DEAN'S CORNER E-NEWSLETTER

Texas College of Osteopathic Medicine
June 30, 2004

We are beginning to prepare for the incoming students at the end of the month! We will have 130 students in the entering class for the medical school and 28 students in the Physician Assistant Studies Program. Luibel Hall renovations continue, with plans for completion by the end of July in time for the new classes. Renovations include new chairs, desks, acoustical tiles, and most importantly, wiring for lap top computers (electrical and Ethernet) at each seat.

In addition, we will welcome two new members of the UNTHSC and TCOM teams. Thomas Moorman, Ed.D., has been named as the new Associate Vice President for Student Affairs. Dr. Moorman has been with the University of North Texas Health Science Center for over nine years. During these years, Dr. Moorman has had the opportunity to work with the Texas College of Osteopathic Medicine, the Graduate School of Biomedical Sciences, the Physician Assistant program and the School of Public Health, where he was most recently the Assistant Dean of the School of Public Health, overseeing admissions and student services. Joel A. Daboub, M.B.A., has been appointed as the Director of Admissions and Outreach for TCOM effective July 5, 2004. Mr. Daboub, who earned his M.B.A. with an emphasis in marketing from the University of North Texas, has many years of experience in higher education, having served as Associate Director of Admissions for the undergraduate programs at the University of North Texas in Denton. In addition, he has served as functional lead for the UNT Enterprise Information System project for admissions and was instrumental in developing system interfaces for all UNT and health science center admissions offices. His skills and experience in the area of computerized management techniques, customer service, team building, and organizational management qualify him uniquely for his new role at the Health Science Center.

Please supply any pertinent information to my office (deantcom@hsc.unt.edu) by the third Thursday of the month, for inclusion in this Newsletter.

Student Affairs: (Thomas Moorman, Ed.D.)
Associate Vice President for Student Affairs

* Ready or not, the Class of 2008 will be arriving on campus for Orientation on July 26. This will mark the beginning of the 2004-2005 academic year.

* The Student EAP Program is an anonymous counseling program for all students at the UNT Health Science Center. You are eligible for six free counseling sessions. Call today (817) 339-8936.

Clinical Affairs/Faculty Practice: (Robert Adams, D.O.)
Senior Associate Dean for Clinical Affairs/Chief Medical Officer

The self-insurance program of the University of North Texas Physicians Group is entering it's third year of existence. Each year the plan utilizes an actuary to determine the premium amount for the following year. This recommendation is based on several factors including claims history, financial reserves, estimated case expenses, and the current malpractice climate in the state. We're happy to report that for fiscal year 05, based on the recommendation of the actuary, the MSRDP Board voted to decrease premiums 20%. This reduction is the partly result of tort reform in Texas and sound financial management of the trust. While it's impossible to predict what our claims will be in the coming year, we are hopeful that this will be the start of a trend in premium reductions.

Educational Programs: (Don Peska, D.O.)
Associate Dean for Educational Programs

We are pleased to welcome our new interns and residents to our affiliated training programs. July 1 marks the annual turnover in the graduate training programs around the country. The Texas OPTI is pleased to have 37 new graduates beginning their postdoctoral training at its member hospitals around the state. This is an exciting time for these young physicians and an anxious time for trainers and administrators. It is reassuring to know that all those who started our programs last year at this time completed the year successfully and have moved on to practice or new educational opportunities. We offer our best wishes to those that are just starting the process.

Academic Affairs: (Bruce Dubin, D.O., J.D.)
Associate Dean for Academic Affairs

No contribution this month.

Clinical Research: (Michael Clearfield, D.O.)
Associate Dean for Clinical Research

This month's contribution will focus on the Osteopathic Research Center (ORC), which is one of the three focused areas of research for TCOM. The ORC has started its third year after TCOM was awarded a four-year grant for $1.1 million grant from the AOA, AOF and AACOM in 2001. In the first two years Dr. Stoll as executive director along with Dr. Cruser as the administrative director and the faculty of OMM plus numerous other individuals both within and outside our institution have been able to receive external funding support in excess of $4.4 million or about a 10 fold return on the initial investment. Currently there is more than a dozen local and multi centered OMM research projects ongoing within the ORC. This is highlighted by the first multi centered trial (5

centers around the country) investigating the utility of OMM in pneumonia. A new multi center trial is under development, which will study the use of OMM in children with otitis media. These studies have the potential to change the profession in a very profound and fundamental way. We all should take pride in the fact that this research will possibly provide the basis for evidence based outcome data that will change the way these diseases are treated not only in our profession but also within medicine in general.
The ORC has also instituted a research-mentoring program that is supported with a NIH Clinical Research Training grant. To date 3 DO's have graduated from this program with a dual DO/MS degree and there are currently 13 predoctoral fellows and one postdoctoral fellow in the program with plans of even greater expansion of numbers and degrees (i.e. PhD).

