DEAN'S CORNER e-Newsletter

December 13, 2002

Looks like the Lame Duck session of Congress is finishing up without a Medicare fee fix for the poor reimbursement to providers, and the planned further cuts next year! Last-ditch efforts to give the Administration some political and legal cover to fix the problem administratively cleared the House but died in the Senate. Senators theoretically sympathetic to the fee problem were unwilling to pull out the physician piece and do it now, while leaving other popular constituencies like hospitals, nursing homes and home health agencies to wait until next year. As it now stands, CMS will issue a new fee schedule rule on or about December 1st, and it will have another cut on the order of 4.4% to the conversion factor. The effective date for the reduction will be delayed a month longer than normal, to Feb 1st, with 2002 rates remaining in effect for January. The annual window to change participation status with Medicare will also be extended somewhat. This is bad news!

As we quickly approach year's end, I wish you all season's greetings, and a healthy and happy new year!

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

Student Affairs: (Dr. Forman and Ms. Graham)

No Input

Clinical Affairs / Faculty Practice: (Dr. Adams)

Associate Dean for Clinical Affairs/Chief Medical Officer

The first quarter of FY 2003 is past and we're assessing our clinical performance. We knew that this would be an extremely challenging year and it's been reassuring to see the efforts that faculty and staff have made. It's too early to know whether our goals will be achieved, but I remain optimistic that we will be successful following the course we've established for this year. It's important that we continue to search for ways to be more efficient and more productive in our clinical activities. Medicare will cut reimbursements in January and this will begin a change that will ripple down through most of our contracts. This will be difficult to absorb, but underlines the need for best business practices and everyone's continued efforts.

Thanks to everyone who completed the annual compliance training. The web training was utilized by many of you, and seems to have been well received. If you have suggestions about how to improve this process in the future, please let us know.

During this holiday season, it is important to reflect on how fortunate we are. Although we all have daily problems, we need to remember that we live in a great country, a great city, and work in a great organization. **Thanks to everyone whose efforts make us successful**. **You are appreciated.** I believe the New Year ahead will be a good one.

NIH EXTRAMURAL LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS RELEASE DATE: December 4, 2002 NOTICE: NOT-OD-03-012 National Institutes of Health (NIH) APPLICATION RECEIPT DATE: 5 PM EST, January 31, 2003

PURPOSE OF THIS NOTICE: The National Institutes of Health (NIH) announces the extension of the deadline for the 2003 Extramural Loan Repayment Program for Clinical Researchers (LRP-CR). The LRP-CR provides for the repayment of educational loan debt of qualified health professionals who agree to conduct clinical research for two years. The program provides for the repayment of up to \$35,000 of

the principal and interest of the educational loans. The program covers the Federal taxes on the loan repayments, which are considered taxable income to program participants.

This year's program is not limited to NIH grantees as was the fiscal year 2002 requirement. The new deadline is now January 31, 2003. A full description of the Extramural Loan Repayment Program for Clinical Researchers (LRP-CR) is available at http://www.lrp.nih.gov. It details all eligibility, benefits, and application requirements; and it contains the on-line application process.

WHERE TO SEND INQUIRIES: For all program, eligibility, and application questions please call the LRP helpline at (866) 849-4047 or e-mail lrp@nih.gov. Scientific questions should be directed to the relevant NIH program contact listed on the LRP website at http://www.lrp.nih.gov/contact/index.htm.

SUBMITTING AN APPLICATION: All potential applicants are encouraged to read the eligibility requirements, benefits, and application procedures for the LRP-CR program located at the LRP website at http://www.lrp.nih.gov. Eligible applicants must submit a completed on-line application at http://www.lrp.nih.gov by January 31, 2003 at 5 PM EST.

Academic Affairs/Graduate Medical Education: (Dr. Blackwell)

Associate Dean for Academic Affairs

The National Board of Medical Examiners has continued to plan the implementation of the Clinical Skills Exam (CSE) as part of the USMLE in 2004. The NBME continues to discuss implementation with medical schools and national associations across the country.

