

**THE NATIONAL PRACTITIONER DATA BANK (NPDB) PUBLIC USE FILE:
A Valuable Resource for Quality Assurance Personnel and Risk Managers
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The National Practitioner Data Bank is a repository of medical malpractice and other adverse action information concerning health care providers. After six years of operation, the NPDB contained over 145,000 records and \$18 billion in medical malpractice payments. To facilitate nationwide medical liability and malpractice research, an anonymous Public Use File was created. This information database constitutes a useful tool for large healthcare organizations, insurers, or others to obtain aggregate statistics on medical misadventures for comparison purposes. The NPDB Public Use File represents the only national source of malpractice data.

Introduction

The Health Care Quality Improvement Act of 1986 established the National Practitioner Data Bank (NPDB).¹ The NPDB, which is administered by the Bureau of Health Professions of the United States Department of Health and Human Services, formally began receiving medical malpractice payment reports and adverse action reports on September 1, 1990. This information database includes particulars on malpractice payments and other adverse actions, such as revocation or suspension of clinical privileges. One of the reasons for establishing the NPDB was to create a more effective mechanism to impair the ability of health care providers with questionable backgrounds to migrate from state to state and establish new practices. An overview of the rules and procedures concerning the NPDB was previously published in the 1997 issue of *Legal Medicine Open File*.²

Generally, the NPDB information about specific health care practitioners is made available upon formal request to hospitals, health maintenance organizations, state licensing boards, professional societies engaged in professional review and other quality assurance and credentialing authorities. The NPDB serves as an important information source for professional review activities.^{3,4}

The final NPDB regulations set forth the criteria and procedures for information to be collected and released. It was clear that the Department of Health and Human Services additionally intended to use the NPDB information to support important medical liability and malpractice research. It was intended that researchers would have access to the NPDB information in such a way that aggregate, anonymous data would be available for examination. Appropriate research user fees for this service were envisioned. Specifically, the regulation states that “a person or entity who requests information in a form which does not permit the identification of any particular health care entity, physician, dentist, or other health care practitioner” may obtain information from the NPDB.⁵

In order to make this information available to researchers, the NPDB Public Use File was created. This article will generally describe the Public Use File, display some of the malpractice data available from the Public Use File and show its value and limitations. Adverse clinical privilege and licensure action data in the Public Use File will not be detailed here.

The NPDB Public Use File

In keeping with the general research theme and governing regulations of the Public Use File, the anonymous

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information provided is devoid of information which could identify specific practitioners or health care entities.

The file itself contains one complete record for each malpractice payment report or adverse action report in the NPDB. There are 32 variables or data elements contained in each record. The smallest geographic unit identified in each record is a state, although researchers may make a request to the Bureau of Health Professions for data at a lower level of aggregation, such as countywide data, which may be made available in some circumstances.

Some of the more useful data elements for researchers in the NPDB Public Use File include the practitioner's residence and state of employment, state of licensure, field of licensure (M.D., D.O., Dentists, Nurses, etc.), age group and graduation year. Medical malpractice information includes primary and secondary act or omission codes, such as failure to diagnose or failure to treat cases, as well as the year of the alleged incident. Payment information includes the payment amount, the number of payments (single or multiple), the number of practitioners included in the payment, whether the payment was the result of a judgment or settlement and the year of payment. Adverse action information includes the classification of adverse action, for example, suspension of clinical privileges for substance abuse, as well as the length and year of the adverse action.

In order to preserve practitioner anonymity, a random identifying number is assigned for each practitioner. The name of the practitioner is never used. The unidentified practitioner's total number of adverse actions, number of malpractice payments, number of adverse licensure or DEA actions, number of adverse privilege actions and number of adverse membership actions are included as data elements. With any large database, data entry errors inevitably occur. The Bureau of Health Professions has predictably observed some coding problems with individual data elements. For example, some entries submitted contain either no entry or an erroneous code for a specific field, such as field of licensure (e.g., M.D. or R.N.).

When an individual or entity requests a Public Use File, it is provided on 3.5 inch high density diskettes. A narrative description accompanies the data set and lists the various codes for each data element. A copy of this file can be obtained by calling the NPDB Help Line at 1-800-767-6732.

National Medical Malpractice Data 1990-1996

As stated earlier, the NPDB began collecting information on September 1, 1990. For the descriptive purposes of this article, a copy of the Public Use File containing information from the inception of the NPDB until December 31, 1996, was obtained and reviewed. The categories of information with the most research utility will be highlighted.

Figure 1 provides a breakdown of the types of reports that were contained in the NPDB as of December 31, 1996. Of the 145,299 reports in the NPDB, 118,211 (81%) were malpractice payment reports, 20,707 (14%) were licensure adverse actions and only 5,963 (4%) were clinical privilege adverse actions. The Public Use File contains 268 Professional Society membership adverse actions and 150 Drug Enforcement Agency actions taken against practitioners.

Table 1 provides a listing of the ten most frequent fields of licensure for malpractice payment reports in the NPDB. The overwhelming majority of malpractice payments relate to acts committed by allopathic physicians (71%), while dental malpractice payments are second in frequency (15%).

Table 2 provides a display of the general categories of primary acts or omissions. The acts or omissions in the NPDB are coded based on an adaptation of the Harvard Risk Management Foundation Allegations of Negligence.

NPDB PUBLIC USE FILE
Types of Reports in NPDB
n=145,299

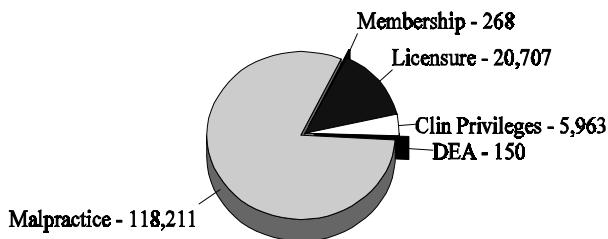


Figure 1

NUMBER OF MALPRACTICE PAYMENT REPORTS
BY TOP 10 FIELDS OF LICENSURE (1990-1996)

Licensure Category	Number of Reports	Percent
Allopathic Physician	83,821	71%
Dentist	17,469	15%
Osteopathic Physician	4,990	4%
Podiatrist	2,769	2%
Chiropractor	2,253	2%
Registered Nurse	1,326	1%
Allopathic Intern/Resident	904	<1%
Pharmacist	772	<1%
Clinical Psychologist	631	<1%
Nurse Anesthetist	469	<1%

Table 1

Treatment, diagnosis and surgery-related acts or omissions are the most frequent categories. The most expensive act or omission is the diagnosis-related category, costing over \$6 billion during the 76-month period. The total monetary amount of malpractice payments contained in the NPDB during this 76-month period is over \$18 billion.

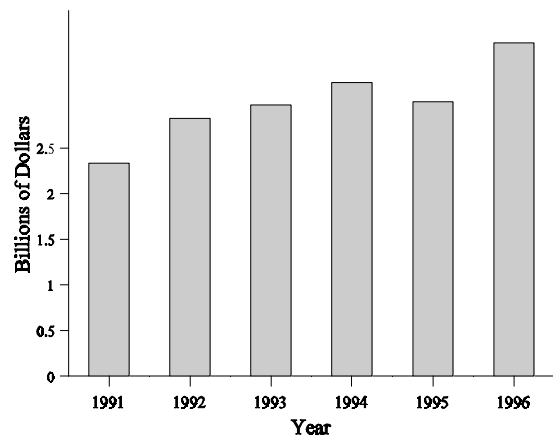
NPDB PUBLIC USE FILE
PRIMARY MALPRACTICE ACTS OR OMISSIONS (1990-1996)

Acts or Omissions	Number of Acts or Omissions	Percent	Total Payments
Treatment-Related	33,050	28%	\$3,166,043,034
Diagnosis-Related	31,931	27%	6,068,653,848
Surgery-Related	28,102	24%	3,851,200,397
Obstetrics-Related	8,428	7%	2,824,280,036
Medication-Related	7,472	6%	920,577,368
Anesthesia-Related	3,765	3%	752,770,562
Miscellaneous	2,494	2%	227,351,412
Monitoring-Related	1,594	1%	285,397,928
Intravenous/Blood-Related	571	<1%	87,352,002
Equipment-Related	557	<1%	33,110,918
TOTAL	117,964	100%	\$18,216,737,505

Table 2

in the NPDB. Three of the top five specific acts or omissions relate to problems with patient diagnosis. This may have important implications in the changing health care arena where the modern trend is for primary care physicians to assume more diagnostic responsibility with reduced specialty referrals.

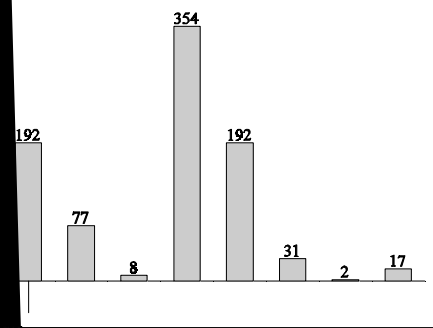
Figure 2 provides a breakdown of the total amount of malpractice payments by year (not adjusted for inflation). The number of payments has remained steady at about 19,000 individual payments per year. The amount of money paid out for malpractice payments has steadily increased over the years to a total amount of approximately \$3.6 billion in 1996. It should be noted that the payment amount recorded in the NPDB Public Use File is generally only the amount of the initial payment. A structured settlement, which is frequently utilized in malpractice settlements, may have many payments over a number of years. These subsequent amounts would therefore not be included in the NPDB payment amount field, meaning the total malpractice cost is actually higher than figures contained in the



79 malpractice payments greater than \$1 million by field designation. As reflected in Figure 3, these large individual payments. Figure 4 shows that 192 payments greater than \$1 million which had an act or omission as the most expensive, comprising 26% of the total payments made, when compared to Table 1. The most common adventures related to intravenous means

quality assurance personnel in surveying health care organizations. Previously, obtaining data from health care organizations, such as the Physician and Surgeon Malpractice Insurance Company, do share and publish malpractice statistics. This Public Use File, on the other hand, is not only much larger but truly comprehensive. It includes data from a major malpractice insurer of the Department of Defense, the Tricare program, and the Assistant Secretary of Defense for Health Care.

