



APR 1 - 1998

MEMORANDUM FOR THE PRESIDENT

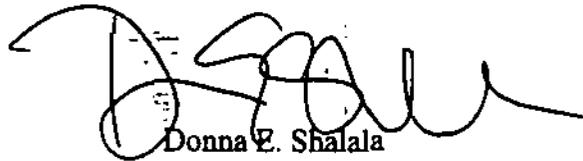
The Census Bureau released the official 1996 poverty numbers last September. The National Center for Children in Poverty (NCCP) reanalyzed the census data focusing on young children -- those under age six. The NCCP released its report, "Young Children in Poverty: A Statistical Update," Thursday March 12, 1998. This year's report shows that while the poverty rate among young children declined from 1993 to 1996, the percentage of poor children with working parents increased substantially over the same time period. Several important findings from the report are highlighted below.

- The number of poor children under age six declined by almost 14 percent over the past three years, from 6.4 million in 1993 to 5.5 million in 1996. NCCP analysis shows that this decline is largely due to improved employment rates in the population rather than lower poverty rates among those employed.
- Poverty and near-poverty remain widespread among young children. In 1996, 5.5 million children under age six lived in poverty and an additional 4.8 million young children lived in near poverty (i.e., lived in families with a combined family income between 100 percent and 185 percent of the Federal poverty line).
- In 1996, nearly half (47 percent) of the 5.5 million poor children under age six lived in extreme poverty (i.e., lived in families with a combined family income below 50 percent of the Federal poverty line).
- The percentage of poor young children with working parents increased between 1993 and 1996. In 1996, more than three-fifths (63 percent) of poor children under age six lived in families with at least one employed parent, an increase of 16 percent over the past three years.
- The Earned Income Tax Credit (EITC) had a strong anti-poverty effect. Using an alternative measure of poverty that includes additional sources of income (i.e., benefits and taxes), NCCP estimates show that the 1996 poverty rate among young children would have been 23 percent higher in the absence of the EITC.

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Page 2 - The President

The full report which I am attaching includes greater detail on poverty, near poverty and extreme poverty among young children as well as a more comprehensive discussion on alternative measures of poverty.

A handwritten signature in black ink, appearing to read "Donna E. Shalala". The signature is fluid and cursive, with a large initial "D" and "S".

Donna E. Shalala

Attachment



**NATIONAL
CENTER FOR
CHILDREN IN
POVERTY**

COLUMBIA SCHOOL OF PUBLIC HEALTH

YOUNG CHILDREN IN POVERTY

A Statistical Update

March 1998 Edition

This publication updates the National Center for Children in Poverty's (NCCP) 1996 volume, *One in Four: America's Youngest Poor*, and continues a series of reports and statistical updates about young child poverty in the United States. It incorporates information from the 1997 March Supplement to the Census Bureau's Current Population Survey (CPS), which provides poverty estimates for 1996.* The highlights of this update include:

- a new profile of the extremely poor, poor, and near poor population of young children in the United States using the federal government's official poverty measure;
- the use of an alternative measure of young child poverty that provides new insights into the impact of programs and policies on the economic well-being of young children; and
- a brief examination of why the young child poverty rate (YCPR) has decreased since 1993.

Both the official and alternative measures indicate that despite the recent decline in the young child poverty rate, the U.S. YCPR ranks among the worst of the Western industrialized nations. However, the alternative measure reveals that policy can make a significant difference. In particular, the expansion of the Earned Income Tax Credit has served to reduce young child poverty substantially over the past few years.

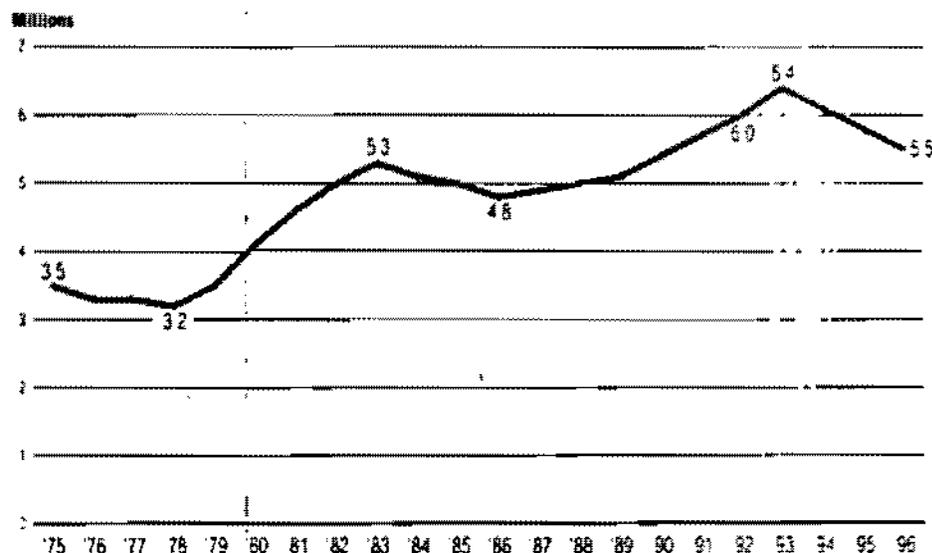
* The official federal poverty line (PL) adjusts for annual cost-of-living increase; and family size. In 1996 the poverty line was \$10,233 for a family of two, \$12,516 for a family of three, and \$16,036 for a family of four. Unless otherwise noted, family income used for the calculation of poverty statistics is pre-tax income. It excludes non-cash public assistance and the Earned Income Tax Credit (EITC).

Poor Children Under Age Six: How Many Are There, Who Are They, and Where Do They Live?

The poverty rate for young children and the number of poor young children have declined yet remain high.

The early 1990s marked a staggering increase in the number of poor children under age six. The number of poor young children reached six million for the first time in 1992, and rose to almost 6.4 million in 1993. The number of poor children under age six declined by almost 14 percent over the past three years, to 5.5 million in 1996—a figure that is still higher than that in any year between 1975 and 1990. (See Figure 1.) At the same time, the young child poverty rate (YCPR)—defined as the percentage of young children who live in families with a combined income below the federal poverty line*—decreased from 26 percent to 23 percent. (See Figure 2.)

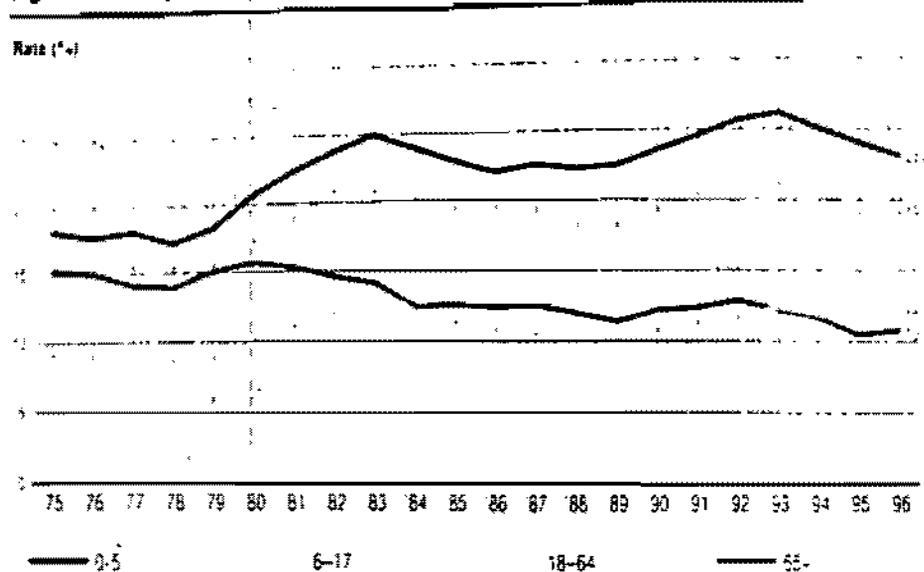
Figure 1: Number of poor children under age six, 1975–1996



Over the past two decades, the young child poverty rate has increased dramatically. It is considerably higher than the poverty rates of all other age groups.

The YCPR began to rise in 1979 and reached 25 percent in 1983. After a slight decline during the 1980s, the YCPR peaked again at 26 percent in 1993. Although the poverty rate for young children has declined since 1993, it remains the highest among all age groups. In 1996, the official poverty rate for children under age six was 23 percent, more than twice as high as those for adults 18 to 64 years of age and for the elderly (both at about 11 percent). (See Figure 2.)

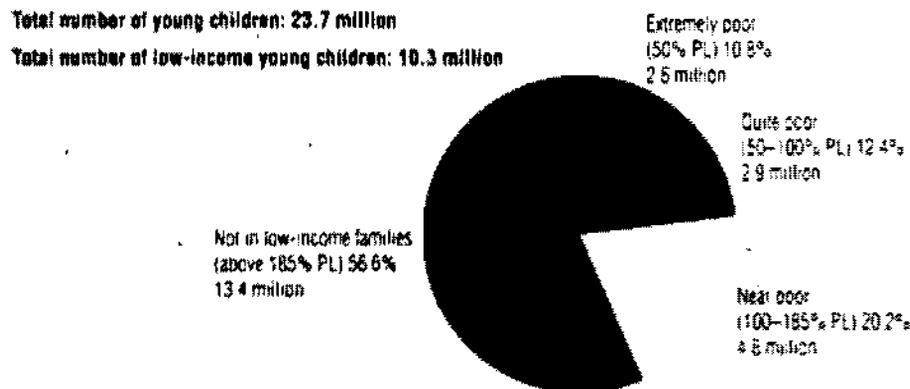
Figure 2: Poverty rates by age, 1975-1996



Over 10 million young children live in low-income families.

By 1996, 43 percent of all children under age six were living in poverty or near poverty (i.e., in families with incomes below 185 percent of the poverty line*). In addition to the 5.5 million young children who lived in poverty that year, an additional 4.8 million young children lived in near poverty, with a combined family income between 100 percent and 185 percent of the federal poverty line. (See Figure 3.) The total number of young children living in low-income families continued to surpass the 10 million level first reached in 1992.

Figure 3: Percentage distribution and number of children under age six by poverty status, 1996



* Children in families with incomes between 100 and 185 percent of the federal poverty line (PL) are designated near poor because they are served by a number of government assistance programs for low-income people — such as Medicaid, the Food Stamp and School Breakfast programs and the special supplemental Nutrition Program for Women, Infants, and Children (WIC) — that use 185 percent of the poverty line as the upper limit to determine eligibility.

Nearly half of all poor young children live in extreme poverty.

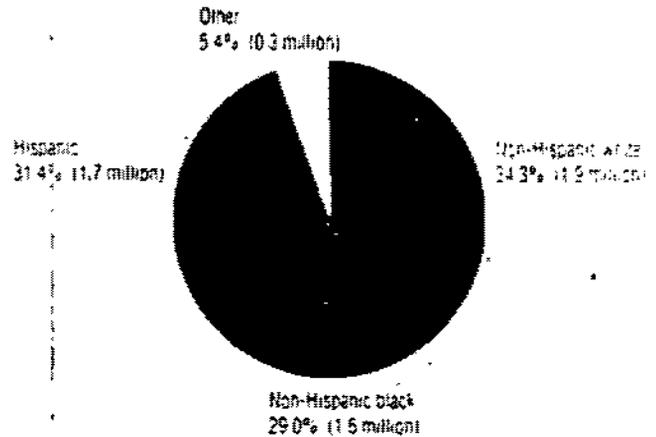
In 1996, whites were the largest racial or ethnic group of young children in poverty.

In 1996, more than one in 10 young children—11 percent—were extremely poor, living in families with a combined family income below 50 percent of the federal poverty line. Of the 5.5 million poor young children, almost half (47 percent) lived in extreme poverty. (See Figure 3.)

Of the 5.5 million poor children under age six in 1996, 1.9 million (34 percent) were non-Hispanic white, while 3.6 million were from minority groups—1.6 million non-Hispanic black (29 percent), 1.7 million Hispanic (31 percent), and 0.3 million (5 percent) members of other racial or ethnic groups. (See Figure 4.)

Figure 4: Number and percentage distribution of poor children under age six by race/ethnicity, 1996

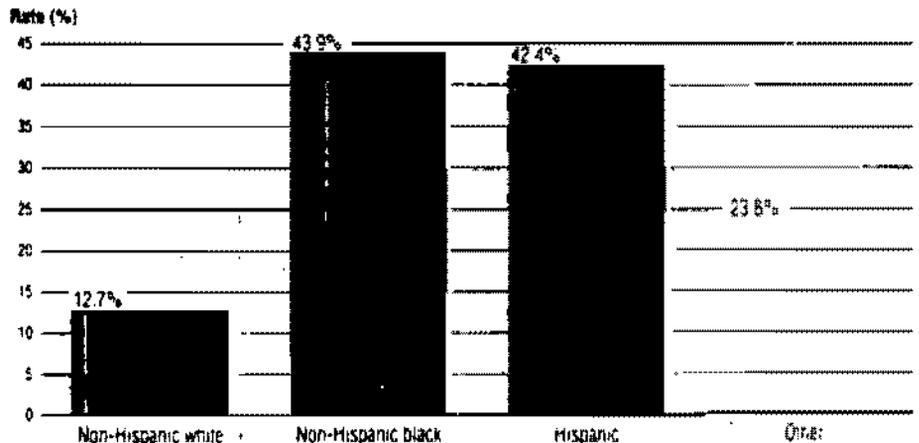
Poor children under age six: 5.5 million



Black and Hispanic young children are much more likely to be poor than are white young children and the young child poverty rate has increased the fastest among Hispanics.

Poverty rates vary greatly for different racial or ethnic groups. In 1996, the poverty rate for non-Hispanic black children under age six was 44 percent; for young Hispanic children it was virtually the same, at 42 percent. The poverty rate for young non-Hispanic white children was 13 percent in 1996. (See Figure 5.) Between the late 1970s (1975-1979) and the early- to mid-1990s (1992-1996), the YCPR increased most rapidly—by 54 percent—among Hispanics. This compares to a 30 percent increase in the YCPR among whites and a 15 percent increase among blacks.

Figure 5: Poverty rates of children under age six by race/ethnicity, 1996



The majority of young children living with unmarried mothers are poor.

About one-third of all poor young children live with married parents.

In 1996, children under age six living with unmarried mothers were about five times as likely to be poor (55 percent) as were those living with married parents (11 percent). The poverty rate of children born to teenage mothers was 47 percent in 1996. In contrast, the poverty rate of children born to adult mothers was less than half that rate (21 percent). (See Table 1.)

In 1996, more than half of all poor children under age six were living only with their mothers (56 percent, 3.1 million). About one-third of poor children lived with married parents (34 percent, 1.9 million). (See Table 1.)

Table 1: Number and percentage of poor children, and poverty rates of children under age six by age of mother at birth and by family structure, 1996

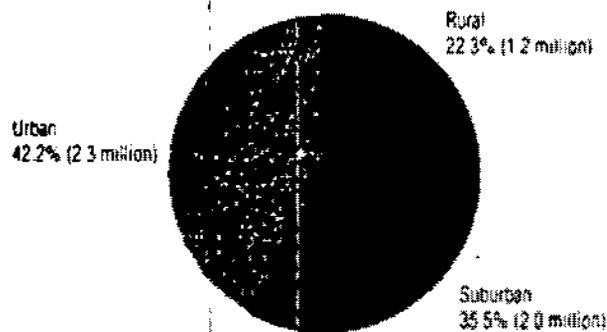
Family structure and maternal age at birth	Poor children under age six		Poverty rate
	Number	%	%
Children born to teenage mothers	688,745	16.2	47.1
Children born to adult mothers	4,602,943	83.8	21.1
Living with two parents	1,887,779	34.4	11.5
Living with father only	340,534	6.2	31.6
Living with mother only	3,082,262	56.1	54.8
Living with neither parent	181,113	3.3	33.1

Poverty rates for young children are highest in urban areas but most poor young children live in suburban or rural areas.

In 1996, the poverty rate among children under age six living in urban areas was 32 percent, compared to 16 percent in suburban and 27 percent in rural areas. Of the 5.5 million young children in poverty, 42 percent lived in urban areas (2.3 million), 36 percent in suburban areas (2.0 million), and 22 percent in rural areas (1.2 million). (See Figure 6.)

Figure 6: Percentage distribution and number of poor children under age six by type of residential area, 1996

Poor children under age six: 5.5 million



Poor Children Under Age Six: Why Are They Poor?

Several factors help to explain why 5.5 million young children were poor in 1996. Each variable, taken alone, raises the risk of being poor. The cumulative effects of these factors are economically devastating. Some of the main elements are:

- Single parenthood
- Low educational attainment
- Part-time or no employment
- Low wages

Young children living in mother-only families are particularly vulnerable to the risk of poverty.

Seventeen percent of children under age six living with unmarried mothers who were employed full time were poor in 1996. In comparison, 59 percent of young children living with unmarried mothers who were employed part time were poor. The poverty rates of children under age six living with unemployed parents varied little between those in married two-parent families (82 percent) and those with unmarried mothers (81 percent). The high rates of poverty among children in single-mother families—even in those in which the mother is employed full time—stem primarily from the lack of a second source of income. (see Table 2) but also from reduced wages, which are associated with lower educational attainment. (See Table 3.)

In contrast, the poverty rate for children under age six in married two-parent families was quite low—only 6 percent—when at least one parent was employed full time. The poverty rate rose to 41 percent among those children under age six living in married two-parent families when at least one parent was employed part time but neither was employed full time. (See Table 2.)

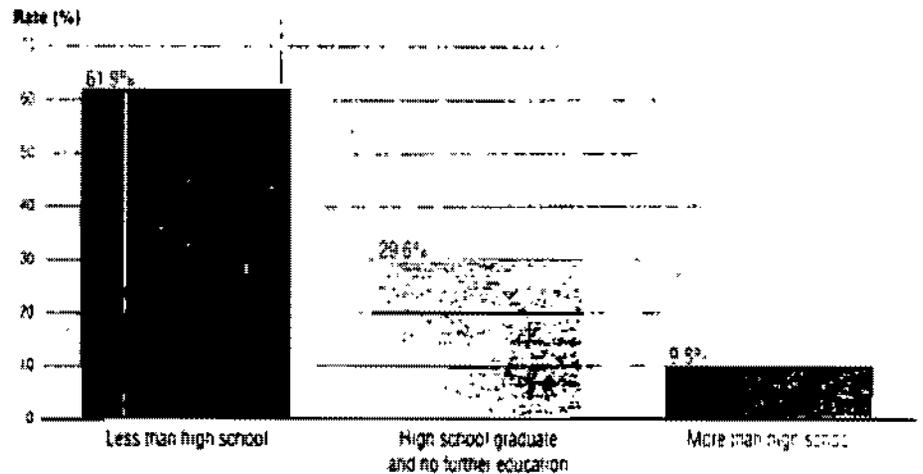
Table 2: Percentage distribution, number, and poverty rates of all children under age six by family structure and parental employment status, 1996

Family structure and parental employment status	All children under age six		Poverty rate %
	Percentage distribution	Number (in millions)	
Married two-parent families	100.0	16.5	11.5
At least one parent employed full time	87.0	14.3	6.4
At least one parent employed part time (neither employed full time)	11.5	1.9	40.7
Neither employed	1.5	0.3	82.0
Mother-only families	100.0	5.6	54.8
Employed full time	27.0	1.5	16.8
Employed part time	38.5	2.2	58.5
Not employed	34.6	1.9	80.5

Young children with well-educated parents are much less likely to be poor, but high school graduation is not enough to insure against poverty.