The USMLE CSE will consist of 10-12 encounters between candidates and standardized patients. Each encounter will consist of a 15 minute session between the candidate and the standardized patient. Candidates are expected to gather information related to the patient's chief complaint, perform a focused physical exam, answer questions the patient has regarding his condition, and explain plans for further evaluation. Following the encounter, each candidate will have 10 minutes to prepare a note that documents pertinent historical and physical findings, makes an assessment of the patient's problem, and lists plans for further evaluation. During this time, the standardized patient grades the candidate's performance using carefully developed standardized checklists and rating scales. Candidates notes are subsequently scored by specialty trained physician raters.

The examination is designed to rate a candidate's ability to gather information during the history and physical examination, as well as to judge the ability to communicate findings to the patients. A candidate must pass both the information-gathering and communication components of the examination to receive a passing score. More details regarding this exam can be found at www.nbme.org

Medical Education: (Michael Martin, Ph.D.)

Acting Associate Dean for Medical Education

Our medical and physician assistants teaching programs continue at a rapid pace as we complete are fourth and fifth months of fall semester courses and clerkship rotations for Years 1-2 and Years 3-4, respectively. Meanwhile, spring semester schedules are in the final stages of preparation and will be distributed in early December.

Notable progress is being made in one of our major goals of curricular evolution, active learning strategies. Research and our own experience tells us that students learn much more, and retain information longer, when they are actively engaged with faculty rather than passively listening to a lecture. Faculty are finding the "Keypad" audience response system a particularly useful tool for actively engaging students. This system, originally introduced by our Continuing Medical Education specialists, allows students to make individual responses to a question posed to the class by using a hand-held keypad

unit similar to a TV remote controller. The question is projected as a PowerPoint slide on the screen and thus can contain unlimited text or images such as a graph, an x-ray, or a color image of a patient. Once the question is posed, the students simply press a button representing their answer choice. A radio receiver on the podium picks up the signals from the individual keypad units (up to 175 units in one room), and the associated computer software gathers, collates, and stores the data received. A computer program then generates a color graphic representation of the responses. Both the instructor and the students get immediate feedback about the question posed. This immediate feedback makes it abundantly clear whether a particular concept is well understood and by how many students. When a significant proportion of the class provides incorrect responses to a question, the instructor can immediately review the concept and the reasons why a particular answer choice was correct or incorrect. Instructors in both the Year 1 and 2 curricula are using the system to present fundamental basic and clinical science concepts, clinical cases, and quizzes.

Clinical Research: (Dr. Clearfield)

Associate Dean for Clinical Research

The Clinical Research Skills Workshop for Investigators was a success. 30 faculty and housestaff were given the basic workshop for Clinical Trials. This workshop was supported by a grant from the AOA abd Pfizer pharmaceuticals. All the participants will receive a certificate for their training and have a better basis of how to successfully approach a clinical trial.

I also would like to congratulate the department of pathology for their recent grant of \$640,000 from the Federal Bureau of Investigation for development of SNP assays for human identification.

PA Studies: (from PA Lemke)

NEWEST US SURGEON GENERAL WAS ONCE A PA

A recent news release, published through *PA World*, points out that the newest U.S. Surgeon General was at one point in his career a physician assistant. States Surgeon General Richard H. Carmona, M.D., M.P.H., FACS, was sworn in as the 17th Surgeon General of the United States Public Health Service on August 6, 2002. *PA World* reports that Dr. Carmona "... unknowingly helped lead the way as a decorated Viet Nam combat medic whose advanced medical training and medical expertise laid the foundation for what is now called the Physician Assistant profession... After having first served our country as a Special Forces medic in Vietnam, receiving the Bronze Star, a Purple Heart and a Combat Medical Badge, Dr. Carmona furthered his service to our nation by studying advanced medical training and developing medical expertise in the early formation of the Physician Assistant concept. He now holds the rank of Vice Admiral and serves as the Commander of the United States Public Health Service's Commissioned Corps, numbering around 6,000 officers.... Dr. Carmona has worked in various positions in the medical field including paramedic, registered nurse, and a physician assistant."

PA PROGRAM ADMISSIONS PROGRESS CONTINUES

As of this week, the PA program has received 239 applications, while another 201 are still in progress at the centralized application service offices. Of the 238 received so far, 158 have been applications have been evaluated and 40 applicants have been interviewed. Interviews will continue through the next few months. The program expects to enroll 28 new PA students in August of 2003. We began sending offers of acceptance in December and will continue to do so throughout the next few months until the class is filled.

