

Medical research bill opposed at hearing Biotech industry, universities against adding state oversight

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Legislation that would subject human medical experiments in Maryland to greater public scrutiny and government oversight drew opposition yesterday from the state's universities and the biotechnology industry.

During a hearing before the House Environmental Matters Committee, the critics argued that a bill introduced by Del. James W. Hubbard would overlap with existing federal regulations and would scare away millions of dollars in research grants. "The legislation is unnecessary," said Donald N. Langenberg, chancellor of the University System of Maryland. "It will also cause our major research institutions to devote precious resources to duplicative procedures."

But advocates of the bill -including 16 co-sponsors, the state attorney general's office and two organizations that work for greater safety in medical research -said a pair of scandals in experiments approved by the Johns Hopkins medical institutions last summer demonstrate why more oversight is needed.

"If you are going to put people's bodies at risk [in medical experiments], let's at least have more accountability by having more transparency," said Michael Susko, president of an advocacy group called Citizens for Responsible Care and Research. Hubbard, a Prince George's County Democrat, said he drafted the bill to reassure the public after a Johns Hopkins review board approved a lead paint experiment at the Kennedy Krieger Institute in which two parents claimed their children were poisoned. A healthy volunteer died during an asthma experiment in June at the Johns Hopkins medical school.

The bill would require university review boards to let the public read their minutes, although it would allow the boards to cut any "confidential or privileged information."

The legislation would extend existing federal protections to medical research conducted by private industry, as well as universities, which are now regulated. It also would authorize the Maryland attorney general's office to seek court injunctions to shut down any experiments that it finds too dangerous.

Joining Langenberg in criticizing the bill were officials from Johns Hopkins and from the Technology Council of Maryland, which represents 850 biotech companies. An official of Johns Hopkins Medicine told lawmakers the institution opposes the bill as drafted. The school offered several amendments that Hubbard said would make the legislation meaningless. They would essentially make the legislation identical to federal regulations that governs university research.

"Using the federal definitions and standards will ensure that research institutions and researchers in Maryland are not disadvantaged when competing for federally funded and other sponsored research," Hopkins Medicine Vice President Joanne E. Pollak said in a letter to the committee.

Amendments drafted by Hopkins officials also would have weakened a section of Hubbard's bill requiring private institutions like Hopkins to make public the records of the review boards that approve experiments.

When asked about that amendment minutes before yesterday's hearing, Pollak said the school would support the right of the public to examine its records. She called the provision a "drafting error" that the school would fix.

"We support anything that will build the trust of people in participating in the good research that is going on at Hopkins and other institutions in the state," said Pollak. The committee may vote on the proposal next week.

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