

## MOVERS & SHAKERS

### HBA Honorees

#### WOMAN OF THE YEAR, HONORABLE MENTOR, AND STAR VOLUNTEER

Meryl Zausner, VP and CFO of Novartis Oncology, has been named as 2007 Woman of the Year by The Healthcare Businesswomen's Association.

Ms. Zausner was a founding member of the Novartis Oncology global business unit, established in 2000 with fewer than 1,000 employees and \$1.5 billion in sales. Today, Novartis Oncology is one of the world's top oncology companies with more than 4,000 employees and \$6 billion in sales.

"In a day and age when women are emerging as public leaders, this award takes on a special significance for me," Ms. Zausner says. "I am excited about the recognition from friends and colleagues at Novartis and fellow members of the HBA, and am proud to add my name to the list of past Woman of the Year recipients."

Based on many strong nomination letters, the HBA

board of directors agreed that Ms. Zausner personified the criteria for Woman of the Year, which includes success in the healthcare industry, strong leadership capabilities, proven mentoring skills, dedication, giving back to women, and contributions to the community.

The HBA also has selected Lonnel Coats, president of Eisai, as the HBA Honorable Mentor for 2007. As noted in one of the nominations received for Mr. Coats, he has mentored every member of the Eisai leadership team, men and women equally, and has clearly defined mentoring as a priority for moving Eisai's leaders to the next level of performance and professionalism.



Meryl Zausner



Lonnel Coats



Shellie Caplan

The HBA has selected Shellie Caplan, president of Caplan Associates, as the HBA Star Volunteer for 2007. Ms. Caplan has given so often of her time to the HBA and is described as always the first to welcome members and guests at events.

Ms. Zausner, Mr. Coats, and Ms. Caplan will be honored at the HBA's 18th annual Woman of the Year (WOTY) Luncheon on May 3rd at the New York Hilton.

An outstanding group of Rising Stars, whose accomplishments have made a difference in their companies and the industry, also will be honored.

The WOTY luncheon also kicks off a year-long celebration of the HBA's 30th anniversary.

## Postmarket Update

### NOT POST-HASTE FOR POSTMARKET STUDIES

Drug Makers Fail to Begin  
of Promised Studies of Drugs  
Already Approved

71%

Despite being plagued by major safety problems in recent years, **drug makers have failed to initiate more than 70%** of promised studies on drugs already approved for the market, according to the latest numbers from the FDA.

A recent report from the FDA shows that **899 of the 1,259 postmarket studies committed to by drug makers had not been started** as of Sept. 30, 2006. That's an increase of 5% over last year, when the FDA reported that 65% of the promised 1,231 studies were still pending.

The report found that **185 — or 15% — of studies were ongoing**, 31 were delayed, and 144 were submitted.

and reap great rewards by making innovation an enterprisewide, cross-functional process: ideation, project selection, product development, and commercialization.

■ **AFTERMARKET SERVICE** — Manufacturers would do well to develop their service businesses, which can be a driver of long-term profitability and sustainability.

■ **SMART CUSTOMIZATION** —

Costly initiatives in response to growing customer demand for customization need to be carefully planned and managed.

## INDUSTRY REPORT

### Manufacturing Trends

#### SIX KEY ISSUES WILL DEFINE THE INDUSTRY IN 2007

- **GLOBALIZATION OF R&D** — Few companies are structured to reap the gains of a globalized R&D network despite the fact that a 2006 Booz Allen study found 77% of new R&D sites built 2005-2008 will be in China and India, reflecting market growth and the pool of affordable talent.
- **AVOIDING "MANUFACTURING MYOPIA"** — Six Sigma and benchmarking exercises often fail to yield meaningful results. Companies need to look at how they can redesign for greater flexibility in technology, network sophistication, in-plant transformation, and labor modernization.
- **INTEGRATION OF SOFTWARE IN TRADITIONAL MANUFACTURING** — With software one of the leading drivers of quality issues in manufactured products, companies need to manage the process carefully, as it plays a key role in the customer experience.
- **HIGH-LEVERAGE INNOVATION** — It's possible to spend significantly less



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## VOICE OF REFORM

Nation's  
Leading  
Physician  
Groups Join  
Together

Ten of the nation's leading physician associations have announced principles for reforming the U.S. healthcare system. This unity among physician groups is intended to help provide the impetus for bipartisan Congressional action to cover the uninsured. Recognizing that many newly elected members of Congress campaigned on fixing the healthcare system, the principles serve as a guide for Congress to improve both individual health and the collective healthcare system.

