

(shortly after  
5-27-66)

## STATEMENT IN RESPONSE OF DR. PAGE'S EDITORIAL

The spirit of science is intrinsically one of skepticism in the pursuit of truth. The self-appointed scientific critic, however, fashionable though he may be today, above all others perhaps, must guard against the delusion of objectivity since, in fact, his idiocratic attitudes, prejudices, and incomplete knowledge produce misconceptions and obliquities of judgment. The assumption by Irvine Page of the "conscience of medicine" in his editorial in a forthcoming issue of Modern Medicine is indeed an overwhelming undertaking, to say the least, rightfully imposing some embarrassment even on the most perspicacious, tutored aspirant to the post or on the sagest of Solomons. In the case in question, this assumption requires unusual wisdom, a clear, broad knowledge and a sound, sober evaluation of not only the scientific issues to which he takes exception but the social, ethical, moral, political, economic, national, international, and other implications. The substance and tone of the editorial do not reflect these qualifications in the author. Skepticism regarding the artificial heart program is understandable--the idea is beyond the imagination of some--and has accompanied every other completely new scientific concept. Some find it more difficult than others to assimilate dynamic phenomena and more fearful than others of the new and the unknown. As long as skeptics remain rational, open-minded, dispassionate, and impartial, they serve a useful purpose. When their views become distorted by personal myopia, intolerance for new ideas, or prejudices, they only impede and obstruct the search for further knowledge. Criticism of scientific work is valueless, indeed is treacherous, unless based on detached analysis rather than private opinion of those who make fault-finding a profession.

Reiteration of well known problems related to the development of artificial organs and to public dissemination of information about the progress of medical science has become wearisome to most of us. Certainly the time devoted to such effort could be more profitably spent in more constructive endeavors. The problems have all been spelled out repeatedly by the investigators themselves, whose intensive studies have led to the recognition that solutions are neither easy nor general, but rather must be approached on an individual basis. Discursive, emotional editorials marked by caviling contribute nothing to these solutions. Despite Page's promise of objectivity and accusations of emotion-laden coverage by science writers, language designed to appeal to the emotions rather than the reason of his audience pervades his editorial. Note how many of the following words used by him characterize political campaign speeches and slanted writings: startled, fascinated, bewildered, nonsense, modest advances, outraged, irresponsible, irritating, appalling, perilously, retribution, catastrophe, Roman circus, frenetic, emotion-laden atmosphere, emotion-laden interview, emotion-laden announcements, "overheating", melodramatic, shabby excuse. The effect on the medical profession of the following incendiary, explosive terms and expressions is too well known to deserve comment: Krebiozen, experiment concerned with a man's life, inviolable doctor-patient relationship, serious problem to all of us in medicine and science, blow by blow exhibition, celebrity-building, sensation-seeking public.

Page's lip homage to avoidance of the "problem of personalities, of claims for priority, or even of vying for publicity" is a well known rhetorical device to camouflage his attempt to ignore the "flaring of tempers over priority

and propriety" over these matters. His statement is belied by his repeated use of specific names rather than impersonal discussion of the matter at issue, his covert references to priorities, and his apparent rancor over recognition of achievements. His use of the exclamation point at this point in his editorial makes his intent unmistakable. On the one hand, he speaks of the "inviolable doctor-patient relationship" while on the other he considers a patient's faith in Dr. De Bakey's ability to help him a "serious problem." Is it so reprehensible for a patient to have faith in his surgeon?

Neither the medical profession nor the public had cause to be startled or bewildered by the recent left ventricular bypass operation on Mr. DeRudder, since cardiovascular scientists for some time have been preparing the public for the development of an artificial heart within the reasonably near future and since numerous scientific reports of experimental models have been presented at scientific meetings and published in scientific periodicals for the past several years. Page appears deliberately to have falsified the medical facts in the case of Mr. DeRudder. He prejudiciously omitted vital points from his inaccurate, garbled account of the operative and postoperative events and related his misinterpretation in a sequence designed to persuade the reader that the patient's death was due to the use of the artificial pump. He insisted on using the erroneous term "booster pump," for example, despite being informed personally that it was a left ventricular bypass pump capable of assuming the entire pumping function of the left ventricle. In Mr. DeRudder's case, the pump assumed as much as 80% of the left ventricular output. The term "artificial heart" for the left ventricular bypass pump therefore parallels the term "heart-lung machine" for that now-popular apparatus.