PA CURRICULUM REVISIONS

PA faculty members remain involved in a review of the didactic portions of the PA curriculum. That review includes analysis of course sequencing, methods of delivery, and scope of learning objectives. A

primary question we are seeking to answer is "What are the best means for meeting the educational needs of the PA students?" The review is focused on "Year 2 courses" but is expected to incorporate (eventually) the entire curriculum model. We anticipate having a proposal ready for the Dean's review by the end of January 2003.

UNTHSC will GRADUATE ITS FIRST MASTER'S PAS IN 2003

2003 will be another banner year for the PA program because we will be graduating our very first class of PA students with Master of Physician Assistant Studies degrees. This event is significant because it marks the culmination of many years of growth and effort by the Health Science Center's PA program. UNTHSC is host to the first "state-funded" master's PA program in Texas. And for the first time ever at UNTHSC, after the PA Class of 2005 finishes clinical rotations, the PA students will have an opportunity to participate in the same commencement ceremony as their fellow TCOM graduates; alongside graduates from the GSBS and the SPH.

Science and Health News:

NEW YORK TIMES-December 11, 2002 After Long Hiatus, New Contraceptives Emerge After years of little innovation in birth control, an assortment of new methods offering a broad variety of choices is emerging, including a skin patch that is changed weekly, a hormone-enhanced IUD and a permanent sterilization procedure that requires no anesthesia. All the new contraceptives are directed at women, and none of them offer proven protection against sexually transmitted diseases. But the new devices offer longer-lasting alternatives to a daily pill and are viewed as long overdue in light of an estimated three million unplanned pregnancies in the United States each year, about half of them ending in abortion. The lack of variety in birth control for Americans can be traced to a tangle of issues, including the length of time it takes to develop any new medical product and a deeply rooted Puritanical culture. Basic biology has figured in the delay of a long-awaited male pill, since it is easier to suppress one egg a month than millions of sperm all the time. The chilling effect of controversy has had a role, too. Several experts, including manufacturers, said the current crop of contraceptives were influenced by the stormy history of Norplant, a device that was hailed as the greatest innovation in birth control since the pill, but it was taken off the market in July. Click here to read more.

STATINS: Miracles for Some, Menace for a Few **By JANE E. BRODY:** Statins have been hailed as miracle drugs for their ability to prevent deaths from heart attacks by lowering cholesterol. Some doctors go so far as to say the statins have had a greater effect on heart disease than anything else introduced in the last 50 years. Last year, a national group of experts issued guidelines saying statins should be prescribed to some 36 million Americans, three times as many as were taking them then, to reduce their risk of heart disease. In addition to protecting people at high risk, statins protect people who have already suffered one heart attack.

Three large studies have shown that statins reduce the risk of second heart attacks by 30 percent and the risk of death from second heart attacks by 40 percent. There are also strong hints that statins may protect against strokes, Alzheimer's disease and osteoporosis and may perhaps one day be useful in treating multiple sclerosis and other autoimmune diseases. Given their apparent wide range of actions, statins have been called the modern-day equivalent of aspirin. Some experts have even suggested that they be sold over the counter. But like aspirin and all other drugs, statins sometimes cause serious side effects. The most serious involves the muscles, a disorder called rhabdomyolysis, rare but debilitating and deadly if not detected in its early stages. In August 2001, Bayer voluntarily recalled cerivastatin, marketed as Baycol, after 31 people died from rhabdomyolysis caused by the drug. This complication occurs far less often with the five statins still on the market, but any and all of them can occasionally cause muscle disorders, even years after the drugs have been used with no apparent ill effects.

And, it appears, many patients are unaware of the signs of trouble associated with statins, and many prescribing doctors fail to warn patients about dangerous drug interactions or to perform the periodic tests needed to assure continued safe use of a prescribed statin. For example, last summer an 82-year-old Kansas woman died as a result of longstanding but undetected muscle disease caused by the statin she had been taking for years to control her cholesterol. For the entire time she was taking it, the woman experienced muscle pains that were never properly attributed to the drug. She even had a shoulder operation, which did nothing, of course, to cure the drug-induced pain that might have been correctly diagnosed through a simple blood test. Then she was mistreated with an antifungal agent for skin lesions that actually resulted, not from a fungus, but from the muscle breakdown caused by the drug.

