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The California Alpha-Fetoprotein Screening Program: An Advocacy Program for Handicapped Children

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I. The Problem

Neural tube defects (NTD) is a collective term for a group of birth defects which include anencephaly, encephalocele and spina bifida. In California, the incidence of NTD is 1.1 per thousand live births. By type and incidence, NTD can be subgrouped as:[1]

Anencephaly	0.5 /1000
Encephalocele	0.08/1000
Spina bifida	0.5 /1000

Anencephaly is incompatible with life—the affected neonate succumbs within a few hours of birth. Encephalocele is rare and generally results in some degree of mental disability.

Spina bifida will affect approximately 185 newborn infants in California each year. Successful treatment exists for most cases of even the worst

physical disability, and most of these children are not mentally impaired. NTD, therefore, is not a leading cause of morbidity and mortality for children in California; rather, it is a potentially handicapping disorder for which effective postnatal therapy has generally been realized.

The technology now exists which enables the detection of only eighty percent of neural tube defects during the middle of pregnancy. This technology consists of screening the serum of their mothers for alpha-fetoprotein during the 16th to the 18th week of pregnancy. Alpha-fetoprotein is the fetal analogue of adult albumin, and it is usually elevated in both the maternal serum and the amniotic fluid if the developing human is affected with an NTD or omphalocele. Interestingly, the maternal serum alpha-fetoprotein (MSAFP) is depressed in some instances when the developing human has Down's syndrome.

II. Informative Digest

In 1982, Section 289.7 of the Health and Safety Code was amended, requiring the Department of Health Services to promulgate regulations governing the alpha-fetoprotein test kits that were soon to be approved for marketing by the FDA. The intent of the legislative mandate was to protect the public from unscrupulous marketing by the private sector which could lead to inaccurate testing and misinterpretation of test results.[2] The department failed to provide regulations, and the legislature therefore amended the FY 1983/84 Budget Act requiring emergency regulations. It was never the intent of the legislature to implement a mandatory statewide alpha-fetoprotein screening program, and this fact is appropriately demonstrated by the rejection of the emergency legislation AB 1846 (Margolin) in 1985.

Lori Andrews, J.D., project director in medical law for the American Bar Foundation, questions whether such regulations can be responsive to public opinion: "If you're going to make policies that force people to undergo medical services, should the decisions be made in a back room or in the legislature where all interests are heard?"[3] Nevertheless, the regulations were drafted in a "back room" fashion and subsequently implemented, contrary to legislative intent.

III. The Position of Professional Organizations

In 1982, responding to the call to screen all pregnant women for NTDs, the American College of Obstetrics and Gynecology (ACOG) stated: "The risks and costs appear to outweigh the advantages and the program should not be implemented."[4]

Contrary to the misinformation which has been promulgated, the ACOG has never altered its position. The American Medical Association (AMA) stands by its report by the Council on Scientific Affairs which concluded: "Maternal serum alpha-fetoprotein screening of all pregnant women should not be advocated at this time."[5]

The following discussion will clarify the reasons why the ACOG and the AMA hold this position.

The Program

In California, 370,000 women annually are in prenatal care by the 16th to the 18th week of pregnancy.[6] Using available statistics[7,8,9], the statewide program in California will work as is shown in Tables I and II.

Neural Tube Defects

The problem with the NTD screening program is the lack of reliability of the serum alpha-fetaprotein test. The test is falsely positive (that is, unaffected women will test as if their baby is affected) in 95 percent of the cases.[10] More distressing to the DHS is the fact that the test is falsely negative (that is, infants with NTD who test as normal) in 22 percent of the cases.[11]

