524-8946

DRAFT - July 17, 1978

Amended S-2466 does not correct objections to the creation of overlapping authorities in that portion of the bill that creates the National Center for the Evaluation of Medical Technology. The authorities of the Center appear to duplicate the funded authorities of the National Institutes of Health.

Review of the authorities of several Institutes of the NIH indicates an ability and appropriations in these Institutes to evaluate medical technology as envisioned by the new medical Center. For instance, the mandate for the NHLBI provides for:

> "Research into the development, trial and evaluation of techniques, drugs and devices used in . . . prevention of heart, lung and blood diseases."

Clearly, NHLBI could undertake and has undertaken with the consent of its Advisory Councils the review of the efficacy of coronary by-pass surgery which is repeatedly cited as an example for the need for the new Center. The study being conducted by the Cardiac Diseases Branch will run for four to five years and measure the difference in death rate between patients having the cardiac by-pass surgery and those who have been treated only medicinally. Other variables will also be measured. At the end of the test the safety and efficacy will be evident and whether its cost is justified.

The study has been in process since 1974 and involves an investment of $2 million annually to closely monitor 800-900 heart patients.

Proponents of the bill indicate that several HEW sub-units "conduct some research on medical services and procedures." In the Rogers hearing

on HR 12584, a bill similar to S-2466, it was determined that 120 million dollars annually were being utilized for clinical trials on such evaluations as:

The widely publicized diabetic retinopathy trial.

Studies on oral anti-diabetes agents.

Breast cancer screening.

Multiple risk factor intervention trial (hypertension, cigarettes and lipids).

Aspirin myocardial infarction study.

Beta-Blocker heart trial.

Coronary drug project (this project determined that clofibrate was not useful in the ~~proposed study~~ evaluate population)

Prenatal review of 50,000 children born between 1957 and 1965 to determine the etiology of cerebral palsy.

The last study has involved over 100 million dollars, which could ~~hardly~~ barely be covered by the proposed budget anticipated for the National Center. Evaluation of fetal electronic monitoring, an area which has come under criticism as increasing Cesarian deliveries of children although within the authority of the NICHD, has not been undertaken. ~~Although~~ while admitting an increase in such Cesarians, there is no evidence that the children so delivered will not be healthier ~~healthy~~ on a long term basis than those not so monitored. Theoretically, a small study involving five hospitals over a period of seven years to study such children is estimated to cost 20 million dollars.

If the Center is created, are the proponents of the bill ready to reduce the NIH budget by a corresponding amount and to alter the

authorities of the several institutes in order to assure against internal in-fighting over jurisdiction over an evaluation of a technology such as coronary by-pass.

If, as the proponents of this bill indicate, the Center "would have no regulatory authority and its findings would have no direct impact on any existing programs," why is the authority not provided to the Public Health Service presently not sufficient?

It appears clear that the steps necessary to coordinate NIH studies have already been taken and require no new legislative authority but creation of the new Center, as noted, will clash with many existing legislative authorities. The proposed bill has already created confusion amongst agencies such as HSA, HRA and NIH on what their responsibilities will be if the legislation is passed. Further, Dr. Richmond in testifying on HR 12584 expressed the view that it would be premature and disruptive for the Department of HEW to undergo ~~such~~ a major structural change without a more fundamental understanding of the complexities involved in technology assessment.

While the proponents of S-2466 de-emphasize that the National Center would have direct impact on existing Federal programs and costs, the House Committee noted that the Center for Health Care Technology "can have great influence in holding down health care costs, since a careful assessment of the health care technology by the Center will enable decision makers to make sophisticated and supportable determinations with respect to the rational distribution and utilization of new and existing health care technology." Since amended S-2466 and HR 12584 appear to be similar or identical in language, which philosophy will prevail? Most important it appears that the evaluations now conducted by NIH would inherently involve an ability to determine cost effectiveness.