

**Median Vaccination Levels at the Second Birthday
Retrospective School Enterer Surveys - School Year 1991/92
Excluding Territories
by Universal Purchase Status**

Universal Purchase States: Connecticut, Maine (excluding polio), Massachusetts, New Hampshire, Vermont, Wyoming and Alaska
Reports not received from South Dakota and Michigan (DTP only)

Vaccination	Universal Purchase	Other Areas
4:3:1	62.2% (78.9-52.7) [N=6]	55.8% (69.5-17.9) [N=43]
4DTP	65.8% (73.3-56.6) [N=6]	56.6% (72.1-20.5) [N=40]
3Polio	83.4% (85.4-68.5) [N=5]	71.3% (88.9-49.8) [N=40]
MMR	84.3% (90.8-73.7) [N=7]	76.5% (85.0-47.2) [N=41]

Note: Universal Purchase areas - Alaska consistently the lower range value.

- Kindergarten and first grade children surveyed during school year 1991/92 were generally born during 1985 and 1986. These children would have been included under universal purchase of vaccine for the years 1985-1988, depending upon the grade surveyed.
- Universal purchase states included have been providing DTP, polio, and MMR continuously since at least 1985. Maine only provides DTP and MMR. Maine was excluded from estimates for 4:3:1 and polio.
- Idaho discontinued universal purchase for the years 1986-1989. Children in the Idaho survey were 5 years of age at the time of the survey and would have been receiving their vaccinations during the time universal purchase had been discontinued. Therefore, Idaho has been included in the 'Other Areas'.
- Washington State began universal purchase for the first time in late 1990 and has been included in the 'Other Areas'.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

December 15, 1992

Dear Colleague:

Thank you for your efforts to improve collection of preschool immunization assessment data for each of the immunization projects.

As you remember, the collection of assessment data for children at their second birthday was a reporting requirement, beginning with the 1991-1992 school year. The document, "Sampling Procedure for Conducting Immunization Assessment/Validation Surveys for School and Day Care Centers, Retrospective Surveys Using School System Databases and Guidelines for Public Health Immunization Clinic Audits for Immunization Project Areas" (dated July, 1992) outlined the procedure for collecting these data. This procedure was presented at the 25th National Immunization Conference in June 1991, and was also used to conduct retrospective immunization surveys of children at their second birthday in 20 cities/counties and in one rural area during 1991 and 1992.

Enclosed with this letter is information which we plan to publish in the near future. As of November 13, 1992, 51 immunization projects have submitted immunization assessment reports for children 2 years of age. Two of these projects submitted current data rather than conducting the recommended retrospective immunization survey. It has taken an unusual amount of time for several projects to complete this data collection process for the 1991-1992 school year. Disappointingly, 10 projects have not yet submitted reports and two projects were unable to collect data during this past school year.

The provisional results from the 1991-1992 school year have been summarized in both tabular and map format. Remember that the data for children entering school during this past school year represent the immunization status at their second birthday. Critics will say this is "old data" and "does not present the current situation," which is true. However, these surveys are record-based, population-based and are relatively inexpensive to conduct.

It is remarkable to note that all the results present fairly low, up-to-date (DTP4, OPV3, MMR) immunization levels for these children. Sixteen immunization projects reported immunization levels below 50 percent. Only four projects

reported levels above 66 percent and one (Palau) reported levels above 80 percent. The project-by-project "4:3:1" immunization levels are presented in the enclosed table and map. Please notice that "3:3:1" and antigen specific (DTP4, OPV3 and MMR) are presented in the table. These data indicate that much work must be done, both to improve the data collection process in terms of timeliness and to improve the up-to-date ("4:3:1") immunization levels for children at their second birthday in terms of the vaccine delivery process.

A brief summary shows antigen specific, median levels and ranges of:

	<u>N</u>	<u>Median</u>	<u>Range</u>
4:3:1	50	55.9%	17.9%-100%
MMR	49	76.7%	43.0%-100%
DTP 4+	46	57.5%	20.5%-100%
Polio 3+	47	73.7%	41.0%-100%

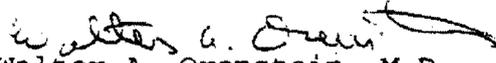
These results, both the median and the individual estimates (excluding Palau), when compared to the 90 percent goal by the Year 2000, indicate how far we have to go. Using these data as a springboard, we hope to dramatically increase both our antigen specific and up-to-date preschool immunization levels.

The 21 cities/counties/rural areas mentioned above collected similar retrospective immunization information with the direct assistance of CDC staff. A more in-depth analysis of those data sets suggested that more than 90 percent of our preschool population received their first immunization during their first year of life (Retrospective assessment of vaccination coverage among school-aged children--selected U.S. cities, 1991. MMWR 1992:41(6):103-7). Other studies have presented data confirming that a very high percentage "get into the delivery system," but a substantial number drop out before their second birthday.

In bringing this to your attention, I encourage you to analyze your retrospective school immunization data for the present school year in more detail. An in-depth analysis can be completed by using two retrospective survey analysis software packages developed by the Data Management Branch. These data sets "bring alive" a description of the recent past history of the vaccine service delivery system in your area.

Please submit data for the 1992-1993 school year to the Division of Immunization by April 1, 1993. You will need to contact Ron Teske with the Program Services Branch at (404) 639-1414 if you are unable to meet the deadline. If you have any questions about the survey analysis software packages, conducting the survey or analysis of survey data, please contact Betty Zell, John Stevenson or Don Eddins of Data Management Branch at (404) 639-1884.

Sincerely yours,


Walter A. Orenstein, M.D.
Director
Division of Immunization
National Center for Prevention Services

2 Enclosures

cc:
Regional Offices
Immunization Program Managers
Immunization Program Consultants

Retrospective Survey Results of Immunization Status
of Children at Second Birthday
by Immunization Project: School Year 1991/92
United States
(Reports Received by 13 November 1992)

PROJECT	GRADE	4:3:1	3:3:1	DTP4	POL	MMR	ANY
CONNECTICUT	K	59.4	71.2	62.0	83.4	78.3	88.6
MAINE	K	65.29	75.29	72.61	82.87	85.19	98.64
MASSACHUSETTS	K	64.92	75.63	69.57	84.93	84.25	97.79
NEW HAMPSHIRE	1	78.9				89.0	
RHODE ISLAND	K	67.6	79.7	72.1	88.9	85.0	98.4
VERMONT	NR						
NEW JERSEY	1	50.2	65.0	58.3	62.5	64.5	97.2
NEW YORK STATE	K	55.8	70.4	59.8	79.4	81.8	97.7
NEW YORK CITY	K	37.8	46.4	47.8	56.8	70.5	95.3
PUERTO RICO	K	38.4	61.1	41.5	79.2	67.2	96.7
VIRGIN ISLANDS	K	38.0	40.0	39.0	41.0	43.0	68.0
DELAWARE	NR						
DISTRICT OF COLUMBIA	K	38.7	55.2	43.4	73.8	61.6	85.1
MARYLAND	1	56.6	69.5	62.2	79.8	80.5	97.7
PENNSYLVANIA	K	58.1	74.6	62.2	78.7	79.4	100.0
VIRGINIA	K	57.8	68.74	65.2	76.61	78.78	96.46
WEST VIRGINIA	K	48.1	61.1	51.5	68.8	77.3	97.8
ALABAMA	K	57.0				81.0	
FLORIDA	K	49.3	62.2	53.8	72.2	70.8	95.8
GEORGIA	K	50.64	63.76	52.96	70.27	76.65	94.43
KENTUCKY	K	60.3		63.1	69.6	83.0	
MISSISSIPPI	NR						
NORTH CAROLINA	1	58.1	72.0	60.0	79.1	81.7	97.7
SOUTH CAROLINA	NR						
TENNESSEE	CUR	69.5					
ILLINOIS	K	60.7		63.6	76.1	69.4	
CHICAGO-PUBLIC SCH	K	27.3	34.7	35.6	49.8	47.2	82.4
INDIANA	K	56.0		59.0	75.0	76.0	98.0
MICHIGAN	NR						
MINNESOTA	K	61.4	68.3	64.7	73.7	82.8	97.4
OHIO	K	51.0	57.0	59.0	69.0	78.0	96.0
WISCONSIN *	K	60.9	72.0	63.0	77.9	83.7	96.5
ARKANSAS	K	42.0	53.4	44.4	58.3	73.9	96.0
LOUISIANA	K	58.0	58.0	61.0	71.0	77.0	97.0
NEW MEXICO	K/1	54.8	53.4	65.0	60.5	76.5	95.4
OKLAHOMA	K	56.7		45.4	62.0	75.5	
TEXAS	DNC						
HOUSTON	K	17.9	49.6	20.5	64.3	59.5	84.3
SAN ANTONIO	K	58.0	66.0	42.0	65.0	68.0	93.0
IOWA	K	51.73	59.75	53.4	63.92	78.01	95.76
KANSAS	K	58.4		61.2	77.4	79.9	
MISSOURI	K	44.1	61.2	48.8	71.6	70.8	94.0
NEBRASKA	K	65.0	77.0	70.0	84.0	85.0	99.0
COLORADO	K	60.8					
MONTANA	K	53.2	77.0	53.6	65.5	80.4	
NORTH DAKOTA	CUR	58.3	63.1	61.0	65.8	74.8	99.4
SOUTH DAKOTA	DNC						
UTAH	K	35.8	46.6	37.9	64.5	57.5	78.5
WYOMING	NR						
AMERICAN SOMOA	NR						
ARIZONA	K	48.7	64.9	53.1	78.9	70.7	93.4
CALIFORNIA	K	48.2	62.7	54.1	77.6	70.2	94.9
GUAM	NR						
HAWAII (PUB SCH)	K	60.8	54.5	64.0	76.7	80.8	96.3
NEVADA	1	41.6	56.8	44.5	67.2	71.2	94.7
FED. STATES/MICRONESIA	1		97.1		97.3	97.9	
PALAU	1	100.0		100.0	100.0	100.0	
MARSHALL ISLANDS	NR						
NORTHERN MARIANA	NR						
ALASKA	K	52.7	59.4	56.6	68.5	73.7	95.0
IDAHO	K	49.4	59.6	52.6	66.2	72.2	93.9
OREGON	1	47.2	58.8	50.5	69.2	72.5	94.4
WASHINGTON	K	50.5	66.2	54.8	75.9	76.0	97.1

K - Kindergarten

1 - First Grade

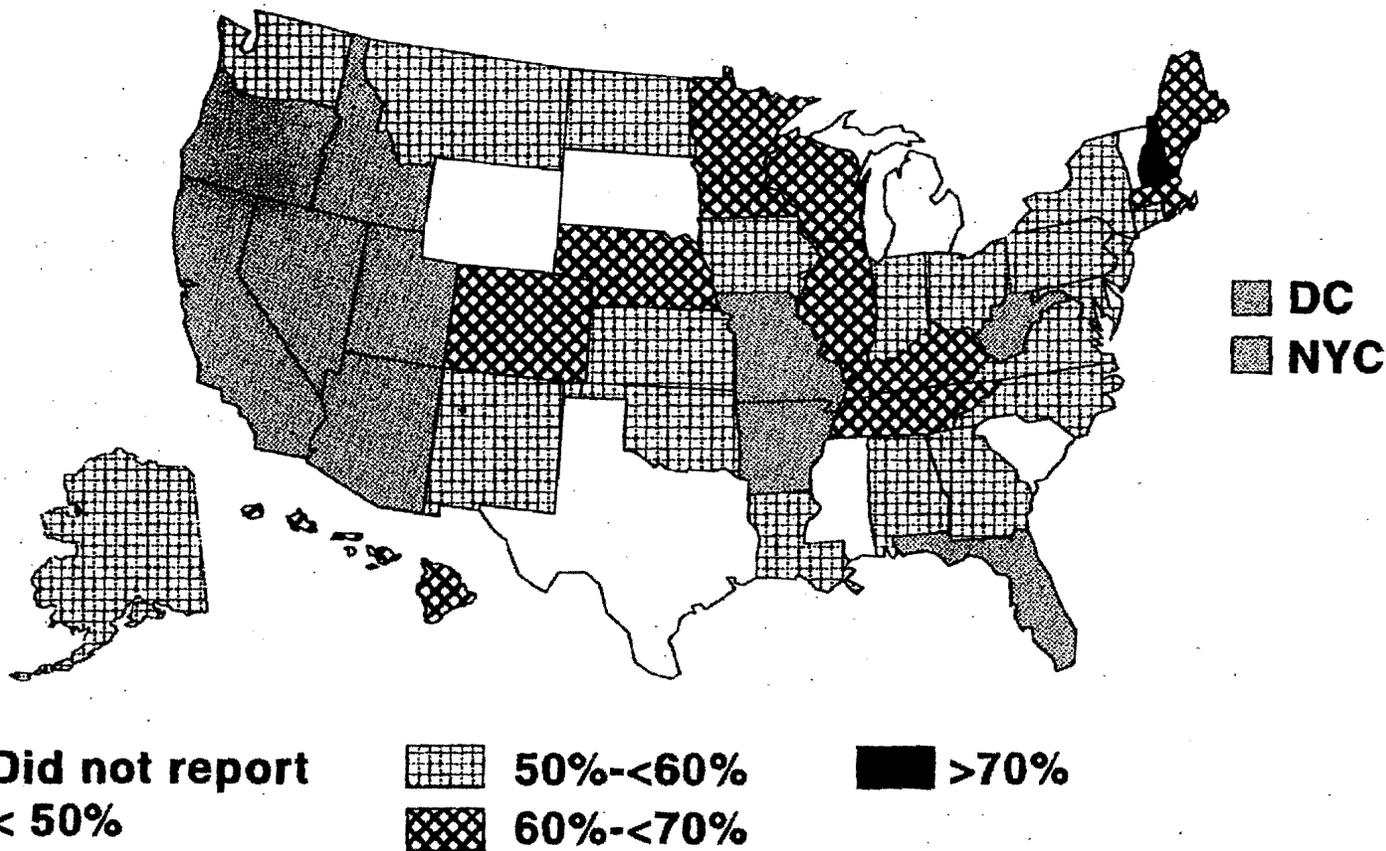
* - Excludes Milwaukee

NR - Reports not received

CUR - Current information, i.e., not retrospective

DNC - Did not conduct survey

Immunization Status* of School Enterers** at the Second Birthday, U.S., 1991-1992



