Follow-up on the Problem of Increased Incidence of Thyroid Carcinoma from the Effects of Childhood Irradiation

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There has been widespread concern in both the medical and lay community on how to deal with the problem of the increased incidence of thyroid cancer in patients irradiated in the head and neck during childhood, including the difficult question of whether all of these patients should be recalled and screened. Such an approach is not deemed logistically feasible and the desired benefits of the program which hinge on treatment through early detection are nullified by the protracted nature of the disease.

The iatrogenic nature of the problem has raised ethical questions concerning professional duty and responsibility. The principle of "similar treatment for similar cases" seems fairest and most justifiable in pursuit of the goal of equal access to health care.

The most effective plan appears to be a carefully devised public education campaign. Informing practicing physicians not already aware of the problem should be an important part of this effort. The responsibility for seeking treatment would be left to the patient who would see his personal physician or be recommended to a previously designated physician in his area.

From the early 1900s until the early to mid 1960s it was considered good medical practice to use irradiation therapy to treat patients with such benign disorders as enlargement of the thymus, hypertrophy of tonsils and adenoids, cervical adenitis, mastoiditis, sinusitis, hemangiomas, tinea capitis, and acne. Since the thyroid gland was situated in the same area, it frequently received direct or scatter radiation during these treatments. Although short-term effects appeared

to be excellent,¹ evidence has been accumulating since 1950 which suggests a relationship between head and neck irradiation during childhood and an increased incidence of thyroid carcinoma. This begins to appear quite significant when one realizes that it has been estimated that possibly over one million people in the United States received irradiation to the head and neck area during childhood for these benign disorders.²

A large number of good studies have been conducted in this population of irradiated patients and the incidence of thyroid carcinoma ranges from 3.5³ to 7⁴ to 9⁵ percent in three relatively large groups. This rate of occurrence, obviously much higher than one would expect to find in the general population, has been established as unassailable evidence that those people who received the ir-

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radiation therapy are at a significantly higher risk for developing the tumor. The latency period between the time of irradiation and the development of the cancer has been shown to be extremely variable, and may range from 20 to 30 years⁵ or be relatively short with the cancer predominating in the 20 years and below age group.⁶ It is probably longer than was originally expected, but the best estimate at present is that the latency period averages about 20 years as was found by DeGroot and Paloyan in one Chicago study.⁷ Refetoff et al, in their group of 100 patients, noted a mean interval of 24.3 years between the date of irradiation and diagnosis in the 15 patients on whom surgery was performed.⁴

There has been widespread concern in recent years from quarters in both the medical and lay community regarding this strong positive correlation between irradiation in the neck in childhood and the increased incidence of thyroid carcinoma. A number of efforts have been made in various parts of the country to deal with this problem, producing varying degrees of success. These efforts have come mainly through individual hospitals or through cooperation of hospitals with medical societies and public health personnel. Also, there has been a significant degree of media coverage alerting the public to the possible dangers involved.8 Since this is not a new problem and since its specific components have been well defined through numerous studies, no attempt will be made here to review the literature in this regard. Rather, there will be a consideration of some important factors in the process of attempting to formulate a workable solution to the problem and specifically to examine the feasibility of conducting a nationwide epidemiological investigation and recall program. Later, the focus will be on some of the more important ethical questions raised by this issue.

This paper is being written in response to Gifford's proposal in 1975 to form an organization for the purpose of finding and treating probable cases of thyroid dysfunctioning resulting from childhood irradiation. To carry out the objectives of the organization, it was suggested that a nationwide epidemiological study be conducted by a qualified public health consultant to determine who the people are in the United States who were irradiated and then to establish methodologies involved in seeking out, examining, and treating

those individuals who evidence thyroid abnormalities.9

Feasibility of National Epidemiological Approach

At this point, it is essential to briefly outline the specific functions involved in an epidemiological nationwide approach to this problem. First, the people who were irradiated in the neck area as children would have to be identified through documentation of their irradiation by searching old hospital records and records kept by individual physicians. Next, a scheme for tracking these people down would have to be devised and implemented. As this phase was being carried out, the epidemiological team would locate possible contact and detection centers on national, state, and regional levels. Before any patients were actually brought in, the physicians involved in the investigation would be called on to devise an acceptable framework of guidelines on the "state of the art" for the detection, diagnosis, treatment, follow-up, and post-operative radiation and drug administration procedures. This would also require inventory and documentation of the location and number of physicians and surgeons available to work in implementation programs as well as assistance to institutions and facilities that could be properly utilized in the treatment process. The last step involved in the project would be the examination and treatment of the patients recalled-including physical examination, laboratory tests, radioisotopic scans, surgery, and any other medical procedures deemed necessary.9 These functions represent the major objectives of the epidemiologist assigned to such a project, but do not actually give a complete list since a great amount of his time would be spent in basic organizational and administrative duties.