The poverty rate among children under age six whose more educated parent had more than a high school education was 10 percent, compared with 30 percent among those whose more educated parent graduated from high school and had no further education. The poverty rate was substantially higher—62 percent—among young children who had no parent(s) with a high school diploma. These statistics indicate that high school graduation alone does not insure an adequate family income. (See Figure 7.)

Figure 7: Poverty rates of children under age six by educational level of the more educated parent, 1996



More educated parents are more likely to be employed full time and to earn enough to avoid poverty.

Individuals with higher levels of education generally have more job opportunities, higher wages, and greater job security than those with lower levels of education. In 1996, among children under age six whose more educated parent had more than a high school education, 84 percent lived in families in which at least one parent held a full-time job. The poverty rate for this group was less than 4 percent. Among children under age six whose more educated parent was a high school graduate and had no further education, 63 percent lived in families in which at least one parent held a full-time job. The poverty rate for this group was 10 percent. (See Table 3.)

Among children under age six whose parents did not finish high school, only 37 percent lived in families where at least one parent was employed full time. The poverty rate for this group was 38 percent. (See Table 3.)

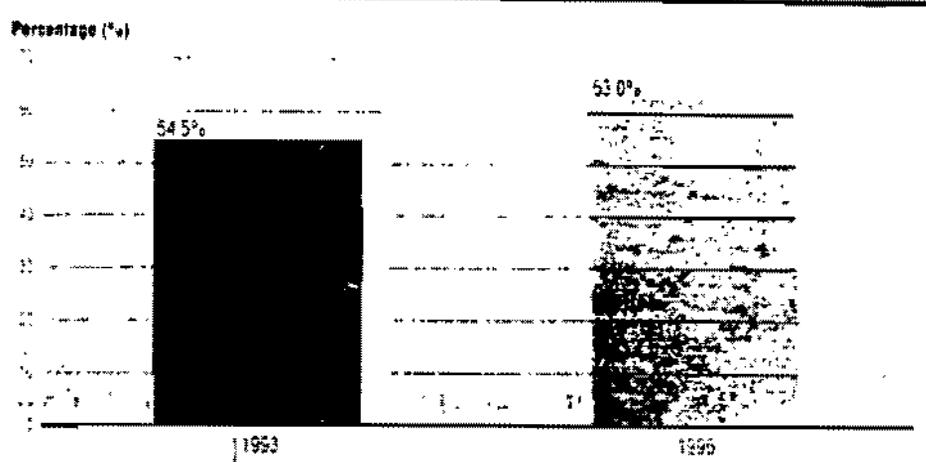
Table 3: Percentage distribution, number, and poverty rates of all children under age six by parental educational level and employment status, 1996

Educational level of more educated parent and employment status	All children under age six		Poverty rate %
	Percentage distribution	Number (in millions)	
Less than high school	100.0	3.4	61.9
At least one parent employed full time	37.0	1.3	38.4
At least one parent employed part time (neither employed full time)	28.8	1.0	63.8
Neither employed	34.1	1.2	85.9
High school graduate and no further education	100.0	6.4	29.6
At least one parent employed full time	63.2	4.1	10.0
At least one parent employed part time (neither employed full time)	26.3	1.7	56.9
Neither employed	10.5	0.7	79.0
More than high school	100.0	13.3	9.8
At least one parent employed full time	83.8	11.2	3.5
At least one parent employed part time (neither employed full time)	12.7	1.7	35.1
Neither employed	3.5	0.5	69.7

Over three-fifths of poor young children live in families in which at least one parent is employed.

In 1996, 63 percent—an increase from 55 percent in 1993—of poor young children had at least one parent employed part time or full time. (See Figure 8.) Forty percent of poor children under age six lived in families receiving public assistance—down from 53 percent in 1993. Twenty percent of poor young children lived in families relying exclusively on public assistance—down by over one-third from the level (31 percent) in 1993.

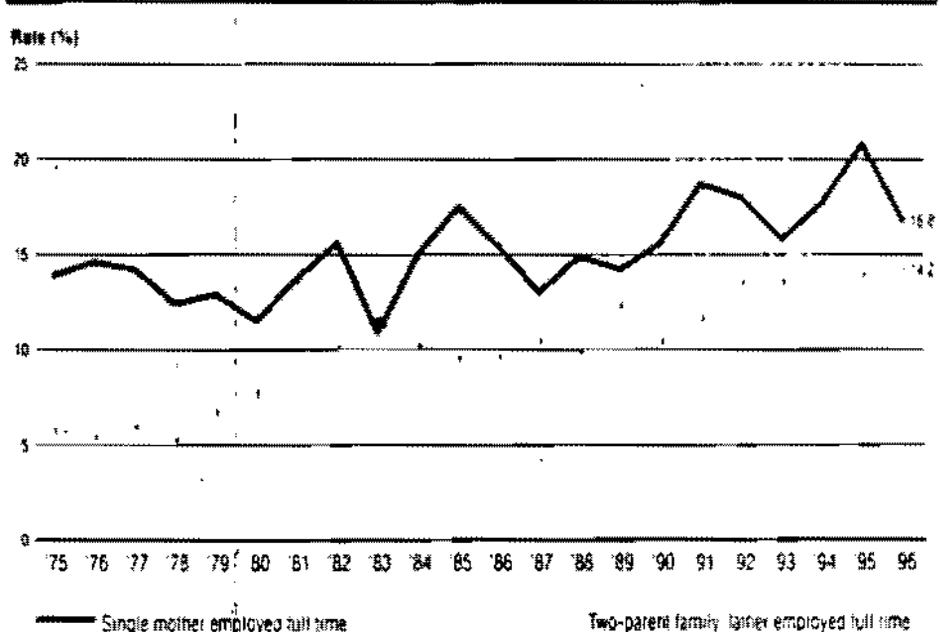
Figure 8: Percentage of poor young children in families with at least one parent employed part time or full time



One parent's full-time employment is no guarantee against poverty.

One in six young children (17 percent) living with unmarried mothers who were employed full time were poor in 1996. Among children under age six living in married two-parent families in which the father was employed full time and the mother was not employed, the poverty rate in 1996 was 14 percent. For children in both kinds of families, the poverty rate has been increasing steadily over the past two decades. (See Figure 9.)

Figure 9: Poverty rates of children under age six with single mother employed full time and in two-parent families with father employed full time and mother unemployed, 1975-1996



Judging the Impact of Programs and Policies: The Power of Alternative Poverty Measures

In choosing a particular poverty measure to gauge the economic well-being of young children in the United States, it is necessary to ask what kinds of income should be counted in determining who should be considered poor. The official poverty measure adopted by the federal government and used in the first part of this *Update* takes account of a variety of income sources such as wages and salary; earnings from self-employment; AFDC, General Assistance, Social Security, interest, dividends, and disability, just to mention a few.

The official measure, however, is deficient in that, in many instances, it does not reflect sources of income influenced by changes in policy and programs, for example, food stamps and the Earned Income Tax Credit (EITC).

NCCP has conducted analyses using an alternative measure of poverty to obtain a more complete picture of the economic impact of programs and policies on low-income families. This measure incorporates the same income sources as the Census Bureau does, but in addition includes cash equivalents of the following "near-cash" benefits:

- Food stamps
- Housing subsidies
- School lunch benefits

Further, NCCP:

- includes income derived from the Earned Income Tax Credit
- subtracts federal, state, and payroll taxes from income

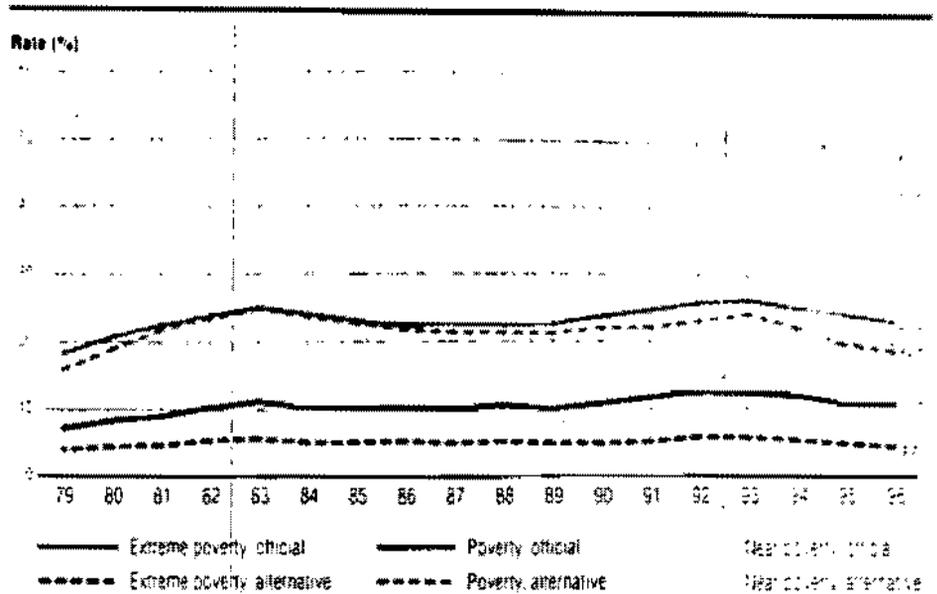
What do we learn about trends and distributions of young child poverty from the alternative poverty measure?

Using the alternative measure in 1996 cuts the extreme poverty rate by over one-half, reduces the poverty rate by one-fifth, and significantly increases the near poverty rate.

As Figure 10 illustrates, the official and alternative poverty measures paint somewhat different pictures. The underlying reason for these differences is that at very low income levels—namely, below 50 percent of the poverty threshold—near-cash benefits contribute significantly to overall income. Also, taxes play a minimal role. Thus, the alternative measure of poverty yields significantly fewer extremely poor individuals than does the official measure—a 59 percent decrease in the rate, from 11 percent to 4 percent. In contrast, for incomes in the near poverty range—that is, between 100 and 185 percent of the poverty threshold—benefits are relatively few and taxes predominate. The net result is a substantially greater number among the near poor population. The alternative near poverty rate, 49 percent, is six percentage points higher than the corresponding official rate. When estimating poverty rates, including benefits and taxes generally diminishes somewhat the estimated number of poor individuals. For 1996, the alternative poverty rate was 19 percent, compared with the official rate of 23 percent. However, it is only in recent years that the two series of poverty rates have begun to significantly diverge. (See Figure 10.)

* This alternative measure does not include the costs associated with employment, such as child care, transportation, clothing, etc., which unfortunately are not available in the LFS. Taking these costs into account would serve to raise poverty estimates. This alternative measure also does not account for the significant regional variation in cost of living. The most complete measure of poverty that would address these issues was recommended by the Panel on Poverty and Family Assistance of the National Research Council in their volume, *Measuring Poverty: A New Approach* (1995) edited by C. F. Citro and B. T. Michael, Washington, DC: National Academy Press.

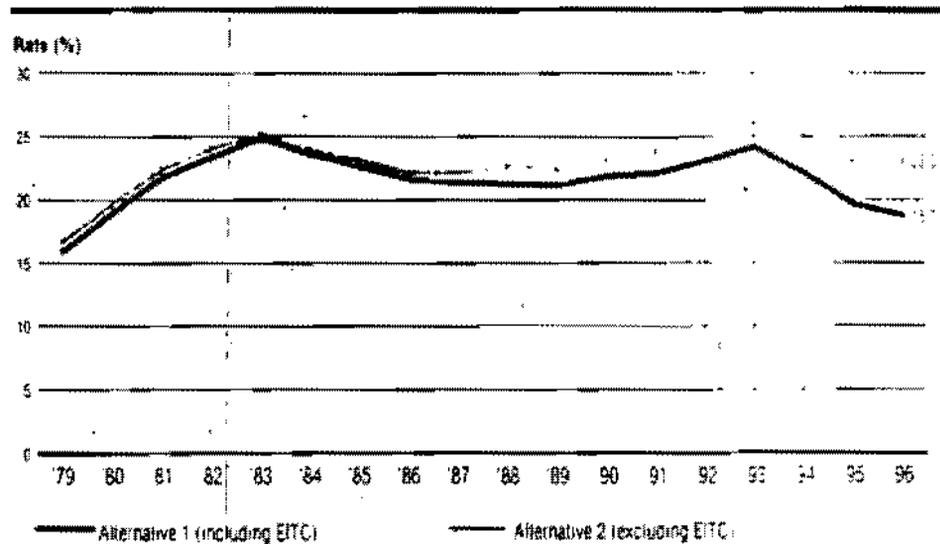
Figure 10: Extreme poverty, poverty, and near poverty rates for children under age six by official and alternative measures, 1979-1996



The Earned Income Tax Credit has become an increasingly effective tool against poverty.

The divergence in recent years between official and alternative poverty rates coincides with the expansion of the EITC in 1993. The result of this expansion is easily seen in Figure 11, which graphs the alternative measure, both including and excluding the effects of the EITC.* In 1996, the YCPR using the alternative young child poverty measure would have been 23 percent higher in the absence of the EITC; in 1993 the increase would have been only 8 percent. NCCP's analysis shows that the EITC has especially benefited groups that have historically had higher poverty rates, such as single-parent families, blacks, and Hispanics. (See Figures 12 and 13.)

Figure 11: A comparison of poverty rates for children under age six using alternative measures of poverty with and without the EITC, 1979-1996



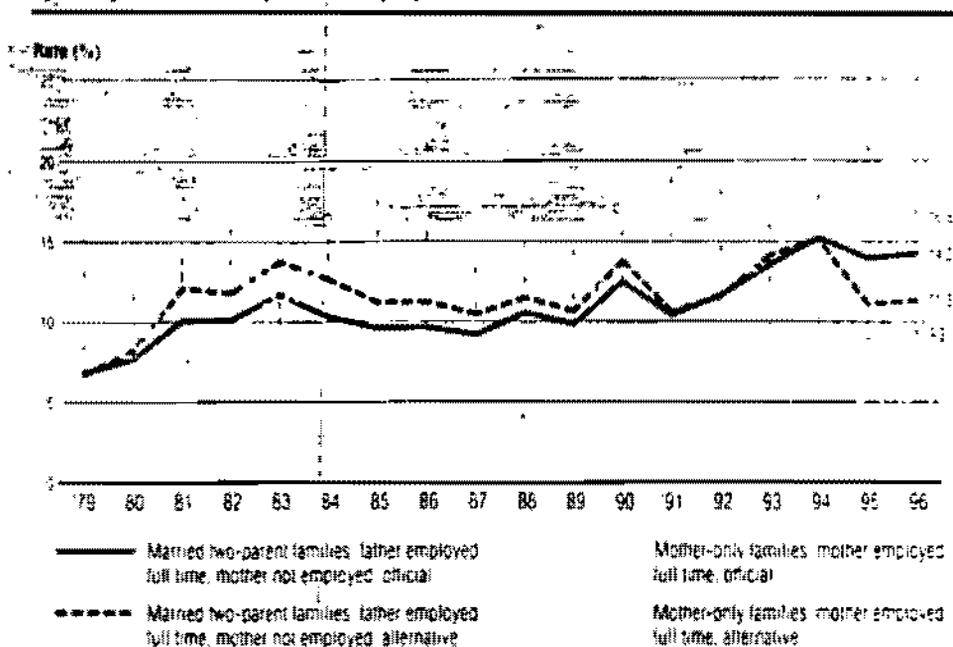
* The Census Bureau imputes the EITC for all individuals in the CPS and assumes that all eligible persons actually obtain it. Thus, any CPS analysis using a measure that incorporates the EITC should be interpreted as addressing the potential, and not necessarily the actual impact of the EITC. In 1981, the estimated participation rate was 80 to 86 percent (Scholar, K. (1994). The Earned Income Tax Credit: Participation, compliance, and antipoverty effectiveness. *National Tax Journal*, 47(1), pp. 63-87). According to White and the Center on Budget and Policy Priorities, the participation rate is likely to have increased since 1981 in response to public awareness campaigns. Also, the amount of the credit has grown and eligibility for the EITC has been expanded.

The Census Bureau attributes the EITC income it imputes to the previous year rather than the year in which the EITC recipient files taxes. (Only about 1 percent of those eligible for the EITC receive a portion of their EITC income through their employer, as the same year it was earned.) In analyzing the CPS, one cannot properly apply EITC income to the year in which it was actually received because that would require two consecutive years of income information for the same individuals—information that is not available in the CPS.

The alternative poverty measure may lead to different conclusions regarding the relative poverty of different groups.

According to the official poverty measure, a greater percentage of young children are poor in mother-only families in which the mother is employed full time than is the case in two-parent families in which the father is employed full time and the mother is not employed. In contrast, however, the alternative measure indicates that since 1993 the reverse is true. This is likely due to the recent expansion of the EITC. (See Figure 12.)

