

## Let's Focus on Professionalism and Ethics in Urology

The mission of the American Board of Urology (ABU) is **“To act for the benefit of the public to insure high quality, safe, efficient and ethical practice of Urology by establishing and maintaining standards of certification for urologists.”** Accordingly, the ABU assesses the professionalism and ethical practices of urologists. This assessment is primarily through peer review, examination of billing records, and queries to state licensing boards at periodic intervals.

Urologists are confronted consciously and unconsciously with practice decisions that are influenced by the business of medicine. Increasingly, urologists struggle with the economic realities of running a practice despite falling reimbursements and rising expenses. Do these struggles lead to unprofessional or unethical actions? If criteria for an abnormal laboratory value become more liberal (e.g. PSA), is it unethical to perform more frequent biopsies or other diagnostic testing, even if this leads to an escalation in interventions that may have an unclear health benefit? Is it wrong to consistently utilize a more highly reimbursed test or procedure if another procedure has nearly equivalent outcomes and is equally safe? Likewise, if owning a pathology laboratory or a therapeutic device such as equipment for intensity modulated radiotherapy (IMRT) makes economic sense, why shouldn't urologists make sound business decisions and own these centers? Indeed many patients perceive more testing and less invasive procedures to be in their best interest. Administering a test or treatment within the doctor's office provides smoother, more seamless care. Apropos regarding these questions, the American Board of Urology has witnessed a surprising shift in the composition of billing logs, which demonstrate a reduction in surgery and an increase in diagnostic testing (e.g. urodynamics, lab tests) and office procedures. Aside from implications for training and maintenance of certain skills, this trend in and of itself is not troubling and reflects a variety of forces. In many cases this may lead to “improved” patient care.

At what point do individual practice behaviors compromise ethics or professionalism? Recent reports of financial remuneration to urologists for referrals to non US sites for FDA unapproved interventions has heightened the awareness of the ABU, and caused concern and even provoked scrutiny by the Ethics Committee of the American Urological Association. Of particular concern are payments to urologists who refer patients for non FDA approved high intensity focused ultrasound (HIFU) to treat prostate cancer. These practices have prompted commentary in the lay press and by colleagues in professional periodicals (1-2). Although the procedures may be beneficial to patients and legal if performed by urologists licensed in the foreign countries, the degree of remuneration to the referring physician seems excessive. Further, the potential for delayed and unrecognized complications and the loss of continuity of care when non treating urologists back in the U.S. have to provide emergency interventions is disturbing. In a strict legal sense, this may not be fee splitting. Perhaps it does not violate health care industry guidelines for physician gifts since “work” is done such as making a diagnosis, performing an examination, staging and planning treatment. Participating urologists can rationalize their referrals by believing that they are offering an effective, minimally

invasive therapy withheld by our government bureaucracy. Patients often travel overseas of their own accord to seek either novel therapies or less costly care. So, what is wrong with urologists facilitating the process and receiving a finder's fee?

Although it is the patient's right to seek unapproved treatments here or abroad, the ABU believes that the referring physician should not profit excessively from this practice. One might ask how this practice differs from high dollar honoraria awarded by industry to physicians for their lost time when they travel to lecture. Our opinion is that the principal difference is that the former situation involves direct patient care and the trust the patient confers in his/her surgeon. This bestowed trust assumes a treatment recommendation is being made in the **patient's** best interest, not in the economic interest of the doctor. This is distinct from a urologist enrolling a patient in a clinical trial in which there may be a small financial incentive for enrollment. In the latter scenario this falls under the scrutiny of an Institutional Review Board and the oversight of the government to insure reasonable cost recovery, risk/ benefit, follow-up, safety etc. Furthermore, trials in the U.S. are overseen by Data Safety and Monitoring Boards. In short, public safeguards exist to protect the patient. These safeguards may be absent or far less stringent in foreign countries. Moreover, incentivizing physicians to send patients to foreign countries for unapproved therapies indirectly subverts U.S. clinical trials that might scientifically prove (or disprove) the benefits of the therapy and more accurately report adverse events.

Our society admires and celebrates entrepreneurs. However, since Hippocrates, balancing economic benefit to the provider against the needs of the patients has proven difficult. A fine demarcation exists when the quest to discover new therapies provides a disproportionate financial benefit to the physician entrepreneur or referring physician. The ABU feels such practices merit close scrutiny and Diplomates may be asked to clarify such practices.

1. Despite doubts cancer therapy draws patients: HIFU prostate cancer procedure. New York Times Aug 31, 2008.
2. Williams, R. HIFU: Promising therapy merits clinical trial participation. Urology Times, Aug 1, 2008.

*Trustees of the American Board of Urology*