Medical and Educational Malpractice Issues in Patient Education

Richard E. Easton, MD, FACPM
Melinda C. Easton, RN, NP, and Maurice Levy, EdD
Virginia Beach, Virginia and Augusta, Georgia

This paper discusses the concept of educational malpractice as a cause of prolonged patient morbidity equal in magnitude to medical malpractice. Statements by national groups sanctioning and urging increased patient education efforts are reviewed. An example of specially designed problem-oriented patient education materials is provided. Also described are the process of materials development, the concept of an "Educational Prescription," the place for the "Educational Prescription" in problem-oriented medical records, and the value of hospital-based patient education as a cost-containment activity.

It is incumbent upon a physician to give such instructions as are proper and necessary to enable the patient or his nurses and attendants to act intelligently in the further treatment of the case, and a failure to do so is negligence which will render him liable for injury resulting therefrom.[1]

The purpose of this article is fourfold: (1) to note the statements of major health-care organizations regarding their official policies toward patient education, (2) to review legal judgments about liability and patient education, (3) to draw attention to the frequently neglected area of medical practice – patient education, and (4) to present a new approach to the development of patient education materials.

In May 1974, the American Hospital Association (AHA) approved its "Statement on the Role and Responsibilities of Hospitals and Other Health-Care Institutions in Personal and Community Health Education."[2] The introduction to that statement included reiteration from the previously published AHA statement on Provision of Health Services. It read in part:

> . . . .In order to encourage individuals to take care of themselves to the maximum extent possible, programs of education to teach people how to exercise this responsibility must be developed, conducted, evaluated, and maintained.

In the body of that statement, hospitals and other health-care institutions were admonished that they "have an obligation to promote, organize, implement, and evaluate health education programs."

The AHA emphasized its feeling that such patient education could "contribute to important health-care goals, such as improved quality of patient care, better utilization of outpatient services, fewer admissions and readmissions to inpatient facilities, shorter lengths of stay, and reduced health-care costs." They felt that "significant (hospital) corporate commitment, including staff and financial resources, is essential." They also encouraged program development by independent groups of consumers and professionals. The AHA statement includes their opinion that "financial responsibility for health education that is integral to the treatment and care of the patient is a legitimate part of the cost of caring for the patient. Health education, that is designed to maintain the good health of the community at large and to prevent illness, should be viewed as a service to the community. Such services are legitimate activities for hospitals . . . ."[2]

Richard E. Easton and Melinda C. Easton are faculty members at Eastern Virginia Medical School. Maurice Levy is Professor and Coordinator of Educational Planning at the Medical College of Georgia. Requests for reprints should be addressed to Dr. Richard E. Easton, Associate Professor of Community Medicine, Eastern Virginia Medical School (Norfolk), 5541 Parliament Drive, Suite 104, Virginia Beach, Va 23462.

Legal Precedence for Patient Education

In addition to the items cited in the quotation which begins this article, other acts or omissions relating to patient education may, if proved, result in physician liability. The following passage from the *American Law Review* also has specific relevance to this discussion: "It is the duty of a physician to give instructions for the patient's care and treatment, if necessary, and a failure to do so will render him liable for any injury resulting therefrom."[3]

While instructions to inpatients and their nurses and attendants are discussed in a series of cases, the liability is no less, and perhaps more, in treatment of homebound patients. One such example is described in Miles vs Hossman:[4] "The patient was at home in the country, some miles from the physician's office, and being nursed by women without nursing experience. The doctor knew of the situation, but failed to leave any instructions or warning, visited infrequently, made no repeated examinations, and failed to detect an infection in a wound, resulting in increased morbidity to the patient."

The physician's malpractice liability from prior precedent, the current litigious population, and the policy backing of organizations such as the AHA have led individuals and groups to increase patient education activities. Both have been supported in these activities by Medicare, a number of private foundations, and occasionally, state health department grants and Medicaid.

