CONSUMER HEALTH PERSPECTIVES

Vol. VI. # 4 (1979) PUBLISHED BY THE CONSUMER COMMISSION ON THE ACCREDITATION OF HEALTH SERVICES, INC. Pub. August 1979

Fee-for-service Private Practice Medicine: Problems and Contradictions

Steven Jonas, M.D.

Steven Jonas, M.D., M.P.H., is an associate professor in the Department of Community Medicine, School of Medicine, State University of New York at Stony Brook.

In terms of meeting people's needs for good medical care, fee-for-service, private practice medicine is an idea whose time has gone. It is also a reality which will remain with us for quite some time, primarily because of the political power of the fee-for-service private practitioners and their allies in the hospital, insurance, drug, and hospital supply industries. In this paper, I will briefly discuss the following aspects of fee-for-service private practice:

1. The central position of the physician in the health care delivery system.
2. The principal influences on the work mode of the physician.
3. The problems of the health care delivery system (HCDS) which are related to fee-for-service private practice (FFSPP, or PP for short).
4. The basic contradictions of private practice in a modern, industrialized society.

The reader will forgive me, I hope, for the telegraphic style of this paper. At the request of the editor, I am attempting to present a rather large number of observations and ideas in a necessarily small amount of space. I hope to have the opportunity to discuss these ideas at much greater length in another setting at some time in the future.

Physicians are central to the operation of the contemporary HCDS. There are three reasons for this:

1. Our health system is oriented to disease treatment rather than to prevention. Through the licensing laws, the physicians have control over the three major functions of this "disease-oriented" system: diagnosis of disease, the prescription of restricted drugs and the performance of surgery.
2. Of all health care professionals, physicians have the most training (not necessarily of the right kind, however), in the scientific basis of any modern HCDS: biomedical science.
3. Physicians determine about 70% of all expenditures in the HCDS.

Thus, the physician is a powerful personage indeed.

There are two principal influences on the mode of work of physicians: how they are trained and how they are paid. I have dealt at some length elsewhere with the problematic influence of medical education on the work of the physicians and the HCDS.[1] The mode of paying physicians for their services is likewise a major contributing factor to HCDS problems in this country. In the United States, about 80% of physicians other than hospital house staff (interns and residents) are in PP.

PP is a piece-work system: income is directly related to the amount of work done. PP is also entrepreneurial: physicians organize, manage, and promote their own practices/businesses. PP is basically connected to the following, well-recognized problems of the American HCDS:

1. The lack of attention to prevention. The great preventionist C.-E. A. Winslow put the point more eloquently than I can:

   "So long as the doctor is paid on a fee-for-service basis, his income and his opportunity

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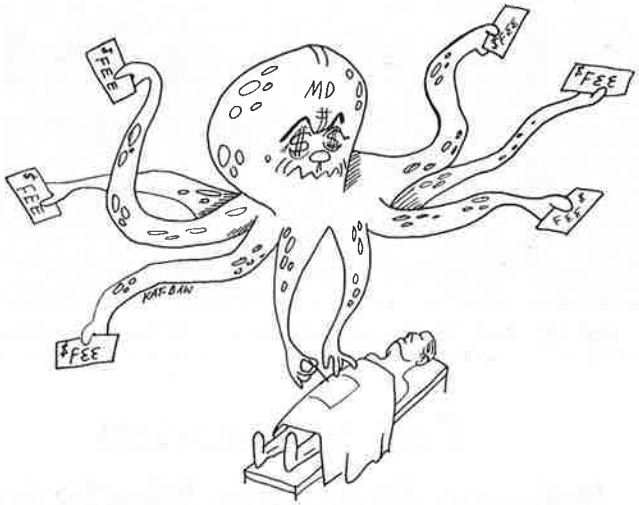
for service must depend on the treatment of disease, since he will be called in only when something hurts...Only when the doctor is habitually employed on a pre-payment basis for health service will preventive and constructive medicine really become vitally significant."[2]

