

SoCalBio SYNERGIES

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Southern California
Biomedical
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SoCalBio Profile – Michael Phelps, Ph.D.

Pioneering Developer of PET Imaging Seeks to Help in Transforming UCLA's Tech Transfer Culture

Michael Phelps, Ph.D. is known in the scientific community as the "godfather" of PET (Positron Emission Tomography). He is credited as its co-inventor and foremost advocate, helping PET become a major clinical imaging modality. Ronald Nutts' article, "The History of Positron Emission Tomography," published in the journal **Molecular Imaging and Biology** (Vol. 4, No. 1, 11–26, 2002) suggested that as the imaging technology of molecular medicine, PET has the potential to in fact exceed the incredible success and contributions made by CT and MRI.

PET is also serving as a catalyst for "systems biology," a field of research that merges biology, chemistry, mathematics, engineering and medicine. This approach to studying life forms is enabling scientists to identify the molecular errors that underlie disease, and develop new highly-targeted therapeutics to correct them.

For nearly three decades, Dr. Phelps has worked to position UCLA as the leader in systems biology-based molecular medicine. He has also been at the forefront of efforts to reinvent how UCLA engages in tech transfer and works with companies to commercialize its inventions.

Dr. Phelps recently spoke with **SoCalBio Synergies** to discuss the promise of systems biology, as well as the future of tech transfer in Los Angeles.

Q: What is systems biology?

"Systems biology" is a term used to describe life forms by focusing on the programmed sets of instructions that create protein-based integrated circuits within cells. These circuits enable the intercellular communications that underlie the organized functions of living systems. According to this view of biology, disease occurs when cells are re-programmed to gain or lose functions. The resulting change inflicts harm on the body. Systems biology research is an intensely collaborative pursuit, requiring contributions from engineers, physicists, chemists, biologists and medical scientists.

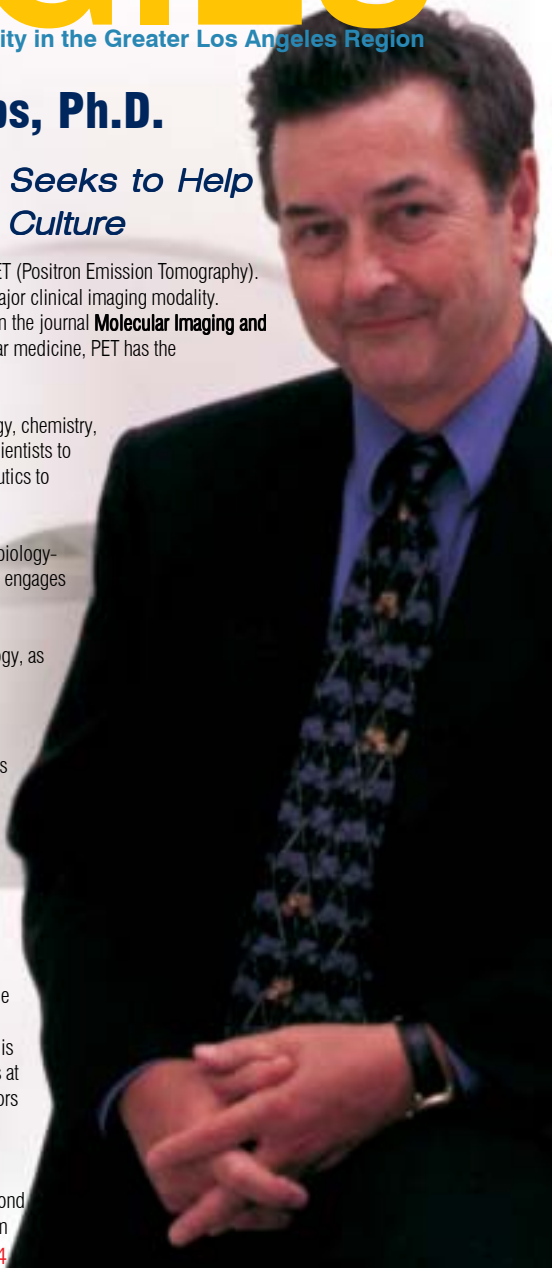
Q: How has PET contributed to systems biology as a field of research?

The increasing appeal of this research approach is due to progress in nanotechnology and the development of new experimental tools such as integrated microfluidics, computational biology, and molecular imaging. The role of PET and other molecular imaging technologies is to provide an unprecedented view of the chemical and biological functions of living subjects at the molecular level. In this manner, PET helps guide molecular therapeutics to target the errors that cause disease.

Q: What effect is the systems biology approach having on drug development?

It's a little known fact that about 70 percent of patients who receive drug therapy do not respond in a way that can be objectively described as effective. This means that the healthcare system

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Agensys Harnesses the Power of Genomics to Develop Novel Cancer Therapies

Company Files IND to Test Antibody Treatment for Prostate Cancer

Founded in 1997, Agensys is a local biotech company focused on building a competitive edge in the field of cancer therapeutics by combining its discoveries in genomics with expertise in developing therapeutic antibodies. The company is working to combat urological cancers and other oncology indications for which there are currently few targeted therapies under development.

According to Aya Jakobovits, Ph.D., who serves as Agensys' senior vice president of technology and corporate development as well as chief scientific officer, the company develops therapies directed to its proprietary novel targets that are over-expressed in specific types of cancer cells, and have limited expression in vital organs. This approach is markedly different from conventional chemotherapy, in that it is highly targeted to have a minimal effect on normal cells.



Aya Jakobovits, Ph.D.
Sr. VP & CSO
Agensys

On June 30th, Agensys filed an Investigational New Drug (IND) application with the FDA to initiate a Phase I clinical trial of AGS-PSCA, a fully human monoclonal antibody specific to Prostate Stem Cell Antigen (PSCA). This initial trial will examine the safety, pharmacokinetics, and early effectiveness of AGS-PSCA as monotherapy for patients with advanced-stage prostate cancer.

With the exception of skin cancer, prostate cancer is the most common type of cancer affecting American men. It is also the second leading cause of cancer-related death, behind only lung cancer. The American Cancer Society

"Agensys' goal is to identify genomic targets and develop therapeutic antibodies to treat cancer"

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Jump-Starting the USC Biomedical Research Park - A Project Whose Time Has Come

Mayor Villaraigosa's Leadership Is a Must for Success

By John Hisserich, Dr.P.H.
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including several potential investors. In addition, the City of Los Angeles has been exploring ways to participate.