Tangentially, it should be noted for conceptual relevance that in 1972, the Massachusetts legislature passed a Special Education Law, Chapter 766, describing the authority and responsibility of the Department of Education in diagnosis and treatment of children having special educational needs.[5] Of special interest is the description of a multidisciplinary core evaluation team, which includes private practitioners. Medicaid regulations specify that the evaluating physicians are responsible for ensuring the delivery of needed services and that this responsibility does not cease, nor is it discharged, until their recommendations are carried out and the problems resolved.[6] Translation of these ideas into adult patient education may be cumbersome and difficult, but is possible.

Patient Education Activities

Individual teams, such as Drs. Young and Rardin in Asheville, NC, have reported[7] on the favorable results of educating their private rheumatoid arthritis patients taking antimalarial therapy. They have devised their own educational materials to specifically meet the needs of the patients. The major purpose of the education is to inform the patients of possible adverse side effects, so that they will discontinue use of the drug before they sustain any irreversible side effects.

On a more comprehensive, statewide scale, the Rutgers Medical School Office of Consumer Health Education has maintained a program since September 1972, under the direction of Anne Somers.[8] This program has educated thousands of students, uses nearly 100 physicians and other professionals as teachers, and functions with the assistance of a large Advisory Council, including representatives of the state medical society, hospital association, and nurses association.

A New Source of Liability: Educational Malpractice

Standard liability from errors in medical judgment or procedure is only one aspect of the malpractice problem. A second form of liability may be educational malpractice. In an original work on the subject,[9] Stewart defines a series of educational malpractices, some of which are briefly described in Table 1. These malpractices relate specifically to secondary school and college-level situations, but given a legal precedent in which any "student" (in the generic sense) has successfully brought suit against a "teacher" or educational system, then the relevance of these conceptual remarks increases markedly.

As a result of the belief that avoidance of educational malpractice (EM) is important when designing informational materials (irrespective of the legal implications), each EM has been considered vis-a-vis the creation of a new patient information segment. Table 1 matches each of Stewart's EMs with a short summary statement describing how each EM was avoided in designing problem-oriented patient information materials.

There are some interesting parallels between the attitudinal set of many teachers in regard to certain students, and that of physicians and allied health professionals toward educating patients. Some of these are cross-cultural ("Patients won't understand, so why tell them anyway."); some grow out of the God-like syndrome ("Only a doctor should know certain things."); and some have their roots partially in reality ("We could teach, but we don't really have the time and even if we take the time, we will not get paid for it."). One approach (which avoids these barriers to initiation of a patient education program) is to reject all excuses for why patients are not educated by health professionals; assume that it *must* be done as a therapeutic and cost-containment measure, create the materials avoiding EMs as described, provide the time and manpower, and charge a reasonable fee for the service provided.

Patient Education Project

With the ideas of both medical and educational malpractice in clear relief

and with recognized institutions, such as the AHA and AMA, on record as favoring patient education, a design project was undertaken in early 1974, by a team including a nurse practitioner, an internist, two pharmacists, and a doctor of education. Each segment of educational materials was structured in a format described by Easton[10] as Problem-Oriented Patient Care Instruction. This material has two major aspects:

1. *Problem-Finding:* The substance of the material is information which will help patients find problems (ie, help patients identify whether they are getting worse because of disease progression, lack of therapeutic efficacy, or other causes).

The substance is further divided into subjective information which only the patient can detect (eg, pain, nausea, dizziness) and objective information which others could verify about the patient (eg, patient looks pale or sweaty).

2. *Problem-Solving:* The style of the material forces the patient (or those helping him) to synthesize the *Subjective* information (eg, feels more chest pain, weaker, short of breath and dizzy) with the *Objective* data (eg, appears pale, sweaty, and is vomiting) together into an *Appraisal* (eg, patient is worse, medicine must not be working properly, and patient requires medical assistance). The final step suggests elements of an initial *Plan* upon which the patient should embark immediately (eg, Take two nitroglycerin pills and call the physician immediately.)