2. Sky-rocketing costs. PP requires physician independence for its operation and physicians will strive mightily to maintain that independence. The physician is a private entrepreneur who determines the majority of expenditures in the HCDS (that is, it is the doctor who determines who will be hospitalized, for how long, and what drugs, tests and treatments will be ordered, both in and out of the hospital). Being an independent contractor, with his or her own income relatively well-assured, the physician has no responsibility for or stake in maintenance of the financial stability of the system as a whole.
3. Overspecialization. Under PP, specialists make more money than do non-specialists. The connection is obvious.
4. Geographic Maldistribution. At least one study[3] suggests that an important factor in the migration of private practitioners is changes in the geographic distribution of per-capita income levels, that is, that doctors follow dollars.
5. Over-hospitalization *and* excess surgery. PP and the system's orientation towards disease treatment encourage doctors to use the most expensive part of the HCDS, the acute-care hospital. If for no other reason, this is so because fees for hospitalized patients are guaranteed at least in part by the insurance which many people have for doctors' fees while in the hospital. Such fees are often easy for physicians to earn. Furthermore, the PP system has fought hard against the expansion of insurance coverage to end the bias toward hospitalization which the present system has. As to excess surgery, it is well known that population/surgery rates climb with increasing surgeon/population ratios. This reflects in part a condition that a surgeon friend of mine once referred to as "acute remunerative appendicitis."
6. Suppression, then inhibition of the growth of pre-paid group practice. HMO's are supported by Federal law. Conspiracy in restraint of trade is prohibited by Federal law. Some states have specific group practice protection laws. The American Medical Association supports HMOs, in public. However, local medical societies, flying in the face of the law, fight the establishment of HMOs overtly and covertly, legally and illegally. After all, "free competition" really means nothing when the future of PP is at stake.
7. Non-existence of national health insurance. American PP has fought NHI since 1920, the most successful such struggle in world history. The reasons given are many. The real reason is only one: money.



8. Deficits in the quality of care. Independent action is essential to private entrepreneurship. Thus, PP has had little interest in promoting quality control mechanisms other than medical licensing. The latter, of course, does more to limit medical competition than it does to control medical quality.
9. The two-class system of medical care. In a society in which some people are too poor to pay the fees of the PP system while others can afford them, if care is to be provided at all for those who cannot afford private care, it must be provided by some other system. Thus, we have two classes of medical care.
10. Distorted motives and incentives for working in health care. PP promotes working for a monetary reward, rather than for the intrinsic social worth of the activity. PP thus epitomizes capitalist values of individualism and self-aggrandizement.

Central to the problems of PP are its three principal contradictions. First, the provision of virtually any health service in our era requires the work of a group of people performing various functions as health care workers. The majority of these people are paid on a salaried basis and are part of an administrative structure which subjects their work to certain supervision and controls. On the other hand, the physician, and other private practice health care providers, are paid on an individual basis and are subject to little supervision and few outside controls.

For example, when a person is hospitalized, the bulk of his or her care is provided by a group of salaried workers, who are part of an administrative structure. They work on a *social* basis. The patient has an implicit contract with this group of persons to receive a set of services. The patient has a separate implicit contract with the physician to provide another set of services, closely intertwined with and often determining the nature of those provided by the hospital group. Yet the physician works on an individual basis and is rarely employed by the hospital. Thus, a fundamental contra-

diction is established between the privately-paid, self-regulating physician and the salaried, administratively controlled group of health workers without whom, in most cases, the physician would be unable to function. This contradiction has to date rarely surfaced as a cause of direct conflict in this country. It has done so in Great Britain, however, where job actions by salaried National Health Service workers forced the gradual elimination of private pay beds, used by patients of private, fee-for-service practitioners, in NHS hospitals.

