UNC Board of Governors - Personnel and Tenure Committee
Overview of Conflict of Interest Policy Update

The U.S. Public Health Service (PHS) issued a final rule August 23, 2011 changing the requirements for the disclosure and reporting of financial interests of faculty researchers and institutions that apply for or receive funding from the National Institutes of Health (NIH). Institutions must be in compliance with the final rule by August 24, 2012.

The UNC System received over $1.1B in external funding in FY 2010 with approximately 46% awarded by PHS/NIH. UNC-CH receives ~60% of its external funds from the NIH and all UNC campuses except NCSSM and UNCSA have received some NIH funding.

Why are we seeing changes now?

Growing complexity of interaction among government, research institutions and the private sector in the research enterprise

Events over the last several years involving medical school/clinical faculty and their financial interests in pharmaceutical firms that either sponsor their research or whose drugs they are testing (links and attached)

http://chronicle.com/article/Emory-U-Penalizes-Another/47727/
http://www.nytimes.com/2009/03/03/business/03medschool.html

The PHS/NIH want greater transparency, greater assurance that research results are not biased and greater accountability from institutions and investigators

What policies are in place now?

PHS sets the tone for most federal regulations that affect UNC researchers. Both PHS and the National Science Foundation (NSF) have agency-specific conflict of interest policies that apply to faculty funded by these agencies. We expect NSF to adopt the PHS changes in the coming years.

Current UNC policy was last amended in 2006. It provides broad direction to campuses and applies to all faculty/EPA non-faculty. Some campuses have adopted implementing policies and procedures that exceed the requirements of the BOG policy.

How has the UNC System responded to-date?

The proposed regulatory changes surfaced early in 2010 and comments were submitted by the research community to the PHS in late summer. Presentations about the proposed changes and final rule have been presented to the Chief Academic Officers, Chief Research Officers, the University Attorneys and the Sponsored Programs and Research Council.

A team comprised of conflict of interest/research compliance, technology transfer and legal affairs staff completed a review of the proposed changes, has reviewed the final rule and has proposed updates to BOG policy for alignment with the final rule and campus policies.

Richard Best, NCSU, Res. Compliance
Joy Bryde, UNC-CH COI Officer
John Chinn, ECU, Research Compliance
Donna Eaton, NCA&T, Compliance Officer
Undi Hoffler, NCCU, Compliance Officer
Cathy Innes, UNC-CH, Tech. Transfer
Carl Mahler, UNCC, Tech. Transfer
Paul Zigas, ECU, Legal Affairs
Sarah Smith, UNCGA, Sponsored Programs
David Harrison, UNC-GA, Legal Affairs

How will UNC System proceed?

We have an opportunity to harmonize BOG and campus policies. Specific changes include: expansion of definitions, acknowledgement of prevailing federal regulations, improved organization of information and the addition of a "Guidelines" section that provides more structured parameters for the development of campus implementing policies and procedures.

Continue the vetting process for change to BOG policy to include campus input from functional stakeholders including CAOs, CROs, University Attorneys and internal auditors.

What are our specific concerns about the new regulations?

Requirement that campuses determine if a disclosed financial interest is related to the employee's institutional responsibilities

The de minimis threshold in lowered, the scope of outside compensation subject to disclosure is broadened and sponsored travel must also be disclosed

Reporting for financial interests held in the previous 12 months (prior requirement was disclosure of anticipated interests in the coming 12 months)

Mandatory training requirement

Increased reporting requirements for institutions (to PHS/NIH)

Public accessibility to disclosed financial interests for which a management plan is required through website or written response to inquiries

When do campuses have to be in compliance?

Institutions that apply for or receive funding from PHS must certify they are in compliance by August 24, 2012.

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Emory U. Penalizes Another Psychiatrist With Hidden Financial Conflicts of Interest

Emory U. Penalizes Another Psychiatrist With Hidden Financial Conflicts of Interest

Emory University has yet another case of a psychiatrist with hidden financial conflicts of interest involving the pharmaceutical industry.

The university's medical-school dean, Thomas J. Lawley, issued a letter of reprimand to Zachary N. Stowe, a professor of psychiatry, after learning that Dr. Stowe was being paid by GlaxoSmithKline, a manufacturer of antidepressants, at the same time Dr. Stowe was conducting a federally backed study of the use of the drugs in pregnant women, The Wall Street Journal reported today.