This problem has received a great deal of attention in the last few years. A number of local communities have initiated recall programs, and a statewide effort has been undertaken in Illinois. Various difficulties have been encountered which are worth noting. One of the most frustrating of these was that of finding the patients, as many have moved or changed their name through marriage, making mail and telephone contacts almost impossible. It becomes apparent that in order to locate a good percentage of this population, an extensive field epidemiological approach would

have to be employed wherein the worker in a particular area could, on location, research old city records or directories and talk with townspeople who might provide information. At this point one begins to realize how enormously complicated and time consuming such endeavors could become. Phillips notes that, as neighborhoods change, friends or acquaintances of former patients become harder to find, making the search more difficult with each passing year. There is an illustration of the degree of the patient-search problem in the experience of Rush Presbyterian, St. Luke's Medical Center, Chicago. Letters were sent to 640 of the 710 patients on record as having received the irradiation treatments and only 110 of these reached their destination.8 In a large Chicago study by Favus et al, only 20 percent of their atrisk population became available for evaluation.² Recall efforts were abandoned at Roper Hospital in Charleston, South Carolina, when their attempts to track down the people whose records indicated irradiation proved unsuccessful. But at Michael Reese Hospital, nearly half of the 5,000 patients irradiated between 1939 and 1958 were found and Ingalls Memorial Hospital, Harvey, Illinois, has had unusual success in locating former patients. Aside from some letters, much of the success was attributed to a luncheon held for long-time area residents where efforts were made to determine the whereabouts of other past patients. To date, 90 of the 150 former patients have been tracked down.8 Still, it is clear that a very large percentage of these patients cannot be expected to be retrieved.

In a massive callback program, the most immediate obstacle encountered by many hospitals is the location of medical records of persons who received the treatment 15 to 25 years ago. A number of hospital medical record storage areas have suffered water or fire damage, while it is apparent many hospitals simply cannot find records beyond a certain date.8 Many filing systems are not satisfactory and are not maintained in a suitable fashion to meet the present need. Compounding the problem of finding existing records is the fact that this procedure was performed commonly by private physicians who might likely not have kept complete records for such routine work1 and whose methods for filing old records certainly reveal inadequacies. This seems even more fettering when the fact that it is not known which physicians were

radiating patients is taken into account. Undoubtedly, many of these physicians are no longer in practice or have died.8 The complicated and difficult nature of the record search is only part of the larger problem of deciding exactly who received the treatments. In one study 33 percent of the treated group denied having had irradiation and 23 percent of the control group believed that they had had radiation therapy.² Tristan has concluded that the mobility of the American population, the uncertainty of whether the patient was ever exposed or not, the lack of adequate records, and above all, inability to accurately assess the amount of radiation received can make the cost of such a massive callback program astronomical.3 This lack of accurate dosimetry makes the job of identifying the at-risk patients much more difficult since only those who received moderate-range doses are susceptible.3,11

A big question remains concerning exactly what diagnostic and therapeutic measures should be taken once the patient is brought in for examination. There seems to be a significant amount of disagreement in the medical community regarding this problem. The first uncertainty involves the determination of the most effective means of detecting a lesion. All sources reviewed stressed meticulous palpation of the thyroid as the first step in evaluation. 1,2,10 But there are divergent opinions on whether to do thyroid radioisotopic scans on all patients, although most protocols for treatmentrecall programs recommend this. 2,3,10 Supporting this policy is the study by Favus et al where, in 1,056 subjects, palpable nodular thyroid disease was found in 16.6 percent and nonpalpable lesions were detected by thyroid imaging in an additional 10.7 percent.2 On the other hand, the majority of experts who participated in a workshop in September 1975 on the late effects of irradiation therapy to the head and neck concluded that a thyroid scan is not mandatory if palpation of the gland by an experienced examiner reveals no abnormalities.1 Also, there is a question on how to follow-up on an individual whose scan reveals a "cold" or nonfunctional area in a gland and has no palpable abnormality. Some experts feel that surgery is indicated at this point,2,10 while the majority of workshop participants would prefer to keep the patient under annual observation until or unless a nodule becomes palpable.1