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includes Osteopathic Intern/Resident (2), Dental Resident (3), Pharmacist (1), Nurse Midwife (3), LPN (7), Podiatrist (2), Clinical Psychologist (1), Physical Therapist (1).

Acts or Omissions

Figure 3 PRIMARY ACTS OR OMISSIONS (1990-1996) Payments Over \$1 Million = 1,382 Figure 4 Field of Licensure

However, there are certain obvious limitations in using this data. Payments which involve large health care entities but do not specifically name individual practitioners are not reported. Some civilian institutions may conceivably use this to avoid reporting individual practitioners, shielding them behind the "corporate veil." Also, the Department of Defense generally only reports payments for claims in which a determination was made that the standard of care was not met by a practitioner, rather than all malpractice payments made.^{7,8} As with any large database with multiple individuals entering data, inappropriate data entry occurs in some records. Additionally, information is limited to some extent because the NPDB was not chiefly designed for research. Certain potentially useful fields, such as physician specialty and the diagnosis or the procedure involved, are not collected. Elaborate details about the facts and circumstances of the individual malpractice cases are likewise not available in the Public Use File. Nevertheless, the Public Use File is the most complete source of national malpractice data and should be reviewed by any health care organization that desires to compare itself with the national malpractice picture. In the future, it is expected that this growing database will further facilitate research and provide even more information and insight into medical malpractice and quality assurance on a national basis.

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AUTOMATED PAP SMEAR RESCREENING: THE “DUTY TO INFORM” CONTROVERSY

by **KENT HARSHBARGER, M.D., J.D., CPT, MC, ILARNG***

The Papanicolaou (Pap) stained cervical vaginal smear is the best cancer screening test ever developed. Many statistics can be offered to substantiate this claim, but the most dramatic success story is a decline in the cervical carcinoma death rate from 70 to 80 percent through entire populations. This decline is even more remarkable when one takes into account the prevalence of cervical cancer.¹ This success may unfortunately be in jeopardy.

Increasing professional liability has created an environment of increasing cost complicated by private and governmental payor cutbacks. These cutbacks have decreased reimbursements both for the Pap smear exam itself and laboratory testing in general. Many long-time insurance underwriters have discontinued offering liability coverage to cytotechnologists and many small-to- medium laboratories have stopped interpreting Pap smear cytology. These groups consistently blame expensive legal claims and complex regulatory requirements as being responsible for further reducing the revenue margin and forcing the termination of services.

Adding fuel to the fire by opening another avenue of liability, the Food and Drug Administration (FDA) recently approved computer-assisted devices for rescreening Pap smears (PAPNET and Neopath). These devices are used to analyze routinely prepared cervical cytology slides which have been determined negative by prior human screening and are intended for use in quality control programs. Quality control programs in cervical cytology have always included human review of negative cases; however, these cases are selected at random. Automated devices allow the laboratory to review all cases previously interpreted as negative. The computer selects out those cases which meet the programmed criteria and which may represent a false negative. These cases are then submitted for human review as part of the normal quality control program.

The companies that manufacture these devices have begun an aggressive “direct-to-consumer” marketing campaign designed to raise public awareness. This method of advertising has also instilled fear by suggesting that manual screening alone is insufficient, and, therefore unreasonably places women in danger of undetected cervical cancer. Many articles are being published warning that this fear may lead to lawsuits claiming a failure to diagnose based on a medical standard of care that includes automated rescreening. This risk of liability, created in part by these advertising campaigns, has resulted in laboratories believing they have little choice but to add automated devices to their cervical cancer screening programs. Furthermore, some authors warn that gynecologists, family physicians and other primary care doctors may also be at risk of liability for not informing patients of this rescreening option.²

In spite of this big business driven mania, most involved physicians agree, the appropriate non-corporate sponsored research has not been done to determine if these systems provide any significant benefit. A few studies are available indicating an increase in sensitivity with automated rescreening, but critics are quick to point out that any rescreening will result in an increased sensitivity but decreased specificity. Most of the cervical abnormalities detected by these devices are low-grade lesions, and there is no prospective study to date to indicate they can reduce the incidence of invasive cancer in any population.

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Besides a lack of conclusive data, the cost of these automated systems is a significant obstacle to widespread use. In fact, if automation is demanded by the public after these anxiety-producing advertisements, it may actually result in fewer women being able to have a Pap smear. Women will be deterred from needed testing because the cost will become prohibitive. First, fewer labs will be offering interpretation, creating a reduced supply which drives up consumer costs, and second, those labs that continue will be forced to increase the price by approximately two to three-fold based solely on the use of the automated equipment.³ One estimate from the state of Victoria in the country of Australia indicates that the addition of ThinPrep and PAPNET to their network would add \$30 million to the cost of annual screening. This added expense would benefit an estimated maximum of eight women who died of cervical cancer in 1994 and were felt to be true failures of the screening program.⁴

This increase in direct cost is significant as most insurance companies do not pay for automated rescreening. Recently, however, Ohio's largest insurer announced it would pay for all Pap smear rescreening by PAPNET which is manufactured by Neuromedical Systems. Many other large insurers, particularly in the eastern United States, have also agreed to pay for automated rescreening with this device. In the past, lawyers would argue that the lack of reimbursement indicated a particular test was not part of the standard of care and it seems clear that lawyers will now argue the opposite in this case. Thus, the emerging willingness to pay for this testing by insurers angles the playing field in favor of those who feel automated rescreening should be part of the standard of care in cervical cancer screening. Juries will hear that cervical cancer was missed and automated rescreening was not even offered despite the availability and the insurance company's willingness to pay.

Some feel there is no current justification to believe that automated Pap smear rescreening will be part of the standard of care.⁵ This opinion is generally based on the fact that the majority of courts apply a professional standard of care which requires expert medical testimony to define what care was appropriate. Thus, in most jurisdictions, a failure to offer automated Pap smear rescreening would not currently subject physicians to liability as it would easily be shown that the majority of professionals do not believe these machines have proven themselves. However, there is legal precedent indicating that the failure to make use of available but emerging medical technology can result in liability despite incomplete data to indicate the technology's usefulness.

A recent article in CAP TODAY⁶ discussed case law from specific jurisdictions which, by analogy, could be used to argue that a laboratory was liable for not offering automated rescreening and some of these are noted here. In *Ray v. American Red Cross*,⁷ the appellate court for the District of Columbia held that claims of negligence should be based on a "uniform standard of conduct: that of reasonable care under the circumstances." The court determined that the Red Cross should have been judged based on their resources and not in relation to what the lower industry standard may have been. In *Hoemke v. New York Blood Center*,⁸ the court stated that, "if a given industry lags behind in adopting procedures that reasonable prudence would dictate be instituted, then we are free to hold a given defendant to a higher standard of care than that adopted by the industry."

These cases do not specifically address the issue of whether the primary care physician might be liable for not informing a patient that automated rescreening is available at an added cost. This leaves the medical community with no clear answer, but many suggest that physicians begin to educate patients about the Pap

smear to include the false negative rate and the need for annual rescreening. This education would also include the possibility of automated rescreening as an elective test despite the lack of data to support the effectiveness of automated testing. Currently, many labs are including disclaimers with the diagnostic reports to indicate the Pap smear is not 100 percent sensitive and that yearly exams are the best method to improve screening success. Also, some include a statement noting the availability of automated rescreening as an additive elective test. One lab has gone as far as requiring a signed informed consent form prior to interpreting a Pap smear as a method to further reduce liability.⁹ If a duty to inform a patient about automated rescreening does exist, it would certainly be even stronger and create greater legal risk in cases where the insurance carrier has agreed to pay for the testing.

The risk of liability based on the duty to inform a patient about the automated rescreening is unknown, leaving room for lawyers, risk managers and physicians to argue what the future holds. Despite this disagreement, it seem inevitable that lawsuits will be brought claiming a failure to inform patients of an available new technology, resulting in a failure to diagnose cervical cancer and consequent injury or death. Therefore, all those who obtain or interpret Pap smears must remain vigilant about this controversy and educate themselves about these automated devices so an informed decision can be made about current liability risk and the various methods being developed to reduce that risk.

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MEDICOLEGAL PITFALLS IN EVALUATION OF RECTAL BLEEDING

by **RAYMOND B. WEISS, M.D.***

In this column, a senior consultant shares his medicolegal insight with fellow clinicians.

Physicians evaluating rectal bleeding should bear in mind that colorectal cancer is the third most common cancer in the United States. Moreover, bleeding is one of the most common presenting symptoms of this form of cancer. Medico-legal problems are frequently experienced by physicians who assume that a benign cause, such as hemorrhoids, is responsible without a proper evaluation to exclude the presence of colon or rectal cancer. Anemia, with features of iron deficiency, should never be treated with iron replacement without fully evaluating the gastrointestinal tract for an occult source of chronic blood loss.

In a familiar scenario, the patient comes in for an office visit because he or she has been having some bright red rectal bleeding. An anal and digital rectal examination is done, and the patient indeed has some large hemorrhoids. Alternatively, the patient comes for “a check-up” because he or she has been feeling more fatigued than usual. The three actual case histories below illustrate these typical scenarios and highlight the liability pitfalls that threaten unwary practitioners.

Case-1

A 45-year-old woman came to a physician’s office with a complaint of “some blood on stool” noted several times in the past two weeks. A digital rectal examination revealed some external hemorrhoids. A single-contrast barium enema radiograph was ordered, and the report came back with the result of “unremarkable barium enema.” The patient was given a prescription for a hemorrhoidal preparation and was reassured that she only had hemorrhoids.

She returned for an office visit four months later with an unrelated problem. “No bleeding” had occurred after the previous visit. Nine months later she came again for another unrelated problem, and a routine CBC was done. Her hemoglobin was 10.0, hematocrit 32.2 and MCV 77.8. It was thought that the patient may be having hemolytic anemia, so a direct antiglobulin (Coombs’) test was done. It was negative, and no specific treatment was given.