With unaffected pregnancies testing falsely positive, the level of maternal anxiety for those women participating has increased dramatically. This has already led participating physicians to conclude that the "California Alpha-Fetoprotein Screening Program should be halted or abolished altogether".[12] This verifies the warning by U.S. Surgeon General C. Everett Koop who, prior to the implementation of the program, warned: "A positive alpha-fetoprotein test can lead women to have abortions because they can have the impression that they are carrying a spina bifida child".[13] James N. Macri Ph.D., director of the NTD Laboratory at the State University of New York at Stony Brook, noted that not all false-positive results can be eliminated so that there is a risk of aborting a normal fetus.[14] Furthermore, Leroy Walter Ph.D., of the Kennedy Institute's Center for Bioethics at Georgetown University, said that some women whose first MSAFP screening test results were positive were sufficiently frightened "that they went off and secured an abortion then and there."[15] This creates a dilemma for all public health screening programs. A proponent of this program, Prof. Joe Leigh Simpson, head of the section of human genetics at Northwestern University, even worries that "unnecessary abortions are likely to occur . . . potentially leading to a loss of public confidence in genetic screening".[16]

Since elevated MSAFP levels will lead to 6,263 amniocenteses per year in California (see Table I), "the demand for chromosomal studies of amniotic fluid fibroblasts [will] be greatly increased because, for legal reasons, it [will] be hazardous to perform amniocentesis without performing genetic studies".[16]

Analysis of the data in Table I reveals that 323 developing humans will be identified as having an NTD. The alleged goal of the screening program is to detect affected infants so that appropriate life-saving surgical intervention can be delivered immediately upon birth. It is appropriate to determine the number of these affected infants who would require this intervention.

Referring to Section I of this report, almost one-half of those infants with NTDs will have a condition compatible with life: that is, 142 will have spina bifida cystica. According to Mitchell S. Golbus M.D., professor of obstetrics, gynecology and pediatrics at the University of California at San Francisco, the only malformation requiring immediate post-natal sterile surgical correction is uncovered meningomyelocele.[17] Eighty percent of all spina bifida cystica births consist of uncovered meningomyeloceles, and 25 percent of these will be stillborn.[18] Thus, only 85 infants would have been live-born with an uncovered meningomyelocele. Can the cost of screening justify identifying these infants, especially since effective post-natal therapy antedates the implementation of the screening program?

Omphalocele

As mentioned, omphalocele can also be detected by an elevated MSAFP. This condition is rare: its incidence is only 1:6000.[19] According to Dr. Golbus, only a ruptured omphalocele requires immediate post-natal sterile surgical correction;[20] approximately 18.5 percent are ruptured.[21] The sensitivity of the screening program is 73 percent.[22] Of the 35 affected infants detected by the California Alpha-Fetoprotein Screening Program, only six will have what Dr. Golbus defines as a surgical emergency—a ruptured omphalocele. This condition is almost always amenable to medical and surgical treatment after birth, leaving affected infants with no physical or mental disability. Late complications have been virtually nonexistent.[23]

Down's Syndrome

The overall incidence of Down's Syndrome is 1:800 live births.[24] A low MSAFP suggests its presence; however, the sensitivity of the test is only 20 percent[25], and the test is falsely positive in over 97 percent of the women tested.[26] False positive screening tests are obtained with even greater frequency than is the case in neural tube defect screening. Analysis of the data in Table II indicates that 92 women will be determined to be carrying infants with Down's syndrome by the California Alpha-Fetoprotein Screening Program. There is no current surgical imperative to identify these infants antenatally other than for the purpose of abortion.

V. Data Analysis

The stated goal of the California Alpha-Fetoprotein Screening Program is to enhance the survival chances of affected infants. Proponents argue that this can only be done by detecting affected infants antenatally in order to have a surgical team present at the instant of delivery, immediately repairing the neural tube defect or ruptured omphalocele. The following analyses show that the purported goal of the program is not substantiated.

Cost Analysis

The cost of the technical aspects of the NTD screening program itself, as determined from Table I, is:

A.	$5,550,000
B.	274,725
C.	1,571,427
D.	5,166,975
G.	444,000
H.	2,095,236
I.	6,043,950
Total:	$21,151,313

The costs of the technical aspects of the program for a different level of utilization (or for other areas in the United States where such a program might be proposed) can be estimated by:

$$\text{cost}(\$) = (57.16)x,$$

where x = the number of women screened.