The potential benefits of a research park near the USC Health Sciences campus are significant. The presence of hundreds of biomedical

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There has been considerable discussion over the past few years about the creation of a new research park adjacent to USC's sprawling Health Sciences Campus.

Such a project would finally bring a centralized home to LA's biomedical community, positioning start-up and established ventures next to some of the region's top research institutions, including the Keck School of Medicine, the USC School of Pharmacy, the Norris Cancer Center, and the USC University Hospital. Immediately adjacent are the Los Angeles County+USC Medical Center, with a new 600-bed hospital nearing completion, and the enormous existing hospital building which will soon become available for re-use.

USC and the County of Los Angeles have financed two comprehensive studies of the potential for a biomedtech park in the area located where the communities of Boyle Heights and Lincoln Heights intersect on the Eastside of Los Angeles. Both studies validated the feasibility of such an enterprise.

County Supervisor Gloria Molina and USC President Steven Sample have forged an alliance stating their intent to create such a park. To back up these pronouncements, the University has appointed a high level advisory group,



The soon-to-be-vacated LAC+USC, a historical landmark, can be the centerpiece of a commercial biomedical community attracting researchers and entrepreneurs who can live and work in one convenient location.



FDA Prepares to Use Medicare Data in Assessing Medical Treatment Outcomes

Will This Create a Case of Evidence-Based Medicine Gone Wild?

By Joel Slomoff, Esq.
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devices such as cardiovascular, spine, and joint replacement implants. The largest medical database in the world will be used to assess medical treatment events and outcomes

In a speech before the Pharmaceutical Care Management Association on May 11th, Mark McClellan, M.D., Ph.D., administrator of CMMS, defended this change by arguing: "If the FDA has got concerns that a drug may have a risk, we will now have the data capability to provide much more complete evidence on whether there is a problem."

Recent safety concerns about drugs and devices such as VIOXX, Celebrex, Bextra, pedicle screws, stents and defibrillators have helped build support within the FDA for McClellan's position.

Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation

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At the moment, the FDA employs various tools including post-marketing studies, mandatory Adverse Event reporting, and anecdotal literature reports to drive drug and device label changes or justify product withdrawal from the market because of safety concerns. These mechanisms have operated in public view, with participation in the risk-benefit recalculations by the medical community, life-science companies, and patient advocates. But this is soon to change.

Next January, the Centers for Medicare & Medicaid Services (CMMS) will start sending the raw adverse reaction reports to the FDA about all medical products covered by the Medicare system. Medicare covers four of every 10 prescriptions written in the US, and an even larger proportion of medical

CompuMed Merges Osteoporosis Screening with Digital Mammography

Company Joins Forces with Leading Imaging Firms to Improve Access to Timely, Low Cost Diagnostics

Los Angeles-based medical informatics and diagnostics firm CompuMed, Inc. is determined to change how women are screened for osteoporosis – a silent disease that affects more than 44 million Americans and costs the nation's healthcare system more than \$18 billion annually.

While osteoporosis-related hip fractures alone account for more deaths each year than breast cancer, postmenopausal women most at risk for the disease are often not tested on a routine basis.

CompuMed's novel strategy for addressing this issue is to team up with partners such as Fujifilm Medical Systems USA (Stamford, CT) to integrate the company's OsteoGram osteoporosis detection system with digital mammography equipment. The goal is to enable women to get tested for osteoporosis at the same time, and on the same equipment, as their routine mammogram.



Jerry McLaughlin
President & CEO
CompuMed

The OsteoGram is used to screen, diagnose and monitor osteoporosis using images derived from digital or film-based hand x-rays. The images are analyzed via a proprietary software-based system that produces a bone mineral density (BMD) report. It is far less costly and cumbersome than conventional hardware-based BMD systems, which require dedicated and expensive equipment, computers, office space and staff.

"Our strategy is driven by the fact that osteoporosis is a very treatable disease if it's caught in the early stages," said

"Digital imaging systems have become the fastest growing segment of the global radiology market. Combining low cost osteoporosis screening with digital mammography and radiography systems is a concept whose time has come."

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NIH Grant Winner Spotlight

Neurion Pharmaceuticals In Search of the Perfect Chill Pill

Neurion Pharmaceuticals is unique among the handful of biopharma companies in the Los Angeles area. Founded on Caltech science and backed by Convergent Ventures of West LA, Neurion is the region's only new biotech company that uses drug discovery to develop ion channel therapeutics.

Ion channels are proteins that control cell signaling. Neurion is focused on identifying small-molecule therapeutics to target these proteins. In fact, the company is in the race for the "holy grail" of anxiolytics, which is based on finding ion channel modulators to help people manage anxiety while remaining fully functional.

Earlier this year, Neurion won an NIH Phase I SBIR grant (see list of new SBIR grant winners below) to support this research effort.

"Our objective is to discover safer anti-anxiety drugs without the risk of sedation and memory impairment," said William Robbins, Neurion's chairman, president and CEO. "Such adverse effects limit the use of current drugs, such as those based on benzodiazepines (BZ)."



William Robbins
Chairman, President & CEO
Neurion Pharmaceuticals

Traditionally, the U.S. market for sedatives and hypnotics has been dominated by a few big players, such as Hoffman La Roche (Nutley, NJ), that concentrated on making drugs based on BZ compounds. The first brand-name BZ drug was Librium, introduced by Roche in the late '50s to combat anxiety. In 1963, Roche also introduced Valium, a potent tranquilizer made of a simplified version of the Librium molecule. Until the early '80s, Valium was the most widely prescribed tranquilizer, earning Roche about \$600 million a year⁽¹⁾. Currently, generic versions of Xanax and Ativan account for most BZ prescriptions (see Table 1).

BZ molecules enter the brain and interact with receptors regulated by gamma-aminobutyric acid (GABA). GABA is a neuro-transmitter that serves as the brain's endogenous tranquilizer by opening certain ion channels and dampening the electrical excitability of neurons. Because BZ tends to exaggerate GABA's natural action, it was widely used in sedatives and hypnotics⁽²⁾.

But all BZ drugs have side-effects, ranging from slight impairment and memory loss to addiction and suicide. Since the early '90s, a frantic commercial race has taken place to find safer alternatives. Table 2 below provides a list of non-BZ sedatives and hypnotics on the market or in the testing phase. All are based on compounds that target GABA receptors.

The search for better non-BZ drugs has led to some major successes, mainly in the market for insomnia drugs, where Sanofi's Ambien replaced Upjohn's BZ-based Halcion as America's favorite sleeping pill⁽³⁾.