The second basic contradiction of PP is found in the way funds are raised to pay for health services. Over two-thirds of the money spent on health services is raised socially (i.e., by a collective rather than individual effort): over 40% via taxation and over 25% via insurance premiums, most of which are deducted from total wages and are a sort of tax themselves. Yet again, although the vast majority of health workers are paid socially, by salary, physicians are paid individually, on a fee-for-service, piece-work basis. This contradiction reveals itself in practice in two ways. One is the ongoing struggle between private medical practitioners and the several types of health services that pose a threat to the continuation of private practice, such as pre-paid group practice. Organized groups of private practitioners will not hesitate to break the law, (anti-trust and group-practice protection laws, for example), in their efforts to stifle the growth of Health Maintenance Organizations. Second is the more recently emerging struggle by physicians to evade or defeat attempts by government to establish some sort of accountability by physicians for tax monies paid for their services. The battles, overt and covert, against Professional Standards Review Organizations and Health Systems Agencies are examples of this.

History teaches us that social contradictions are always resolved, sometimes peacefully, sometimes not until a great deal of struggle has taken place. Similar contradictions in other professions in the past have been resolved in favor of a system under which virtually everyone is salaried. For example, in the nineteenth century the teaching profession worked on a fee-for-service basis. (Private fee-payment to medical school teachers lasted until the end of the last century.) Students, although grouped in classes, paid teachers on an individual basis. This practice disappeared as communities took on the responsibility of supporting education through taxation. Once the social basis of education financing was established, it seemed to make no sense to pay teachers on an individual, per student, piece-work basis.

A similar progression took place in engineering. The 19th century predecessor of modern engineering was the profession of "inventor." Inventors worked alone, and were paid on a fee basis if and when they sold an invention to a manufacturer. However, as technology became more complex, so did inventing. Increasingly, inventing, and project development following upon a particular invention, became a social process involving a group of people working together. Many of Thomas Alva Edison's inventions, particularly the later ones, did not spring from his mind alone, but were the product of a group of people, who were really engineers, who worked for him on a salaried basis. In the 20th century, inventing by and large gave way to engineering, and today most of its practitioners work for a salary.

The third contradiction of the fee-for-service system is that physicians do well by treating diseases in individual patients. The more diseased persons they treat, the greater their income. There is little emphasis on public health and prevention even though historically the most successful measures for improving health levels have been those preventive measures directed at the population as a whole.[4] In relation to health then, the contradiction is clear: health status is most affected by preventive measures of a social nature, while doctors, the supposed leaders of the health care delivery system, spend most of their time treating disease on an individual basis.

The medical profession is subject to the same historical laws that other professions and occupations are. Medicine is one profession that struggles with particular ferocity against the force of history. Unfortunately, for the supposed self-interest of the profession, history never loses; only the profession—and the people it is supposed to serve—can be hurt by this struggle.

Resolution of these contradictions will obviously require a change in the way physicians, and other private practitioners in the HCDS, are paid. Two alternatives are capitation and salary. Capitation (in which a physician is paid according to the total number of patients in his or her care) represents an interim stage on the way from fee-for-service to salary, a system of payment for work that is virtually unknown outside of medicine. Since in its largest application, in the British National Health Service, it is accompanied by private entrepreneurship, it potentially has many of the problems of fee-for-service. The contradictions are certainly similar. Thus, salary would seem to be the only feasible alternative to fee-for-service, if the inherent contradictions of PP are to be resolved, and the problems caused by PP are to be dealt with.

Well then, how do we get from A to B? A social reform will have to be achieved. The questions then become which one and how. A consideration of those questions will be the subject of the next part of this paper. □

References:

1. Jonas, S. *Medical Mystery: The Training of Doctors in the United States.* New York. W. W. Norton. 1978.
2. Winslow, C.-E.A. "The Place of Preventive Medicine in the Medical Curriculum." *American Journal of Public Health, 34,* 1285, 1944.
3. Clark, L. J. and Koontz, T. J., "Analysis of the Impact of the Hill-Burton Program on the Distribution of the Supply of General Hospital Beds and Physicians in the United States, 1950-1970." Delivered at the Annual Meeting of the American Public Health Association, San Francisco, Nov. 1973.
4. McKeown, T. *The Role of Medicine: Dream, Mirage, or Nemesis.* London: The Nuffield Provincial Hospitals Trust, 1976.

