

HIPDB: A Tool to Combat Health Care Fraud (Part I)

By Richard L. Granville, M.D., J.D.* and
Robert E. Oshel, Ph.D.**

Health care fraud is a serious, ongoing problem in the United States. Unscrupulous individuals, including health care providers, have illegally billed private health care insurers, the Medicare program, the Medicaid program, the TRICARE program of the Department of Defense (DoD), and other health insurance programs for years. It has been estimated that approximately 10% of health care expenditures or about \$130 billion in 2000¹ are inappropriately paid because of fraudulent billing or the fraudulent performance of services.

In response to this important and growing economic problem, Congress directed the Secretary of the Department of Health and Human Services (HHS) acting through the Office of the Inspector General (OIG) to create the Health Care Integrity and Protection Data Bank (HIPDB) in 1996. This was accomplished through language in the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, which created Section 1128E of the Social Security Act and authorized establishment of the HIPDB.² Final regulations regarding HIPDB were codified at 45 CFR Part 61.³

The HIPDB, under the direction of the OIG of the HHS and operated by the Division of Practitioner Data Banks of the Health Resources and Services Administration of the HHS, has developed into a flagging system that alerts its users to undertake a more detailed review of a provider's, practitioner's, or supplier's credentials.⁴ This article in Part 1 will provide an overview of the health care fraud problem in the United States, explain commonly recurring examples of health care fraud, and offer general HIPDB information. Part 2, in *Legal Medicine 2004*, will provide an overview of HIPDB operations including querying the HIPDB, reporting to the HIPDB, eligible users of the HIPDB, and subjects of the HIPDB. The extent of DoD participation in the HIPDB will be presented, as well.

Types of Health Care Fraud

Medicare defines health care fraud as "the intentional deception or misrepresentation that an individual knows to be false or does not believe to be true and makes, knowing that the deception could result in some unauthorized benefit to himself/herself or some other person."⁵ A 1993 survey by the Health Insurance Association of America (HIAA) categorized examples of fraud in the health care industry as follows:

- 43% of cases due to fraudulent diagnosis,
- 34% of cases due to billing for services not rendered, and
- 21% of cases for waivers of deductibles or co-payments.⁶

* Richard Granville is Deputy Chairman of the Department of Legal Medicine, Armed Forces Institute of Pathology, in Washington, D.C. His responsibilities include production of DoD risk management data for the Department of Defense (Health Affairs) and the TRICARE Clinical Quality Forum.

** Robert Oshel is the Associate Director of the Division of Practitioner Data Banks in Rockville, Maryland. Dr. Oshel is responsible for activities related to research and Secretarial Review of disputed reports within the Division.

Many cases of health care fraud are quite sophisticated and involve the actions of multiple parties from a myriad of backgrounds.

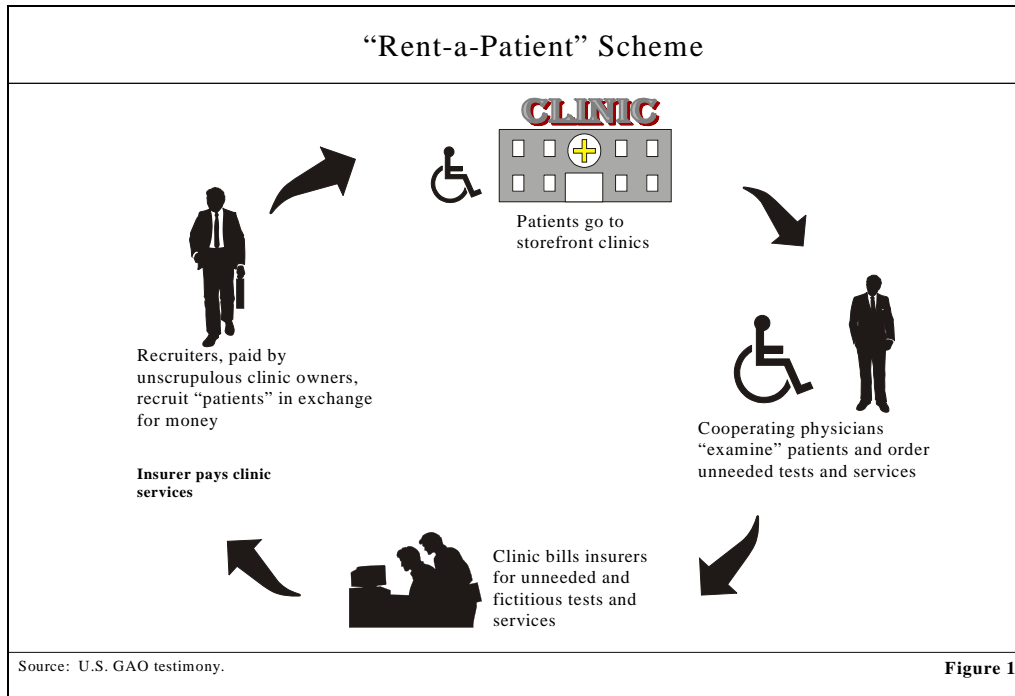
Government health care programs are frequent targets of fraud, perhaps because of the magnitude of their size. The Medicare program has struggled with health care fraud for years, with “billing for services not furnished” listed as the most common form of fraud (Table 1). Medicaid has also been the victim of fraudulent schemes such as billing for “phantom patients” or for medical services that were not provided, billing for more hours than there are in a day, and charging Medicaid for personal expenses that were outside the scope of patient care.⁷ DoD has experienced issues of health care fraud through its TRICARE program that contracts with health care providers through managed care support contractors. In an effort to reduce the burden on the system, DoD has created an effective organization known as the TRICARE Program Integrity Office that has dealt very successfully with many cases of health care fraud.⁸

In a recent GAO report, Robert D. Hast, Assistant Comptroller for the General Special Investigation of the Office of Special Investigations, outlined several schemes used to defraud the Medicare and Medicaid programs, as well as private insurance companies.⁹ He noted that there are a large number of career criminals and organized criminal groups actively involved in health care fraud across the country. Many individuals have previous charges of securities fraud, narcotics or weapons violations, grand theft, or forgery and often move from one category of illegal acts or fraudulent activity to another. Descriptions of some of the schemes involved are instructive in seeing how advanced the fraudulent activities can become.

Most Common Forms of Fraud in Medicare	
◆	Billing for services not furnished
◆	Misrepresenting the diagnosis to justify payment
◆	Soliciting, offering, or receiving a kickback
◆	Unbounding or “exploding” charges
◆	Falsifying certificates of medical necessity, plans of treatment, or medical records to justify payment
◆	Billing for a service not furnished as billed

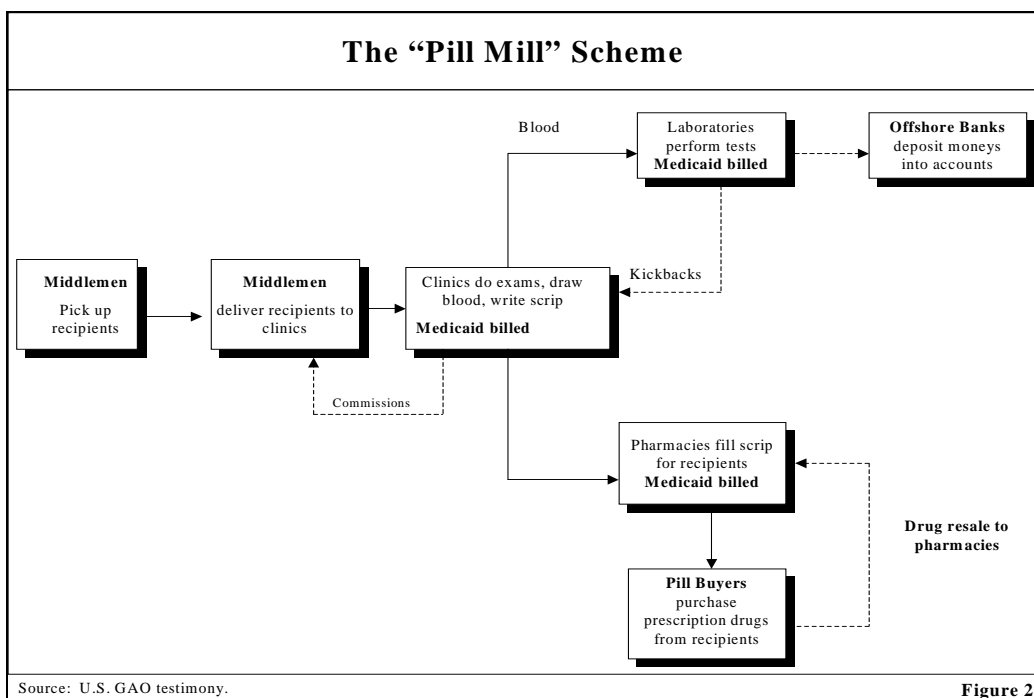
Source: Health Care Financing Administration Website

Table 1



Rent-a-Patient

In one scheme called “Rent-a-Patient” (Figure 1), criminals pay other individuals (“recruiters”) to organize and recruit so-called patients (“beneficiaries”) to visit clinics that the criminals own or control. The beneficiaries are often picked up and driven to the clinics from low-income residences or from retirement communities by the recruiters themselves and may even be paid by the recruiters. At the clinics, a shortened history and physical may be taken and laboratory tests are ordered. Medical equipment referrals may also be made. In some cases medical school graduates fill out medical charts, and even licensed physicians have been paid to sign off on fraudulent charts. The insurance carrier is billed for services and procedures that were not actually performed.¹⁰



Pill Mill

In a second scheme, called the “Pill Mill” (Figure 2), the fraudulent activities involve pharmacies, clinics, laboratories, beneficiaries, brokers, and recruiters. A beneficiary is brought in for an unnecessary examination, tests, and medications. The lab bills the insurance company. Pharmacists, if involved, may also bill the insurer. The beneficiary then sells the medication he received to a “pill buyer” who resells the medication back to the pharmacy—and the cycle repeats itself. Monies generated are moved to offshore banks to prevent law enforcement entities from gaining access to the funds. While medication that was sold and re-sold may eventually reach a legitimate patient, by then it may carry an expired date and have less potency because it has passed through this cycle a number of times.¹¹ Such outdated medication may be less effective and provide a reduced therapeutic benefit for subsequent actual patients who are innocent of any wrongdoing.

With recurring egregious cases of this type, the creation of the HIPDB as a central repository of individuals and entities that have committed health care fraud is an extremely important tool that, if properly utilized, can help prevent future losses.