By comparison, results in the anti-anxiety market have been mixed. On the one hand, patients can now manage anxiety using alternatives to Xanax and

(Table 1)
Top-Selling Benzodiazepines

Generic Name	Brand Name	Indication	Introduced by	2004 Sales (\$ Million) ^a
Lorazepam	Ativan	Anxiety	Wyeth	396.63
Alprazolam	Xanax	Anxiety	Upjohn ^b	396.18
Clonazepam	Klonopin	Panic Disorders	Roche	231.90
Diazepam	Valium	Anxiety	Roche	107.87
Temazepam	Restoril	Insomnia	Sandoz ^c	75.55
Clorazepate	Tranxene	Anxiety	Abbott	62.35
Oxazepam	Serax	Anxiety	Wyeth	< \$30

(a) Drug Topics, Feb. 21, 2005 (b) Now part of Pfizer (c) Now part of Novartis

Ativan, such as the GABA receptor-targeting BuSpar (introduced by Squibb). The FDA has even allowed doctors to prescribe selective serotonin reuptake inhibitors, such as Lexapro and Paxil, and serotonin and norepinephrine reuptake inhibitors such as Effexor, to treat anxiety⁽⁴⁾.

On the other hand, none of these alternatives can satisfactorily eliminate unwanted side-effects, so psychiatrists continue to prescribe BZ anti-anxiety drugs widely. In fact, BZ sales in 2004 generated about \$1 billion (see Table 1).

"The nagging problem has been finding the right molecules that can be targeted precisely to activate only the receptors responsible for the anxiolytic effect," Robbins added. "This precise targeting is challenging because of the tight and complex structure of the GABA family of receptors."

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(Table 2)
Non-BZ Drugs Targeting GABA Receptors

Top Sellers			
Drug	Indication	Introduced by	2004 Sales (\$ Million) ^a
Ambien	Insomnia	Sanofi-Aventis	1,719.25
BuSpar ^b	Anxiety	Bristol Myers Squibb	155.80
Recently Approved			
Drug	Indication	Company	2005 Sales (\$ Million) ^c
Lunesta	Insomnia	Sepracor	220
In the Pipeline			
Drug	Indication	Company	Stage
Ambien CR	Insomnia	Sanofi-Aventis	Approval Pending
Indiplon	Insomnia	Neurocrine	NDA Filed
Ocinaplon	Anxiety	Dov Pharmaceuticals	Phase III
Gaboxadol	Insomnia	Lundbeck & Merck	Phase III
SEP-174559	Anxiety & Muscle Spasms	Sepracor	Phase II
Sonata	Insomnia	King Pharmaceuticals	Phase II
NGD 96-3	Insomnia	Neurogen	Phase I
NG2-73	Insomnia	Neurogen	Phase I

(a) Drug Topics, Feb. 21, 2005 (b) Generic name is Buspirone (c) Estimate by Sepracor

Clinical Studies

Epeius Biotechnologies (Monrovia, Los Angeles County):

On July 14th, Epeius announced the launch of a Phase I clinical trial opened at Mayo Clinic (Rochester, MN) to test the safety of its gene therapy vector, Regin-G. This vector is designed to treat pancreatic cancer, the fourth leading cause of cancer death in the United States. A maximum of 24 eligible patients will be enrolled in the safety study. Epeius expects this phase of Regin-G trials to be completed by November 2006. ❖

MannKind Corporation (Valencia, Los Angeles County):

MannKind Corporation (NASDAQ: MNKD) announced on June 29th that it initiated patient enrollment for its U.S. Phase III clinical trial of inhaled Technosphere Insulin. The study will evaluate the safety of Technosphere in diabetics. This formulation of inhaled insulin is already the subject of a Phase III efficacy study in Europe launched in late 2004. On August 3rd, MannKind also announced its \$175 million private placement financing. This infusion of capital will help further the development of the Technosphere system. ❖

Edwards Lifesciences (Irvine, Orange County):

Edwards (NYSE: EW) announced on June 23rd that Duke University Medical Center (Durham, NC) initiated a Phase I clinical trial to evaluate the safety of EW-A-40, a therapeutic gene transfer compound licensed by Edwards from Sangamo BioSciences (NASDAQ: SGM0). The trial will test the compound for treating limb ischemia, which is a form of peripheral artery disease that results in amputation. EW-A-401 is designed to stimulate the natural healing and repair of oxygen-starved tissue. This announcement follows Edwards' decision on June 14th to halt a clinical trial of its percutaneous aortic heart valve after 10 patients developed complications. Edwards plans to incorporate a new system for the catheter to deliver the valve to the heart. ❖

Savacor (West LA, Los Angeles County):

On June 20th, Savacor -- a Cedars Sinai spin-off and an alumnus of the SoCalBio Investor Conference -- announced that it commenced a first-in-man clinical trial of The HeartPOD device in New Zealand. The HeartPOD is designed for congestive heart failure patients. It consists of an implanted intracardiac sensor that allows the patient to directly monitor left atrial pressure, the intracardiac electrogram, and core body temperature. The HeartPOD is implanted like a pacemaker via a cardiac catheterization procedure. The implant's readings are transmitted to a hand-held computer, and the information generated is used to adjust medications on a dose-by-dose basis according to the physician's instructions. Left atrial pressure is believed to be a key predictor of acute worsening of heart failure, which in turn leads to lung congestion and the need for urgent hospitalization. ❖

Watson Pharmaceuticals (Corona, Riverside County):

Watson Pharmaceuticals (NYSE: WPI) announced on June 13th that it commenced Phase III clinical studies on Silodosin, a novel alpha(1)-adrenoceptor antagonist with high uroselectivity. Licensed from Kissei Pharmaceuticals of Japan, Silodosin is used to treat Benign Prostatic Hyperplasia (BPH), which is characterized by a non-cancerous enlarged prostate that leads to obstructive urinary symptoms. In the U.S., BPH affects more than half of all men in their 60s, and as many as 90 percent of men who reach the age of 85. About \$1.2 billion is spent annually on BPH prescription drug treatment. ❖

Peregrine Pharmaceuticals (Tustin, Orange County):

On May 31st, Peregrine (NASDAQ: PPHM) -- formerly Techniclone International -- announced that it received FDA permission to commence a Phase I clinical trial of its Hepatitis C drug, Tarvacin. In this phase of the trial, up to 32 patients will receive increasing doses to determine a safe level of the drug. Tarvacin is also in Phase I clinical trials to treat solid cancerous tumors. The drug is the company's first product developed under its anti-phospholipid technology. Aminophospholipids are parts of the cell membrane that become exposed as a result of certain viral diseases. The phospholipids envelop the viruses, making them a target for the therapy. In a presentation at BIO 2005 in Philadelphia, Peregrine announced that Tarvacin also binds to other viruses such as HIV 1 and 2, Influenza A and B, and measles. ❖

