



July 9, 1981

MEMORANDUM

TO: The Secretary

FROM: Deputy Assistant Secretary for Health

SUBJECT: Neural Tube Defects and Alpha Fetoprotein Screening

In view of the fact that the FDA will have to approve or disapprove Alpha Fetoprotein (AFP) screening kits and because whatever decision is made will precipitate a howl of disapproval from the other side, I thought you should be aware of some recent studies that bear upon the issue.

BACKGROUND

Neural Tube Defects (NTD) occur much more commonly in the United Kingdom, particularly in the midlands, than in the United States. Just as abortion on demand in Great Britain preceded the same social change in the United States by about six years, so did the sub-rosa practice of infanticide of defective infants get an earlier start in the United Kingdom.

In the United States today, about 95% of children born with NTD are operated upon and a rehabilitation effort instituted. In United Kingdom only about 25% of the children born with NTDs are operated upon and the remainder are left to die. The technique of getting rid of these youngsters is to sedate them so heavily that they are unable to take their feedings and they therefore die in about three weeks from starvation and dehydration.

Along with the assault on the born child with NTD there arose in the United Kingdom a nationwide voluntary screening of pregnant women to detect NTD in the fetus by measuring AFP in the maternal serum. An elevated AFP level is usually followed by amniocentesis. If NTD is confirmed, abortion is recommended.

RECENT DISCOVERIES AND UNCERTAINTIES

Use of Ultra-Sound in Diagnosis. Amniocentesis cannot be carried out until the 16th or 20th week of pregnancy at which time it is also possible to make the diagnosis of NTD by ultrasonography (a non-invasive technique) with a 95% degree of accuracy. Those NTDs which are missed by this technique are small and low in the spine and therefore among the most favorable of NTDs in reference to function of the child.

Uncertainties in Prenatal Screening for NTD in England. A report in the British Medical Journal May 2, 1981, by Rodney Harris, long-time advocate of national AFP screening for NTD in the United Kingdom, raises some questions that suggest caution in proceeding with AFP screening. Among the facts cited to suggest caution are: the use of ultrasound (see above); a false negative rate of AFP screening of at least 20%; the introduction of a new diagnostic technique employing qualitative electrophoresis of acetyl cholinesterase in amniotic fluid, the low incidence of NTD in the population at large which makes the yield very expensive per case found, the increase in the number of lesions other than NTD which produce an elevated AFP in maternal serum, and the false positives in elevated AFP levels due to spontaneous fetomaternal transfusion.

PREVENTION OF NTD BY VITAMIN SUPPLEMENTS BEFORE CONCEPTION

It was noted in 1965 that a large proportion of the NTDs in the midlands of England were in the very lowest socio-economic classes. It was also noted that these people all had one thing in common -- they had bought and eaten low-priced blighted potatoes. Blighted potatoes have no folic acid in them and a poorly controlled small study indicated that the simple expedient of taking "one-a-day" vitamins reduced the incidence of NTD in high risk mothers.

The British Medical Journal of May 9, 1981, carries the report of a double blind randomized controlled trial of folic acid treatment before conception to prevent recurrence of NTDs in families at risk. It is concluded that folic acid might be a cheap, safe, and effective method of primary prevention of NTDs. Of course, this must be confirmed by a large multi-center trial.

I would be pleased to discuss this with you if you wish.

C. Everett Koop, M.D.