An example of problem-oriented, patient educational therapy material on chest pain (angina pectoris) is given in Table 2. Note that each of the four steps: (1) Subjective, (2) Objective, (3) Appraisal, and (4) Plan (SOAP) is identified and defined for the patient in a short paragraph. The initial portion of each paragraph defines the step itself and part of the *problem-solving sequence.* The remainder of the step provides the *problem-finding substance,* upon which the patient's decision will be based. The patient (or "helper" accompanying him) is given this written material to keep. The instructor reviews the material verbally with the patient and the "helpers" responsible for his continuing care.

Pictures are drawn when necessary. Finally, the instructor seeks feedback from the patient and "helpers," and clarifies misunderstandings or misconceptions before ending the session.

The language is kept simple and unsophisticated. The patients may return or phone in for repeated instruction and may request (or copy for themselves) additional or replacement copies of the information. Instruction continues during repeat patient contact to ensure either complete retention (where relevant and possible), or to ensure that the patient is keeping the printed information available at all times.

Evaluation of success is based upon patient behavior (Does he keep the handout?), patient problem-finding knowledge (Are post-education scores higher than scores on the pre-education test?), patient understanding of problem-solving approach to his own care (Can the patient reiterate the SOAP sequence and define each step?), and patient satisfaction. Each of these criteria, except the last, is objective, and may, therefore, be assessed by any of the instructors.

Educational material reviewing approximately 73 different problems and medications has been prepared, using this problem-solving style with the appropriate problem-finding substance.

The Educational Materials Development Process

Accepting the necessity of patient education, the questions then become: How does one develop the educational materials? Who should be involved? What sort of people, and from which disciplines, are required in the developmental process? The answers to these and other relevant questions are discussed by Waldron.[11] He outlines the services and capabilities, structure, staffing, position descriptions, space, and equipment requirements of an instructional development unit whose specific purpose would be to design educational materials for "health science educational institutions." Although his comments are specifically directed to medical schools, the concepts can be easily adapted by interested patient education groups to their own needs. Waldron describes an eight-step process which includes: (1) definition and analysis of the instructional problem; (2) organization of management resources; (3) identification of behavioral objectives and performance measures; (4) specification of methods; (5) construction of prototypes and evaluation design; (6) tryout of prototype; (7) analysis of tryout results, and (8) decision concerning subsequent steps. The monograph is not intended to provide an in-depth understanding of the process, but with its modest bibliography it provides an adequate starting point for the interested reader.

The Concept of an "Educational Prescription"

Ideas are worth more if they can be understood as part of the existing system. The objective of the following brief discussion is: (1) to demonstrate how patient education can be viewed in terms of the "diagnostic-therapeutic model" so familiar to medicine, and (2) to suggest how patient education can and should be integrated into the overall patient-care milieu. An inpatient model will be used, but as noted above, outpatient models have obviously been in use for some time.

Normally, patients present with medical problems, are diagnosed and treated. If the problem is acute and the therapeutic plan is correct, the problem may be cured rapidly. If the problem is chronic, the plan may only control it. In either the acute or chronic situation, we would not expect the patient to be discharged from care until the problem has been cured, or at least controlled. In the latter case, the patient may still not be discharged, but referred to others for continuing care, observation, and repeated evaluation. If *medical* diagnosis and treatment, and continuing care, observation, and evaluation are the

Table 1. Educational Malpractices to Avoid When Designing Patient Education Materials*

