

# Integrated Drug Development News

Winter 2007

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## FDA News—Two Proposed Rules Address Availability of Investigational Drugs

By Cathy Anderson Ph.D., R.A.C.

On 13 December 2006, the FDA announced two proposed rules affecting access to and payment for investigational drug products.

*Expanded Access to Investigational Drugs for Treatment Use* reforms and clarifies the role of investigational drug expanded access programs. Traditionally, these programs have allowed access for individual patients (and through a treatment IND a larger group of patients) not eligible for treatment in a clinical study intended to support marketing. Under the proposed rule, expanded access to investigational drugs for treatment use would be available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment IND. Treatment would continue to be limited to patients with serious

See FDA News, Page 2

## Cato Research Partners with Johns Hopkins University's MCC Campus—Metropolitan Washington D.C. Office Relocates in January

By Omar Ali, Ph.D., R.A.C., C.C.R.P.

Cato Research moved its Washington, DC metropolitan area office to the Johns Hopkins University Montgomery County Campus on January 29, 2007.

“Our mission is to be the premier, scientifically and medically based, international, healthcare research and development service company,” said Lynda Sutton, Chief Operating Officer, CATO. “Locating on Johns Hopkins University’s Montgomery County Campus will allow us to be in close contact with valuable resources to achieve our mission.”

“Cato Research is a great addition to our vibrant community,” said Elaine Amir, Executive Director, Johns Hopkins Montgomery County. “They’re a valued resource for our growing M.S. in Bioscience Regulatory Affairs program.” “The arrival of Cato Research strengthens our long-range community-building mission,” Amir added. “The company’s expertise in regulatory affairs will be a huge benefit for tenants that join the Campus in our planned accelerator for post-incubator stage companies.”

The new address for Cato Research Washington is: 9605 Medical Center Drive, Suite 390, Rockville, MD 20850; phone: (301) 309-1260; fax: (301) 309-8470.

Keep your eyes open for news of an upcoming wine tasting and reception. ❄️

See Web-Based Safety System, Page 3

## Cato Research to Sponsor The CATO 2007 Midwest Biotech Symposium—Targets Early- and Mid-Stage Biopharma Companies *by Jennifer Weidman, Ph.D.*

Cato Research is proud to sponsor the CATO 2007 Midwest Biotech Symposium, to be held April 25-27, 2007 at the MGE Innovation Center, University Research Park, Madison, Wisconsin.

The CATO 2007 Midwest Biotech Symposium will bring together regional early- and mid-stage biopharmaceutical companies with other core stakeholders to discuss the development of novel pharmaceutical products.

The symposium will begin with a wine reception on the evening of Wednesday, April 25<sup>th</sup>, followed by talks and panel discussions on key topics on Thursday, April 26<sup>th</sup>. The CATO 2007 Midwest Biotech Symposium will close on Friday, April 27<sup>th</sup> with the opportunity for one-on-one meetings with presenters to discuss participants' specific development programs.

Symposium topics will focus on alternative financing strategies, CMC development, nonclinical study requirements, regulatory strategies that promote FDA agreement to proposed development plans, and designing successful early clinical trials.

*See CATO Biotech Symposium, Page 3*

## Cato Research and Cato BioVentures Establish Law and Entrepreneurship Program

Cato Research, and its venture capital affiliate Cato BioVentures, recently announced the establishment of the Law and Entrepreneurship Program. The program is intended to provide second- and third-year law students with an interest in corporate law, the life sciences industry, and venture capital to obtain real world experience and explore career path options in these and similar areas. The Program will accept one student each year for a full-time summer position and one to four students each year for part-time positions during the academic year. The program will be based at Cato Research's corporate headquarters in Durham, North Carolina. The Law and Entrepreneurship Program is coordinating closely with the University of North Carolina at Chapel Hill Law School and hopes to begin working with the Duke University School of Law.

"We are very excited about the establishment of the Law and Entrepreneurship Program" said Shawn Singh, General Counsel of Cato Research and Managing Principal of Cato BioVentures. "Opportunities to work in a corporate legal department are rare for law students, and this program will give students exposure to both corporate law and venture capital activities." ❄️

### *FDA News, continued from Page 1*

or immediately life-threatening diseases or conditions, who lack other therapeutic options, and who may benefit from the therapies. The proposed rule clearly spells out when it is appropriate to include an expanded access program as part of product development, and how to obtain approval.

*Charging for Investigational Drugs* reforms and clarifies the conditions under which it is acceptable to charge for investigational drugs. Although the FDA originally expected companies would charge in order to cover the cost of a drug under development, in fact many companies are seeking to charge for currently marketed drugs used as a comparator or add-on in clinical trials. The proposed rule clarifies when these charges are appropriate and also includes charging for investigational drugs used under a treatment protocol, where the patient is expected to benefit from the investigational drug. Because treatment use is not a necessary part of drug development, and does not benefit the company by providing data intended to support marketing, it may be more reasonable to charge under these circumstances provided that charging does not hinder drug development. Finally, the proposed rule clarifies the type of costs that can be recovered, which would include only those costs directly attributable to providing the investigational drug. Additional information is available at <http://www.fda.gov/cber/rules.htm>. Comments on the proposed rules are due by March 14, 2007. ❄️

Specific CATO 2007 Midwest Biotech Symposium topics include:

- Alternative financing methods and current financial trends
- Creative financing of CMC programs
- Nonclinical development and safety regulatory requirements
- Balancing product development risks with corporate milestones
- Regulatory issues typical to early- and mid-stage development, and special regulatory programs such as Fast Track, Orphan Drug, and Accelerated Approval