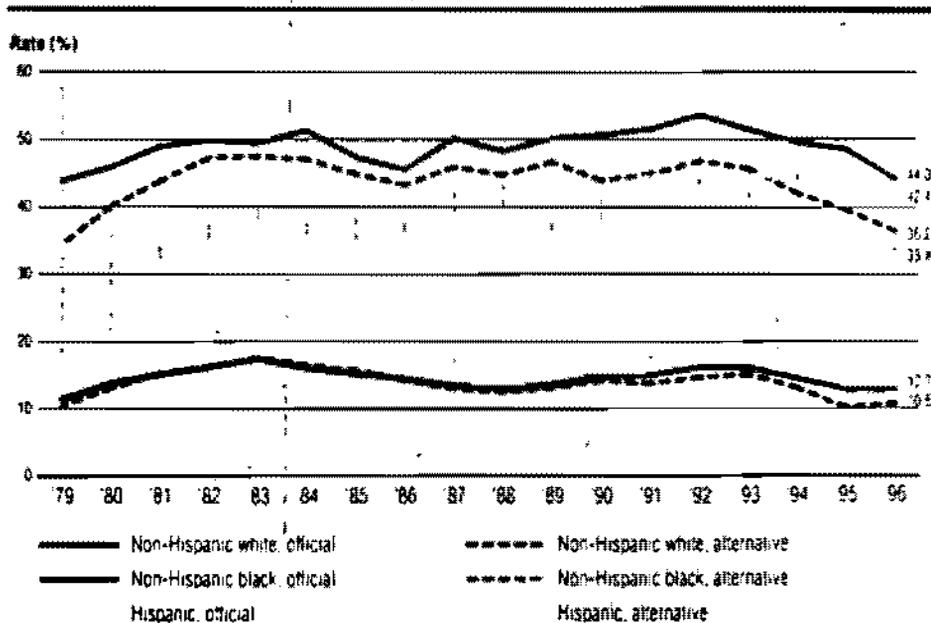
Figure 12: Official and alternative poverty rates for children under age six by family structure and parental employment status, 1979-1996



On the other hand, evidence from alternative poverty measures can buttress findings implied by the official measure.

Using the official poverty measure reveals that over the years non-Hispanic black young children have had the highest poverty rates, followed by Hispanic young children, and then by non-Hispanic white young children. The alternative estimates of young child poverty show the same pattern, although at moderately different levels. (See Figure 13.)

Figure 13: Official and alternative poverty rates for children under age six by race, 1979-1996



Understanding the Poverty Rate Decline Between 1993 and 1996

The official poverty rate for families with young children decreased by almost three percentage points—from 23.5 to 20.9 percent from 1993 to 1996.⁷ Why did this decline occur? NCCP's analysis rules out some potential explanations. Changes in family structure cannot explain the decline because there was actually a continued trend towards more single-parent families which, due to their tendency to have lower incomes, worked against improvements in the YCPR. The educational attainment levels of parents of young children improved marginally between 1993 and 1996, but the impact of this progress on the YCPR was insubstantial.

Parental Employment Patterns and Young Child Poverty

Two possible explanations exist for the decline in the official poverty rate between 1993 and 1996: (1) a greater proportion of the population was employed, or (2) there were lower poverty rates among those who were employed. NCCP explored these two alternatives and found that the first explanation was more powerful. From 1993 to 1996, the proportion of families with young children that had no parent employed full time decreased by 14 percent, from 33 percent to 28 percent.

At the same time, the poverty rate decreased modestly for such families, from 59 percent to 57 percent and the poverty rate increased insignificantly for families in which parents were employed full time. (See Table 4.) NCCP's decomposition analysis indicates that 85 percent of the overall decline in the official poverty rate can be attributed to improved employment rates rather than lower poverty rates among those employed.⁸

Table 4: Official and alternative poverty rates by employment status among families with children under age six, 1993 and 1996

Parental employment status	1993			1996		
	Official poverty rate (%)	Alternative poverty rate (%)	Percentage of families in category	Official poverty rate (%)	Alternative poverty rate (%)	Percentage of families in category
At least one parent employed full time	6.3	6.5	67.5	6.7	4.6	71.9
No parent employed full time	59.0	51.7	32.5	57.1	46.9	28.1
Total	23.5	21.2	100.0	20.9	16.5	100.0

Note: The poverty rates shown in this table differ somewhat from those appearing elsewhere in this Update because the unit of analysis is families rather than children.

⁷ These poverty rates differ somewhat from the YCPR used earlier in this Update. The latter is based on the child as the unit of analysis while the former uses the family as the unit of analysis. As will be clear from the following discussion, we use the latter as the unit of analysis because at one point NCCP compares families without young children with those with young children.

⁸ This is a bivariate analysis which does not control for other factors that might be associated with the rise in full-time employment.

Welfare Reform and Young Child Poverty

Alternative Measures and the 1993-1996 Decline in the Young Child Poverty Rate

Between January 1993 and August 1996, 43 states received federal waivers allowing them to implement significant changes in state welfare laws. NCCP found no substantial evidence that these state-initiated welfare reforms contributed to the decline in the young child poverty rate that occurred during the 1993-1996 economic recovery. Gains in employment and lower poverty rates were similar for both families without young children (only 3 percent of whom received public assistance in 1996) and families with young children (who were about four times as likely to receive such assistance). Consequently, there is little evidence that welfare reform contributed significantly to lower young child poverty rates.

The same pattern holds true for 1983 to 1986—a similar period of substantial economic recovery, yet one unaffected by substantial changes in state welfare policies. The contribution of a boost in employment rates to the three-point decrease in the official poverty rate is virtually identical to the contribution inferred for the more recent three-year period. At this date, it is still too early to conduct a thorough analysis of the 1996 federal welfare reform law's impact on the incidence of young child poverty.

Viewed through the lens of the alternative poverty measure, NCCP found a more substantial drop in poverty among families with young children, from 21.2 to 16.5 percent, than that obtained using the official measure. The use of the alternative measure reveals significant reductions in poverty among both families with full-time employed parents—a 30 percent drop from 6.5 percent to 4.6 percent—and among families without a full-time employed parent—a 10 percent decline from 51.7 to 46.9 percent. (See Table 4.)

NCCP's decomposition analysis finds that 40 percent of the overall decline in the alternative poverty rate between 1993 and 1996 can be attributed to improvements in the full-time employment rate. This is in clear contrast to the 85 percent figure derived in the analysis of data based on the official poverty rate. NCCP's analyses of alternative measures including or excluding the EITC indicate that the EITC is responsible for much of the decrease in poverty among both families with full-time and part-time employed parents.

These analyses of the reductions between 1993 and 1996 in the official and alternative poverty rates offer two different windows into the realities of young child poverty. The use of the official rate suggests that the decline was due primarily to changes in the employment structure; the use of the alternative measure implies that government policies—particularly the EITC—also played an important role. The alternative poverty measure adopted in this *Update* is a first step towards the development and use of a poverty measure that would be capable of better reflecting the changes in policies and programs that affect the economic well-being of our nation's families and young children.

Young Children in Poverty: A Statistical Update, March 1998 Edition. Prepared by Jiali Li and Neil Bennett.

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NCCP was established in 1989 at the School of Public Health, Columbia University, with core support from the Ford Foundation and the Carnegie Corporation of New York. The Center's mission is to identify and promote strategies that reduce the number of young children living in poverty in the United States, and that improve the life chances of the millions of children under age six who are growing up poor.



**NATIONAL
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POVERTY**

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APR 1 1998

NOTE TO THURGOOD MARSHALL, JR.

FROM: MARY BETH DONAHUE *ms*

SUBJECT: MEMORANDUM FOR THE PRESIDENT

Attached is a memorandum from Secretary Shalala to the President which provides highlights from the National Center of Children in Poverty's report "Young Children in Poverty: A Statistical Update." Secretary Shalala has requested that this memorandum be forwarded to the President.

Attachment



FEB 19 1998

MEMORANDUM TO THE PRESIDENT

THROUGH: THE VICE PRESIDENT

On November 20, 1997, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, which I co-chair with the Secretary of Labor, presented you with its *Consumer Bill of Rights and Responsibilities*. At that time, you directed the Secretaries of Defense, Labor, Health and Human Services, Veterans Affairs, and the Director of the Office of Personnel Management to report to you by February 19, 1998, on the extent of each agency's current compliance with the Bill of Rights, and to identify impediments to further compliance.

This Department has made the pursuit of full compliance with the Commission's recommendations a high priority. This Memorandum explains not only what we have accomplished to date, but also what we have underway and plan to accomplish in the near future, and the obstacles we still face.

EXECUTIVE SUMMARY

At the outset, I would like to emphasize that protection of health care consumers -- in the broadest sense -- is critical to virtually every activity in which HHS is engaged. The reach of HHS programs is very broad, affecting specific and often vulnerable populations, and the nation as a whole. Through these programs, we establish and ensure that basic standards of quality are met by drugs and devices, as well as by providers and facilities. We provide grant funding, directly and through States, to insure that vulnerable populations -- children, low-income parents, people with disabilities, people with mental health or substance abuse problems -- get access to needed care from providers who respect their needs. We conduct research to identify ways to measure and communicate information about quality and the availability of consumer choice in health care. We work with the entire health care industry -- public and private -- to set and achieve goals for prevention and health promotion.

Because protecting consumers is such a critical element of our mission, we have responded to your directive in three ways:

- First, I commit this Department to implementation of all regulatory changes needed to bring us into full compliance with the Bill of Rights (where such changes can be made under existing statutory authority).
- Second, I have established a working group, comprised of every HHS component responsible for providing, monitoring, or advancing knowledge about consumer protection, that will report to me on an on-going basis about how to continue to improve the consumer protections afforded by all HHS programs. I have asked this working group

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to look not only at the protections recommended in the Bill of Rights, but also at other ways we can improve consumer protection in HHS activities and programs.

- Third, I have asked all programs that fund health services to individuals, either directly or through block grants to States, to begin discussions with grantees about how they can apply the Bill of Rights in their programs. This includes working with both States and the private insurance industry to set standards for the recently enacted Children's Health Insurance Program.

In addressing the directive, we focused our evaluation of the Bill of Rights on Medicare, Medicaid and the Indian Health Service, three programs that are either health care systems or plans in their own right or that contract with plans for managed care services. Such a broad approach reflects the realities of an increasingly complex health care system that is striving to balance the pursuit of quality with the need to hold down costs. It also reflects the Commission's stated intention that the Bill of Rights apply to all consumers, regardless of the type of health plan in which they are enrolled.

I am pleased to report that these Programs' current compliance with the Commission's recommendations is substantial:

- Medicare meets or exceeds nearly all of the Commission's recommendations and has the statutory authority to achieve compliance in all but a few areas. Additional authority is needed to bring the program into full compliance with all aspects of the Commission's recommendations regarding choice of providers (for certain enrollees), confidentiality, transitional care, and nondiscrimination.
- Medicaid meets or, with the implementation of the provisions in the Balanced Budget Act, will soon be in compliance with the Commission's recommendations in all but a few areas. As with Medicare, additional authority is needed to bring the program into full compliance with all aspects of the Commission's recommendations regarding choice of providers (for certain enrollees), confidentiality, transitional care, and nondiscrimination.
- The Indian Health Service is in general compliance with the Commission's recommendations for those aspects of its program that are directly under its control. I am initiating a consultation with the tribes in order to further enhance the availability of protections to all American Indians and Alaskan Natives.

Additionally, we have begun reviewing how HHS programs that deliver health services to individuals, either directly or through block grant programs, comply with the Commission's recommendations. A brief discussion of these programs, as well as some of the other activities underway that will contribute to our understanding about how to protect health care consumers, is included in Section II of this report. Because the Children's Health Insurance Program was enacted only recently and regulatory development is in the early stages, it is premature to assess

this program's compliance with the Bill of Rights. However, the Bill of Rights will inform HHS activities as the Department implements this program.

I Medicare, Medicaid, and the Indian Health Service

A. Introduction

The Medicare and Medicaid programs and the Indian Health Service are together responsible for health services for over 70 million aged, disabled, low-income or Native American people. Each program has its unique legislative and regulatory infrastructure as well as different programmatic requirements, with respect to implementing the Bill of Rights.

- Medicare is a national health insurance program for people 65 years of age and older, certain people with disabilities, and people with kidney failure. Medicare currently enrolls about 38 million persons -- 33 million elderly and 5 million individuals with disabilities.

The Medicare program is entirely federal; where there is not sufficient statutory authority to implement the consumer protections recommended by the Commission, an Act of Congress can provide the necessary authority.

- Medicaid is a Federal-State program for certain low-income vulnerable individuals and families. Within broad Federal guidelines, the States administer the Medicaid program. Medicaid currently enrolls about 36 million individuals -- 18 million children, 7 million adults in families with children, 5 million elderly, and 6 million individuals with disabilities.

While Medicaid has historically provided services through fee-for services arrangements, in recent years, it has moved quickly into managed care. State Medicaid programs provide managed care through voluntary managed care systems and mandatory enrollment systems. Many States currently are operating their programs under waivers from HCFA that permit them to require beneficiaries to enroll in managed care. Moreover, the BBA recently added a new State Plan Option under which a State can require certain classes of beneficiaries to enroll in managed care, without obtaining a waiver. The availability of the protections recommended by the Commission must, in some instances, be assessed on a State by State basis. In some state Medicaid managed care purchasing strategies, consumer protections meet and may even exceed those identified by the Commission.

Unlike Medicare, the authorities governing consumer protection in Medicaid are a combination of State and Federal requirements. Because of the importance of State flexibility in administering the Medicaid Program, where protections do not exist or are

not uniform, Congressional action must take into account the different needs and desires of the State Medicaid programs.

Indian Health Service: The Indian Health Service (IHS) is the principal federal agency charged with delivery of health services to 1.4 million American Indians and Alaska Natives. These services are provided in a unique health care system operated in partnership with Indian tribes.

As a system of fee-for-service providers, the IHS sets standards for the conduct of the providers and clinics under its control; under limited circumstances, the IHS will purchase services from non-IHS providers when those services are not otherwise available. Indians are also eligible for Medicare and Medicaid, which will pay for covered services provided to eligible individuals in all IHS and tribal facilities that meet HCFA's standards.¹

Significantly, for an increasing portion of its budget, the IHS provides funds directly to tribes which themselves make decisions about the provision of care and allocation of resources -- this may or may not involve IHS facilities. The tribal health care systems are autonomous and diverse. Beyond accreditation standards, which include general requirements to insure patients rights, it is not possible to detail the extent to which each tribe's practices are in compliance with the Bill of Rights.

The partnership between the IHS and the tribes is both legal and political. While the Federal government no longer negotiates treaties with the Indian nations, changes in the conduct of health care by the tribes require extensive consultation.²

In the analysis that follows, we begin with the Commission's statement of each Right. In addition to assessing compliance with each Right as stated, we also evaluate our compliance with some of the additional qualifications and concerns discussed by the Commission, where feasible. With respect to Medicare and Medicaid, the following analysis describes planned uses of HHS administrative authority that will improve compliance with the Bill of Rights as well as the statutory obstacles to full compliance. We are in the midst of developing regulations to implement the Balanced Budget Act of 1997 (BBA), which added or clarified many of the consumer protection identified in the Bill of Rights. These policies are noted where relevant.

¹ For example, IHS and tribal organizations rely on the Joint Commission for the Accreditation of Health Organizations (JCAHO) and other accrediting bodies as the yardstick for quality health care delivery. Accreditation of facilities has been an emphasis of the IHS for the past 15 to 20 years. Currently all IHS and tribally operated hospitals are accredited by JCAHO and all eligible IHS outpatient facilities are accredited by JCAHO or an alternative accrediting body.

² For example, under the Indian Self Determination Act, last amended in 1994, and related authorities, tribal government entities have unique authorities concerning such issues as non-discrimination and confidentiality of patient records as they apply to facilities they operate. Modification of the Act (or the related authorities) would require consultation with the tribes.

Because of the importance of tribal autonomy, a detailed assessment of IHS compliance with the Bill of Rights, and of administrative authorities and statutory obstacles to compliance, is not relevant to the IHS. Instead, the following analysis describes in general terms the extent to which IHS facilities are in compliance. To address the IHS in its entirety I have, with the assistance of the IHS, begun consultation with the tribes to identify how best to insure their compliance with the Bill of Rights.

B. Compliance with the Bill of Rights

1. Information Disclosure

"Consumers have the right to receive accurate, easily understood information, and some require assistance in making informed health care decisions about their health plans, professionals, and facilities."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare. Medicare currently does, or with the implementation of the BBA will, provide enrollees with substantial information in all of the major categories identified by the Commission, and thus is in substantial compliance with this Right (although not every information element identified in the Commission's extensive discussion is or will be provided). HCFA is in the midst of identifying the kinds of information it has available and the most effective ways to provide it, and is dedicated to improving the assistance it provides its beneficiaries. Some of the most noteworthy examples of current activities include:

- All Medicare beneficiaries, whether they are enrolled in fee-for-service or managed care, currently receive a copy of the *Medicare Handbook* from HCFA. The *Handbook* provides comprehensive and easy-to-understand information for Medicare enrollees about the program, addressing such questions as: covered and excluded services under Medicare; differences between managed care and fee-for-service under Medicare; and how to proceed with complaints about Medicare-covered services. Updated regularly, the next version of the *Handbook*, describing the broader array of health plan choices enacted in the BBA, will be sent to beneficiaries in Fall 1998.
- Medicare publishes a number of issue-specific pamphlets, such as "What Medicare Beneficiaries Need to Know About Health Maintenance Organizations: Know Your Rights" (in collaboration with the HHS Office of the Inspector General). Many of these publications are available in non-English languages and other specialized forms of communication such as braille and audiotape.
- Through its National Marketing Guidelines for Managed Care (which prescribe how a plan may describe such features as its benefits, cost sharing, and grievance and appeals procedures), HCFA sets standards for the content of all marketing materials provided by

managed care plans to potential Medicare enrollees. HCFA also reviews all marketing materials before plans are allowed to use the material. Hence, it is able to assure both the consistency and accuracy of these important communications with beneficiaries.

The Department has also made significant progress toward addressing the Commission's concern that some consumers may "require assistance in making informed health care decisions about their health plans, professionals and facilities." Statewide Insurance Counseling and Assistance (ICA) programs, partially funded by HCFA and operated by the Administration on Aging through the State Agencies on Aging, provide beneficiaries with information about Medicare managed care and the types of health insurance available to supplement Medicare, including Medigap and long-term care insurance. Counselors help answer questions about medical bills, insurance claims, and Medicare benefit explanation forms. HCFA also operates a toll-free information line, as well as phone-lines for hearing and speech-impaired individuals.

Medicaid. Medicaid is a State-administered program, with ultimate responsibility for administration resting in each State. While there is no Federal analog to the *Medicare Handbook* for Medicaid, each State is obligated to make its policies about its program available to beneficiaries, including eligibility, covered services, and beneficiary rights and protections—including the right to a fair hearing.

With the rise in the Medicaid managed care programs, States have been more active in efforts to improve the availability of information about quality and consumer satisfaction. HCFA is continuing to work collaboratively with States and the National Governors' Association to develop Medicaid-relevant consumer information strategies, such as Medicaid HEDIS measures, a Medicaid-relevant module of the Consumer Assessments of Health Plans Survey (CAHPS) and several related efforts to improve communication and comprehension of information among low-literate and non-English speaking individuals. HCFA has disseminated the best practices of leading states as part of its technical assistance activities.

