

United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

September 9, 2008

Via Electronic Transmission

Mark G. Yudof
Chancellor
The University of Texas System
201 West Seventh Street
Austin, TX 78701

Dear Mr. Yudof:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by recognized experts, like those at the University of Texas (University/Texas System) system's medical schools who are discussed throughout this letter, often have a profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

Moreover, and as has been detailed in several studies and news reports, funding by pharmaceutical companies can influence scientific studies, continuing medical education, and the prescribing patterns of doctors. Because I am concerned that there has been little transparency on this matter, I have sent letters to almost two dozen research universities across the United States. In these letters, I asked questions about the conflict of interest disclosure forms signed by some of their faculty. Universities require doctors to report their related outside income, but I am concerned that these requirements are sometimes disregarded.

I have also been taking a keen interest in the almost \$24 billion annually appropriated to the National Institutes of Health (NIH) to fund grants at various institutions such as yours. As you know, institutions are required to manage a grantee's conflicts of interest.^[1] But I am learning that this task is made difficult because physicians do not consistently report all the payments received from drug and device companies.

^[1] Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).

To bring some greater transparency to this issue, Senator Kohl and I introduced the Physician Payments Sunshine Act (Act). This Act will require drug and device companies to report publicly any payments that they make to doctors, within certain parameters.

I am writing to assess the implementation of financial disclosure policies of the University of Texas system. In response to my letters of October 26, 2007, your University provided me with the financial disclosure reports that Dr. Augustus John Rush, Jr., at the University of Texas Southwestern Medical Center at Dallas (UTSW) and Dr. Karen Wagner at the University of Texas Medical Branch at Galveston (UTMB) filed during the period of January 2000 through June 2007. (the Physicians)

My staff investigators carefully reviewed each of the Physicians' disclosure forms and detailed the payments disclosed. I then asked that the University confirm the accuracy of the information. In February 2008 your counsel provided clarification and additional information from the Physicians pursuant to my inquiry.

In addition, I contacted executives at several major pharmaceutical companies and device manufacturers (the Companies) and asked them to list the payments that they made to Drs. Wagner and Rush during the years 2000 through 2007. These Companies voluntarily and cooperatively reported additional payments that the Physicians do not appear to have disclosed to the University.

Because these disclosures do not match, I am attaching a chart intended to provide a few examples of the data reported to me. This chart contains columns showing the payments disclosed in the forms the Physicians filed with the University and amounts reported by some of the Companies.

I understand that UTMB did not require that dollar amounts be reported in financial disclosures until 2002, despite federal requirements which required such reporting for NIH grantees in 1995. I also understand that UTSW's disclosures do not disclose if payments were made during a calendar year or an academic year.

I would appreciate further information to see if the problems I have found with these two Physicians are systemic within the University System.

INSTITUTIONAL AND NIH POLICIES

The Texas System requires that all compensation (income or monetary value given in return for services) be reported. Its policies consider compensation in the aggregate that meet or exceeded \$10,000 for the current calendar year, or are expected to meet or exceed that amount in the next 12 months, to be a significant financial interest.

Further, federal regulations place several requirements on a university/hospital when its researchers apply for NIH grants.^[2] These regulations are intended to ensure a

^[2] Id.; see also <http://grants.nih.gov/grants/partners/0706NIHExtramuralNexus.pdf>.

level of objectivity in publicly funded research, and state in pertinent part that NIH investigators must disclose to their institution any “significant financial interest”^[3] that may appear to affect the results of a study. NIH interprets “significant financial interest” to mean at least \$10,000 in value or 5 percent ownership in a single entity.

Based upon information available to me, it appears that each of the Physicians identified above received NIH grants to conduct studies. During the years 2003-2005, Dr. Rush received an NIH grant to conduct a clinical intervention training program that was to provide trainees with, among other things, “...knowledge and experience in the proper conduct of clinical intervention research, ethics, human subjects issues...”^[4] However, my inquiry discovered that Dr. Rush did not disclose all of the drug and device industry payments to the University. For example, in 2001, Dr. Rush disclosed \$3,000 in outside income for his work as an Advisory Board member for the Eli Lilly Company (Lilly). In contrast, Lilly reported to me that it paid Dr. Rush \$17,802 for advisory services that year.