The patient saw another physician 23 months after the initial visit to the first physician with the complaint of several months of constipation and crampy abdominal pain before a bowel movement. Another barium enema was done, and a fungating lesion almost totally obstructing the colonic lumen was seen 15 cm from the anal verge. A biopsy

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All three of these cases illustrate typical presentations of colon carcinoma, and all three resulted in successful lawsuits against the physicians initially managing these patients.”

was positive for adenocarcinoma. A chest x-ray showed several small metastatic lesions bilaterally. She had the colon lesion surgically removed and had chemo-therapy for the metastases, but she died of metastatic colon cancer approximately nine months later. There was subsequent debate whether the original barium enema had been misread by the radiologist, but the study was not fully satisfactory for evaluating the site where the cancer was later found.

Case-2

A 55-year-old man came to a physician's office with a complaint of abdominal pain for six days and some rectal bleeding. A digital rectal examination showed "some hemorrhoids." Testing for occult blood was positive. The patient was told to eat a meatless diet and collect six stool samples for occult blood testing. When the samples were brought for testing, they were all negative. His abdominal pain later had disappeared.

Ten months later he saw another physician for "a check-up" because of intermittent abdominal pain for two months and some rectal bleeding for two weeks. A rectal examination showed both external and internal hemorrhoids. Flexible proctosigmoidoscopy showed a partially-obstructing mass at 35 cm, and a biopsy confirmed adenocarcinoma. A sigmoid colectomy was performed soon thereafter. The cancer had penetrated the bowel wall and metastasized to two mesenteric lymph nodes. No gross intra-abdominal metastases were noted by the surgeon.

Adjuvant chemotherapy to reduce the risk of cancer recurrence was then administered over the next 11 months. Just prior to discontinuing the planned year-long chemotherapy, an elevated serum CEA level was found, and abdominal carcinomatosis was discovered. He subsequently died of metastatic colon cancer.

Case-3

A 39-year-old woman presented to a physician's office (a walk-in facility) for a "check-up" because of leg cramps. She had just completed a menstrual period several days previously. A full physical examination was done including a pelvic examination. A possible uterine fibroid was palpated. A CBC and serum chemistry panel were done. The hematocrit was 20.3, and MCV was 66. Liver function tests were normal.

She was diagnosed with iron deficiency anemia and was offered a blood transfusion. She declined this offer, but she did agree to undergo the substitute therapy that was suggested which was weekly injections of iron-dextran complex. Over the ensuing four weeks, she had the recommended injections of iron. A repeat hematocrit was now up to 31.5, so she was switched to an oral preparation of ferrous gluconate.

The patient then had a pelvic ultrasound study that showed a normal-sized uterus. An upper GI series was ordered, and this showed "minimal gastritis." Mylanta and Zantac were prescribed. A repeat hematocrit was now up to 33.0.

Medicolegal Pitfalls . . . , cont'd

A month later (a total of four months after the initial visit) the patient was rechecked, and the hematocrit had decreased

entire colon and rectum. Such evaluation can be accomplished by either of two methods: a flexible proctosigmoidoscopy and a double-contrast barium enema or a colonoscopy. Either process will allow full visualization of the colon and rectum for detection of a cancer or even a polyp that has the potential for developing a malignancy at some later time. Adenomatous polyps (either tubular or villous) have potential for evolving into a carcinoma (i.e., they are premalignant lesions), and they can also bleed. The villous adenoma, which most often occurs in the rectum, has the highest risk of either already containing a malignant focus or evolving into a cancer in the future. Removal of such polyps that do not already have malignant foci should prevent development of a cancer in that polyp.

The most common presenting problem associated with a right-sided colon cancer is chronic and occult blood loss, which takes the form of an iron deficiency anemia. The patient presents with complaints of general fatigue or "not feeling right." A CBC is done as part of a general evaluation and a mild-to-moderate anemia is discovered. The typical American diet, with its iron supplementation in many processed foods, is not likely to allow iron deficiency to develop unless there is blood loss of some kind. Blood loss in a menstruating female having heavy menses can cause iron deficiency anemia, but one must always consider occult GI blood loss as the cause of such anemias, whether female or male. Upper GI bleeding from some source, such as a gastric or duodenal ulcer, is often associated with symptoms of abdominal pain and dyspepsia. An iron deficiency anemia developing without any abdominal symptoms is more likely to be due to blood loss from a colonic source.

“Colo-rectal cancers are one of the carcinomas where early diagnosis can make a difference in outcome.”

What is the proper procedure when an adult presents with iron deficiency anemia unexplained by obvious recent blood loss? Testing of fecal samples for occult blood is the first and simplest step. The usual process involves testing of at least three separate fecal samples. A positive test warrants evaluation of the colon for an occult neoplasm (either benign or malignant) as the cause of the positive sample. However, negative samples (even a total of six as were done in Case-2) do not exclude the possibility of a colonic neoplasm as the cause of the blood loss and anemia, because the bleeding may be sufficiently intermittent not to give a positive result in random samples. Full evaluation of the colon and rectum by either colonoscopy or double-contrast barium enema with proctosigmoidoscopy is necessary to exclude an occult lesion causing the blood loss.

Case-3 illustrates some other physician errors besides the failure to evaluate the colon adequately for occult sources of bleeding. Injectable iron-dextran complex should only be used in the rare instances where iron malabsorption has been proven or the patient is unable, or repeatedly fails to heed instructions, to take oral iron. Ferrous sulfate is the cheap and effective iron therapy of choice if the source of blood loss has been elucidated. A failure to correct the iron deficiency with such therapy should cause the physician to suspect either the patient is not taking the medication or the source of blood loss has not yet been located. Patient #3 had a persistent anemia despite her assurance she was taking the iron tablets as prescribed.

Colo-rectal cancers are one of the carcinomas where early diagnosis can make a difference in outcome. The usual natural history of such cancers is to arise in the mucosal epithelium, penetrate the bowel wall, and

spread to distant sites via the lymphatics and/or the portal venous system or across the peritoneal surfaces. The cure rate of lesions involving only the mucosa (stage I Dukes' A disease) is greater than 90 percent. Such early lesions are often those found in adenomatous polyps. Even when the cancer has started to invade, but not yet penetrate, the muscularis (stage II or Dukes' B₁, Astler-Collier modification), the five-year, disease-free survival rate is still greater than 85 percent. Penetration through the bowel wall (Dukes' B₂) decreases this rate some, but greater than 70 percent still survive disease free. Only when the cancer has spread to lymph nodes does the cure rate drop below 50 percent. Adjuvant chemotherapy can moderately improve the outcome for patients with involved nodes, but the obvious goal is to diagnose this cancer sufficiently early so that lymph nodes are not involved. Thus, not only does the symptomatic patient with rectal bleeding warrant investigation for this cancer, but screening among *asymptomatic* patients can also be of value for cancer detection, earlier diagnosis and better outcome. Randomized studies have shown a reduction in mortality from this cancer by screening for fecal blood.³ Screening with fecal occult blood testing and flexible proctosigmoidoscopy in addition can improve the efficacy of the screening process and overcome the limitations of each method.

Clinical practice guidelines for screening have now been published by the American Gastroenterological Association⁴ and the American College of Physicians^{5,6} and have been endorsed by such respected organizations as the American Cancer Society. The reader is invited to review these articles for details.

“Colo-rectal cancer is a common cancer in this country, and rectal bleeding or unexplained anemia are common presenting symptoms of this cancer, whether the patient is 25 or 65 years old.”

Conclusion

The three most important points to keep in mind include:

- * colo-rectal cancer is a common cancer in this country and that rectal bleeding or unexplained anemia are common presenting symptoms of this cancer, whether the patient is 25 or 65 years old;
- * rectal bleeding should never be dismissed as being due only to hemorrhoids (even if hemorrhoids are present on anal examination); and
- * anemia with features of iron deficiency should never be treated with iron replacement without first fully evaluating the GI tract (especially the large bowel) for an occult source of chronic blood loss.

Finally, because outcome of this cancer can be significantly improved by early diagnosis, screening with fecal occult blood testing and flexible proctosigmoidoscopy is worthwhile and recommended as part of routine medical care. Failure to follow these important guidelines can result in a poorer outcome for the patient and an adverse outcome for the physician who unwisely neglected to consider the presence of colon or rectal cancer as the etiology of rectal bleeding.

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MEDICOLEGAL GRAND ROUNDS

by James G. Zimmerly, COL, MC, USA (Ret.),* and Frank T. Flannery, COL, MC, USA

Evaluation of Shoulder Pain

Shoulder pain is a common clinical entity seen in all types of clinical practice from the emergency department to the post surgical unit to the primary care physician's office. A differential diagnosis of shoulder pain is essential to sort out the sometimes obscure causes of the pain. Often the complaint is coupled with a history of trauma and represents an easily diagnosed sprain, fracture, or dislocation of the shoulder. Less frequently, the underlying diagnosis is not orthopedic in nature, but represents another serious underlying condition. In these circumstances, the medicolegal risks are heightened as illustrated by the following cases.

The 1994 case of *Matney v. Lowe*¹ involved several defendant physicians and resulted in an out-of-court settlement for the plaintiff. In *Matney*, the patient underwent a spinal fusion and subsequently developed postoperative symptoms of shoulder and chest pain. His evaluation included arterial blood gases, a chest x-ray, and a ventilation-perfusion scan of the lung, which was read as consistent with a "low probability for pulmonary embolus." The patient was diagnosed with pneumonia but later died from a massive pulmonary thromboembolism. Experts for the plaintiff contended that the ventilation-perfusion scan was misread, inducing several defendants, including the radiologist, to settle the case prior to trial.

Shoulder pain can also be a symptom of internal bleeding, resulting from dia-phragmatic irritation causing referred pain to the shoulder via the phrenic nerve. The case of *Schuler v. Berger*² involved postpartum care of a 24-year-old female who developed left shoulder pain with back and abdominal pain following delivery. No diagnostic studies were ordered, and a diagnosis of postpartum psychosis was made, explaining the patient's occasional screaming. Subsequently, continued pain was attributed to postpartum cramping. The patient was later discovered cold and pulseless in her bed and resuscitation was unsuccessful. Autopsy findings included diverticulitis of the sigmoid colon with acute rupture of the diverticulum resulting in peritonitis. The patient's estate brought suit for wrongful death, and the jury returned a verdict for the plaintiff.