Indian Health Service. IHS hospitals and clinics provide their patients with information about the facilities consistent with the standards of their accreditation. In addition, the IHS has undertaken an active campaign to improve Indian peoples' understanding of the benefits and services it provides, as well as the consumer rights and protections available in both Federal and tribal facilities. Its brochure, "Customer Satisfaction in the Indian Health Service: Providing the Best in Health Services to American Indians and Alaska Natives," has had wide circulation.

IHS is engaged in an effort to begin to collect patient satisfaction and quality of care information, which it plans to make available to its patients.

Current and Planned Use of Administrative Authorities:

Medicare. The BBA added a significant new array of managed care choices for beneficiaries and identified information disclosure requirements appropriate to those choices. Consequently, we

believe that we have the tools to remain in compliance with the Right, even as the program undergoes substantial change.

HCFA is also engaged in efforts to provide Medicare beneficiaries with comparative information that will ultimately include measures of quality and consumer satisfaction.

- Later this year, HCFA will bring the Internet closer to its beneficiaries by inaugurating *Medicare Compare*, an interactive site (based at <http://www.Medicare.gov>) that will offer beneficiaries market-specific, comparative health plan information about the managed care alternatives available in their areas.
- Later this year, HCFA will begin to report to the public on the performance of Medicare managed care organizations based on audited information, using the Health Plan Employer Data and Information Set (HEDIS 3.0). HEDIS 3.0 is the industry standard, representing the collective efforts of public and private purchasers, health plans, consumers and researchers to establish a common and meaningful set of measures for evaluating managed care plans.
- HCFA will soon begin to collect beneficiary satisfaction information from enrollees in managed care organizations using a newly developed independently-administered survey instrument, the Consumer Assessments of Health Plans Survey (CAHPS). CAHPS is the product of a major research and development effort under the aegis of the Agency for Health Care Policy and Research (AHCPR).

Medicaid. The BBA also provides important tools to bring Medicaid into full compliance with the Commission's recommendations concerning information disclosure. For example, the BBA requires each State to disclose specific categories of information about the managed care plans available to its Medicaid beneficiaries, including information about quality. States that require individuals to enroll in managed care organizations under a State Plan Option must also provide information about benefits and cost sharing. The BBA also requires managed care entities to receive prior approval from the State before releasing marketing materials.

Statutory Impediments to Full Compliance.

Medicare. As a result of the BBA, Medicare has the regulatory authority it needs to maintain compliance with the information disclosure Right articulated in the Bill of Rights.

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2. Choice of Providers and Plans

"Consumers have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare. Under fee-for-service Medicare, beneficiaries have virtually unimpeded access and unlimited choice. Most Medicare beneficiaries are also free to choose between fee-for-service and any of the managed care plans available in their area.

Medicare managed care is in full compliance with the Commission's recommendations concerning provider network adequacy, which require that plans be able to provide all covered services (directly or under arrangement) without unreasonable delay; indeed, the recommendations mirror existing Medicare requirements. Medicare managed care is also in compliance with the Commission's recommendation that consumers have access to appropriate high-quality providers.

At present, Medicare managed care plans are not required to authorize direct access to specialists for enrollees with complex or serious medical conditions. In addition, under current Medicare law and regulation, plans have the flexibility to determine which types of providers are appropriate to render which types of services, as long as the provider is qualified by state law. Thus, some plans may not be in full compliance with the Commission's recommendation that women be able to choose any type of provider for routine and preventive women's health care services. Similarly, Medicare plans do not currently provide persons with chronic or disabling conditions continued access to providers who have been terminated from the plan for other than cause, as recommended by the Commission. Specifically:

- If a beneficiary elects to enroll in a managed care plan, his or her choice within the plan is more constrained than under fee-for-service. Under current law and regulation, plans are permitted to assign each patient a "gatekeeper", who is permitted to control referrals to specialists. If a plan's gatekeeper referral system impedes access to appropriate care—including timely access to necessary specialty care—HCFA may use its oversight authority to find the plan out of compliance with the statute's "access and availability" requirements.
- Plans are free to develop the gatekeeping system they find appropriate for their population, within HCFA's "access and availability" constraints. A number of Medicare managed care organizations have begun offering "open access" plans, in which enrollees do not have to go through a gatekeeper to obtain specialists services or services of a particular provider. There is no requirement that plans authorize direct access to specialists for any group of enrollees.

- ▶ Current law requires that all covered services be provided by qualified providers, and the plan has the flexibility to determine which types of providers it will offer for particular services. Plans are not currently required to permit women to identify for themselves the type of provider they wish to use for routine and preventive services, nor does HCFA intervene in plans' decisions about which provider types to include in their networks. Again, HCFA's "access and availability" requirements guarantee that appropriate care is available.
- ▶ Medicare does not currently have a means to accommodate the transitional care needs of individuals undergoing a course of treatment who experience an involuntary change of either plan or provider and who wish to remain in managed care.

Unlike many in the private sector, Medicare enrollees retain the right to switch plans or disenroll from managed care altogether and return to fee-for-service. Currently, such changes can be made on a monthly basis, although eventually this will become annual, as a result of changes made by the BEA. In some cases, however, returning to fee-for-service can be accompanied by difficulty in obtaining or restoring supplemental Medigap insurance; this has been somewhat addressed by the BEA but additional improvements could be made (as discussed below.)

Medicaid. The Medicaid program's compliance with this Right is comparable to that of Medicare.

Under fee-for-service, Medicaid beneficiaries have the right to choose any provider who will accept Medicaid payment as payment in full.

With regard to managed care, States have generally been permitted under waivers to limit the number of managed care plans from which a beneficiary may choose to no fewer than two, but must permit beneficiaries to change their managed care organization. With certain exceptions (involving "carve out" arrangements for dental care or mental health care services), plans must guarantee beneficiaries the right to choose a health professional from within the managed care network.³

As with Medicare, Medicaid managed care plans generally are not required to authorize direct access to specialists for enrollees with complex or serious medical conditions, nor to allow women to choose any type of provider for routine and preventive women's health care services. Similarly, Medicaid plans do not currently provide persons with chronic or disabling conditions continued access to providers who have been terminated from the plan for other than cause, as recommended by the Commission. While plans are free to provide such choices, they are not required to do so.

³ The Commission's recommendations regarding network adequacy apply somewhat differently in the Medicaid program, because States may contract with a managed care plan for only a sub-set of Medicaid benefits, and make other arrangements (including fee-for-service) for the remaining services.

Indian Health Service. Within the IHS system, eligible Indian people are free to choose the clinic at which they receive care as well as the provider within a specific facility. Through the Contract Health Services (CHS) program, the IHS has the ability to contract with non-IHS providers for specific care that cannot otherwise be obtained. Historically, however, the highly constrained annual appropriation for these services imposes a discipline on the selection of cases (priority to preservation of life and limb) and contracted providers that, as a practical matter, constitutes a limitation on the nature and extent of beneficiary choice otherwise available.

Current and Planned Use of Administrative Authorities.

Medicare. With implementation of the BBA, Medicare will offer more choices to beneficiaries by allowing new types of health plans to participate in the program and by extending availability of Medicare+Choice plans to new geographic areas, particularly underserved rural and urban areas. Medicare+Choice will also expand upon current Medicare standards requiring availability and accessibility of covered services.

Using its current authorities, HCFA can address only one of the areas in which Medicare plans may not be in compliance with the Commission's recommendations. HCFA could issue a regulation (or other policy guidance) requiring plans to develop treatment plans that authorize an adequate number of direct access visits to specialists for patients with complex and serious medical conditions. HCFA has identified this issue as a potential area for Presidential action. Such an expansion could permit greater flexibility in response to an individual patient's needs while retaining the coordination that is the hallmark of well-managed care.

Medicaid. With some limited exceptions, the BBA codifies the existing waiver program requirements and permits States to limit beneficiary choice to no fewer than two managed care organizations. Each managed care organization will be required to provide assurances to the State and HHS that the range of services and access it offers are appropriate for their anticipated Medicaid enrollment and that it will maintain a sufficient number, mix, and geographic distribution of providers. This will bring Medicaid into compliance with the Commission's recommendation concerning provider network adequacy.

As with Medicare, under current authority, Medicaid can only address the Commission's recommendation concerning direct access to specialists for those with serious or complex conditions. HCFA could achieve compliance with this recommendation through regulation or other policy directive, and has identified this as a potential area for Presidential action.

Statutory Impediments to Full Compliance.

Medicare. Current law and regulations allow managed care plans discretion to choose the type of practitioner who will provide a particular service, including women's health care services. For example, under current law, a plan may designate a primary care physician instead of a gynecologist to provide routine pelvic and breast exams. A statutory change would be needed if

Medicare were to specify (or allow beneficiaries to specify) the type of practitioner a plan must use to provide women's health services, as the Commission recommends.

Similarly, a statutory change would be needed to compel a plan to pay for the services of a physician it had dropped from its panel. In the case of a termination of a contract, by a plan or by HCFA, resulting in involuntary disenrollment of Medicare beneficiaries, a statutory change would be needed (a) to ensure continued access to specific providers during a transition period, and (b) to establish how, and by whom, such providers are to be paid during the transition period.

Finally, the BBA partially addressed the difficulty in obtaining or restoring Medigap coverage that some beneficiaries have experienced when they return to fee-for-service from managed care, by requiring guaranteed issue under certain circumstances. A statutory change would be needed, however, to provide Medigap protection for beneficiaries leaving managed care under all circumstances.

Medicaid. Under Medicaid, Federal legislation would be needed to require all plans to permit women to select a particular type of provider for routine and preventive women's health care services. Many State Medicaid programs currently provide this option under waivers or are required by State law to provide such access to gynecologists in a managed care setting, but there is no Federal authority for imposing this requirement on all States and plan.

Federal legislation would also be necessary to require States to provide coverage for transitional care under Medicaid.

3. Access to Emergency Services

"Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a prudent layperson could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare and Medicaid. The Medicare and Medicaid programs are in full compliance with this Right. In fact, aspects of the current HCFA requirements were incorporated into the Commission's recommendations. The Emergency Medical Treatment and Labor Act mandates that all persons -- not just Medicare and Medicaid beneficiaries -- have access to emergency services at any Medicare-participating hospital that offers such services. As recommended by the Commission, Medicare and Medicaid go further and require payment for such services.

With regard to payment for emergency services under Medicare and Medicaid, fee-for-service beneficiaries may obtain emergency services from any qualified provider. Under Medicare and Medicaid managed care, plans are financially responsible for emergency services provided to their enrollees both by in-network and out-of-network providers, and are prohibited from requiring prior authorization for emergency services. Such services are defined according to a "prudent layperson" standard, which stipulates that the need for emergency services should be determined from a reasonable patient's perspective.

Indian Health Service. Where emergency situations arise that require service in non-IHS facilities, the Contract Health System (CHS) applies a standard consistent with that described in the Bill of Rights.

Current and Planned Use of Administrative Authorities.

Medicare and Medicaid. The BBA codifies the "prudent layperson" standard for both Medicare and Medicaid. It also requires Medicare+Choice and Medicaid managed care plans to provide information to enrollees about emergency coverage. The implementing regulations for the BBA, to be published this summer, will reflect this policy. The BBA also authorized the Department to develop guidelines to insure adequate coordination of post-stabilization care for both Medicare and Medicaid managed care; these guidelines will also be included in the larger BBA implementation regulation to be issued this summer.

Because the Medicaid provisions of BBA have an earlier effective date (October 1, 1997), we are examining the possibility of sending letters to all State Medicaid directors to ensure that they are aware that plans are financially responsible for emergency care and to remind them that enrollees should be informed about their rights to emergency services. A similar letter could be sent to all Medicare managed care plans when the underlying regulations are published. This is an area where Presidential action could further the Program's consumer protection efforts.

Statutory Impediments to Full Compliance.

Medicare and Medicaid. Both Medicare and Medicaid are in compliance with this Right.

4. Participation in Treatment Decisions

"Consumers have the right and responsibility to fully participate in all decisions related to their health care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare and Medicaid. The Commission states that patients should have sufficient information to decide among treatment options, consistent with the informed consent process, and that providers should be able to advocate for their patients without constraint or fear of reprisal. Medicare and Medicaid have long been committed to ensuring that beneficiaries are active participants in decisions about their care and are generally in compliance with this Right. For example, both Medicare and Medicaid require discussion of and respect for advance directives, which are intended to involve the beneficiary in a discussion of relevant treatment options, including the opportunity to refuse treatment altogether.

Recent actions by HCFA have strengthened and extended protections applicable to the right of beneficiaries to receive unimpeded information.

- ▶ **Prohibition of "Gag Clauses."** In 1996, HCFA issued guidance to all Medicare managed care plans and State Medicaid Directors to clarify that managed care plans are explicitly prohibited from restricting physician-patient communication about medically necessary treatment options, a practice often referred to as a "gag clause". This policy is intended to prohibit plans from penalizing or seeking retribution against health care professionals who provide information to or who advocate on behalf of their patients.
- ▶ **Information About Financial Incentives.** In 1996, HCFA issued regulations intended to prevent Medicare and Medicaid managed care plans from using financial arrangements--either direct or indirect--that induce providers to limit necessary services. Under both Medicare and Medicaid, managed care plans must disclose information about these arrangements to beneficiaries upon request.

Indian Health Service. Informed consent is a fundamental component of the IHS risk management protocol as well as an accreditation requirement; the IHS is in compliance with the Right as it applies to its settings. With regard to cultural competence, the IHS incorporates traditional healers and treatments.

Current and Planned Use of Administrative Authorities.

Medicare and Medicaid. There is potential to improve HCFA's efforts to support the ability of patients to participate meaningfully in their treatment decisions. For example, cultural competence is not explicitly addressed in Medicare or Medicaid statute or regulation (although some providers have adopted policies on their own or in response to State policies, in order to respond to the needs of their enrollees). HCFA could develop regulations requiring that culturally competent treatment information be made available to Medicare and Medicaid beneficiaries. This is an additional area where Presidential action could further the Program's consumer protection efforts.

HCFA will also issue regulations this summer to reflect the BBA provision codifying the existing "anti-gag rule" policies for Medicare and Medicaid. Finally, HCFA addresses many of the issues encompassed by this Right in its proposed Quality Improvement System for Managed Care (QISM/C), which will integrate the quality and consumer protection standards for Medicare and Medicaid Managed care plans.

Statutory Impediments to Full Compliance.

Medicare and Medicaid. No further statutory authority is required.

5. Respect and Nondiscrimination

"Consumers have the right to considerate, respectful care from all members of the health care industry at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system."

"Consumers must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment."

"Consumers who are eligible for coverage under the terms and conditions of a health plan or program or as required by law must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare and Medicaid. The Social Security Act requires Medicare and Medicaid managed care plans to enroll all eligible beneficiaries (until they reach capacity), and also requires providers in these managed care networks to provide services to all beneficiaries enrolled in the plan (again, until they reach capacity). Thus, Medicare and Medicaid managed care enrollees are protected to the full extent of the Commission's Recommendations. Because each State determines who is eligible to enroll in its Medicaid managed care program, there is some room for States to differentiate among Medicaid beneficiaries with respect to eligibility for services.

Under fee-for-service, Medicare and Medicaid protections against discrimination are largely a function of Federal anti-discrimination rules that apply to recipients of federal funds. These rules address some, but not all, categories of protection and providers recommended by the Commission. As a result, these Programs are in partial, but not complete, compliance with the Commission's recommendations.

Indian Health Service. As a Federal provider of services, the IHS in its own facilities, is bound by the Civil Rights Act, the Americans with Disabilities Act, and other rules concerning non-discrimination. Indian tribes, are bound by the Indian Civil Rights Act of 1968.

Current and Planned Use of Administrative Authorities.

Medicare and Medicaid. We are exploring ways to more clearly articulate the protections inherent in these programs.

Statutory Impediments to Full Compliance.

Medicare and Medicaid. Existing Civil Rights authorities do not provide the complete set of protections recommended by the Commission.

6. Confidentiality of Health Information

"Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare and Medicaid. The privacy protections applicable to beneficiaries in these programs do not fully comply with the Commission's recommendations. A patchwork of protections covers many of the records held by HCFA (and its contractors) and by State Medicaid agencies, but these protections do not cover the records held by many categories of providers and, significantly, do not protect verbal communications between beneficiaries and their providers.

Specifically:

- For the Medicare Program, the Privacy Act (and implementing regulations) protects certain information obtained by HHS and its contractors (carriers, intermediaries, and managed care organizations with risk contracts) in the course of administering the Medicare program.⁴ The Social Security Act (and implementing regulations) protects some additional information held by contractors and certain providers from inappropriate disclosures.

⁴ The Privacy Act establishes procedures for appropriate protection, use and release of individually identifiable information, ensuring that beneficiaries have their individually identifiable records held in confidence and released only under specified circumstances, guaranteeing beneficiaries the right to review, copy, and request amendments to their own records. The Privacy Act applies only to records maintained in a "system of records," that is, records that are accessed by personal identifier.

- The Privacy Act protects Medicaid records held by HHS, but not records held by the State Medicaid Agencies. The Social Security Act requires States to provide safeguards which restrict the disclosure of information concerning Medicaid applicants and recipients to purposes directly connected with the administration of the State plan.

Thus, together, these Federal laws and regulations protect certain written records held by an array of entities from disclosure outside the Programs, but do not protect all forms of written information nor do they protect verbal communications between enrollee and provider. Protection of such communications between patients and their providers is a matter of State law. Many States' privacy laws do not provide the protections recommended by the Commission.

In addition, these Federal laws do not apply to all Medicare and Medicaid providers. For example, the laws do not apply to information obtained by most physicians and other individual providers, nor to Medicaid managed care plans. Protection of beneficiary information obtained by these providers is a matter of State law.

Indian Health Service. The confidentiality of all patient records in Federal IHS facilities are protected by the Privacy Act. Under the Indian Self-Determination Act, records maintained by tribes are not, but the IHS generally insures their confidentiality through their contracts with the tribes.

Current and Planned Use of Administrative Authorities.

General (including Medicare and Medicaid). The Health Insurance Portability and Accountability Act (HIPAA) requires the Secretary of Health and Human Services to take certain actions to help protect the confidentiality of medical records for all consumers (not just Medicare and Medicaid beneficiaries):

- Last September, the Secretary submitted a report to the Congress, recommending standards for federal legislation to protect all individually identifiable health information held by all payers and providers (not just in the Medicare and Medicaid programs).
- HIPAA requires HHS to promulgate standards for a specified set of electronic health care transactions (again, applicable across all health care transactions, not just Medicare and Medicaid transactions), including standards to protect the security of those transactions. HHS is preparing a Notice of Proposed Rulemaking to establish these standards and plans to publish it this spring.
- If Congress fails to enact privacy legislation by August 26, 1999, HHS is required to promulgate privacy regulations governing the electronic health care transactions listed in the HIPAA.