This does not include program costs. For example, it is estimated that one genetic counselor is required for every 150 individuals identified at risk.[27] Referring to Tables I and II, (Levels D and I, respectively), it can be seen that the California program would require up to 91 full-time genetic counselors. The program will have to rent facilities at each of the 19 regional centers throughout the state. In addition, it will have to fund the necessary support staff. A proposed program budget is outlined in Table III.

The total program cost (excluding $743,850 for abortions) of the proposed screening program would therefore be $28,228,566. For different levels of utilization, the program costs can be estimated by:

$$\text{Program cost}(\$) = 2778545 + (67.686)x,$$

where x = the number of women screened.

Assuming the unlikely event of full participation, it will cost an average of $76.29 for each woman screened. Claiming to be self-supporting, the California Alpha-Fetoprotein Screening Program proposes to charge $40 for every woman who participates. This $36.29 per woman discrepancy ($13.4 M) will have to be compensated by the state of California, Medi-Cal (Medicaid), and third party insurance carriers. Underutilization of the program will increase the differential, and it is therefore not surprising that the Screening Program has already petitioned the legislature for operational funding. The FY 86/87 Budget Act originally authorized $7M, but this was augmented to $12M as the program was initiated. Medi-Cal is authorized to pay for the fee for participating women covered under California's Medicaid program.[28]

Cost:Benefit Analysis

The stated goal of the program is "to detect those infants who would require immediate surgery". The California Alpha-Fetoprotein Screening Program will detect 91 developing humans with an uncovered meningomyelocele or ruptured omphalocele at a total cost of $28,228,566—that is, $310,204 for each case identified. Since it has been estimated that the lifetime medical cost of care for each person with spina bifida is $80,000[29], it is obvious that the program is not justifiable on a cost: benefit analysis.

Benefit:Risk Analysis

The human cost of this proposed program is extremely objectionable. For every 10 developing humans identified with spina bifida cystica, omphalocele or Down's syndrome, 18 who are affected will be missed and *18 normal unaffected ones will be killed.* (268 affected ones; 469 normal developing humans killed—see Tables I and II). This analysis does not even address the enormous public health consequences for the 783 women undergoing late mid-trimester abortions (see below).[30] Obviously, the program is not designed to enhance the well-being of affected infants; rather, it is a program of eugenics which institutionalizes discrimination against handicapped children.

VI. Goal Analysis

What is the real purpose of identifying these developing humans? Doctor Berkowitz of the Mount Sinai Medical Center in New York says that such a program exists so that "a diagnosis can be made prior to the time when pregnancy can legally be terminated (sic)".[31] The Hastings Center concludes that the screening program "does detect a serious condition . . . but the condition cannot be arrested or treated except by aborting the affected fetus."[32] Even the California Department of Health Services concurs when it states: "As the screening program is implemented it is estimated that the number of cases diagnosed at birth should drop by up to 80%."[33] Dr. George Cunningham, Chief of the Genetic Disease Branch in the California Department of Health Services, states that he expects 90 percent of women with abnormal screening to obtain abortions[34] even though their children's disabilities would not usually be severe.

There is no *in utero* treatment for the affected ones. The California Department of Health Services, in speaking of "prevention strategies", is using a euphemism to cover the destruction of these developing humans *in utero.* The program is not even an efficient population purification program: it must be distressing to the eugenicists in the DHS that this Screening Program will actually miss 472 affected infants. Since the cost of discovery for each case (including aneuploidy) is at least $108,106 and since there is no *in utero* treatment, should not these funds be used to care for the affected infants rather than to destroy them?

VII. Ethical Implications

The California Alpha-Fetoprotein Screening Program raises ethical concerns in at least four areas.

Participation by Mandate

The regulations make it mandatory for physicians to participate in this "search and destroy" program which is part of the "prevention strategy" of the Department of Health Services. It is unethical to mandate screening tests for conditions which are not treatable. It is a violation of conscience for many physicians to participate in this program.

Participation by Coercion

If an expectant mother decides not to participate, she must sign this waiver: "No. I refuse to have the alpha-fetoprotein blood screening test done. I understand and accept the consequences of this decision." If she agrees to participate, she signs: "Yes. I request that blood be drawn for the alpha-fetoprotein screening test."[35] The bias is obvious, and its intent is to frighten the expectant mother into participation.