Presenting symptoms for oncology patients can include shoulder pain as well. In the case of *Wilson v. United States*,³ a woman with a breast nodule was diagnosed with fibrocystic breast disease. Several years later she repeatedly presented with left shoulder pain. Over a six-month period her shoulder symptoms failed to improve, and eventually x-rays of her shoulders were obtained, revealing lytic lesions of the left scapula and right clavicle. Further evaluation led to the diagnosis of metastatic breast cancer which shortly thereafter caused her demise. The patient's daughter successfully brought an action for wrongful death. Similar "failure to diagnose" malpractice cases involving complaints of shoulder pain have included patient diagnoses of adenocarcinoma of the lung,⁴ Hodgkins disease,⁵ giant cell tumor of the head of the humerus,⁶ malignant hemangiopericytoma of the right post-scapula area,⁷ and malignant chondrosarcoma.⁸

Additionally, there is the somewhat more familiar scenario of cardiac disease presenting in the form of shoulder pain. In the case of *Morales v. United States*,⁹ a 69-year-old hypertensive patient presented to the

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hospital with several days of shoulder and neck pain. The patient related that movement seemed to aggravate the pain, and no electrocardiogram or other cardiac evaluation was performed. The patient was discharged from the emergency department and within hours died at home of a myocardial infarction. The decedent's estate recovered damages based on an allegedly negligent medical evaluation.

Postoperative shoulder pain is not rare and may be due to benign as well as life-threatening conditions. In the case of *Madden v. Linhardt*,¹⁰ a 58-year-old female died of complications following gallbladder surgery. Postoperatively, she allegedly complained of shoulder pain. The defendants denied the allegation but maintained that shoulder pain is common after gallbladder surgery and treated her postoperative pain with narcotics. Her estate argued that a retained common bile duct stone caused the postoperative right shoulder pain and the complications that led to death. The jury awarded \$2,812,000 in compensatory damages.

Shoulder pain can be the predominant area of referred pain in injuries to the cervical spine. In *Parsons v. Keys and Wilkes Regional Medical Center*,¹¹ a 34-year-old male was the driver in a serious single car motor vehicle accident. Upon admission to the emergency department, he complained of left shoulder pain as well as neck and lower back pain. He had some tenderness to palpation over his lower cervical spine, as well as his left shoulder, but he had full range of motion in all extremities. Inadequate cervical spine films as well as an erroneous interpretation of those films led to a diagnosis of "cervical neck strain." In fact, the patient had a subluxation of C-7 on T-1 with associated prevertebral soft tissue swelling and a severe comminuted fracture at the same level, which required a CAT scan to delineate. The patient developed a partial paralysis as a result of the injury and prior to his transfer to a regional trauma center. The case against the attending surgeon and community hospital was settled prior to trial.

Unlike many other joint complaints, shoulder pain may represent the most routine condition or serve as a harbinger of life-threatening disease and significant medicolegal complications. As in other high-risk situations, there is no substitute for a high index of suspicion, thorough evaluation and careful follow-up.

The Cost of Malpractice

The question is often asked, what is the "cost" of malpractice in the United States? One national source to answer this question is the National Practitioner Data Bank (NPDB). Since 1990, malpractice payments have

settlement provisions, only a fraction of that amount would be paid annually, and only the first annual payment is reported to the NPDB.

Very significantly, the NPDB figures may be somewhat low for two additional reasons. First, only malpractice payments made on behalf of individual providers are reportable. Settlements made on behalf of corporations and hospitals, on the other hand, are not reported to the NPDB. Undoubtedly, then, some malpractice payments made in the name of a hospital or corporation are hidden behind this "corporate veil." Second, for an individual practitioner's name to be reported, the provider's name must appear on both the legal pleadings and settlement documents. If it is left off either document, no name is submitted.

Even if NPDB data, an excellent source, were perfect, we still would not capture all malpractice costs. Investigative expenses are extensive and include record review by insurers, hospitals and private investigative firms. Interviews of patients, doctors and others are time-consuming and expensive. Litigation costs can stretch over many years due to the long "tail" of malpractice controversies. Actual trial time is usually less than the prior law office preparation time. Then there is the time and expense of the judge and jury in hearing the case to be considered, as well as expert witness time and expenses.

Further costs include those of the medical malpractice insurance industry, where premiums alone run in the billions. Coupled with this are the "hidden" costs of defensive medicine, including extra tests, excessive electronic fetal monitoring, needless x-rays, time-consuming documentation and unnecessary admissions, all performed in an effort to avoid or limit liability.

The monetary question is so perplexing that Congress asked the General Accounting Office (GAO) to calculate the national cost of medical liability. GAO reviewed some studies indicating that medical liability costs would exceed \$22 billion annually, but in 1996 concluded that the question is too difficult to definitely answer for all of the above reasons. The cost of the present medical liability system remains enormous and is difficult to calculate with any degree of precision.

Confidentiality - Physicians v. Pharmacists

The rules of physician-patient confidentiality are well known, but a recent South Carolina case concerned the question of whether pharmacists are bound by the same constraints. In *Evans v. Rite Aid Corporation*,¹² a customer presented a prescription to the pharmacy which was then filled. Subsequently, the customer learned that a pharmacy employee falsely related to third parties that the customer's prescription was for treatment of a venereal disease.

The customer sued, claiming breach of confidentiality, negligent failure to supervise employees, outrage and negligent falsehood. The trial court dismissed the plaintiff's action, and she appealed. In reviewing the matter, the South Carolina Supreme Court found no common law or statutory requirement of confidentiality between pharmacist and patient. Moreover, examination of the Code of Ethics of the American Pharmaceutical Association revealed no specific provision on pharmacist-patient confidentiality.

The court affirmed dismissal of this particular action on multiple grounds, including the lack of specific statutory language requiring a duty of confidentiality by a pharmacist. Interestingly, however, the South Carolina Supreme Court held open the possibility for future causes of action under different circumstances stating that “pharmacists do have a duty to conform to the generally recognized and accepted practices in their profession.” Thus, while no specific duty of confidentiality was identified, the court suggested that future unprofessional disclosures by pharmacists could be actionable.

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MEDICAL DECISION MAKING, LEGAL LIABILITY, and MANAGED CARE

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In the last few years, many physicians have begun to change their analytic approach to the practice of medicine. As Jerome Kassirer, the editor of the *New England Journal of Medicine*, pointed out, in the old days:

teachers of clinical medicine . . . [used] standardized histories and physicals, book chapters that list the myriad causes of individual symptoms, an apprentice system in which the student is expected to imitate others, formal approaches to recording patients' problems, and lock-step algorithmic charts for blind guidance. None of these methods focuses on the essential reasoning processes critical to optimal performance.¹

Doctors took pride in developing an extensive differential diagnosis for each case, then systematically ruled out alternatives until one clearly ruled in. This inclusive method was suited to the medicine of the nineteenth and early twentieth century when physicians, with few effective diagnostic and therapeutic interventions, could do little more than observe the natural progress of the disease.²

Consider, for example, myocardial infarction (MI). Until the 1960's, acute MI was treated with bedrest for five or six weeks, affording much time for detailed observation.² Physicians gave digitalis for heart failure, quinidine for arrhythmias and sometimes anti-coagulants. That represented the entire medical armamentarium of the day. However, in the last 30 years a dizzying array of tests and treatments have become available for MI and its complications: defibrillators and pacemakers, thrombolytics, angiography, coronary artery bypass surgery and angioplasty, Swann Ganz catheters, treadmill stress testing, echocardiography, MUGA scans, myocardial perfusion scintigraphy, Holter monitoring and electrophysiological studies. Moreover, patients are continuously monitored in the specialized, high-tech, high-cost setting of an intensive care unit. These advances markedly reduced morbidity and mortality in a major disease category and, starting in the 1970s, many acute MI patients got most or all of them. Similar proliferation of diagnostic and treatment options occurred in virtually every medical speciality.

Even without regard to managed care, it has become apparent to many practitioners that continuation of this course — doing everything for everyone, as more and more options become available — cannot be sustained. There is just not enough money. Furthermore, as clinicians and researchers have become more sophisticated, there has been growing dissatisfaction with resort to tests and treatments based on anecdotes, historical custom, or intuition. Hence, in recent years, many in the profession have begun to adopt new techniques of clinical decision making designed to generate the best results for the most patients, given finite resources and the tremendous uncertainty inherent in medicine. The new method is often based on so-called Bayesian analysis, i.e., the determination of probabilities in the setting of uncertainty. In medicine, we rarely have the perfect test, one that will always be positive for people who have the disease and always negative for people who do not. (The particular characteristics of each test are called sensitivity and specificity.) A test will almost always miss a few people who have the disease (false negatives) and pick up a few people who do not have the disease (false positives). If we treat everyone with a positive test, we will treat a few people who are not sick, and we will fail to treat a few people who are sick and who will therefore suffer as a result. In

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addition, the predictive value of the test is based on the prevalence of the disease in the population being tested; the lower the prevalence, the more false positives we will get. As a disease becomes very rare, we may treat more false positives than true positives if we continue to test widely.

Bayesian analysis is not just an interesting theory, it has been applied in practice and it has important clinical consequences. For example, even in 1996 only about 30 percent of patients who were admitted to cardiac care units for chest pain ultimately were found to have suffered a MI.³ The rest, more than two-thirds, were “false positives,” people receiving expensive high-tech care who do not need it. Yet the most conservative commentators believe we should be admitting people with chest pain who have as low as a five to seven percent likelihood of MI. Even if we followed that recommendation, which might involve treating many more “false positives,” we would still be sending home a finite number of patients who would ultimately “rule in” (say those with a two percent chance of MI, or two in 100).