General HIPDB Information

The HIPDB is a national database that allows the reporting and disclosure of certain final adverse actions taken against health care providers, practitioners, or suppliers. Only actions taken on or after August 21, 1996, the date of enactment of the legislation, may be reported. The final actions may include health-care-related civil judgments or criminal convictions in federal or state courts; injunctions; federal or state licensing or certification actions (including revocations, reprimands, or suspensions); exclusions from federal or state health care programs; and certain other adjudicated actions, most notably contract terminations by health plans.¹² Note that the HIPDB does not accept the reporting of medical malpractice payments which are instead made to the National Practitioner Data Bank (NPDB).¹³ The HIPDB serves as an important tool for federal and state agencies and health plans to utilize in evaluating the qualifications of health care practitioners, providers, or suppliers whom they choose to license, credential, hire, contract with, or with whom they wish to form some other affiliation. The Division of Practitioner Data Banks of the Health Resources and Services Administration of the Department of Health and Human Services has produced an excellent guidebook outlining the specific rules related to the HIPDB.¹⁴

The information in the HIPDB is confidential. The Privacy Act of 1974 protects the contents of the HIPDB except for specified “routine” uses¹⁵; Section 1128e of the Social Security Act limits disclosure of records in the HIPDB to federal and state government agencies and health plans.¹⁶ The general public does not have access to the HIPDB. Health care providers, practitioners, and suppliers can request information about themselves, however. In what might have been an oversight by Congress, the information contained in the HIPDB is not available to hospitals or health care entities other than health plans, but HHS is considering a proposal to overcome this limitation.

Part II of this article, describing many of the specific rules pertaining to the operation of the HIPDB, will follow in *Legal Medicine 2004*.

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- ¹⁶ Social Security Act Section 1128E. This section also contains provisions for immunity from liability to individuals and entities in a civil action for reporting to the HIPDB unless those individuals or entities have actual knowledge of the falsity of the information that is reported. *See* <http://www.npdb-hipdb.com/legislation/1128E.html>. Accessed April 21, 2003.

Alternative Therapy...A Medical Enigma

by Georgia A. Martin, J.D., Ph.D., MSN*

The medicine of ancient peoples was a combination of faith, blind luck, smoke, heat, and reliance on what nature provided, such as leaves, herbs, and roots. The ancients knew about healing, preventing diseases, and potions that could cure, kill, make one sick, or ease the pains of snakebites, rheumatism, or child birth.¹ Now, centuries later, the United States has the most advanced medical system in the world, yet increasingly the population is turning to unscientific, alternative, natural healing methods. When conventional "Western" medicine is used in conjunction with this alternative therapy, the combination is known as complementary therapy.²

Alternative therapy is defined as interventions neither widely taught in medical schools, nor generally available in U.S. hospitals.³ Broadly speaking, alternative medicine includes prayer, laying on of hands, acupuncture, acupressure, aromatherapy, color therapy, homeopathy, intuitional diagnosis/healing, massage, music/sound as therapy, nutritional healing (orthomolecular medicine), oxygen therapy, therapeutic touch, body movement therapies (yoga, Tai Chi, Chi Gong), and mind/body/spirit therapies such as meditation and hypnotherapy. Although the traditional medical community might believe chiropractic practitioners and naturopathic practitioners are also alternative in their therapies, these practitioners must be licensed in their specialties and are not alternative therapies in the same sense as the others listed above.

Alternative Medicine Trends

The use of alternative therapies is widespread in the U.S., as evidenced by the multimillion-dollar sales of natural substances such as herbs and vitamins. A study of four family practice clinics in Oregon revealed that 50 of 100 patients surveyed used alternative treatment modalities.⁴ Another study documented that 34% of the respondents used at least one non-conventional therapy in the preceding year. When the data was extrapolated, it was determined that 425 million visits were made to practitioners of unconventional therapies in 1990.⁵ In another survey, one-third of all Americans reported using alternative medicine, spending \$13 billion for alternative therapy in 1993.⁶ By 1997, the use of at least one alternative therapy per patient per year increased to 42%.⁷ Since 1989, consumer spending on alternative therapies has escalated 69% and the alternative market may be growing as fast as 30% annually. Approximately 90% of the population worldwide uses alternative therapies.⁸

Currently, nearly 33% of medical schools (including Yale, Harvard, and Johns Hopkins) and several nursing schools incorporate alternative therapy components into their curricula. Many teaching hospitals use complementary therapy to assist in relaxation prior to surgery.⁹ Oxford Health Plans, Health Net, and several other managed care organizations, health insurers, and employers include some alternative therapies in their health care benefits.¹⁰ In 1992, the U.S. Congress established the Office of Alternative Medicine within the National Institutes of Health to evaluate alternative treatments and to integrate effective ones into mainstream medicine.

* Ms. Martin is a consultant with AFIP's Department of Legal Medicine on medical malpractice issues. She has previously contributed to **Legal Medicine**, most recently regarding medication errors.

Legal Issues Regarding Alternative and Complementary Therapies

Health care in the United States is significantly regulated at both the state and federal levels; however, the practice of complementary and alternative therapies remains contentious because there are few, if any, laws and regulations clarifying their use. Currently, most alternative therapists are not held accountable for their performance, nor have the majority of their methods been scientifically studied for effectiveness. In addition, there is general disagreement about the appropriateness of many alternative therapy techniques and there are very few uniform standards of practice.¹¹

Theories of Liability

If an alternative health care provider is sued and found liable for injury to a patient, it is most probably based on the theory of negligence. Medical malpractice is the type of negligence denoting injury to a patient caused by a health care provider's conduct that deviates from professional standards of practice. In determining the strengths and weaknesses of a case, expert witnesses with similar experiences and training testify whether the health care provider's actions were within acceptable standards of practice. Liability attaches when a preponderance of the evidence shows that a standard of care was not met.¹²

Standard of Care Liability

State medical practice acts grant physicians a great deal of latitude in their scope and standards of practice. Courts normally rely upon these standards of care, as well as the AMA Code of Ethics, various peer-reviewed medical journals, position statements of specialty organizations, information published by drug manufacturers and others as to the appropriate use of medications, additional product information, and case law to make judgments about the safety and efficacy of medical treatments. There is little case law regarding standards of care for physicians who provide alternative therapies.

Deviation from traditional standards might be considered by the courts to be unaccepted, unorthodox, experimental, nonstandard, or substandard care.^{13,14} Nonstandard care is not actionable per se, whereas substandard care is clearly a basis for liability. Since the law and liability risks are presently unclear, courts would most probably compare a physician's use of alternative therapy with a conventional medical standard of care.

It is also possible that a court might use a more flexible standard of care based on the testimony of other physicians who practice similar alternative therapies. In such a scenario, a physician sued for negligent injury of a patient while providing complementary medicine would not be able to cite adherence to an accepted medical standard of care as a defense, but instead would essentially have the burden to demonstrate that the treatment was safe and medically appropriate, and could not have caused any harm to the patient.

In *In Re Guess*,¹⁵ the state medical board of North Carolina revoked the license of a family physician for failing to conform to acceptable and prevailing standards of practice. The physician routinely administered homeopathic remedies in combination with allopathic treatments and had never injured a patient. The appeals court set aside the disciplinary action, finding that the board failed to demonstrate that the physician posed a danger to the public or his patients or deviated from an acceptable standard of practice. However, the state supreme court reinstated the board's disciplinary action, relying on a state statute that required only a

failure to conform to standards of prevailing medical practice, regardless of whether the patient was thereby injured.

Standards of care vary among the non-physician alternative medicine modalities, and are normally less formal and less detailed than standards of care for physicians. The flexible and amorphous nature of these alternative therapy standards makes it difficult to prove that a standard of care was either followed or breached in a malpractice claim.

The standard of care that a court would most probably apply in a lawsuit against a non-physician alternative therapy provider is the standard of care of the provider's profession. For example, the use of certain medications or medical conditions preclude the use of massage therapy for some individuals, and all certified massage therapists should be aware of the common situations or conditions that would make massage contraindicated in these cases. The failure of a massage therapist to take an appropriate history to disclose any health problems that would make massage contraindicated in these cases. The failure of a massage therapist to take an appropriate history to disclose any health problems that would preclude the use of massage would be negligent. Thus, the determination of negligence would be based on whether or not a reasonable provider of massage therapy would have taken an appropriate history under the same or similar circumstances.¹⁶

Scope of Practice, Referral Liability, and Vicarious Liability

Chiropractors and naturopaths are licensed to both diagnose and treat health problems, but they are generally more limited than physicians in their scope of practice and in their legal ability to diagnose. They are expected to make proper referrals when medically necessary. Liability can attach for failure to make appropriate referrals for medical conditions that are outside their scope of practice.

Any comments regarding a medical diagnosis by alternative providers who are not licensed to diagnose and treat would constitute practicing medicine without a license. In addition, their training and background may not provide them with the requisite knowledge to make appropriate referrals. Thus alternative providers may be obligated to inform patients that they need to seek medical attention, but they should not make any specific referrals to physicians.

Alternative providers frequently have a solo practice or practice in small groups (known as teams) where multiple providers see patients. A legal question about vicarious liability that is often asked is whether a referring or collaborating health care provider can be held liable for the negligent acts of a receiving provider. Even though there are significant exceptions, the general rule is that the referring provider is not liable for negligent acts of receiving providers as long as the referring provider had no reason to know or suspect that the receiving provider was incompetent.¹⁷ The referral must also have been appropriate. Liability risk increases when the association between the two alternative health care providers suggests that the negligent provider is an agent or employee of the other.¹⁸

To help limit liability exposure in a team or networked alternative practice, a knowledgeable health care attorney should be consulted to assist in structuring the venture. Quality assurance mechanisms should be implemented to check all the providers' state licenses, certifications, education, training, and credentials, as well as the National Practitioner Data Bank for possible findings of legal or disciplinary actions. All providers must practice within the scope of their

license, and if no license is required, then they must practice within the scope of practice of similarly situated providers.¹⁹

Informed Consent Liability

Some alternative therapies, including herbal remedies, are considered experimental. Therefore, obtaining informed consent assumes added importance for physicians incorporating alternative therapy treatments into their practice, as well as for alternative medicine therapists. Prior to prescribing herbal remedies and administering alternative treatments, a health care provider should obtain the patient's written informed consent. Informed consent in this context involves the disclosure of the material risks, benefits, and alternatives to herbal remedies and alternative treatments.²⁰

This is particularly important when a patient decides to forego traditional medical treatment recommended by his or her physician, instead relying entirely upon alternative therapies for treatment. In this case, a discussion between the patient and the physician or other health care provider must occur and must be documented in the medical record concerning, among other issues, the experimental nature of the alternative therapies and the fact that their efficacy is not currently proven.

Lack of informed consent often forms the basis of malpractice litigation and can be a cause of action that is separate from a malpractice claim. In this type of claim, the plaintiff alleges that a health care provider failed to properly inform him or her of the attendant risks and recognized alternatives for a treatment. A health care provider's legal privilege to treat a patient derives from the patient's informed consent. If a patient is not adequately informed, the consent is in essence revoked and the touching or treatment of the patient by the provider becomes nonconsensual and tantamount to a civil battery.²¹

In *Charell v. Gonzalez*,²² an alternative medicine practitioner recommended that a cancer patient forego conventional cancer treatment and instead follow his alternative nutritional therapy. The patient brought a medical malpractice action for lack of informed consent. The jury concluded that the provider failed to inform the patient of the risks of his treatments and the alternatives thereto, and awarded a verdict of \$4 million to the patient for her injuries.