Spectrum Pharmaceuticals (Irvine, Orange County):

Spectrum (NASDAQ: SPPI) announced on May 31st that it obtained FDA approval to conduct clinical trials for its SPI-153 drug to treat hormone-dependent prostate cancer. The company has already initiated testing in Europe. Spectrum acquires and develops prescription drug products for treating cancer and other life threatening diseases. ❖

I-Flow Corporation (Lake Forest, Orange County):

I-Flow (NASDAQ: IFLO) announced on May 20th that it will partner with the Tulane University Health Sciences Center (New Orleans, LA) to conduct a pre-clinical study evaluating the anti-microbial benefits of its ON-Q device. The company hopes that this research will yield positive results that enable it to expand the use of ON-Q beyond its current indication of reducing pain and narcotics intake after surgery. ON-Q is a device consisting of a small balloon pump that holds a local anesthetic delivered automatically to the surgical site through a specially designed catheter. The ON-Q catheter provides more even distribution of local anesthetic over a wider area, as compared to other catheters. ON-Q is used to deliver narcotic-free pain relief for many surgeries including cesarean section, hysterectomy, knee replacement, and cosmetic procedures. ❖

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NIH SBIR Grants

New Grants During January - June 2005

Los Angeles County (15 grants totalling \$3.50 million)

Amount	Grant Focus	Investigator	Company	City Location
\$885,379	Hi. Res. Multiplexed DNA Reverse-SSO Typing Assay	Jarhoo Lee	One Lambda	Canoga Park
\$532,280	UDP -Glucuronic Acid Regeneration System	Inmar Munir	BioCatalytics	Pasadena
\$493,963	Laser Lancing Device	Gregory Zeltser	Physical Optics Corp.	Torrance
\$250,000	Targeting the Alpha-2 GABA-A Receptor Subtype	Mark Nowak	Neurion Pharmaceuticals	Pasadena
\$191,488	MAQDOTS: Multi-Analyte Quantum Dot Test Strips	S. Venkatasubbarao	Intelligent Optical Systems	Torrance
\$138,000	Production of a Lung Surfactant SP-B Mimic	Gary Fuji	Molecular Express	Los Angeles
\$133,091	Ablation Fiber Optic Probe for Surgical Maze Procedure	Vladimir Rubtsov	Intelligent Optical Systems	Torrance
\$129,030	Humanizing the Mouse Immune System using BAC	Hiroaki Shizuya	Aliva Biopharmaceuticals	Pasadena
\$113,339	Miniature Capnometer	Gregory Zeltser	Physical Optics Corp.	Torrance
\$107,000	Novel BIV-Based Vectors with Retina-Specific Promoter	Mojun Jin	Cytopro	Norwalk
\$103,000	CI Therapy and Novel Virtual Environments	Carolee Winstein	Metagenesis	Studio City
\$100,000	Imaging Brain Amyloid with a Bispecific Antibody	Yun Zhang	ArmaGen Technologies	Santa Monica
\$100,000	Photon-Counting X-Ray Detector for Crystallography	Neal Hartsough	DxRay	Northridge
\$100,000	High Efficiency X-Ray Detector for Electron Microscopy	Carolyn Tull	Photon Imaging	Northridge
\$97,972	Polarization Sensitive OCT for Imaging Caries Lesions	Ira Bush	Optiphase	Van Nuys

Santa Barbara County (4 grants totalling \$2.23 million)

Amount	Grant Focus	Investigator	Company	City Location
\$938,225	A Novel Technology to Improve HIV Medication Compliance	Vesta Brue	Lifetechniques	Santa Barbara
\$581,399	Multi-Wavelength Probe for Quantitative Tissue Analysis	V. Jayaraman	Praevium Research	Santa Barbara
\$515,055	Ultra-Broadband Sources for Optical Coherence Tomography	V. Jayaraman	Praevium Research	Santa Barbara
\$198,864	Pills & Patient Behavior Smarter Experience Tracking	Vesta Brue	Lifetechniques	Santa Barbara

Orange County (4 grants totalling \$1.03 million)

Amount	Grant Focus	Investigator	Company	City Location
\$440,494	Adjuvants for Agile Vaccine Development	Philip Felgner	Immport Therapeutics	Irvine
\$320,184	A Dual Electrospray/Photoionization Source	Jack Syage	Syagen Technology	Tustin
\$170,066	Aminoketone Inhibitors of the Dopamine Transporter	John Reinhard	Brain Insights	Irvine
\$100,000	S.T.R.A.P. Sonos Transportable Renal Application Product	Martin Roberts	Sonos Medical	Huntington Beach

Alliances & Collaborations

Hurel (Beverly Hills, Los Angeles County):

On July 21st, Hurel -- an alumnus of the SoCalBio Investor Conference and developer of a microfluidic in vivo-surrogate cell-based assay platform technology -- announced an R&D collaboration agreement with Johnson & Johnson Pharmaceutical Research and Development. According to the agreement, J&J will fund Hurel's efforts to validate its microfluidic device and prepare it for commercial release. ❖

Allergan (Irvine, Orange County):

On July 13th, Allergan (NYSE: AGN) and Pharmacoepia Drug Discovery (NASDAQ: PCOP) announced an agreement to collaborate on research involving new treatments for vision loss, including compounds to target age-related macular degeneration. ❖

Amgen (Thousand Oaks, Ventura County):

On July 11th, **Forbes.com** mentioned that Amgen (NASDAQ: AMGN) may have forged an alliance with ReOx, Ltd., a private company spun out of Oxford University (Oxford, UK), to develop oral inhibitors of hypoxia inducible factor (HIF) prolyl hydroxylases. ReOx is developing a technology based on research by Peter Ratcliffe, Patrick Maxwell and Chris Pugh of the Wellcome Trust Centre for Human Genetics focusing on the enzymes that regulate HIF. The company is also tapping research findings by Christopher Schofield of Oxford University's Department of Chemistry related to the molecular inhibitors of these enzymes. ❖

Diagnostic Products Corporation (West LA, Los Angeles County):