Current research with OMM through the ORC includes research in pneumonia and otitis media as mentioned but also in areas as diverse as diabetes, carpal tunnel, pregnancy, S/P CABG, low back pain along with basic science concepts such as lymphatic flow.
The collaborative efforts of the ORC include all the schools of UNTHSC, the AOA, all the colleges within the profession and several other collaborative partnerships. The ORC stands as a beacon for TCOM to shine its light into the community, nation and medical profession and it is through the tremendous efforts of Dr. Stoll, his staff, the department of OMM and many others including support from all the schools of the HSC that an effort of this magnitude is possible.

If you would like more information about the ORC or if you would like to participate in their research program you can contact myself or Dr.'s Stoll or Cruser for more information.

PA Studies: (Hank Lemke, P.A.)
Director for PA Studies Program

UNTHSC PA Students Compete Again in AAPA Challenge Bowl
A number of our PA students and faculty attended the 32nd Annual American Academy of Physician Assistants (AAPA) Conference in Las Vegas in June. The conference includes hundreds of exhibitors from the health care industry, a job fair, and a chance to meet leaders and practicing PAs from all over the Nation. PA students represented themselves in the Student Academy of the AAPA and the PA program in the AAPA National Medical Challenge Bowl, where they pitted their medical knowledge and game-playing strategies against other PA programs in friendly competition. UNTHSC was represented by Class of 2006 PA students Jorge Barak, Celeste Ferencak and Rachel Boyer. Well done students!

PA Student Receives DFW Hospital Council Scholarship
PA student Fara Lynn Rives was recently awarded the 2004 Rex McRae Student Scholarship by the DFW Hospital council at their annual awards banquet at the Windham Arlington Hotel in Arlington. Rives is a Class of 2006 student. The scholarship was created in May of 1998 and is named for Rex McRae, former President of Arlington Memorial Hospital for 28 years and Board Chairman of the Dallas Fort Worth Hospital

Council in 1987. This is the first time a PA student from UNTHSC has received this scholarship.

Science and Health News:

Supreme Court Rules on Texas HMO Malpractice Case

WASHINGTON (AP) - The Supreme Court said Monday that patients who claim their HMOs wouldn't pay for needed medical care cannot sue for big malpractice damages, an issue at the heart of the long debate over efficiency versus service in managed health care.

The court was unanimous in saying that two HMO patients in Texas cannot pursue big malpractice or negligence cases against their insurers, as they claimed a Texas patient protection law allowed them to do.

The case involves an issue that has stymied Congress, which has tried and failed to pass national patients' rights legislation. Some states have passed their own patient protection laws in the meantime, but the scope of protection varies.

The biggest question unresolved until Monday was whether patients could seek hefty damage awards in state courts, or whether they are limited only to federal courts, as insurers claimed.

The choice is significant, because state court juries can often be generous to sympathetic victims. Insurers have claimed that patients could only go to federal court, and then only to recover the value of whatever benefit the HMO denied.

New York Times
June 21, 2004
A Medical Journal Quandary: How to Report on Drug Trials
By BARRY MEIER

The issue of The American Journal of Psychiatry that hit the desks of its 37,000 readers this month reported test results for the antidepressant drug Celexa, indicating it could help children and teenagers.

Before publication, the article received the kind of scrutiny common among medical journals. The study's authors had been asked to divulge their financial ties, if any, to the drug's marketer, Forest Laboratories Inc., which sponsored the clinical trial. And the report was sent to reviewers who examined the trial methodology and checked to make sure that the article reflected other relevant research about the use of antidepressants in youngsters.

But neither the article nor the 27 scholarly footnotes that accompanied it mentioned another major drug-industry-sponsored trial completed in 2002, which found that Celexa did not help depressed adolescents any more than a placebo. Nor would the article's reviewers have been likely to find any clues of that trial's existence. The results of that trial

were first noted last year on a single line of a chart that appeared on Page 96 of a textbook - one written in Danish.