Glassman, et. al, suggests another useful example.⁴ It notes that we now know the rate at which an abdominal aortic aneurysm of any given size will rupture: 0.25 percent for aneurysms 3.5-3.9 cm in diameter, three percent for those 4.0-4.9 cm in diameter, 9 percent for those 5.0-5.9 cm in diameter, and 24 percent for those greater than 6 cm in diameter. Of course, the key therapeutic intervention is to repair the aneurysm before it ruptures. However, while we know the percentages of rupture in each group, we as yet have no way to predict which individuals will suffer. Therefore, to prevent harm to them we must treat everyone at risk, increasing the number of “false positives” as the size of the aneurysm gets smaller.

In all of these situations, the physician faces not an up-or-down decision, not a clean algorithmic branch point, but rather a continuum, and there is no obvious way to decide where to draw the line. For example, after all his analysis, Dr. Lee Goldman, a leader in the movement to rationalize clinical decision making and a clinician himself, concluded in 1996 that despite fifteen years of extensive study, “there is no precise risk threshold that can uniformly dictate which patients [with chest pain] should be admitted from the emergency department to a specific hospital unit or how long they should remain hospitalized.”⁵ There is nothing in medicine that says one cut-off is better than another along the curve, except that we know intuitively we do not want to be at either end, treating large numbers of people who do not need treatment or treating only a fraction of those who really do. Moreover, MI and aortic aneurysm are two conditions for which we have extensive information about prevalence and predisposing factors (so-called pretest probabilities), which is expensive to obtain and organize. For many equally common and serious conditions we have far less. In addition, even if we can predict the probable outcome of any test or treatment for a particular category of patients, it may be difficult for the physician on the front lines to determine which class his or her patient is in. Patients do not “read the textbooks” and occasionally present with very atypical findings without any of the common findings.

Given the limits to our understanding and underlying biological variability, there should, for the foreseeable future, be a range of acceptable medical practice rather than a specific point. Two clinicians, faced with two similar situations (two patient situations are rarely, if ever, exactly the same), may opt for two different solutions, and neither one may be wrong, at least with the present state of medical knowledge.

Managed care, the recent movement to drive down health care costs by making medicine more efficient, is presumably taking advantage of the move to analytical decision making and evidenced-based medicine. After all, if there is a range of acceptable options, why not pick the least expensive? If there is no persuasive

evidence that a particular expensive procedure reduces mortality or morbidity (such as a CABG for single vessel disease), why do it? Indeed, capitation forces a physician to perform Bayesian analysis. He or she often receives a fixed fee per patient per month. A doctor can only succeed by playing the percentages. This results in treating the patients most likely to need treatment and taking the risk that those patients less likely to need expensive workups, are in fact disease free, not outliers with uncommon presentations of common illnesses or with rare diseases with common symptoms.

The new thinking may produce better medicine and almost certainly makes for better economics, but will it stand up in court? Can a doctor defend his decision not to do a mammogram on a 30-year-old woman with no risk factors who subsequently turns out to have cancer by arguing that the yield of mammography in this class of patients is so low that the test is just not indicated? How about the performance of a treadmill stress test on a 30-year-old man with atypical chest pain, a normal EKG, and no risk factors?

We do not have the answer yet. So far it does not appear that anyone has even made such a defense explicitly, but the prognostic signs are not good. Indeed, just the term “defensive medicine” already suggests that there is a divergence between medicine and the law, that the law requires measures that even a conscientious doctor would not otherwise take because the yield is too low.

The legal test for malpractice sounds deceptively simple: to prevail, a doctor must demonstrate “the degree of care ordinarily exercised by a reasonably skillful, careful and prudent health care professional engaged in similar practice under the same or similar circumstances.”⁶ Qualifiers like “ordinarily” and “reasonably” do seem to suggest that a range of practices should be acceptable, and, in fact, judges have said they will give physicians wide berth. For example, quoting from older cases, a federal court in Missouri recently said:

members of the medical profession are entitled to a wide range in the exercise of [their] discretion and [can] not be found guilty ‘unless it be shown that the course pursued was clearly against the course recognized as correct by the profession generally’ . . . [M]ere evidence that the conduct of a physician or surgeon did not measure up to the standards of an individual member of the profession, as opposed to the standards of the profession at large, does not constitute substantial evidence of probative force to support a submission of negligence in a medical malpractice case as individual standards may be higher or lower than the standards of the profession as a whole.⁷

In addition, one might expect this standard to incorporate, or at least accommodate, some rough weighing of costs and benefits, just as the more general tort standard — what a “reasonably prudent person would do” in a variety of situations — does.

Nevertheless, this has not been the case. As a recent *Yale Law Journal* article pointed out, malpractice doctrine to date “reflects the belief that there is a ‘best way’ to practice medicine, one that is supported by a professional and scientific consensus. Courts allow few exceptions to this unitary standard of care”⁸ and never on the basis of cost-benefit analysis.

As noted earlier, no doctor has yet defended a failure to do a test on the sole grounds that the yield was too low, at least not in a case that has reached the appellate courts, and therefore generated a published written opinion. However, where someone has made this argument part of a defense, either implicitly or explicitly, the courts have brushed it aside as soon as the plaintiff introduced a credible expert witness to testify that he would have done the test and, of course, the plaintiff is by definition the rare true positive.

For example, in September 1991, a 57-year-old man, Bernard Short, presented to a family physician at the Brattleboro Vermont Veterans Administration Hospital with frequency, urgency, incontinence and nocturia.⁹ The physician did a digital rectal examination, noted that the patient's prostate was firm but not irregular, checked a urinalysis, ruled out diabetes on some basis and diagnosed benign prostatic hypertrophy (BPH). He did not obtain a prostate specific antigen (PSA) test or refer the patient to a urologist. The patient turned out to have prostate cancer which, when ultimately diagnosed in February 1992, had spread beyond the capsule. At trial, Dr. Barry, an internist at the Massachusetts General Hospital in Boston, testified for the defendant that it would be impossible to refer every male over 50 who is diagnosed with BPH to a urologist; therefore, Dr. Fisher's (the defendant) clinical judgment that a "referral of Mr. Short was unnecessary" did not violate the standard of care in effect in 1991. Furthermore, in 1991, PSA testing had only been approved by the FDA for the monitoring of patients already diagnosed with prostate cancer. He also testified that the American Cancer Society did not advocate routine PSA testing until 1993 and admitted on cross-examination that it would also have been reasonable to order a PSA test in 1991. The urologist who diagnosed the cancer testified for the plaintiff that "most" family doctors and internists "in his experience" knew that digital rectal examination and PSA testing "were important" and that "many" would refer PSA test results to him for interpretation.

Prostate cancer, of course, is a relatively rare cause of relatively common symptoms. The evidence in this case seems a rather clear demonstration of a situation where, in fact, the profession had not reached consensus, at least not in 1991. The question of whether to check a routine PSA was an issue on which, as lawyers would say, reasonable people could differ. A physician would not be wrong to do it or to omit it. Yet it appears that the court assumed that the standard of care had to be one way or the other, and not surprisingly in view of what happened to the plaintiff, went for the more inclusive one.

The issue of considering costs in the practice of medicine has arisen more directly in three recent cases involving managed care. All three, *Wickline v. State*, *Wilson v. Blue Cross of Southern California*, and *Corcoran v. United Healthcare, Inc.*, decided by appellate courts in the late 1980s and early 1990s,¹⁰ involved utilization review. This is a practice adopted early on in managed care for cost containment, whereby outside reviewers (sometimes medical professionals, sometimes not) review a doctor's treatment plan to be sure it is not inordinately expensive. In each of these cases, the reviewers cut back the original plan the attending doctor submitted, resulting in death in two cases and limb amputation in the third. In general, the courts all recognized that the reviewers were engaging in the practice of medicine. However, the judges all appear to believe that this is inappropriate and that cost should have no role in clinical decision making. Of course, in all three cases the decision to withhold treatment because of its expense was not made by the treating physician but was, in fact, imposed on him from the outside over his objection. Nor were the facts helpful. None of the plaintiffs were outliers, patients who generally could have been expected to do well, where Bayesian analysis would have made sense. In these three cases, utilization reviewers made crude attempts to save money by reducing treatment to below an undisputed standard of care.

However, since then at least one federal court has suggested that even where the treating physician makes his own decisions, not subject to external utilization review, he should not consider costs.¹¹ The case involved a child who from age 11 to 16 was treated at Kaiser Permanente in Virginia for recurring headaches but was never sent for MRI or a neurology consult. The child had a brain tumor.

This case is closer to a Bayesian problem that every clinician dreads: How many headaches do we see, and how many of them are brain tumors? To paraphrase the witness in the *Short* case, we cannot afford to order a MRI on everyone with a headache. Of course, the plaintiff's response will be: This was not "just" a headache — it had special features, its consistent progressive nature, etc., that warranted a higher index of suspicion and gave it a higher pretest probability. This will always be the response to a Bayesian defense. To prevent thousands of normal MRIs, Kaiser had in place a financial incentive program whereby doctors apparently received bonuses for avoiding excessive treatments and tests. The District Court implied (it did not have to decide) that if the plaintiff can show that Kaiser doctors based their treatment plan on anything besides "sound medical consideration"¹² (for example, cost), that would almost certainly be malpractice.

However, this District Court did recognize if all doctors began to consider cost, it would ultimately affect the standard of care for the worse:

A more subtle point worth noting is that the [Kaiser] Incentive Program may have the pernicious effect of lowering the standard of care for reasonably prudent practitioners. If a financial incentive was sufficiently robust so as to induce enough physicians to refrain from ordering MRIs and other diagnostic tests in situations such as the one at bar, this cost containment program would effectively diminish the 'objective' benchmark for assessing physician competency. Put another way, the denial of benefits on this basis over time might subtly alter the standard by which to measure whether health care providers have rendered adequate medical care.¹³

Under those circumstances, the court would not go so far as to impose its own 'objective' standard of care on the whole profession.

Getting courts to accept the new clinical decision making techniques will not be easy, unless the whole medical profession undergoes simultaneous conversion. The way courts reason is almost the opposite of the way we do Bayesian analysis. A Bayesian analysis starts with a class of patients and determines probabilities prospectively; a court looks at one plaintiff-patient at a time, retrospectively. For its decision in a tort case, a court looks not only to a general rule, but also to prior malpractice cases in the jurisdiction and decides in what respects the new case is like, or not like, the previous ones. The approach is called the "common law" method and it has centuries of tradition behind it. Compare the class of patients we look at to determine appropriate tests and treatments — all patients with the same symptoms or diagnoses — and the class the courts see — only those who did not get the intervention but had the disease. A more biased sample is hard to imagine.