Educational Malpractice	Ways To Avoid
EM-1: Requiring students who are illiterate to learn from the written word alone.	Use handouts (written), explained (verbal) to the patient, responsible family, or friends by a health educator-professional, use pictures (visual) where appropriate.
EM-2: Using sophisticated materials for lay, disadvantaged, or unsophisticated students.	Use simple language, or local jargon or colloquialism, and an unsophisticated, personal approach to patients.
EM-3: Promoting a student when he has not learned the material (eg, telling a patient something once and discharging him).	Allow patients to return or call as needed for re-instruction, question-and-answer sessions, or a replacement copy of lost instructions.
EM-4: Grading "on a curve" so that a certain percentage of students fail.	Set the objective that 100 percent of the patients (or families) will know (or have available) 100 percent of the information we give them. (It is inconceivable that we would purposely "fail" a patient in a "course" where his own health and life are at stake).
EM-5: Requiring a student to pay for and retake an entire course, when he has only failed to learn a small part of the material.	Test the patient for educational deficiencies and review only those with him (see EM-3 solution).
EM-6: Teaching one thing and testing for another.	Use the *same materials* to teach and test the patient. This is like giving out the "Final Exam" at the start of the course.
EM-7: Punishing a student caught with a copy of the test (it is presently considered wrong for a student to find out what he or she is supposed to learn).	(See EM-6 solution).
EM-10: Teaching students facts and how to interpret situations based on those facts, but testing with multiple choice questions.	Teach patients facts about the decision-making process, then verbally testing them for their ability to describe the decision-making process. The factual handouts are organized in a decision-making sequence.
EM-14: Requiring students to learn information by a given date and assuming all students learn at the same rate.	Allow patients an unlimited time (with repeated exposure) to learn 100 percent of the information.
EM-20: Giving up on teaching without trying different teaching methods.	Use verbal, visual, and written methods of presentation; use family members or friends to reinforce or explain.
EM-25: Basing the student's progress on a subjective (prejudiced) view by a teacher, especially when the evaluation is more an indication of which teacher is doing the evaluation than what the student is able to achieve.	Assume all patients, regardless of race, national origin, ability to pay, or other criteria can learn, given proper time and instruction; do not assume that "clinic patients can't learn" or "patients shouldn't be taught because they will misapply the knowledge."

*Adapted from Stewart[10]

norm for acute or chronic medical problems, and if ignorance may result in a prolongation of morbidity and/or mortality from the original medical problem or its therapy, then it would seem logical to conclude that *educational* diagnosis and treatment, and continuing care, observation, and evaluation are of equal importance to their medical counterparts.

The analogy between medical and educational diagnosis and therapy may be extended further to arrive at the concept, new to some, of the "Educational Prescription." In the problem-oriented medical record, there are specific places for the Educational Prescription in (1) the primary work-up of the patient, (2) the initial plans, and (3) the subsequent details of care documented in the daily progress notes. Table 3 shows the format of a problem-oriented progress note, its plan and subcomponents as originally suggested by Weed[12] and as modified to more accurately portray the inclusion of educational diagnosis and therapy.

The logical application of the analogy, not often applied to patient-care situations, would dictate that the normal admission and the subsequent care process should be modified to parallel a sequence similar to the following: (1) a patient with a medical problem is admitted to the hospital; appropriate medical diagnostic and medical therapeutic activities are begun; (2) the patient's medical condition stabilizes; (3) soon after the patient's condition stabilizes and components of his/her medical disease and medical therapy are assessed, an *educational* diagnosis is made and educational therapy begun; (4) efficacy of both medical therapy and educational therapy are assessed and reassessed at appropriate intervals; (5) the patient is considered ready for discharge only when medical problems are controlled by medical therapy and educational problems (ignorance) are controlled by educational therapy, since failure of either medical or educational therapy could result in disease recurrence or exacerbation (prolonged or recurrent), costly hospitalization, morbidity and/or mortality; and (6) after discharge the patient is referred to a source of educational therapeutic assistance and medical therapeutic continuing care (probably at the same site, but not necessarily).

Table 2. Angina Pills (Nitroglycerin, etc) Patient Educational Material

Step 1.
Things only you (the patient) could know about what this drug does to you: how it makes you feel, how fast it works, if it helps you, if it makes you feel worse, when you take it, when you don't take it. These are all things your doctor will want to know about. This is called *Subjective Information.* Knowing this information will help him decide whether you should continue the medicine or not:

Do you get throbbing headaches, flushing of your face, or feel dizzy after you take your angina pills? (This may go away after you have used these pills for a few days).

Do you get dizzy when you stand or sit up suddenly?