* 4 DTP, 3 Polio, 1 MMR

** North Dakota & Tennessee results from children 2 years of age 1991

Reports received as of November 13, 1992



OFFICE OF MANAGEMENT AND BUDGET

**Legislative Reference Division
Labor-Welfare-Personnel Branch**

Telecopier Transmittal Sheet

*Recommendation
was made
NOT to send
letter per
Janet Forsgren*



*JUL 28 RECD
3:50 pm
PV*

*Janet:
Failed to
Cookie last
evening
7/27/93
OK - Pat*

FROM: Janet Forsgren -- 395-3925

DATE: 7/27/93

TIME: 6:00 PM

*No need
to do
anything*

Pages sent (including transmittal sheet): 4

COMMENTS: HHS WOULD LIKE TO SEND THIS LETTER TO THE RECONCILIATION CONFEREES ASAP ON WEDNESDAY, JULY 28TH. PLEASE GIVE YOUR COMMENTS TO BOB PELLICCI BY 10:30 AM ON WEDNESDAY. HIS PHONE NUMBER IS X 4871

TO: NANCY-ANN MIN
HOWARD PASTER
COOKIE WALDEN (SARA ROSENBAUM)
JOHN ANGELL

RECONCILIATION

FINAL
DRAFT LETTER TO CONFEREES: IMMUNIZATION 7/27: S.W.A.M.

Dear Conferees:

As the conference deliberations on reconciliation draw to a close, I again urge your unqualified support for the President's childhood immunization initiative. It is imperative that the conferees support a compromise that 1) makes vaccines available where children are - in doctors' offices; 2) rebuilds our Nation's immunization delivery, outreach and education systems; and 3) uses federal and state purchasing power to expand the availability of lower priced vaccine.

In addition, I am taking this opportunity to share my thoughts with you on key immunization related issues, including vaccine affordability, vaccine bulk purchase and measures to compel public assistance recipients to immunize their children.

Everyone agrees that the United States childhood immunization rate is deplorable. Also, there is a consensus that a range of barriers exist to getting children immunized. Most recognize that a comprehensive solution, addressing each of the barriers to immunization, is the best means of significantly increasing our child immunization rates. Finally, there is widespread agreement that the best solution would increase the number of children being immunized at an appropriate age by their own providers of primary care, especially those seeing private physicians.

Vaccine affordability is one of the major barriers to age-appropriate immunization. Last week, a new General Accounting Office (GAO) report to Chairman Dingell found that it is not possible with available data to quantify specifically the impact of vaccine prices alone--or for that matter for each of the relevant factors--on immunization rates. The GAO report noted that the average immunization rates in "states distributing free vaccine to all children was 66%, compared to 57% in other states," and concluded that "while policies designed to affect vaccine prices alone would not be sufficient to achieve the Public Health Service's goal for the entire country, providing free vaccines may increase the immunization rate."

Another GAO report released in March 1993, Childhood Immunization: Opportunities to Improve Immunization at Lower Cost, found that 9 European countries that provide universal access to vaccines showed preschool immunization rates substantially higher than those found in the United States.

These GAO studies, like many others, support the belief strongly held by the Clinton Administration that an effective immunization strategy must be a comprehensive one that addresses all barriers that inhibit children from receiving vaccines. The Administration has always argued that vaccine affordability is only part of a comprehensive solution and is not, in and of

itself, the only answer to increasing immunization rates.

Public purchase and distribution of vaccine to private doctors' offices addresses another key barrier to immunization--ease of access. Studies have shown that unvaccinated children do have multiple contacts with private doctors but that the cost of vaccines and immunization services is causing patient shifting from private doctors' offices to already overburdened public health clinics where vaccines are usually free. However, because of understaffing, long clinic waits, short clinic hours as well as transportation and other related barriers to reaching a second site, many of these children are not being immunized. That is why it is all the more important to provide vaccines where the children are--at the doctors' office.

I believe that an expanded federal bulk purchase program would increase the number of children immunized. I am hopeful that the conference committee will include provisions to expand access to vaccines for children who currently are not eligible to receive free vaccine. Under the House-passed immunization plan, all Medicaid children and all children without private insurance for immunization benefits would be eligible for free vaccine. According to the Congressional Budget Office in addition to the Medicaid children already eligible, approximately 7.8 million additional children would be covered under the House-passed bill. Unfortunately, under the Senate-passed version no additional children would be eligible for free vaccines. As the conference weigh competing budget pressures to determine the number of children we can afford to serve this year, it should be clear that the Senate passed number of zero is unacceptable.

In addition to federal purchase authority, I would like to highlight other provisions that address key barriers in our comprehensive immunization initiative.

A critically important provision is the state option to purchase additional vaccines with state funding at the CDC price--like all taxpayers, residents in states which purchase vaccines in bulk are entitled to the best available price for their hard earned dollars. This provision is vitally important to the twenty-three States that now purchase vaccines in bulk at the CDC price and to those additional States that have requested, but have so far been denied, the CDC price from vaccine manufacturers.

Second, we must rebuild our decayed immunization infrastructure at the state and local level. Strengthening our vaccine delivery system by increasing the availability of immunization services at clinics, by providing for immunization registries, and by launching an ongoing outreach effort to educate parents and providers is a keystone to our comprehensive strategy.

We must continue to explore approaches for increasing parental responsibility so that parents get their children immunized. As part of that effort, the Administration has proposed language

that directs the Secretary to conduct 5 Aid to Families with Dependent Children demonstration projects to develop successful strategies that accomplish the goal.

In closing, I would urge that the Conference Committee measure provide a multi-faceted, comprehensive solution, with provisions for strengthening immunization services at the State and local level, increasing parent and provider education and outreach programs, and for providing vaccine without charge to those families least able to afford it.

Donna Shalala

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FILED
NOV 6 1992
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

5616

The People of the State of California ex rel.)
Eloise Anderson, Director of the California)
Department of Social Service, in her official)
capacity,)
Plaintiff,)

No. C923930VRW

POINTS AND
AUTHORITIES IN
SUPPORT OF MOTION
FOR PRELIMINARY
OR PERMANENT
INJUNCTION

v.)

DATE: 11/13/1992
TIME: 10:30
DEPT:

Dr. Louis Sullivan, Secretary of the U.S)
Department of Health and Human Services,)
in his official capacity; and)
JoAnne Barnhart, Assistant Secretary of the)
Administration for Children and Families,)
in her official capacity,)
Defendants.)

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1 **I. INTRODUCTION**

2 Amicus California Consortium for the Prevention of Child Abuse (Consortium) files
3 this memorandum of points and authorities in support of an injunction directing the U.S.
4 Department of Health and Human Services (DHHS) to distribute to California its
5 proportionate share of the funds available to eligible states under the Child Abuse
6 Prevention and Treatment Act (CAPTA), 42 U.S.C. section 5101 et seq. The Consortium
7 supports the State and presents additional, separate argument in its request. While 46 other
8 states are currently able to support their child abuse prevention programs with CAPTA
9 funds, California is denied funds categorically.

10 The Consortium also supports, in the alternative, the continuation of the TRO now
11 in force in the form of a preliminary injunction pendente lite. Such a preliminary injunction
12 maintains the status quo by assuring the funds here in dispute will be available for
13 distribution to California should the State prevail in this litigation.

14 **II. PLAINTIFFS ARE ENTITLED TO A PERMANENT INJUNCTION AND ORDER**

15 **A. Introduction**

16 The rejection of California CAPTA funding here at issue has occurred in a manner
17 requiring clarification. DHHS argues that the standard of review for the permanent
18 injunction is narrow and that the court's inquiry is circumscribed to the "administrative
19 record." The defendants' Motion to Strike the declarations of experts Professors Wald and
20 Fellmeth similarly refers to an "APA" administrative record that declarants presumably
21 improperly contradict.

22 The actual procedural history of this case is that the State of California applied to
23 DHHS for CAPTA funds which would be spent under state contract by Consortium
24 members for the benefit of California children. DHHS announced its objection to certain
25 California laws, communicated with certain State officials regarding these objections,
26 received an Attorney General letter seeking to explain California law, and then issued a
27 final rejection letter shortly before the October 1, 1992 funding date. DHHS' denial of
28 CAPTA funds was never subjected to any notice or hearing process. Rather, the denial was

1 an administrative decision after limited private discussions with several state officials.
2 Although Defendants' declarations of Lloyd, Wright, and Gillet indicate an allegedly
3 complicated procedure of weighing and discussing the adequacy of respective state systems,
4 followed by consideration of "waivers" or informal extension to certain states based on "good
5 faith" efforts to comply, these proceedings are entirely private and in-house, or with certain
6 state officials. No open process existed.

7 The involvement of the Consortium or the Children's Advocacy Institute (CAI), here
8 serving as counsel for the Consortium, was limited to comments to the State concerning the
9 prospective denial. The Consortium and CAI are aware of no person or organization,
10 including themselves, who had any formal communication with DHHS about the denial.
11 DHHS never invited such comment. The failure to give APA notice or to provide for public
12 comment or hearing in any form precluded any give and take. No discussion or review of
13 DHHS' denial criteria occurred in the manner countenanced by APA procedure or due
14 process standards. The Consortium and its members, whose interest in this action arises as
15 likely beneficiaries of the funds at issue, have had no prior opportunity to object to DHHS'
16 regrettable decision. There is simply no APA administrative record for the court to review
17 in this case; DHHS never complied with the APA. The standard of review and the factual
18 setting of this case involves the review of an administrative decision made without a public
19 record.

20 From the outset, two unexpected DHHS' approaches exacerbated the substantive
21 problems with its methodology in considering California's compliance. First, DHHS
22 consistently claimed that a consideration of caselaw is inappropriate to interpret California
23 statutes in weighing their compliance with federal standards. (See Declaration of Professor
24 Robert C. Fellmeth.) The Consortium respectfully contends that all statutes are properly
25 considered in light of judicial interpretation of their meaning. Second, the defendants have
26 contended that California would be evaluated tabula rasa and without regard to any other
27 state. Id. The Consortium objects to this premise as well, and contends that a denial of
28 funds to one state based on an alleged statutory term commonly found in the law of other

1 states receiving funding constitutes a clear abuse of discretion warranting reversal. One
2 constant in judicial review of administrative actions is an insistence on uniform, consistent
3 standards, equitably applied.

4 B. The Applicable Standard of Review

5 The relevant statute for the judicial review of administrative agency decisions, 5
6 U.S.C. section 706, provides:

7 To the extent necessary to decision and when presented, the reviewing
8 court shall decide all relevant questions of law, interpret constitutional
9 and statutory provisions, and determine the meaning or applicability
10 of the terms of an agency action. The reviewing court shall...

11 * * *

12 (2) hold unlawful and set aside agency action, findings, and conclusions
13 found to be...

14 * * *

15 (A) arbitrary, capricious, an abuse of discretion, or otherwise not in
16 accordance with law;

17 (B) contrary to constitutional right, power, privilege, or immunity;

18 (C) in excess of statutory jurisdiction, authority, or limitations, or
19 short of statutory right....

20 Here, the dispute arises primarily from the legislative intent of the applicable federal
21 substantive statute (Subsection B of CAPTA), DHHS' interpretation of regulations (45
22 C.F.R. section 1340.14), state statutory law, and interpretive state caselaw. Each of these
23 areas of inquiry involves interpretation of law, which is within the domain of a reviewing
24 court. Pollgreen v. Morris, 770 F.2d 1536 (11th Cir. 1985), reh. den., en banc, 781 F.2d 905
25 (11th Cir. 1985).

26 Under 5 U.S.C. section 706(2)(A), discretionary agency decisions are reviewable for
27 abuse of discretion. Wolchuck v. Bowen, 871 F.2d 869 (9th Cir. 1989). Even the rational
28 basis test considers whether the decision was "based on the relevant factors" and whether
that has been a clear "error of judgment." Western & Southern Life Ins. Co. v. Smith, 859
F.2d 407 (6th Cir. 1988). Even where an agency is interpreting its own regulation involving
its expertise, the deference given to it is limited:

As where the courts review an agency's construction of a statute which
the agency administers, the deference owed to an expert tribunal

1 Although Arizona has a very similar statute, DHHS contends its additional statute closing
2 "initial" records provides compliance. Def. P&A in Opp. to PI at 14. But "initial" is not
3 defined and has different meanings for child abuse reporting. "Initial" could mean the first
4 call to police or a child protective service. The reporter of child abuse is then interviewed
5 by an investigator, but as this is not the "initial" report, the investigative interview would
6 then be disclosable. Another meaning could reasonably be considered. Frequently, a child
7 abuse or neglect investigation has multiple reports over time. An "initial" report would then
8 be the first report and investigation in time, so that all subsequent reports and investigations
9 could be disclosed. Because Arizona continues to have its own balancing test, the new
10 window-dressing statute is irrelevant and would not prevent a disclosure of the identity of
11 the child abuse reporter. DHHS' acceptance of the Arizona statute may arise from its lack
12 of knowledge of actual child abuse reporting.