NYC Update

CITY HOSPITALS: I've Been There

by John Eric Jacoby, M.D., M.P.H.

I know New York City's hospitals quite well. I worked and trained in many of them as a medical student, intern, resident and student of public health. Now, working with the state Health Department, I visit New York City hospitals of all types and sizes for the purpose of reviewing the quality of medical care.

The hospitals in New York—no matter what their size and no matter who is operating them—have one thing in common: financial constraints are visibly cutting into their ability to maintain a consistent level of quality.

The causes of financial stress may be complex, but the results are clear. Hospitals have gone bankrupt, hospital administrations have been corrupted into poor practices, hospitals have cut back on maintenance and housekeeping services. The phrase, "hospital clean" no longer has meaning in New York today.

I have also seen the results of the job freeze in the Health and Hospitals Corporation. Basic components of care are neglected or left undone entirely because the reduced staff of nurses and other workers cannot perform all necesssary tasks—especially since today's highly trained health workers are not interchangeable. If someone leaves, the job remains undone.

The atmosphere created by staff attrition and service cutbacks undermines the morale of hospital workers, a change which ultimately affects the quality of service. Hospital workers are taking home less real income in a time of inflation. In at least one department, a hospital is giving enforced cuts in the work week. These measures take a severe psychological toll on the staff and reduce their ability to do a compassionate and thorough job.

Physicians are affected along with other hospital workers. In one hospital, several physicians were laid off with only two weeks notice, a course of action which the administration had planned well in advance. Residency places are going unfilled in teaching hospitals where there are financial dificulties. With all the staff shortages, if one must enter a New York hospital now, it is well to have a private duty nurse or a family member in constant attendance.

For a hospital to function safely and effectively, it must have adequate staffing and housekeeping. But the terrible financial situation in New York today has forced many hospitals to tolerate and even to make decisions which bring about substandard practices.

The downward spiral in New York's hospital services must be halted. We need a planned and rational health policy based on need for services and conforming to high quality standards. Public health decisions cannot be made by accountants and bankruptcy judges. □

Dr. Jacoby is a Pediatrician and Public Health Physician. He has personally participated in hospital inspections for the Health Department. All opinions expressed are those of the author and do not reflect the view of any agency.

Delay Exposed

HEW TO INVESTIGATE NYC HOSPITAL CLOSING PLAN

On May 4th, HEW's Office of Civil Rights (OCR) announced that it would begin an investigation into proposed New York City municipal hospital closings to determine whether the cutbacks in health services planned by Mayor Koch's administration constitute a violation of Title VI of the Civil Rights Act of 1964.

The investigation was prompted in response to a complaint lodged by the Metropolitan Council of Branches of the National Association for the Advancement of Colored People, which charged that public hospital closings would have an inordinate and discriminatory impact on the ability of minorities to obtain health care.

FIRST REQUEST DENIED

The federal order to investigate, however, did not come promptly. David Bryan, Jr., who heads the NAACP's Metropolitan Council of Branches, first submitted his request for an investigation in a letter to Secretary Califano in mid-January of this year. In response, DHEW undertook a preliminary look at the New York situation to determine if a full-scale investigation were warranted. The results of that preliminary review did not immediately become known to the NAACP, but it did receive a letter from OCR on February 16th stating that a full scale investigation would be "premature" chiefly because the cutbacks in question were "proposed" rather than actual.

