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THE DEVIL'S BEING GOD'S BEST INSPIRATION:

THE BOUNDARY BETWEEN RESEARCH AND CARE

The patient as Job, the researcher as Faust; such are the roles in the relation of despair in which physician and patient are tempted to use one another. So runs the logic of Jan van Eys, who claims that, since "research has a different intent from therapy," there is no such thing as "therapeutic research." Research and therapy, or "care" in Ramsey's terminology, have different objectives, different goals, van Eys maintains. Van Eys makes these distinctions in the name of fighting against excesses committed by researchers. "Doctors are culpable," van Eys charges, "when they hold out hopes of cures for any diseases when all they can offer are experiments."

In his response (pp. 208-212) Ramsey confesses that he is not convinced by van Eys' rejection of "therapeutic research." Just because the *intention* of the researcher and the therapist are different does not logically require that these are fundamentally incompatible goals, Ramsey asserts. Neither does this distinction mean that these two goals cannot reside in a single moral agent. While we may have practical reasons for separating these two aims they are not mutually exclusive. Ramsey has great admiration for the boundary-keeping that van Eys suggests. But, he asks, "can I never with modest hope *intend* and (with my physician-researcher) *aim* at both my own (remotely possible) *cure* and *the cure*?" If there is even "a centimeter of *overly*," Ramsey claims, we cannot dispense with "therapeutic research."

This argument aside, Ramsey greatly admires the overriding ethical thrust that emerges from van Eys' critique, regarding the *quality* of research. Contrary to what Ramsey may have implied in the past, he asserts, this is an *ethical* question (albeit one that can best be known by the physician-researcher). Hence Ramsey (p. 212) is comfortable in stating that "the quality of the research is *that part of medical ethics* that is the responsibility of the research community itself, and morally sensitive physicians...to discharge." Van Eys' participant perspective makes all the more effective his prophetic "crying destruction upon complacency over cruelties masquerading as triumphs in high places and white coats." Ramsey concludes that van Eys has crafted an appropriate *ethics of care* for the quality of research, notably in "his additional requirement that 'the research must be good and beneficial now' if done within the setting of clinical care."

Es irrt der Mensch, so lang' er strebt

In spite of all the progress in modern medicine, much disease is still incurable, and much suffering from relentless chronic deterioration is still unavoidable. It is a time-honored tradition in the healing arts for the physician to draw upon past experience and new knowledge, to try the untried in an attempt to help.

Modern medicine has generated so much molecular biological knowledge and so much technology that no individual physician can master it all. Nor can an individual physician alone evaluate the appropriateness of these tools for a given intervention. Research structures have been devised to evaluate the new ideas and to generate priorities in therapies among available options. Much has been gained through this development; unfortunately, much has also been lost. The system of research has become a mode of care in the mind of physicians who are faced with diseases for which they have no cure or with patients for whom they have no further accepted therapy.

The intermingling of research and care has been accepted as beneficial by a health care delivery system that wants untreatable patients treated, and by a society that wants incurable diseases cured and prevented. Patients are in a captive situation wherein they must see the research structure as it is seen by the health care delivery system and by society. To make patient participation in research and research directed care seem appropriate, the system of informed consent was devised with content and structure to be approved by Institutional Review Boards (IRBs).

We talk about informed consent in medical care as a necessary component of honest dealing with the patient. Usually the interpretation focuses on the concept "informed." This term is used to mean that knowledge--information--is freely and fully transmitted. However, the accent should be on the consent. What a patient does with the information is the business of the patient. Why one refuses to have surgery or participate in a clinical trial is not the business of the person obtaining the informed consent, although it is natural to be curious about it.

It is extremely rare that the knowledge content of the information *per se* sways the consent. After all, the protocol was arrived at with considerable thought by the originators, careful scrutiny by review bodies, and an approval process by authorities charged with oversight. The conduct of care and research is monitored on an ongoing basis, and the experience is used to adapt, modify or abort the care or clinical trial that is being considered. It is almost preposterous that a patient would make a decision for or against the proffered intervention based on facts.

What makes the patient decide are gut reactions, emotional projections, fear and hope, need to display trust, or anxiety about abandonment by loved ones. Decisions are highly personal, and ought to be that way. It remains therefore the burden of the physician as a healer and not the doctor as a researcher to interpret the questions about research as an avenue to care.

Often it seems that patients are coerced in the zeal to solve the problem presented by the disease. They seem to become unwilling participants in the drama of modern medicine. However, it is indeed the physician as healer who, as often as not, tries to adapt research to his calling rather than that the patient is caught in the snares of research hailed with promises of cure and care.

It is the purpose of this paper to point out that physician and patient relive the same human drama, in the two versions in which it is recorded: the patient as Job and the physician as Faust. There is a felt kinship between physician and patient, both of whom strive for control, for justice, and above all, for understanding. Both

will do almost anything to achieve that understanding until they both learn to say: "Behold, the fear of the Lord, that is wisdom; and to depart from evil is understanding" (Job 28:28).¹ The problem of the boundary between research and care is one of *relationship* between fellow humans who do not know the boundary of being human.

I. THE CONCEPT OF THERAPEUTIC RESEARCH

Before we can sketch out an understanding of the kinship between the hopeless patient and impotent physician researcher, we need to examine two major and related problems--the concept of therapeutic research and the popular misinterpretation of recent research results as immediate hope. My examples will come from oncology, but other medical specialties could have served equally well.

Some years ago, Emil Freireich (1974, pp. 110-114) spoke for the majority of research physicians in oncology when he defended the concept that experimental therapy is the best therapy. He meant to convey the basic rationale for the concept of therapeutic research: when there is no known standard cure for a disease, the patient optimizes his or her chances by enrolling in a research protocol. After all, the research is based on the best ideas and rational extrapolations of current knowledge. It is likely to be a better approach than what is currently known. Freireich clearly conveys his intent with his clinical experimentation: he wants to benefit the patients *now*, even while he wants to solve the problem of cancer for those patients yet to come.

The concept of therapeutic research--defined in distinction from nontherapeutic research--had vigorous public debate in the time before the reports of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the National Commission). Many felt such distinctions "meaningless" and "spurious" (Levine 1977, pp. 368-383) while others felt the distinction keenly. Paul Ramsey was one of the latter group. However, Ramsey's argument (1978, pp. 67-68) was not an endorsement of therapeutic research but an argument against nontherapeutic research. Ramsey wanted to maintain the distinction in order to protect the harmless child from becoming subject to research for the benefit of other children at the judgment of the caregiver. To quote Ramsey: "The welfare of children as a class could be given higher priority than parental protection of one's own child."²

Paul Ramsey and I had a long correspondence about the distinction between therapeutic research and nontherapeutic research. I learned then, and now I am convinced, that the distinction is indeed spurious: research has a different intent from therapy. "Therapeutic research" is not a meaningful conjunction. However, Ramsey and I then fell into a debate on the distinction between the concerns of the researcher and the ethicist, especially as it relates to the quality of research as an ethical issue. Ramsey argued again (1977) that there was a distinction: "I concede that its low quality or inelegance--while of *concern* to everyone, if this is the case--is

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