Traditional informed consent components that need to be discussed with a patient are listed in Table 1. Risks that usually need not be disclosed are those that are commonly known or remote unless the risk is deemed significant to the patient.²³

Traditional Informed Consent Components

- ❖ The patient's medical problem that requires the proposed therapy (including medication, treatment, or procedure)
- ❖ The therapy's purpose, description of what is involved, and probable outcome
- ❖ Likely benefits of the therapy
- ❖ Probable complications, temporary pain, or discomfort
- ❖ Probable permanent results (including disfigurement, disability, or scarring), required care, and related medical costs
- ❖ Known, anticipated, or foreseeable material risks (including possible death)
- ❖ Alternative procedures and treatments and their known side effects, risks, and benefits (including no treatment at all)
- ❖ The consequences and rights of the patient to refuse or withdraw consent for any reason

Table 1

Using a comprehensive consent form that at a minimum explains all of the traditional informed consent components can reduce liability exposure. In addition, the form should define limits of the alternative provider's scope of practice, explain that some alternative therapies are considered experimental, and contain a clear assumption of risk statement that the patient understands and consents to in writing. Patients are less likely to file lawsuits when they are personally involved in their treatment choices, so liability exposure can be further reduced by including patients in the decision making process.²⁴

Herbal Drug Therapy Liability

The practice standards for most alternative therapy providers generally do not expressly allow them to diagnose and prescribe drugs for medical conditions. Therefore, prescribing herbs for medical ailments may be legally outside a non-medical provider's scope of practice. Some creative alternative medicine therapists have limited their liability exposure by providing patients with research information about the traditional uses of herbs for specific ailments, rather than diagnosing ailments and prescribing herbs themselves. For example, providing a patient with research information that Kava Kava and Valerian have been shown to reduce anxiety is arguably freedom of speech protected by the First Amendment.

Any herb prescribed for a health condition is considered a drug. A drug not approved for specific use is considered experimental and is subject to control by the Federal Food and Drug Administration (FDA). The use of unapproved drugs for medical purposes may invalidate a health care provider's professional liability insurance policy, making the provider personally responsible for all damage awards. In *Meza v. Southern California Physicians Insurers Exchange*,²⁵ the plaintiff filed a lawsuit against an osteopathic physician after the plaintiff's

finger had to be partially amputated following the injection of a wart with tea-tree oil, and herbal salve. At trial, the court found for the plaintiff and awarded damages. The insurance company, however, refused to pay the damages alleging that the physician's insurance policy excluded coverage for the use of drugs not specifically approved by the FDA. The physician argued that tea-tree oil was not a drug because neither the manufacturer nor distributors made claims as to the salve's therapeutic effects. Using the Federal Food, Drug, and Cosmetic Act's definition of a drug, the court concluded that a drug is defined by the physician's intent for its usage even if it is an herb or vitamin supplement. The court agreed with the insurance carrier that the tea-tree oil was a drug within the meaning of the policy's exclusion, and that the patient's injuries were caused by the use of the oil.

Some patients may not tell their primary care physicians that they are visiting complementary or alternative therapists, or taking herbal remedies or vitamin supplements. Since many herbal products interfere with or even inhibit the action of prescription drugs, it is extremely important for physicians to discuss with their patients the importance of informing them of all prescription, herbal, and over-the-counter treatments and medications. This discussion should be documented in the patient record, along with the patient's responses. The health care provider should consult with a pharmacist if there are any questions regarding the interactions among prescription drugs, vitamins, and herbal supplements.²⁶

Summary

Professional liability law regarding complementary and alternative therapy is an emerging field with many uncertainties and medical and legal challenges.²⁷ Since alternative techniques are normally less invasive, the risk of malpractice actions involving alternative health care providers is relatively low compared with the liability risks for providers of traditional medicine and surgery. The potential for patient injuries and malpractice claims still exists for alternative therapists, however.

Notable triggers for malpractice actions include failure to remain current with accepted practices within one's profession, using risky or unacceptable techniques that are outside the standard and scope of practice, inattention to signs and symptoms, failure to make appropriate referrals, and promising good results. Alternative providers' liability exposure can be significantly reduced by protecting patients from harm, following the standards of practice accepted by their professions, confining their interventions to those they are trained to offer and thoroughly informing patients of the risks involved in specific treatments.

Before use of complementary or alternative therapy can become more acceptable and commonplace, standards of practice must be developed for all alternative techniques. It is also paramount that health care providers who desire to become practitioners of alternative medicine attain the education, licensing, credentialing, and training required for using the modalities.

Alternative therapists must be thoroughly knowledgeable of their state laws governing alternative medicine. Some states require a license to practice certain alternative techniques, and some modalities are totally banned. An alternative provider who practices without a license or who practices a therapy not legally authorized may face civil and criminal penalties. Additionally, practicing in a state without a valid license can invalidate professional malpractice coverage, making the provider personally liable for damage awards if found guilty in a lawsuit.

Likewise, those who practice alternative medicine not authorized by their employer are practicing outside the scope of their employment and would not be covered by the employer's liability policy. To limit liability exposure, health care providers working in the area of alternative medicine should obtain individual professional liability policies that cover their specific modalities, and should contact their attorneys and malpractice carriers to ensure that their specific practices are covered.

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Levels of Liability: It's Not Just the Physician Anymore

By Jane D. Weaver, J.D., COL, USAFR*

Historically, only physicians were sued for medical malpractice. They were seen as the “captain of the ship”¹ and held responsible for all aspects of a patient’s care -- even care delivered by others. Today, however, non-physician health care providers as well as their employing institutions and supervisors are increasingly being named as defendants in malpractice suits and held liable for their own actions. Effective risk management requires that every health care provider, health care administrator, and health care facility must recognize the various roles each fulfills and the many levels of liability that co-exist.

Nurses, pharmacists, social workers, respiratory therapists and other individual non-physician health care providers are recognized by the courts as professionals in their own right and may be found professionally negligent with absolutely no ensuing liability placed upon the physician. Managers, supervisors, or administrators who knew or should have known about specific personnel problems have been held accountable for patient incidents. Employers such as a hospital, agency, or clinic also can be determined liable in a court of law for the actions of their employees. Various levels of liability abound and it is important for the practicing physician to be aware of them.

Individual Non-Physician Liability

A classic case in which a nurse was found individually liable for medical malpractice is *Ramsey v. Physician’s Memorial Hospital, Inc.*² Here the parents of two minor children sued the hospital and physician for failure to diagnose Rocky Mountain spotted fever. The mother testified that she told the emergency department nurse that several days earlier she had removed two ticks from one of the children. The nurse failed to advise the defendant physician about the ticks. Both children had a rash and, subsequently, the physician made a diagnosis of measles. Subsequently, one child died and one became seriously ill. The jury rendered a verdict in favor of the physician, finding that he acted within the appropriate standard of care based on the information he had received. The nurse was found to be negligent.

In *Daniel v. St. Francis Cabrini Hospital of Alexandria, Inc.*,³ a diabetic patient suffering from organic brain syndrome was taking a number of drugs whose side effects included dizziness and weakness. After administering an enema to the patient, a nurse left him unattended on the commode in the bathroom. The patient sustained injuries when he became dizzy and weak and fell off the commode. Because of the nurse’s negligence, the court rendered a verdict for the patient.

* COL Weaver, an IMA consultant for the United States Air Force Office of the Surgeon General, is assigned to the International Health Specialist Team located at Bolling Air Force Base in Washington, DC. She maintains a private law practice in North Carolina.

The liability of agency nurses and nursing students is no different: agency and student clinicians are responsible for their own actions and may be held personally liable for acts that are deemed negligent. In *Payne v. Garvey*,⁴ for example, a student nurse just eight months into her training was shaking down a glass thermometer when it broke, throwing glass and mercury into a patient's eye and permanently damaging the patient's vision. The patient sued his physician and the hospital, alleging that the latter breached its duty to provide safe equipment. The court held that neither the physician nor the hospital was responsible for the student nurse's independent act.

In *Parks v. Perry*,⁵ a gynecology patient sustained permanent impairment to her hand from ulnar nerve damage that she did not have prior to surgery. After hearing testimony that it was the nurse anesthetist's responsibility to position patients' arms during surgery so that ulnar nerve damage would not occur, the jury was allowed to determine if the nurse was liable. The jury was not allowed to consider if the assistant surgeon was liable because there was no testimony or evidence that the assistant surgeon had any duty to inspect the patient's arms or supervise the nurse.

Supervisory or Administrative Liability

Another level of liability extends to clinical managers or supervisors, or others with management or administrative responsibilities. This does not relieve those being supervised of their individual liability; rather it extends and expands liability. Supervisors may be held accountable for the negligent acts of individual clinicians if duties are delegated inappropriately or supervision is inadequate. If a nurse — or intern or medical student — is assigned duties that are beyond his or her ability and patient injury results, the supervisor could be held liable for what the supervisor knew or should have known about the capabilities of the subordinate assignee. If a nurse is not qualified to carry out the assignment, then the manager must provide adequate supervision.

In *St. Paul Medical Center v. Cecil*,⁶ hospital personnel assigned a nurse to night duty even though it was known that she often fell asleep at her station and her employee evaluation forms showed unsatisfactory ratings. Medical testimony demonstrated that a patient under this nurse's care suffered prolonged hypoxia, and that this nurse failed to notice it in a timely manner or provide any intervention for it. The court allowed the jury to decide whether the hospital was liable for negligence in assigning, supervising, or retaining this particular employee.

These principles are further illustrated by the case of *Merritt v. Karcioğlu, M.D. and Administrators of the Tulane Educational Fund*.⁷ In this case, an intern became aware that an elderly patient assigned to him had tried to get out of bed without assistance. The intern did not order restraints, so hospital management assigned one nurse exclusively to that patient. That particular nurse, however, was also on the unit's code response team. One day when there were six critical patients on the ward and only three nurses, a code was called. During the time the code nurse was away from the elderly patient's room, the patient fell out of bed and suffered a broken hip. The jury apportioned its \$555,000 verdict for the plaintiff as follows: intern, 10% liable; nurse, 35% liable; hospital, 55% liable.⁸

Employer Liability

Even when no errors in training, delegation of duties, or supervision are present, supervisors or managers may be deemed “vicariously liable”⁹ for the negligent acts of those for whom they are responsible.¹⁰ An additional level of liability can attach to an employing entity, such as a hospital, agency, or clinic. Again, the individual health care practitioner’s liability is only extended. The individual does not escape liability unless a plaintiff strategically decides that because an employer, like a large HMO or hospital, is far more likely to have sufficient funds to satisfy a judgment it does not make sense to sue individual providers. Thus, an employee’s alleged negligence may result in the employer being sued and held liable.