Statutory Impediments to Full Compliance.

General (including Medicare and Medicaid). There is no Federal statutory authority that provides comprehensive and systematic protection of the right of confidential communications between patients and individual providers. Existing State and Federal authorities do not provide the protection recommended by the Commission. (For example, HHS authority under the HIPAA to promulgate privacy regulations is limited to certain specified electronic transactions.) The increasingly interstate nature of health information makes it impossible for even the best State laws to provide the protections recommended by the Commission. New legislation is required to ensure that all consumers are assured appropriate privacy in their medical communications.

The Secretary's Privacy Recommendations, if enacted, would bring all beneficiary information obtained by Medicare and Medicaid providers and plans (and by all other providers and plans), and by the Medicare and Medicaid programs and contractors, under the protection recommended by the Commission's recommendations.

7. Complaints and Appeals

"All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review."

Extent of Current HHS Compliance with the Bill of Rights.

Medicare. The Medicare program is in compliance with the Commission's recommendations.

Under fee-for-service, a beneficiary can file an initial appeal to the Medicare carrier or fiscal intermediary that processed his claim, with further review available through hearings before an Administrative Law Judge, the Department Appeals Board, and ultimately, Federal District Court (all subject to certain amount-in-dispute thresholds).

Under managed care, a beneficiary can similarly file a initial appeal with the plan. If the plan's determination is not wholly favorable to the beneficiary, the beneficiary's appeal is automatically forwarded for external review to HCFA's contractor, the Center for Health Dispute Resolution. For Medicare beneficiaries who remain dissatisfied, further external review is available before an Administrative Law Judge, the Department Appeals Board, and ultimately, Federal District Court (also subject to certain dollar-value thresholds).

Last year, HCFA established an expedited process for resolving both internal and external reviews of claims arising out of managed care. Instead of current timeframes, which by regulation can take up to 60 days at each level, under expedited review, such questions as the imminent cancellation of a treatment or the need to quickly see a specialist must be resolved as medically

appropriate or within 72 hours for initial review, or within 10 days for external review. This process permits individuals to receive a quick answer to questions about getting needed care. Furthermore, Peer Review Organizations, responsible for overseeing quality of care, can also intervene quickly in the event of imminent discharge from a hospital or nursing home.

Medicaid. Medicaid is in compliance with this Right, although current program requirements lack the specificity found in parts of the Commission's discussion. Medicaid managed care organizations are required to establish an internal process that affords prompt resolution of complaints and appeals and assures participation by individuals with the authority to require corrective action. Federal law requires an external review, in the form of a "State fair hearing process," which is generally conducted by an independent unit in the Medicaid agency.

Indian Health Service. The Contract Health Service (CHS) is operated by the IHS through semi-autonomous local areas. If an individual disputes either the pre- or post-service decision of the local CHS Board, the individual can appeal to the Area Director (internal review) and, if still adversely affected, to the head of IHS (external review). There is no appeal beyond this level. For all disputes involving tribal health operations, appeal is through tribally-determined mechanisms, culminating with ultimate review by the Chief.

Current and Planned Use of Administrative Authorities.

Medicare. The Balanced Budget Act includes a number of provisions related to complaints and appeals that will be applicable to Medicare+Choice plans, and we are in the process of implementing them. These provisions will strengthen Medicare's existing protections for managed care enrollees.

Medicaid. The BBA requires that Medicaid health plans establish grievance procedures. In implementing regulations, we plan to specify requirements that would include the Commission recommendations, such as timely written notification of a decision to deny coverage or payment for services.

Statutory Impediments to Full Compliance.

Medicare. No further authority is required.

Medicaid. No further authority is required.

8. Consumer Responsibilities

"In a health care system that protects consumers' rights, it is reasonable to expect and encourage consumers to assume reasonable responsibilities. Greater individual involvement by consumers in their care increases the likelihood of achieving the best outcomes and helps

support a quality improvement, cost-conscious environment."

The *Consumer Bill of Rights and Responsibilities* articulates a long and diverse list of consumer responsibilities, underscoring the importance of active and involved health care consumers. The Department is involved in many projects intended to empower and inform health care consumers. In the section that follows, we describe many of these efforts, as well as other important activities of the Department.

II. Other HHS Efforts to Improve Consumer Protection

The Consumer Bill of Rights and Responsibilities is relevant to all of the Department's health care programs. These programs are diverse in purpose, focus, and scope. Some programs fund direct care for specific populations, directly and through grants to States. Other programs support research into how consumers use information to make health care choices, or develop information to help consumers and their providers make treatment decisions. Still others are involved in developing model contract language for purchasers of managed care, to insure the availability of preventive services or to protect those receiving behavioral health care services. Because of the diversity of our providers and the services they offer, we are still examining the implications the Bill of Rights may have for these programs.

I have established a working group, comprised of every HHS component responsible for providing, monitoring, or advancing knowledge about consumer protection, that will report to me on an on-going basis about how to continue to improve the consumer protections afforded by all HHS programs. I have asked this working group to look not only at the protections recommended in the Bill of Rights, but also at other ways we can improve consumer protection in HHS activities and programs. I have also asked all programs that fund health services to individuals to begin discussions with their grantees about how they can apply the Bill of Rights in their programs.

The community health centers and other health-service related organizations that are funded through the Health Resources and Services Administration (HRSA) are an important example of the challenge that the Bill of Rights poses to non-traditional health services arrangements. The HRSA-funded organizations range from community and migrant health centers to projects that support services for specific populations, such as mothers and children, migrant workers, and persons living with AIDS or HIV.

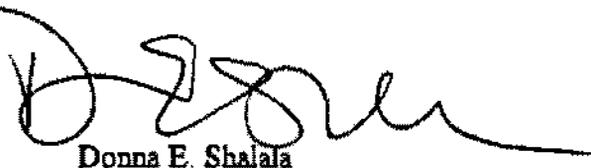
The Consolidated Health Centers (community and migrant health centers, Health Services for Residents of Public Housing Programs, and Health Care for the Homeless Programs) provide the most comprehensive range of health care services of the HRSA-funded entities. While over half of the Consolidated Health Centers contract with managed care plans or with their State Medicaid agency for managed care enrollees, many other HRSA-funded entities have only recently begun relationships with managed care organizations. Well before the Bill of Rights, HRSA had begun to identify ways to meld the protections and practices appropriate to a provider of last resort with

the requirements of public and private purchasers. Consequently, the Consolidated Health Centers are already in compliance with many Bill of Rights elements through their own staffing protocols, confidentiality and patient grievance procedures and quality measures.

HHS is also engaged in a number of research, development and outreach activities, particularly in the areas of consumer information needs and health promotion, that will result in improved consumer protections for HHS beneficiaries as well as the population at large. These programs offer an opportunity to move beyond compliance with the Bill of Rights, and to focus on promotion and improvement of those basic consumer protections. For example, the Agency for Health Care Policy and Research, the National Institutes of Health, the Centers for Disease Control and the Office of Disease Prevention and Health Promotion are all engaged in extensive research and development of information and decision tools to assist consumers with their health care choices. Furthermore, the Administration on Aging, HCFA and the Substance Abuse and Mental Health Services Administration fund ombudsman and consumer assistance programs for their specific populations.

I am attaching a list that highlights a number of the HHS activities that address particular aspects of the Bill of Rights. As you can see from this list, the Department will continue to be active in implementing the Bill of Rights both in HHS programs and in the nation at large.

A critical player in achieving true consumer protection is an informed and empowered consumer -- we believe that our programs must provide consumers with both process protections and with information adequate for informed decision-making. We enthusiastically support the protections identified in the Bill of Rights and look forward to beginning a dialogue with you, the public and the Congress concerning how to address those areas where we currently find statutory impediments to achievement of these Rights.



Donna E. Shalala

Attachment



A/C
PO-4-3

MEMORANDUM FOR THE PRESIDENT

FROM: DONNA E. SHALALA *Donna E Shalala*
**SECRETARY, DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

SUBJECT: **ADVANCES IN PREVENTION OF MOTHER-TO-INFANT
TRANSMISSION OF HIV**

DATE: **FEBRUARY 18, 1998**

I want to provide you with important new information about the ability of developing countries to decrease HIV transmission from mothers to their infants. The CDC released this information in a press conference today in Atlanta.

The CDC, working with the governments of Thailand and Cote d'Ivoire, started clinical trials in 1996 to identify an effective therapeutic intervention that decreased HIV transmission from mother to child and that was realistically affordable in the developing world. The trials are now complete and conclude that a significantly shorter course of treatment is effective. This short course, four weeks of oral AZT, will be affordable in most of the developing world. (In comparison the standard of care in the U.S. requires several months of treatment for the mother and the infant and an intravenous dose.) As a result, the trials are being stopped and the new shortened oral course of AZT is being offered to all participants.

These trials are of great significance to children throughout the developing and developed world. For the first time we can offer a therapeutic intervention that may effectively diminish the chances of the baby becoming infected from a HIV-positive mother. The new therapy has profound implications in the developing world where over 1,000 HIV-positive babies are born each day. We now have the opportunity to prevent hundreds of thousands of HIV infections in newborn infants worldwide.

As you may know, questions have been raised concerning these clinical trials. If the two studies had not been undertaken by the CDC, NIH and the World Health Organization (WHO), we would not have identified an effective mode of preventive therapy that could be implemented in the developing world.

HHS has already begun discussions internationally and domestically to develop strategies to incorporate these findings into existing standards of practice. The discussion has included planning for an international meeting with HHS, the State Department, UNAIDS, WHO and senior public health officials in the developed and developing world.

Attachment - HHS Press Release

cc: The First Lady

2/24/98/050

CDC/Neleen

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, Feb. 18, 1998

Contact: CDC, National Center
for HIV, STD and TB Prevention
Office of Communication
(404) 639-8895

CDC Office of Communications
(404) 639-3286

***Short-Course Regimen of AZT Proven Effective in
Reducing Perinatal HIV Transmission: Offers Hope for Reducing
Mother-to-Child HIV Transmission in Developing World***

In an announcement that has important implications for many developing nations, the Centers for Disease Control and Prevention (CDC) stated today that a short course of AZT given late in pregnancy and during delivery reduced the rate of HIV transmission to infants of infected mothers by half and is safe for use in the developing world. The Ministry of Public Health of Thailand (MOPH), who conducted the study in collaboration with CDC, announced the results earlier today in Thailand.

The findings, from a preliminary analysis of data from the CDC/MOPH collaborative study, offer real hope to many developing nations that previously had no realistic therapy options to prevent HIV-infected pregnant women from transmitting infection to their babies.

"We are very fortunate in the U.S. and Europe to have been in a position to offer preventive therapy to HIV-infected pregnant women for several years, and thousands of infections in infants have been prevented as a direct result, said HHS Secretary Donna E. Shalala, "Now we are a step closer to seeing the kind of progress that we've made at home extended to the developing world."

Prior to these findings, the only AZT regimen proven effective for perinatal HIV prevention was essentially out of reach for the countries in which over 90 percent of HIV infections occur.

The AZT regimen used in the U.S. is costly and requires several months of treatment for the mother and the infant and an intravenous dose that is not feasible in many developing countries. In order for policy makers in developing nations to provide HIV-infected women a preventive therapy, they urgently needed conclusive scientific evidence that there is a practical treatment regimen that is safe and more effective than what they have been able to provide which, tragically for most, has been no preventive therapy at all.

"By using a much shorter course during pregnancy, an oral dose rather than an intravenous dose during delivery, and no infant dose, we evaluated a regimen that could be realistically implemented in developing nations," said Dr. Helene Gayle, Director of CDC's National Center for HIV, STD, and TB Prevention. "Now that the regimen has been proven safe and effective in Thailand, these findings offer hope of extending perinatal prevention to HIV-infected women throughout the developing world."

The Thailand study was one of two CDC collaborative perinatal HIV prevention studies. The CDC studies, conducted with the Ministries of Health in Bangkok, Thailand and Abidjan, Côte d'Ivoire, were part of an international collaborative research effort coordinated by the Joint United Nations Programme on HIV/AIDS (UNAIDS) to help identify practical solutions for the developing world.

The Thailand study, which began enrollment in 1996, provides the first conclusive scientific data on the preventive effectiveness of a short-course regimen of AZT.

Although final data are not yet in, CDC has now received conclusive interim data from Thailand. Enrollment into the study has been completed and over 90 percent of the data have now been reviewed by CDC and the independent Data Safety and Monitoring Board (DSMB) overseeing the research. Because this regimen has proven both safe and effective, the placebo-control component of CDC's Abidjan study is no longer necessary. Therefore, CDC and its collaborators have begun offering all pregnant women enrolled in the Abidjan study the short-course AZT regimen. Research collaborators worldwide are currently being notified of the findings. In a joint statement released today by UNAIDS, the National Institutes of Health (NIH), and the French National Agency for AIDS Research (ANRS), it was announced that an international meeting will be soon be held to discuss the far-reaching scientific and policy implications of these findings.

"As the international health community now faces the challenges of making this prevention opportunity a reality for HIV-infected women worldwide, the really hard work begins," said Dr. Kevin DeCock, Director of the Division of HIV Prevention, NCHSTP. "The remarkable news is that we begin with the first conclusive evidence that simpler, practical therapies can make a difference."

CDC stressed that these studies were not designed to address perinatal prevention needs in the U.S. and other industrialized nations. Because HIV-infected pregnant women in the U.S. already have access to the more effective longer treatment regimen, recommendations for perinatal HIV prevention in the U.S. will not change.

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Note: HHS press releases are available on the World Wide Web at: <http://www.hhs.gov>.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, Feb. 18, 1998

Contact: CDC Press Office
(404) 639-3286

STATEMENT BY DONNA E. SHALALA
Secretary of Health and Human Services
Regarding Findings of Thailand Study of "Short Course" AZT

"Since the AIDS epidemic was first identified 17 years ago, some 380,000 Americans have lost their lives to this disease. In the same period, we estimate that worldwide AIDS deaths have been 11.7 million.

"In recent years, we have had some hopeful developments in the United States and other industrialized nations. New treatments, as well as prevention efforts, have brought about reductions in the number of AIDS deaths in America. But in the developing world, there has been little to report except growing numbers of infected persons and growing numbers of deaths, including the spread of infection from pregnant women to their infants. Treatments that have been proven most effective in the industrialized nations have generally been unaffordable and impractical for countries of the developing world.

"Today's news from Thailand is one of the first hopeful signs for countering HIV and AIDS in the developing nations of the world. While we are still far from control or cure of this disease, it now appears we may have a preventive therapy which is affordable and feasible in less developed nations, and which can significantly reduce the transmission of HIV from mother to infant. For tens of thousands of women in developing nations who are pregnant and infected with HIV, this is a vitally important development.

"Now, with the leadership of UNAIDS and the cooperation of the leading industrial nations, we must move to translate these findings into effective public policy and health care practice."

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FEB 10 1998

H/C
PO-4-17

MEMORANDUM FOR THE PRESIDENT

Following your May 16, 1997, formal apology for the Tuskegee Syphilis Study, you outlined activities for the Department of Health and Human Services to take to restore trust by ensuring and demonstrating our commitment to the highest ethical principles in all of the Department's activities, especially in the conduct of research involving human participants.

In response to your directive, I formed a steering committee comprising the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Health Resources and Services Administration (HRSA), the Food and Drug Administration (FDA), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to carry out the follow-up activities. Subsequently, the Agency for Health Care Policy and Research (AHCPR) was added to the steering committee. I also asked CDC to assume lead responsibility for developing strategies to improve the collaboration and participation of communities, especially minorities, in research conducted by the Department of Health and Human Services. The attached progress report was prepared by CDC in collaboration with NIH, HRSA, FDA, SAMHSA, and IHS.

In addition to this report on community participation, the Department has made substantial progress on other follow-up activities. Briefly:

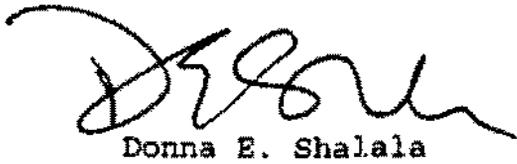
- In September 1997, CDC awarded a planning grant to Tuskegee University to pursue the establishment of a Center for Bioethics in Research and Health Care.
- Fellowships in bioethics training will be offered through two programs. On November 7, 1997, announcements were published in the NIH Guide for Grants and Contracts soliciting:
 - Applications for grants to develop, conduct, and evaluate short-term courses on ethical issues in research involving human participants
 - Applications from health professionals interested in training in research ethics.
- The agencies are exploring the development of a guidebook that will direct researchers to available bioethics education resources.

2/18/1998/0006

CDC/Bart

Page 2 - The President

I appreciate your continued support of the Nation's efforts to improve the health status of all Americans.

A handwritten signature in black ink, appearing to read "Donna E. Shalala". The signature is fluid and cursive, with a large initial "D" and "S".

Donna E. Shalala

Attachment

BUILDING COMMUNITY PARTNERSHIPS IN RESEARCH
Recommendations and Strategies

Centers for Disease Control and Prevention
National Institutes of Health
Food and Drug Administration
Health Resources and Services Administration
Substance Abuse and Mental Health Services Administration
Indian Health Service

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BUILDING COMMUNITY PARTNERSHIPS IN RESEARCH

EXECUTIVE SUMMARY

This report is in response to the President's request to the Secretary of Health and Human Services (HHS) to identify strategies to improve the participation of communities, especially minority communities, in research and to build trust between researchers and communities. It provides a framework through which Federal health agencies can establish an ethical basis for community-based research, enhance scientific and public credibility, and provide mechanisms to help build public trust in health research.

Minority and poor communities lag behind the overall U.S. population on virtually all health status indicators, underscoring the need for continued focus on health research to identify solutions to improve health status in these communities. Through commitment to a participatory approach, communities and researchers have the opportunity to build trust through true partnership. By working in partnership, communities, researchers, and funding agencies can further maximize the benefits of research by translating research findings into comprehensive health programs.