In general, legal reasoning is far more compatible with the old medical decision paradigms based on anecdote, custom and algorithms than with the new statistical models. If an expert clinician like Dr. Lee Goldman cannot figure out where the treatment threshold should be — at what (low) level of probability is it "safe" to send home a patient with chest pain — how is a judge to do so, let alone a jury?

Of course, not all malpractice cases involve some outliers and zebras. Many malpractice cases still have nothing to do with probability and uncertainty but involve unambiguous errors like leaving surgical sponges in body cavities or, more importantly, failing to follow up on abnormal results.

Nevertheless, as documented in previous Open File articles, repeated Physician Insurance Association of America (PIAA) analysis of plaintiffs in failure to diagnose or treat cases demonstrates high numbers of outliers — people without classic findings — or in categories thought to be at low risk for disease. In the breast cancer study of paid claims, for instance, more than 60 percent of the patients were less than 50 years old.¹⁴ Mammography was negative or equivocal in almost 80 percent of cases. The data for MI were similar.¹⁵ Many of the plaintiffs were men less than 50 years old. Two-thirds of all patients reported no history of coronary artery disease. Reviewers determined that all these plaintiffs, nonetheless, had a good chance of prevailing in court and so settled the cases.

Decisions like these push the profession in a direction exactly opposite from the new Bayesian analysis. Faced with a patient with an uncharacteristic presentation and a low pretest probability of disease, the new Bayesian paradigm would suggest that we hold the diagnostic test because even a positive result might be hard to interpret. However, based on the malpractice cases, we are told to maintain a high index of suspicion when anything is wrong. For example, a prior MI analysis concludes, “do not abandon diagnostic pursuit because you are unimpressed with the results of diagnostic testing; . . . if clinical suspicion is present, in spite of an unchanged or negative electrocardiogram, recommend an exercise tolerance test.”¹⁶ The breast cancer study warns us not to disregard patients in their twenties and thirties with painful lesions or negative mammograms.

As many observers have now realized, the contradiction between rational medical cost containment and classic medical malpractice doctrine puts physicians in a tight bind. If we treat everyone for everything, we cannot save much money; if we do not, we run an increased risk of malpractice liability.

No one has yet found a persuasive solution to this dilemma, though many are trying. Some have suggested that we just abolish the tort system for medical malpractice as unsuited for modern medicine.¹⁷ But when managed care is trying by whatever means to reduce costs, not necessarily insisting on refined analysis and large trials (consider the facts in *Wickline*, *Corcoran* and *Wilson*), this is probably the last time we want to jettison such patient protection as the courts afford. It is also clear that traditional “tort reform” measures, e.g., caps on jury awards, abolition of joint and several liability and changes to collateral source rules, do not really address this problem. (Mandatory arbitration may be an exception.) Legal commentators have suggested that patients aggregate together in large groups to bargain with HMOs over the standard of care. It is hard to see how that would work because it would be difficult to draft standards that were specific enough to be useful. On the other hand, perhaps we could alter the standard of judicial review such that courts would have to accept a medical decision if the defendant could show it had a rational basis and/or decent empiric support.

Since redefining the standard of care is so difficult, other reformers would instead change the process of delivering care to keep the cost cutting under control. For example, there have been both legislative and legal attacks on utilization review, capitation and other incentive programs designed to encourage doctors to reduce tests and treatments; *Kaiser* was such a case.¹⁸ The Health Care Financing Administration (HCFA) of the Department of Health and Human Services is issuing regulations designed to control HMOs that recruit Medicare patients. Incorporating legislation is passed or pending in many states. Disclosure has been proposed as a remedy. If patients knew in advance what constraints under which their doctors operated, they could make informed choices about where they wished to be seen, and they could not then object to the consequences of their choices.¹⁹ The recent Federal Task Force on managed care which produced the

“patient bill of rights” took this tack. But process reforms, however salutary, do nothing about the contradiction between evidence-based medicine and the current standard of care.

An alternative option is the guidelines movement.²⁰ Committees of appropriate medical professionals could convene and set out average or minimum standards of care for each clinical entity, at least where there was consensus. It would also be useful to know where there was no consensus. This could be done at the national level, the local level or the clinic level, where adjustments could be made for local demographics and resources. The ill-fated Clinton health care plan, anticipating mass migration to managed care provided by huge entities over whom consumers would have little control, incorporated something like this. However, guidelines have problems of their own because they are static in a dynamic environment, and different groups with different agendas set the guideposts in different places. (Consider the recent fierce controversy over screening mammography.)

Whatever we decide, we must do something soon. The crisis grows more urgent as managed care grows and technology advances. It is one thing to ask physicians to risk their bonuses on their performances, it is another to ask them to risk their licenses.

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CENTRALIZED CREDENTIALS AND QUALITY ASSURANCE SYSTEM

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A Department of Defense (DoD) Inspector General report following the Persian Gulf conflict highlighted several serious deficiencies in the Department's credentialing processes, particularly in the Reserve and Guard components. As a result, in 1993, a Tri-Service credentials working group developed and deployed the Interfacility Credentials Transfer Brief (ICTB), which allows sharing of credentials information among military medical facilities through standardized message or letter format.

The concept of a Centralized Credentials Quality Assurance System (CCQAS) was developed from that group's work and reflects the function of three legacy systems: the Army's Medical Quality Assurance System, the Navy's Centralized Credentials Database System and the Defense Practitioner Data Bank maintained by the Department of Legal Medicine at the Armed Forces Institute of Pathology (AFIP). In January 1995, the Military Health Services (MHS) System Proponent Committee approved a functional description for CCQAS, which was developed with input from Tri-Service, Guard and Reserve components. At the same meeting, the Navy's Centralized Credentials Database (CCDB) was selected as the best model for modification to implement the CCQAS operation. The system was funded in May 1995. Based upon a memorandum published by the Office of the Assistant Secretary of Defense for Health Affairs ((OASD)(HA)) in June 1995, a uniform taxonomy and policies for appointing and privileging across the services were developed, eliminating several barriers to inter-service provider sharing.

The first version of CCQAS, denominated as version 1.0, was deployed during the summer of 1996. It provides automated management of credentials information and limited readiness data on health care practitioners in the MHS. Additionally, it provides a standard automated approach for all credentials authorities and will include information on physicians, dentists, nurses, allied health workers and contract health care employees. Data collected includes demographics, specialty data, professional and additional training, licensure/certifications, affiliations, medical treatment facility (MTF) information and medical readiness training. CCQAS has been approved by the Joint Commission on Accreditation of Healthcare Organizations as a solution for electronic transfer of prime source verified credentialing data and other related material. CCQAS incorporates the Peterson's Guide for schools and institutions, and a mailing list for hospitals. CCQAS contains a variety of features that support applicability and transportability across different credentialing practices and organizations. These include the following: security maintenance through appropriate log-ins and controls by the local database administrator, controls over information that may be edited or restricted (such as the Peterson's database), and use of the social security numbers as provider identification. Data entry is facilitated by both direct typing and the use of "drop down lists" for standard selections for many data fields. There is also an audit trail for critical data entries or edits which display clerk-user identification, date and time. Finally, CCQAS can operate on 486 personal computers typically used throughout the government.

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The next version of CCQAS, 2.0, will add malpractice and adverse action modules (risk management data) as well as client server architecture, encryption, a central database and global replication of local databases. It will be able to track continuing medical education, MTF assignment history and flag expiring licenses or certificates. The program is also identified as a model under the guidelines of the Federal Health Care Provider Credentialing Initiative led by the Department of Health and Human Services. CCQAS 1.0 is designed to electronically query the National Practitioner Data Bank (NPDB). An interface with the NPDB's software will be used for reporting malpractice and adverse actions to the NPDB. CCQAS 2.0 is currently in Beta testing. The CCQAS Configuration Control Board has generally met on a monthly basis to discuss and oversee the development of the program. The three military services, OASD(HA) and the Department of Legal Medicine, among other DoD organizations, participate in this working group. Litton/PRC, the contractor developing CCQAS, also participates on the Committee.

The Naval Medical Information Management Center (NMIMC) plans to maintain the central database and necessary hardware for the system. The Department of Legal Medicine, AFIP, at the direction of the OASD(HA), will monitor and report on the risk management data for trending and analysis.

CCQAS will significantly improve readiness in the MHS by providing timely access to the credentials and risk management data of thousands of health care practitioners to include all uniformed health care providers and DoD civilians. CCQAS will provide accountability for collecting and tracking this data throughout the MHS, enhancing the deployment readiness of the Department's health care practitioners. Moreover, it will provide a source of accurate information to leaders and planners at service headquarters and operational and peacetime medical treatment facilities.

<i>ANSWERS TO CME QUESTIONS</i>			
1. D	6. C	11. E	16. C
2. C	7. E	12. C	17. B
3. D	8. B	13. A	18. B
4. D	9. E	14. E	19. E
5. B	10. E	15. A	20. D

LEGAL CHALLENGES TO THE IMPLEMENTATION OF TELEHEALTH WITHIN THE UNITED STATES AND INTERNATIONALLY

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Introduction

Health care in the United States is significantly regulated on both the state¹ and federal level. Licensing and practice standards for health care providers vary from state to state as does the definition of what constitutes specific practices. If a health care professional does not obtain a license to practice in a state but provides health care in that state, he may face civil and criminal penalties, whether acting in person or through electronic means.² Since the establishment of “Medicare” in 1965, the federal government has assumed a greater role in health care.³ Along with the billions of dollars the federal government spends on Medicare and related programs, comes mandates requiring a variety of different actions by those accepting these funds.⁴ Areas of health care with greater political scrutiny have fallen under increased federal control. High profile examples include minimum length of hospitalization requirements for mothers and newborn children⁵ and federal mammography standards.⁶

Insurance laws also vary from state to state. Several states, including California and Louisiana, now require insurers to pay for telehealth services; many others do not.⁷ One undetermined issue is the status of a provider’s malpractice insurance once he crosses state lines into a jurisdiction in which he is not licensed. Is the provider covered or not? The answer is important to both provider and patient since insurance guarantees a source of funds.