13 Given the intent of the confidentiality regulations, DHHS abused its discretion by not
14 even considering how California actually implements confidentiality. Although Charles
15 Gillet claims to have considered caselaw (Declaration at p. 3), no California case which has
16 ever released information in violation of federal sensibilities has been cited. The
17 Consortium believes that none can be cited; they do not exist.

18 **4. DHHS Claims California Permits Impermissible Deference to Religion**
19 **in Child Abuse Reporting and Intervening**

20 The relevant DHHS regulation, 45 C.F.R. section 1340.2(2)(ii), provides:

21 Nothing in this part should be construed as requiring or prohibiting a
22 finding of negligent treatment when a parent practicing his or her
23 religious beliefs does not, for that reason alone, provide medical
24 treatment for a child; provided, however, that if such a finding is
prohibited that prohibition shall not limit the administrative or judicial
authority of the State to ensure that medical services are provided to
the child when his health requires it.

25 The state's definition of "neglect" for reporting purposes, at Penal Code section 11165.2,
26 includes the paragraph:

27 For the purposes of this chapter, a child receiving treatment by
28 spiritual means...or not receiving specified medical treatment for

1 religious reasons, shall not for that reason alone be considered a
2 neglected child. An informed and appropriate medical decision made
3 by parent or guardian after consultation with a physician or physicians
4 who have examined the minor does not constitute neglect.

5 In part, WIC section 300(b), describing a neglected child who comes within the jurisdiction
6 of the juvenile court, provides:

7 Whenever it is alleged that a minor comes within the jurisdiction of
8 the court on the basis of the parent's or guardian's willful failure to
9 provide adequate medical treatment or specific decision to provide
10 spiritual treatment through prayer, the court shall give deference to the
11 parent's or guardian's medical treatment, nontreatment, or spiritual
12 treatment through prayer alone in accordance with the tenets and
13 practices of a recognized church or religious denomination, by an
14 accredited practitioner thereof, and shall not assume jurisdiction unless
15 necessary to protect the minor from suffering from serious harm or
16 illness. In making its determination, the court shall consider....
17 (emphasis added)

18 DHHS first objection (letter, at page 3) is that the reporting statute, Penal Code
19 section 11165.2 above, is "ambiguous" because it focuses on the child as possibly neglected,
20 rather than the "status of the parent to be affected." But it is DHHS which is confused.
21 Why should this provision of law focus on "parents"? This is not a criminal statute for child
22 neglect in withholding treatment out of religious conviction. This statute has to do with
23 reporting to the juvenile court; it is not germane to adult criminal jurisdiction—that is found
24 elsewhere. At the time of reporting and in juvenile court, the child's status is at issue, not
25 the parents' culpability. After testimony, the court simply orders the appropriate medical
26 treatment for the child. Other than an objection to grammatical style, DHHS' concern is
27 irrelevant to the issue—the protection of children.

28 DHHS' position on this issue is also contradictory. Its own definition of the
applicable regulation, 45 C.F.R. section 1340.2(d)(3), states: "(T)hreatened harm to a child's
health or welfare means a substantial risk of harm to the child's health or welfare"
(emphasis added). WIC section 300(b) varies from this regulation only in that it uses
"serious" rather than "substantial." California clearly complies with the language of the
regulation. See the attached Declarations of David Chadwick, MD, and Professor Michael

1 Wald.

2 The Consortium is extremely concerned with the effect of the letter's
3 recommendations. Does government really want parents reported because they pray when
4 their children are sick? Some harm is threatened in every cold, tummy ache, fever, and
5 earache for children. If parents pray as to sprains and minor ailments and only seek
6 medical attention when a child is seriously ill, should the state remove these children from
7 their parents?

8 In the Consortium's experience, California has no religious exception for reporting,
9 investigating, and prosecuting parents for child abuse and neglect. The Declaration of
10 Professor Michael Wald is instructive as to the appropriate language in California statutes
11 and caselaw. DHHS' interpretation exceeds the reasonable words of its own regulation;
12 where there is a threat of serious harm, the juvenile court is empowered to take custody of
13 the child and order medical treatment. DHHS' interpretation is facially unreasonable and
14 an inaccurate description of the law and its enforcement in California. It is unclear what
15 California would have to do to comply that it does not already do.

16 Again, virtually every state has language similar to the wording of the California
17 statutes here discussed. DHHS admits that California's so-called religious exemption
18 statutes it deems objectionable are nearly identical to those in 37 other eligible states. In
19 addition, this review for religious deference was begun in 1990. Def. P&A in Opp. to PI at
20 8-9. With two years to review state statutes, only California is ineligible for funding.
21 Apparently, although California is in the identical statutory position as 37 other states, the
22 lack of funding was not related to eligibility but due to a personalized DHHS interpretation
23 of "due process and fairness." Oct. 2 Dec. of David Lloyd, p. 10.

24 **E. The Standards Here Demanded of California Are Not Applied to Any Other**
25 **State; Most Have Provisions Identical to the California Statutes Here at**
26 **Issue—None Have Been Denied Funds**

26 The Defendants' Memorandum of Points and Authorities in Opposition to
27 Preliminary Injunction correctly quotes from Section 110(b) of CAPTA as to the mandatory
28

1 standard for DHHS administration of CAPTA funds as follows: "Section 110(b)...requires
2 the Secretary to 'establish criteria designed to achieve equitable distribution of assistance
3 under this Act among the States..." (emphasis added, quoting 42 U.S.C. section 5106d(b)
4 at Def. P&A in Opp. to PI at 5). In the same Points and Authorities, DHHS presents a
5 detailed discussion of its own internal administrative procedures (Def. P&A in Opp. to PI
6 at 3-10).

7 As that discussion indicates, federal concern has generally focused on the issue of
8 deference to religion. DHHS points out that it has requested that some states' Attorneys
9 General write opinions clarifying that their statutes do not allow religious practices to
10 supersede the health of a child. [California's Attorney General has provided just such
11 assurances.] DHHS also indicates that seven states were informed that they must change
12 their laws in this regard. DHHS is able to present but two additional examples from among
13 the fifty states of application of any relevant standard objecting to any state child abuse
14 law—outside of California. First is Massachusetts being warned of its use of the term
15 "serious" (to limit child abuse reporting to "serious" abuse); and the other is Georgia
16 allegedly permitting child abuse information disclosure to the public. See Def. P&A in Opp.
17 to PI at 8-10. The Consortium is informed and believes that this discussion and the
18 accompanying Lloyd declaration entirely captures the field in the application of the relevant
19 standards by DHHS.

20 However, none of the states cited have had funds cut off. Taking the examples of
21 defendants seriatim: the seven states which allegedly have offending religious exemption
22 statutes include far greater religious deference than do California statutes, particularly where
23 applicable California caselaw is considered. In fact, the existing laws of most states not on
24 the list of DHHS are less clear than is California law in practice. (See Declarations of
25 Professors Wald and Fellmeth.) DHHS' request of Massachusetts to delete "the qualifier
26 'serious' in its reporting law" (emphasis added, Def. P&A in Opp. to PI at 9) cannot apply
27 to California at all. As noted above, California has no such qualifier to its reporting
28 law—only to its provision conferring juvenile court jurisdiction to supersede parental

1 authority. The final example, that of Georgia, also does not help defendants. The
2 allegation against California is not that it "provides for public disclosure of child abuse
3 reports where the child dies," as with Georgia, but that California has a balancing test
4 permitting courts in some circumstances to disclose such information; a balancing test
5 conforming to a recent U.S. Supreme Court decision constitutionally requiring it.

6 DHHS also cannot argue that the combination of four objections applicable to
7 California warrants distinguishing it. Not only are all four of the objections incompetently
8 made, but as the undisputed declarations of two of the nation's leading experts attest, as to
9 all four of the areas noted, California's laws here objected to generally reflect terms typical
10 of the other states, or are more protective of children. (See Declarations of Professors Wald
11 and Fellmeth; see also analysis of Plaintiff State.) Yet California is here denied funds, and
12 only California. Standards of judicial review of administrative action include notions of
13 consistency. Even if one is consistent between parties, an agency must also be consistent
14 over time, and cannot—without explanation—suddenly impose an unexpected and disparate
15 standard. See Illinois v. Interstate Commerce Comm., 722 F.2d 1341 (7th Cir. 1983).

16 **F. Permanent Injunctive Relief Is Warranted At This Time**

17 DHHS' final argument against a permanent injunction is that no irreparable injury
18 exists to California if the allotment is simply held in reserve pendente lite. DHHS cites two
19 cases for the proposition that the temporary loss of money is not irreparable injury. (L.A.
20 Memorial Coliseum v. N.F.L., 634 F.2d 1197, 1202 (9th Cir. 1980), and Sampson v. Murray,
21 415 U.S. 61, 90 (1974), Def. P&A in Opp. to PI at 20-21.) The N.F.L. case involved a
22 contract dispute between two parties over money. Sampson v. Murray found injunctive
23 relief premature where administrative appeals had not been exhausted. This case is far
24 different. Here, CAPTA funds provide direct services for abused children and are designed
25 to prevent that abuse. This case is not about money damages to a party, but about money
26 specifically designated for an empirical purpose and for the benefit of third parties. Its
27 deprivation causes a hardship to those for whom it was intended. (See Declarations of
28 Goldberg, Lever, and Chadwick filed with the Consortium's Motion for Intervention and

1 Preliminary Injunction, respectively).

2 The nature of the hardship at issue is irreparable in two distinct respects. First, it
3 is irreparable because the money is intended to be used now for programs which prevent
4 child abuse. Moneys were scheduled for disbursement and were rightfully expected as of
5 October 1, 1992. As time passes, the money lost for those programs cannot be
6 recompensed. The services are not provided; children who are not served as the money is
7 sequestered, and abuse which is not caught or prevented, are not remediated by a later
8 infusion of money. In the most classic sense, the remedies at law are inadequate. No later
9 arriving moneys, even with a significant bonus, will ameliorate the harm which could have
10 been prevented had these moneys been forthcoming earlier—as intended by federal law.

11 Second, the nature of the harm is not compensable through damages; beatings and
12 molestations comprise child abuse. Indeed, no such damage remedy available by statute or
13 through these proceedings can compensate the victims. The remedies at law are not only
14 inadequate; they do not exist.

15 The relief sought in these circumstances may take the form of a mandatory
16 injunction, or a writ of mandamus. A writ, as requested in the complaint of the State, is
17 issuable to an executive official under the instant circumstances. The court has the power
18 to order an action which, if not taken, would constitute an abuse of discretion. See Wilbur
19 v. United States, 280 U.S. 306 (1930); see also Kingsbrook Jewish Medical Center v.
20 Richardson, 486 F.2d 663 (2nd Cir. 1973); Deering Milliken, Inc. v. Johnston, 295 F.2d 856
21 (4th Cir. 1961).

22 **G. Conclusion Regarding a Permanent Injunction**

23 Some states may have deficient statutes not meeting federal standards. But the
24 statutes which are the subject of DHHS objection are not child abuse system flaws. And
25 California is among the last, not the first and only state, deserving approbation on the bases
26 here stated.

27 Did the Congress intend that states should be required to write their statutes as here
28 demanded? To include in mandated reporting "mental injury" without limitation? To

1 remove "serious" from "child abuse" warranting the removal of parental authority? To
2 preclude court discretion to ever order disclosure of abuse records, even under defined state
3 standards and where constitutionally compelled? To remove deference to religious practice,
4 even where specifically limited to circumstances not involving child health and safety? Not
5 many votes could be obtained for these propositions in the Congress. And they will attract
6 no greater support from the California legislature than they would from the Congress,
7 making legislative "cure" – even if consistent with federal law – a practical impossibility.

8 **III. IF A PERMANENT INJUNCTION IS NOT GRANTED AT THIS TIME,
9 PRELIMINARY INJUNCTIVE RELIEF IS COMPELLED**

10 In reviewing requests for injunctive relief, the Ninth Circuit considers the factors of
11 likelihood of success on the merits and the relative hardships to the parties. Vision Sports,
12 Inc. v. Melville Corp., 888 F.2d 609 (9th Cir. 1989). The Court analyzes these factors with
13 some flexibility. In the traditional test, the court considers the likelihood that the moving
14 party will prevail on the merits and whether the balance of irreparable harm and the public
15 interest favor the moving party. In the "alternative" test, if the balance of hardships
16 decidedly favors the moving party, this party must raise only "serious questions" on the
17 merits. Caribbean Marine Services Co., Inc. v. Malcolm Baldrige, Secretary of Commerce,
18 844 F.2d 668 (9th Cir. 1988). At other times, the court describes the traditional and
19 alternative tests not as separate standards but as a relative weighing of the success on the
20 merits and hardship factors. Rodeo Collection, Ltd. v. West Seventh, 812 F.2d 1215 (9th
21 Cir. 1987). However, when a case impacts the public interest, such interest must be
22 considered as an additional factor in reviewing the request for an injunction. Caribbean
23 Marine Services Co., supra.