Basic issues of involving the community in research must be acknowledged and addressed. Inclusion is the core issue for building community partnerships in research, and it requires "grassroots" involvement. Researchers must reach out broadly so that all pertinent experience is represented. By bringing together the knowledge and experience of communities and researchers, excellence in science is enhanced. True collaboration and partnership entails sharing risks and responsibilities as well as resources and rewards. Commitment of adequate time and resources is essential--building a research relationship generally takes from two to five years, and resources must be available to support the activities and infrastructure necessary to build and sustain such partnerships. Building an effective partnership requires acknowledgment of the impacts of history, culture, and society on many of our most challenging health issues.

Trust must be built on the actions of researchers, not just faith in the benefits of research, and decision-making power must be shared throughout the research process. History demonstrates that people have been harmed when medical and public health research is planned and conducted without consideration of the human context of such work or regard for human rights. Individuals who participate in such research are directly affected in a variety of adverse ways; however, as members of a demographic or geographic group, the individuals' entire group or "community" is also indirectly affected and unintended, negative outcomes are often the result. Therefore, ethics must be addressed at the community level as well as at the individual level. Policies must be developed that facilitate participatory research through appropriate funding mechanisms. Education and training mechanisms must be developed to provide both communities and researchers with the necessary skills for a balanced partnership. Accountability and oversight mechanisms are necessary to ensure that mutual commitments are kept and that a system for corrective action is implemented when errors in judgment or overt abuses occur.

The goal of HHS is to promote awareness of and appropriate community participation in health research. Dialogue must continue among HHS agencies, researchers, and communities to provide ongoing development and guidance for building meaningful health research partnerships with communities. HHS will undertake the following action steps to attain this goal:

- **Establishment of a federally mandated Task Force on Participatory Research.** The Task Force will be composed of representatives from diverse communities, research institutions, and HHS agencies.
 - The Task Force will conduct regional hearings to gain grassroots community input on mechanisms and actions needed to build partnerships in research.
 - The Task Force will develop guidance on participatory research based on these hearings and other appropriate processes.
 - The Task Force will develop a plan to increase community participation in government-funded research.
- **Development and implementation of an HHS-wide evaluation plan to assess the impact of current health research processes, procedures, and funding mechanisms on community participation in health research and implementation of changes as needed to facilitate the use of participatory research models.**

BUILDING COMMUNITY PARTNERSHIPS IN RESEARCH

INTRODUCTION

Although most research over the years has been conducted ethically and yielded great benefits to many individuals, history demonstrates that people have been harmed when medical and public health research is planned and conducted without consideration of the human context of its work or regard for human rights. As a result, laws and regulations have been passed to protect people who participate in research. However, there has been little or no consideration of the role of communities in influencing and guiding research that involves and affects its members. Inclusion of communities has great potential for reducing the likelihood of harm and for engendering trust in research.

Recent events have set the stage for an open dialogue among government, communities, and researchers that considers the inclusion of communities in the planning, conduct, and application of health research. Most notable among these events was the Presidential apology for the wrongful conduct of the government-sponsored Tuskegee Study of Untreated Syphilis in the Negro Male. On May 16, 1997, President Clinton apologized to the Study's survivors and families, the African-American community, and to the American people as a whole, stating, "What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful, and I am sorry. The American people are sorry-- for the loss, for the years of hurt." The President further stated that the study at Tuskegee served to sow distrust of our medical institutions, especially where research is involved, and that this distrust impedes efforts to conduct promising research and to provide the best health care for all Americans.

This report is in response to the President's request to the Secretary of the Department of Health and Human Services (HHS) to identify strategies to improve the participation of communities, especially minority communities, in health research, and to build trust between researchers and communities.

Much of the input for this report was provided by community, researcher, and Federal agency participants at an interagency workshop on *Enhancing Community Participation to Restore Trust and Improve Science in Health Research* held at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, on October 16-17, 1997. A list of participants is included at the end of this report. Insights and lessons learned were also garnered from an inhouse symposium held at CDC in May 1997 on *Community Partners for Prevention Research: Implications for the Science and Practice of Public Health*. Literature reviews, agency reports, and compilations of previously implemented strategies to enhance partnership were also consulted in the development of this report.

BACKGROUND

Health research is a set of investigative activities undertaken to improve the health of all people and communities by seeking to understand the causes of disease, illness, and death and the circumstances that promote well-being. Some aspects of health research can be conducted in laboratories or with computers; however, the laboratory specimens and data must be collected from people. Health research is, therefore, a fundamentally social activity, dependent on collaborative human interaction. To achieve our goal of improved health, we must value and cultivate the fundamental skills necessary for collaboration.

Health research is also a privileged and empowered activity in that the researchers have special access to resources and sensitive information about people and, through the analysis and presentation of research findings, are able to influence the way people think and have considerable influence on decisions regarding the allocation of resources. With the privilege and power given to researchers comes the potential for abuse. Guarding against such abuse is the personal and professional responsibility of every researcher and the collective responsibility of every institution that sponsors research. History has shown that we as a Nation must establish and enforce protections against abuse perpetrated in the name of research. We must commit to basic moral values such as respect for all persons, the preservation of their dignity, and the upholding of social justice in order to avoid harm.

While it is not possible to document all harms that have occurred in research in this report, it is nonetheless important to describe some of the harms and their social, historical, and cultural contexts. The recommendations and strategies described later in this report have been developed in response to the complexities of the real world that give rise to harm.

The Tuskegee Syphilis Study

In 1932, the Public Health Service, working with the Tuskegee Institute and other agencies, began a study in Macon County, Alabama, called the *Tuskegee Study of Untreated Syphilis in the Negro Male*. The study involved 600 black men--399 with syphilis and 201 who did not have the disease. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. Although originally projected to last six months, the study actually went on for 40 years. In July 1972, a front-page *New York Times* story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the Study. The panel found that the subjects had agreed freely to participate in the Study based on various incentives, but there was no evidence that the researchers had informed them of the Study's purpose. In fact, the men had been misled and had not been given the necessary information about the study or the opportunity to provide informed consent.

In the summer of 1973, a class action lawsuit ended in a settlement that awarded more than \$9 million to the study participants and their families. As part of the settlement, the U.S. government promised to give free medical and burial services to all living participants. The Tuskegee Health Benefit Program was established to provide these services. It also gave health services for wives, widows, and children who had been infected because of the study. The Centers for Disease Control and Prevention (CDC) was given responsibility for the program, where it remains today within the National Center for HIV, STD, and TB Prevention.

Other Examples of Research Abuse That Have Led to Distrust in Research

- The history of research among American Indians and Alaska Natives has often been one of disregard for tribal sovereignty and basic human rights. From 1987 to the present, approximately 3,000 articles have been published in which American Indians or Alaska Natives were cited as research participants. Some American Indians and Alaska Natives have suggested that this volume of research indicates that their communities are used to evaluate therapies and preventive strategies that are intended to benefit other, particularly majority, communities. They believe that there has been little or no concern for how or when the results would directly benefit American Indian and Alaska Native populations, or how ongoing research could be used to improve the health of their communities. To address these concerns, many tribes have taken steps to ensure that all research is now undertaken with explicit concern for and involvement of their people. Model agreements between tribes and researchers have been developed by the Navajo Nation, the American Indian Law Center, and others.
- Some populations have suffered harm as a result of geographical location. The U.S. government actively developed and tested nuclear weapons for approximately 50 years. As a result of classified intentional releases such as the 1949 "green run" release of radioactive iodine from the Hanford Nuclear Facility in eastern Washington State, many communities believe they unknowingly were part of experiments conducted by the government that may have adversely affected their health [Jensen 1996]. Hundreds of such releases took place in secret and remained secret for decades. Also, from 1944 to 1974, the U.S. government sponsored classified human subjects research that was the focus of investigation by a 1994 Presidential Advisory Committee on Human Radiation Experiments. The Committee found significant lapses in ethical conduct. Many of the communities affected by the operations of the U.S. nuclear weapons complex are poor and require a specific environmental justice activity to address their needs and concerns [Environmental Health Perspectives 1995].
- Similarly, the U.S. nuclear weapons testing program at the Nevada Test Site and in the Republic of the Marshall Islands is being investigated to determine the possible influence of weapons testing on the health of the U.S. population and Marshall Islanders. Between 1946 and 1956, 67 atmospheric and above-ground nuclear tests were conducted in the Marshall Islands, equivalent to the power and radiation of 7,000 Hiroshima atomic bombs. During the

hydrogen bomb detonation in 1954 (Castle BRAVO test), radiation fell directly on 253 Marshall Islanders. The now unclassified documents about the BRAVO test show that the Chief of Mission knew that wind changes would result in fallout over this population. In addition, other Marshall Islanders were moved back into radioactively contaminated areas, then were relocated months to years later after it was found out that these areas were still contaminated. At no time was there any community participation in the process, or informed consent, and the Marshall Islanders were told that this was for the "good of mankind." The truth was hidden from the public and the Marshall Islanders for many years in classified documents. The Marshallese people continue to suffer from the effects of the testing and have great mistrust of the U.S. government.

- Research conducted at Willowbrook State Hospital in Staten Island, New York, for over 15 years highlights the vulnerability of institutionalized populations and their families. In this instance, mentally retarded children were deliberately infected with hepatitis A and B viruses so that researchers could assess the natural history of the disease and its response to treatment. Parents were induced to consent to the research because hospital admittance for their child was at least implicitly contingent upon enrollment in the study at a time when hospital bed space was limited.
- In the mainland United States, the illegality of abortion in many States posed a challenge for human trials of the prototype contraceptive pill in the 1960s. Large trials were needed to find the optimal estrogen-to-progesterone ratio and to evaluate potential side effects. Researchers believed that they needed to be able to provide women participating in the trials with the option for abortion if the pill failed to prevent pregnancy. To simplify follow-up, they also wanted a large field population that was geographically contained and relatively stable. Abortion was legal in Puerto Rico at this time, and residents of a housing project in the San Juan metropolitan area were targeted for recruitment. Most of the women had low incomes and several children. They were approached by researchers who offered them the contraceptive pill as an option for having fewer children while continuing to have sexual relations. Other U.S. locales where abortion was legal were not targeted, and the burden of untoward side effects of the medications was experienced by mainly one group. Because this research targeted one socially disadvantaged group, it violated the principle of social justice and was unethical.

In addition to these specific examples of wrongs by researchers, the simple conduct of research on certain health issues can result in negative stereotyping and stigmatization. Many health conditions are burdened with stigma, such as HIV, sexually transmitted diseases, tuberculosis, mental illness, substance abuse, and violent injury. Individuals with these conditions can suffer severe consequences including social avoidance, economic boycott, discrimination in housing or provision of other goods and services, and violent "bashing" from others. When research is conducted or research findings are reported in a way that is disrespectful or insensitive, the result is further negative stereotyping and stigmatization of the affected individuals and the

communities in which they live. Minority communities are understandably concerned about the potential for harmful labeling and discrimination that may arise from research on stigmatizing diseases.

A New Beginning

When research causes harm, that research contributes to, rather than lessens, the stresses endured by communities. The harm endures through years of emotionally and often financially taxing attempts to effect redress. Communities who have been harmed by research believe that trust must be built, not rebuilt. Establishing a foundation for trust requires commitment and right action. The actions of researchers today must be clearly distinct from those that led to the wrongs of yesterday. This report provides individuals, institutions, and Federal health agencies engaged in research with a framework for establishing an ethical basis on which to build trust and partnerships with communities.

PARTICIPATORY HEALTH RESEARCH

Defining "Community"

While an understanding of the concept of "community" is integral to community participatory research, there is no consensus on a definition of "community" or its operationalization within health research. At its simplest, a community is a "group of individuals with a common interest and who identify themselves as a group" (Labonte 1997). While many people tend to think that a community requires geographic proximity—that is, people living and working in the same place—many modern communities are based primarily on shared interests or characteristics such as culture, ethnicity, occupation, or a sense of purpose or vision (Hatch et al. 1993, Royal Society Report, Jewkes and Murcott 1996, Labonte 1997, Minkler and Wallerstein 1997).

Communities are dynamic and emergent, with fluid, flexible boundaries (Walter 1997; CDC 1997), and are often characterized by diversity. The multiple constituencies and interests within a community must be acknowledged and appropriate strategies and processes developed for full partnership (Minkler and Wallerstein 1997). For these reasons, no single definition of community will be adequate to meet the needs of every situation.

From a participatory research perspective, "community" should ultimately be defined in terms of those whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the conduct of the research.

The Importance of Health Research

Minority and poor communities lag behind the overall U.S. population on most health status indicators. The extent of this disparity and the consequent waste of human lives and productivity has been extensively chronicled. An estimated 60,000 excess deaths occur among African Americans, Hispanics, Asian and Pacific Islanders, and American Indians annually. (Excess deaths are defined as deaths that would not occur if mortality rates for minorities were the same as for nonminorities.) More than 80 percent of these excess deaths occur in six categories--cancer, heart disease and stroke, homicide and unintentional injuries, infant mortality, diabetes, and chemical abuse (primarily alcohol abuse)--all of which have contributing factors that can be controlled or prevented.

African Americans experience some of the greatest disparities in health in the United States. At birth, African Americans have consistently lower life expectancies: in 1993 their life expectancy was 69.2 compared to 76.2 years for whites and 75 years for Hispanics. Similarly, African-American babies are almost two and one-half times more likely than white babies to die in the first year of life. In 1993, the African American infant mortality rate was 16.8 per 1,000, while for whites it was 6.8 per 1,000. Elevated infant mortality rates have also been reported for American Indians and Puerto Ricans.

To improve the health status of the U.S. population as a whole, disparities in the health status of our subpopulations must be addressed.

The Participatory Research Model

Community participatory research is not a methodology but rather an approach that combines systematic investigation, learning, and action (George et al. 1996). Researchers and community members each bring unique and important contributions to the research process. Researchers bring skills in research design and methods and knowledge of health. Community members bring knowledge about the community's culture, social norms, and networks. In the participatory approach, the community collaborates in the conduct of all aspects of the research process as an active, influential partner. Through such participation, community members and researchers work together to develop a set of priorities and identify research questions that can "satisfy the needs of both" (Hatch et al. 1993).

A major benefit of community participatory research is the sustainability of subsequent interventions or prevention programs (Altman 1996). Population-based prevention research is an ideal type of research for community participation. The importance of community-based programs for improving health is outlined in *Healthy People 2000*; community-based programs are increasingly comprehensive, taking a positive approach to health and well-being through planned, coordinated, ongoing efforts. By working in partnership, communities, researchers, and

funding agencies can maximize the benefits of research by translating research findings into comprehensive programs for improving health.

Participatory research requires sufficient time for partners to become acquainted and build trust. However, as noted by the Royal Society of Canada, there may be times when "problems cry out for more urgent solutions and expedient ways of gathering knowledge and taking action" (p. 58). And, there may be types of research (e.g., multisite clinical trials) that are not easily adapted to a participatory approach.

Researchers should strive to work within a participatory model to the extent possible, always remembering that any research study must include the qualities of respect, honesty, and integrity. Participatory research should be the "gold standard" toward which all federally funded research aspires.

HHS will conduct a department-wide evaluation of the impact of current health research processes, procedures, and funding mechanisms on community participation in health research and implement changes as needed to facilitate the use of participatory research models.

BASIC ISSUES IN COMMUNITY PARTICIPATION

Inclusion

Inclusion is the core issue for building community partnerships in research. Who should be included? How and when are they included? Do the decision-makers include the people who are affected by the consequences of the decisions, and how much weight do they carry when decisions are being made? Who will be held responsible for the consequences of decisions?

The research process is currently dominated by formally educated people who bring extensive information and expertise to the research situation, but who are often personally detached from that situation. Traditionally, these researchers or others who are articulate in the language of science have articulated the concerns of the research participants and consumers. But their voices often do not sound the same as or resonate with the voices of the people "in the trenches." As one community representative phrased it, "inclusion means that however 'broken' my language may sound to you, permit me to speak it as I see it; then we will work together to put the ideas together." Even those who doubt the most or have their own agendas must be heard. We must reach out broadly so that all experience is represented.

Inclusion means establishing deliberate and explicit mechanisms for enabling voice and vote in each step of the research process by research participants, beneficiaries, and other affected parties. Inclusion means "grassroots" involvement to the extent possible, of the people most affected, either directly or indirectly. It means making the effort to include individuals and

various local organizations (like block clubs and local school councils) whose organizing methods include door-to-door contact, involvement of people beyond their own membership, provisions for "bottom up" planning and decision-making, and creation of indigenous leadership. Persons at the grassroots level, in this context, are people who do not work for organizations that conduct research and whose views are not influenced by research-oriented employment.

Obtaining grassroots input is an ongoing process that requires constant attention to the issue of inclusion and an understanding of the complexities of a participatory community partnership.

Excellence in Science

The goal of inclusion should be to improve science by expanding effective research methodology, not replacing it or creating alternatives. Scientific rigor must be preserved while incorporating the skills, talents, knowledge, and strengths of the participants and beneficiaries of the research. Excellent science benefits everyone.

Scientific rigor is defined as "the scrupulously precise and scientifically exact application of research methods for gathering data and of analytic techniques used to treat and analyze the data" (Ratcliffe and Gonzalez-del-Vale 1988). Scientists are trained to strictly adhere to prescribed methods for data collection and analysis so as not to introduce bias into a study. Community involvement benefits scientific decision-making by requiring researchers to make their methods and assumptions explicit and understandable by all. Scientific credibility is strengthened when researchers are challenged to interpret study results in ways that reflect the realities experienced by those living in the community. Ethical research is enhanced when data collection methods are respectful of study participants.

Concerns that community involvement may interfere with the strict requirements of accurate measurement and with the process of conducting objective research are outweighed by the potential for improved and more effective research design and maximally beneficial results for the community.

Collaboration and Partnership

Collaboration is not a consultative process where opinions are sought from one group, but decisions are made by another; nor is it negotiation where parties with unequal resources use win-lose strategies to protect their interests. True collaboration entails sharing risks, responsibilities, resources, and rewards and includes shared and balanced investment, responsibility, liability, goals, expectations, and benefits. Collaboration requires partnerships among policymakers, funders, researchers, evaluators, communities, families, and individuals.

Collaboration is shared decision-making where all those affected participate in making decisions, and all parties are willing to contribute their resources to benefit the partnership.

Commitment of Adequate Time and Resources

There is often tension between inclusion and efficiency—the more people involved in the research process, the more complex it becomes and the longer it takes. Researchers and community members who have conducted participatory research uniformly describe the need for a commitment of adequate time to the participatory process. Building a research relationship with a community can take from two to five years. Attempts to speed up the process are likely to backfire, adding to the historical accumulation of distrust and creating an even more challenging situation for the next researcher seeking to conduct research with the community.