Illustrating this principle is the case of *Guilbeaux v. Lafayette General Hospital*¹¹ in which the defendant hospital had to pay \$212,652.36 plus interest because a nurse failed to properly remove a Jackson-Pratt drain as ordered from a post-operative patient. After the nurse left a 3.5-inch strip of tube in the patient’s back, the patient subsequently sustained nerve damage and impotence and required additional surgery. The employing hospital was determined liable for the actions of its nurse/employee. The trial judge’s original award of \$50,000 for general damages was found to be too low on appeal.

Under the legal doctrines of “vicarious liability” and “respondeat superior”¹² an employer is almost automatically liable for the acts of its employees. This is based upon public policy that encourages employers to hire responsible employees and to provide them with the facilities, equipment, and additional assistance needed to offer competent care to the public. If an employee performs negligently, the employer will most always be held accountable for that employee’s negligence.

In *Butterfield v. Okubo, et al*,¹³ parents took their newborn to a hospital’s emergency department twice because of concerns with the infant’s irregular breathing and because the baby had turned blue upon occasion. At the first visit they testified they were “sort of laughed at” by the physician and nurse who assured them the baby was just developing its own breathing pattern. A month later they were told much the same, even after reporting the previous visit and stating that the baby had once actually stopped breathing. The infant died at the age of six months from SIDS, Sudden Infant Death Syndrome. At trial the parents’ expert testified that the history taken was inadequate, and that it was below the standard of care for the nurse at the second visit not to retrieve the chart from the first visit. The expert opined that if a home apnea monitor had been prescribed, the baby would not have died of SIDS. The Supreme Court of Utah decided such testimony was sufficient to let a jury decide if the hospital should be liable for the actions of its nurse and emergency physician or if it was liable on its own for failure to provide an apnea monitor.

When a patient seeks out a particular health care institution rather than a specific physician or other health care practitioner and the physician at that institution performs negligently, many courts are holding the institution liable since it chose the health care practitioner for the patient. A typical example is the emergency department physician who is an independent contractor. A patient would perhaps seek out a particular emergency facility because of its proximity rather than select a given emergency department physician. Because of an apparent agency relationship (i.e., holding out to the public) between the independent contractor and the health care institution, the facility has a duty to provide a competent health care practitioner and may

be held liable for damages if it does not. See, for example, *Baptist Memorial Hospital System v. Sampson*.¹⁴

While physicians are still almost always included in the list of named defendants in a medical malpractice lawsuit, it is important to keep in mind that they are not always the ones ultimately determined to be liable for patient injuries. Thus, physicians should understand the various levels of liability and legal theories that might be involved in today's health care negligence and medical malpractice claims.

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¹ The legal doctrine known as "captain of the ship" held that a patient's attending physician was in charge of all aspects of that patient's care. The physician was thought to be the supervisor (captain) of all others (crewmembers) involved with caring for the patient, and it was he or she who had final authority and legal responsibility for the patient's course and outcome.

² *Ramsey v. Physician's Memorial Hospital, Inc.*, 373 A.2d 26 (Md. 1977).

³ *Daniel v. St. Francis Cabrini Hospital of Alexandria, Inc.*, 415 So.2d 586 (La. 1982).

⁴ *Payne v. Garvey*, 142 S.E.2d 159 (N.C. 1965).

⁵ *Parks v. Perry*, 314 S.E.2d 287 (N.C. 1984).

⁶ *St. Paul Medical Center v. Cecil*, 842 S.W.2d 808 (Texas 1992).

⁷ *Merritt v. Karcioğlu, M.D. and Administrators of the Tulane Educational Fund*, 668 So.2d 469 (La. 1996).

⁸ On application for rehearing in 1997, the Supreme Court of Louisiana reduced the award to \$157,556. It cited several factors for the reduction, primarily that the patient was already ill with life-threatening diseases and was 92 years old.

⁹ "Vicarious liability," also termed "imputed liability," attaches responsibility to a person or entity for harm or damages caused by another person. In this situation, vicarious liability means that an employer is liable for the negligence of an employee who injures someone while in the scope of his or her employment. The employer is thus legally liable for damages to the injured person.

¹⁰ Kota J, Martoglio J. *Legal Issues in Supervising Nurses*. Eau Claire, WI: Professional Education Systems, Inc. 1991.

¹¹ *Guilbeaux v. Lafayette General Hospital*, 589 So.2d 629 (La. 1991).

¹² "Respondeat superior" is similar to "vicarious liability." In Latin, it means "let the master answer." It is a key doctrine in the law of agency providing that a principal (employer) is responsible for the actions of its agent (employee) in the normal course of the agent's employment. If an employee causes damages, the employer will be held liable for the injuries.

¹³ *Butterfield v. Okubo, et al*, 831 P.2d 97 (Utah 1992).

¹⁴ *Baptist Memorial Hospital System v. Sampson*, 969 S.W.2d 945 (Texas 1998).

Linking Health Promotion, Health Educators and Medicine: A Prescription For Success

By Charlene A. Day, Ph.D.^{*}, CHES, Anita Hawkins, Ph.D.^{**}, and Jean Henry, Ph.D.^{***}

While many health professionals assume the task of educating patients, comparatively few have actually completed an advanced degree in the subject area earning the professional certification that enables them to rightfully claim the title of Health Educator.¹ It can be argued that health education is one of the most misunderstood professions within the health promotion and disease prevention arenas. Despite governmental recognition of the profession, national organizations that represent the practitioners, and federal, state and local mandates for increased health education,² the roles and responsibilities of health educators remain unclear even to other health practitioners and their expertise continues to be under utilized.³

Medical care costs are rising and limitations have been imposed on medicine by means of malpractice insurance, litigation, and legislation. Today it is of utmost importance that health professionals work together to provide patients with the best care possible.⁴ A good collaboration—one in which the health educator's expertise is more fully understood, appreciated, and utilized by other health care providers—can increase:

1. patients' knowledge about disease specifics and treatment regimens,
2. providers' opportunities to focus on medical and diagnostic concerns in patient interactions, and
3. patient or client knowledge and understanding of appropriate health promotion and disease prevention regimens.⁵

This article briefly highlights the roles and responsibilities of the health educator and then discusses ways in which practitioners of medicine and health promotion can work together to advance health care.

Health Promotion and Health Education

At its foundation health promotion is the aggregate of all purposeful activities designed to improve personal and public health through a combination of strategies, including the competent implementation of behavioral change strategies, health education, health protection measures, risk factor detection, health enhancement, and health maintenance.⁶

^{*} Dr. Day is a founding partner of Health Evaluation Research Services, a consulting firm specializing in the evaluation of health promotion and disease prevention programs. She is also an Assistant Professor in the Department of Health Promotion at the University of Nevada, Las Vegas, Nevada.

^{**} Dr. Hawkins is also a founding partner of Health Evaluation Research Services and holds adjunct faculty positions with the University of Maryland (UMUC) and Lincoln University of Pennsylvania.

^{***} Dr. Henry is an Assistant Professor in the Department of Health Promotion at the University of Nevada, Las Vegas, Nevada.

Health education is a term closely associated with health promotion. Cited frequently in the professional literature, health education is any combination of learning experiences designed to facilitate voluntary actions conducive to health.

Roles and Responsibilities

The role of a health educator has evolved over time, beginning with school health hygiene education in the mid-1800's and gradually moving into the public health arena in the 1900's when writers, journalists, social workers, and visiting nurses disseminated information about healthy behaviors. Today, health undergraduate and graduate degree recipients design, implement, and evaluate large-scale health promotion programs that reach millions of people around the world. Listed in the U.S. Department of Labor, Bureau of Labor Statistics, the job description for health educators includes to "promote, maintain, and improve individual and community health by assisting individuals and communities to adopt healthy behaviors."⁷ Additionally, health educators are charged with the responsibility to "collect and analyze data to identify community needs prior to planning, implementing, monitoring and evaluating programs designed to encourage health lifestyles, policies and environments."⁸ The health educator may also serve as a resource to assist individuals, other health professionals, or the community and may administer fiscal resources for health education.

Health educators can be found in a variety of settings, including schools (K-12, colleges, and universities), community health agencies (both governmental and nongovernmental), worksites (business and industry, for example), and medical settings such as clinics, hospitals and managed care organizations. Health educators are responsible for the following:

1. Assessing individual and community needs for health education.
2. Planning effective health education programs (program design).
3. Implementing health education programs.
4. Evaluating the effectiveness of health education programs.
5. Coordinating provision of health education services.
6. Acting as a resource person in health education.
7. Communicating health and health education needs, concerns, and resources.⁹

Patient Counseling and Education

Two areas in which health educators can successfully collaborate with other health practitioners include patient counseling and education. A physician is not the only health professional who can educate and counsel patients. Utilizing health educators to provide health care services can decrease medical costs and improve the efficiency of health care delivery.¹⁰

Counseling and education from the viewpoint of the professional health educator is very different from the perspective of the physician or other medical clinical personnel. Health counseling involves an action oriented and participative relationship between a patient who needs to reduce health risks or change life-style patterns and a skilled counselor who can facilitate the patient's acquisition and maintenance of these health changes. As such, counseling and education can be defined as intensive and interactive processes.

Typically, an office visit to the primary care physician includes only a brief face-to-case conversation with the physician with the focus of the visit being the provision of medical services—preventive, diagnostic and curative. Health educators, on the other hand, can offer

extensive and detailed information about the patient's particular health issues (for example, a recommended change in diet) that fits the patient's lifestyle and personality and is specifically related to the patient's individual concerns after a diagnosis by the physician.

Services that can be rendered by the health educator in patient education include, but are not limited to, bridging the medical terminology gaps between the physician and the patient, disseminating information on related topics, verbally informing patients about the relationship between specific behaviors and the patient's health condition, and providing person-to-person education on the health issue of concern. These services fit the model proposed for collaboration between the health educator and physician whose encounters with the patient are, by necessity, limited in time.¹¹ Formal health counseling sessions may last 30 minutes each week for a period of six weeks or more. Obviously this level and intensity of patient education is not what normally occurs within the average physician office visit.

Research

Health educators are frequently called upon by federal agencies, state and local governments, and community-based organizations to develop and direct prevention programs and community health education programs. Research in these areas may consist of traditional control/comparison groups and needs and risk assessment. Even time spent by patients in medical office waiting rooms or emergency room assessment centers could be used by a health educator to collect valuable data on health behaviors in order to design or implement better health programs

Working together to offer the best patient care, the medical provider often serves as the initial contact who then refers patients to appropriate health promotion programs or research studies that are conducted by health educators. This collaboration works well for the physician or other health care provider, the health educator, and, of course, the patient.

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White House Medical Support

By George F. Fuller, M.D., COL, MC, USA*

In a nutshell, the mission of the White House Medical Unit (WHMU) is to provide comprehensive worldwide medical care and emergency actions to the President of the United States, the Vice President, and their families—otherwise known as the “Principals.” The WHMU has existed since World War II as a sub-unit of the White House Military Office (WHMO) and is proudly served by a contingent of Department of Defense (DoD) medical professionals. This article will focus on the role of the White House Physician (WHP).