Another controversial aspect of the treatment

part of the program is centered around whether to administer thyroid suppressive therapy to those patients who show no clinical abnormality. The rationale behind this type of therapy is twofold: to reduce the chance of the carcinoma becoming manifest and to make any existing nodule palpable when it was not so previously.1 The use of suppressive doses of thyroid hormone has gained support in animal studies in which thyroid neoplasms are experimentally induced with radiation. Also, Young et al, in a retrospective study of 576 patients with differentiated thyroid carcinoma, showed that surgery alone was associated with a 32 percent local recurrence whereas those who received thyroid hormone postoperatively had a recurrence rate of only 11 percent. Although thyroid suppression of clinically "normal" irradiated subjects has been advocated, its efficacy in preventing thyroid tumor formation many years after radiation exposure is unknown.2 There have not yet been any controlled clinical trials of thyroid suppression therapy in the population at risk. One of the major problems in this therapeutic measure is getting full patient cooperation in taking replacement thyroid medication when the patient is asymptomatic and when he may not feel as though he needs it. This can lead to poor compliance and inconsistent use of the drug, thus creating the likelihood of wide fluctuations in serum TSH levels which might increase the probability of nodule formation. This, in addition to the possibility of patient overuse of the medication with risks of patient-induced thyrotoxicosis, 10 makes the decision of whether to place a clinically normal and asymptomatic person on thyroid replacement therapy for the rest of his life a particularly difficult one.

Since the basic idea of the recall program is to bring the at-risk persons in to examine and possibly treat them, there is necessarily the hope that this process will significantly reduce the chance of those people suffering the morbidity and mortality associated with thyroid cancer. We must examine this relationship more closely since its verification would do much to enhance the argument that a massive recall program is efficacious. The central question seems to be whether early detection of this thyroid tumor is of great advantage in treating a patient with the disease.

Thyroid cancer has been shown to be a very low-grade malignancy tumor. There is no differ-

ence in the behavior clinically between cancer arising from a nonirradiated thyroid gland than from one which has been irradiated, according to Harkness et al, 10 although DeGroot and Paloyan found that the tumors from the irradiated patients were less invasive and never undifferentiated.7 Differentiated papillary and follicular neoplasms are the common types seen in the post-irradiation population, and they are characterized by slow growth, a propensity to metastasize relatively late, and the likelihood of surgical curability while still contained in the neck.1 Survival is usually measured in decades after diagnosis and even when distant metastases have developed, it can be measured in years. Most physicians regard differentiated thyroid cancer as essentially a "benign" process. This indolent biological behavior also explains the discrepancy between the number of surgically diagnosed differentiated thyroid cancers and the low incidence of death from the disease. All thyroid cancer results in only approximately 0.1 percent of cancer deaths. 11

To demonstrate more clearly the relatively benign course of this cancer, consider the study of 140 occult papillary carcinomas treated surgically at the Mayo Clinic over a 30-year period. Fiftyeight were associated with nodal metastases and 82 were found incidental to thyroid operations for other conditions. Of the 58 patients with nodal metastases, four have died from causes unrelated to thyroid carcinoma and one patient has been untraced. The remainder of them are alive, without evidence of carcinoma, 3 to 32 years after operation. Of the 82 patients without metastases, 11 have died of known causes other than carcinoma. The remainder are living after periods ranging up to 30 years, and in none is either local or distant metastases known to have developed. 12 In a study of 47 patients with a definite prior history of irradiation, Paloyon and Harper found zero mortality, serving to illustrate the typically protracted course of the disease and relatively good prognosis, in spite of the high incidence of lymphogenous metastases.6 Winship and Rosvoll found that 13 percent died during the first ten years after the disease was discovered in a total group of 562 cases of childhood thyroid carcinoma in which 35 percent were treated with surgery alone and the remainder treated with surgery and x-ray or biopsy and x-ray. 13 Considering a 25 percent fiveyear survival rate when distant metastases are present,² a more realistic estimate of the survival rate is probably 90 percent. It should be noted that ten-year statistics are required to ascertain a meaningful survival rate, and Harper and Paloyon state that 20-year statistics are actually needed.⁶