Managed care has changed medical practice. The use of “nurse triage” systems with centralized phone banks manned by nurses taking calls from thousands of beneficiaries is becoming more common. Nurses may take calls from states in which they are not licensed. They may determine the patient’s condition, need for immediate treatment, schedule an appointment or suggest a home remedy. While this may be “appropriate” and “legal” in the state they are receiving calls, it may violate the law where the call originates.

Rules vary from state to state on subjects such as privacy and access to medical information. (Can a parent access medical information regarding their 17-year-old and are there any limitations?) Laws regarding emancipation differ from state to state⁸ as do rules regarding what specific information the provider must give before local informed consent requirements are met⁹ including third party consent rules for children and incompetent adults.¹⁰

When determining which law to apply when health care crosses state lines, one issue that is not easily addressed is who has the greatest interest and, therefore, which jurisdiction’s regulations apply. For example, let us assume that a radiology telehealth consult results in an allegation that a patient was harmed due to the radiologist failing to identify a suspicious mass on an x-ray. Should the burden be on the patient to find legal counsel and file suit where the provider is located, or should the burden be on the physician to respond to a lawsuit filed where the patient was?¹¹ If the patient files a complaint with a state board, in which state should it be done? The patient’s state has no authority over a provider licensed and located in another and the provider’s state may not be as diligent in following up on a complaint filed from a nonresident based on care delivered out of state. Distance alone may make it more difficult for a state agency to investigate the allegations. If we give the patient’s state authority to take action against an out-of-state telehealth provider, where should the proceedings take place and which standards apply? If the system is changed, and we allow multiple states to process complaints, what happens if there are different or varying results?

**This article is based on a presentation given by Maj Kaar at the International Bar Association meeting in New Delhi, India, on November 5, 1997.*

In order to understand the complexities of establishing uniform standards throughout the United States, it is essential to understand how the nation is structured and why this structure was established.

Historical Background

In 1776 when 13 American Colonies declared independence from England, the intent was to establish 13 nations. In 1781 the colonies implemented the Articles of Confederation outlining their interactions in areas of common need such as defense and trade. In 1783, with the Treaty of Paris, England recognized the independence of 13 separate nations. It was not until 1787, as problems with trade, finance and defense developed among the members of the Confederation, that a fourteenth separate limited government was proposed and the United States Constitution was drafted.

The Constitution

The U.S. Constitution set out the duties and functions of the new government and listed the powers the states were ceding. Two chambers, a House of Representatives and a Senate, with similar but not identical powers, were created. House members were elected by the people, whereas members of the Senate were originally elected by the State Legislatures from which they came.¹² Both chambers were based on state boundaries (congressional districts could not cross state lines) with membership of the House based on a proportional share of the nation's population.¹³ The Senate contained two members from each state; therefore, each state was equally represented in the Senate. Only the Senate had the authority to confirm Presidential appointments and ratify treaties.¹⁴ States could ban together and amend the federal Constitution without the federal government, but the federal government could not change the Constitution without the concurrence of the states.¹⁵

The Shift of Power

Over the years there has been a shift of power from the states to the federal government. This may have begun with the U.S. Supreme Court's 1803 decision in *Marbury vs. Madison*¹⁶ where the Court decided it had the authority through "judicial review" to determine the constitutionality of governmental actions. The ratification of the 16th Amendment in 1913, which allows federal taxation of income, provided the federal government more money and more influence. Congress is specifically authorized by the Constitution to regulate interstate commerce—commerce that crosses state lines.¹⁷ Control over intrastate commerce was generally recognized as a state function.¹⁸ In 1935, the Supreme Court struck down a farm product pricing system stating it was an unconstitutional extension of federal power into local matters (Congress cited their interstate commerce authority when passing the act).¹⁹ Seven years later, the Supreme Court upheld a \$117 fine imposed on a farmer who had grown wheat for his own personal consumption, thus violating the 1937 Federal Agriculture Act.²⁰ Declaring that under Congress' power to regulate interstate commerce there was an implied power to regulate anything that may affect interstate commerce, the Court concluded Congress may prohibit people from doing acts that appear to be intrastate in nature. The justices reasoned since the farmer grew his own wheat, he would not purchase it on the open market which may affect interstate commerce. Gradually the federal government extended its power to regulate interstate commerce to include regulating a variety of activities which might affect interstate commerce.

Federal Health Care Licensing

The federal government does not have the resources to regulate all the areas traditionally controlled by state governments. In 1994 we witnessed an ill-fated attempt to federally restructure health care. In spite of numerous proposed federal requirements, the plan did not contain a federal licensing requirement and the health care "alliances" to be formed under the plan did not cross state lines.²¹ Many support a federal health care license, but what would happen if it became a reality? Included within the proposals for national health care were limits on the number of

specialists,²² geographical allocation of health care providers²³ and management of professional and other fees.²⁴ Would a national license for medicine or telemedicine include these types of controls as well? That depends on the political winds of the day. In the 105th Congress there is a proposal requiring all health care professionals assigned to Department of Veterans Affairs medical facilities to be licensed in the state in which the facility is located and a separate concurrent resolution which suggests that states consider waving their license requirements for those providing health care to indigents.

Federal licensing is unlikely due to the inability to duplicate functions performed by various state agencies. Those who envisioned using the state agencies which presently handle testing, licensing, discipline and so forth to carry out federal licensure have been forced to reevaluate their positions in light of recent Supreme Court pronouncements. In June 1997, the Court effectively forbade the use of state governmental resources without the consent of state governments when it decided the case of *Mack vs. United States*.²⁵ While most people think of *Mack* as the case which invalidated a portion of the *Brady Gun Control Law*, the court actually reaffirmed a long standing constitutional principle that the federal government cannot dictate the roles and functions of the executive branch of state government. While *Mack* does limit what the federal government can do, it does not preclude a federal role.

Alternatives to Federal License Federal Incentives

The ability to tax and spend allows the federal government to set conditions for receiving and spending federal funds. This has worked with varying degrees of success in other areas including the “national” 55 mile-an-hour speed limit, which mandated that states change their speed limits in order to receive federal funds. This type of “incentive” program may be used to support access to telehealth and is supported by numerous groups including the Center for Telemedicine Law.²⁶

Telemedicine License

The Federation of State Medical Boards (FSMB) has proposed a model act to regulate the practice of telemedicine across state lines. This proposal would allow a health care provider with a full unrestricted license in one state to apply through a streamlined process for a limited practice license under which a provider could practice telemedicine but could not practice “in person” in the state in which the special license was issued.²⁷ As with all model acts, each jurisdiction must enact it without modification for the system to work, and the courts and regulators must act uniformly. Under the FSMB proposal, each state retains the right to deny a license for an “appropriate reason.” The reason may relate to health care or conceivably involve failure to pay child support, student loans or some other reason and would likely vary from state to state.

Simplified Application Procedures

At its June 1996 House of Delegates meetings, the American Medical Association addressed the telehealth licensing issue by adopting a position that all states should require full and unrestricted licensure for telemedicine. The board also called for non-burdensome application requirements.²⁸ Keeping with this philosophy is the concept of a uniform medical license application, possibly coupled with a centralized credentials database. This approach is based on the premise that the largest barrier to licensing is the different requirements and complexities that each state has and the need for repeated verification of core information (schooling, licensing, boards, etc). It has been suggested that a uniform application with “one stop” verification will destroy most of the barriers that exist to interstate practice. Individual state standards and licenses would still be maintained. This approach is among the easiest as it does not require a legislative change.

Mutual Recognition Model

The National Council of the State Boards of Nursing (NCSBN) has proposed a modified driver's license approach. The concept allows nurses to practice on the license of their state of residence and provide health care services across state lines based on that license. State of residence was chosen for it is easy to determine, and the precedent has already been established with driver's licenses. This proposal requires legislative changes in each state recognizing the legitimacy of the out-of-state license and would likely require the establishment of a compact between all of the participating²⁹ states.

State Compacts

State compacts are another way to facilitate interstate telehealth. Constitutionally, states, with the consent of Congress, may enter into agreements or compacts with one another. Unlike Model or Uniform Acts, in a compact each state must agree to the same thing. A legislative body may not change or vary the legislation. At present, this has typically been done in areas such as port and bridge authorities, but there are no limits on the possibilities.

International Applications of Telehealth

Within the European Economic Community (EEC) it is permissible to consult with another physician licensed in another EEC country, but the other physician may not directly provide care.³⁰ In Asia, the Malaysian government recently enacted a law requiring all health care providers treating Malaysians to be licensed in the country regardless of where the physician is located. International Telehealth in the U.S. is conducted daily by the Department of Defense. Beyond this, any large scale use of telehealth services would have to operate under an international treaty. To establish a treaty, safeguards must be established to ensure that health care providers are "appropriately" qualified and trained. But what is "appropriate?" Two important elements in the U.S. health care delivery system are verification of credentials (training/qualifications) and privileging (the medical procedures and care that a medical institution will allow a health care provider to perform). Within the United States, both of these are monitored by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private health care quality review organization whose "seal of approval" is required for a health care organization to qualify for payment under the multi-billion dollar federal Medicare program. Internationally, standards similar to those presently instituted by JCAHO would have to be established by one or more international organizations. Subsequently, a system to quickly provide verification of credentialing and privileging requirements would have to be established.

The ability to consent to treatment for health care as well as the amount of information that the health care provider must provide to the patient, or his surrogate, varies widely within the U.S. and internationally. A uniform method of dealing with these issues is also desirable. Christian Dierks, an attorney in Berlin, has suggested an international patient "Bill of Rights" be established which would standardized practice.³¹ Methods of dealing with the proper venue for negligent actions, and professional and other disciplinary actions would have to be determined. Perhaps an international agreement along the lines of the Warsaw Convention dealing with international air travel will be developed regarding liability limits and other legal issues. Mr. Kelly Cameron, a Washington, DC attorney specializing in Telecommunications Law, has suggested the appropriate forum for resolving this may be the World Trade Organization or by using the General Agreement on Tariff and Trade (GATT) since telehealth is by its nature dependent on telecommunications.³²

Conclusion

There are no easy solutions to the questions and barriers facing the implementation of telehealth. The technology is here. It is now a matter of deciding what the best course of implementation will be. For non-federal providers dealing in this area, it is best to contact your attorney and your malpractice carrier to ensure that you are covered.