Page conveniently failed to mention the critical preoperative status of the patient and high risk of death without operation or use of the bypass. As every physician knows, the surgeon must make instantaneous decisions at the operating table when unexpected crises occur; it is therefore difficult to understand how Page, on the basis of what is vaguely "said to be," can casually label Mr. DeRudder's progressive left ventricular failure after valvular replacement as a "short-lived phenomenon" when he did not witness the operation. Perhaps he should be more discriminating in selecting his sources of information. He finds it further convenient to his specious argument to omit the fact that Mr. DeRudder had a long history of embolizations before the operation and that a large amount of thrombus which was the source of embolization was removed at operation. The patient's unconsciousness was due to an embolus in the left middle cerebral artery and was unrelated to use of the bypass pump.

It is disconcerting indeed to find that a late-twentieth-century physician seems surprised that a patient should die suddenly five days after operation "despite encouraging reports." The official hospital bulletins were completely factual, and anyone who has had any experience with surgical patients knows that death may occur suddenly from causes beyond the surgeon's control. Mr. DeRudder, in fact, died from causes unrelated to use of the pump and would have died from these same causes had the pump not been used. Notwithstanding Page's deceptive manipulation of the facts, the left ventricular bypass pump functioned perfectly for five days in providing normal circulation without producing trauma to the blood or thrombosis. This accomplishment had never before been realized in man. The Journal of the American Medical Association news section headline that the clinical use of the bypass "may help point

the way" to the ultimate development of a complete artificial heart is perfectly reasonable, since the bypass demonstrated conclusively that the pumping function of the heart can be replaced by a mechanical device for a prolonged period.

As a self-appointed critic, Page is obligated to prove the data inadequate, not merely label them so. On the one hand, he terms the operation on Mr. DeRudder "highly experimental" and on the other admits his knowledge of its previous successful use in calves. As every surgeon knows, every new operation is experimental, but all previous experimental evidence justifying clinical application is of the utmost relevance. Such experimental evidence has been published in numerous national scientific journals and even if Page had neglected to search for these published reports, he cannot deny his knowledge of the experiments, since he attended a recent medical meeting in Washington, at which these data were presented in detail, supported by a movie of the procedure. Had Page troubled himself to read published reports of animal experiments, "carefully documented to substantiate that mechanical devices are ready for human experiments," he would not have suggested that this has not been done in the case of the left ventricular bypass pump. His mere opinion that the data are inadequate is worthless. Seven years of research, reported in national periodicals, cannot be ignored as a basis for clinical application of an apparatus. The physician-scientist is best equipped to decide when his experimental work is ready for application to clinical problems which have no other known solution--nor can ever have without such application. Without such a decision every new operation will remain forever clinically unproved. Page's persistent reference

to the operation as an experiment overlooks completely the obligation of researchers to obtain as much clinical information and data as possible, rather than to rely exclusively on theoretic application of animal data to clinical circumstances.

Page seems to underestimate the intelligence and educational level of the American public of 1966. His assertion that they were misled "into believing that an artificial heart had been inserted into the chest" is unfounded, since the public was given the facts precisely as they occurred, complete with diagrams and close-up photographs of the bypass pump resting on the outside of the chest of the patient. The mechanism of the pump was described in lay terms on television and radio and in most national magazines that carried the story. The science writers thus fulfilled their responsibility of factual, reputable reporting and cannot be held accountable for surmises or false impressions gained by those who failed to inform themselves of published facts. In characteristic contradictory fashion, Page is dissatisfied with the detailed coverage of the operation by the press on the one hand, while on the other he berates the science writers for misleading the public.

The charge of irresponsibility of science writers has been grossly exaggerated by Page. The same charge is made whenever people allow their emotions to rule their reason: during political campaigns, wars, and industrial and sociologic revolutions. Almost without exception, when a major step forward has been made in modern medical science, the harbingers of doom, designating themselves as custodians of professional ethics, feel compelled to sound the siren against "undue and unethical publicity." This

eventuation is invariably predictable. In whatever walk of life, a small segment is bound to fall short of the ethical ideal, but for the most part national news media have shown a clear sense of responsibility and constraint in reporting medical news. When they have erred, the fault has usually been assignable not to their lack of integrity, or that of the investigator, but rather to the linguistic and philosophic problems intrinsic in communication of highly complex scientific and technologic information to the laity. The "hoopla" to which Page refers is part of twentieth-century reporting, and I doubt that his loud shoutings, multiplied even a thousandfold, will silence it. It accompanies unusual news of both serious and humorous varieties, whether it is the space program, runaway boys who survived ten days in a sealed boxcar, or importation of birds from South America by a city in the United States to combat the insect problem.