24 The three salient factors considered for granting injunctive relief—public interest,
25 relative harm to the parties, and likelihood of success on the merits—weigh heavily in favor
26 of California and the Consortium. The Consortium has submitted points and authorities on
27 these three factors and incorporates them by reference here. See Consortium's
28 Memorandum of Points and Authorities in Support of Preliminary Injunction. The

1 Consortium adds the following argument:

2 **A. Balance of Hardships**

3 The CAPTA grant is not general support money for California's general fund, or even for
4 state administration overhead of existing programs. The funds are designated for programs
5 which Consortium members plan, administer, and implement. Although this burden is
6 spread among many organizations, no comparable burden exists either for DHHS or other
7 states. Further, the money is not akin to "damages" for a party, but finances child abuse
8 prevention programs. The loss of funding for specific purposes of abuse prevention has
9 irreparable harm implications assuredly not lost on this Honorable Court.

10 DHHS misstates the relative hardships in this case. Def. P&A in Opp. to PI at 20-
11 22. DHHS claims that 46 other states will be burdened if they do not receive California's
12 funds. This assertion fails to consider that 46 states are already enjoying their own funds.
13 California does not pursue this action to gain other states' share of CAPTA funds, but to
14 request judicial review of what would result in an inequitable bonus to other states from
15 California taxpayers. Indeed, the failure to reserve these funds may work a hardship on
16 other states since they will then possibly expect and plan for a somewhat larger
17 appropriation than might be forthcoming. It is a greater hardship to be deprived with little
18 warning of expected funds than to receive a small additional amount during the year. With
19 the reservation of funds by preliminary injunction, the latter is a minor "hardship"; without
20 it, the more significant and harmful unexpected taking from other states may occur.

21 **B. Plaintiffs Are Likely to Prevail on the Merits**

22 A careful reading of all of the moving papers, exhibits and declarations of DHHS
23 supports the merits of the case for the Plaintiff State.

24 **C. The Public Interest Favors a Preliminary Injunction**

25 Our cases have emphasized...that when the public interest is involved,
26 it must be a necessary factor in the district court's consideration of
27 whether to grant preliminary injunctive relief...The district court must
28 consider the public interest as a factor in balancing the hardships when
the public interest may be affected.

1 Caribbean Marine Services Co., Inc. v. Malcolm Baldrige, Secretary of Commerce, 844 F.2d
2 668, 674 (9th Cir. 1988). The public interest here supports a preliminary injunction. While
3 other states are planning programs with their funds, California and the Consortium are
4 expending considerable resources in their efforts to obtain funds.

5 **IV. CONCLUSION**

6 The Consortium joins the defendants in observing that the Court is in a position to
7 grant a permanent injunction at this point; that is, to make a decision on the merits. The
8 Amicus Consortium respectfully contends that erroneous application of federal law and
9 erroneous interpretation of state law is facially apparent upon an examination of the four
10 bases for denial stated by DHHS. The Consortium also supports the State in its argument
11 that clear facial inconsistency exists in DHHS' review of relevant standards—however
12 flawed—to California while most other states with similar provisions are funded. On each
13 of these grounds independently, this Honorable Court has ample grounds to grant a
14 permanent mandatory injunction and order the disbursement of funds to California for the
15 benefit of its abused children at the earliest possible time.

16 **WHEREFORE**, for the reasons stated above, Amicus Consortium supports that the
17 permanent, mandatory injunction ordering the disbursement of funds to California prayed
18 for be granted, or in the alternative, that a preliminary injunction be granted reserving the
19 relevant sums pendente lite.

20
21 DATE: 11-3-92

Respectfully Submitted,

Kathleen Murphy Mallinger
K. Murphy Mallinger, Children's Advocacy Institute
Attorney for Amicus
California Consortium for the Prevention
of Child Abuse

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

FILED
Oct 9 3 02 PM '92

RICHARD W. WIEKING
CLERK
U.S. DISTRICT COURT
NO DIST OF CA

The People of the State of)
California ex rel.,)
Eloise Anderson, Director of the)
Department of Social Services,)
in her official capacity; and)
California Consortium for the)
Prevention of Child Abuse,)
Plaintiffs)

C92-3930 VRW

Declaration of

Professor Michael S. Wald

v.

Dr. Louis Sullivan, Secretary)
of the U.S. Department of)
Health and Human Services)
in his official capacity; and)
JoAnne Barnhart, Assistant)
Secretary for Children and)
Families, in her official)
capacity,)
Defendants)

I, Michael S. Wald, declare:

I have been a member of the faculty of the Stanford Law School since 1967 and currently hold the Jackson Eli Reynolds Chair. I teach courses dealing with child abuse and neglect, child custody, and public policy towards children and families. I have extensive experience with respect to the operation of the child abuse and neglect system in California and similar systems throughout the country.

From 1972 to 1975, I was a reporter for the American Bar Association's Juvenile Justice Standards Project, drafting the volume entitled Standards Related To Abuse and Neglect. The proposals in this volume have been adopted by many state legislatures as the basis for their child abuse/neglect laws. I was the one of the principal drafters of the Adoption Assistance and Child Welfare Act of 1980 (PL 96-272), the main federal legislation regulating the child welfare area. I also have been involved in the drafting of virtually all of California's laws regarding the legal response to child abuse and neglect. I was a member of the 1980 California legislative task force which drafted the California child abuse reporting law. I was the principal draftsman of SB14 (1981), which established the main elements of the legal structure governing California's child abuse and neglect system and was a member of the 1987 legislatively-appointed task force which revised SB14 and established the current definitions for juvenile court jurisdiction and all of the other substantive

and procedural rules that regulate the legal response to child abuse and neglect. (SB243, 1987). I drafted much of the language in this bill, including the provisions that relate to the relevance of parental religious beliefs in determining the adequacy of medical care of children.

In addition to my legislative activities, I have been actively involved in the administration of the child abuse response system. I was one of the original members of the California State Advisory Committee on Child Abuse and Neglect and served as its chair during 1978-79. I have served as a judge pro tem in juvenile court in San Francisco and Santa Clara counties and have trained judges, social workers and attorneys in virtually every county in California. I served for six years on the board of the National Committee For the Prevention of Child Abuse. I have published numerous articles and books regarding child abuse laws and authored three chapters in the CEB Juvenile Court Practice book.

If called as a witness, I would qualify as an expert in child abuse law and policy, including California's laws and their comparable counterparts in other states.

I have been informed that California has been denied all of the funds for which it applied under the Child Abuse Prevention and Treatment (CAPTA) programs of the federal government by the Department of Health and Human Services of the federal government. I have read the official letter of denial written by Ms. Sharon M. Fujii, which cites four specific alleged deficiencies in California law as a basis for the denial.

In my professional opinion the letter misinterprets the relevant state and federal laws in at least two areas.

1. In her letter, Ms. Fujii indicates that California law does not comply with federal mandates because the term serious modifies the definition of physical harm in Section 300 of the Welfare and Institutions Code. This conclusion reflects a misunderstanding of both federal and California law. Under 42 U.S.C. Section 5106g(4), a state must have a reporting law that meets certain federal requirements in order to be eligible for federal funds. The reporting law must provide, among other things, for reporting to a protective agency any non-accidental physical injury. California Penal Code section 11165.6 clearly requires reports for all such injuries. Welfare and Institutions Code Section 300, to which Ms. Fujii refers, has nothing to do with child abuse reporting, however. Section 300 defines the substantive grounds which must be established before a juvenile court can take jurisdiction over a minor and require supervision of the family or removal of the minor from the parents' home. While 42 U.S.C. Section 5106 requires that certain definitions be used for purposes of state laws regarding reporting and investigation of child abuse and neglect, this statute does not establish any requirements with respect to state statutory laws regarding juvenile court jurisdiction. States are permitted to define

substantive juvenile court law however they wish.

Distinguishing between reporting laws and jurisdictional statutes reflects a considered judgment regarding the best way of protecting children. In general, a reporting law should use broader definitions than those used to establish court jurisdiction. Reporting laws are designed to insure that all possible threats to the well-being of a child are investigated, in order to see how serious a threat there is to the child. Because reporters are not investigators, they are required to report a wide range of possible harms which can then be investigated. Having a broad net at this point can be justified as a means of insuring that no potentially serious situations are overlooked. Since investigation constitutes far less of an intrusion into family life than court involvement it may make sense to tip the scales in favor of looking at a wide range of situations at this stage of the system. For this reason, the federal statute mandates a broad definition if a state wants to apply for federal funds.

Court intervention is a far more serious step - however. Unnecessary intervention can harm children as well as parents. Moreover, the scope of intervention has enormous implications for the use of state resources. The federal statute appropriately leaves it to each state to decide when court intervention is appropriate and how state resources should be used for supervising families or placing children into foster care.

2. The objections raised under point four in Ms. Fujii's letter also are wrong. First, the primary objection seems to be essentially the same one as raised in point number 2, that the word serious cannot be used to modify harm in Section 300. To the extent that it merely restates the previous point it is wrong for the reasons just discussed.

The letter also indicates that Ms. Fujii finds the statutory language indicating that religious treatment of a medical illness is not "alone" a sufficient reason to report a case a child abuse ambiguous. There is nothing at all ambiguous about this language. Penal Code Section 11165.2 on its face requires a report whenever a parent's behavior or inaction endangers a child's health. When a parent's behavior does not endanger a child's health there obviously is no reason that the family ought to be investigated. This is recognized in 42 U.S.C. Section 5106 and 45 C.F.R.1340. The provision regarding treatment by spiritual means merely makes it clear that a child should not be reported if the child is not endangered. It is not the means of treatment but the possibility of harm that requires investigation. Thus, spiritual treatment alone, without evidence of harm or possible harm, is not considered neglect, since the whole purpose of the reporting law is to identify harmful situations. The fact that spiritual treatment threatening or resulting in harm is to be reported was clearly specified in the legislative discussions of this provision, was understood by the representatives of the religious groups that requested this language and is clear on the face of the statute.

It is my opinion that in seeking to deny federal funds on these grounds the government is overreaching its authority under the relevant federal statutes and acting in an arbitrary and capricious manner.

I declare the foregoing to be true and correct this 1st day of October, 1992, in San Francisco, California.



Michael S. Wald

Carol

MEMORANDUM

To: Jerry Klepner
Fr: Sara Rosenbaum
Re: Comments on immunization bill

Thanks for sending along the draft bill. I have written comments directly in the margins but also wanted to summarize my principal notations and suggestions separately.

1. Findings

I am not a big believer in findings, but if you want to use them, then these need to be considerably strengthened. The original decision memorandum summarizes many of the critical facts that ought to appear in these findings, particularly those findings related to the universal purchasing program. By far, this is the most controversial portio of the legislation, yet the findings are virtually barren on this point.

Additional findings making the following points should be added:

- o The "infrastructure" to immunize children is both public and private. There is considerable evidence to suggest that the "private" infrastructure has been damaged over the past decade as a result of the significantly increased cost of privately purchased vaccine.
- o In some cases costs have risen by as much as ___ percent, with private rates exceeding the rates paid for like vaccines in other first world countries by as much as ___ percent.
- o High costs, coupled with the growing number of uninsured and underinsured families mean that increasingly private physicians are referring their private patients to overburdened public clinics for vaccinations. This results in countless missed opportunities. As part of an overall effort to improve childhood immunization rates, therefore, the unraveling of the private system must be addressed.
- o 10 states now have universal programs. Many have been in place for more than 20 years, with virtually no burden or controversy. Numerous other states that have sought to establish such programs have been denied additional discount vaccines by manufacturers.
- o There is no evidence to suggest that a negotiated price that takes into account the reasonable cost of production, marketing, research and development and distribution will

not fairly compensate vaccine manufacturers. Indeed, a recent report by the Congressional Office of Technology Assessment adds support to the notion of negotiated rates that assure fair compensation while holding down costs.

o The Secretary of HHS has experience negotiating vaccine purchase through the federal contract system.

Additionally, I do not understand para. 3, page 3. Is this paragraph meant to address the need for outreach or the need to beef up the public service delivery infrastructure? There is a need for a service delivery improvement paragraph, as well.

2. §2141 (a) The bill should provide for prompt updating of the list as changes occur in vaccines and dosages. The list should be published annually and should apply to all federally funded programs providing or financing vaccines. The point here is to assure that this list is used by HCFA and by state Medicaid programs, as well as by CHAMPUS, OPM, etc. These programs often are well behind in terms of current knowledge about childhood vaccine standards.

3. §2141 (b): The procurement panel should also include the federal agencies that administer programs providing or paying for childhood vaccine (HRSA, HCFA, IHS)

4. §2141 (c): The language should be strengthened to authorize the Secretary to purchase to meet all childhood immunization needs, whether ongoing, current and routine or additional needs caused by public health or other emergencies. I find "current" needs vague.