1. Healthcare coverage for all is needed to ensure quality of care and to improve the health status of Americans.
2. The healthcare system must provide appropriate healthcare to all people within the U.S. borders, without unreasonable financial barriers to care.
3. Individuals and families must have catastrophic health coverage to provide protection from financial ruin.
4. Improvement of healthcare quality and safety must be the goal of all health interventions, so that optimal outcomes for the resources expended are assured.
5. In reforming the healthcare system, society must respect the ethical imperative of providing healthcare to individuals, responsible stewardship of community resources, and the importance of personal health responsibility.
6. Access to and financing for appropriate health services must be a shared public/private cooperative effort, and a system that will allow individuals/employers to purchase additional services or insurance.
7. Cost management by all stakeholders, consistent with achieving quality healthcare, is critical to attaining a workable, affordable, and sustainable healthcare system.
8. Less complicated administrative systems are essential to reduce costs, create a more efficient healthcare system, and maximize funding for healthcare services.
9. Sufficient funds must be available for research (basic, clinical, translational, and health services), medical education, and comprehensive health information technology infrastructure and implementation.
10. Sufficient funds must be available for public health and other essential medical services to include, but not be limited to, preventive services, trauma care, and mental health services.
11. Medical liability reform is essential to ensure access to quality healthcare.

## BUDGET MEETING

## \$2.1 Billion for Fiscal Year 2008

The FDA is requesting almost \$2.1 billion to protect and promote public health as part of the President's fiscal year (FY) 2008 budget, more than a 5% increase over the budget submitted to Congress last year.

The FY 2008 request, which covers the period of Oct. 1, 2007, through Sept. 30, 2008, includes \$1.64 billion in budget authority and nearly \$444 million in industry user fees.

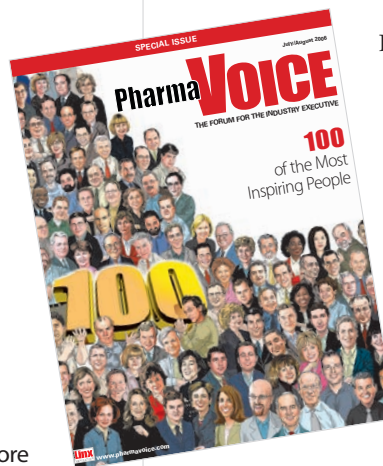
## THE FOLLOWING ARE THE FDA'S KEY PROPOSED BUDGET INCREASES:

- **\$10.6 million** to strengthen food safety
- **\$11.2 million** to modernize drug safety
- **\$7.2 million** to improve device safety
- **\$5.6 million and \$15.7 million** collected in user fees for the FDA to conduct more — and more timely — generic drug reviews
- **\$27 million** in other new user fees: the Reinspection User Fee to ensure that laboratories and facilities that fail to comply with health and safety standards bear the cost of re-inspection and the Export Certification user fee to cover the cost of issuing export certificates required by several foreign governments when companies export food products
- **\$21.8 million** for a cost-of-living pay increase that allows the FDA to retain its highly trained and specialized workforce and to recruit staff of the same caliber
- **\$13.3 million** for the White Oak consolidation, a new campus in Maryland, where the FDA will consolidate 7,700 employees located at 20 different sites across the Washington, D.C., region

SOURCE: FDA, BETHESDA, MD.

## PHARMAVOICE 100

## Who has Inspired You?



The third annual PharmaVOICE 100 will be determined by the collective participation of you, our readers. This is your opportunity to recognize the people who inspire you and others; who are having the greatest influence on corporate leadership, research and development, technology, creativity, marketing, strategy, and more; and who are impacting the life-sciences industry through their actions.

These individuals should view industry trends as challenges not burdens, as opportunities not obstacles. They should embody panache and conviction. They should be leaders who plan for the future rather than respond to change. They should be innovative, creators of outside the box and breakthrough strategies, products, and services. They should be pioneering new paths and lifting their companies to new heights.

The deadline for submissions is May 1, 2007. Please visit [pharmavoice.com/100](http://pharmavoice.com/100).