Visit [www.catobioventures.com/symposium](http://www.catobioventures.com/symposium) for more information. Email [biotechsymposium@cato.com](mailto:biotechsymposium@cato.com) to register or call (919) 768-1137. The **registration deadline is April 11<sup>th</sup> 2007**. Space is limited. ❄️

## PUZZLE OF THE QUARTER: SUDOKU

*Fill in the grid so that every row, every column, and every 3X3 box contains the numbers 1 through 9, each only once.*

	2	5	9		4	7	8	
3	7	9		8				
			6					3
		3			1			9
				2	5			
		8		4			6	7
	1	4	8					
	3	6			2	4		

*The solution will appear in the Spring 2007 Newsletter.*

## CALENDAR OF UPCOMING REGIONAL, NATIONAL, AND INTERNATIONAL EVENTS

### FEBRUARY 2007

- **22-23 FEBRUARY 2007—STANDARD OPERATING PROCEDURES (SOPs) DEVELOPMENT AND IMPLEMENTATION**, WYNDHAM ST. ANTHONY HOTEL, SAN ANTONIO, TX
- **27-28 FEBRUARY—510(K) SUBMISSION “101”**, HAMPTON INN TROPICANA, LAS VEGAS, NV
- **28 FEBRUARY-02 MARCH—FDA PHARMACEUTICAL QUALITY INITIATIVES: A MODERN RISK-BASED APPROACH**, BETHESDA NORTH MARRIOTT HOTEL & CONF. CENTER, BETHESDA, MD

### MARCH 2007

- **01-02 MARCH 2007—PMA SUBMISSIONS AND PMA SUPPLEMENTS**, HAMPTON INN TROPICANA, LAS VEGAS, NV
- **05-07 MARCH—BIOEUROPE SPRING 2007**, MILANO CONVENTION CENTER, MILAN, ITALY
- **05-07 MARCH—1ST ANNUAL FDA/DIA STATISTIC FORUM**, DOUBLETREE HOTEL & EXECUTIVE MEETING CENTER, BETHESDA, MD
- **18-20 MARCH—22ND ANNUAL DIA CLINICAL DATA MANAGEMENT CONFERENCE AND EXHIBITION, INTEGRATION ACROSS THE CLINICAL TRIAL CONTINUUM**, BUENA VISTA PLACE HOTEL, LAKE BUENA VISTA, FL
- **19-21 MARCH—CLINICAL BIOMARKER SUMMIT**, HOTEL DEL CORONADO, CORANADO, CA
- **19-22 MARCH—WORLD VACCINE CONGRESS 2007**, FOUR SEASONS HOTEL, WASHINGTON, DC
- **28-30 MARCH—RAPS 2007 HORIZONS CONFERENCE & EXHIBITION**, THE PALACE HOTEL, SAN FRANCISCO CA
- **19-23 MARCH 2007—CLINICAL SCIENCE COURSE FOR CLINICAL RESEARCH PROFESSIONALS**, RENAISSANCE CHARLESTON HOTEL HISTORIC DISTRICT, CHARLESTON, SC
- **19-20 MARCH 2007—PROJECT MANAGEMENT FOR CLINICAL TRIALS**, TBD, CHICAGO, IL
- **27-28 MARCH 2007—CONDUCTING INTERNAL AUDITS - BEST PRACTICES FOR GXP COMPLIANCE AUDITING**, TBD, CHICAGO, IL

### SPRING 2007

- **APRIL 30-MAY 2—BIO-IT WORLD CONFERENCE & EXPO**, WORLD TRADE CENTER, BOSTON, MA
- **MAY 6-9—BIO INTERNATIONAL CONVENTION**, BOSTON CONVENTION AND EXHIBITION CENTER, BOSTON, MA
- **10-11 MAY—RAPS ADVERTISING, PROMOTION, AND LABELING CONFERENCE**, MINNEAPOLIS MARRIOTT CITY CENTER, MINNEAPOLIS, MN

FOR A COMPREHENSIVE LISTING OF DRUG DEVELOPMENT AND BIOTECHNOLOGY EVENTS WORLDWIDE, PLEASE VISIT THE CATO BIOTECHNOLOGY CALENDAR: [HTTP://WWW.CATO.COM/FYI/](http://www.cato.com/fyi/)

The new Cato Research Washington D.C. area office. Details on our move are in this issue.



Address Correction Requested

Place address label here

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**ABOUT CATO RESEARCH**

Founded in 1988 and headquartered near Research Triangle Park, NC, Cato Research is a full-service contract research organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, and medical device industries. Services range from design and management of preclinical and clinical studies to submission of the regulatory documents required for marketing approval. Located in the United States, Canada, Europe, Israel, and South Africa, Cato Research consistently demonstrates an unsurpassed level of responsiveness, flexibility, attention to detail, and passion in bringing a sponsor's products to market rapidly and cost effectively. Visit the company's web site at [www.cato.com](http://www.cato.com) or call Cato Research in the metro Washington D.C. area (301-309-1260) to speak directly with one of our drug development experts.

**ABOUT CATO BIOVENTURES**

Cato BioVentures is the venture capital affiliate of Cato Research Ltd. helping both entrepreneurs and established management teams build successful life science companies. Cato BioVentures offers promising life science companies immediate access to a broad range of essential CRO services on a non-cash basis. Access to these time-critical CRO services enables management to achieve key value-added development and regulatory milestones with less reliance on other sources of capital. For more information, visit the Cato BioVentures web site at [www.catobioventures.com](http://www.catobioventures.com).

Strategies. Solutions. Success. Making a difference in drug development.

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