5. §2141 (c)(3) : You need to clearly state that in negotiating with the manufacturers the Secretary shall take into account the cost of production, research, marketing and distribution. I would not leave any doubt in anyone's mind that the Secretary knows full well what goes into pricing a drug or biological and that she intends to take all factors fairly into account. Assuming that the Secretary is going to have the manufacturers distribute directly (suggested by § 2142(a), page 8) this cost needs to be explicitly laid out.

6. §2143 Tracking

oI see nothing here that authorizes the Secretary to develop one or more tracking models and to require states, as a condition of the receipt of free vaccine, to use an approved model and provide minimum required information to the national system. I have this vision of multiple state tracking systems with chaos at the point at which the federal government tries to make them all fit into the national system.

o While the section does list some data elements that state systems must capture, the section does not require the state to report the data to the Secretary -- just a requirement to "share" it (§2(B))

o Why are states not required to link their immunization systems to their birth records? This permits access to far greater levels of information. Perhaps this is implied by §2(A), but it is unclear.

o Other state agencies (such as state welfare or child support agencies) should be clearly denied access to these data.

7. §2145

I assume that we are sure that the appropriations authorization (§2145) is the magic set of words that guarantees that this will be mandated spending?

8. Section 5 Vaccine Compensation Amendments

Why not permit the payment of retroactive claims (with a capped payout amount annually to control the retroactive flow) from the Trust Fund? If the TF is overfunded and the retro claims are languishing, what is the problem in addressing this?

Didn't you want the authority to delete certain vaccines from the injury table as well? I read the bill as permitting only the addition of vaccines.

9. Medicaid: Not at all addressed here is the requirement that the Medicaid program pay the reasonable cost of administration for all children. Arguably, the waiver of administration language will lead HCFA to claim that the administration is free and therefore that no payments can be made. We definitely will need Medicaid amendments clarifying states' obligation to pay administration fees in my opinion.

have you decided to simply let states keep the Medicaid money they would have paid out for the vaccine and to instead pay for the vaccine out of the new source of funding? I have no objection to that, but this is the import of the bill. I want to be sure that this is what you meant.

10. Infrastructure: Why did you not provide for a set-aside of some of the vaccine funds as "capital development" to engage in ongoing improvements in the public delivery infrastructure? This is consistent with our long term national health reform thinking about funding service delivery through directed spending subject to an annual budget. You leave all infrastructure and

registry activities subject to annual discretionary appropriations (§2145).

Please call if you have questions.



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
CONGRESSIONAL LIAISON OFFICE
WASHINGTON, D.C. 20201**

PHONE: (202) 690-6786

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TO: Sara Rosenbaum P6/(b)(6)

FROM: Jerry D. Klepner

NAME:

NAME:

OFFICE:

OFFICE:

ROOM NO.:

ROOM NO.:

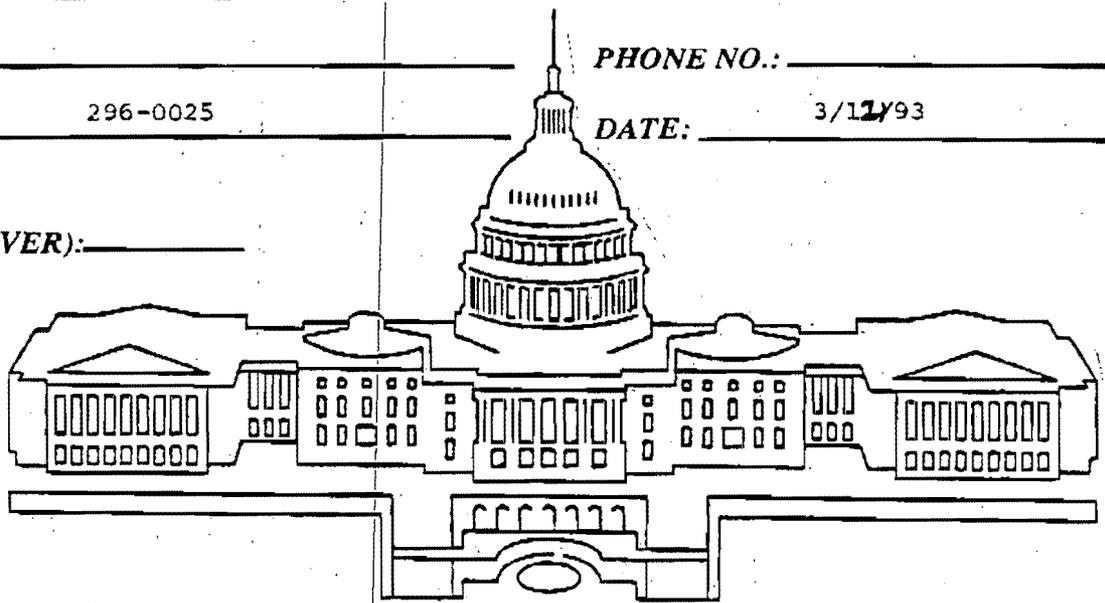
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FAX NO.: 296-0025

DATE: 3/12/93

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(INCLUDING COVER):**



REMARKS:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

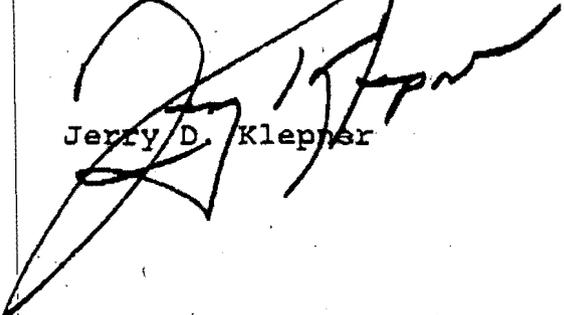
Office of the Secretary

Washington, D.C. 20201

March 12, 1993

MEMORANDUM TO SARA ROSENBAUM

Attached is a corrected version of the Comprehensive Child Health Immunization Act of 1993. On page 18, (e) (B) (1) and (2) were dropped due to a computer malfunction.


Jerry D. Klepper

draft 3/12/93

SR's
edits
3/13/93

A B I L L

To provide for the immunization of all children against vaccine preventable diseases, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCES IN ACT.

(a) Short Title.--This Act may be cited as the "Comprehensive Child Health Immunization Act of 1993".

(b) References in Act.--The amendments in this Act apply to the Public Health Service Act unless otherwise specifically stated.

SEC. 2. PURPOSE OF ACT.

The purpose of this Act is to assure that all children in the United States are protected against vaccine preventable infectious diseases at the earliest appropriate age.

SEC. 3. FINDINGS OF CONGRESS.

(a) Current Circumstances.--Congress makes the following findings as to current circumstances:

(1) Immunizations represent one of the most cost-effective means of the prevention of disease.

(2) Although Federal support for childhood immunizations has been in existence since 1962, the full potential of immunizations remains to be achieved. Enactment and enforcement of school immunization requirements have resulted in excellent immunization levels (96% or greater) in school children. However, approximately 80% of vaccine doses should be received before the second

birthday in order to protect children during their most vulnerable periods. Many children do not receive their basic immunizations by that time, and in some inner cities as few as 10% of 2-year olds have received a complete series. This low level of immunizations has been reflected in recent years by outbreaks of measles among inadequately immunized pre-school children.

(3) Many factors contribute to the low level of pre-school immunization. These include deterioration of the public health infrastructure, inconvenient hours or location of immunization facilities, financial and administrative barriers, lack of parental understanding of the importance of immunization, and inadequate familiarity on the part of health care providers with recommendations for achieving the full immunization of children at the earliest appropriate age.

do not address the needs of who care through private practice

and accepted practice standards

Don't we want specific findings on regulatory holding system?

Undertake

(4) Current law provides ^{the Public Health Service with} sufficient authority ~~for~~ ^{to} activities ^{that} to support ^{and strengthen} the infrastructure ^{publicly funded} necessary for immunization services as well as the outreach activities necessary to increase ^{both} parental knowledge about and motivation to obtain immunizations. All States and the

largest cities have prepared comprehensive plans to improve immunization levels. However, adequate resources have been lacking to support the planned activities.

and wonder of understanding immunization practice

Very wealthy

(5) The cost of childhood vaccine is itself a barrier to immunization. The cost of private sector purchases of

through the private immunization delivery infrastructure namely physicians in private office or organizational group practice

vaccines has led to greater demand for vaccines from the public sector.

(6) The National Childhood Vaccine Injury Compensation Program is an essential element in a comprehensive immunization program and should be strengthened and applied to additional vaccines recommended for universal use in children.

(b) Needed Actions.--Congress makes the following findings as to actions needed to assure the full immunization of children at the earliest possible age:

(1) A tracking system must be established in order to remind parents of children who need vaccine.

(2) A coordinated national information and education program must be established, as well as an ongoing program of professional education to increase the awareness and knowledge of health care providers concerning recommendations for achieving the full immunization of children at the earliest appropriate age.

(3) ~~The full range of Federal and State programs that are able to reach children must begin to take advantage of every contact with young children to encourage their parents to get them fully immunized at the earliest appropriate age and to refer those who need immunizations to a source from which they can receive immunizations without administrative or financial barriers.~~

(4) The Federal Government should purchase and provide free of charge vaccines recommended for universal use in

In 1992, the average cost of the vaccine alone needed to fully immunize a child under age 2 was \$2 in the public sector & in the private sector with the administration fee included. All immunization series in the private sector can support \$.

With anecdotal evidence from studies indicate that physicians in an effort to reduce the cost of health care for low & moderate income uninsured or underinsured patients have increasingly turned to increasing their already overburdened public clinics.

(New) escalation in the cost of vaccines in the private sector will give rise to a public health crisis (out of control) from costs.

This is the additional support needed for more services.

Health care programs in many communities provide pediatric care. We must receive the additional support they need to develop additional service capacity. Particularly in underserved & health systems shortages areas.

permit accurate assessment of the immunization status of children & in many states.

What does this mean?

arise the provision

To all providers

children. This action will not only remove financial barriers to immunization that impede children from being vaccinated at the appropriate time, but will also facilitate development of an immunization tracking system.

by both public & private insurers

(5) Private and ~~public~~ health insurers ~~should be encouraged~~ to provide adequate reimbursement for the administration of childhood vaccines,

should be encouraged

the Medicaid program, which mandates coverage of all necessary childhood immunizations

(6) Volunteer community activities to promote the full immunization of children at the earliest appropriate age should be encouraged.

should reimburse parents appropriately

(7) The National Vaccine Injury Compensation Program should be extended and improved. Vaccine information materials should be simplified to assure that parents can understand the true benefits and risks of vaccines.

the administration of vaccine

SEC. 4. FEDERAL PURCHASE AND TRACKING OF CHILDHOOD VACCINES.

(a) In General.--Title XXI of the Public Health Service Act is amended by adding at the end a new Subtitle 3 as follows:

"Subtitle 3--Federal Purchase of Childhood Vaccines.

"SEC. 2141. PURCHASE BY THE SECRETARY.

"(a) Recommended Childhood Vaccines.--The Secretary shall promulgate a list of vaccines that provide immunization against naturally occurring infectious diseases and are recommended for universal use in children. The Secretary shall additionally promulgate recommendations regarding appropriate dosage for each vaccine, and the age or ages of children at which each vaccine should be administered for optimal safety and effectiveness.

Should be added to additional changes

Do we need recommendations for immunization of children who are behind in kind of catch-up shots?

that

the

Procurement

"(b) Establishment of Vaccine ~~Requirements~~ Panel; Duties.--

The Secretary may establish a Vaccine Procurement Panel, composed of representatives of Federal agencies involved in research regarding, or the regulation or procurement of vaccines. The Panel shall advise the Secretary on the amounts of vaccines ~~necessary to be purchased under subsection (c).~~

"(c) Purchase of Vaccine.--

"(1) In general.--The Secretary shall ~~periodically~~ purchase recommended childhood vaccines in amounts necessary for distribution under section 2142 to meet current needs for the immunization of children in the United States in accordance with the recommendations promulgated under subsection (a) and to maintain an additional supply sufficient for a six-month period.

"(2) Pre-procurement consultations.--The Secretary may consult with representatives of State governments, experts in vaccine delivery, health care providers, and others with expertise in purchasing and pricing pharmaceutical products prior to soliciting bids or offers for recommended childhood vaccine under this subtitle.

"(3) Cost or pricing data.--A manufacturer of recommended childhood vaccine shall provide cost or pricing data in support of its requested price at the time it responds to a procurement instituted by the Secretary under this section. A manufacturer shall also provide such data upon the request of the Secretary whenever the Secretary determines that contract modifications are necessary. This

Enumerated under (a)

not need to

In accordance with procedures described in bar

Very vague, 1 normal needs of mes, 2 cur's add, 3 needs because of new vac

(Should all clear system applied to all EDC recommended)

Frequency of contract negotiations

of all recommended vaccines

Need of that clearly states one criteria see shall take into account in entering procurement to avoid argument that unfair

- 1) prediction
- 2) K+S
- 3) rate of return
- 4) distribution
- 5) net cost / appropriate

In essence verify that the vacancy into under of 3 is sought precisely because there are 14/15 are available

6

information shall include data related to the research and development costs of the vaccine, production costs (including technological advances and other factors affecting production), distribution costs, profit levels sufficient to encourage future investments in research and development of new or improved vaccines, the cost of maintaining adequate capacity for outbreak control, and any other data the Secretary determines is relevant.