How many of these pills do you take each day? Or, how many do you have to take a week? What is the *most* nitro you have ever had to use in one day? When was that? Why did you have to use so many?

Do they relieve your chest pain in a minute or two? Do you ever take two or three pills to relieve one episode of chest pain?

Have you had chest pain that lasted longer than a few minutes and was not helped by your angina pills?

Have you ever had chest pain and shoulder, arm, or neck pain all at once?

Do you perspire (sweat) a lot when you have chest pain?

These are things you should tell your doctor.

Step 2:
Sometimes *other people* will tell you things they notice about how you look or behave when you are taking certain medicine. You might not notice these things about yourself. Someone else may have to tell you before you notice them. This is called *Objective Information.*

Have other people noticed how often you seem to have chest pain?

Do they notice that your angina pills help you quickly?

Have they noticed that you looked pale or grey, or that you perspire a lot when you have chest pain?

What other things in Step 1 have they noticed?

Step 3:
After thinking about Steps 1 and 2, you should come to some conclusions about what you think is going on. This is called your *Appraisal* of what the drug is doing:

Is the medicine making you feel better?

Is it making you feel worse even though you are taking it just the way your doctor told you to?

Is it doing what it is supposed to do?

Is it causing you problems that you did not have before taking it?

Do those problems go away when you stop taking it?

Step 4:
Once you have decided what you think is going on (your *Appraisal*), you should have a *Plan.* You should stick to the Plan exactly so you can tell your doctor what you have done if the Plan doesn't work. That way he will know what you have already done and will be able to suggest things which may work better. Your *Plan* follows:

Take these pills exactly as your doctor has told you to take them.

Keep your pills with you at all times.

Never take your pills out of their original bottle. Make sure you keep the bottle top tightly closed between usage. Do not let these pills get hot and do not leave them in the direct sunlight (they may lose their strength).

If you have chest pain: sit down, put a nitro pill under your tongue and wait two minutes. If the pain has not gone away in two minutes, put another nitro pill under your tongue. After the second nitro pill wait two minutes. If the pain does not ease off or begin to go away or if the pain continues to get much worse, have someone notify your doctor immediately.

The purpose of this information is to help you understand your medicine better, to help prevent side effects which may make you worse and to help you recognize these side effects (if they do happen to you) so you can do something about them quickly.

If you have suggestions about how we can make this information more helpful, please fill out the evaluation sheet.

Thank you.

Table 3. Problem-Oriented Progress Note Formats: Traditional and Modified

"Title of Problem"

Subjective:
How the patient feels

Objective:
Factual data about the problem

Appraisal:
What we think is going on given the subjective and objective data

Plan:
What to do about the problem
- Diagnosis:
- Diagnostic plan subcomponent
- Therapy:
- Medical therapeutic subcomponent
- Patient Education:
- Educational subcomponent

or

Plan:
- Diagnosis:
- Medical and educational
- Therapy:
- Medical and educational

The hospital could be the place in which patients could obtain the majority of "educational prescriptions" for a number of reasons: (1) it could serve both inpatients and outpatients; (2) nursing service personnel (RNs, LPNs), or other employees, could be taught necessary skills in order to deliver educational prescriptions (in addition to their present delivery of medical prescriptions); (3) given that the service is viewed by third parties as a legitimate activity, the costs involved in delivering it could be recouped, thus creating a source of income to continue, expand, and perfect the service and its educational offerings; and (4) the educational service might function as a cost-containment measure from three points of view: reduction of hospital and physician liability insurance premium costs; reduction of the number of rehospitalizations of discharged inpatients due to educational deficiencies leading to recurrent morbidity; and reduction of the number of unnecessary new admissions of outpatients due to educational deficiencies leading to new morbidity which could have been prevented by education.

Conclusions

People provide service for which society dictates there is a felt or real need. When a service for which there is a felt need does not take place, the legal profession will claim negligence by the party felt to be responsible for providing the service. Providing the service should decrease the total liability.