Selection Process

The first Physician to the President (P to P) was appointed under George Washington. Today the exact process of selecting the White House Physician hinges on the needed personnel mix of the WHMU. Specifics, like many of the duties of the WHMU, are “black” and thus secret. However, in general a worldwide search is executed for a candidate who meets the criteria set forth by the unit for that position. While the specific skill set will vary, usually a physician must have completed two tours of duty (a total of at least five years) after finishing residency training.

While the President of the United States (POTUS) does not meet directly with the candidates, his wishes and operating style are conveyed through the Senior Physician. The parent service screens each candidate and submits a short list to The White House. Review of the military records, curriculum vitae and confirmatory contacts are made, followed by a preliminary security screen, interviews, and then a final selection. Without a high probability of success in the security process, no candidate can be considered. Once a final selection is made, the first order of business is initiation of a full security background check. To function in this position, a Top Secret clearance with a Yankee-White adjudication (TS-SCI) is required—a process that can take a year or more, depending on the complexity of the case and current security backlogs.

Team Members

The WHMU team is comprised of all military members except for one civilian secretary and can vary in exact number, but includes from five to six physicians from the Army, Navy, and Air Force. The physician remains in his or her service, is assigned to the Chief of Staff (in the case of the Army), and detailed to the White House. Typically there is one Emergency Room physician, sometimes an Internal Medicine physician, and the rest are Family Physicians. One of the physicians will always be the Senior Physician. The President is free to name a military or civilian physician as the P to P if he wishes, usually after a year or more in office. The last two Presidents have chosen a military physician as P to P, but President Bush (Bush 41) named a civilian physician. President Clinton did not name any P to P until almost 7 years into his Presidency, although he had the same Senior Physician from the beginning of his term.

* COL Fuller was a White House Physician during the Clinton and Bush 43 Presidencies. He is the Associate Chair for Administration and Finance in the Department of Family Medicine and the Army Brigade Surgeon at the Uniformed Services University of the Health Sciences in Bethesda, Maryland. Dr. Fuller sees patients in the University Health Center, teaches in all four years of the Medical School, and conducts clinical research.

Currently, Colonel Richard Tubb, a Family Physician in the USAF, is the P to P for President George W. Bush (Bush 43). Previously, Dr. Tubb served as Vice President Gore's physician for approximately 5 years. Tradition dictates that the P to P always leaves his position before a new President takes office, although other White House Physicians may remain in the WHMU to assist with transition at the request of the new Senior Physician or P to P, with typically a confirmatory word from the POTUS. Filling out the WHMU are also five to six registered nurses, five to six physician assistants, and three to four administrative support personnel.

Orientation into the WHMU is a long, formal, and tedious process. It can take a full year before an individual is independently capable of executing all missions on a worldwide basis. None of this can even begin until the TS-SCI is completed. Therefore, the investment in the individual is a major one and his or her success is essential for the health of the unit.

Primary Missions

The WHMU has two primary missions. The first, "Executive Medicine," is the confidential, immediate, and private access to preventive, routine, and urgent care for the Principals. This is a twenty-four hour, seven days a week commitment with no exceptions. The senior physician may be chosen Physician to the President, a title that includes official designation as Assistant to the President. This individual is the personal primary care physician for the President and the First Family, and is kept aware of all their medical issues at all times. The White House Communications Agency (WHCA) provides both secure and non-secure communications continuously on a worldwide scale, making specialty care coordination and inpatient care available as well as press coordination and advisory services.

The second mission, "Protective Medicine," is the medical support of emergency actions and evacuations. It is minutely and carefully planned for all known contingencies and flexibly structured to respond to novel threats. The seriousness of this commitment is witnessed by the fact that the President cannot even ride an elevator in the Eisenhower Executive Office Building (EEOB) without a physician escort. The two missions, Executive Medicine and Protective Medicine, are simultaneously operative at all times.

Supporting Missions

Supporting missions exist side-by-side with the primary missions. Continuous training with the United States Secret Service (USSS) at their training facility in Beltsville, Maryland is mandated for, from the USSS perspective, the medical team is part of the Principals' protective umbrella. The goal of a WHP is to be close, but not too close, since a wounded physician is of no use to the Principal.

There is also ongoing training that fosters the highest level of continuing medical competency. The WHMU maintains a Medical Intelligence Center (MIC) that houses the Global Medical Intelligence and Travel Medicine Support missions for both domestic and international trips.

Finally, a very broad mission of "care by proxy" exists, whereby medical care is provided for those who assist the Principals. Staff, USSS, and official White House guests are among those served. Even unofficial guests, such as participants in White House tours, in need of immediate medical attention are evaluated and treated for minor problems or referred if more extensive care is needed. George Washington University Hospital is the designated Level 1 trauma center in the White House vicinity.

Medical Facilities

A number of medical facilities support the missions of the WHMU. These include the White House Residence medical and dental clinics, located in the main section of the White House, just below the State Floor next to the private Presidential elevator. Next-door are the EEOB medical and optometry clinics, staffed during normal duty hours and funded by the National Naval Medical Center (NNMC) for clinical services to authorized beneficiaries only. The NNMC Medical Evaluation & Treatment Unit (METU), a dedicated wing of the hospital on the NNMC main campus, provides inpatient services and the coordination of the annual Presidential physical exam. The METU can also be made available to other dignitaries, solely at the discretion of the POTUS.

The Naval Observatory (home of the Vice President and his family) first aid facility is staffed at all times the VP is on the grounds. The Second Residence first aid facility (currently at the the Texas Presidential Residence) is active whenever the President is in residence at that location. On Air Force One, the treatment compartment is always staffed by a physician and a nurse when the plane is in flight. In addition, there are other facilities that support contingency operations.

North of Washington, DC, on top of a mountain in Maryland, stands Camp David. It is comprised of roughly 100 acres and has been a Presidential Retreat for many years. It is a completely secure site, offering great and unique freedom to the President. Here the President can fully run the government under any foreseeable scenario or he can participate in any number of recreational activities. The Camp David Medical Clinic, credentialed by NNMC, is a fully equipped and supplied outpatient clinic. It is staffed for the cadre assigned there (Navy Seabee and Marine Guard personnel, plus others) by Navy Independent Duty Corpsmen. The WHMU then augments this medical staffing whenever the President is in residence. All the usual outpatient procedures can be performed, with access to anything available at NNMC. There is full emergency and evacuation capability as well.

Presidential Travel

Supporting a major international trip is one of the many challenges and rewards of Presidential service. Typically, a major diplomatic effort will be planned many months in advance. When travel is first announced, the WHMU will assign a physician to be trip director. The trip director's first actions will be to determine a medical threat assessment and plan necessary immunizations and medical prophylaxis. Once tentative sites are identified, preliminary assessment of local medical facilities begins. The WHMU keeps a unique and extensive library of medical facilities throughout the world.

An initial planning mission, or "pre-advance," is scheduled several months before the actual trip. A small number of individuals will travel to the host country and work out details of the President's visit. This is an opportunity for the WHMU trip director to visit the probable medical facilities and assess the adequacy of care. The ideal is the equivalent of a U.S. Level 1 trauma facility, though this is not always possible. The key issue during the pre-advance is to determine whether a host facility will meet the needs of the WHMU. When this is not possible a mobile military hospital can be tasked to provide trip support.

After the pre-advance, a formal, lengthy trip document is prepared by the WHMU detailing environmental and medical threats and providing contact information for the staff at each site.

Traveling staff are immunized and prepared for the trip. A large foreign trip will include well over 1,000 individuals spread out over many countries, all requiring medical support. There is extensive cooperation with the State Department and utilization of their expertise and personnel whenever possible. A WHMU member will advance each site several days before the trip begins in order to finalize plans and get acclimated prior to the arrival of the official Presidential party. Another team travels on Air Force One with the President.

For example, on one trip President Clinton traveled to India and Bangladesh. The WHMU had elements in place in all eight sites visited and used State Department assets in four locations. HMX-1 Medical Support (the Marine helicopter), the USAF SPEARR (Small Portable Expeditionary Aeromedical Rapid Response) team (capable of emergency surgery), Secret Service support, and Johns Hopkins medical contract personnel on Secret Service planes were all available to provide medical assistance. TALCE (Tactical Airlift Control Element) and IDMT (Independent Duty Medical Technician) teams were established at utilized airports. Aeromedical evacuation plans involving Thailand, Singapore, and PACOM (Pacific Command) TPMRC (Theater Patient Movements Requirement Center) in Yakota, Japan were also in place along with others. During the trip, visits to Pakistan, Oman, and Switzerland were added emergently and additional preparations had to be made on very short notice.

When President Clinton traveled to Africa, because there were no medical facilities that could meet WHMU needs in several countries the USAF sent a deployable hospital that they set up on airport runways. Helicopters were available to provide evacuation from the official sites.

White House medical support is an extremely important military mission. It is also one of great satisfaction and incredibly fascinating life experiences. It is a unique opportunity to serve our great Nation while growing as a person and physician. It is a true team effort which highlights many of the best facets of the military work ethic. Above all it is an honor and a privilege.

DTC Advertising of Prescription Drugs: How Does it Impact Patient Behavior?

By Sarah Oetgen, MPH*

Despite its profoundly important contributions to the advancement of health information, treatment, and technology, the pharmaceutical industry receives continuous criticism from political leaders, health care providers, managed care organizations, and the general public. Two of the most common complaints about the pharmaceutical industry—the price of drugs and the companies' huge profits—are related to the advertising and promotional costs of prescription drugs. Many critics argue that money spent on advertising could be better used for research and development of new products or could reduce the costs of existing medications. Alternatively, proponents claim that direct-to-consumer (DTC) advertising aids patients in ultimately making better health care decisions.

Most would agree that marketing in some form is essential to prescription drug development, distribution, and utilization. Historically, drug companies directed promotion and advertising of new pharmaceuticals, including their benefits and risks, at physicians and other medical personnel. This “detailing” was carried out by pharmaceutical sales representatives who present physicians with information about and samples of the products their companies market, and by advertising in professional journals and at medical conferences.¹ One of the driving forces behind the rise in DTC spending was the need for pharmaceutical companies to stimulate demand in an increasingly competitive marketplace.

Since 1997, when the Food and Drug Administration (FDA) loosened its regulations on direct-to-consumer advertising, ads featuring prescription drugs have appeared in growing numbers on television, radio, and in print media outlets. In 2001, the pharmaceutical industry spent approximately \$2.5 billion on all forms of DTC ads.

The fundamental debate surrounding prescription drug advertising is whether marketing strategies once limited to physicians are appropriate for consumers with little or no medical or scientific background and whether DTC marketing tactics provide any ultimate value to consumers.

Advertising History

In 1981 the pharmaceutical industry first proposed expanding its marketing strategy beyond physician-focused advertising to include consumers. The industry argued that DTC marketing and advertising provided the public with educational benefits. At the same time, there was a movement among political and regulatory groups to allow consumers more choice and to encourage them to share in medical decision-making.²

* Ms. Oetgen is Vice President of Sensei Health, a media relations and marketing communications firm specializing in health care issues. She has received multiple awards for health promotion and education programs in various health care arenas.