"(4) (A) Confidentiality of data.--Information provided to the Secretary under paragraph (3) shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code and section 1905 of title 18, United States Code and shall not be revealed, except as provided in subparagraph (B), to any person other than those authorized by the Secretary in carrying out official duties under this section.

"(B) Subparagraph (A) does not authorize the withholding of information provided under paragraph (3) from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make such information available to the subcommittee or committee and shall, at the same time, notify in writing the manufacturer that provided the information of such request.

"(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under

paragraph (3). Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent --

"(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file, and

"(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

"(5) Multiple suppliers.--To assure a reliable and adequate supply of vaccine and to stimulate competition, the Secretary may enter into multiple contracts with manufacturers of the same recommended childhood vaccine, under such terms and conditions and utilizing such procurement processes as the Secretary deems appropriate.

"(6) Reporting requirements.--Each contract for the purchase of recommended childhood vaccine under this section shall require the manufacturer to report to the Secretary or the Secretary's designee, at intervals determined by the Secretary, data regarding the distribution of doses of vaccines by lot number and recipient.

"SEC. 2142. DISTRIBUTION OF VACCINES.

"(a) In General.--The Secretary shall provide for the distribution without charge of recommended childhood vaccines purchased under this subtitle to (1) health care providers who are members of a uniformed service or who are officers or employees of the United States, (2) health care providers who receive assistance under this Act, title V of the Social Security Act, or the Indian Self-Determination and Education Assistance Act, and (3) other health care providers located in States receiving grants under section 2143(b). The Secretary may provide for such distribution through any State that receives a grant under section 2143(b).

"(b) Duties of Health Care Providers.--

"(1) Free provision to children.--A health care provider receiving vaccine under this section may use such vaccine only for administration to children. A provider may not impose a charge for such vaccine. A provider may impose a charge for the administration of such vaccine, except that a provider may not deny a child a vaccination due to inability to pay an administration fee. Medicaid agencies must pay fee when imposed in the case of providers.

"(2) Reporting requirements.--A health care provider receiving vaccine under this section shall report to the applicable State registry established pursuant to section 2143(b) (or to the Secretary if there is no such State registry) the data described in section 2143(b)(1) for each dose of vaccine administered to a child. The provider shall additionally report to such State registry any occurrence reported to the Secretary pursuant to section 2125(b). Such

Contacts have the cost of cover distribution

*329, 330, 340
like x)*

*26-1985
26-1986
26-1987*

Is "this Act" the POTS Act?

under S1(b) mention of provisions not included by or through

to providers

Center

what if state receives no grant or does not want request?

Is the want to cover all publicly funded private provider children from state vovr

reports shall be made with such frequency and in such detail as the Secretary may prescribe.

"SEC. 2143. TRACKING OF CHILDHOOD IMMUNIZATIONS.

§3171
"(a) National Tracking System.--The Secretary shall establish a national system to track the immunization status of children. The system shall be designed to obtain timely information about the immunization status of individual children and to monitor immunization rates at the State and local levels. In addition, the system shall be designed to monitor the safety and efficacy of vaccines, to provide for the coordination of vaccine administration information with the information on adverse events reported under section 2125(b), and, in the case of under-immunized children in States not receiving grants under subsection (b), to notify the parents of those children of the need for specific immunizations.

"(b) State Registry Grants.--

"(1) In general.--The Secretary may make grants to the States to establish and operate State immunization tracking registries. A state receiving a grant under this section shall maintain a registry that includes the following information for each child living within the State:

"(A) type and lot number of each recommended childhood vaccine received after September 30, 1994,

"(B) identification of the health care provider administering such vaccine,

"(C) address and other demographic data needed to find the child,

Enforcement!
Condition receipt of PHSIC of Title V funds or other funds on state parties

AD Agency to require State assistance to immunization system

shall?

"(D) notations of any adverse events associated with each immunization, and

"(E) such other information as the Secretary may prescribe.

"(2) Grant conditions.--Each State, as a condition of receiving a grant under this subsection, shall comply with the following requirements:

"(A) The State registry shall provide for entry of the birth of each infant within the State within six weeks following the birth, and for timely entry thereafter of all information received from health care providers pursuant to section 2142(b)(2) or section 2125(b).

"(B) Subject to subparagraph (G), the State shall provide for the sharing of appropriate information from the State's registry, including immunization status and reports of adverse reactions, with the Secretary and with health care providers who offer immunizations.

Health care insurers, other than those that are direct providers of health care, shall not be given access to any personally identifiable information from the State's registry other than that information necessary to process a claim. *No access by*

State Medicaid agencies or private

"(C) The State shall provide for notification to the parents of under-immunized children of the need for specific vaccinations.

any other state agency local

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"(D) Subject to Subparagraph (G), the State shall provide for the coordination and exchange of information with other State registries to allow the tracking of the immunization status of children changing residence.

"(E) The State shall monitor and enforce compliance of health care providers with the requirements of section 2142(b), and may disqualify any noncompliant provider from receipt of vaccine under this subtitle.

"(F) If the State distributes recommended childhood vaccines within the State on behalf of the Secretary pursuant to section 2142(a), the State shall compile monthly data, including lot numbers, on the vaccines distributed to each health care provider.

"(G) The State shall adhere to standards prescribed by the Secretary designed to assure that information furnished to the State under this subtitle is used only to carry out the purposes of this subtitle and is not used or redisclosed for any other purpose.

"(3) Applications.--Each State shall submit an application for a grant under subsection (b) in such form and containing such information as the Secretary may prescribe. The application shall include a description of the methods by which the State will comply with the requirements of paragraph (2), and the methods by which the registry will provide information to health care providers

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on an interactive basis. The application shall also include a description of the expenses that the State will incur in connection with its responsibilities under the grant.

"(4) Allowable uses of grant funds.--A State may use a grant awarded under this subsection for reasonable costs associated with the development and operation of its registry, including computer needs, technical assistance and training, education of health care providers, personnel costs, travel expenses, and other appropriate activities.

"(5) State reports to the Secretary.--Each State shall submit periodic reports to the Secretary regarding the operation of the State registry and other activities conducted pursuant to the grant under this subsection. The reports shall be submitted in the form and at the frequency prescribed by the Secretary, and shall contain such information as the Secretary may prescribe.

"(c) Authority to Use Social Security Numbers.--
Notwithstanding any other provision of law, the Secretary and States receiving grants under subsection (b) may utilize the social security number of a child or the child's parents for purposes of identification of a child in any registry established under this section, and may require a parent or other legally responsible individual to furnish such number (in any case where such a number has been assigned by the Social Security Administration) as a condition of receiving recommended childhood vaccine under this subtitle.

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"(d) Reports by Secretary to the Congress.--The Secretary shall submit a report to Congress on January 1, 1996, and biennially thereafter on the operation of the national tracking system and the State registries.

"SEC. 2144. DEFINITION.

"For purposes of this subtitle, a 'recommended childhood vaccine' is a vaccine on the list promulgated by the Secretary pursuant to section 2141(a).

"SEC. 2145. AUTHORIZATION OF APPROPRIATIONS.

"(a) Vaccine Purchases.--

"(1) For the purpose of making vaccine purchases under section 2141, there shall be made available to the Secretary such sums as may be necessary for fiscal year 1995 and for each fiscal year thereafter.

"(2) Amounts to carry out section 2141 shall constitute direct spending for purposes of the Budget Enforcement Act of 1990 and shall not be subject to reduction pursuant to a sequestration.

floor language?

"(b) National Tracking System and State Registries.--For the purpose of making grants under section 2143 and for the operation of the tracking system authorized by such section, there are authorized to be appropriated \$_____ for fiscal year 1995, \$_____ for fiscal year 1996, and \$_____ for each of fiscal years 1997, 1998, and 1999."

(b) Authority to Ensure Supply of Biologicals.--Section 351 is amended--

(1) in subsection (a), by striking "No person" and inserting instead "Except as provided in subsection (i), no person", and

(2) by adding at the end the following:

"(i) Waiver Authority with Respect to Biologicals Necessary to Protect Public Health.--(1) Waiver to address critical shortage.--Where the Secretary finds a critical shortage of a biological product specified in subsection (a) based on a determination--

what is this?

"(A) that there is (or is likely to be) a shortage of supply of such product (for any reason including unavailability of a sufficient supply at a reasonable price), and

"(B) that such shortage presents a significant risk to the public health,

the Secretary may, in accordance with the provisions of this subsection, waive requirements applicable to such product to the extent necessary to permit the production, sale, distribution, and use of such product during such period as is necessary to prevent or eliminate such shortage.

As determined by the Sec. in accordance with procedures described in

"(2) Alternative standards.--Where the Secretary has found a critical shortage of a biological product pursuant to paragraph (1), the Secretary, in consultation with the Commissioner of Food and Drugs, may waive any applicable requirement of this section, this Act, the Federal Food, Drug, and Cosmetic Act, or regulations thereunder, with respect to a such product if--

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"(A) the Commissioner of Food and Drugs has determined that the product meets standards that are satisfactory alternatives to the requirements waived under this subsection, and

"(B) the Secretary determines that sufficient information exists to support a conclusion that the waiver is justified by the need to protect the public health.

"(3) Limitation of waiver.--(A) A waiver under this subsection with respect to a biological product shall be available--

"(i) only for such period as is necessary to avoid a critical shortage of such product, and

"(ii) only while such product continues to meet the alternative standards specified under paragraph (2).

"(B) The Secretary shall redetermine at least annually, in the case of each waiver granted under this subsection, whether the conditions supporting the waiver continue to be met.

"(4) Treatment of licensed product.--(A) A product which the Secretary has permitted to be produced and distributed pursuant to the provisions of paragraph (1) shall be considered to be licensed pursuant to subsection (a) for purposes of the provisions of this Act and of the Federal Food, Drug, and Cosmetic Act.

"(B) The Secretary shall have the same regulatory authority with respect to products granted waivers under this subsection as with respect to products licensed pursuant to subsection (a)."

(c) Use of Social Security Numbers.--

(1) Authority to redisclose.--Notwithstanding section 205(c)(2)(vii)(I) of the Social Security Act, a State may redisclose to another State or to the Secretary, and the Secretary may redisclose to a State, any social security number obtained in connection with activities under subtitle 3 of title XXI of the Public Health Service Act, provided that the redisclosure of such number is in furtherance of an activity under such subtitle.

(2) Technical amendment.--Section 205(c)(2)(C)(i) of the Social Security Act is amended by inserting "immunization tracking registry conducted under subtitle 3 of title XXI of the Public Health Service Act," after "general public assistance,".

SEC. 5. NATIONAL VACCINE INJURY COMPENSATION PROGRAM AMENDMENTS.

(a) Use of Vaccine Injury Compensation Trust Fund.--

(1) Section 9510(c)(1) of the Internal Revenue Code of 1986 is amended by striking out ", and before October 1, 1992,".

(2) Section 6601(r) of the Omnibus Budget Reconciliation Act of 1989 is amended by striking out "\$2,500,000 for each of fiscal years 1991 and 1992" each place it appears and inserting in lieu thereof " \$3,000,000 for fiscal year 1994 and each fiscal year thereafter" (in three places).

(b) Permanent Extension of Authority to Impose Taxes For The Vaccine Injury Compensation Trust Fund.--

Why not permit the fund to pay retroactive claims?

(1) Permanent extension of tax.--Section 4131(c) of the Internal Revenue Code of 1986 is repealed.

(2) Reinstatement during interim termination period.-- If, prior to the date of enactment of this section, the tax imposed by section 4131 of the Internal Revenue Code of 1986 shall have been terminated pursuant to subsection (c) thereof, such section shall be construed to impose such tax on all taxable vaccines sold during the period beginning with the termination of the tax and closing with its extension pursuant to this section. For purposes of section 9510 of such Code, the tax imposed by reason of the preceding sentence shall be considered to be imposed by section 4131 thereof.

(c) Amendment of Vaccine Injury Table.--(1) Section 2114 is amended by adding at the end thereof the following new subsection:

"(f) Addition of Vaccines to Table.--The Vaccine Injury Table set out in subsection (a) also includes any recommended childhood vaccine included in the list promulgated by the Secretary under section 2141(a). The Secretary may modify the Table with respect to any vaccine added by operation of the preceding sentence only in accordance with subsection (c). For purposes of section 2116(b), the addition of a vaccine to the Table by operation of the subsection shall constitute a revision of this Table."

(2) Section 2116(b) is amended by striking out "such person may file" and inserting in lieu thereof "or to significantly

affect the likelihood of obtaining compensation, such person may, notwithstanding section 2111(b)(2), file".

(d) Extension of Time for Decision.-- Section 2112(d)(3)(D) is amended by striking out "540 days" and inserting in lieu thereof "30 months (but for no more than 6 months at a time)".

(e) Simplification of Vaccine Information Materials.--

(1) Section 2126 (b) is amended--

(A) by striking out "by rule" in the matter preceding paragraph (1);

(B) by striking out, in paragraph (1),
", opportunity for a public hearing, and 90" and
inserting in lieu thereof "and 30"; and

(C) by striking out, in paragraph (2),
", appropriate health care providers and parent
organizations".

(2) Section 2126(c) is amended--

(A) by inserting "shall be based on available
data and information," immediately after "such
materials" in the matter preceding paragraph (1), and

(B) by striking out paragraphs (1) through (10)
and inserting in lieu thereof the following:

"(1) a concise description of the benefits
of the vaccine,

"(2) a concise description of the risks
associated with the vaccine, and

"(3) a statement of the availability of the
National Vaccine Injury Compensation Program.".