When combined with statins, the antifungals can greatly increase the risk and severity of muscle disorders. Within three months, the woman's condition worsened and she became so weak she could not stand or breathe on her own. Two weeks later, she was dead.

Statins may also cause a liver disorder in about 1 percent of patients. Because of that, everyone taking them should have a periodic blood test to spot early signs of trouble.

How Statins Help: The five statins now on the market are Lipitor (atorvastatin), Mevacor (lovastatin), Zocor (simvastatin), Pravachol (pravastatin) and Lescol (fluvastatin).

They all work to lower blood levels of cholesterol by the same mechanism: they inhibit a liver enzyme called HMG CoA reductase that enables the liver to make cholesterol. The liver is the body's main source of cholesterol, a fatty alcohol needed to form important hormones and perform other critical cell functions. When the liver cannot make its own, it removes cholesterol from the blood to fulfill these bodily needs. Thus, blood levels of cholesterol fall and the tendency for arteries to become clogged with fatty deposits is reduced.

Furthermore, statins reduce only the levels of the so-called bad cholesterol, L.D.L., or low-density lipoprotein, which promotes arterial clogging. Statins can also lower another damaging blood fat, triglyceride, somewhat. But the "good" cholesterol — protective H.D.L., or high-density lipoprotein, which acts like an arterial drain cleaner — actually rises in most people who take a statin drug.

But while cholesterol reduction may be the main effect of statins, the drugs are thought to perform in several other ways to reduce cardiovascular risk. They appear to stabilize the deposits on artery walls, reducing the chance that clumps will break loose and block major vessels. They also relax blood vessels, inhibit clotting and may promote the growth of new vessels, all actions that would make heart attacks and strokes less likely.

Perhaps statins' most exciting and potentially most beneficial action seems to be their ability to reduce inflammation, which may play a major role in arterial disease, heart attacks and strokes and is a critical factor in flare-ups of autoimmune diseases.

Detecting a Statin Hazard: In a clinical advisory issued recently, the American College of Cardiology, the American Heart Association and the National Heart, Lung and Blood Institute noted that statins had proved "to be extremely safe in the vast majority of patients receiving them."

But the advisory warned doctors about possible serious adverse effects and factors that could increase the risk of statin-caused muscle disorders. "A common complaint," the advisory stated, "is nonspecific muscle aches or joint pains." But far more rare is severe myositis characterized by muscle aches, soreness or weakness and associated with greatly elevated levels of an enzyme, creatine kinase, indicative of muscle breakdown.

If this occurs and the drug is not immediately discontinued, myositis can progress to complete muscle breakdown, or rhabdomyolysis, kidney failure and death. These conditions can occur at any time in statin therapy. The advisory noted that adverse muscle reactions were less likely when lower doses of statins were prescribed, rather than the maximum dosage approved by the Food and Drug Administration.

Severe muscle damage is more likely to occur when statins are combined with certain other medicines, including fibrates (like gemfibrozil) and niacin (used to treat blood lipids); the immunosuppressant cyclosporine; certain antifungal drugs (including ketoconazole); macrolide antibiotics, erythromycin and clarithromycin; H.I.V. protease inhibitors; the antidepressant nefazodone; verapamil, used to treat certain heart abnormalities; and more than a quart a day of grapefruit juice.

Other factors that raise the risk of adverse muscle reactions include advanced age, especially over 80; a small body frame and frailty; chronic kidney disease, especially related to diabetes; and concurrent surgery.

Statins should be stopped in anyone soon to have major surgery. Anyone experiencing muscle pain of unknown origin while taking statins should contact the doctor without delay. If a blood test shows a very high level of creatine kinase, the drug should be stopped immediately.

All patients taking statins should have periodic blood tests for the liver enzyme transaminase, which is elevated when the liver is being damaged. In addition, the advisory stated, statins should not be prescribed for patients with acute or chronic liver disease, although there is as yet no clear evidence that statins worsen existing liver disease.

