



Nesreen Berwari and Kennedy School classmates Michael Fenzel (left) and Michael Shinnars with fellow Kennedy School alumnus Stafford Clarry, M.P.A. '90, in Erbil, in the Kurdish region of Iraq.

Society, and spoke to students in the Harvard Hippocratic Society. She says she was in daily e-mail contact with many Iraqi doctors following her visit, but adds, "For a while after the revelations of prisoner abuse at Abu Ghraib, the number of e-mails went way down. Now they're back up again." A few Iraqi colleagues wrote her on July 4 to wish her a happy holiday.

Under any circumstances, Ritchie admits, the connection between the academy and the military is likely to be uneasy. "I'm careful about proclaiming my Ivy Leagueness, for fear it might not go over well." She notes that at her fifteenth reunion, her Harvard classmates expressed surprise at her pursuit of a military career because "We all grew up in the '70s so we all were, to a certain extent, flower children." Meanwhile, as newspapers daily report rising rates of troop stress, Ritchie leads discussions on the use of antidepressants in a war zone and on the tactical need for sending therapists to their patients, rather than vice versa.

She hopes to return to Iraq this September.

"We have nowhere else to go"

"THOUGH BAGHDAD is the city where I was born, lived for many years, and where I completed my undergraduate studies, after 13 years away from it, I dreaded my

tempt on her life. Two bodyguards, traveling in a separate car, were killed.

Berwari worked with the UN in liberated Kurdistan until 1998, when she was accepted as a Mason Fellow at the Kennedy School. She writes, "The Kennedy School experience enabled me to re-enter Iraq at a level where I could make a more robust contribution to improve living conditions....The KSG-instigated approaches I take and the public-service language I now speak have attracted invaluable support from governments and international organizations."

In Berwari's new capacity as minister, she officially oversees some 300 municipalities, 40,000 employees, and 100,000 buildings throughout Iraq. Yet equally important, she believes, is the protection and advancement of women's rights, particularly through the codification of civil, rather than shari'ah, law. In the U.S. State Department newsletter *Washington File*, she says, "For Iraq to move faster it is essential for women to play stronger contributing roles. Women need to have opportunities to more actively participate in decision-making....An enabling environment to promote women's participation needs to be enshrined within the fundamental law of administration." This enshrinement, Berwari had hoped, would take the form of a constitutional amendment guaranteeing

return," writes Nesreen Berwari, M.P.A. '99, upon learning of her appointment to the post of Minister of Municipalities and Public Works in the Interim Iraqi Government cabinet. Her e-mail continues, "The chaos and confusion, the out-of-control security situation, and my role as one of five Kurds in the cabinet and its only woman all generated in me a strong reluctance." Her "strong reluctance" requires no exaggeration: in late March, Berwari survived a second at-

women 40 percent of the posts in all public and legislative bodies. The interim constitution has set the quotas at 25 percent.

Yet Berwari is somberly optimistic. As she noted in the *Washington File*, "For the first time in Iraq's history, it is the education, water, and health sectors that are getting the highest allocation in the Iraqi budget." To the Harvard community, Berwari writes, "We will get through the current turmoil just as Iraqi Kurdistan got through a very similar period in the early 1990s, under arguably far more threatening circumstances and with extremely limited international support. Now that responsibility for our future has been returned to the people, we have confidence that our leadership will determine the means to collectively get this country under control and in a forward-looking mode. Our lives and future depend on it. Unlike the coalition administrators and forces, we have nowhere else to go."

Sara Houghteling '99, a former Berta Greenwald Ledecy Undergraduate Fellow for this magazine, interviewed Iraqi-linked fellow alumni by telephone and e-mail from California.

Controlling Conflicts of Interest

FOLLOWING A BROAD REVIEW begun in early 2003, Harvard Medical School (HMS) this May formally reaffirmed and updated its policies governing faculty members' potential conflicts of interest in conducting their research. The revisions maintain the basic architecture of prohibited and permitted activities, and of universal disclosure of researchers' pertinent financial interests, first drafted 15 years ago, but carefully address new aspects of faculty involvement in medical clinical trials and business management, among other matters. The changes reflect current relationships between the academy and industry in the push to move promising research into practical use: "from bench to bedside."

HMS dean Joseph B. Martin, who commissioned the policy review, cites "two very important principles" that governed the work: "to be absolutely certain that

human subjects be protected” at any stage of research, and to assure that “there is not even a perception of bias” in basic or clinical research.

