three decades has ended.”

See story #4

FROM THE ADVISORY BOARD

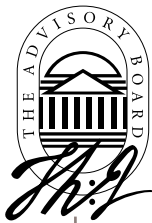
Enhancing laboratory speed, efficiency, and profitability

Innovations Center research examines models for leveraging technology to improve laboratory speed, efficiency, and profitability. The publication investigates point-of-care testing, automation, and outreach testing.

See story #5

NAMES IN THE NEWS

Arizona State University (#7) ■ Cleveland Clinic (Ohio) (#1) ■ Cooper University Hospital (N.J.) (#7)
Duke University Medical Center (N.C.) (#8, #4) ■ Harvard University Medical School (Mass.) (#1) ■ St. Vincent Health (Ind.) (#7)
Weill Cornell Medical College (N.Y.) (#3) ■ Witham Health Services (Ind.) (#7)



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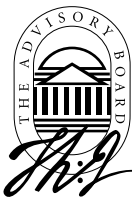
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Note on Editorial Policy: The *Daily Briefing's* mission is to "cover the coverage" of other news media—to provide members with an informative, readable synthesis of the nation's health care news as gathered from newspapers, journals and other sources of health system, physician and clinical news. The publication is not based upon original reporting by Advisory Board staff, nor does it represent Advisory Board opinion. While striving for coverage that is comprehensive and unbiased, the Advisory Board Company cannot guarantee the accuracy of the sources covered or information provided.

► Today's Headlines

1 FDA's drug-review deadlines associated with safety problems

Drugs approved by the **FDA** in the last two months before review deadlines are more likely to later be withdrawn for safety reasons, carry subsequent black-box warning labels, and have one or more dosage forms voluntarily discontinued by the manufacturer compared with drugs approved at other times, according to a study in today's *NEJM*. The Prescription Drug User Fee Act first enacted in 1992 required the FDA to act on 90% of all drug applications within 12 months of receiving them—a deadline that was narrowed to 10 months in 1997—or face the possibility of losing its authority to collect fees from drug companies. High-priority drugs deemed eligible for fast-track status, meanwhile, must be reviewed within six months. Recognizing concerns that these deadlines sometimes contribute to rushed approvals and the emergence of “unanticipated safety problems” after a drug reaches the market, researchers led by a **Harvard University Medical School** professor analyzed drugs approved by the FDA since 1993 and used exact logistic regression to determine whether drugs approved immediately before the review deadlines were associated with higher rates of postmarket safety problems. According to the findings, 97 of the 313 drugs approved by the agency between 1993 and 2004 were approved “just before deadline” and 14% of those drugs had postmarket safety problems compared with just 3% for 216 other drugs. Specifically, drugs approved just before deadline were two to three times more likely to be withdrawn for safety reasons, two to seven times more likely to receive black-box warnings, twice as likely to experience changes in manufacture, and two to seven times more likely to be voluntarily discontinued by the manufacturer because of “weak clinical demand.” Additionally, 14 of the 21 withdrawals and black-box warnings for drugs approved since 1993 were for drugs approved within two months of the review deadline, including **Merck's** withdrawn painkiller Vioxx (rofecoxib), **Pfizer's** withdrawn diabetes drug Rezulin (troglitazone), and **Bayer's** statin drug Baycol (cerivastatin).

While noting that drug review deadlines have helped to significantly accelerate the drug review process and should not be completely abandoned, the study authors suggest that “drug safety might improve under an FDA approval protocol that is more flexible and less driven by deadline pressures and more by stable growth in FDA resources.” Specifically, the researchers say that “relying more on staffing and less on deadlines could result in the same degree of review efficiency without the increasing risk (and resulting greater cost) of unanticipated drug safety problems.” The chairman of the department of cardiovascular medicine at the **Cleveland Clinic** echoed those recommendations, saying that “the right answer [is] to provide more resources so the FDA [can] evaluate applications more accurately [and] in a way that doesn't put the FDA in the bind of making decisions too quickly.” The FDA, meanwhile, disputes the study findings, noting that its own database of drug approval times does not match the data used by the researchers. Moreover, the FDA's drug evaluation director says that the deadlines are guidelines the agency has the freedom to miss if needed. The agency plans to send a letter disputing the results to the *NEJM* (Carpenter et al., *NEJM*, 3/27 [subscription required]; Harvard University [release](#), 3/26; Winstein, *Journal*, 3/27 [subscription required]; Gardner, *HealthDay*, 3/26).