Like most medical journals, The American Journal of Psychiatry does not require company sponsors of drug trials to divulge information about all relevant trials of a medication. But that may soon change, as some leading journal editors try to address what they see as shortcomings in the way clinical tests are designed and analyzed by the drug industry, and how test results are disclosed.

"There is so much sophistication, that if the journals are not careful they could end up being part of the drug industry's marketing arm," said Dr. Richard Smith, the editor of The British Medical Journal.

In written responses to inquiries from The New York Times, Forest stated that the negative Celexa test, sponsored by a related company, was not mentioned in the recent article because "there was no citable public reference for the authors to examine."

But drug makers often announce trials with positive results without waiting for the results to be published. Forest, for example, issued a news release three years ago that highlighted the outcome of the positive Celexa trial. That was shortly after the test's completion, when the findings were first presented at a medical conference, but before the study was even submitted to The American Journal of Psychiatry for consideration. Three of the authors of the Celexa drug article in this month's issue are Forest employees.

Dr. Smith and other editors say the challenges they face are not limited to the tendency by companies and academic researchers to showcase positive tests results while playing down trials with negative or inconclusive findings. Editors say they must also be vigilant against companies' cherry-picking favorable but limited data from a trial that had originally set out to test other aspects of a drug's performance.

Some companies, several editors said, have also apparently milked tests for maximum publicity by submitting different parts of them under different authors' names to different medical journals.

A group of 12 medical journals worldwide including The Journal of the American Medical Association, The New England Journal of Medicine, The Lancet and The Annals of Internal Medicine are weighing a proposal that would require a drug trial to be listed at its start in a public database or registry as a prerequisite to its results being considered for publication. The British Medical Journal is not part of that group, which is known as the International Committee of Medical Journal Editors, but Dr. Smith said he also supported the initiative.

Editors say that a database could offer several benefits. Assigning a test a unique number could allow it to be tracked from start to finish. The results, be they positive or negative, could then be put into context with other relevant trials of the same drug. Moreover,

journal editors say that if a trial's objectives were listed at the outset, they would know how to better assess an article that presented its results.

"It would be useful for us from an editorial perspective if trials were registered, so we could see what was on the mind of investigators when they started," said Dr. Jeffrey M. Drazen, the editor of The New England Journal of Medicine.

Some critics, however, have argued that medical journals themselves have been a part of the problem. A growing number of studies in recent years have shown that journals publish more trials with positive results than those with negative or inconclusive ones. And critics say the journals have moved too slowly to address such issues.

Dr. Catherine D. DeAngelis, the editor of The Journal of the American Medical Association, said the idea of requiring trial registration had been kicking around among editors for about a decade. She said the issue came up again during a discussion at a meeting earlier this month of the International Committee of Medical Journal Editors, partly out of frustration.

"We have tried editorials," said Dr. DeAngelis. "We tried getting the pharmaceutical companies to do it. We tried talking to leaders in government. But it hasn't happened."

While Dr. Drazen and Dr. DeAngelis said their group was likely to decide over the coming months what course to follow, it is not clear how the drug industry will react. Last week, Merck said it would support the idea of a government-run test registry. And GlaxoSmithKline said it would soon begin posting on its company Web site the trial results of all its drugs on the market, including tests for potential new uses of them.

Some other companies and the drug industry's trade group, the Pharmaceutical Research and Manufacturers Association of America, said last week that they could not comment because they had not seen specific registry proposals. But one official of the trade group raised concerns that registries could release company trade secrets or present data in ways confusing to doctors and the public.

Whatever the case, the example of the little-known test of Celexa in adolescents shows how medical journals can now miss information about a major trial of a drug that is the subject of an article.

Dr. Nancy C. Andreasen, the editor of The American Journal of Psychiatry, which is the flagship publication of American Psychiatric Association, said it was the responsibility of a study's authors to provide a scholarly overview of the published articles discussed in their paper. She said that her publication did not specifically ask authors or companies that sponsor trials about unpublished studies.

"We didn't have a checklist that includes that question," Dr. Andreasen said. She added, though, that the publication regularly reviews its policies.

The Celexa trial in question was run in Europe from 1996 to 2002 and was sponsored by H. Lundbeck, the Danish company that developed the drug.

Forest Laboratories sells the drug, which is generically known as citalopram, in this country under a license with Lundbeck.