In 1983 in response to the mounting pressure from industry and the lack of formal policies in place concerning advertising, the FDA called for a voluntary moratorium on DTC advertising campaigns for pharmaceutical products. In 1985 the moratorium was withdrawn. The FDA allowed pharmaceutical companies to advertise to consumers, provided they follow the existing standards for advertisements directed at physicians. It was also requested that manufacturers provide DTC ads to the FDA for preliminary review.

Following a public hearing in 1997, the FDA issued new guidelines for broadcast DTC advertising that allowed television and radio ads, for the first time, to promote a specific drug without disclosing all of the product's risks. Advertisements were required to provide a fair balance between descriptions of the product's benefits and side effects, and had to list sources (such as a toll-free telephone number, website, physicians, and pharmacists) available for additional information about the product. Although the FDA did not require pre-clearance on advertising materials, the agency had the authority to review materials if there was a question as to whether the guidelines were being followed appropriately.

Today, more than five years after the FDA issued the revised guidelines, DTC marketing of prescription drugs remains the focus of considerable debate. Several factors have motivated pharmaceutical companies to increase their DTC marketing efforts over the past few years. For example:

- As more patients take an active role in their own health care, DTC marketing of prescription drugs educates them about available treatments, presumably empowering them to make informed choices about their own health.
- DTC advertising effectively reaches patients and physicians who would not be accessible through other marketing efforts.
- Increased competition in the marketplace has led pharmaceutical companies to market many new drugs in order to maintain a healthy market share.³

Current Advertising Regulations

Under regulations contained in the Food, Drug, and Cosmetic Act (FDCA), direct-to-consumer drug advertisements fall into one of the following three categories:

1. Health Seeking. Advertisements educate consumers about a disease or condition, but a specific drug is not named. For example, an advertisement aired by Upjohn in 1989 encouraged men who were concerned about hair loss to see their doctor, but their product, Rogaine, was never mentioned.
2. Reminder. Here, advertisements provide the name of the drug and other minimal information but do not discuss the drug's use, effectiveness, or safety. No summary of product risk is required.
3. Product-specific. These advertisements mention a drug by name, describe its therapeutic uses, and discuss its safety and effectiveness. The majority of drug advertisements fall into this category.⁴

Opponents of DTC advertising have argued that pharmaceutical ads induce inappropriate consumer demand for prescription drugs, especially the newer, higher-priced drugs. Additionally, they note that increased consumer demand leads to increased prescription drug use. Opponents also suggest that the ads place an added burden on physicians who are often

required to spend extra time during office visits to properly educate patients about the advertised pharmaceuticals.

On the other side of the debate, proponents of DTC advertising claim the ads serve to educate the public about health conditions and available treatments, therefore encouraging patients to seek care for health problems they may not have known existed. Proponents state that information empowers patients and claim that because the pharmaceuticals in question require a physician's prescription, the ads themselves do not lead to inappropriate drug use.

Current Trends

Before reviewing the research surrounding these arguments, it is important to note the current trend towards higher drug pricing, larger advertising budgets and increased overall spending on pharmaceuticals.

Price of Drugs

The average price of a prescription has increased steadily since 1990. This rise in cost has been fueled by increases in manufacturers' prices for existing drugs as well as higher prices for newer, brand name drugs. In 2000 the overall retail price for a brand-name prescription drug was \$65.29, more than double the average price in 1990 which was \$27.16.⁵

Advertising Budgets

While drug prices have risen, promotional activities for prescription medications have also grown in the last several years. Although pharmaceutical companies' spending on detailing and sampling in physicians' offices has increased steadily, growth of DTC advertising has been the most rapid. DTC promotion spending increased nine-fold from \$266 million in 1994 to \$2.5 billion in 2001, largely due to more television advertising. In 2000 costs for DTC advertising comprised 16% of total promotional spending, up from 9% in 1996. Detailing and sampling, however, remain the major expenditures for promoting prescription drugs.

Overall Spending

Perhaps the result of rising drug prices and increased promotional efforts, overall health care expenditures for prescription drugs are growing at a faster rate than spending for hospital care and physician and clinical services. Despite this growth, prescription drugs remain a relatively small percentage of total personal health care expenditures.⁶

One clear example of DTC advertising's growth and its effect on drug sales was highlighted in a study released by the National Institute for Health Care Management Research and Education (NIHCM). The study found that retail prescription drug spending in the United States increased to approximately \$131.9 billion in 2000, from \$111.1 billion in 1999. The NIHCM study found that sales of the 50 drugs most heavily advertised directly to consumers accounted for 48% of this increase. The approximately 9,850 other prescription medicines sold in the United States were responsible for the remaining 52% of the increase. The top 50 drugs pulled in \$41.3 billion in 2000, roughly 31% of the total amount that Americans spent on all prescription drugs that year.⁷

Patient Awareness and Attitudes

In order to better understand the impact of DTC advertising on patient behavior, one must first examine consumer exposure to, awareness of, and attitudes about DTC advertising. Several studies have attempted to capture consumers' feelings about advertising.

A survey conducted in 1986 found that older consumers were more accepting of DTC advertisements than were younger respondents. The researchers suggested that older people might view taking prescription drugs as a sign of health, whereas younger people may consider taking prescription drugs to be a sign of illness.⁸

In 1998 it was reported that 66% of pharmaceutical consumers in the central part of the United States recalled seeing a particular product advertised in print media and that 61% of consumers in the South recalled seeing one advertised on television.⁹ Based on these findings, DTC advertising was reaching the majority of consumers in these parts of the country. A later survey in 1999 examined consumers' understanding of and exposure to DTC advertising. On average respondents knew of 3.7 out of the 10 drugs included in the survey. The survey found that awareness of DTC advertisements was closely associated with having been diagnosed with a condition for which a specific drug was advertised. In another study 91% of consumers said they had seen or heard an ad for a prescription drug.¹⁰

High consumer awareness does not mean that consumers are being educated or increasing their knowledge about the drugs or conditions being advertised. The lack of educational impact derived from DTC ads is illustrated by a recent survey conducted by the Kaiser Family Foundation that reported 70% of respondents said they learned little or nothing about the health condition mentioned in the ads they saw and approximately 60% said they learned almost nothing about the featured drug. Similarly, the survey found that many consumers were not clearly informed about a drug's side effects nor were they clear about where to turn for more information. These findings demonstrate that potential consumers are still not obtaining useful and understandable information about the benefits and risks and benefits of the advertised drugs.

Patient Behavior

An important question to ponder is how patients' awareness of drug ads and their attitudes about these promotional activities translate into behavior and, ultimately, health outcomes. While some argue that advertisements act as a springboard for better communication between patients and their health care providers, others caution that the same advertisements cause inappropriate demand, overuse of medications, and lead to a belief among consumers that there is a pill to cure everything. A discussion of both the positive and negative impact of DTC advertising follows.

Positive Impact

Motivates Discussions

Studies have shown that DTC advertising stimulates important discussions between patients and their physicians.¹¹ If a consumer learns through DTC advertising of new information about or a treatment available for a condition, he or she can raise this topic with the physician.

A survey¹² conducted in 1998 found:

- More than 53 million consumers talked to their physicians about medicine they saw advertised.
- An additional 49 million people sought information about the drugs they saw advertised from another source, such as the Internet.
- After viewing DTC advertising a projected 21.2 million consumers felt encouraged to talk with their doctor about a medical condition or illness they had not spoken about before.

The survey concluded, "DTC advertising may play a very real role in enhancing public health."¹³

Increases Patient Education and Knowledge

Many believe that the explosion of DTC drug advertising has led to better-informed consumers. While healthy people cannot be expected to seek out a physician's advice if they do not consider themselves at risk for illness, advertisements may help to raise awareness about symptoms or risk factors for a disease and may prompt a consumer to seek a physician's advice. Given the current managed care system that encourages physicians to control costs and decrease unnecessary patient visits, some argue that the cost of advertising targeted to susceptible groups is much lower than the cost of a physician's seeking out and examining every patient perceived as being susceptible to a specific disease.¹⁴

The point has also been raised that DTC advertising provides information about side effects and risks that physicians may not always share with their patients. If consumers are unaware that the symptoms they are experiencing could be side effects of medications, they may not know to consult their doctors and request alternative medications. Additionally, some physicians may consider some drugs too risky and choose not to share information about these drugs with their patients. However, unless patients are aware of all options available, those patients cannot make informed decisions about the best treatment for their personal conditions.

Encourages Patients to Seek Treatment

Many diseases may be present for a long time before symptoms occur. Oftentimes consumers may experience symptoms that they do not realize are associated with a disease (e.g., thirst as a symptom of diabetes). If consumers do not recognize their symptoms as a sign of illness, they may put off consulting a physician, thus allowing the disease to progress.¹⁵ Some suggest that advertisements encourage patients in need of medical attention to consult physicians. In the long run, early diagnosis and intervention could improve overall health and reduce treatment costs.

Additionally, for individuals who know they are at high risk for a certain disease, knowledge of a new vaccine or preventive medication would be helpful. It is argued that advertising would be more likely to reach them than if physicians were the only source of information. Information about a new drug with an easier dosing schedule or better side-effect profile may lead people who have already been diagnosed with a disease, but have discontinued treatment, to consult their physicians again to try this new treatment.

In a recent telephone survey conducted by the FDA, adults were asked about their views on DTC promotion of prescription drugs and its effects on visits to the doctor. When asked if an

advertisement for a prescription drug ever caused them to look for more information about their health, 51% of the respondents said it did. Of those, 81% said they went to their doctors for more information, 52% consulted a pharmacist, 36% looked in a reference book, and 30% asked a relative, friend or neighbor.¹⁶

Another survey conducted in 1999 gauged the public's response to drug ads in general.¹⁷ The survey found that nearly a third (30%) of adults have talked to their doctor about a drug they saw advertised, and 44% of those who talked to their doctor received a prescription for the medication they asked about. Thus, approximately one out of every eight Americans (13%) has received a specific prescription after seeing an advertisement for that drug outside the physician's office.

Negative Impact

Financial Motives

On the other side of the debate, many say that DTC advertising by the pharmaceutical industry is simply driven by financial motives and provides information of questionable quality with little benefit to the consumer. Instead of educating consumers and promoting healthier lifestyles, DTC advertising creates inflated consumer demand and undermines the physician's role in deciding the best treatment strategy for patients.¹⁸

Research suggests that DTC ads are simply promotional pieces that increase brand awareness rather than educational tools to help increase consumer knowledge. In one survey¹⁹ after watching a series of ads, respondents were asked to comment on the information they saw. Seventy percent (70%) of the respondents said they had learned little or nothing more about the health condition the product was supposed to treat, and a majority (59%) said they knew little or nothing more about the drug itself.

Increases Demand and Use of Rx Drugs

DTC advertising may be responsible for cultivating a belief among the public that there is a pill for every illness, thus leading to increased drug demand and over-medication. Some suggest that consumers do not have the clinical or pharmacological background to properly understand and evaluate DTC advertisements.²⁰ Absent this foundation of medical expertise, viewing DTC ads can lead to confusion and inaccurate perceptions of a drug's effectiveness and safety.