The case followed the resignation last year of Charles B. Nemeroff as chairman of Emory's psychiatry department after Dr. Nemeroff failed to report more than $800,000 he received from Glaxo over a seven-year period.

Emory's School of Medicine last week issued another updated policy on financial conflicts of interest. The new policy bans Emory faculty and staff members, students, and trainees from receiving any industry compensation for speaking engagements; prohibits any receipt of gifts; allows industry representatives to enter Emory facilities for "necessary interactions" only; and further restricts the involvement of Emory faculty members in start-up companies. — *Paul Basken*

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The New York Times

March 3, 2009

Harvard Medical School in Ethics Quandary

By DUFF WILSON

BOSTON — In a first-year pharmacology class at Harvard Medical School, Matt Zerden grew wary as the professor promoted the benefits of cholesterol drugs and seemed to belittle a student who asked about side effects.

Mr. Zerden later discovered something by searching online that he began sharing with his classmates. The professor was not only a full-time member of the Harvard Medical faculty, but a paid consultant to 10 drug companies, including five makers of cholesterol treatments.

"I felt really violated," Mr. Zerden, now a fourth-year student, recently recalled. "Here we have 160 open minds trying to learn the basics in a protected space, and the information he was giving wasn't as pure as I think it should be."

Mr. Zerden's minor stir four years ago has lately grown into a full-blown movement by more than 200 Harvard Medical School students and sympathetic faculty, intent on exposing and curtailing the industry influence in their classrooms and laboratories, as well as in Harvard's 17 affiliated teaching hospitals and institutes.

They say they are concerned that the same money that helped build the school's world-class status may in fact be hurting its reputation and affecting its teaching.

The students argue, for example, that Harvard should be embarrassed by the F grade it recently received from the American Medical Student Association, a national group that rates how well medical schools monitor and control drug industry money.

Harvard Medical School's peers received much higher grades, ranging from the A for the University of Pennsylvania, to B's received by Stanford, Columbia and New York University, to the C for Yale.

Harvard has fallen behind, some faculty and administrators say, because its teaching hospitals are not owned by the university, complicating reform; because the dean is fairly new and his predecessor was such an industry booster that he served on a pharmaceutical company board; and because a crackdown, simply put, could cost it money or faculty.

Further, the potential embarrassments — a Senate investigation of several medical professors, the F grade, a new state law effective July 1 requiring Massachusetts doctors to disclose corporate gifts over $50 — are only now adding to pressure for change.

The dean, Dr. Jeffrey S. Flier, who says he wants Harvard to catch up with the best practices at other leading medical schools, recently announced a 19-member committee to re-examine his school's conflict-of-interest policies. The group, which includes three students, is to meet in private on Thursday.

Advising the group will be Dr. David Korn, a former dean of the Stanford Medical School who started work at Harvard about four months ago as vice provost for research. Last year he helped the Association of American Medical Colleges draft a model conflict-of-interest policy for medical schools.

The Harvard students have already secured a requirement that all professors and lecturers disclose their industry ties in class — a blanket policy that has been adopted by no other leading medical school. (One Harvard professor's disclosure in class listed 47 company affiliations.)

"Harvard needs to live up to its name," said Kirsten Austad, 24, a first-year Harvard Medical student who is one of the movement's leaders. "We are really being indoctrinated into a field of medicine that is becoming more and more commercialized."

David Tian, 24, a first-year Harvard Medical student, said: "Before coming here, I had no idea how much influence companies had on medical education. And it's something that's purposely meant to be under the table, providing information under the guise of education when that information is also presented for marketing purposes."

The students say they worry that pharmaceutical industry scandals in recent years — including some criminal convictions, billions of dollars in fines, proof of bias in research and publishing and false marketing claims — have cast a bad light on the medical profession. And they criticize Harvard as being less vigilant than other leading medical schools in monitoring potential financial conflicts by faculty members.

Dr. Flier says that the Harvard Medical faculty may lead the nation in receiving money from industry, as well as government and charities, and he does not want to tighten the spigot. "One entirely appropriate source, if done properly, is industrial funds," Dr. Flier said in an interview.