Since this cancer has such a protracted course, it is doubtful whether discovering the tumor somewhat earlier would modify significantly in a sizable number of patients the clinical course of the disease. Interestingly, the evidence suggests that patients under age 40 years with encapsulated lesions that are less than 1.5 cm in diameter have a prognosis no different from that for unaffected persons.14 At some point one might expect the patient to discover a nodule himself while rubbing the neck, applying make-up, or by having a friend notice it, and these are the most frequent modes of discovery.11 Even in those patients in whom neck metastases have developed, it is clear there is still an excellent prognosis,2 and it would seem unlikely that many would remain unaware of their condition for such long periods that distant metastases might develop. The characteristics of the behavior of the tumor, the small population involved, the likelihood of the majority of people discovering a nodule themselves and seeing a physician, and the observation that the early detection and treatment of such tumors seems to offer little advantage in any sizable number of patients, all weaken the argument for instituting a nationwide recall program.

Another possible problem area, inherent in the proposal to conduct an epidemiological investigation and recall program involves the uncertainty of the actual number of people still at risk. The practice of irradiating children and adolescents in the neck area for benign disorders began to decline quite sharply in the late 1950s as an accepted therapeutic endeavor when incriminating data began to accumulate. This practice had virtually completely ceased by around 1960, meaning it has been approximately 18 years since the last irradiation. If one then considers that the average latency period for appearance of the tumor is around 20 years, it is apparent that the great majority of patients irradiated in the 50 years prior to 1960 have either already developed the neoplasm or have passed the stage beyond which there is little or no risk. Since the longest observed latency period in a very small number of patients is between 35 to 40 years, 15 it seems logical to assume

that no one irradiated before 1940 is still at any significant risk. Of those irradiated after 1940, perhaps as many as 500,000 patients, easily one half of those patients either have already been affected by the disease so that the hoped for benefits of prophylaxis and early detection would not be realized, or comprise that group of patients who could have developed the cancer in the first 20 to 25 years post-irradiation but did not. This would conceivably put the population of those who may still be harboring the latent carcinoma at around 250,000.

Using this figure and then sequentially eliminating certain segments of this population due to logistical restrictions in the location process or epidemiological and biological characteristics of the tumor, one can obtain an idea of the number of previously irradiated people who will eventually succumb to the disease. Although some of the following percentage deductions seem arbitrary and cannot be substantiated, they were the product of the most accurate estimates of staff epidemiologists and physicians, and an attempt was made to give the maximum number of people who could be benefited.

1. The maximum estimate of percentage of irradiated patients whose records could be recovered is 60%.

60% of 250,000 results in 150,000 possible patients.

2. The maximum estimate of percentage of irradiated patients who could be found and would consent to come in for examination is 70%.

70% of 150,000 results in 105,000 possible patients.

3. The incidence of thyroid cancer arising from the population of irradiated patients is estimated at 7%.

7% of 105,000 results in 7,350 possible patients.

4. Taking into account the 90 percent ten-year survival rate for this cancer, the mortality in this group is estimated at 10%. (A percentage may additionally be deducted for those people who would not have been aided by early detection or who would not have responded to any preventive measures.)

10% of 7,350 results in 735 patients.

One may consider, then, this bottom figure to be a group of people who will die from thyroid cancer, but who might be saved by preventive efforts or surgery before the cancer becomes inoperable if the recall and treatment program were implemented. The purpose of the calculation was to demonstrate the relatively small number of patients who might expect to directly benefit from such a program.