Some ad-motivated discussions with physicians focus on specific brand name drugs or trivial complaints that do not pose serious health risks. It is arguable that this takes up time that could be better used discussing a patient's condition or symptoms, the range of available treatments, and the context or cause of the patient's illness.

In a California study²¹ respondents were asked how they would react if their physician denied their request for a drug they saw advertised. This survey found:

- Almost half (46%) of respondents would be disappointed;
- One-quarter (25%) said they would try to change their physician's mind;
- Another one-quarter (24%) would try to get the prescription from a different doctor; and
- Almost one in six (15%) thought they would switch to another doctor entirely.²²

Of prime concern is the fact that DTC advertising rarely mentions lifestyle changes or other non-pharmacological interventions that are often a critically important part of therapy. Reports have profiled patients who became angry when their physicians insisted on a low-fat diet, stress management or allergen avoidance rather than simply writing a prescription for drugs to treat some medical conditions.^{23,24}

Challenges the Physician

It is likely that patients who arrive at office visits with a print advertisement in hand or with requests for drugs they saw promoted on television are another part of the "hassle that often accompanies patient care in modern medical practice."²⁵ Indeed, some physicians are becoming frustrated with the increasing amount of time they must spend re-educating patients about an advertised drug or decreasing patient expectations of certain pharmaceuticals.

Patients who learn about a treatment through advertising and are lead to believe it will help them may become annoyed if their physician does not prescribe the specific product. This could put a strain on the patient-physician relationship. Under the worst-case scenario, DTC advertising could lead to partially informed, distrustful patients who demand that physicians prescribe drugs against their better judgment.

Creates False Sense of Prescription Drug Safety and Effectiveness

Some of the most alarming research has suggested that DTC ads create a belief among consumers that a simple pill can solve everything, without sufficient warning about possible side effects. Parallels can be drawn with old cigarette ads that featured a healthy, vigorous, and rugged "Marlboro Man" who was actually an obvious misrepresentation of the average heavy smoker. Eventually, cigarette advertisements were banned from many venues and an anti-smoking campaign more realistically depicted the "Marlboro Man" as having emphysema. Some of today's prescription drug ads could be viewed as being guilty of a similar type of misrepresentation.

Drug companies have faced serious criticism for marketing AIDS medications through direct-to-consumer advertisements that "do not convey the seriousness of the disease and are contributing to an 'upsurge' in HIV infection rates."²⁶ The debate over whether such ads portray a dangerously unrealistic picture of what life is like for people taking these medications and whether the ads contribute to a complacency surrounding safe sex was further fueled by initial survey results from the San Francisco Department of Health released in 2001. The survey found that these ads affected individuals' decisions regarding whether or not to engage in unprotected sex. The survey also found that the ads "glamorized" the lives of HIV-positive individuals and led gay men to think unprotected sex was the norm. In early 2001 the FDA ruled that the advertisements had to more accurately reflect the realities of HIV and AIDS.²⁷

DTC advertisements for drugs that treat attention deficit-hyperactivity disorder (ADHD) have also raised concerns among pediatricians, government regulators, teachers, and parents. Last year, at the expiration of a 30-year agreement with the federal government to refrain from marketing controlled substances that are highly addictive to consumers, pharmaceutical companies began DTC marketing of drugs such as Ritalin to treat ADHD in children. Critics argue that the ads oversimplify this highly complex disorder, for which there is no simple lab or blood test, and create an expectation among parents that every childhood behavioral problem is attributable to ADHD.²⁸ In addition, findings from a Massachusetts Department of Public Health

survey revealed a growing problem with Ritalin abuse among children in schools, which would only be worsened as, over time, more children were prescribed the drug.²⁹

Furthermore, the FDA appears to be backing off from policing DTC advertising. Through September of 2002 it demanded that companies fix distortions in ads just 18 times, down from 64 times for all of 2001, despite rapid growth in the number of ads and leaflets promoting drugs. The FDA also is actively considering whether it should loosen rules governing ad content. According to critics these actions could put the public's health at risk and help to push drug spending even higher than the present \$154 billion as patients buy drugs they do not need.³⁰

Recommendations for More Responsible DTC Advertising

The ability of DTC ads to educate the public about medical conditions and treatments depends on the quality of drug information in the ads themselves. While individual studies have limitations, the data as a whole suggest that, at the very least, the quality of information in DTC advertisements should be improved in order to avoid a negative impact on patient behavior.

Several studies show that DTC drug advertisements are effectively reaching consumers, leading consumers to talk with their doctors and increasing demand for drugs. At the same time, other research demonstrates that important messages about drug risks, the location of further information, and preventive measures consumers can take to protect themselves from disease are not being retained by consumers. Patients quickly forget these specific messages even if they are included in DTC ads. In order to better understand how DTC ads affect patient behavior, future research should be designed to determine if the ads:

- Enhance or detract from office visits.
- Increase or decrease patient/physician trust.
- Lead to early diagnosis or treatment.
- Are more effective or less effective than physicians in educating consumers about treatments.

Assuming DTC advertising is here to stay, there are at least four steps the pharmaceutical industry can take to develop more responsible ads that would effectively promote their products while providing valuable information to consumers.

1. In DTC print ads, pharmaceutical companies should fully disclose important information about their advertised drugs, including what condition the medication is for, who should or should not consider taking it, potential benefits, and potential risks. This information should be provided in a simple and easy-to-read format—perhaps similar to nutrition labels on food—so that consumers are more likely to take the time to read the information. A telephone survey conducted in 1999 by the FDA showed that the majority (56%) of consumers read “none” or “very little” of the small print information that provides important details found alongside drug advertisements in newspapers and magazines.³¹
2. Print and television advertisements should not use medical jargon or scientific language that cannot be easily understood by the average consumer. By using only “layman's terms” in DTC ads, pharmaceutical companies could potentially save physicians time and

resources that they currently spend by having to explain information in advertisements or educate patients about the use and appropriateness of certain medications.

3. DTC advertisements should be more “disease-focused” rather than “drug-focused.” Drug companies would benefit by raising consumer awareness of diseases that their products can help by providing responsible health information to the public.
4. Pharmaceutical companies could also participate in research to determine the impact of DTC advertising on patient behavior. This research could be focused on the specific drugs they market, or conducted to quantify the potential benefits of DTC advertising in general.

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The National Practitioner Data Bank and Its Inclusion of Unlicensed Residents and Interns

By Sandeep K. Narang, M.D., J.D., LT, MC, USNR*

Almost 20 years ago, the United States legislature took specific action because it was concerned about the crisis in the delivery of quality health care. The considerable public outcry led Congress to enact Public Law No. 99-660, Title IV of which is the Health Care Quality Improvement Act of 1986 (HCQIA or the Act). The National Practitioner Data Bank (NPDB), through the Secretary of Health and Human Services, emanated from HCQIA.

Amidst today's current health care crisis and renewed public concern, our focus has again turned to modifying the present health care system. It was recently estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors.¹ Based on these figures, deaths secondary to medical errors exceed the number of deaths attributable to the eighth leading cause of death in the U.S. and represent additional estimated costs to this nation in the tens of billions of dollars.² The collective conscience of the United States is once again wondering what can be done to help remedy the situation.

This article addresses the reasons for creation of the NPDB, its level of success, and whether or not residents and interns in authorized training programs (and not yet licensed by any state) were ever intended by Congress to be reportable and thus included in the NPDB.

Legislative History

Through extensive investigation and data gathering, face-to-face interviews with numerous nationally recognized health care experts, and long meetings at the committee and subcommittee level, in the 1980s Congress determined that a significant contributor to substandard medical care was the ability of incompetent or unethical physicians to move from state to state without the ability of the new state to uncover those physicians' previous incompetent acts.³ The Act as subsequently written reads in part:

"The Congress finds the following:

- (1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual state.
- (2) There is a national need to restrict the ability of incompetent physicians to move from state to state without disclosure or discovery of the physicians previous damaging or incompetent performance..."⁴

* Dr. Narang is presently serving as Medical Officer aboard the USS Sacramento, a fast attack combat supply ship at sea in support of Operation Enduring Freedom. He wrote this article while he was a pediatric resident at the National Naval Medical Center, in Bethesda, Maryland. Any opinions expressed are those of the author himself.

It was Congress' intent that the NPDB be the vehicle by which free and undisclosed movement of incompetent or unethical physicians was restricted.

What Is Reported?

The HCQIA requires essentially three types of information to be reported to the NPDB: 1) reports on medical malpractice payments, 2) reports of adverse actions, and 3) Medicare/Medicaid Exclusion Reports.⁵ Insurance companies, state patient compensation funds, and other entities that make payments in satisfaction or settlement of a medical malpractice action or claim must report these payments to the NPDB. Self-insured practitioners are exempt from this reporting requirement.⁶ Every state medical board must report to the NPDB adverse actions such as revocations, censures, or reprimands that result from a physician's questionable professional competence or conduct.⁷ Each health care entity that makes a professional review action that adversely affects the clinical privileges of a physician for longer than 30 days, or accepts the surrender of a physician's clinical privileges in exchange for not investigating that physician, must report such an action to the NPDB.⁸

Information contained in every medical malpractice payment report, for example, that goes to the NPDB generally includes the name of the health care provider, amount of payment, name of affiliated hospital (if any), and general description of the acts or omissions and injuries or illnesses upon which the action or claim was based.⁹ This information in turn is disseminated to appropriate, authorized querying entities.

By the end of the year 2000, data in the NPDB included 164,320 practitioners (primarily physicians, dentists, nurses, and other health care providers) with some type of report, whether medical malpractice, adverse action, or Medicare/Medicaid Exclusion.¹⁰

Has the NPDB Succeeded?

Given the troubling statistics regarding the continued number of patient deaths secondary to medical errors, it can be argued that the quality of American health care today is not significantly better than it was in the 1980s. Was Congress not entirely correct in concluding that a significant contributor to America's substandard health care is the ability of incompetent or unethical physicians to move undetected from state to state? Or has the NPDB simply been unsuccessful in restricting these movements?