2 FDA issues draft guidelines for stent testing, development

The **FDA** yesterday proposed more rigorous guidelines for testing drug-eluting stents (DESs), saying that longer studies are needed before and after device makers apply for FDA approval, the *Wall Street Journal* reports. The recommendations—which are not expected to affect stents already on the market—are the first since the agency held a two-day meeting in December 2006 about the risk of

late-stent thrombosis associated with the DES use compared with the use of bare-metal stents. A number of studies in 2006 raised concern about patients developing late-stent thrombosis after DES implantation and prompted some cardiac centers to cut back on the use of the devices (see related story in the June 22, 2006, [Daily Briefing](#)). In its recommendations, the FDA says that a “12-month primary endpoint, with a substantial proportion of patients having [two]-year data at the time of marketing application submission, is critical” to assess the risk of adverse events. The agency also provided guidance on assessing the toxicity of drugs used on stents and made recommendations addressing engineering tests, biocompatibility tests, and animal studies to evaluate the DESs overall safety. In its most rigorous recommendation, the FDA says that companies should be prepared to monitor patients for blood clots, heart attack, and other complications for up to five years after device approval—an undertaking that can cost companies millions of dollars, according to the Associated Press. Although the agency’s guidelines are not legally binding, companies typically follow them to ensure approval of their devices. Commenting on the recommendations—which will be open to public comment for 120 days—the FDA’s device chief says they are intended to “minimize risks while preserving for patients the benefits of drug-eluting stents” (Levitz, [Journal](#), 3/26 [subscription required]; [AP](#), 3/26; [FDA release](#), 3/26). The draft guidelines can be accessed at <http://www.fda.gov/cdrh/ode/guidance/6255.html>.

3 Cigarette maker paid for landmark lung cancer study, *N.Y. Times* reveals

A highly publicized *NEJM* lung cancer screening study published in 2006 was financed in part by a tobacco company, a discovery that some prominent cancer researchers say has tainted the research and could undercut early detection lung cancer screening efforts underway since the study’s release, the *New York Times* reports. Led by Dr. Claudia Henschke of **Weill Cornell Medical College**, the study found that routine computed tomography (CT) scans boosted early stage lung cancer detection, and recommended that annual CT scans be considered for detecting lung cancer among high risk patients (see related story in the Oct. 26, 2006, [Daily Briefing](#)). While controversial among some cancer researchers who questioned, for example, Henschke’s survival projections and voiced concerns that routine screening would lead to unnecessary biopsies and lung surgeries, many lung cancer advocates have since “embraced” her work and pushed for legislation to create trust funds to pay for lung cancer screening, according to the *Times*. In a review of the tax records of a foundation mentioned at the end of the *NEJM* study, the *Times* found that the organization—of which Henschke was president—was underwritten “almost entirely” by \$3.6 million in grants from the Vector Group, the parent company of the Liggett Group, which makes the Liggett Select, Eve, Grand Prix, Quest, and Pyramid cigarette brands. Noting that cigarette makers “are so reviled among cancer advocates and researchers that any association with the industry can taint researchers and bar their work from being published,” the *Times* says that *NEJM*’s editor in chief was “surprised” at the funding revelation and would not have knowingly published a study funded by a cigarette maker. Commenting on the disclosure, Henschke and a colleague said that the gift from Vector was announced publicly and was “fully disclosed to grant funding organizations.” Although a Vector spokesperson said the company had no influence over research, studies have shown that corporate financing can have “subtle effects on research” resulting in conclusions favoring the sponsor. Additionally, the tobacco industry has a “long history” of sponsoring research to “make cigarettes seem less dangerous.”

