

TESTIMONY IN SUPPORT OF HOUSE BILL 917

The Honorable Clarence Blount
Senate, Education, Health, and Environmental Committee
Room 2 West Miller Senate Office Building
Annapolis, Maryland 21401-1991

April 3, 2002

To Chairman Blount and members of the Senate, Education, Health and Environmental Affairs Committee,

I am President of CIRCARE, Citizens for Responsible Care and Research, a national organization that has long advocated for ethics in scientific research. I also chair the PAIMI advisory council to the Maryland Disability Law Center. Both organizations cast their support in favor of this bill.

We support this legislation because:

- 1) Granting greater transparency by making the IRB minutes public would help bring more accountability to research. The recent death of Ellen Roche at Johns Hopkins Medical System revealed (by outside review) that the IRB review was perfunctory. When life and death matters are involved, there need to be mechanisms to insure that the decision to go into research is handled with the utmost care.
- 2) The failure to cover private research by any minimal standard – ie federal or state regulation – means there is a major gap in current protection, one that is afforded to animals and one that has led to laws to protect human subjects in several other states. Private research, usually financed by pharmaceutical companies, can involve up to half of all research conducted at major universities. When studies such as induction of psychosis to people who are in hospitals already (by Ketamine, a PCB derivative) are suspended by the federal government due to ethical considerations, this should not mean that such studies can simply be shifted to the private sphere leaving the citizen without any protections in place.
- 3) Due to the overwhelming power disparity between subject and research institution, there needs to be more checks and balances. For instance, a homeless man in Baltimore participated in a cholera induction experiment to obtain enough money to get out of homelessness – a case reported on CBS's 48 hours. We need to insure that subjects are not left to rely on their own wariness to be insured of safety. This bill offers but a modest beginning in this regard.

This testimony is also joined by Dr. Adil Shamoo, co-founder of CIRCARE, who has published results showing the statistical occurrence of thousands of adverse events and deaths in human subject research.ⁱ As there is currently no mandated reporting of adverse effects

- which should be the subject of future legislation - there is no full accurate way to document the scope of the problem.

We urgently seek the adoption of these measures to help ensure that deaths like that of Ellen Roche will not be repeated.

Thank you,

Michael A. Susko
President of CIRCARE
President of PAIMI, Maryland Disability Law Center

ⁱ Shamoo, A.E. (2001), "Adverse Events Reporting – The Tip of an Iceberg," *Accountability in Research* 8:1-22.