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> By SHARON BEGLEY
> Research Involving Tests on Newborns Highlights Need for Stricter Ethics
> It hasn't been a good time for scientists who experiment on people -- or
> the
> people they experiment on.
> Last summer a 24-year-old died from medication she inhaled in a study at
> Johns Hopkins University; the federal government briefly suspended many
of
> the school's human experiments and demanded reforms in how it protects
> volunteers. In 1999, an 18-year-old died during a gene-therapy trial at
> the
> University of Pennsylvania. The government is considering permanently
> barring the lead researcher, Dr. James Wilson, from human research (Last
> month, Dr. Wilson announced that he will resign as director of Penn's
gene
> institute). Also in 1999, the feds shut down human studies at Duke
> University for six weeks. Every year the National Institutes of Health
> identifies dozens of violations in human experiments.
> One outrage now before a court has stunned even bioethicists who thought
> they'd seen it all. In 1985, University of Wisconsin researchers launched
> a
> study to learn whether early diagnosis and treatment of cystic fibrosis
> helps newborns. An inherited disease, CF's defining symptom is the
> production of thick mucus that hurts respiration and digestion. Half of
CF
> cases are diagnosed by six months of age, 90% by age four. An idea
> occurred
> to UW pediatricians Philip Farrell and Norman Fost: Would diet
supplements
> stave off the malnutrition that CF often brings?
> Thanks to a blood test developed in the 1970s, doctors could identify
> newborns at risk for CF. For their study, then, the researchers began
> screening every newborn in Wisconsin. They randomly assigned each
> CF-positive baby to one of two groups: a treatment group whose parents
> were
> told their baby tested positive and who received dietary intervention,
and
> a
> control group who received no such help and -- here's where things get
> ethically dicey -- whose parents weren't informed of the screening
result.
> If they had told the parents, the scientists reasoned, the parents might
> have demanded treatment for their kid. No more control group.
> From the start, red flags bloomed like poppies. NIH asked Dr. Farrell in
> 1985, "Will you state specifically that the results of half [the babies]
> will not be known by the parents until the child is four? ... Isn't a
> lawsuit possible?" Dr. Fost, who also chaired the UW panel that OK'd the
> study, wrote in a 1985 letter to the CF Foundation that "it would be
> ethically impermissible to conduct the project at all if the benefits ...
> of
> early treatment were established."

> In 1989, Drs. Fost and Farrell acknowledged the ethical problems of
> "withholding of diagnostic information." Their justification? Early
> treatment was of unknown value. And besides, were it not for the study,
no
> parent would know if their newborn had CF anyway.
> That rationale doesn't sit well with the bioethicists I asked. "It would
> have been possible to do the research and still inform the parents," says
> Thomas Murray, president of the Hastings Center, a bioethics think tank
in
> New York. Even if some parents opted for therapy for their asymptomatic
> child, he says, "It would not have been as statistically clean, but in
> human
> experiments the interests of the subjects are supposed to outweigh those
> of
> the scientists."
> Cut to 1991. In a paper in the American Journal of Clinical Nutrition,
Dr.
> Farrell concluded that "normal growth and ... nutritional status can be
> achieved" in most CF babies if they're treated early. Six years into the
> study, then, he knew kids receiving early treatment did better than those
> untreated. Yet newborns testing positive for CF were still being randomly
> assigned to the don't-treat, don't-tell group. Even when Wisconsin
started
> requiring CF screening for all newborns in 1994, parents from the study
> weren't called.
> That became acutely relevant for at least one pair of parents. Linda and
> Charles Ande had a daughter, born in July 1993. The UW study identified
> her
> as at risk for CF but, consistent with the study protocol, no one told
the
> Andes. Their pediatrician diagnosed CF in 1995. By then, the Andes had
> conceived another baby. He, too, was born with CF, in 1996. Had they
known
> their little girl had the disease, say the Andes, they wouldn't have had
> another child. They sued the researchers in Circuit Court in Dane County,
> Wis.
> Last year, the circuit court dismissed the Andes' wrongful birth claim.
As
> government employees, ruled the court, the doctors enjoy "qualified
> immunity" from prosecution. Dr. Farrell is now dean of the UW medical
> school. Dr. Fost, too, remains at the university. Neither would talk to
> me,
> but a UW statement calls the study "important" and "ethically
> appropriate."
> The case is now before a state appeals court. It makes you wonder if
> researchers learned anything from the federally funded Tuskegee Study.
> From
> 1932 to 1972, black men were denied treatment for syphilis and not told
> they
> had the disease -- all in the name of science.
> Send comments to sciencejournal@wsj.com1.
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