The news about the *NEJM* study’s funding surfaced amid a recent report that Henschke and her colleague failed to disclose in lectures and articles that they have 10 patents pending related to CT screening and follow-up, and one patent issued by GE—a maker of CT scanners—in 2001. *JAMA* this week published corrections about unreported financial disclosures from the physicians. Meanwhile, the **Accreditation Council for Continuing Medical Education** says that an increasing number of physicians and institutions are creating foundations to accept funding from companies without being required to disclose the source (Harris, [Times](#), 3/26 [registration required]).

4 **USA Today finds PCI procedures declining amid safety, efficacy concerns**

An independent analysis commissioned by *USA Today* reveals that the number of percutaneous coronary intervention (PCI) procedures performed annually appears to have declined by 10% to 15% across the past two years, suggesting “the meteoric rise of [PCI] during the past three decades has ended.” Based on data from 337 hospitals, the analysis by the National Cardiovascular Data Registry was one of two commissioned by the newspaper regarding PCI procedures—which are performed between 650,000 and 1 million times each year in the United States. The second, an analysis of **IMS Health** data conducted by the market-analysis firm Qforma, found that the decline in PCI procedures and the use of stents began in June 2006 after highly publicized studies cast safety and efficacy doubts on the procedure. According to *USA Today*, both analyses point to “a distinct shift in practice patterns,” as physicians are increasingly choosing bare-metal stents rather than newer DESs. The Qforma analysis finds that sales of DESs dropped off quickly in 2006 following the publication of studies that showed an increased risk of late thrombosis in certain patients who had received a DES. The finding is in line with data to be presented this weekend at the **American College of Cardiology** annual meeting showing the use of DESs fell from a high of 90% to roughly 50%, and that the use of bare-metal stents increased about 10% since early 2006, according to a **Duke University** physician who reviewed the results of *USA Today*’s registry analysis. Saying, however, that physicians were unable to control for other contributing factors such as improved heart-attack prevention or fewer repeat PCI procedures because of the effectiveness of certain stents, *USA Today* notes that the findings do not represent the “final word” on PCI procedures and the use of different types of stents, adding that the topic will again be debated this weekend at the college’s meeting (Sternberg, [USA Today](#), 3/27).

► From the Advisory Board

5 **Enhancing laboratory speed, efficiency, and profitability**

Given the imperative for ever-faster turnaround times and the opportunity to win outpatient testing business, hospitals are looking to technology to enhance laboratory performance. *The Virtual Laboratory* provides an overview of the market forces leading to the increased pressure on the laboratory function and examines models for leveraging technology to improve laboratory speed, efficiency, and profitability, including point-of-care testing, automation, and outreach testing.

The study finds that laboratory automation can be effective in reducing turnaround times, and labor demand and adding “virtual” capacity in order to grow outpatient business; however, institutions must balance the costs and benefits of piecemeal automation versus the larger investment required for total seamless automation across all instruments.

For more information

For more information about the research initiative and to access an electronic copy of the research, click [here](#). To order a copy of the publication, click [here](#).

6 Advisory Board Academies launch goal alignment workshop

The Advisory Board Academies is pleased to announce the launch of its latest workshop: “**Strategic Goal Alignment: Aligning Strategy and Operations Through Effective Performance Management.**”

This highly interactive course highlights common mistakes in goal management and provides an approach to create achievable goals that support the organization’s objectives. The key is to establish a well-structured dialogue among different levels of the organization, capturing the strongest possible contributions from staff. This approach ultimately ensures that goals remain aligned as they are cascaded down through the organization.