In attempting to formulate a cost to benefit ratio, a budget analysis for the epidemiological investigation, recall, and treatment program was worked out for the state of South Carolina. This analysis was based on the assumption that the population at risk is evenly distributed in the United States. The first phase of the program was concerned with the acquisition of old records by field epidemiologists and, in addition to salaries, would include such expenses as travel, telephone, postage costs, computer costs, and consultation services. The second phase analyzed the expenses of examination and treatment including physical examination, thyroid scan, laboratory tests, and, as recommended by DeGroot and Paloyon, surgery in that percentage expected to display thyroid abnormalities. An approximation of this percentage is well demonstrated in the study by Quansing et al, in which they found that 18.2 percent of their 500 patients with prior radiation had thyroid abnormalities including solitary nodules, diffuse enlargement, multinodular goiters, and previous surgery. 16 Another report places the incidence of thyroid abnormality at 23 percent with one third of those having a malignant neoplasm at surgery.14 The final phase would be concerned with followup of treatment and preparation for a final report. Each phase of the program was allowed three years to be completed and the total time frame for completion of the project was six years.

The total cost of the project was calculated to be approximately \$3.5 million. The largest expenses appeared in the treatment phase of the program. Assuming only 30 percent of the patients were located and only 15 percent of this population had surgery, the treatment cost for surgery and other tests was almost \$2 million. The remainder of the budget was comprised of operational and personnel costs in the first and final phases of the program.

Phenomenal costs have been incurred by previous institutions attempting to recall and treat patients. An outstanding example is Michael Reese Hospital where they found nearly one half of 5,000 irradiated patients at a cost of nearly

\$700,000 spent so far on recall, screening, and follow-up procedures. It must also be understood that at their disposal was a ready-made, 20-year-old card file containing the records of the irradiated persons, thus bypassing the time and talent needed to review past records.8

The cost of a nationwide effort becomes overwhelming considering the project expenses for a small, moderately populated state such as South Carolina. The cost to benefit ratio works out to be well in excess of \$5,000 a patient. By any contemporary public health or community medicine standard, the implementation of such a program would represent a gross misuse and waste of valuable funds. Although the immediate reaction of many is to impugn this idea of attaching a monetary value to the preservation of human life, it must be pointed out that, given the fact that there are limited resources allocated to public health care, it is a fundamental objective of this sector of the medical community to implement those programs which can do the most to reduce morbidity and mortality in the general population. Therefore, a mathematical appraisal of the efficacy of a certain proposal is necessary in order that some other program with perhaps a far greater capacity to relieve suffering or save lives is not preempted.

Some Ethical Considerations

In considering some important standard conceptions of social justice as they apply to the goal of equal access to health care, Outka cites that the practical bearing of "similar treatment for similar cases" is especially relevant when the goal of equal access on some occasions collides with the realities of finite medical resources and needs which prove to be insatiable. He states that the formula's allowance of no positive treatment whatever may justify exclusion of entire classes of cases from a priority list and yet it forbids doing so for irrelevant or arbitrary reasons. In accepting the case for equal access and realizing that the medical profession simply cannot, physically cannot, treat all who are in need, it seems more just to discriminate by categories of illness rather than between the rich ill and the poor ill, for example. A case is given of a rare noncommunicable disease which could not receive priority where the costs were inordinate, the prospects for rehabilitation remote, and for the sake of equalized benefits to many

more. The most relevant aspect of this problem remains the illness itself so that "the goal of equal access then retains its prima facie authoritativeness. It is imperfectly realized rather than disregarded."¹⁷

It is puzzling that a widespread recall program with its tremendous cost, demonstrable operational difficulties, and questionable therapeutic value has garnered such strong support. It is likely that a unique feature of this problem, the fact that the disease was iatrogenically induced, is responsible for much of the backing prospective recall programs have been able to capture. Important questions have been raised by this issue regarding professional duty and responsibility of the medical community in situtations where the health of former patients has been jeopardized by previous medical therapy. The case is made less clear by the fact that nothing was done that could be considered negligent and that no real legal liability exists for having performed a medical procedure that reflected the "state of the art." If any of these aforementioned conditions did not exist, certainly there would be no doubt that these former patients would be required to be tracked down and screened. The central question then seems to be whether the medical community is obliged to assume a "special responsibility" to track down, screen, and treat these patients. The term "special responsibility" here connotes the moral duty of trying to undo the damage of a therapeutic miscalculation in iatrogenic form by instituting a widespread recall program in view of its obviously unacceptable cost to benefit ratio and other associated problems.