Discrimination

As discussed in the preceding section, the California Alpha-Fetoprotein Screening Program institutionalizes discrimination against handicapped children.

Restriction of Utilization

The Department of Health Services has implemented regulations that restrict MSAFP testing to the California Alpha-Fetoprotein Screening Program, at a cost of $40 to every woman participating. The test could be performed in the private sector for approximately $7. Expectant mothers, the majority of whom are opposed to it, are thus being coerced to support a program which promotes abortion.

Conclusion

The California Alpha-Fetoprotein Screening Program must be seen for what it really is: a eugenic population control program masquerading as an advocacy program for children with disabilities. More normal unaffected children will be killed than will be the number of abnormal ones identified by this program. The morality, motives and tactics of the proponents of this program need to be fully exposed. It is an ethical as well as a civil rights violation to force expectant mothers and their physicians to participate in the California Alpha-Fetoprotein Screening Program.

TABLE I

NTD Screening Program

LEVEL	1 # of women	2 test	3 cost ($)	4 % abnormal	5 # abnormal	6 comments
A.	370,000	MSAFP	@15	5	18,500	1% loss 2° maternal anxiety
B.	18,315	MSAFP	@15	60	10,989	
C.	10,989	US-I[a]	@143	57	6,263	
D.	6,263	US-II[b] amnio[c]	@825	5	323	1% loss 2° to amnio
E.	323	D&E	@950			plus 35 with omphalocele

Note: 185 developing humans voluntarily aborted at Level A; 63 succumbed at Level D solely as complications of the screening program.

Note: since false negative rate = 22%, 95 with NTD missed: # missed = ([D5+(D6) (D4) (D1)] / (1-FNR)) - D5 = (323+3) / (0.78) - 323 = 95

a = level I ultrasound at $143 per Grossmont Hospital, La Mesa, CA
b = level II ultrasound with amniocentesis for alpha-fetoprotein at $375 per the Fetal Diagnosis and Treatment Center (FDTC), UCSD
c = an additional $450 for karyotyping per the FDTC, UCSD

TABLE II

Down's Syndrome Screening Program

LEVEL	1 # of women	2 test	3 cost ($)	4 % abnormal	5 # abnormal	6 comments
F.	370,000	MSAFP	@15	8	29,600	
G.	29,600	MSAFP	@15	50	14,800	1% fetal loss 2° anxiety
H.	14,652	US-I[a]	@143	50	7,326	
I.	7,326	US-II[b] amnio[c]	@825	1.25	92	1% loss 2° to amnio
J.	92	D&E	@950			

Note: 148 developing humans voluntarily aborted at Level G; 73 succumbed at Level I solely as complications of the screening program.

Note: since false negative rate = 80%, 373 with Down's missed: # missed = ([I5+(I6) (I4) (I1)]/(1-FNR)) - I5 = (92+1)/(0.20) - 92 = 373

a = level I ultrasound at $143 per Grossmont Hospital, La Mesa, CA
b = level II ultrasound with amniocentesis for alpha-fetoprotein at $375 per the Fetal Diagnosis and Treatment Center (FDTC), UCSD
c = $450 for karyotyping per the FDTC, UCSD

TABLE III

Technical/Operational Program Budget

Item	Total
Salaries	
Program Director	$ 59,565
Deputy Director	$43,875
Admin. Assistant	22,530
Genetic Coun. (91)	2,936,678
Cler. Assist. (19)	293,825
Secretarial (19)	360,000
Data Entry Clerk	31,290
Temporary Assist.	10,000
Regional Cnt. liaison	5,265
Fringe Benefits	1,260,050
Tech Costs (Tables I & II)	21,151,313
Travel	24,000
Other Direct Costs	
Telephone	90,000
Postage	30,000
Duplicating	90,000
Printing	120,000
Office supplies	33,020
Computer costs	125,000
Facility leasing	275,000
Indirect Costs	890,000
TOTAL COSTS	$28,228,566

References

1. Crandall BF, Robertson RD, Lebherz TB, King W, Schroth PC, "Maternal serum alpha-fetoprotein screening for the detection of neural tube defects," *Western Journal of Medicine*, 138:524-529, 1983.