Health Policy News:

<u>CMS Scrutinizes Medicare Outlier Payments</u>: In a Dec. 3 press release and program memorandum, the Centers for Medicare and Medicaid Services (CMS) announced it is directing its fiscal intermediaries to identify hospitals that have been receiving large amounts of Medicare outlier payments. Further compliance actions against hospitals that may be *abusing* the outlier policy, including possible referrals to the Office of Inspector General, will be announced in another program memorandum to be issued by Dec. 15.

CDC Set to Release Select Agents Rule: The CDC Dec. 2 announced in the Federal Register that it will release its interim final rule on the *Possession, Use, and Transfer of Select Agents and Toxins* on Dec. 9. The widely anticipated rule, mandated by the Public Health Safety and Bioterrorism Preparedness and Response Act signed by President Bush in June, will govern universities and other institutions in handling select biological agents that might be misused for terrorism.

White House Releases DHS Reorganization Plan: Upon signing legislation (P.L. 107-296) Nov. 25 creating the new Department of Homeland Security (DHS), the President released a reorganization proposal setting deadlines and outlining the functions that fall under the four directorates in the department: Information Analysis and Infrastructure Protection; Science and Technology; Border and Transportation Security; and Emergency Preparedness and Response.

<u>CMS Announces Changes to Physician Documentation Requirements</u>: The Centers for Medicare and Medicaid Services (CMS) Nov. 22 published changes to the Carrier Manual Instructions (CMI), Section 15016, Supervising Physicians in Teaching Settings. The revised CMI should

significantly reduce the documentation burden on teaching physicians for E/M services when a resident also is involved in the care of a patient.

<u>NIH Extends Deadline for Loan Repayment Programs</u>: NIH has extended the application deadline for its loan repayment programs for clinical researchers and pediatric researchers until Jan. 31, 2003.

<u>VA Names New Research Chief:</u> The Department of Veterans Affairs (VA) Dec. 4 announced the appointment of Nelda P. Wray, M.D., as the VA*s new Chief Research and Development Officer.

Research and Funding Opportunities:

= Call for Abstracts =

"The National Academies of Practice and Interdisciplinary Health Care Team Conference", scheduled for May 9-10, 2003 at the Sheraton Crystal City Hotel, Arlington, VA, has a call for abstracts on "Health Professions' Role in Preventing Violence". For additional information, contact Linda Crawford, Administrative Specialist, Office of the Dean, College of Health and Human Services, Bowling Green State University, Bowling Green, OH 43403-0280, email: lcrawfo@bgnet.bgsu.edu, (419)732-8243; fax (419)372-0599. The deadline for submission is January 10, 2003.

Bush Signs Bills Allowing Funds for Rare Disease Research, Creating New NIH Office [Nov 08, 2002] President Bush on Nov. 6 signed two bills (HR 4013 (http://thomas.loc.gov/cgibin/query/z?c107:h.r.4013:) and HR 4014 (http://thomas.loc.gov/cgi-bin/query/z?c107:h.r.4014)) that aim to bolster medical research on rare diseases, the AP/Long Island Newsday (http://www.newsday.com/news/politics/wire/sns-ap-bush-billssigned1107nov06,0,7712802.story?coll=sns-ap-politics-headlines) reports (AP/Long Island Newsday, 11/6). Rare diseases are defined as those affecting fewer than 200,000 people. Some 25 million people in the United States are diagnosed with "at least one" of the 6,000 known rare disorders, including Tourette syndrome; ALS, also known as Lou Gehrig's disease; and sickle cell anemia (National Organization for Rare Disorders release (http://www.rarediseases.org/washington/bush signs), 11/7). The first bill will establish an Office of Rare Diseases at NIH and also set up "regional centers of excellence" for research on rare diseases or medical conditions. The second bill allows for but does not allocate federal funds to be given as grants and "contracts" to develop drugs to treat rare diseases, the AP/Newsday reports (AP/Long Island Newsday, 11/6). Diane Dorman, vice president for public policy at the National Organization for Rare Diseases, said, "The bills authorize increased funding for both NIH and FDA research programs, but lawmakers still must approve the funds to finance them. So we'll be turning to ... the 108th Congress [for help] to ensure that the programs are fully funded in accordance with Congressional intent," adding, "Our work is still cut out for us" (NORD release, 11/7).

Quotes

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

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

An eye for eye only ends up making the whole world blind. *Mohandas Gandhi*

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