19

(3) Subsections (a) and (d) of section 2126 are each amended by inserting "or to any other individual" immediately after "to the legal representative of any child".

(4) Subsection (d) of section 2126 is amended--

(A) by inserting "written or video" immediately after "intends to administer such a vaccine a",

(B) by striking "or other written information which meets the requirements of this section", and

(C) by striking "or other information" in the last sentence.

SEC. 6. CHILDREN'S VACCINE INITIATIVE.

Title XXI, as previously amended by sections 4 and 5 of this Act, is further amended by adding at the end a new subtitle 4 as follows:

"Subtitle 4--Miscellaneous Provisions

"SEC. 2151. CHILDREN VACCINE INITIATIVE.

"(a) Authority.--The Secretary shall undertake a Children's Vaccine Initiative to develop a single dose vaccine that could be administered to the children of the world early in infancy and that would afford them lifetime protection against multiple infectious diseases.

"(b) Consultation.--The Secretary shall organize the Initiative in consultation with the World Health Organization and the United Nations Children's Fund so that the benefits of such Initiative will accrue to all of the children of the world.

"(c) Activities.--The Secretary shall conduct those vaccine research, operational research, development, production, and delivery activities under the Initiative in collaboration with non-government institutions and with other Federal agencies to ensure the full use of the scientific and industrial capacity of the United States to prevent infectious diseases.

"(d) Authorization of Appropriations.--There are authorized to be appropriated to carry out this section \$ 32.9 million for fiscal year 1994, and such sums as may be necessary for each of the ___ following fiscal years."

Clarification of Medicaid obligation to pay was under § 1902(a) (needed the waiver language because of)

\$ = to 20% of \$ estimate to be needed for vaccine purchase for infrastructure improvement activities - PHS/IGMS - like to put in registry cost ~~but~~ as direct as cost sharing well?

1.

FILED

FEB 9 10 08 AM '93

RICHARD W. WIERING
CLERK
U.S. DISTRICT COURT
NO DIST OF CA

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

The PEOPLE of the STATE OF)
CALIFORNIA ex rel., ELOISE)
ANDERSON, Director of the)
California Department of Social)
Services, in her official capacity)

Plaintiff,)

v.)

LOUIS SULLIVAN, M.D., Secretary of)
the United States Department of)
Health and Human Services, in his)
official capacity; and JO ANNE)
BARNHART, Assistant Secretary of)
the Administration for Children)
Families, in her official capacity.)

Defendants.)

No. C-92-3930-VRW

ORDER GRANTING INJUNCTIVE
RELIEF.

The Child Abuse Prevention and Treatment Act ("CAPTA"),
42 USC § 5101 et seq., authorizes the United States Department of
Health and Human Services ("DHHS") to make grants to states and
certain territories to help them develop, strengthen, and carry
out child abuse and neglect prevention and treatment programs. 42

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United States District Court
For the Northern District of California

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1 USC § 5106a(a). To qualify for a CAPTA grant, a state must meet
2 the eligibility requirements set out in 42 USC § 5106a(b). These
3 eligibility requirements consist largely of requiring that the
4 state have a system of laws and programs designed to prevent,
5 treat, report, and prosecute child abuse and neglect. See 42 USC
6 § 5106a(b).

7 At issue in this case is California's eligibility for a
8 fiscal year 1992 federal Child Abuse and Neglect grant in the
9 amount of \$1.8 million. The DHHS has divided each CAPTA state
10 grant into a Part I "Basic State Grant" and a Part II "Medical
11 Neglect/Disabled Infant Grant." In fiscal year 1992, California
12 applied for both a Part I and a Part II CAPTA state grant. On
13 August 28, 1992, a regional DHHS office in San Francisco informed
14 California that it would recommend denial of a Part I CAPTA state
15 grant to California because it allegedly did not meet federal
16 CAPTA requirements in four areas. The four areas of California's
17 child abuse statute which the DHHS contend disqualify California
18 are: (1) its ambiguous religious exemption provision, (2) its use
19 of "serious" to modify the definition of child abuse and neglect,
20 (3) its deficient confidentiality provision, and (4) its
21 permissive rather than mandatory system of reporting mental
22 injury.

23 On September 30, 1992, the court issued a temporary
24 restraining order to prevent the DHHS from distributing to other
25 states that portion of the 1992 Part I funds that are to be
26 allocated to California if California meets all eligibility
27
28

1 requirements. Plaintiff now moves the court for injunctive and
2 declaratory relief on the four issues allegedly disqualifying
3 California from eligibility.

4 I.

5 Section 1340.13 of title 45 of the Code of Federal
6 Regulations, which contains regulations governing the award of
7 CAPTA state funds, grants the Commissioner of the Administration
8 for Child Youth and Families of the DHHS discretion and authority
9 to award CAPTA funds. In relevant part, this section states:

- 10 (a) The Commissioner shall approve an application for
11 an award for funds * * * if he or she finds that
12 * * * [t]he State is qualified and has met all
13 requirements of [CAPTA] and § 1340.14 of this part
14 * * * .

15 In addition, section 706 of title 5 of the United States
16 Code provides the applicable standard of judicial review of the
17 Commissioner's decision. It states:

18 The reviewing court shall * * * hold unlawful and set
19 aside agency action, findings, and conclusions found to
20 be * * *

- 21 (A) arbitrary, capricious, an abuse of discretion,
22 or otherwise not in accordance with law;
23 (B) contrary to constitutional right, power,
24 privilege, or immunity; [or]
25 (C) in excess of statutory jurisdiction,
26 authority, or limitations, or short of
27 statutory right * * * .

28 The state of California's primary contention in this
case is that the DHHS abused its discretion by acting arbitrarily
and capriciously in finding California ineligible for a Part I
CAPTA grant. Accordingly, California requests this court to issue
an injunction enjoining the DHHS from withholding from California

1 its share of the CAPTA funds.

2 II.

3 To obtain injunctive relief, a plaintiff must show
4 either (1) a likelihood of success on the merits and the
5 possibility of irreparable injury, or (2) the existence of serious
6 questions going to the merits and the balance of hardships tipping
7 in plaintiff's favor. Diamontiney v Borg, 918 F2d 793, 795 (9th
8 Cir 1990) (citations omitted). The court may also consider the
9 public interest. Tribal Village of Akutan v Hodel, 859 F2d 662,
10 663 (9th Cir 1988).

11 Having considered the extensive and capable oral
12 arguments of counsel and having reviewed the papers of both
13 parties, as well as those of the California Consortium for the
14 Prevention of Child Abuse appearing as amicus and those of the
15 Children's Healthcare Is a Legal Duty, Inc., the court finds that
16 the state of California has shown a likelihood of success on its
17 claim that the DHHS acted capriciously, arbitrarily and in abuse
18 of its discretion in denying California Part I CAPTA funds. The
19 court also finds that California has shown the possibility of
20 irreparable injury. Accordingly, the court hereby **GRANTS**
21 California's request for an injunction to prevent the DHHS from
22 withholding from California its share of the fiscal year 1992
23 child abuse prevention funds. Further, declaratory judgment is
24 **GRANTED** as to the four eligibility issues in dispute because the
25 court finds that the California laws substantially comply with the
26 CAPTA eligibility requirements.

III.

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2 Last year, California was the only state to which the
3 DHHS denied a Part I "Basic State Grant" under CAPTA. All other
4 states and territories which applied for CAPTA grants received
5 them. Out of the fifty-four states and territories which applied,
6 fifty-three received Part I CAPTA grants. The court finds it
7 difficult to believe that these fifty-three states and territories
8 have qualified child abuse prevention and treatment laws and
9 programs but California does not. The letter and spirit of
10 California's child abuse laws and programs appear to be at least
11 as protective, if not more so, than many of the other states
12 receiving the grants. The court finds that the DHHS's denial to
13 California is based upon narrow, literal interpretations of
14 certain words in certain selected statutes and that the DHHS has
15 intentionally ignored and refused to consider how California's
16 extensive statutory scheme is actually interpreted and applied.

17 Moreover, the DHHS has awarded CAPTA funds to states and
18 territories with laws nearly identical to the laws in California
19 and also awards the grants to states with laws explicitly less in
20 compliance with CAPTA than California's. Examples of these
21 "double standards" employed by the DHHS are set forth in more
22 detail below. In short, the court concludes that the DHHS's
23 denial of a Part I "Basic State Grant" to California is arbitrary
24 and capricious because California law complies with CAPTA and is
25 comparable to the laws of other states receiving grants from the
26 DHHS.

A.

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2 One of the most glaring examples of the DHHS's abuse of
3 discretion was its denial of CAPTA funds on the grounds that
4 California's religious exemption provision is ambiguous. A
5 religious exemption statute basically provides that children
6 receiving medical treatment by "spiritual means" are not
7 necessarily being abused or neglected. Nearly every state has, in
8 one form or another, a religious exemption in its child abuse
9 laws, and thirty-six of these states received CAPTA funds in 1992.
10 The DHHS contends that California's provision is ambiguous. The
11 court finds, however, and the DHHS admits, that California's
12 religious exemption statutes are nearly identical to those in the
13 thirty-six other states found eligible. Thus, the DHHS acted
14 capriciously and arbitrarily in denying California a Part I grant
15 on the basis of an allegedly non-complying religious exemption
16 provision.

17 In addition, the DHHS previously approved this religious
18 exception provision and, in fact, the DHHS previously required
19 states to enact this provision in order to be eligible for CAPTA
20 funds. See 48 Fed Reg 3698, 3699 (January 26, 1983).

21 Even assuming that it is not arbitrary or capricious for
22 the DHHS to change its mind on this issue, the court finds
23 California's provision substantially complies with CAPTA because
24 California's Reporting Act on its face mandates that a report is
25 required where a child's health or welfare is threatened. Penal
26 Code § 11165.2 and § 11165.6. Accordingly, California's allegedly
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1 noncomplying religious exemption provision should not provide a
2 basis for denying California its share of CAPTA funds.)

3 B.

4 The DHHS's denial of CAPTA funds to California on the
5 grounds that its laws on the confidentiality of child abuse
6 reports do not comply with CAPTA regulations is also arbitrary,
7 capricious and an abuse of discretion. The DHHS's primary
8 complaint about California's confidentiality provision was that it
9 allowed a court to disclose child abuse reports and records if the
10 court determined that the interest of justice outweighed the need
11 for confidentiality. According to the DHHS, CAPTA guidelines
12 explicitly require states to "provide for methods to preserve the
13 confidentiality of all records * * * ." 42 USC § 5106a(b)(4).
14 The DHHS contends that these guidelines leave no room for any such
15 balancing test. California's laws on the confidentiality of child
16 abuse reports, however, comply fully with CAPTA regulations. In
17 case there is any doubt in interpreting California's
18 confidentiality provision, the last subdivision of Calif. Penal
19 Code § 11167.5 provides:

20 (d) This section shall not be interpreted to allow
21 disclosure of any reports or records relevant to the
22 reports of child abuse if the disclosure would be
prohibited by any other provisions of state or federal
law applicable to the reports or records relevant to the
reports of child abuse.

23 (Emphasis added).

24 In fact, several other California statutes prohibit
25 court disclosure of child abuse reports or records. For example
26 California Evidence Code §§ 1040 and 1041 do not permit courts to
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1 disclose confidential information if disclosure "is against the
2 public interest or is forbidden by an act of the Congress of the
3 United States * * * ." Calif. Evid. Code § 1040(b) and § 1041(a).

4 In addition, a California appellate court has recently
5 ruled that Welfare and Institution Code § 10850 does not allow
6 courts to "balance interests," but rather absolutely prohibits
7 courts from disclosing child abuse records in Child Protective
8 Services files, except for purposes "directly connected with the
9 administration of [a Social Services] program, or any
10 investigation, prosecution, or criminal or civil proceeding
11 conducted in connection with the administration of any such
12 program." McClatchy Newspapers v Fresno County Dept. of Social
13 Services, 8 Cal App 4th 855, 869 (5th App Dist 1992), 10 Cal Rptr
14 2d 504, 512-515. It is important to note that portions of the
15 child abuse records in McClatchy were redacted to conceal the
16 identity of individuals named, and that the children in question
17 were dead, yet the court of appeal still held that the records
18 could not be disclosed, except to government agencies in
19 particular circumstances. Id. at 872-873. Since disclosure is
20 prohibited by the California Evidence Code and § 10850 of the
21 Welfare and Institution Code, the court finds California's laws in
22 compliance with CAPTA confidentiality requirements.

23 Moreover, the DHHS awards CAPTA funds to some states
24 which expressly allow disclosure if ordered by the court. For
25 example, Colorado's statute allows disclosure, even of "the name
26 and address of the child and family and other identifying
27 information * * * when authorized by a court for good cause."

1 Colorado Revised Statutes (1992), § 19-1-120(1)(b). Georgia
2 statutes also permit access to child abuse records and reports by
3 courts "upon its finding that access to such records may be
4 necessary for determination of an issue before such court" and
5 even authorizes public disclosure if necessary. Official Code of
6 Georgia Annotated (1992), § 49-5-41(a)(2). The Massachusetts
7 statute permits child abuse reports to be "made available" by "an
8 order of a court of competent jurisdiction." Massachusetts
9 General Laws Annotated (1992), Chapter 119 § 51E. Since
10 California clearly provides methods to preserve confidentiality
11 and since the DHHS grants CAPTA awards to states with
12 confidentiality provisions similar to California, the DHHS abused
13 its discretion in denying CAPTA funds to California.