2. Wetherall RC, "Emergency regulations for filing," R-93-94, *NTD* Reporting, October 9, 1985.

3. Zoler ML, "Genetic testing creating a deluge of dilemmas," *Medical World News, p. 48, Sept. 22, 1986.*

4. *ACOG Technical Bulletin*, #67, October, 1982.

5. Council of Scientific Affairs, "Maternal serum alpha-fetoprotein monitoring," *Journal of the American Medical Association*, 247:1478-1482, 1982.

6. "Prevention 1990: California's Future," Department of Developmental Services, DHS, p. 41, Aug. 30, 1984.

7. Crandall BF, *ibid.* p. 526.

8. Kaye CI, MD, PhD, at the Cook County Graduate School of Medicine, Chicago, April 30, 1986.

9. Myhre, Carolyn, personal communication. Coordinator, the San Diego-Imperial Counties Regional Center, The California Alpha-Fetoprotein Screening Program, Sept. 15, 1986.

10. Cuckle H, Wald N, "Report of UK Collaborative Study on alpha-fetoprotein in relation to neural tube defects," *Lancet*, 1:1332, 1977.

11. Milunsky A, Alpert E, "Results and benefits of a maternal serum alpha-fetoprotein screening program," *JAMA*, 252:1438, 1984.

12. Stillman PC, Hoffman JK, "AFP anxiety," *California Physician*, 145:393, 1986.

13. Koop CE, Statement. Public Relations Office of the Surgeon General of the United States, June 12, 1986.

14. Marwick C, "Controversy surrounds use of test for open spina bifida," *JAMA*, 250:576, 1983.

15. Marwick C, *ibid.*, p. 577.

16. Simpson JL, "Genetics for the practicing physician," *ACOG Advances in Obstetrics and Gynecology*, 1(5601):56, 1985.

17. Simpson JL, *ibid.*, p. 62.

18. Stark, GD, *Spina Bifida: Problems and Management*, (London: Blackwell Scientific Publications, 1977), pp. 6, 7, 17.

19. Martin LW, Torres AM, "Omphalocele and gastrochesis," *The Surgical Clinics of North America*, 65:1235, 1985.

20. Simpson JL, *op. cit.*

21. Mahour GH, "Omphalocele," *Surgery, Gynecology and Obstetrics*, 143:822, 1976.

22. Wald NJ, Cuckle HS, et al, "Early antenatal diagnosis of exomphalos," *Lancet*, 1:1368, 1980.

23. Martin LW, *op. cit.*, p. 1243.

24. Simpson JL, *Genetics*, Council of Residency Education in Obstetrics and Gynecology, Washington, D.C., 1986, p. 43.

25. Macri JN, "Critical issues in prenatal maternal serum alpha-fetoprotein screening for genetic anomalies," *American Journal of Obstetrics and Gynecology*, 155:245, 1986.

26. Myhre C, *op. cit.*

27. Prevention 1990: California's Future, *op. cit.*, p. 43.

28. Medi-Cal Advisory, Computer Science Corporation, 1986.

29. *Hastings Center Report*, 15:18, 1985.

30. Marimon P, *Sequelae of induced abortion*, 1984.

31. Berkowitz RL, in *ACOG Update: Alpha-fetoprotein*, 10:2, 1984.

32. *Hastings Center Report, op. cit.*

33. Kizer KW, Notice of public hearing on emergency regulationsof the Dept of Health Services regarding NTD reporting, DHS, pp. 1-2, Oct. 7, 1985.

34. Cunningham G, *Fiscal Impact Analysis*, December, 1985.

35. Statement of Informed Consent/Refusal for Alpha-Fetoprotein Screening, in *Prenatal Screening Tests for Neural Tube and Other Birth Defects*, Genetic Disease Branch, DHS, 1986.