On July 7th, Diagnostic Products Corporation (NYSE: DP) and Waltham, MA-based Thermo Electron Corporation (NYSE: TMO) announced an agreement to co-develop a high-throughput

clinical chemistry platform. This platform seeks to combine Diagnostic Products' experience in immunochemistry with Thermo's clinical chemistry and automation expertise to provide clinical laboratories and hospitals with an automated and comprehensive diagnostic test solution. ❖

Applied DNA Sciences (West LA, Los Angeles County):

Applied DNA Sciences announced on June 21st that it reached an agreement with Advanced Coding Systems (ACS) to collaborate on the development of new methods for detecting and combating counterfeiting. This collaboration will combine Applied DNA Sciences' proprietary botanical DNA security technology with ACS' MicroWires in developing DNA-encrypted MicroWires to provide forensic security for brand owners. ❖

Beckman Coulter (Fullerton, Orange County):

Beckman (NYSE: BEC) announced on June 16th that it signed an agreement with Chestnut Hill, MA-based Nephromics to access the latter's intellectual property and biologics related to the detection of preeclampsia -- the second leading cause of maternal deaths in the developed world. Beckman will use these assets to develop new kits for early detection and improving outcomes in certain at-risk pregnancies. ❖

Valeant Pharmaceuticals International (Costa Mesa, Orange County):

Valeant (NYSE: VRX) -- a biopharma company focused on neurology, infectious disease and dermatology -- announced on June 21st that it reached an agreement with Irvine-based Allergan (NYSE: AGN) to serve as the exclusive distributor of Allergan's BOTOX in Hungary and Poland. Valeant (formerly ICN Pharmaceuticals) has commercial strength throughout Central and Eastern Europe. ❖

Mergers & Acquisitions

Biosource International (Camarillo, Ventura County):

After rejecting an unsolicited takeover bid last April by Bio-Rad Laboratories (Hercules, CA), Biosource International's board of directors accepted an acquisition offer on July 26th from Carlsbad, CA-based Invitrogen (NASDAQ: IVGN) for \$130 million, \$50 million more than Bio-Rad's offer. According to an Invitrogen press release, acquisition of the publicly-traded Biosource (NASDAQ: BIOC) is expected to bolster "Invitrogen's offerings in both kinase and cytokine assay technologies for research applications and provides the company an opportunity to enter new markets in immunology, oncology and neurodegenerative disease." ❖

Gamma Medica (Northridge, Los Angeles County):

Gamma Medica, a developer and manufacturer of clinical and pre-clinical molecular imaging systems, announced on June 21st that it will merge with Ideas ASA (Oslo, Norway), a producer of solid-state integrated digital detector electronics and imaging

detector subsystems. The new company will be called Gamma Medica Ideas. This merger seeks to "blend Ideas' advanced solid-state radiation detection electronics with Gamma Medica's highly innovative medical imaging equipment," said Bradley Patt, Ph.D., president and CEO of the newly combined company. "The goal is to become a global leader in integrated pre-clinical imaging for medical research and drug development, as well as molecular breast imaging that is more effective cancer screening." ❖

IRIS International (Chatsworth, Los Angeles County):

On June 6th, IRIS (NASDAQ: IRIS), a 200-employee manufacturer of automated urinalysis systems and medical devices used in hospitals and reference clinical laboratories, announced that it completed its acquisition of the urinalysis business previously owned by San Diego-based Quidel (NASDAQ: QDEL). On July 27th, IRIS announced record revenues of \$15.6 million for the second quarter ended June 30th, and six-month revenues of \$29.5 million. These figures represent increases of 51% and 50% respectively versus the same period last year. ❖

Premarket Applications

Approvals During January - June 2005

	Jan	Feb	Mar	Apr	May	Jun
All PMAs	2	0	4	4	3	2
CA PMAs	1	0	0	0	0	1
Greater LA PMAs	1	0	0	0	0	1

Recent PMA

Dako Cytomation (Carpinteria, Santa Barbara County):

Last June, Dako obtained FDA approval for its DakoCytomation c-Kit pharmDx on the Dako Autostainer. The c-Kit pharmDx assay is described in the company's PMA as "a qualitative immunohistochemical kit system used on the Dako Autostainer

for the identification of c-kit protein/CD117 antigen expression in normal and neoplastic formalin-fixed paraffin-embedded tissues for histological evaluation." Dako's assay incorporates rabbit polyclonal antibodies to specifically detect the c-kit protein in CD117 antigen-expressing cells. This assay is useful in the diagnosis of gastrointestinal stromal tumors. ❖

Biologics Approvals

Baxter BioScience (Westlake Village, Ventura County):

On April 27th, Baxter BioScience -- a division of Baxter International (NYSE: BAX) -- obtained a biologics license application approval from the FDA for its Gammagard Liquid. This biologic is used to treat primary immunodeficiency disorders associated with defects in humoral immunity. These include congenital X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. ❖

MEDSEP (Covina, Los Angeles County):

On April 14th, MEDSEP -- a subsidiary of East Hills, NY-based materials science and engineering firm Pall Corp. (NYSE: PLL) -- obtained a biological device approval from the FDA for its Leukotrap SC RC Filtration System. This device will be used in leukocyte reduction and storage of a single unit of packed red blood cells or whole blood. MEDSEP manufactures blood collection bags, and employs about 700 people in the San Gabriel Valley. ❖

Coming
March 29 - 30, 2006

SoCalBio Investor Conference

Los Angeles, California

For presentation and sponsorship opportunities, send e-mail to scbc@socialbio.org

510(K) Decisions

Devices Cleared During January - June 2005

	Jan	Feb	Mar	Apr	May	Jun
All 510(k)s	215	264	284	246	262	263
CA 510(k)s	25	50	61	45	54	56
Greater LA 510(k)s	14	21	26	20	19	19

Spotlight

Recently-Cleared Health Informatics Products

PerMedics (San Bernardino, San Bernardino County):

Last January, the FDA cleared PerMedics' Odyssey package for marketing. The system is a collection of software modules that execute algorithms to produce radiation dose estimations for patients undergoing radiation therapy. It was created under the direction of Daniel Miller, a professor of radiation medicine at Loma Linda University Medical Center. PerMedics is a subsidiary of Optivus Technology -- also based in San Bernardino -- which provides proton beam therapy for the treatment of cancer. ❖

Karl Storz (Culver City, Los Angeles County):

In April, Karl Storz obtained a 510(k) clearance for its AIDA/DICOMIHL 7, a picture archiving and communication system (PACS). This system captures and annotates surgical procedures for documentation purposes, and is not intended for primary diagnosis. ❖

Medical Technologies International (Indian Wells, Riverside County):

Medical Technologies International's Prowin software program was cleared by the FDA for marketing in April.