14 C.

15 Another example of the DHHS's abuse of discretion was
16 its denial of Part I CAPTA funds to California on the basis of
17 California's use of the word "serious" to modify its definition of
18 child abuse and neglect. California's definition of child abuse
19 complies with CAPTA's regulations and are comparable to and even
20 more protective than those in other states receiving CAPTA funds
21 from the DHHS.

22 The DHHS does not, however, appear interested in how
23 California's statutes actually operate, or what California is
24 actually doing to prevent and treat child abuse and neglect. The
25 DHHS instead focuses on one word ("serious") in the definition of
26 child abuse in one of many statutory schemes. With its focus
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1 narrowed to § 300 of the Welfare and Institutions Code, the DHHS
2 concludes that California does not comply with CAPTA regulations.

3 What should be the center of focus, however, is the
4 definition of child abuse utilized by California's Office of Child
5 Abuse Prevention ("OCAP"). OCAP is the entity which applies for
6 and disburses the CAPTA funds once California has received them
7 from CAPTA. OCAP's definition is one of the most all-inclusive
8 and protective definitions of child abuse. In addition to listing
9 more serious types of abuse and neglect, OCAP also defines child
10 abuse as "[a]ny condition which results in the violation of the
11 rights or physical, mental, or moral welfare of a child or
12 jeopardizes the child's present or future health, opportunity for
13 normal development or capacity for independence." Calif. Welf. &
14 Inst. Code § 18951(e)(1)-(5). It is this definition which
15 defendants should be scrutinizing, not § 300, as it is the OCAP
16 definition which is utilized for the distribution of CAPTA funds.

17 Instead, the DHHS focuses only on § 300. Section 300 is
18 the jurisdictional statute for courts to adjudge children wards or
19 "dependents" of the state. To come within § 300, the minor either
20 needs to have "suffered, or there is a substantial risk that the
21 minor will suffer, serious physical harm * * * ." Calif. Welf. &
22 Inst. Code § 300(a). It makes sense that the laws require a high
23 threshold of harm or risk of harm before removing the child from
24 the custody of the parents.

25 Finally, as with the other provisions which the DHHS
26 contends do not comply with CAPTA regulations, other states
27 receiving CAPTA grants have comparable modifiers in their statutes
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1 to ensure that children are not adjudged wards or dependents of
2 the state where the only evidence of abuse is trivial injury. For
3 example, Alaska's equivalent to § 300 of the California Welfare &
4 Institution Code requires "substantial physical harm," and lists
5 the same examples of mental harm as § 300(c) (i.e., "serious
6 emotional damage"). Alaska also requires a child to have
7 "suffered substantial physical abuse or neglect." Alaska Statutes
8 (1991), Title 47, Chap. 10, § 47.10.010(a)(2)(B)-(D) and (F).
9 Yet, Alaska continues to receive CAPTA funding.

10 D.

11 The DHHS also erroneously claims that California does
12 not mandate reporting of mental injury. According to the DHHS, an
13 eligible state must require "mental injury" to be reported as
14 child abuse because 45 CFR § 1340.2(d) includes the term "menta-
15 injury" in its "definitional range of child abuse and neglect."

16 California's Reporting Act, Penal Code § 11165 et seq.,
17 has continuously mandated the reporting of mental injury ever
18 since its enactment in 1980. The Reporting Act defines as child
19 abuse and requires the reporting of "willful cruelty or
20 unjustifiable punishment of a child." This is specifically
21 defined in the Act as "a situation where any person willfully
22 causes or permits any child to suffer, or inflicts thereon,
23 unjustifiable physical pain or mental suffering." Penal Code §
24 11165.6 and § 11165.3. (Emphasis added). Section 16513 of the
25 California Welfare and Institutions Code further requires that
26 "[a]ny person required to report under Sections 11165 and 11166 *
27 * * who has reason to believe that the home * * * is unsuitable *
28

1 * * because of neglect, abuse, or exploitation * * * shall bring
2 such condition to the attention of the law enforcement agency
3 pursuant to Sections 11165 and 11166 * * * ." Welf. & Inst. Code
4 § 16513. (Emphasis added). This statute brings virtually all
5 types and levels of harm within the mandatory reporting statute
6 and is one of the more protective laws in existence among the
7 states, even among those states receiving CAPTA funds. Cf. e.g.,
8 Oklahoma Statutes (1992), Title 21, Section 846(A) and
9 Massachusetts General Laws Annotated (1992), Chapter 119, § 51A.

10 Further evidence of California's compliance with CAPTA's
11 mandatory reporting of mental injury requirement is the fact that
12 22,586 reports of emotional abuse were made in California in 1991
13 out of over 571,000 total reports. The court finds such a high
14 percentage of mental injury reports unlikely if California had a
15 permissive rather than a mandatory system of reporting.

16 E.

17 The DHHS also acted arbitrarily in another respect.
18 From 1980 through 1985, the DHHS found three out of the four
19 provisions at issue in this dispute in compliance with CAPTA
20 regulations, but now finds those identical provisions not in
21 compliance. The three areas under the California Child Abuse
22 Reporting Act of 1990, Penal Code §§ 11164-11174.3, which complied
23 are: (1) the provision of the Act which mandates the reporting of
24 emotional abuse (or "mental injury"); (2) the provision in the Act
25 authorizing disclosure of the identity of a reporter of abuse by
26 court order; and (3) the religious exemption provision in the Act.
27 Although neither California's laws nor CAPTA's regulations changed

1 in these three areas from when the DHHS previously found
2 California in compliance with CAPTA regulations, the DHHS now
3 claims that the exact same provisions violate CAPTA guidelines.
4 The court agrees with California that there can be no clearer
5 evidence of capriciousness nor arbitrariness than a DHHS which in
6 one year finds noncompliance and in another year finds compliance
7 in the exact same provision.

8 F.

9 Finally, although judicial deference dictates that the
10 reviewing court defer its interpretation of the eligibility
11 requirements to the DHHS, the court shall set aside an agency's
12 action upon a finding that the DHHS exceeded its statutory
13 jurisdiction in applying the CAPTA regulations. 5 USC
14 § 706(2)(C). In the present case, the DHHS exceeded its statutory
15 authority.

16 Judicial deference does not extend to regulatory actions
17 or regulations which deviate from statutory authority or
18 congressional will. An agency's interpretation of its regulations
19 must sensibly conform to the purpose of the regulations.

20 "Deference * * * does not mean we abdicate our responsibility to
21 review agency action under the regulations promulgated * * * .

22 The interpretation must sensibly conform to the purpose and
23 wording of the regulations." St. Elizabeth Community Hospital v

24 Heckler, 745 F2d 587, 592 (9th Cir 1984) (citations omitted)

25 (emphasis added). The court in Regents of University of

26 California v Heckler, 771 F2d 1182, 1187-1188 (9th Cir 1985)

27 (citations omitted), stated,

1 We will not abdicate our judicial responsibility by
2 affirming administrative actions which are 'inconsistent
3 with a statutory mandate or . . . frustrate the
4 congressional policy underlying a statute.' Thus, if
5 the Secretary's regulations are found to deviate from
6 congressional will, either on their face or as applied,
7 they must be invalidated as contrary to law.

8 In the present case, if the DHHS applied the CAPTA
9 regulations uniformly to all states, plaintiff estimates
10 noncompliance by 80% of the states. Clearly, Congress did not
11 intend to deny funds for the prevention of child abuse and neglect
12 to 80% of the states and territories which applied for such funds.
13 Accordingly, the court owes no deference to the DHHS's decision to
14 deny California CAPTA funds because it goes against congressional
15 intent.

16 IV.

17 Having concluded that the state of California has shown
18 likely success on the merits, the court must also find irreparable
19 harm before granting injunctive relief. Diamontiney v Borg, 918
20 F2d at 795. In this case, the court finds that there is a
21 possibility that California will be irreparably harmed if it is
22 denied the 1992 CAPTA funds.

23 In 1991, five hundred seventy one thousand two hundred
24 forty one (571,241) children in California were reported abused or
25 neglected. Of those, one hundred nine (109) died as a result of
26 abuse. Although California, through numerous statutes, is making
27 serious efforts to address this problem, these efforts are clearly
28 not enough. Because of continuing budget crises in California,
state funds available to all programs are shrinking. If
California is denied assistance from the federal government to

1 prevent, identify and treat abuse and neglect of children, this
2 downward slide will continue. California is in need of CAPTA
3 funds. As stated by Congress in the Child Abuse, Domestic
4 Violence, Adoption and Family Services Act of 1992, Pub L No 102-
5 295, § 101, 106 Stat 187, 189 (1992),

6 (4) the failure to coordinate and comprehensively
7 prevent and treat child abuse and neglect threatens the
8 futures of tens of thousands of children and results in
9 a cost to the Nation of billions of dollars in direct
expenditures for health, social, and special educational
services and ultimately in the loss of work
productivity.

10 The harm is irreparable because without the money,
11 services will not be provided. Children who are not served and
12 abuse which is not caught or prevented are not remediated by a
13 later infusion of money. Unless this court prevents California's
14 share of the fiscal year 1992 state grants from being distributed
15 to other states, California will be permanently deprived of those
16 funds, and the state and its children will suffer irreparable
17 harm.

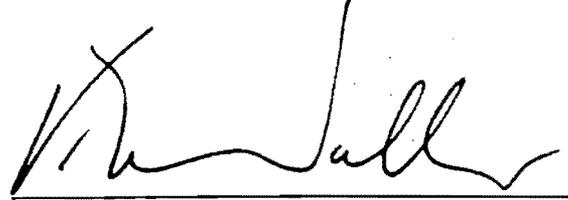
18 V.

19 For the foregoing reasons, the court hereby **GRANTS**
20 California's motion for injunctive relief. If the DHHS contends
21 that there are factual issues which prevent the court from issuing
22 a permanent injunction, the court requests the DHHS to submit a
23 written response by February 16, 1993. Otherwise, California's
24 motion to enjoin permanently the DHHS from withholding from
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California its share of the fiscal year 1992 child abuse prevention funds is hereby GRANTED.

IT IS SO ORDERED.



VAUGHN R. WALKER
United States District Judge

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

The PEOPLE of the STATE of
CALIFORNIA ex rel.,
ELOISE ANDERSON,
Director of the
California Department of
Social Services, in her
official capacity,

Plaintiff,

v.

DONNA SHALALA, M.D.,
Secretary of Health and Human
Services, et al.,

Defendants.

NO. C-92-3930 VRW

STIPULATION TO EXTEND
TEMPORARY RESTRAINING
ORDER

In order to enable the new administration to fully evaluate its
position in this case and also to enable the Court to fully evaluate
all of the materials presented, the parties, through their undersigned

///
///
///

1 counsel, hereby stipulate and agree that the Temporary Restraining
2 Order issued on October 16, 1992 may be extended until April 15, 1993.

3 DANIEL E. LUNGREN, Attorney General
4 State of California
5 STEPHANIE H. WALD
6 Supervising Deputy Attorney General

7 DATED: *January 24, 1993* BY:

Amy J. Hertz
8 AMY J. HERTZ
9 Deputy Attorney General
10 Attorneys for Plaintiff

11 JOHN A. MENDEZ
12 United States Attorney

13 DATED: *Jan 21, 1993* BY:

George C. Stoll
14 GEORGE CHRIS STOLL
15 Assistant United States Attorney
16 Attorneys for Federal Defendant
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The First Church of Christ, Scientist

in Boston
Massachusetts

Washington, D.C. Office
Committee on Publication

March 11, 1993

The Honorable Carol H. Rasco
Assistant to the President for Domestic Policy
Executive Office of the President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Ms. Rasco:

Subject: California v. Sullivan

Enclosed is the copy of a decision from the United States District Court, Northern District of California, regarding CAPTA funding for the state of California. The judge found the Department of Health and Human Services's withholding of CAPTA funds to be arbitrary and capricious. He issued a Stipulation to Extend Temporary Restraining Order, in his words, "to enable the new administration to fully evaluate its position in this case." This order was extended until April 15, 1993.

In addition, we have enclosed documents from the California Consortium for the Prevention of Child Abuse and from Professor Michael S. Wald (Stanford University). We have highlighted specific portions of these documents and of the court's decision that specifically apply to religious provisions.

We believe that the strong language in these documents opposing HHS's position on the religious provisions in California would also apply to other states where similar provisions exist.

We hope this new information will help in your discussions with Secretary Shalala and in the administration's reevaluation of HHS's policy.

Thanks again for your consideration.

Sincerely,

Philip G. Davis/ko

Philip G. Davis
Federal Representative

(continued)

The Honorable Carol H. Rasco
March 11, 1993
Page 2

Enclosures

1. Order Granting Injunctive Relief, California v. Sullivan
(N.D. Cal. 1992) (No. C-92-3930-VRW).
2. Stipulation to Extend Temporary Restraining Order,
Sullivan
3. Points and Authorities in Support of Motion for
Preliminary or Permanent Injunction, Attorney for
Amicus, California Consortium for the Prevention of
Child Abuse, Sullivan
4. Declaration of Professor Michael S. Wald, Sullivan