A spokesman for Lundbeck said the company reported the trial results to Forest, although he could not say when. Forest executives did not respond to written inquiries from The Times seeking that information.

But Forest executives apparently had an opportunity to know about the European test before the publication of the positive trial's results this month in The American Journal of Psychiatry. Forest executives said they presented safety data concerning potential suicide risk from both the positive study and the European trial last fall at a medical conference. It was around that time that regulators in Britain and this country expressed concerns that several antidepressants might cause some depressed teenagers to consider suicide; the issue is still under study.

The Lundbeck spokesman said that an abstract about the European trial had been presented in April at a Swedish medical meeting, and both companies said that an article about that trial was being prepared for publication. Both companies also said that they did not promote the drug's use in children because regulators had not approved it for pediatric use. (Doctors can legally prescribe a drug for any use, once it has been approved for at least one purpose.)

Dr. Andreasen and other journal editors interviewed said that a single failed trial of a drug did not mean that the treatment was ineffective, because the study's design might have been flawed. By the same token, of course, a single positive test of a drug does not necessarily mean that it works.

In a Lancet article in April, British researchers sought to compare the benefits and risks that widely used antidepressants pose for children and adolescents, based on published and unpublished data. They reported that their analysis of the pooled results from two unpublished Celexa trials - the one since published in The American Journal of Psychiatry and the European study cited in the Danish textbook - suggested that citalopram was unlikely to produce a "clinically important reduction in depressive symptoms."

"With no good evidence for efficacy and the potential for increasing the risk for suicide, the risk-benefit balance is unfavorable," the researchers reported.

Dr. Karen Dineen Wagner of the University of Texas Medical Branch in Galveston, who was the lead outside investigator on the study published in The American Journal of Psychiatry, did not respond to interview requests through a hospital spokeswoman. The two other outside researchers involved, however, both said that Celexa worked well in their test and that the young patients did not experience increased suicidal thoughts.

"I don't know what the raw data looks like from the European study," said one of them, Dr. Adelaide S. Robb of the Children's National Medical Center in Washington.

She said that she was informed by Forest executives in 1999 that the European study was under way but that she was never told that it had been completed.

Health Policy News:

Pharmaceutical Companies Overcharge 340B Hospitals

On Tuesday, June 29, 2004, investigators from the Office of the Inspector General, in the Department of Health and Human Services (HHS), confirmed that pharmaceutical companies have continually overcharged public hospitals and clinics for medications prescribed to low-income patients.

According to the section 340B of the 1992 Public Health Service Act, pharmaceutical companies are required to provide a minimum discount of approximately 15% off the manufacturer's price to public health entities supported by tax-payers' dollars. However, according to the investigators, 31% of the sampled prices were greater than the would-be discount price. Additionally, of the 37 health care providers participating in the investigation, 36 paid prices above the ceiling price put in place by Congress.

The investigation shows that within a single month, participating hospitals lost $41.1 million dollars due to overcharges on prescriptions. According to this data, the national costs of such overcharging is likely immense, as 340B participating entities spent $3.4 billion on outpatient prescription drugs last year.

William H. von Oehsen, a principal at Powers, Pyles, Sutter and Verville, P.C. and legislative counsel for the Public Hospital Pharmacy Coalition (PHPC), stated that the Coalition has long suspected overpricing and now has "independent corroboration that [those] suspicions were correct." The Public Hospital Pharmacy Coalition represents over 200 340B-participating safety net hospitals and health systems. For more information on PHPC visit www.phpcrx.org.

Under the law, no penalties exist for companies that violate the Public Health Service Act and, therefore, the government cannot step in to correct the situation. However, several legislators and invested parties are calling for legislation that inflicts penalties on pharmaceutical companies that overcharge 340B participating entities. Senator Jeff Bingaman (D-NM) has stated he is currently drafting such legislation.

Medicaid Payment Increase Expires

In 2003, the federal government granted states $10 billion in fiscal relief to temporarily increase federal Medicaid payments. However, on July 1, 2004, those increases expired and states are expected to see drops of up to 3 percentage points in their Federal Medical Assistance Percentages (FMAP).

Several states have expressed concern over the expiration of the FMAP increases. While the fiscal situations of most states have improved since 2003, many report that their Medicaid programs are still fragile and will likely suffer with the termination of this federal assistance.

Senators John D. Rockefeller (D-WV) and Gordon Smith (R-OR) have stated they plan to introduce in early July legislation extending the FMAP increases for another 15 months.