This course was created to address the frustration that executives often express about the difficulty of making progress against strategic objectives. Underlying this frustration is the fact that managers frequently struggle to set ambitious goals that are both actionable and aligned with those organizational objectives—thereby hampering any real progress for the hospital or health system. Unfortunately, as many organizations are learning, these problems persist regardless of the sophistication of the system used to track progress against goals.

For more information

For more information on the workshop or any of the other Advisory Board Academies offerings, please contact Marie Knight at knightma@advisory.com or 202-266-5403.

► Regional Round-up

7 Around the nation: Bite-sized hospital and health industry news



- **Arizona:** Arizona State University (ASU) on April 1 will break ground on its second nursing school in downtown Phoenix, a \$29.2 million, five-story facility that will feature a large auditorium, faculty offices, student amenities, and research space. The new building will be adjacent to ASU’s other nursing school on the downtown campus, where it will serve as a northern gateway.

Plans for the new school come as the state’s registered nurse to population ratio—which stands at 681 nurses per 100,000 people—falls below the national average of 825 nurses per 100,000 people (Gonzales, *Business Journal of Phoenix*, 3/25 [registration required]).

- **California:** The state Board of Pharmacy has for the second time postponed the implementation of a statewide electronic drug-tracking program designed to keep counterfeit prescription drugs from reaching consumers, after drug companies, distributors, and retailers said they were not ready to meet the Jan. 1, 2009 implementation deadline. In a statement, the board said it “reluctantly agreed” to put the program on hold for two more years after concluding that “the California drug supply and potentially the entire U.S. drug supply may very well be negatively impacted” by a shortage of certain medications in the absence of the delay. The proposed system would electronically track information about a prescription drug’s dosage, manufacturer, and handling in the supply chain (Lifsher, *Los Angeles Times*, 3/26 [registration required]).

- **Indiana: Witham Health Services and St. Vincent Health** will jointly operate a 14-bed, free-standing ED and imaging center that is planned as part of a multimillion development by Duke Realty Corp. Construction is expected to begin this fall on the \$12 million center, which will also include medical offices. As part of the project, Witham and St. Vincent have agreed to collectively invest \$12 million in technology and medical equipment, and are discussing the possibility of constructing a full-service hospital and surgery center at the site (Annis, [Indianapolis Star](#), 3/26).
- **New Jersey:** A \$222 million patient pavilion is under construction at **Cooper University Hospital** in downtown Camden, featuring an ED expansion, new patient rooms and new ORs. The hospital—Camden County’s largest employer with more than 5,000 workers—has proposed additional projects as part of a \$500 million expansion plan, including an \$80 million cancer center, a \$50 million biomedical research building, and a \$140 million medical school building (Graham, [Philadelphia Inquirer](#), 3/25).

► Endnotes

8 Et cetera

Weight-loss winner: Personal support helps weight-loss maintenance more than website

Personal contact with a trained weight-loss counselor helps more than online support to keep unwanted pounds from creeping back on, according to a study that appeared earlier this month in *JAMA*. For the study, researchers at four institutions led by **Duke University Medical Center** tracked 1,032 volunteers who had lost an average of 18.7 pounds. The volunteers were divided into three groups—those who received personal contact with a trained weight-loss counselor, those who received Internet support from an interactive website created by the researchers, and those who only received printed lifestyle recommendations at the beginning of the study period. After 30 months, the participants in the group that received personal support—in the form of 5- to 10-minute phone calls with a weight-loss counselor each month, along with hour-long in-person sessions every four months—regained an average 8.8 pounds, compared with an 11.4 pound average weight gain among those in the Internet group and a 12.1 pound average weight gain among participants in the control group. The chief scientific officer for Weight Watchers International says the results are consistent with the findings of previous weight-loss maintenance studies that found support is associated with keeping weight off, adding that the “weight only stays off for as long as you’re thinking about it and doing something about it.”

—Cromley, [Los Angeles Times](#), 3/14 [registration required]