Why should such problems even arise? First, faculty members are permitted to use 20 percent of their time on outside activities—from lecturing to entrepreneurship—for which they may be compensated by honoraria, consultant fees, stock options, or equity. Second, since 1980, federal policy has encouraged commercialization of faculty inventions to speed relief to patients, allowing scientists and their institutions to benefit financially if federally sponsored research yields marketable products. Third, beyond the patent and royalty arrangements and ownership stakes offered in return for academic intellectual property, industrial support of research is common and may grow more so as new kinds of science encourage sharing of costly laboratories and tools; companies such as Merck and Novartis have recently established major facilities near HMS and its affiliated hospitals.

As a result, Martin says, “over the last 15 years there has been much broader acceptance of the idea that our intellectual property” has wider application, and a recognition that such application might yield the “occasional real financial boon back to the institution.” That in turn has spurred wider acceptance of commercial ties to research, particularly in the affiliated hospitals—where much clinical research is based and where most of the several thousand professionals holding HMS faculty appointments work.

The school’s initial response to such changes in academic medicine emerged from a committee chaired in the late 1980s by Barbara McNeil, a radiologist who is Watts professor of health care policy and head of the department of health care policy. She remembers its work as “fairly contentious,” as members struggled to define a “financial interest,” “family” who might benefit, the precise meaning of “royalties,” and the distinctions between “clinical” and “basic” research.

The guidelines (including subsequent minor amendments, available as “Faculty

Policies on Integrity in Science” at www.hms.harvard.edu/integrity) prohibit two situations. A faculty member may not participate in clinical research on a technology owned by or obligated to a business in which he or she or a family member has any financial interest (consulting, ownership). Clinical or basic research, not involving human subjects, is also forbidden if the faculty member’s institution receives research funding for the work from a business in which he or she holds stock. Exceptions permitted include “de minimis” holdings of \$20,000 of publicly held equity—so long as there is no tie between that stake and specific research to be conducted—and \$10,000 per year of consulting fees or honoraria. Other activities are governed by disclosure and prior approval requirements, or are routinely permitted (for example, receiving royalties for published work).

For most of the decade, says associate dean for faculty affairs Margaret L. Dale, who joined HMS in 1991, the conflict of interest procedures provoked little comment.

But in what he characterizes as the “boom time” in the years after his appointment as dean in 1997, Martin recalls, some faculty members “felt we were missing out in biotech and our investment in our intellectual capital” and encouraged HMS to review its policies. That review began as the ugly side of conflict problems became evident—notably the death of a patient in a gene-therapy experiment at the University of Pennsylvania. In May 2000, Martin announced that HMS would

not modify its policies, and called for national debate on how best to maintain the integrity of research. That work, effected through discussion with peer institutions and through the Association of American Medical Colleges (AAMC), led to model guidelines in 2002.

When Martin initiated a new review of HMS practices in 2003, he appointed McNeil to chair a clinical-research committee. Kuhn professor of biological chemistry and molecular pharmacology Christopher T. Walsh, a member of McNeil’s initial group in the late 1980s, this time was tapped to chair a separate committee examining basic research.

Reflecting a fundamental change in science, McNeil’s group clarified the definition of “clinical research” so it continues to include “human subjects in vivo or the use of human samples” but now excludes “commercially obtained de-identified” cell lines and tissues.

The committees also broadened the definition of who is considered a “participant” in research to include study designers—who may play a critical role in determining what samples are included in a research panel—and anyone who may be an author on the publication of research findings. The clarifications reflect the growth in and complexity of contemporary clinical studies and trials. McNeil notes the high stakes: trial design plays an important role in securing Food and Drug Administration approval of therapies and in subsequent decisions by healthcare payers to reimburse new treatments—a

Professors Barbara McNeil and Christopher T. Walsh have worked on HMS conflict-of-interest policies since the late 1980s.



Photograph by Stu Rosner

critical factor in financial success if an invention is marketed.

In other refinements, the new language specifies that the *de minimis* levels of stock ownership and fees be adjusted upward to \$30,000 and \$20,000, respectively. At the same time, to be sure the rules are not circumvented, the committees insisted that any allowed royalties shared with a faculty member under an institutional licensing agreement must be made *after* an invention is marketed; no earlier-stage payments—equity, say, or payments for research in progress—are permitted outside the *de minimis* rules. A faculty member's freedom to acquire an equity interest in a company will now begin not when sponsored research funding ends, but only after publications on the relevant research are completed. Finally, to clarify the limit on outside obligations, faculty members may not hold such positions as chief executive officer, scientific director, or medical director of for-profit biomedical enterprises.