People do what they have been trained to do. In the absence of courses in educational technology in our schools of medicine and the allied health professions, there is no reason to believe health professionals have, or will soon acquire, the skills to adequately diagnose and treat patients' educational problems. Neither is it apparent why they should acquire these skills, given the excellence of available professional educators.

People do what they are paid to do. In the absence of general reimbursement for patient education per se, there is no reason to believe that the majority of health professionals will voluntarily choose to spend their time in financially unproductive pursuits, developing new materials, or administering those now available. Grocers do not order food they cannot sell, nor do they give away the products on their shelves.

People do what they are conceptually prepared to do. In the absence of a concept, clarifying the essential diagnostic and therapeutic similarities between organic medical problems and functional educational problems, disease and "ignorance" respectively, no action should be expected to: (1) create patient education development groups; (2) institutionalize patient education activities; (3) educate patients on a broad scale; nor (4) reimburse the professionals in health and education for doing this on a significant scale, especially at the private practice and community hospital level. People need a conceptual framework within which to accomplish most tasks on any broad scale.

If the consequences of not meeting the growing demand for education are recognized by society, and if there are professional educators available and willing to collaborate with physicians and a reimbursement system which views patient education as a valuable service with cost-containment advantages, then involvement of medical and allied health professionals would be more easily accomplished. Future efforts to organize patient education should maintain an awareness of these factors and their implications for medical, educational, and allied health disciplines and the communities of patients which they are supposed to serve.

References

1. 22 American and English Encyclopedia of Law 802, as quoted in Yard vs Gibbons, 95, US Supreme Court, p 810, January 1915
2. Statement of the Role and Responsibilities of Hospital and Other Health-Care Institutions in Personal and Community Health Education. Chicago, American Hospital Association, May 1974
3. 57 ALR2d, 411-416, § 23
4. Miles vs Hossman, 127 Wash 653, 221, p 316, 1923
5. Massachusetts Department of Public Welfare: Massachusetts Public Assistance Policy Manual. Evaluation and treatment of Medicaid children according to the Massachusetts Special Education Law. Boston, 1974, chap 7
6. Haas G., Levine MD: Chapter 766 and educational prescriptions. N Engl J Med 292:1077-1078, 1975
7. Dana M: Informing patients is best cure. Virginian-Pilot, G10, June 30, 1974
8. Somers AR: Educating the consumer: It can mean better health, lower costs. Am Med News, p 9-10, May 27, 1974
9. Stewart D: Educational malpractices — The Big Gamble in Our Schools. Pasadena, Geddes Press Printers, 1971
10. Easton R: Problem-Oriented Medical Record Concepts. New York, Appleton-Century-Crofts, 1974, pp 138-141
11. Waldron JS: Instructional Development Unit: A Guide to Organizing an Instructional Development Unit. Atlanta, National Medical Audiovisual Center, 1972
12. Weed LL: Medical Records, Medical Education, and Patient Care. Chicago, Year Book Medical Publishers, 1971

Book Excerpts

The following article has been selected by the Publisher from its new book, *Legal Medicine 1976,* edited by Cyril H. Wecht, in the hope that it will have immediate usefulness to our readers who otherwise might not have had access to it.

Physicians' Liability for Failure to Anticipate and Control Reactions and Interactions Precipitated by Prescribed or Administered Drugs

James J. Junewicz, Esq

Side effects in the use of drugs are an old story. Practically every useful drug causes with its administration the danger of one or more side effects.[1]

No drug is absolutely safe. If it were, it perhaps would not cure anything.[2]

I. Introduction

The anticipation, control and prevention of reactions and interactions among prescribed and nonprescribed drugs is a primary goal of our national health care policy.[3] Any administration of drugs, however well-intentioned, may precipitate a wide range of adverse consequences, including death.[4] As indicated by the Permanente Medical Group of Oakland, California:

> Undesirable effects of drugs present a real threat to health and a substantial burden to medical practice. Recent studies have shown that about four to six percent of hospital administrations are due to adverse drug reactions and about 10 percent to 18 percent of hospitalized patients experience a drug reaction before discharge. *While many reactions are mild and temporary, a substantail number are seriously disabling and life threatening.*[5]

The medical profession has tried diligently in the past decade to eliminate complications arising from the adverse response of patients to drug reactions and interactions.[6] Physicians and hospitals alike have called for a heightened awareness of the problem.[7] In addition, the looming spectre of legal action by aggrieved patients or their legal representatives, *qua* plaintiffs, has stimulated the anticipation, control and prevention of drug reactions and interactions.