And school officials see corporate support for their faculty as all the more crucial, as the university endowment has lost 22 percent of its value since last July and the recession has caused philanthropic contributors to retrench. The school said it was unable to provide annual measures of the money flow to its faculty, beyond the $8.6 million that pharmaceutical companies contributed last year for basic science research and the $3 million for continuing education classes on campus. Most of the money goes to professors at the Harvard-affiliated teaching hospitals, and the dean's office does not keep track of the total.

But no one disputes that many individual Harvard Medical faculty members receive tens or even hundreds of thousands of dollars a year through industry consulting and speaking fees. Under the school's disclosure rules, about 1,600 of 8,900 professors and lecturers have reported to the dean that they or a family member had a financial interest in a business related to their teaching, research or clinical care. The reports show 149 with financial ties to Pfizer and 130 with Merck.

The rules, though, do not require them to report specific amounts received for speaking or consulting, other than broad indications like "more than $30,000." Some faculty who conduct research have limits of $30,000 in stock and $20,000 a year in fees. But there are no limits on companies' making outright gifts to faculty — free meals, tickets, trips or the like.

Other blandishments include industry-endowed chairs like the three Harvard created with $8 million from sleep research companies; faculty prizes like the $50,000 award named after Bristol-Myers Squibb, and sponsorships like Pfizer's $1 million annual subsidy for 20 new M.D.'s in a two-year program to learn clinical investigation and pursue Harvard Master of Medical Science degrees, including classes taught by Pfizer scientists.

Dr. Flier, who became dean 17 months ago, previously received a $500,000 research grant from Bristol-Myers Squibb. He also consulted for three Cambridge biotechnology companies, but says that those relationships have ended and that he has accepted no new industry affiliations.

That is in contrast to his predecessor as dean, Dr. Joseph B. Martin. Harvard's rules allowed Dr. Martin to sit on the board of the medical products company Baxter International for 5 of the 10 years he led the medical school, supplementing his university salary with up to $197,000 a year from Baxter, according to company filings.

Dr. Martin is still on the medical faculty and is founder and co-chairman of the Harvard NeuroDiscovery Center, which researches degenerative diseases, and actively solicits industry money to do so. Dr. Martin declined any comment.

A smaller rival faction among Harvard's 750 medical students has circulated a petition signed by about 100 people that calls for "continued interaction between medicine and industry at Harvard Medical School."

A leader of the group, Vijay Yanamadala, 22, said, "To say that because these industry sources are inherently biased, physicians should never listen to them, is wrong."

Encouraging them is Dr. Thomas P. Stossel, a Harvard Medical professor who has served on advisory boards for Merck, Biogen Idec and Dyax, and has written widely on academic-industry ties. "I think if you look at it with intellectual honesty, you see industry interaction has produced far more good than harm," Dr. Stossel said. "Harvard absolutely could get more from industry but I think they're very skittish. There's a huge opportunity we ought to mine."

Brian Fuchs, 26, a second-year student from Queens, credited drug companies with great medical discoveries. "It's not a problem," he said, pointing out a classroom window to a 12-story building nearby. "In fact, Merck is right there."

Merck built a corporate research center in 2004 across the street from Harvard's own big new medical research and class building. And Merck underwrites plenty of work on the Harvard campus, including the immunology lab run by Dr. Laurie H. Glimcher — a professor who also sits on the board of the drug maker Bristol-Myers Squibb, which paid her nearly $270,000 in 2007.

Dr. Glimcher says industry money is not only appropriate but necessary. "Without the support of the private sector, we would not have been able to develop what I call our 'bone team' in our lab," she said at a recent student and faculty forum to discuss industry relationships. Merck is counting on her team to help come up with a successor to Fosamax, the formerly $3 billion-a-year bone drug that went generic last year. But Dr. Marcia Angell, a faculty member and former editor in chief of The New England Journal of Medicine, is among the professors who argue that industry profit motives do not correspond to the scientific aims of academic medicine and that much of the financing needs to be not only disclosed, but banned. Too many medical schools, she says, have struck a "Faustian bargain" with pharmaceutical companies.

"If a school like Harvard can't behave itself," Dr. Angell said, "who can?"