COVER-UP CHARGED

There the matter appeared to rest until three months later evidence surfaced raising the suspicion that Secretary Califano was deliberately dragging his heels on the matter of the investigation. Two incriminating internal DHEW documents were obtained by the Metropolitan Council of the NAACP in early May. One was a memorandum written to OCR by DHEW's Office of General Counsel. The other, entitled, "Title VI Pre-Investigation of Anticipated Reduction of Hospital Services in N.Y.C.," came from the Office of Civil Rights itself.

The General Counsel's memo (dated February 16) sharply contradicted the reasoning given the NAACP when the OCR turned down the idea of a wider investi-

MALPRACTICE AND QUALITY

by Donald Rubin

It is an irrational system which will not allow consumers or their governmental representatives to participate in activities which might promote quality and prevent malpractice, but which allows them to try for a chance at recompense after injury has occurred.

The consumer has never been in a position to judge the competence of an individual practitioner or the quality of a particular health facility. Physician licensing, hospital accreditation and review of hospital utilization have remained the closely guarded domain of health professionals. An aura of sanctity and secrecy surrounds the process by which peers review one another's practice. Meanwhile, ignorance and passivity have been encouraged as the traits of the ideal patient.

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Unfortunately, there is little doubt that poor and negligent care is a pervasive problem in our health system. The shocking figures on unnecessary surgery give us some sense of the scope of the problem, yet most of the data on poor medical practice, when collected at all, is unobtainable by the public. Meanwhile, doctors who are untrained or inadequately trained for the tasks at hand continue to treat patients.

* * *

Discipline and standard setting for hospitals has also been entrusted to the providers. With the passage of Medicare legislation more than a decade ago, the right to set standards and inspect participating hospitals was claimed by health providers, in the form of the Joint Commission on the Accreditation of Hospitals. The federal government virtually abdicated its responsibility to guarantee hospital quality on behalf of the public, and many state governments are giving up on their inspection duties.

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In this context, the need to strengthen and support the patient's right to sue for malpractice damages is the more clear. However, it must be said that the cluster of interests which surrounds malpactice law, does not work in the best interests of consumers. The malpractice insurer's drive for profit, the doctor's fear of malpractice litigation, and the lawyer's custom of being paid a "contingency fee"—all work against consumers, whether or not they have ever been involved in suing a doctor or hospital for negligence.

* * *

During the period of the "malpractice crisis" of 1974, the public was bombarded with newspaper and magazine articles and with radio and TV spots on the subject of malpractice insurance and malpractice law. Yet discussion of the issues revolved around doctors, lawyers and insurers—around the costs to physicians of malpractice coverage, the profitability of these policies to insurance companies, and the size of fees paid to lawyers. Missing from the media blitz was any discussion of the legal rights of patients and the impact on consumers of high malpractice rates. One result of this omission was the frittering away of the rights of patients to seek legal redress in case of injury or disability sustained because of medical negligence.

Another media omission was the failure to mention that it would ultimately be the consumer—not the doctor or hospital—who would pay the high cost of malpractice premiums. The costs of insurance would finally be passed along in doctors' fees and hospital charges and would ultimately be borne by consumers through taxes, insurance premiums and out-of-pocket payments. The consumer who could not pay a doctor's inflated fees would simply be deterred from seeking care.

* * *

For the malpractice insurance system to make sense, medical negligence would have to be a rarity. The system would have to operate by strict standards and reliable monitoring of quality.

Donald Rubin is President of the Consumer Commission on the Accreditation of Health Services. Published here are excerpts from a paper presented before the Columbia University symposium on "Medical Malpractice and its Remedies—A Contemporary Review" on May 24, 1979.

gation. In fact, the document revealed that the Office of General Counsel had advised the OCR that there was clear jurisdiction under Title VI regulations to investigate "threatened" as well as current discrimination in federally funded programs.

The other document, the eight-page "Pre-Investigation" report had unearthed quite a bit of preliminary evidence that the proposed closings were discriminatory and concluded that the OCR was "obligated" to conduct a fuller investigation.