It is interesting to speculate on the psychological position of those in medicine or those outside deeply concerned with health care who would strongly urge that a public health team undertake this project. Their desires seem to reflect an attitude of controlling omnipotence, the embodiment of a profession which cannot allow for the humanness of mistakes, and if mistakes do occur, require somehow that they be expunged. In a sense, the primary motivations for supporting it might be likened to the alleviation of a sort of collective guilt or an attempt to expiate oneself. In assuming some of the characteristics of a classical obsessive-compulsive act of undoing, it begins to appear that instituting this massive search and recall program might be in a sense partly a response

to certain internal conflicts and insecurities. When viewed in this perspective, it appears there may be a failure to recognize what practices are fairest and assure justice in pursuit of the goal of equal access, as it applies to the mass allocation of funds for health care.

Another aspect of this issue which warrants consideration relates to the constantly expanding domain of the medical profession into the lives of people and encroachment on the boundaries of personal responsibility in maintaining their own state of health, a phenomenon Illich has called "medical nemesis." He believes medicine has become so highly technological in its efforts to kill pain, eliminate sickness, and struggle against death that it has created a new king of un-health by expropriating the potential of people to deal with these aspects of the human condition in an autonomous way. It has in a sense denied the need for man's acceptance of these evils. 18 The application to the present problem is immediately apparent. The question arises of whether it is ethically sound to contact these former patients, over 90 percent of whom will be healthy from the standpoint of the organ-system to be checked, inform them that they may not be healthy, and administer to them sophisticated medical tests and possibly chemotherapy. There can be no doubt that subjecting the individual to such medical procedures can create a different kind of iatrogenic disorder from the original one, that of a stress reaction to this invasion with all its potential hazards for inducing illness. Illich asserts that since health is essentially a process of personal adaptation and coping with pain, sickness, and death, the society which can reduce professional intervention to the minimum will provide the best conditions for health.18

Lastly, if one rejects the proposal to conduct a nationwide search for the formerly irradiated patients, other methods which will offer a more reasonable and justifiable approach to this problem must be considered. In a joint statement in 1975, the American Hospital Association and the American Medical Association urged hospitals and physicians "to work together in their communities and regions to develop guidelines and procedures for screening persons who may have received this treatment, and to determine the best way to educate the public about seeking treatment."

In view of the inherent difficulties in recalling

and screening these patients, perhaps more concentrated effort could be given to education. This feeling was put forth by the National Cancer Institute after concluding it would be logistically impossible to recall all patients. Their recommendation was primarily to inform and advise practicing physicians not already aware of the problem through state and national medical organizations, state and local health departments, and the American Cancer Society and the National Cancer Institute. Following this step, a well-planned, lowkeyed program would be launched to educate the public about the problem, stressing the need for medical examination, the low incidence of cancer, and the high probability of cure. The agencies mentioned above would be assigned this task along with the patient's own physicians. This approach could be augmented by public service announcements on national television or radio concerning the problem. Advertisements alerting physicians and/or lay people to the problem could be placed in journals, newspapers, and magazines. The most effective means of reaching former patients who would be candidates for screening has been the media, according to the report by Phillips. Following the initial announcement of Milwaukee County's areawide screening operation, the medical complex there received 700 to 800 calls regarding either information or thyroid scanning,8 and the screening of 1,700 patients out of an estimated 5,000 at-risk patients in that area was attributed to a public awareness campaign. 16 One must assume that more concentrated endeavors to inform the public in other areas of the country would produce favorable results.

It has been urged that hospitals which have available records initiate recall and screening programs themselves. 19 However, it is obvious that it would be cost prohibitive for most hospitals to undertake this,8 and it would seem a poor decision to install these operations at the expense of other services or hospital programs. However, informational and educational efforts on the part of hospitals which are not so costly might be considered. After a patient has been informed, the responsibility would be his to contact his personal physician or a previously designated physician in his area.

A central agency could be maintained in each state primarily for registering patients but also to counsel and advise patients and be responsible for follow-up. According to this general plan, it is not the intention to find every patient at risk, but as many as are within justifiable means.

This issue is a complicated one and one that has to be thoroughly dissected before a disposition can be rendered with confidence in its validity. It has been particularly difficult to sort out because of the ethical, social, and moral implications of the problem, and it has become manifested at a time when there is much heightened sensitivity to such issues as professional reliability and conduct.8 A highly disciplined, rational approach is needed with a keen awareness of the complexities involved and of the specific medical objectives as they become the expression of ethically sound and humane therapeutics.

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