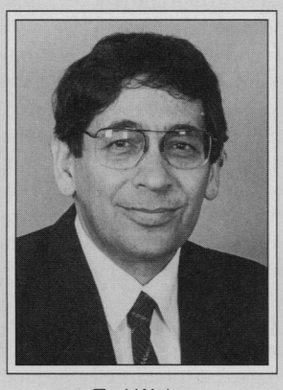
The Tissue Bank's Shaky Underpinnings

Now that neurological transplants using fetal cells are showing signs of paying off (see main story), the next major issue for researchers is ensuring an adequate supply of tissue. And that's where the politics of abortion has become a serious obstacle: Since 1988, the U.S. government has refused to fund transplantation research that uses fetal cells from elective abortions for fear the goals of research might de-stigmatize the procedure and encourage women to have more abortions. Instead, earlier this spring President George Bush proposed to set up tissue banks to collect fetal cells from spontaneous abortions and life-threatening ectopic pregnancies that develop outside the uterus. According to assistant secretary for health James Mason, such sources could produce some 2000 tissue samples every year.

But the Administration's math, long criticized by researchers who claim the tissue bank idea is unworkable, is coming under fresh political attack. Citing internal documents from the Department of Health and Human Services (HHS), Representative Ted Weiss (D–NY) has accused the Administration of ignoring its own scientific advice and deliberately overstating the amount of tissue available. In a similar vein, data submitted to National Institutes of Health (NIH) in nine tissue bank proposals suggest not only that the bank will produce little tissue for research, but that the project's cost is likely to be much higher than previously discussed.

The numbers game. Conceptually, the tissue bank is straightforward. In its first 2-year phase, researchers will put together networks of participating hospitals at up to six sites across the country where pathology experts will characterize and store fetal tissue as soon as it becomes available from spontaneous abortions and ectopic pregnancies. The collection teams will submit each tissue sample to a battery of immunologic and cytologic tests to determine how many are healthy and therefore suitable for transplantation research.

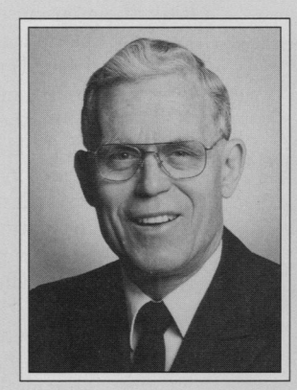


Ted Weiss

No one, however, seems to know with much precision how much tissue this process might produce. Mason's self-described "conservative" estimate of 2000 usable samples a year is based upon two analyses produced by staffers at the National Institute for Child Health and Development (NICHD). These analyses, first reported by *The New York Times* and since obtained by *Science*, suggest that Mason's figure is both optimistic and in some cases based on little actual data. For instance, NICHD staffers based one analysis on the assumption that researchers could test 100,000 tissue samples each year from women hospitalized for spontaneous abortions. Yet the analysis memo acknowledges that "a substantial proportion" of those spontaneous abortions "occurred prior to hospitalization"—meaning that the tissue would be unsuitable even for testing, a fact not reflected in the analysis.

Similarly, NICHD accepted what its own memo concedes is the "arbitrary" estimate that only half the available tissue would be infected (and therefore useless)—an assumption that produced what the memo called a "probable generous" estimate of 1500 tissue samples available from spontaneous abortions. Weiss charges that such projections are little more than "optimistic guesses that have only a peripheral relationship to scientific fact."

Forging ahead. Undeterred by the controversy over the NICHD estimates, NIH is moving ahead quickly with plans to get the tissue bank off the ground. On 3 August, the agency received nine proposals from researchers across the country who hope to participate in the bank's first phase. If all goes according to plan, six peer-approved proposals should be ready for funding on 28 September. Eventually, the Administration hopes to expand the bank to at least 20 centers across the country.



James Mason

But interviews with some researchers who have submitted proposals and a source familiar with all of them bolster the contention that the tissue bank will produce much less usable tissue than HHS has projected. When the researchers estimated how many spontaneous abortions and ectopic pregnancies their own proposals might intercept in a year, their answers ranged from a low of 100 to a high of about 1500. But those numbers reflect the total amount of tissue available, not useful tissue. Once all the potentially disqualifying factors are taken into account, "we could be ending up with [an overall] figure of 30 or fewer specimens" in the coming year, the source says.

Faced with such numbers, the Administration has backtracked rapidly. In a recent letter to *The New York Times*, Mason wrote that HHS had "never planned" to collect 2000 usable fetuses. Instead, he wrote, the department had said only that its tissue bank "could collect enough of these fetuses to provide tissue for expected research needs." According to a transcript of a 19 May press conference, however, Mason said: "So you put the numbers together from spontaneous abortion and ectopic pregnancy and you get, as a conservative estimate, about 2000 tissues a year. And the current demand is probably not 200.... So I would say to you that...this tissue...will be in more-than-adequate supply for the foreseeable demand."

But some researchers say Mason is still being overly optimistic. University of Colorado neurobiologist Curt Freed, whose privately funded lab conducts about 6 transplants a year using tissue from induced abortions, says that his work alone requires about 200 fetuses a year. "We would use the nation's supply in one year."

Cost pressure. Then there's the matter of the tissue banks' cost. Under direction from HHS, NIH was to spend $3 million to set up six centers for tissue collection. But the average cost of the nine proposals is higher than $500,000, and the most expensive is just over $1 million. "I think we'll be doing well to cover four centers," says the source. The plan's overall price tag is also soaring. Beyond the first year, NIH expects the cost of the tissue bank to increase by $1 million a year—bringing the total to $42 million over the project's anticipated 7-year lifetime.

Congress is now considering compromise legislation that, starting in May 1993, would allow researchers to use fetal tissue from elective abortions if they cannot obtain it from the tissue bank within 14 days (*Science*, 3 July, p. 24). Hill staffers say they expect the measure to pass by the end of August and note that Congress stands a fair chance of overriding a threatened presidential veto. Even if they are right, however, NIH will probably be living with the tissue bank for a while.

–David P. Hamilton