Both documents appeared to have been written and read before OCR wrote to Bryan on February 16th that there were insufficient grounds to pursue a federal probe.

Calling these documents the "smoking gun" which proved that an investigation was being suppressed, Bryan announced on May 3rd that he was seeking Justice Department intervention. In a letter to Attorney General Griffin Bell, Bryan charged Califano with an attempt to "impede, delay and obstruct" a lawfully mandated civil rights investigation. Bryan also notified Congressmembers Rangel, Edwards, and Chisolm and Senator Edward M. Kennedy.

On the next day, it was learned that DHEW's Office of Civil Rights would commence a full scale investigation of possible Title VI violations in New York City's proposed hospital closings. □

But this is not the case. Malpractice is a feature of the system. Modern American medicine has many characteristics that encourage a special kind of negligence—the unnecessary ills of overtreatment. The emphasis on specialization, hospitalization, and technology encourages overintervention and discourages interest in public health and prevention.

The profit-oriented, fee-for-service arrangement—whereby doctors, hospitals and labs charge the patient for each service rendered—provides doctors and hospital administrators with a clear economic incentive to over-order tests, to over-prescribe and to over-intervene generally in diagnosis and treatment. Fee-for-service also discourages doctors from referring cases away to physicians who may be more skilled at a particular procedure.

The practice of treating patients within a hospital setting—partly a result of the fact that outpatient services are rarely covered by health insurance—is yet another incentive to overdo, to overcharge and to needlessly increase the risk that injury will occur.

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If a procedure is not really necessary, the risk undertaken with the procedure is indefensible. If surgeons were sued every time an unnecessary operation were performed, there would indeed be a malpractice insurance crisis!

Another feature of contemporary medicine which may contribute to needless medical injury is the trend toward physician specialization and sub-specialization and the corresponding move away from general and primary care practice. Specialization can mean that physicians will tend to think in terms of drugs, surgery and technological intervention which may not be the best thing for the patient.

The final irony is the complaint by doctors that the fear of malpractice suits causes them to practice "defensive" medicine, that is, to order all relevant tests so that they will not later be accused of negligence. The practice of defensive medicine raises the risk that patients will be injured by unnecessary procedures, creating a vicious cycle in which malpractice is generated by its supposed remedy.

* * *

Changing some of the troublesome features of the system by enacting a national health program would have an impact on the occurrence of malpractice and the ability of the malpractice victim to deal with medical and rehabilitative costs. Moving to a system in which doctors are salaried or in which most people received care through pre-paid group practice should have a major impact in reducing the over-intervention associated with fee-for-service practice.

Some Consumer Objectives

While the political struggle for a comprehensive national health program (either national health insurance or national health service) has yet to be successfully waged, there are many intermediate objectives for which consumers can fight, such as:

Public disclosure of information. The most important thing consumers can do in terms of preventing malpractice is to gain autonomy as guarantors of quality in the medical care system. A basic step in attaining this goal is getting access to information. Specifically, consumers must fight for disclosure of 1) hospital inspection reports; 2) tissue committee results; 3) comparative mortality rates, by procedure, by hospital and by physician; and 4) any relevant PSRO and JCAH data relating to quality of physician and institutional care.

Stricter monitoring of physicians.

All physicians should be required to participate in continuing education programs and to be re-tested periodically on current standards of practice, new preventive, diagnostic and treatment equipment and procedures, patient rights and physician responsibilities.

All physicians against whom more than one malpractice suit has been successfully brought should be subject to automatic review by the State medical licensing agency concerning their ability to continue practicing medicine.

Availability of Impartial Medical Testimony.

Because it is difficult for consumers to find a physician who will testify against other doctors in a malpractice case, consideration should be given to establishing, under governmental auspices, a panel of physicians to provide impartial medical testimony at malpractice hearings.