For calendar years 2000 through 2008, Dr. Wagner led NIH-funded studies on depression. These studies involved drugs produced by Lilly (Prozac) and GlaxoSmithKline (GSK) (Paxil).^[5] Lilly reported to me that it paid Dr. Wagner over \$11,000 in 2002. However, and based upon the information in my possession, Dr. Wagner did not disclose this payment to the University in 2002 the first year that UTMB required financial disclosures from its faculty.

It seems that Dr. Wagner also did not report payments she received from GSK. GSK reported paying Dr. Wagner \$53,220 in 2000--the first year of the NIH grant. Further, GSK reported paying her \$18,255 in 2001, and \$34,961 in 2002 and 31,799 in 2003. Between the years of 2000 through 2005, GSK reported paying Dr. Wagner \$160,404. The only report Dr. Wagner made of these payments was in 2005 when she reported \$600 from GSK.

In light of the information set forth above, I ask your continued cooperation in examining conflicts of interest. In my opinion, institutions across the United States must be able to rely on the representations of its faculty to ensure the integrity of medicine, academia, and the grant-making process. At the same time, should the Physician Payments Sunshine Act become law, institutions like yours will be able to access a database that will set forth the payments made to all doctors, including your faculty members.

^[3] “Significant Financial Interest” is defined by the regulation as anything of monetary value, including but not limited to: salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights).

^[4] Mood Disorders Clinical Intervention Training Program, Grant Number 5T32MH067543.

^[5] Treatment of SSRI Resistant Depression in Adolescents, start September 2000, end August 2008 (NIH grant number 5U01MH061856).

Accordingly, I request that your respective institutions respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with the appropriate answer.

- 1) For each of the NIH grants received by the Physicians, please confirm that the Physicians reported to the University of Texas System's designated official "the existence of [a] conflicting interest." Please provide separate responses for each grant received for the period from January 1, 2000 to the present, and provide any supporting documentation for each grant identified.
- 2) For each grant identified above, please explain how the University ensured "that the interest has been managed, reduced, or eliminated." Please provide an individual response for each grant that each of the Physicians received from January 2000 to the present, and provide any documentation to support each claim.
- 3) Please report on the status of the University's review of the discrepancies in the financial disclosures made by Drs. Rush and Wagner to the University, including what action, if any, will be considered.
- 4) For Drs. Rush and Wagner, please report whether a determination can be made as to whether or not there is/was a violation of the guidelines governing clinical trials and the need to report conflicts of interest to an institutional review board (IRB). Please respond by naming each clinical trial for which the doctor was the principal investigator, along with confirmation that conflicts of interest were reported, if possible.
- 5) Please provide a total dollar figure for all NIH monies received annually by the Texas System. This request covers the period of 2000 through 2007.
- 6) Please provide a list of all NIH grants received by the University of Texas System. This request covers the period of 2000 through 2007. For each grant please provide the following:
 - a. Primary Investigator;
 - b. Grant Title;
 - c. Grant number;
 - d. Brief description; and
 - e. Amount of Award.

Thank you again for your continued cooperation and assistance in this matter. As you know, in cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than September 23, 2008. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

Attachment

**Selected Disclosures by Dr. Rush and Related Information Reported by
Pharmaceutical Companies and Device Manufacturers**

Year	Company	Disclosure Filed with Institution	Amount Company Reported
2000	Bristol Myers Squibb	\$4,000	\$2,576
	Eli Lilly	Not reported	\$7,718
	Merck	\$23,800	n/a
	Pfizer	No Amount Provided	\$1,000
2001	Bristol Myers Squibb	Not reported	\$2,921
	Eli Lilly	\$3,000	\$17,802
	Merck ^a	\$30,000	n/a
	Merck ^b	\$30,600	n/a
2002	Bristol-Myers Squibb	No amount provided	\$5,000
	Eli Lilly	\$3,000	\$4,500
	Merck	\$70,000	n/a
	Pfizer	No amount provided	\$7,500
2003	Bristol-Myers Squibb	No amount provided	\$250
	Cyberonics	\$25,000	≤ \$75,000
	Eli Lilly	\$3,000	\$0
	Merck	\$40,000	n/a
2004	Bristol-Myers Squibb	\$250	\$750
	Cyberonics	\$56,250	≤ \$75,000
	Eli Lilly	\$2,000	\$2,000
	Forest Pharmaceuticals	\$5,000	n/a
	Telesessions (Forest Labs)	\$18,000	n/a
2005	Cyberonics	≤\$25,200 ^c	\$62,000 ^e
	Eli Lilly	\$2,000.00	\$0
	Merck ^d	≤\$14,000	n/a
	Telesessions (Forest Labs)	≤\$15,000 ^f	n/a
2006	Cyberonics	≥\$10,000	\$100,000 ^c
	Telesessions (Forest Labs)	≤\$25,000 ^g	n/a
2007	Pfizer	\$2,000	\$2,000

^a Dr. Rush reported on 7/11/01 statement of financial interests for serving as advisory board member.