The program is designed to measure carotid artery intima-media thickness (CIMT) from ultrasound images. It is based on a technology developed at the Jet Propulsion Laboratory and USC. A physician may use this system to monitor atherosclerosis in individuals who are either asymptomatic or symptomatic for cardiovascular disease. ❖

Kinamed (Camarillo, Ventura County):

In May, Kinamed was cleared to market its NaviPro Shoulder Software Module. The module uses a camera and infrared reflective markers to track the spatial position of bones and medical instruments during shoulder replacement surgery. Founded in 1987, Kinamed designs and manufactures orthopedic joint replacements and implantable neurosurgery devices. ❖

Intuitive Imaging Informatics (Bell Canyon, Los Angeles County):

Intuitive's ImageQube PACS was cleared for marketing by the FDA in June. The system is designed for enterprise-wide multimedia capture and distribution of patient information, medical images, reports, key image summaries, user scans and full resolution image datasets via Intranet or Internet. ❖

Agensys

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(www.cancer.org) estimates that 232,090 men in the U.S. will be diagnosed with prostate cancer in 2005, and about 10% will die from the disease.

PSCA was discovered by scientists at UCLA, and the University has an exclusive license with Agensys for PSCA-related intellectual property. The monoclonal antibody, AGS-PSCA, was created by Agensys using XenoMouse technology licensed from Abgenix. This monoclonal antibody provides one of the first targeted therapies for prostate cancer.

"Because PSCA is over-expressed in all stages of prostate cancer, AGS-PSCA can be effective in treating early and late stages of the disease," commented Dr. Jakobovits.

PSCA's significant expression in the majority of patients with pancreatic and bladder cancers suggests that AGS-PSCA has therapeutic potential in targeting those types of cancers. Agensys cites studies in pre-clinical mouse models that show AGS-PSCA's capabilities in affecting relevant clinical endpoints. These effects include inhibiting primary tumor growth, prolonging survival, almost completely inhibiting the spread of disease from the primary site to the distal site, and improving overall health.

"AGS-PSCA represents an encouraging step forward in Agensys' quest to utilize genomic targets for the development of therapeutic antibodies to treat cancer," added Dr. Jakobovits. ❖

Article by *Harnisha Dalwadi, Ph.D., Contributing Editor* (harnisha_99@yahoo.com)

CompuMed

Continued from page 1

CompuMed CEO Jerry McLaughlin. "Integrating the OsteoGram with digital mammography systems will help solve a myriad of public health problems by making BMD testing more convenient for women, while at the same time helping mammography centers add new services and become more profitable."

Healthcare providers from coast to coast have used the first-generation analog OsteoGram for more than a decade. The recently introduced DICOM (Digital Communications and Imaging in Medicine) compliant version is designed specifically for use on digital imaging platforms. CompuMed has filed a provisional patent for the integration and use of OsteoGram software on digital mammography equipment.

In addition to its focus on mammography, the company has made significant progress in linking the DICOM OsteoGram with leading computed radiography (CR) and direct digital radiography (DR) systems. Over the past two years, CompuMed has announced licensing and distribution agreements with market leaders Swissray International (Elizabeth, NJ), SourceOne Healthcare Technologies (Mentor, OH) and Orex Computed Radiography USA (Auburndale, MA).

Orex was recently acquired by Kodak's Health Group, and all three companies, along with Fujifilm Medical Systems USA and Analogic subsidiary Anexa (Peabody, MA), exhibited OsteoGram-integrated products at last year's RSNA (Radiology Society of North America) annual meeting in Chicago. ❖

Article by *Erik Deutsch, Managing Editor* (erik@socialbio.org)

Agensys® @ a Glance

Founded: 1997 (founded as UroGenesys)
Location: Santa Monica (LA County)
Focus: Cancer therapeutics
Leadership: **Donald Rice**, Chairman/Pres./CEO
Aya Jakobovits, Ph.D., Sr. VP/CSO
Paul Kanan, VP/CFO
Chris Morl, VP
Martha Vincent, Ph.D., VP
Capital: \$62 million to date
Employees: 60
Patents: 28 issued, 250 pending
Facilities: 36,000 sq. ft.

COMPUMED @ a Glance

Founded: 1973
Location: City of LA (LA County)
Focus: Healthcare Informatics
Leadership: **Jerry McLaughlin**, Pres./CEO
Phuong Dang, CFO
Xiaoli Bi, VP, Technology
Louai Al-Dayeh, Ph.D., Sci. Director
Employees: 20
Patents: 4 issued
Products: **CardioGram** (electrocardiograms)
OsteoGram (osteoporosis)

Michael Phelps

Continued from page 1

is spending billions of dollars subjecting patients to ineffective drug treatment, while exposing them to risk with no benefit. Systems biology aims to increase the quality and lower the cost of healthcare by understanding how the body is "wired." New tools such as PET enable us to see changes in the integrated circuits of cells, and identify proteins that are critical in controlling disease. These proteins can then be targeted by drugs to drive the circuit back to its normal state, replace lost functions, or terminate the diseased cells. Molecular diagnostics help guide the discovery process and identify the right drug for the right patient.

Q: How has UCLA built competence in systems biology-based molecular medicine?

In 1990, we established the Department of Molecular and Medical Pharmacology. The goal was to create a new department focused on both basic science and clinical capabilities. We accomplished this by bringing molecular imaging diagnostics and molecular therapeutics together under one roof. It is the only such department in the world where PET and Nuclear Medicine are integrated into pharmacology. With its molecular imaging diagnostics clinic, the Department also develops and performs molecular diagnostics on patients participating in drug trials, as well as those undergoing routine treatment. Merging molecular diagnostics and therapeutics helps make UCLA uniquely positioned to apply laboratory science to clinical practice.

Q: How does the Department serve as a central focal point for various research and clinical activities inside and outside UCLA?

There are numerous institutions at UCLA that focus on expanding the resource base for the systems biology community under the Department of Molecular & Medical Pharmacology's umbrella. These include the Crump Institute, which develops pre-clinical molecular imaging technologies, and the Institute of Molecular Medicine, whose scientists are charged with advancing research that lies at the heart of systems biology-based molecular medicine. Recently, Dr. LeeRoy Hood at the Institute for Systems Biology in Seattle, Dr. James Heath of Caltech and

UCLA, and I established the Alliance for NanoSystems Biology. This organization links our expertise for the purpose of developing *in vitro* and *in vivo* molecular diagnostics based on a systems biology view of disease. We also created the L.A. Tech Center in Culver City to help UCLA transfer inventions and discoveries from the Department of Molecular and Medical Pharmacology and its affiliated Institutes to the commercial sector. As a result of these efforts, UCLA is now recognized as a leader in the field of molecular medicine.