Reform of malpractice insurance methods, including

exploration of no-fault and publicly run insurance plans, with the intent of eliminating the profit motive from malpractice insurance.

tying malpractice premium rates to a physician's malpractice experience and will mean that competent medical practitioners are not penalized for the actions of the less competent, and that younger physicians are not rated at the same level as those with established practices.

Preservation and restoration of patient and consumer rights

No adjustments in the malpractice law should be tolerated which abridge the rights of consumers to seek redress in the courts when they have suffered medical injury due to negligence in the health system.

Development of Alternatives to Litigation

Binding arbitration should be open as an option to patients and professionals when mutually agreed upon. □

CORRECTION

The article, "The Myth of Excess Beds" (*Consumer Health Perspectives,* Vol. VI, No. 3, 1979) erroneously stated that Montefiore Hospital's Emergency Room was no longer in operation and that the hospital had eliminated its obstetrical service. In fact, Montefiore, in its nearly 100-year history, has never provided an obstetrics service. A plan which was afoot to close the Emergency Room was averted, and that service is still open.

BOOK REVIEW

Michael M. Gansl, M.P.H.

Assessing the Efficacy and Safety of Medical Technologies,
Congress of the United States,
Office of Technology Assessment
September, 1978

As medicine has become increasingly technological in the last several decades, the costs of medical care have escalated sharply—so much so that expenditures for medical care currently comprise nearly 9% of the Gross National Product (GNP). In 1960, health care costs represented slightly more than 5% of the GNP.

Because of the lack of a direct and explicit relationship between health care cost increases, expanded use of medical technologies and improved health status, numerous questions continue to be raised about the efficiency of our health care delivery system. As its title makes clear, the Office of Technology Assessment report examines only the issues of safety and efficacy, but does not address the question of health status outcomes. However, in the opinion of its authors, an understanding of the safety and efficacy of medical technology is one of the prime keys to understanding many other health care concerns.

Efficacy and risk have to do with immediate medical benefits and harms. The three key concepts are defined in the report's glossary of terms as follows:

- *Efficacy*—the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under *ideal conditions* of use.
- *Safety*—a judgment of the acceptability of *relative risk* in a specified situation.
- *Risk*—a measure of the probability of an adverse outcome occurring, and the severity of the resultant harm to the health of individuals in a defined population for a given medical problem under *specified conditions* of use.

Efficacy and safety are separate concepts that can be measured and discussed in terms of *probability* and *magnitude* of benefit or harm. More importantly, each can be evaluated only in terms of the other. A technology may provide benefits, but the value of those benefits depends on the risks involved in using the technology. For example, the controversy surrounding the use of mammography illustrates the interdependence of these two concepts. The benefits of reduced mortality due to using mammography for detection of breast cancer must be balanced against the risk of developing cancer from radiation emitted by the mammography device.

In a separate chapter which presents 17 short case histories illustrating the diverse nature of medical technologies, the evidence is all too clear that many technologies are *not* adequately assessed before widespread use. Computerized axial tomography (CT Scanning), electronic fetal monitoring and mammography are medical technologies which are used frequently despite the lack of information demonstrating their efficacy and safety. Additionally, many technologies (e.g., tonsillectomy and appendectomy, two of the most common surgical procedures in the United States) have been used extensively, and only later were shown to be of limited usefulness.

It is estimated that only 10 to 20 percent of all procedures currently used in medical practice have had their efficacy demonstrated by the method of controlled trials. Because of shortcomings in the current assessment systems, the examples of technologies that entered widespread use and were shown later to be unsafe or inefficacious, and the large numbers of inadequately assessed current and emerging technologies, the report points out that the process for generating information must be improved and that there is a critical need for enlarging the information base on the subject of efficacy and safety.

Because it is extremely difficult to obtain information about the probable benefits and risks of technologies when used under actual or average conditions, determining the efficacy and safety of a particular technology in *controlled settings* according to this report, must be the *starting point* in the effort to evaluate that technology's potential benefit and risk. Due to the large numbers of people who need and use efficacy and safety information, the development and dissemination of well-validated, timely and relevant information is especially crucial.