The purpose of this paper is to compare the advances of medical technology with respect to drug reactions and interactions with the growing recognition by the courts of the physician's duty to anticipate, control and prevent drug reactions and interactions. In other areas of medical treatment, the law – from the commanding perspective of Mount Olympus – has subjected the conduct of physicians and hospitals to the most severe scrutiny. The law has required physicians to use "reasonable care and skill for the safety and well-being of the patient,"[8] and from that springboard, has imposed liability for a variety of activities common to the physician-patient relationship. This paper will develop the thesis that the law surrounding medical malpractice is, as currently stated, out of step with advances by the medical profession to curb drug reactions and interactions. The upshot is the failure of the law to guide physicians with consistency and specificity regarding their legal duties when they prescribe or administer drugs, and to regulate their conduct to deter otherwise avoidable drug reactions and interactions.

Certain terms merit definition. Drug "reactions" are actions of a drug other than the anticipated pharmacological effect.[9] Drug reactions are distinguishable from "side effects," a term frequently used to denote effects of a drug apart from its intended therapeutic effect, for example, the drowsiness produced by an antihistamine drug used in treating hay fever.[10] Reactions are more severe than "side effects," and more drastically counter the intended therapeutic purpose.

Drug "interactions" are pharmacokinetic events occurring when one agent alters the absorption, distribution, biotransformation (metabolism), or excretion of another agent.[11] An editorial in the *Journal of the American Medical Association* defined "interaction" more specifically when it stated that an interaction is a "pharmacologic response that cannot be explained by a single drug but is due to two or more drugs acting simultaneously."[12] The editorial isolated two kinds of interactions – toxic and indirect. An indirect interaction is the interplay between two drugs in a way that alters the pharmacologic effects of one or both of the drugs,[13] presumably without harm to the patient. A toxic interaction results in harm to the patient.

A frequent manifestation of adverse reactions or interactions is anaphylaxis. Anaphylaxis is an acute reaction which may range from mild, self-limited symptoms to a grave medical emergency, characterized by a massive release into the cardiovascular system of allergic mediator substances, especially histamine, a slow reactive substance of anaphylaxis, as well as complement fractions such as anaphylatoxin. These substances cause generalized vasodilatation and urticaria, increased vascular permeability, bronchospasm, and epiglottic edema.[14]

This paper shall compare the attention paid to drug reactions and interactions by the medical profession and the courts, for the purpose of illumination the deficiencies of present general negligence standards in dealing with this important national health care problem. Accordingly, Part Two shall discuss the medical advances made by segments of the medical profession in the anticipation, control and prevention of drug reactions, and the specific directives made by the medical profession in the anticipation, control and prevention of drug reactions and interactions, and the specific directives made by the medical profession to its practitioners. Part Three shall look to the law now patrolling the area and evaluate the behavior of

Continued on page 282

Continued from page 281

the courts in regulating the administration of drugs with consistency and predictability. Finally, Part Four offers some of the writer's own ideas regarding the response of the courts to the problems of drug reactions and interactions. Part Four suggests that the concept of "specific duties" upon the physician is ideally suitable to malpractice actions concerning adverse reactions and interactions.

II. The Progress of the Science

Medical Advances in the Anticipation, Control and Prevention of Adverse Drug Reactions and Interactions

There is clearly little basis for any attack upon the analytical approach of the courts in dealing with medical malpractice surrounding the reaction and interaction of drugs unless medical science has demonstrated a capability to achieve greater safety in the area. Accordingly, Part Two shall identify the scope of the problem presented by drug reactions and interactions and outline the success of a segment of the medical profession in anticipating, controlling and preventing adverse reactions and interactions.

