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AB 502 – CLINICAL TRIALS MANDATE

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- Clinical Cancer Research Throughout Medical School at University of Colorado.
- Internal Medicine residency and Oncology Fellowship at University of Colorado.
- Oncology Practice in Grand Junction Colorado.
- Participation in Cooperative Group Trials – NCI – Through Academic Medical Centers.

MEDICAL CARE MANDATES

Clinical Trials are very important to the advancement of evidence based medical care. However there are inherent dangers in these trials and these must be understood before either recommending a patient enter into a clinical trial and even more so before passing a mandate to require such.

For example, some State passed mandate coverage for bone marrow transplants for breast cancer. Subsequent findings later revealed that patients were harmed by this procedure. There was also evidence that at least one of the institutions involved reported very flawed and probably fraudulent data.

BILL AS A WHOLE IS BROAD AND ALL ENCOMPASSING

Clinical Trials - Phase I – IV (Sections 1, 4, 6, 8, 12, subsection 1(a)(1) & (2))

- Includes all phases of clinical trials including Phase I, which are not treatment trials and are only used to identify the maximum tolerated dosage.
- I might add that the patients who obtain a complete remission rate is only 0.3%.
- Those patients that die directly from the experimental drug is higher at 0.5%.

Healthcare providers (Sections 1, 4, 6, 8, 12, subsection 6(b))

- Includes all healthcare providers whether or not they are trained in the particular therapy, intervention or device.

Organizations approving clinical trials (Sections 1, 4, 6, 8, 12 subsection 1(b))

- Includes a broad base of approval organizations for the proposed mandated trials. The clinical trials of the National Cancer Institute (NCI), the National Institute of Health (NIH) and the Cooperative Groups is rigorous and generally consistent with patient safety requirements.

ASSEMBLY COMMERCE & LABOR 1 of 3
DATE: 4/09/03 ROOM: 4100 EXHIBIT CC
SUBMITTED BY: Christine Petersen

Institutional Review Boards (Sections 1, 4, 6, 8, 12, subsection 1(b)(6))

- There has been considerable criticism by government agencies, both state & federal, by academic institutions and by other public and private parties over the poor performance of many of the Institutional Review Boards (IRBs).

- In June of 1998 the Office of the Inspector General (OIG) produced a report entitled, "IRB's: A Time for Reform." They noted that the assurance document that IRB's sign is merely an institutional commitment and involves no assessment of performance.

- The OIG went as far as to say that the IRB's limited efforts in conducting continuing review of active research is a serious national issue because it compromises the protection of human subjects. Since then, the Institute of Medicine (IOM) has recommended accreditation of these human research participation programs, which has not yet been instituted.

- The OIG findings of common IRB problems comprised issues such as:
  1) Failure to obtain prospective IRB approval before starting a clinical trial,
  2) Failure to minimize risks for human research subjects,
  3) Failure to obtain legally effective informed consents,
  4) Failure to provide oversight, and
  5) Failure to eliminate or minimize conflicts of interest.

- The seriousness of the OIG report has been reflected in numerous events since the study came out, including:
  1) Twenty deaths at Fred Hutchison Cancer Hospital reported in June 2001, where there was concern over the lack of disclosures of the doctors financial interest in the drugs being tested.
  2) The research program suspension of John Hopkins and Duke University Hospital in 1999.
  3) The Office of Human Research Protection (OHRP) halted 550 human trials at the University of Alabama in January of 2000.
  4) In March of 1999, the Department of Veteran Affairs suspended all clinical research in the clinics of the Greater Los Angeles Health System for failing to meet ethical guidelines. This VA is one of the nation's largest research hospitals.
  5) In October of 2002, the New England Journal of Medicine (NEJM) reported that there was concern over patient safety in clinical trials in academic institutions with issues over conflicts of interest, both financial and non-financial.

THERE HAVE BEEN WIDELY PUBLICIZED DEATHS

Below are just 2 examples:

- The 19-year-old at the University of Pennsylvania who died in the gene therapy trial.
- The 18-year-old who died in the bronchoscopy trial at John Hopkins.

- Additionally, the NEJM last week published 3 articles on clinical trials that highlighted an NIH trial that was placed on a controversial hold by the OHRP, and 2 articles about the conflict, and controversy between the scientific objectives of a trial and the physicians role in individualizing patient care entirely for the patient's benefit (i.e. that clinical medicine aims to provide individual patients with optimal care whereas clinical research is devoted to answering scientific questions in order to produce generalizable knowledge to benefit future patients).

CONCLUSION

- Despite these issues, many clinical trials are important for the advancement in medical care, particularly cancer care, but are not without their problems, including ethical issues, potential financial conflict and patient safety and informed consent.

- Not all trials are created equal, and it is not easy to recognize or deal with substandard ones, even for academic institutions held in the highest regard.

- The public policy controversy remains as to who should be funding clinical research -- pharmaceutical houses? Medical device manufacturers? Government agencies such as the NIH, NCI (which do fund on a limited scale)? Government programs such as Medicare (which does have clinical trial coverage)? Or private health insurance?

- There is a cost to these trial programs. Information is limited, but 3 small studies done by the Mayo Clinic, Group Health of Puget Sound and Kaiser reported ranges of 3.5% to 20% higher cost for cancer clinical trials than for standard therapy. The NIH has funded the Rand Foundation to complete a larger study but this is not yet complete. There is no data yet to my knowledge for non-cancer cost studies.

- Medicare patients are already covered for clinical trials. HPN patients have Phase II-IV coverage for NIH, NCI and Cooperative Group Cancer Clinical Trials. Self-funded ERISA plan would not be covered by this mandate.