Many health care experts have proffered that medical errors are the result of "systems failures," and not human errors.¹¹ They claim that blaming individuals or delineating "bad apples" does little to improve overall safety or to prevent similar errors in the future. The famous report from the Institute of Medicine states, "the common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients requires a systems approach...the problem is not bad people; the problem is that the system needs to be made safer."¹²

Others have proffered that the NPDB has been a poor gatekeeper of not only restricting the movement of incompetent or unethical physicians from state to state, but in simply identifying those alleged incompetent physicians.¹³ In highlighting the NPDB's inadequacies it has been

argued that being reported to the NPDB, particularly through medical malpractice payment reports, does not equal “incompetence.”¹⁴ Several reasons have been offered:

- One reported incident of medical malpractice (which constitutes the great majority of practitioners in the NPDB) does not automatically mean a health care provider is incompetent or unethical.
- Medical malpractice settlements reported to the NPDB are often “nuisance” settlements, i.e., payments which have little or no bearing on whether the standard of care was met in a particular instance, but rather payments made because an insurer has deemed an action less costly to settle than to defend.
- Otherwise reportable practitioners can sometimes escape reporting by hiding behind the veil of a corporate or partnership entity.
- Variations in reporting exist depending on the particular state involved, or the licensing boards or professional societies.¹⁵
- Ambiguity in reporting certain actions can lead to misconstruction of the information contained in the NPDB.¹⁶

Residents and Interns

Did Congress intend to include residents and interns when it wrote the Act? An examination of the extensive legislative history of HCQIA, specific language of the Act itself, reasonable inferences from omissions from the Act, and executive policies of the federal agencies subject to the HCQIA could support the conclusion that Congress did not intend for unlicensed residents or interns acting within the scope of an accredited residency training program to be reported to the NPDB.

To determine Congressional intent, the full 500 pages of the legislative history for HCQIA must be examined, including approximately twenty statements and reports, as well as testimony from 26 different experts in the health care industry. In this entire volume of information, only one document from one witness mentioned residents or interns or residency programs and their impact on the substandard quality of medical care at the time.¹⁷ The document was entitled “Medical Licensure and Discipline: An Overview,” and the witness was Richard Kusserow, Inspector General of the Department of Health and Human Services. It was noted that a major concern of many state licensing boards was the ability of some unworthy medical school graduates to obtain licensure because of a lack of monitoring and reporting by some residency training programs.¹⁸ A remedy, Mr. Kusserow suggested to Congress, was for the Accreditation Council for Graduate Medical Education (ACGME) to require that hospitals and residency programs inform state medical licensing boards of resident performance and conduct. Thus, in months of testimony, meetings, and investigation, Congress spent virtually no time assessing residents or interns and their impact on the quality of medical care, and only a single witness raised the topic.

The specific language of the Act itself indicates that Congress did not mean to include residents or interns within its definition of “physicians” who are subject to the Act. In the “definitions” section of the Act, Congress specified:

“The term ‘physician’ means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or

dentistry by a state (or any individual who without authority holds himself or herself out to be so authorized)."¹⁹

If Congress were truly concerned about residents' or interns' contributions to substandard medical care, it could have included some language identifying physicians or practitioners "in a training status." In the alternative, wording to the effect that the term "physician" includes "any doctor-in-training" could have been incorporated.

In addition, Congress' intent to exclude from the Act residents and interns acting within the scope of an accredited residency-training program can be gleaned from the actions of agencies that implement the Act. The current working statement of the NPDB executive committee reads, "If a resident is working within the confines of written protocols and guidelines established by the ACGME, AOA or AMA accredited program, the responsibility lies with the supervising attending."²⁰ This, however, is only the "working statement" of the NPDB. Because it is not the Executive Policy of the Secretary of the Health and Human Services, it is subject to change.²¹

The Department of Defense (DoD) is charged with reporting to the NPDB. Its Instruction (DoDI) implementing participation in the NPDB also specifies not reporting residents or interns acting within the scope of their training. It states at Section 4.4.1:

"When a healthcare trainee is a significantly involved practitioner...the attending practitioner responsible for the delivered care shall be reported to the NPDB and DPDB. If the Surgeon General makes a specific finding that the attending practitioner clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending practitioner, then the trainee shall be reported to the NPDB and DPDB."²²

Justice and Fairness

In evaluating the concept of whether basic notions of justice and fairness are satisfied, one must look at the resident's or intern's perspective as well as society's perspective. The resident or intern could suffer future negative consequences by being reported to the NPDB. Society could be subject to continued substandard medical care from those unmonitored, incompetent residents or interns. Is the resident or intern being treated fairly by being subject to inclusion in the NPDB? Is society being treated fairly by excluding unlicensed residents and interns from the NPDB?

Since the inception of the NPDB, residents and interns have been reported almost exclusively through medical malpractice payment reports. Since residents and interns are not responsible for Medicare/Medicaid billing, they are not subject to Medicare/Medicaid Exclusion Reports. Nor are they subject to clinical privilege review because neither residents nor interns are formally granted clinical privileges. Additionally, residents and interns are rarely, if ever, subject to state medical board censure, reprimand, or probation, and therefore do not normally receive adverse action reports.

In terms of medical liability and insurance matters, residents and interns are probably the least knowledgeable of any in the medical profession and consequently the most vulnerable to future harmful consequences. A 1993 study²³ of pediatric residents in Pennsylvania revealed that 90%

of the residents had no idea of the policy limits of their liability insurance or, more importantly, that the insurance company could settle malpractice claims without their consent. Furthermore, 57 of the 66 residents surveyed had no knowledge that the NPDB existed, much less its purpose. Without knowledge of the NPDB or its deleterious effects on one's career, a resident or intern could unknowingly be reported and, based on this negative report, be denied future employment or incur higher medical malpractice insurance costs. Unfortunately, this has already happened to numerous surgery residents.²⁴

In addition, it is simply unfair to impute liability to those who lack independent and final decision-making authority and responsibility. Imputing liability to the unlicensed resident or intern acting within the scope of the residency-training program not only negates the tenet of "respondeat superior" (or "let the master answer")²⁵ and undermines the very spirit of medical education and training.

In today's paradigm of patient management in a training setting the intern or resident does not have the independence to solely manage, treat, or make decisions about an attending physician's patient. While he or she may gain more independence in patient management as the level of his or her education and training progresses, in the end, the resident or intern must do what the attending physician decides. Educational mutiny simply does not exist, or if it does, such instances clearly lie outside the proper scope of a residency-training program. There is clearly a hierarchy of decision-making in the training setting. Should the resident or intern acting on orders from a supervisory physician within the scope of a residency program be as liable, in terms of reporting to the NPDB, as the licensed attending physician?

Finally, the very act of imputing liability to the trainee detracts from the value of a residency or internship. By virtue of his or her superior knowledge and authority, the mentor is entrusted with stewardship of the education and training of the resident or intern. When the individual with less knowledge and authority, rather than the individual with more knowledge and authority, is held responsible for acts within the scope of the educational setting trust is broken and consequently the very spirit of education and training is diminished.

Society's interests are not subverted by the exclusion of unlicensed residents and interns from the NPDB. Of the 164,320 practitioners listed in the NPDB in 2000, fewer than 1%, or 1,342, were interns or residents (1,186 allopathic and 166 osteopathic).²⁶ Of those reported residents or interns, 1,188 had a single medical malpractice payment report and 55 had two such reports.²⁷ Thus, 85% of reported interns and residents had only one medical malpractice report. There is considerable reason to believe that the vast majority of reported interns or residents (those with just one malpractice payment report) are not really incompetent physicians.

At present there exists a proper tracking and monitoring mechanism for the quality of interns and residents—the residency-training program. Recently, the Accreditation Council for Graduate Medical Education (ACGME) followed previous recommendations made to Congress by mandating that federal credentialing agencies increase reporting requirements of residency-training programs in order to maintain accreditation.²⁸ In modifying accreditation requirements for all its programs, the ACGME required program directors of transferring residents or interns to obtain proper verification of performance and competence from the previous residency-

training programs.²⁹ It is now almost impossible for interns or residents to move from one program to another without detection of any previous difficulty or incompetence.

The language of HCQIA defining physicians and other health care practitioners reads “licensed or ‘otherwise authorized.’” Licensing and authorization rules vary widely among the States. Some states offer interns and residents a limited license to practice; some grant the training facility the authorization to allow the interns and residents to practice in that facility. Still others that do not specifically grant such authority are satisfied that the residency program itself authorizes the trainees to practice. The bottom line is that all interns and residents are either licensed or “otherwise authorized” to practice in the internship or residency program, and as such they all are subject to being reported to the NPDB for medical malpractice. The American Osteopathic Association and the American Medical Association have in some fashion created resolutions recognizing the inequity of resident or intern reporting to the NPDB, but these subtle gestures have not produced the force necessary to amend the Act. Until such time as that occurs, residents and interns will continue to be reported to the NPDB—a move that could unfairly ruin an otherwise promising medical career without addressing the ultimate question of protecting patients from incompetent health care providers and delivering quality health care to the American public.

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¹ Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Institute of Medicine. National Academy Press. Washington, DC. 1999.

² Id.

³ Reams B, Jr. *The Health Care Quality Improvement Act of 1986: A Legislative History of Pub. L. No. 99-660*. William S. Hein & Co., Inc. New York, NY. 1990.

⁴ 42 USC 11101.

⁵ Health Resources and Services Administration, Bureau of Health Professions, Department of Health and Human Services. *National Practitioner Data Bank. 2000 Annual Report*. Rockville, MD. 20003.

⁶ 42 USC 11131.

⁷ 42 USC 11132.

⁸ 42 USC 11133.

⁹ *Supra* note 6.

¹⁰ *Supra* note 5, at Table 1.

¹¹ For additional information on various patient safety issues including “systems failures” versus “human errors,” refer to the two previous editions of *Legal Medicine*. See specifically “Beyond Rhetoric: Teamwork, a Real Response to Patient Safety” by Mary L. Salisbury and “Obstacles to Error Reporting in a Patient Safety Program” by Eric S. Marks. Both are found in *Legal Medicine 2002* at pages 7 and 35, respectively.

¹² *Supra* note 1.

¹³ Fischer, JE. The NPDB and surgical residents. *Bulletin of the American College of Surgeons*. 1996;81:22-25.

¹⁴ *Id.*

¹⁵ *Supra* note 5.

¹⁶ For example, true adverse actions as well as the reversal of those adverse actions are both called "adverse actions" in NPDB reports.

¹⁷ *Supra* note 3, at pages 241-266. While Congress appeared to have little interest in residents or interns, it dedicated its time and energy to two primary topics: 1) the effectiveness of peer reviews in improving the quality of medical care, and 2) whether or not there should be a federal repository or database for monitoring adverse or disciplinary actions against health care practitioners; and, if so, what would be the most appropriate body to control that repository or database.

¹⁸ *Id.*

¹⁹ 42 USC 11151.

²⁰ Monaco C. Legislative update: National Practitioner Data Bank. *N.Y. State Osteopathic Medical Society Newsletter*. 2002;Spring.

²¹ In a recent NPDB executive committee meeting, some members of the Executive Committee wanted to change the present Working Statement so as to evaluate resident or intern reports on a case-by-case basis.

²² Department of Defense Instruction 6025.15, as amended October 12, 2000.

²³ Back MR, Reuben M. Medical residents lack liability knowledge. *AAP News*. 1994;10:19.

²⁴ *Supra* note 13.

²⁵ For a discussion of "respondeat superior" and other liability issues, see "Levels of Liability: It's Not Just the Physician Anymore" by Jane D. Weaver at page 16 of this publication.

²⁶ *Supra* note 13.

²⁷ *Id.*

²⁸ *Supra* note 3.

²⁹ Accreditation Council for Graduate Medical Education. *Common Program Requirements for 2002*.