As indicated in the report, information obtained from assessments of the efficacy and safety of new and existing technologies can serve three important purposes:

- To ensure that those technologies which have been demonstrated to have potential benefits with acceptable risks are made available rapidly in the private and public sectors;
- To constrain the diffusion and use of technologies which are inefficacious or cause excessive harm;
- To guide the appropriate use of all technologies because they are rarely completely inefficacious or completely unsafe.

There are many techniques used to estimate efficacy and safety. Clinical experience, based on informal instruction techniques, has been the most important technique; although epidemiological studies, formal consensus development, and randomized controlled clinical trials are also frequently used. No technique is universally applicable and combinations of various techniques are used because every methodology has its own strengths and weaknesses.

Optimally, the processes of developing and disseminating safety and efficacy information should be *coherent, coordinated* and the clear responsibility of one or several private or public agencies or groups. There are four basic elements to this process:

Michael Gansl, M.P.H., is Assistant Administrator for Ambulatory Care at Beekman Downtown Hospital in New York City. He is a former senior health care program planner for New York City's Health and Hospitals Corporation.

- *identification* of technologies to be studied;
- *testing* through the use of various techniques to generate information on efficacy and safety;
- *synthesis* of the findings of testing and any other relevant information;
- *dissemination* of the synthesized information to appropriate parties, including decision makers.

In terms of policy, the O.T.A. report recommends that government either expand its own assessment activities or "stimulate" the private sector to undertake them. In the case of the private sector's developing assessment information, government would retain a monitoring function.

In all, the O.T.A. report contains chapters on: (1) the concepts of efficacy and safety, their characteristics and working definitions; (2) a short history of interest in the assessment of efficacy and safety including 17 brief case studies of medical technologies designed to illustrate various aspects of efficiency, safety and their assessment. Policy issues raised by the use of certain technologies are particularly highlighted; (3) the analytical techniques used to assess efficacy and safety; (4) those Federal and private sector agencies and programs that engage in assessment activities; (5) the various aspects and implications of the current assessment systems and programs; and (6) the range of policy alternatives intended to correct some of the shortcomings in the assessment process presented in the report.

Finally, it should be said that although the report discusses the various possibilities for assessing the efficacy and safety of medical technologies systematically and thoroughly, its scope is limited, since only technologies pertinent to traditional biomedical research are explored. The problems of assessing technologies used in psychosocial medicines (e.g., psychiatry, counseling, behavior modification) are not addressed. Nor are efficiency[1], effectiveness[2] or ethical issues pertaining to the various technologies discussed at any length.[3]

Despite this gap in the subject matter, the O.T.A. effort has resulted in a fine report. Bearing the stamp of officialdom, it should be an excellent resource and reference document for consumers. Its conclusions confirm the need for continued vigilance in high technology issues. □

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1. *Efficiency* has to do with productivity, economic efficiency and scale of operation. Often measured by output per man-hour or cost of unit per output.
2. *Effectiveness* (as opposed to efficacy) has to do with the degree to which diagnostic, preventive, therapeutic or any other action produces the intended result, or outcomes. Cost is not a consideration here, unless the action is being compared with another one with similar purposes.
3. An O.T.A. assessment of the impact on society of medical technologies was published in August 1976 entitled, "Development of Medical Technology: Opportunities for Assessment." The effects of public and private policies in the development, diffusion, use and reimbursement of CT scanners was published in August 1978 in "Policy Implications of the Computed Tomography (CT) Scanner."

Shelley B. Frost, Research Director and Associate Editor,
Ellen Goldensohn, Associate Editor

PUBLISHED BY CONSUMER COMMISSION ON
THE ACCREDITATION OF HEALTH SERVICES INC.
377 PARK AVE. SO., NEW YORK, N.Y. 10016
TELEPHONE: 689-8959