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4. See e.g. 42 USC 1395 dd (1992) and 42 USC 14402 (1992).
5. See 42 USC 300gg-4 and 300gg-51(1996).
6. See 42 USC 263(b) (1993) & 38 USC 7319 (1996).
7. See Cal. WELF. & INST. CODE 14132.72 (1997) and 22 LA. REV. STAT. 657 (1997).
8. See NEV. REV. STAT. ANN. Ch 129 (Miche 1993) and TEX. FAM. CODE ANN. 35.001 (West 1996).
9. Texas now requires any telehealth provider regardless of location to comply with Texas informed consent and confidentiality requirements. 1997 Texas Gen. Laws 880. Other states such as Arizona and Georgia have passed statutes requiring compliance with state records laws. See 1997 Ariz. Sess. Laws 94 and 1997 Ga. Laws 276.
10. See as examples NEV. REV. STAT. ANN. 129.40 (Miche 1993) and TEX. CIV. PRAC. & REM. CODE ANN. 313.004 (West 1996).
11. See e.g. OKLA. STAT. ANN. tit. 59 SS 622 (B) (3) which provides that telehealth professionals located outside of Oklahoma who treat patients in Oklahoma are subject to suit in Oklahoma.
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DIET DRUG LIABILITY

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Introduction

The desire of Americans to lose weight has fueled the increasing popularity of a variety of diet pills. Among the most popular of these oral weight loss regimens, until the summer of 1997, was a combination of Fenfluramine (Pondimin) and Phentermine, commonly known as Fen-Phen. Fenfluramine is believed to achieve its anorectic effect by boosting levels of serotonin, thereby promoting feelings of satiety.¹ Phentermine, on the other hand, is a stimulant² and was widely believed to offset the fatigue induced by fenfluramine. Dexfenfluramine (Redux) is a newer, purified fenfluramine with similar activity in boosting serotonin³ and was first approved in 1996.

Until recently, the primary known risk of the fenfluramines was thought to be the development of primary pulmonary hypertension, a rare complication,⁴ generally felt to be a justified risk because morbid obesity itself carries significant risks. Drug sales soared, and the pharmaceutical giant, American Home Products, which manufactures fenfluramine and markets dexfenfluramine, estimates that four million patients have used fenfluramine while two million have used dexfenfluramine.⁵

In the summer of 1997, however, researchers began to link Fen-Phen users with deposits on heart valves. The U.S. Food and Drug Administration (FDA) hastily reviewed available data and concluded that the fenfluramines presented an unacceptable risk, leading to the withdrawal of the drugs from the market. By December of 1997, hundreds of lawsuits had been filed, and it was decided that all federal lawsuits would be consolidated in Philadelphia.⁶

The Medical Evidence

This unprecedented withdrawal of such widely prescribed drugs raises many troublesome medical and legal questions. The first important question to be answered is what available medical evidence exists linking valvular heart disease to such drug usage? In an article by Connolly et al. in the *New England Journal of Medicine*, incidents of valvular heart disease were seen in 24 women being treated with Fen-Phen for obesity.⁷ This article reported the case histories of 24 women who were found to have significant valvular disease during the course of routine evaluation for various clinical problems. All of the patients were thought to be free of cardiovascular disease with the exception of systemic hypertension. Twenty of the patients presented with cardiovascular symptoms and four patients had only a new murmur. The average length of time between initiation of Fen-Phen treatment and discovery of disease was 12.3 ± 7.1 months. All of the patients in this article underwent two-dimensional echocardiography, pulsed and continuous-wave Doppler imaging and color-flow examination. The results of this imaging showed unusual valvular morphology and regurgitation in all patients. Right-sided and left-sided heart valves were involved. Also, there were eight incidents of newly documented pulmonary hypertension. Histological findings of those patients requiring surgical intervention found plaque-like encasement of the leaflets and chordal structures with intact valvular architecture.

In the same issue of the *New England Journal of Medicine*, Graham et al.⁸ reported the summarized findings of an additional 28 female patients who presented with similar disease. Their information came from 18 different states. The patients in this report had a median age of 45 years old and the median duration of Fen-

Phen therapy was 10 months. All of the patients were symptomatic with valvular disease upon presentation, except four patients, who were found with new murmurs. In all of the cases, valvular insufficiency was noted, and all four valves were noted to be affected, at some time. Pulmonary hypertension was noted in 10 patients. Finally, no resolution in valvular disease was noted upon discontinuation of Fen-Phen treatment.

In the same issue of *New England Journal of Medicine*, Cannistra et al⁹ reported the case of a 32-year-old woman with no history of cardiac disease who was referred for evaluation of a heart murmur and recent onset of dyspnea on exertion. She had been taking dexfenfluramine for the previous 10 months. Echocardiogram revealed unusual thickening of mitral-valve leaflets and severe mitral regurgitation. She was also found to have an elevation in her estimated pulmonary arterial pressure to 60 mmHg. Mild to moderate aortic and tricuspid regurgitation were also present. Dexfenfluramine was discontinued and pulmonary hypertension was successfully treated, but severe mitral regurgitation was still present upon follow-up echocardiography.

These three articles make a strong argument for the causal association of Fen-Phen treatment with cardiac valvular disease. It is presently impossible, however, to make a definitive statement linking Fen-Phen treatment with valvular disease because of the lack of prospective scientific experimentation demonstrating this connection. However, the similarities of pathology found in the patients described above, coupled with the pathology found in patients suffering from carcinoid valvular heart disease and valvular disease induced by ergot alkaloids, could reveal a mechanism through which Fen-Phen may induce valvular disease.

There are a number of remaining questions which should be answered about Fen-Phen treatment and its possible role in valvular heart disease. First, is there a true relationship between this drug treatment and valvular heart disease? This would best be answered by prospective scientific experimentation before any final policy on this matter is made. Is this a problem that only affects women? So far all of the cases reported have been women. This is an avenue that needs to be further explored. Is the valvular disease apparently linked to Fen-Phen therapy reversible? Graham et al¹⁰ and Cannistra et al.¹¹ found no improvement in the mitral regurgitation in patients upon follow-up on carcinoid valvular heart disease. Studies found to

as many years to answer as does the litigation involving Fen-Phen claims. Nevertheless, it is possible to examine the current situation and draw significant conclusions regarding the identity of potential defendants and likely theories of liability.

Finger pointing, at best, offers only a partial answer to the question. What is most likely the case and most important to remember is that several independent parties combined efforts in the development, production, marketing and distribution of these drugs.

Government

Fenfluramine was individually approved by the FDA in 1973 for short-term weight loss. It was intended for use only by severely obese patients. The danger associated with morbid obesity far outweighed the risk of development of primary pulmonary hypertension, the only known complication at the time. In the early 1990's, the physicians began to prescribe "fen" in combination with phentermine — the other weight-loss drug approved in 1959 which has not been linked to heart valve damage and remains on the market. This "off label" use of the drugs is a relatively common practice. Further, a study sponsored by the National Institutes of Health in 1992 showed dramatic weight loss possibilities when the drugs were combined. In 1996, the FDA granted approval for Redux despite the initial scientific advisory panel's vote against approval.¹⁴ While the FDA may shoulder some responsibility, federal law generally insulates government agents who were performing routine duties, e.g., approving drugs. Thus, a legal remedy will most likely come from another source.

Drug Manufacturers

Aside from FDA involvement, the drug manufacturers who aggressively marketed their products and the developers who arguably failed to test adequately for negative side-effects cannot avoid claims for responsibility. In these cases, the cause of action is usually product liability.¹⁵ Generally, drug manufacturers have been found liable for patient injury where the drug was improperly, or negligently tested, or for failing to warn adequately of the known dangers associated with its use. Where newly discovered information related to side effects of medication is at issue, merely including such information in the insert may not be sufficient. Drug manufacturer liability can be limited by application of the "learned intermediary" rule and the "unavoidably unsafe product" exception to strict liability.¹⁶ In the instant case, the manufacturers aggressively marketed the non-FDA approved *combination* of the drugs, a combination which was possibly not properly researched and tested. Plaintiff attorneys will argue that the drug companies were aware of the risks, and yet continued to sell their products.

Physicians

As opposed to products liability claims, negligence claims, i.e., medical malpractice, will likely be brought against physicians who prescribed the drugs. While there are strategic legal reasons for joining doctors in suit with drug manufacturers,¹⁷ the general complaint is simply that the physician should have exercised better professional judgment. Safe drug therapy includes the following physician responsibilities: proper prescription, proper instruction and proper monitoring. Claims against physicians could include the following allegations: failure to properly examine the patient before prescribing the drugs; failure to properly warn of known side effects; and improper prescription and improper monitoring, including — but not limited to — failing to perform tests on patients complaining of problems during the drug therapy. Physicians employed by weight-loss centers such as Jenny Craig and Weight Watchers have held themselves out as weight-loss specialists and will conceivably have a more difficult time defending their actions than other

primary care practitioners. Specialists are generally held to a higher standard of care.¹⁸ In some cases, patients who were not obese but only overweight were prescribed the drugs contrary to manufacturer and FDA approval recommendations, and it may be more difficult to defend prescribing practices in these patients.

A fourth group that may bear responsibility in Fen-Phen litigation, and one closely tied to many physicians, is the weight-loss centers which marketed the drug combination. Many centers aggressively advertised the availability of diet drug prescriptions in order to attract clients. The important legal question may be whether they obtained adequate patient histories or offered appropriate physician monitoring.

Conclusion

The medical and legal communities have, to date, only seen the tip of the iceberg regarding the drug combination popularly known as Fen-Phen. As science searches for answers, those persons injured will surely seek justice. In the meantime, it is in everyone's best interest to carefully follow both legal and medical developments, which will undoubtedly take years to conclude.

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