The resources for partnership must be adequate to support the activities and infrastructure necessary to build and sustain the relationship. Researchers, and those funding them, must be sensitive to the actual costs of participation and the ability of communities to share those costs. Some communities, especially highly educated middle and upper class communities, can draw on significant, well-established, diverse resources that can facilitate their involvement in the research process or can help them mobilize and take effective action if they believe that they are being harmed. Conversely, in communities where basic resources are lacking, infrastructure is inadequate, information is unavailable or unreliable, and day-to-day survival consumes the limited resources that people have, community members must balance the demands of a research partnership against all the other demands in their lives. Poor communities are the most vulnerable to exploitation by researchers, and thus stand to benefit the most from inclusion as equal partners in the research process. But a community cannot be an equal partner if it is dependent on the researcher for the resources needed to act as a partner.

Resources must be available to the community to build its capacity for partnerships with researchers.

History, Culture, and Society

There are many dimensions to understanding communities that need to be understood—and respected—by researchers, many of whom are unaware that their own cultural assumptions shape their interpretation of the responses and behavior of others. The particulars of history, especially perpetration of institutionalized racism, internalized oppression, legacies of slavery, and violated treaty rights, have led many communities to establish ground rules for interaction with outsiders; that too often are misunderstood or disregarded in the course of research. Economic factors and their impact on health disparities within their communities should be evaluated. The spiritual and religious beliefs of a community are intimately related to health, healing, and well-being, and should be appropriately respected and addressed. Finally, respect for and willingness to discuss

the emotional content of issues related to health and research within communities is crucially important, but is often a very difficult subject for researchers trained to value intellectual attributions over emotional ones.

A grasp of history, culture, and society is critical to solving many of our most challenging health issues. To practice effective inclusion, researchers need to understand the affected communities. Understanding develops gradually through ongoing interaction with community members, often resulting in the reshaping of assumptions held by the researchers and the community members. With understanding, the researcher gains better insight into both the causes of health problems and their potential resolution, and community members are more likely to incorporate the research findings to improve their health status.

Trust

To build trust, communities need to experience direct benefit from their relationships with researchers and to know that individuals and institutions are held accountable for their actions. These aspects are often complicated by legal and ethical issues such as confidentiality, contractual relationships, and proprietary interests. However complex, they need to be spelled out so that communities are assured that they have full access to information and that the research serves them.

Full disclosure throughout the research process is essential and includes many aspects such as financial status, informed consent, and changes in plans.

Power

There are many forms of power, but the critical one for research is decision-making power. In the research process, researchers tend to have considerably more decision-making power than the people participating in the study. This is especially true for research conducted in poor communities or with vulnerable populations such as the homeless, institutionalized persons, and youth. Because they themselves are answerable to powerful institutions, researchers are not always fully aware of or sensitive to the discrepancies in power that communities clearly perceive. It is usually the researcher, and not the community, who decides that a particular study will be done, secures and controls the funds for studies, and controls the data that can describe the community's problems--and strengths--and apply study results to the solutions to the community's health problems. And it is the researcher, not the community, who determines how the research will be done, how the data will be analyzed, and how the results will be disseminated. Often, the one decision left to community members is whether to participate as subjects during the process of informed consent.

A prerequisite for building trust is a more equitable distribution of decision-making power with a commitment of resources to build capacity in communities.

Ethics

A number of mechanisms are currently in place to promote the highest ethical standards in research. The Office for Protection from Research Risks (OPRR), National Institutes of Health, provides oversight, advice, and clarification of rules on involving people in federally-funded research. OPRR certifies Institutional Review Boards (IRBs) that are required by law comprise members from a variety of disciplines and include representatives from the community. IRBs review research plans to decide whether the proposed studies can be ethically conducted with humans. In October 1995, a National Bioethics Advisory Commission (NBAC) was also created to review current regulations, policies, and procedures to help ensure that all possible safeguards are in place to protect volunteers in research.

Despite these efforts, concerns are still raised about the adequacy of existing mechanisms to ensure the ethical conduct of research. The adequacy of community involvement on IRBs needs to be evaluated. There is debate over the appropriate balance of universal versus culturally specific guidelines, especially with regard to the weight given to individual autonomy. Informed consent at both the individual and community levels should be addressed in detail.

The possibility that research can do social harm in a community through stigmatization or diminishment of resources needs to be explicitly considered and guidelines developed on how to apply the concept of "do no harm" at a community or societal level.

Policy

To arrive at legitimate, community-based solutions to local public health problems, we need to do more than improve the dialogue among communities, academia, and local, State, and Federal health agencies. Dialogue sets the stage for relevant public health research, but ultimately, research is shaped and implemented through funding mechanisms. The majority of public health research funding comes from Federal institutions and private foundations through short-term commitments (generally five years or less) that focus on a particular disease or condition. Rarely are policymakers and funders willing to provide resources to sustain the structures and relationships among communities, health agencies, and academia that identify and make possible relevant public health research.

Sustainability is necessary if successful research is to be translated into programs of lasting benefit to communities.

Education and Training

With their years of specialized education and training, researchers tend to either take for granted that they have the necessary expertise to conduct research in diverse community settings, or they turn to their professional colleagues for guidance. Yet few universities require or provide formal education in ethics, cultural competency, collaboration, or communication skills beyond those needed within the confines of a particular academic discipline. It is assumed that the nobler intentions of the researcher will compensate for any deficiencies in these other skills. This emphasis on scientific over social skills and ethical discipline is often combined with a shallow regard for the importance of local history and culture and a devaluing of community-based knowledge and expertise. Whether intended or not, the end result is stereotypical "researcher arrogance" that undermines the trust of community members. It also robs the researcher of valuable information that could lead to important insights.

Similarly, in order to function as true partners in research, communities need education and training on pertinent health issues, research processes, and research options for identifying and resolving particular problems. Individuals want full disclosure of information related to health issues and research in their communities expressed in language that they can understand, and they want sufficient time and opportunity to review and understand complex information. They do not want information to be presented in a manner that implies that it has been selectively edited for a less intelligent (as opposed to a less educated) audience.

Through education targeted to the community, we can confront the issue of scientific literacy (or illiteracy) in the United States and ensure that more of our citizens are educated about the fundamentals of research and are able to benefit more fully from such activity. In addition, through education targeted to researchers, we can improve the competence of researchers to work with communities effectively by understanding community cultures, history, and needs.

Accountability and Oversight

Many of the issues that underlie public distrust of research are issues of accountability. Researchers should be held accountable when charged with the responsibility of conducting ethical research. This means: (1) following relevant regulations and laws concerning research, (2) being knowledgeable and culturally competent about the community, (3) having the interpersonal skills necessary to work with the community, and (4) practicing proven participatory research techniques.

Researchers often seek help from local stakeholders such as leaders and respected organizations to gain access to communities, especially minority communities, where distrust of research is

very high. If such assistance is given, community stakeholders become accountable for the actions of the researchers. If the researchers lack sensitivity, make a mistake, or cause harm, the community leaders lose credibility within their communities and may lose their effectiveness, either temporarily or permanently, thereby creating a gap that may not easily be filled. The researchers may be oblivious to these consequences as they endeavor to meet their own data collection goals. Efforts should be made to protect the privacy of individuals especially of vulnerable populations and the confidentiality of information they provide. Accountability and oversight are needed to protect local stakeholders and their communities from the negative impacts of insensitivity and exploitation, as well as to reward researchers who invest the time and resources necessary to build sensitive, equitable relationships.

Mechanisms are needed that hold researchers and their institutions accountable when communities are adversely affected by research. These mechanisms may include public forums for the discussion and mutual resolution of unforeseen outcomes and human error, compensation mechanisms for avoidable costs incurred by communities, and criminal penalties for intentional, serious harm to the community.

ACTION STEPS

The goal of HHS is to promote awareness of and appropriate community participation in health research. Dialogue must continue among HHS agencies, researchers, and communities to provide ongoing development and guidance for building meaningful health research partnerships with communities. HHS will undertake the following action steps to attain this goal:

- 1. Establishment of a federally mandated Task Force on Participatory Research.** The Task Force will be composed of representatives from diverse communities, research institutions, and HHS agencies.
 - a. The Task Force will conduct regional hearings to gain grassroots community input on mechanisms and actions needed to build partnerships in research.
 - b. The Task Force will develop guidance on participatory research based on these hearings and other appropriate processes.
 - c. Task Force will develop a plan to increase community participation in government-funded research.

In formulating the plan, the following issues will be considered:

- (1) The need to develop model programs that not only include health research goals, but also community capacity-building goals for conducting specific research activities such as community training on literacy skills, organizational development, and community mobilization skills and researches capacity building goals such as cultural competence, social skills, and communication skills.
- (2) The need for basic research on a range of models for effective collaboration between researchers and communities, on factors that promote and deter effective collaboration, and on how people decide to be research participants.
- (3) The need for social and historical analyses to document episodes of research injustice in a way that will inform monitoring groups and research sponsors of factors that indicate a high potential for exploitation, injustice, and harm in research and the impact of policies that contribute to participatory research in reducing injustice.

2. **Examination of HHS procedures and funding mechanisms to determine whether obstacles exist to community participation in health research and implementation of changes as needed to facilitate the use of participatory research models.** Strategies to enhance community participation in the research process must be implemented within larger societal and institutional frameworks that are supportive of participatory research. Current practices in research funding, dissemination of study findings, and scientific career advancement are based largely on nonparticipatory research models. Federal support for participatory research is the single most effective mechanism for change.

Several key issues that will be included in the evaluation are:

- a. The length of time allowed in grants and cooperative agreements to facilitate community involvement. Currently, funding (project) periods for community research are limited to three to five years; however, the process of even building a research relationship with a community so that research can proceed can take up to five years. Funding agencies need to ensure that there is a logical coordination of funding and research start-up time, with provision of adequate funds prior to the initiation of actual research to support community and researcher efforts to build a trusting relationship. In addition, better intra- and interagency coordination are needed in funding and conducting research in order to avoid overlapping or competing research in communities and to support complementary research based on community-defined priorities.
- b. The diversity of application review committees. Federal review committees need to include reviewers who can effectively evaluate the participatory aspects of research

proposals, and represent diversity through the inclusion of individuals who can speak to the historical, social, and cultural subtleties that affect the conduct of health research.

- c. The need for education and training opportunities for researchers and community members. Researchers could work with communities more effectively if they had knowledge in ethics, cultural competency, and participatory research techniques. Likewise, community members could be more effective with knowledge of research processes. Funding and technical support should be available for career development of students, especially minority students, in community participatory research, and for the development and implementation of training programs for community-based public health paraprofessionals. Communities should share appropriately in the infrastructure costs of conducting research, and funding should be available for communities to explore the use of their own cultural traditions as a basis for answering questions and finding solutions.
- d. Accountability through the use of Federal regulations. Meaningful collaboration among communities, researchers, and HHS agencies should be defined and evaluated on the basis of actions such as the use of respectful and equalizing language; clear statements on the participatory roles of communities, researchers, and agencies; and data sharing plans that outline technical requirements, confidentiality protections, and publication constraints.
- e. Access to information. Effective partnership requires that community members have access to information on research, including basic requirements for the ethical conduct of research, explanations of research terminology, factors to consider when weighing the risks and benefits of study participation, evaluating the credentials of the research team, descriptions of funding sources, and the options available if problems or concerns about the research arise. In addition, currently funded collaborative models should be documented and mechanisms developed to disseminate information on them to communities, funders, researchers, and policymakers to share lessons learned.

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APPENDIX

Enhancing Community Participation to Restore Trust and Improve Science in Health Research
October 16-17, 1987
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FEB 10 1998

MEMORANDUM FOR ANNE MCGUIRE

Attached is a memorandum for the President from Secretary Shalala transmitting a Report on Building Community Partnerships in Research: Recommendations and Strategies. The Report was prepared in response to the President's directive following his formal apology last year to the survivors and their families of the Tuskegee Syphilis Study.

A handwritten signature in cursive script, appearing to read "William V. Corr".

William V. Corr

Attachment

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P6-3



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 27 1998

MEMORANDUM FOR THE PRESIDENT

The purpose of this memo is to outline the information we have so far on the impacts of changes in welfare programs. The information is still quite preliminary, but some conclusions are emerging. These include:

- o The total number of welfare recipients has fallen below 10 million for the first time since 1971. Caseloads have fallen by more than 50 percent since their peak in 1994.
- o Many more recipients are now working, and the proportion of former recipients at work after leaving welfare appears to be somewhat higher than in the past.
- o States are making very serious efforts to move recipients into work, both by mandating work programs and sanctioning those who do not comply, and by increasing the benefits of working through simpler and higher earnings disregards and on-going supports such as child care.
- o As we found with AFDC waivers, States are adopting common approaches but with many variations in specifics. Several large States are devolving key policy decisions to the county level.
- o There has been no "race to the bottom" in State welfare benefits; States are spending more per recipient than in 1994 across TANF and related programs, and State maximum benefit levels are generally unchanged.
- o So far there is little evidence of extreme hardship among those who leave welfare as a result of sanctions, although many do experience fairly large declines in income. Overall, however, half or more of former recipients appear to increase their incomes after leaving welfare.
- o Even when recipients move to work and improve their incomes, they are still likely to have total incomes below the poverty line.

This memo looks first at what the States are doing, in terms of both spending choices and broader policy choices. It then turns to impacts on recipients, assessing both results from evaluations of State waivers similar to current State policies and the very early results from State surveys of recipients and former recipients. Finally, the implications of these findings for Federal and State policy choices are briefly discussed.

cc: Siebenaler, ASL, IGA, ACF

01-27-97 22

State Responses to Welfare Reform

Welfare caseloads have declined dramatically since their peak at 14.4 million recipients in March 1994. Overall, the number of people receiving aid had declined by more than 30 percent to 9.8 million recipients by September 1997 (the most recent monthly report available). This decline has continued at an even more rapid pace since the enactment of welfare reform in August 1996. In the first year of welfare reform alone, almost 2 million recipients left the rolls. As Chart 1 (attached) shows, these declines are spread across almost all of the States.

Changes in State Spending on Welfare Programs. There has been no "race to the bottom" in State welfare spending. Because there are now fewer recipients, total State spending on welfare programs has declined since 1994. On average, however, States are spending somewhat more per recipient than they did in 1994--reported State spending on welfare and related programs is about 18 percent below the level seen in 1994, while caseloads have declined by more than 30 percent. This increased spending has not affected direct payments to recipients, which remain very close to the levels seen in both 1994 and 1996 (about \$370 per family per month on average.) In all, four States have increased maximum benefit levels since the enactment of TANF, while five States have decreased maximum benefits for at least some categories of recipients.

States are reporting that they are meeting their Maintenance of Effort (MOE) requirements under welfare reform. They are required to spend 80 percent of previous (generally 1994) levels, or 75 percent if they meet the minimum participation requirements, and 20 States report exceeding that goal, some by considerable amounts (see Chart 2). Further, reported spending may understate actual amounts spent, since there are no incentives for States to report additional spending once their MOE requirements have been met. There is little in these data to suggest declines in spending levels--rather, States appear to be using at least some of their own money to provide services such as child care and job training and placement and to increase work incentives.

Changing State Policies. A focus on work is a major theme in State welfare policies, although there is considerable variation in plan specifics and in implementation across States. The following key points emerge from an overview of State policies:

1. States are focusing on encouraging and requiring work.
 - o 40 States have enacted policies to make work pay, generally by increasing the amount of earnings disregarded in calculating welfare benefits. (See Chart 3.) Connecticut, for example, now disregards all earnings up to the poverty level. Most States have also simplified the treatment of earnings compared to the AFDC treatment, with the result that recipients can see more clearly how even a low-wage job will make them better off.

o 44 States have raised the level of resources and/or the maximum value of a vehicle allowed to welfare recipients. (See Chart 4.) This will make it easier for recipients to get to work and to accumulate savings that might lead to self-sufficiency.

o Almost all of the States have moved to "Work First" models in their welfare programs, requiring recipients to move quickly into available jobs. Virtually every State has instituted "social contracts" or other personal responsibility agreements in which recipients commit to specific steps toward self-sufficiency. States are enforcing these contracts, sanctioning people who fail to sign or live up to their agreements.

2. Family violence issues and choices about exemptions for parents of very young children are being addressed by the States.

o 24 jurisdictions have elected to screen for, provide appropriate services, and waive requirements where needed to ensure the safety of victims of domestic violence through the Family Violence Option (See Chart 5.) Additional States, including California, are expected to implement this option in the coming months.

o As indicated in Chart 6, most States have chosen to exempt parents of infants under one year of age from work requirements. 16 States have chosen shorter exemptions (the law allows States to require parents with children over 12 weeks to work.)

3. State policies regarding time limits are varied and complex.

o Chart 7 shows that eleven States have chosen "intermittent" time limits that limit the total months of reciprocity allowed within a longer time period (for example, Virginia limits TANF receipt to 24 months in any 60 month period). Nine States have chosen lifetime limits of less than five years. Both of these types of time limits often allow exceptions or exemptions. 27 States have chosen the Federal limit of 60 months. Four States have chosen other options involving supplements from State welfare programs for those reaching the Federal time limits.

o Evaluation and survey data find that recipients are often unclear about the specifics of time limits (and other reform policies) that apply to them, although they do know that the nature of welfare has changed.

o Few recipients have reached State time limits so far.

4. State plans vary considerably in their specifics and in their timing.

- o A few States are making choices that appear to have little to do with work, such as counting the SSI income of disabled children and adults in computing TANF benefits without taking into account the added costs of disability.
- o The amount of time that elapses between the determination of policy choices and their actual implementation varies greatly across States, usually based on whether, when and how extensively they undertook reforms through waivers. Many States have not completed the process of implementing proposed policy changes.

5. Finally, California, New York and several other states are devolving key decisions to counties.

- o Other States in the process of devolving include Maryland, Ohio, Florida, Colorado and North Carolina.
- o These States are devolving decisions about work activities, post-employment supports and, in some cases, sanctions; Colorado and North Carolina are also passing on decisions about other factors including eligibility. Benefit levels will still be determined at the State level, although in some cases the State will mandate only a floor which the counties can choose to exceed.

Impacts of Welfare Reform on Recipients

Moving recipients and potential recipients into work has been the focus of most State policies, and there is some preliminary evidence that employment levels are rising as caseloads decline. Evidence on the impacts of other aspects of the changes on recipients and would-be recipients is somewhat more mixed. Are they indeed better off in economic terms? What has happened to those who haven't gotten jobs? It is still very early to answer those questions, but we have some preliminary data that give a few indications.