^b Dr. Rush reported in a request for prior approval of outside employment for services as consultant to U.S. Strategic Advisory Board for Substance P Antagonists.

^c Dr. Rush reported in a request for prior approval of outside employment for \$600 per hour (October 1, 2005 to October 1, 2007) for a maximum of 42 hours each calendar quarter. Payment for services as Chair of Depression Scientific Advisory Board and Consultant on issues related to clinical studies involving the use of vagus nerve stimulation therapy.

^d Dr. Rush reported in a request for prior approval of outside employment for \$3,500 per day (January 1, 2005 to December 31, 2006) for 4 days per year plus teleconferences. Payment for services as Insomnia Advisory Board Member.

^e Payments reported by Cyberonics for consultation services performed during the year shown, although some of the checks were issued in a different year.

^f Dr. Rush reported in a request for prior approval of outside employment for \$1,000 per call (15 hours per year). Payment for services as a faculty speaker on a series of conference calls as an educational service to physicians.

^g Dr. Rush reported in a request for prior approval of outside employment for \$1,000 per call (25 calls about 50 minutes each). Payment for faculty speaker on a series of conference calls as an educational service to physicians.

Note 1: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported." The Committee contacted several companies for payment information and the notation n/a (not available) reflects that a company was not contacted.

Note 2: The Committee estimated that the payments Dr. Rush disclosed totaled about \$600,000 during the period January 2000 through June 2007. Information reported by the pharmaceutical companies indicate that they made additional payments that are not reflected in his disclosures.

**Selected Disclosures by Dr. Wagner and Related Information Reported by
Pharmaceutical Companies and Device Manufacturers**

Year	Company	Disclosure Filed with Institution	Amount Company Reported
2000 ^a	GlaxoSmithKline	Not reported	\$53,220 ^b
	Pfizer	Not reported	\$5,000
2001 ^a	Bristol Myers Squibb	Not reported	\$4,194
	GlaxoSmithKline	Not reported	\$18,255 ^c
	Pfizer	Not reported	\$3,000
2002	Eli Lilly	Not reported	>\$11,000
	GlaxoSmithKline	Not reported	\$34,961
	Pfizer	Not reported	\$2,500
2003	Eli Lilly	Not reported	\$9,750
	GlaxoSmithKline	Not reported	\$31,799
	Pfizer	Not reported	\$6,350
2004	AstraZeneca	Not reported	\$2,100
	Eli Lilly	Not reported	\$8,632
	GlaxoSmithKline	Not reported	\$17,371
	Pfizer	Not reported	\$1,000
2005	AstraZeneca	\$2,100	\$0
	Abbott Labs	\$14,000	n/a
	Eli Lilly	Not reported	\$300
	Pfizer	\$3,500	\$6,000
	GlaxoSmithKline	\$600	\$4,796 ^d
2006	Abbott Labs	\$10,000	n/a
	Bristol Myers Squibb	\$5,400	\$7,204
	Eli Lilly	\$4,531	\$4,531
2007	Bristol Myers Squibb	\$1,500	\$1,500
	Eli Lilly	\$3,281	\$3,281

^a The University of Texas Medical Branch at Galveston's conflict of interest policy did not provide for annual disclosures until 2002.

^b Payments for 19 talks on Paxil.

^c Payments for 7 talks on Paxil.

^d Honorarium and Expense. Paxil Psychiatry Advisory Board Member. Waldorf Astoria, 301 Park Ave. New York, NY. February 17, 2005.

Note 1: When a Physician named a company in a disclosure but did not provide an amount, the text reads “no amount reported.” When a Physician did not list the company in the disclosure, the column reads “not reported.” The Committee contacted several companies for payment information and the notation n/a (not available) reflects that a company was not contacted.

Note 2: The Committee estimated the payments Dr. Wagner disclosed totaled about \$100,000 during the period January 2000 through June 2007. Information reported by the pharmaceutical companies indicate that they made additional payments that are not reflected in her disclosures.