AARP Report: Drug Prices Increased First Quarter of 2004

A study released by AARP on Wednesday, June 30, 2004, shows that prices of prescription drugs increased at a rate almost three times that of inflation during the first quarter of this year. The study examines 197 pharmaceuticals commonly prescribed to individuals over the age of 50. According to the results, prices for these drugs increased 3.4% during the first quarter of 2004, while the inflation rate was only 1.2% for the same time period. Health care observers have expressed concerns over these increases, questioning whether drug prices rose in anticipation of Medicare's drug discount cards, implemented in June. AARP's report can be accessed at http://research.aarp.org/health/ib69_drugprices.pdf.

Research:

NIH Guide for Grants and Contracts - Week Of July 2, 2004
http://grants.nih.gov/grants/guide/2004/04.07.02/index.html

NOTICES

FINDINGS OF SCIENTIFIC MISCONDUCT
(NOT-OD-04-051)
Department of Health and Human Services
INDEX: HEALTH, HUMAN SERVICES
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-051.html

NOTICE OF LIMITED COMPETITION REQUEST FOR COMPETITIVE RENEWAL APPLICATION: THE BREAST CANCER SURVEILLANCE CONSORTIUM INFRASTRUCTURE
SUPPORT
(NOT-CA-04-014)
National Cancer Institute
INDEX: CANCER
http://grants.nih.gov/grants/guide/notice-files/NOT-CA-04-014.html

ADDENDUM TO PAR-04-076: PROTEOMIC AND METABOLOMIC APPROACHES TO DIAGNOSE
DIABETES AND PRE-DIABETES
(NOT-DK-04-008)
National Institute of Diabetes and Digestive and Kidney Diseases

INDEX: DIABETES, DIGESTIVE, KIDNEY DISEASES
http://grants.nih.gov/grants/guide/notice-files/NOT-DK-04-008.html

ADDENDUM TO RFA-RM-04-018, "NANOMEDICINE CENTER CONCEPT DEVELOPMENT AWARDS"
(NOT-RM-04-013)
National Institutes of Health
INDEX: HEALTH
http://grants.nih.gov/grants/guide/notice-files/NOT-RM-04-013.html

REQUESTS FOR APPLICATIONS

DISABLING INNATE IMMUNE EVASION: NEW ATTENUATED VACCINES
(RFA-AI-04-023)
National Institute of Allergy and Infectious Diseases
INDEX: ALLERGY, INFECTIOUS DISEASES
APPLICATION RECEIPT DATE: November 23, 2004
http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-04-023.html

REGIONAL BIOCONTAINMENT LABORATORIES (RBL) CONSTRUCTION PROGRAM
(RFA-AI-04-032)
National Institute of Allergy and Infectious Diseases
INDEX: ALLERGY, INFECTIOUS DISEASES
APPLICATION RECEIPT DATE: December 29, 2004
http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-04-032.html

MEASUREMENT TOOLS FOR ALTERED AUTONOMIC FUNCTION IN SPINAL CORD INJURY AND
DIABETES: SBIR/STTR
(RFA-HD-04-018)
National Institute of Child Health and Human Development
National Institute of Diabetes and Digestive and Kidney Diseases
INDEX: CHILD HEALTH, HUMAN DEVELOPMENT; DIABETES, DIGESTIVE, KIDNEY DISEASES
APPLICATION RECEIPT DATE: October 21, 2004
http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-04-018.html

PROGRAM ANNOUNCEMENTS

CNS THERAPY DEVELOPMENT FOR LYSOSOMAL STORAGE DISORDERS
(PAS-04-120)
Lysosomal Storage Disease Research Consortium
National Institute of Neurological Disorders and Stroke
Office of Rare Diseases
INDEX: LYSOSOMAL STORAGE DISEASE RESEARCH CONSORTIUM;

NEUROLOGICAL
DISORDERS, STROKE; RARE DISEASES APPLICATION RECEIPT DATE(S):
Multiple
receipt dates, see announcement
http://grants.nih.gov/grants/guide/pa-files/PAS-04-120.html

Quotes

If they want peace, nations should avoid the pin-pricks that precede cannon shots.
Napoleon Bonaparte

Peace and justice are two sides of the same coin.
Dwight D. Eisenhower

Even peace may be purchased at too high a price.
Benjamin Franklin

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