Q: Does the L.A. Tech Center function as an incubator?

The Center is not an incubator, but rather a model partnership between academia and industry where UCLA scientists can team up with researchers from for-profit enterprises to develop new PET technologies and applications. The Center houses a commercial radiopharmaceutical manufacturing facility, as well as R&D labs to identify biomarkers of disease and develop molecular imaging technologies. The Center partners with the CTI Molecular Imaging family of firms, which was acquired by Siemens in May 2005 for \$1 billion.

Q: How does the Center harness these two different cultures - academic and commercial - to foster innovation?

I truly believe that most great discoveries are not planned, but simply happen as a result of chance events. The closer people work together, the greater the likelihood that such events will occur. In this spirit, we deliberately located the L.A. Tech Center off-campus, where academic and commercial scientists could influence each other and thrive together. It is all about chemistry, which starts by increasing the probability of two molecules colliding. When molecules collide, they build and break bonds to form new products. You can also increase the rate of reactions by adding a little



L.A. Tech Center in Culver City helps UCLA transfer inventions and discoveries from the Department of Molecular and Medical Pharmacology and its affiliated Institutes to the commercial sector.

heat. It is amazing what happens when you put people from different backgrounds and cultures together in the same space and mix together their dreams and talents with agreed upon deadlines. The L.A. Tech Center is a successful experiment that is still evolving.

Q: Will UCLA as a whole follow the example set by the L.A. Tech Center to improve its tech transfer practices?

It's no secret that the UC system has a mixed reputation when it comes to tech transfer. UCLA's new Interim Vice Provost, Dr. Kathryn Atchison, along with Executive Vice Chancellor, Dr. Dan Neuman, have embarked on a new course of action to improve UCLA's ability to execute tech transfer agreements and encourage new company formation. In general, research universities such as UCLA need to be more proactive in building America's new economy. This is both a responsibility and a privilege. Also, keep in mind that NIH and NSF funding is on the decline, a trend that I believe will continue for years to come. Therefore, universities must diversify their sources of research funding by fostering better relations with industry.

Q: What specific steps should UCLA take to modernize its tech transfer apparatus?

It is often stated by UC officials that the problems in tech transfer result from policies and laws. This is not true. In my view, we need to make a cultural shift to a new way of doing things. First, we need to learn how to outsource tasks that are beyond our expertise. Second, we need to simplify the process by putting an end to the obsession with the endless minutia of each contract before there's even an agreement on general terms. Third, the relationship between faculty and tech transfer administrators should be based on goodwill, knowledge, and trust. Finally, we need to get rid of the obsession with generating upfront income from licensing. Instead, UCLA must learn how to reap rewards by co-investing in its own spin-offs.

Q: Because of lax tech transfer efforts in the LA area, we lag in biotechnology. Do you think we still have a chance to catch up with leading regions?

Leading biotech regions, from the Bay Area to Boston, feed off their research universities. In fact, if you compare where the top 20 universities and the top 20 biotech companies are located, they overlap perfectly, with the exception of the Los Angeles region. This is despite the fact that we have well-funded research institutions like Caltech, UCLA and USC. Nonetheless, there's reason for optimism, given that the fast pace of technological change is creating a situation where no biotechnology leadership position is guaranteed. Los Angeles may be able to leapfrog the competition by

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riding the next wave of innovation based on breakthrough research in many fields including systems biology. ❖

Interview by Erik Deutsch, Managing Editor, and Harnisha Dalwadi, Ph.D., Contributing Editor.

Michael Phelps, Ph.D. @ a Glance

- ◆ 1970 – Earned a Ph.D. in chemistry from Washington Univ. (St. Louis, MO)
- ◆ 1970-75 – Served on Washington U's medical school faculty
- ◆ 1974 – Invented the first PET scanner
- ◆ 1975-76 – Served on faculty at University of Pennsylvania
- ◆ 1976 – Completed the first commercial PET scanner (made by EG&G ORTEC, later CTI) and began his tenure at UCLA
- ◆ 1985 – Elected to the Institute of Medicine of the NRC
- ◆ 1999 – Elected to the National Academy of Sciences
- ◆ Present titles at UCLA:
 - Chair, Molecular & Medical Pharmacology Dept.
 - Norton Simon Professor
 - Professor of Biomathematics
 - Director, Institute for Molecular Medicine
 - Director, Crump Institute for Molecular Imaging
- ◆ Authored 670 publications, with 410,000 literature citations
- ◆ Attracted \$225 million in research grants
- ◆ Attracted \$17 million in private donations to support research
- ◆ Board Chairman, Norton Simon Research Foundation & Norton Simon Foundation; and Board Member, Norton Simon Art Foundation
- ◆ Earned numerous international honors and awards including the Von Hevesy Prize (1978, 1982), Enrico Fermi Presidential Award (1998), Kettering Prize(2001), and Benedict Cassen Memorial Prize (2002)

proposed. Both are now thriving facilities attracting patients and staff from around the world. The fact is, the Eastside is a convenient, centrally located group of communities where revitalization needs are driven by the departure of a number of potentially toxic heavy industries. What remains are skilled workers and reasonable land prices.

In order to make the dream of a biomedical park a reality, the stakeholders must foster the perception that the proposed site is located in a thriving and desirable community with the capacity to host a world-class research park. That perception could be enhanced through a plan for the imaginative re-use of the architecturally noteworthy existing General Hospital building, which dominates the area's skyline. If it were to become a desirable mixed-use residential and commercial structure, like those now creating a real estate market boom in downtown Los Angeles, it could become the centerpiece of a "biomedical community" attracting doctors, nurses, scientists, and students, all of whom could live, work and study in one convenient location. This in turn would bring economic vitality, without displacing current residents.

But advancing the project to the next level requires proactive leadership from Mayor Villaraigosa. It calls for his proven skills in resource mobilization, as well as his political savvy, to coordinate the activities of numerous stakeholders, including USC and Los Angeles County.

Before he was elected Mayor, Antonio Villaraigosa represented the district that includes the proposed biomed park on the Los Angeles City Council. Over the years he has been a strong advocate, promoting the park's development. Given his expressed challenge to dream of what Los Angeles can become, it seems to me that there is no better place to fulfill that dream than in the historic heart of the City. ❖

John Hisserich, Dr.PH., serves as associate vice president of Health Affairs at USC. He also teaches at the USC School of Pharmacy.