At no time was the "potential promise of the future . . . subtly distorted." Is Page suggesting that the editorial writers of the New York Times or Medical Tribune, or that Page himself for that matter, is in a better position to judge future achievements in development of an artificial heart than the researchers themselves? Interestingly, Page shifts from approbation of science writers to their condemnation, depending on whether or not their opinions agree with his. If he accepts his own premise that "research of a serious kind does not lend itself to crystal balls," then how does he justify the judgment that the "confident prediction of complete and satisfactory replacement of the heart in 3 years is nonsense" by one who is not even engaged in the research and therefore not intimately informed of its progress? It goes without saying, of course, that all knowledge is incomplete and that conclusions are always tentative and subject to change by new thought.

The public was not expected to be, nor does it consider itself, I am sure, qualified to be "judge and jury of the results" of the clinical application of the bypass pump. But let us not overlook our twentieth-century American public's right to know how the millions of dollars of its tax money has been used, particularly if we expect it to continue to support medical research and education. And we obviously can no longer get along without such public support. The improved health standards today are largely attributable to the education of the public regarding health and medical care available. This is an enlightened society we live in, not an ignorant, superstitious one. It demands and deserves information regarding the latest scientific and medical developments. The modern medical scientist can no longer play the ostrich by the self-delusion that medicine is still cloaked in the deepest mystery, a throwback to the ancient days when illness and its treatment were associated with demons and magic. The hackneyed prediction that general publication of medical advances raises false hopes in the minds of the people is indeed anachronistic. There is, moreover, no reason to suppose that public knowledge of an event will inhibit or destroy critical scientific discussion. Solicitation of criticism in an emotionally-charged editorial, however, may indeed suppress objectivity. Perhaps Page, in health, considers the price of promoting the artificial heart program too high, but how many persons would agree with him if it were their lives or the lives of their dear ones that that had the slightest chance of restoration to health by use of a mechanical pump?

Page can be reassured that the Committee of Advisors for the artificial heart program of the Department of Health, Education, and Welfare was indeed informed of the Baylor-Rice experiments demonstrating successful

use of the pump and of the plan to apply it clinically. The Committee raised no objection to this plan and, in fact, generally supported the entire direction of the program. Page's oft-repeated exhortations to national scientific and medical organizations, to the scientific community, and to the medical profession in general to join his scurrilous attack seems designed to arouse emotion and create friction within the profession, not to invite sober analysis of facts. He also seems bent on instilling such trepidation in experimenters that they dare not enter the laboratory without obtaining medical, legal, social, governmental, and all other imaginable clearance for each step of their experimental work. No one engaged in research would suggest that it be conducted under Klieg lights, but research can hardly flourish in an unhealthy atmosphere of restriction and rigidity. The movie of the left ventricular bypass operation was made primarily for purposes of teaching and analysis, and Page knows that this is a common practice in teaching institutions even for well established operations.

The charge of "incredible violation of the right of the patient" cannot be supported in fact. The rights of the patient are, of course, primary. In the case of Mr. DeRudder, all these rights were observed (according to both the USPHS regulations and the Nuremburg Code). He was candidly informed of the gravity of his illness, of the methods of treatment available, of the status of the development of the left ventricular bypass pump, and of the risks involved in the operation. Mr. DeRudder's consent was enthusiastic, not tentative in the least, and both the patient and his wife were thoroughly cooperative. Only if and when a patient so chooses should his privacy be

invaded. He does, however, have the privilege of removing barriers to public view of his medical treatment if he wishes.

The allusion to Krebiozen is not only incongruous, but seemingly rancorous, totally inept, and in exceedingly poor taste, since no possible analogy can be drawn between this event and the recent clinical application of the left ventricular bypass pump. In the Krebiozen case, secrecy shrouded the nature of the drug, and no experimental data were reported. In the left ventricular bypass program, periodic reports of experimental studies have appeared in scientific journals, and nothing about the procedure has been concealed.

It is unfortunate that a patient's death from causes unrelated to the use of the bypass pump has been exploited as a springboard for an unwarranted attack on "the artificial heart program." One cannot help wondering if such critics would have been as vociferous, or indeed have uttered even a whisper, had uncontrollable phenomena not caused him to die. Would they then have condemned the operation as "too experimental"? But Page's editorial can yet be salvaged for some useful purpose if the controversy he has attempted to incite is replaced by a sober search for the fact, which will inevitably lead to recognition of the strong sense of scientific, social, and ethical responsibilities that resides in the investigators in the artificial heart program. With this knowledge and reassurance communicated, the investigators can proceed more efficiently and productively toward the solution of the complex and serious health problem they have chosen to attack.