Walsh says the new policies represent “incremental” change in Harvard's rules, which he terms a “strict constructionist” guide to suitable behavior. “We didn't see any reason to change the basic fabric of prohibition” of research where a faculty member held equity in a company, he says, while permitting consulting within the HMS context of securing disclosure of possible conflicts. (Such disclosure now requires that prospective students, trainees, and new faculty members be informed of potential conflicts before they join a laboratory.)

Walsh says his committee members did not see Harvard's policies as unduly restraining the “translation” of research to applied therapies. As part of its work, the committee “got a very careful description of MIT's policies,” relevant because MIT is widely considered to conduct itself with the highest integrity and to pursue innovative research while being “very embedded in the world.” That Harvard's policies are “very parallel to and congruent with MIT's” was reassuring, he says.

The HMS faculty approved the new language in May “without dissent,” Martin notes. The perception that Harvard's policies are unrealistic, he says, has been dispelled; the challenge he perceives is

communicating fully with faculty members and the wider biomedical industry that the standards protect human subjects, maintain integrity, and accommodate appropriate translation from discovery to medical practice.

Looking ahead, Martin sees three related priorities. First, he worries that some academic research centers “haven't come to address the issues relevant to their institutions” despite the AAMC guidelines. Future conflicts of interest or harm to patients elsewhere could erode public support for biomedical research generally. Second, HMS's policies govern the behavior of individual researchers; policies on institutional conflicts of interest—where the University or an affiliated hospital is offered private equity in return for early access to research, for

example—have yet to be formulated. That issue is on Harvard's policymaking agenda now.

Third, as those issues await resolution, opportunities are at hand “to find ways to work together” with the pharmaceutical enterprises that have set up shop in Cambridge and Boston. Merck's research center, for instance, is adjacent to HMS's huge New Research Building, commissioned last year. The company's focus on cancer, Alzheimer's disease, and obesity all complement HMS strengths, and “positive” meetings have been held on research contracting and investments in core facilities to screen chemical compounds, conduct high-cost imaging studies, and pursue other common needs. Says Martin, “Boston is now *the* center for all this.”

Letter from Phnom Penh

Editor's note: *Arianne Cohen '03, a former Berta Greenwald Leducky Undergraduate Fellow, spent the last academic year in Cambodia. Now, while working for a healthcare consulting firm in New York City, she is writing a book about her time overseas.*

IN AUGUST 2003, I found myself in a spacious Phnom Penh apartment owned by an entrepreneurial Chinese family, surrounded by daytime family shops and nighttime brothels. Four strong security gates and a rare Western toilet compensated for the one-burner kitchen, bucket baths, and lack of hot water, as well as the predictable visits from tropical rats and oversized flying cockroaches.

I can tell you only that my building was bright yellow, because there are no addresses in Cambodia. The street numbers are out of order, no one reads maps, and the postal system is dysfunctional, so my address was superfluous. Instead, I learned to describe the colors of the buildings and brothel signs near my apartment; when that failed, people just asked where the “big white girl” lived and the neighbors pointed.

The landlords, who slept like sardines downstairs with their 12 hired restaurant workers, regularly came to investigate

what I might be *doing* with all my space. In the evening, as I read a book on my couch, the aunts would let themselves in, observe my activities, point at me and talk in Chinese, and then look through the contents of my refrigerator, opening and shutting drawers all the way. Nothing I did in a year assuaged the mystery.

NINE MONTHS EARLIER, amidst the turmoil of senior year, I had applied for a Michael C. Rockefeller Memorial Fellowship. Rockefeller disappeared off New Guinea in 1961, less than 18 months after graduating from the College; in his memory, a few Harvard seniors are chosen annually to expand their horizons with a year of nonpreprofessional activity in the country of their choice. The application requires an essay explaining the candidate's simultaneous indecision about his or her professional path and certainty that a year of shepherding in Mongolia or baking bread in Guatemala will provide future clarity.

I began my essay about Cambodia: “They say that before you can become a writer, something has to *happen*.” I had no trouble arguing that nothing had happened yet. I went on to explain that I had never visited Asia or a third-world