Neurion

Continued from page 2

Neurion capitalizes on recent advances in neuroscience, genomics and computational biology to overcome this hurdle. The company's technology -- called "Neurion Precision Neurochemistry Platform" or "NP2" -- is based on pioneering research conducted by Caltech professors Dennis Dougherty, Ph.D., and Henry Lester, Ph.D. This platform is combined with the company's ion channel Mutant Activity Panel (MAP) technology to map the structure of subtypes of GABA receptors, particularly GABA_A, which is thought to be responsible for inducing the anxiolytic effect.

"Unlocking the mysteries of GABA_A is but one step in a complex discovery process that we hope may lead to finding the perfect anxiolytic," said Robbins.

Neurion's intellectual assets haven't gone unnoticed by big pharma. Pfizer has already signed a deal to use Neurion's platform to study drug toxicity, while Lilly used it to identify novel molecules for CNS disorders. Revenues from these collaborations, along with the initial round of funding from Convergent Ventures, have

so far sustained Neurion's R&D efforts. ❖

- 1) "Leo Sternbach - the Father of Mother's Little Helpers," usnews.com, December 27, 1999.
- 2) See [Medline Plus Drug Information](http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202084.html) at <http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202084.html>.
- 3) "I can Sleep," [Business Week](http://www.businessweek.com), Jan. 26, 2004.
- 4) "Chill Pills," [New York Magazine](http://www.nytimes.com), Jan. 24, 2005.

NEURION
PHARMACEUTICALS
@ a Glance

Founded:	2002
Location:	Pasadena (Los Angeles County)
Focus:	Drugs that target ion channels
Leadership:	William Robbins, Chairman/President/CEO Paul Bennett, Jr., Ph.D., VP, Discovery Nima Shiva, VP, Strategic Development Mark W. Nowak, Ph.D., Associate Director, Molecular Neurosciences John B. Nicholas, Ph.D., Associate Director, Computational Drug Design
Employees:	16
Patents:	6 filed
Partners:	Eli Lilly, Pfizer
Facilities:	8,000 sq. ft.

the financial markets view company and technology valuation. And don't forget to consider the implications of such change on corporate liability as the validity of today's risk-benefit calculations gets eroded over time.

Recent events have uncovered the FDA's difficulties in providing clinicians and patients with contemporaneous guidance for drugs, devices and biologics. Each of the agency's centers has an office for the acquisition and evaluation of "adverse event data." But these offices are already highly challenged to keep pace with present levels of product post-marketing data reporting.

Imagine what will happen when the Medicare data are added to the mix. Not only will the volume of data to be processed increase by orders of magnitude, the flood of Medicare information may also strain an already overwhelmed bureaucracy as it struggles to ensure data consistency and quality.

Finally, there is the nagging issue of how the data will be interpreted, particularly in the case of complicated diseases where number crunching alone is not sufficient to correlate event reports with individual drug or device malfunctions. Many conditions afflicting Medicare patients, including heart disease and diabetes, have complex causes that defy easy analysis.

To avoid criticism, the FDA may be compelled to take drugs or devices off the market before conducting careful verification when adverse product events -- even if spurious -- get detected in the Medicare data. As a result, drug and device companies may be forced to allocate investment dollars to only the most conservative new drug and device candidates.

In short, the rush to use Medicare data for judging medical treatment outcomes may ultimately disserve those who need medical innovations the most. ❖

Joel Slomoff serves as a special consultant to the Health Law Section of Fulbright & Jaworski in its Washington, D.C. office.

Medicare Data

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and Research, said: "The FDA strongly supports the use of data from Medicare ... to identify safety risks for recently approved medications and to learn more about the real world outcomes of medication use."

Paul Seligman, M.D., director of the FDA's Office of Pharmacoepidemiology and Statistical Science, is confident that: "Access to [Medicare] data will play an important role in helping FDA meet its mission."

If you combine such comments with a reading of the FDA's recent guidance on "Good Pharmacovigilance Practices" or its draft guidance for industry on "Premarketing Risk Assessment," you will get a sense that we are fast moving in the direction of a "provisional" product approval regime. This change is advocated by experts including John Somberg, M.D., who serves as a member of the FDA Expert Advisory Panel on Circulatory System Devices and as editor of the *American Journal of Therapeutics*.

While provisional approval is exercised now by the FDA under very limited circumstances, some would like to see it -- along with post-marketing Phase IV clinical trials -- become the norm. They are also pushing for the use of Medicare data for "independent" verification of company-submitted clinical results.

At first blush, the use of Medicare data in evaluating medical treatment outcomes may seem like a good idea. But, a close examination reveals it is just as likely to increase uncertainties in the marketplace and overwhelm the FDA with information it cannot readily process. Such unintended effects will ultimately serve to deter product innovations.

The provisional approval regime will change the essential assumptions that companies make when identifying priorities and determining how to allocate resources. It will affect entry and departure points for projects, facilities, personnel, and lines of business. It will also change how

USC Research Park

Continued from page 1

researchers can provide the intellectual foundation for the development of new therapies, which could be refined further in adjacent industry laboratories. Hundreds of physicians and other health professionals working in close proximity would help speed development of these new concepts into effective treatment modalities. Light industrial facilities could be fostered to provide instruments, medical equipment, pharmaceutical manufacturing/packaging/distribution, and other related business functions.

Compared to other regions in the country where similar industrial parks have been developed, LA's Eastside offers special advantages. The list includes: 1) the presence of several potential building sites, 2) a willing workforce, 3) receptive neighbors, 4) a central location adjacent to transportation hubs, and 5) tax and economic incentives through various government programs.

Furthermore, the specific area under consideration is adjacent to world-class educational institutions prepared to train students for every level of involvement, from industrial through scientific. In addition to the benefits afforded by the synergy of basic and applied biomedical research, the proposed park has the potential to provide tremendous economic improvement to communities very much in need of revitalization.

Given the shortage of research space in LA and the behind-the-scenes progress already achieved in the creation of the proposed park, many observers wonder why development has progressed almost imperceptibly. Some blame the failure to relocate the County's juvenile justice center as a major impediment. While moving the center would free up several acres for the project, there is plenty of nearby land available.

Others disparage the area as "undesirable," despite the fact that such concerns were raised when the Norris Cancer Center and the USC University Hospital were