A. The Increase in the Number of Drugs Has Increased the Number of Possible Reactions and Interactions. The number of drugs available to physicians for prescription has dramatically increased in recent years.

Of the number of drugs in use in 1961, 95 percent were unknown 25 years ago, 90 percent were unknown 15 years ago, and 50 percent were unknown 5 years ago.[15]

As the number of drugs increases, the number of drug reactions increases geometrically.[16]

It is likely that the introduction of many new potent therapeutic drugs during the past decade has increased the risk of drug reactions.[17]

As the result of the introduction of new drugs, the United States Public Health Service estimated that 1.3 million adverse reactions occur annually.[18]

Medical researchers have successfully isolated these reactions and identified their causes.[19]

The number and possibility of drug interactions has also increased in recent years. This increase is attributable to the increase in the number of drugs available for prescription, causing *a fortiori* a geometric increase in drug interactions, and the growing tendency for physicians to prescribe several drugs to attack a single infection or disease.

With the increasing use of *multiple therapeutic agents* it has become increasingly clear that the pharmacologic action of a drug may be qualitatively altered in patients receiving other drugs. Antibiotics may interact with unrelated nonantibiotic drugs and the result may be the increased or decreased activity of the antibiotic or other drug. Two antibiotics may be administered in order to (1) delay emergence of resistant organisms; (2) treat mixed or undiagnosed infections; or (3) to enhance the rate of bacterial infection.[20]

A survey done at two of the largest university medical center hospitals in the country revealed that the average patient in the hospital received in average of 9.2 drugs during that hospital stay.[21]

B. Medical Technology Has Recently Devised Effective Ways to Anticipate, Control and Prevent Drug Reactions and Interactions. Despite their increasing number, medical technology has assiduously detected drug interactions among prescribed drugs and has proliferated detailed literature, usually in short form, through its professional journals.[22]

Interaction between prescribed drugs and over-the-counter medications has also been investigated by medical researchers.[22]

It has been repeatedly documented that interaction of drugs may occur during self-medication ... As the number of drugs taken concurrently by an individual increases the number of adverse side effects increases in a geometric fashion. *A number of over-the-counter drugs and foods may interfere with the gastrointestinal absorption of potent prescription drugs.* For example, combined administration of antacids or milk products with a tetracycline antibiotic causes erratic and incomplete gastrointestinal absorption of an antiinefective drug since tetracyclines form a complex (chelate) with the multivalent calcium, magnesium, and aluminum found in antacids or with calcium in milk.[23] (Emphasis added).

The phenomenon of "potentiation" has also received the critical attentionof the medical profession. Potentiation refers to the accentuation of the effect of one drug by another, so that if one drug is given, the amount of the other drug should be reduced.[24] For example, a recent discovery is that the antimicrobial reaction of neomycin on staphylococcus aureus is potentiated by the drug theophylline and ordinary caffeine.[25]

Dr. Monroe Trout has further differentiated between those interactions that are merely *additive, viz.* caffeine and neomycin, and those that are *synergistic,* referring to the catalytic effect of one drug on another, producing a third, alien substance, significantly more dangerous in effect.

Very early in the pharmacologic game, this (synergism) was shown with the interaction of cocaine and adrenalin. We know that if you give a patient cocaine his blood pressure will stay just about the same or be slightly elevated. If you give the same patient adrenalin, his blood pressure will go up to a certain point. *If you administer the two together, the patient's blood pressure will go up four times higher than when you administer the adrenalin alone.*[26] (Emphasis added.)

The possibility of drug interactions has also increased in recent years. Interaction is not the exclusive characteristic of prescription drugs, since certain antibiotics interact with over-the-counter drugs such as aspirin and common substances like caffeine. Interactions may be additive, mitigating or exacerbating the effect of a drug, or synergistic, creating a new substance or heightened potency. The new substance created by synergism has discreet physical properties, often far more drastic physiologically than

Continued on page 297