Our preliminary data generally relate to the situations found in specific states. Thus, this report draws upon preliminary program evaluation reports of waiver-based policies from Michigan, Iowa, Minnesota, Delaware, and Florida, and on surveys of welfare recipients and people who have left welfare rolls in Massachusetts, Iowa, Wisconsin, Indiana, Maryland, South Carolina and Tennessee. The early stories emerging from these studies appear to be fairly consistent across those states. Although we are beginning to have some evaluation evidence on the impacts of policy changes as opposed to the strong economy, it is very difficult to sort out the relative importance of policy and economic factors at the National level.

Sanctions. States are generally working harder to enforce mandatory work requirements, and sanctions rose by about 30 percent nationally between 1994 and the end of 1996. Anecdotal evidence implies that these rates are still increasing. In the studies of specific States, sanction

rates of as high as 50 percent are seen, with rates in the 25 percent to 30 percent range not unusual. Sanctions may result in either a complete or partial loss of benefits. Across States we find that the majority of sanctions occur because recipients fail to show up for initial appointments. Far fewer families have been sanctioned for refusal to comply with work assignments. Sanctioned families may include many who are already working or who have good job opportunities; in Iowa, for example, families that did not comply with the State's Family Investment Plan tended to be more job-ready than the average.

Employment. Perhaps partly because of stricter work policies as well as the robust economy, more recipients and former recipients are now employed. Evaluations of specific State programs show policy-related increases in employment in the range of 8 percent to 15 percentage points. Surveys of people who have left welfare imply that 50 percent to 60 percent are working in the period following welfare reciprocity (with the remainder not employed). This is comparable to or slightly higher than the 45 percent to 50 percent of welfare exiters who worked after leaving AFDC. Some of this increase in work may result from the strong economy as well as from policy changes.

Incomes. While there do not appear to be dramatic changes so far in the average incomes of welfare recipients and those leaving the welfare rolls, these averages hide a great deal of variation. Among those leaving the program, incomes in the follow up period are very mixed. Generally, about half of former recipients saw increases in their incomes, while half experienced declines. There is some evidence that those who leave the program voluntarily are more likely to have increased incomes, although in both South Carolina and Iowa about 40 percent of those who left because of sanctions also experienced income increases.

There is little evidence at this point of extreme hardship even among families losing benefits altogether as a result of sanctions or time limits. However, events such as homelessness or entry of children into foster care are sometimes hard to observe in evaluations and follow up studies, which are usually unable to trace some proportion of former recipients. In the short run, many families experiencing large income losses appear to rely on help from friends and extended family. It should be noted also that even families whose incomes rise as a result of higher earnings and/or changes in State policies typically still do not have above-poverty level incomes while on TANF or in the period immediately after leaving the program.

Other Benefits. Families who leave TANF are often eligible to continue receiving benefits from other social support programs such as the Food Stamp Program, Medicaid, Supplemental Security Income (SSI) and housing programs. However, relatively low take-up rates for some of these benefits suggest that many former recipients may be unaware of their continued eligibility for other programs such as Medicaid, or that administrative barriers may be preventing some eligible families from participating in these programs. In both South Carolina and Indiana, for example, about half of the adults who were no longer receiving cash assistance reported that they did not have any health insurance.

Policy Implications and Next Steps: Supporting Low-Income Workers

These early results suggest that real progress is being made in focusing recipients on work and in moving them into employment. This is a significant and critical step on the path to reforming welfare. I believe that further steps need to be taken to consolidate and build on this accomplishment. In particular, we need to ensure that low-income working families, whether they are former welfare recipients or not, can continue to work and to earn enough to raise their families, weathering unemployment and other temporary setbacks without relying on long-term welfare receipt. In pursuing this goal, we would be building on the Administration's many achievements for working families, including expansion of the EITC, increasing the minimum wage, expanding health care coverage for children, enacting parental leave, and the introduction of this year's pathbreaking child care initiative. And we would also be building on the widespread and increasing interest of the States, which are starting to grapple with the question of what happens after welfare parents take their first jobs.

Both researchers and practitioners are telling us that when such parents move to work, most are likely to need continuing support in order to keep their jobs, support their families, improve their incomes over time, and avoid going back onto the welfare rolls. These supports can take many forms, from the EITC or increased earnings disregards to services such as child care, health care, transportation and mentoring. Currently, States have resources available to them through the TANF block grant and their Maintenance of Effort funds, as well as through other State resources that have been freed up as a result of declining caseloads. We can make progress on this agenda by challenging States to make key investments, showcasing effective practices and encouraging State innovation as well as by shaping a National agenda to help low-wage workers and their families.

A successful strategy to support low-income workers and their families would involve several components at both the State and National levels. These could include:

1. Raising the incomes of low-wage workers. Most welfare recipients moving into their first jobs continue to earn below-poverty level incomes. The major 1993 expansion of the EITC does a great deal for these families, and it must be protected. In addition, we could challenge States to expand State EITC's and to increase earnings disregards and other programs for low-wage workers. For example, Wisconsin has used TANF MOE funds to expand both its EITC and housing subsidies for low-income owners and renters. At the National level, policies such as a further increase in the minimum wage or tax incentives for employers to promote jobs and higher wages for low-skilled workers could be explored.
2. Providing other job supports. We must ensure that other critical job supports, such as health care, child care, transportation, and mentoring, are available for working families who need them. The Administration's new child care initiative is of course critical to this strategy, and the newly enacted Child Health Insurance Program should go a long way toward ensuring health care coverage for the children of low-wage workers. We need to

continue outreach efforts to make sure that low-income working families are aware of their potential eligibility for Medicaid. The Vice President's work on mentoring provides a valuable example, and States must be encouraged to continue to invest in these programs and other supports.

3. Ensuring that low-wage workers improve skills and earnings over time. Many States are beginning to grapple with the best way to promote growth in skills and earnings over time for former welfare recipients. Over the longer term, such growth will be necessary to meet both the needs of families and the needs of the economy as a whole. We should be challenging States to put together creative strategies and showcasing those that do. These strategies can involve linkages among workforce development, higher education, and welfare systems, as well as work with specific private employers. At the National level, strategies to increase educational opportunities for low-income families are a key to increasing skills and earnings over time.
4. Maintaining the safety net for workers. If a temporary setback is not to result in a return to welfare dependency, the safety net for low-wage workers must be maintained. At the National level, changes could be made in the Unemployment Insurance program to increase the probability that low-wage workers will earn coverage, as is now being discussed within the Administration. At the State level, we should showcase States that are implementing post-employment services and other strategies to address the fact that low-income workers are likely to experience considerable job turnover and some periods of unemployment. We should challenge States to invest in approaches that combine reliable short-term assistance with rapid re-employment help.

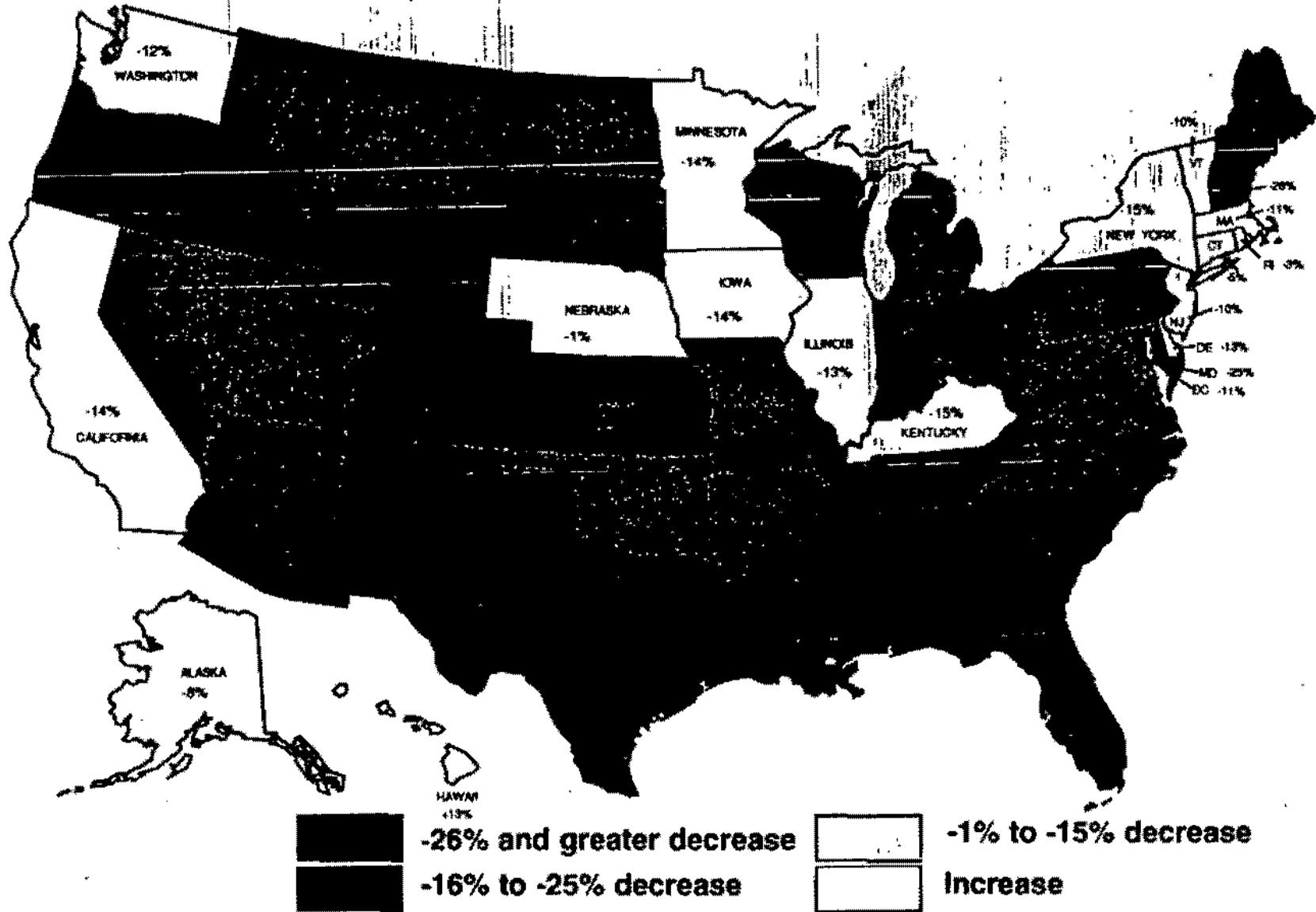
In summary, we must build upon and continue our efforts on behalf of low income workers. I look forward to further discussions with you regarding these important issues. Please let me know if you would like a briefing or further information.



Donna E. Shalala

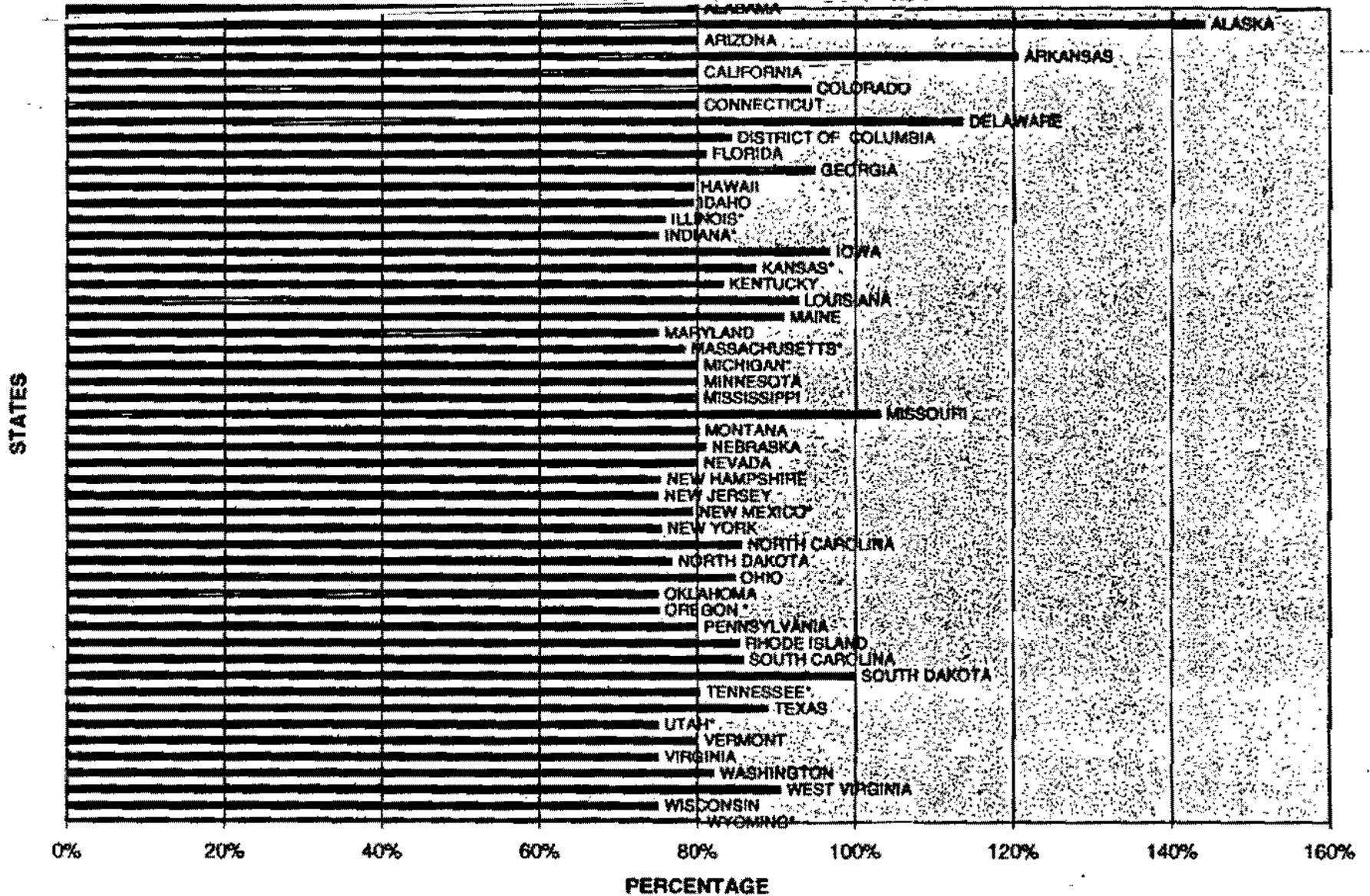
Attachments

Chart 1: RECIPIENT COUNT DOWN 2.4 MILLION SINCE ENACTMENT OF NEW WELFARE LAW (August 1996-September 1997)



TANF PROGRAM

Chart 2: EXPENDITURE OF STATE FUNDS IN FY 1997 AS % OF MOE



Data as of January 23, 1998

Chart prepared by U.S. Dept. of Health and Human Services
Administration for Children and Families

Chart 3: Earnings Disregards

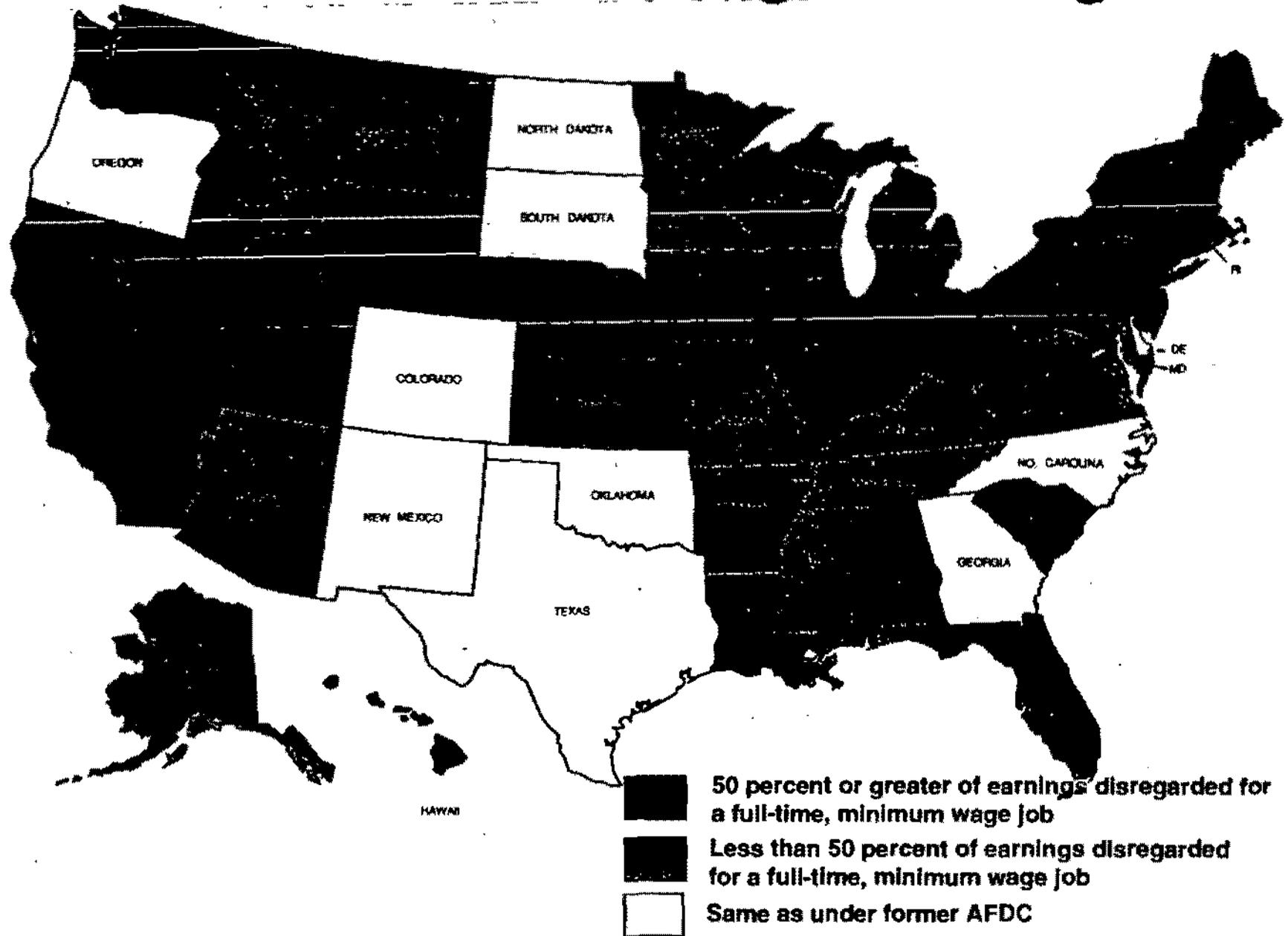
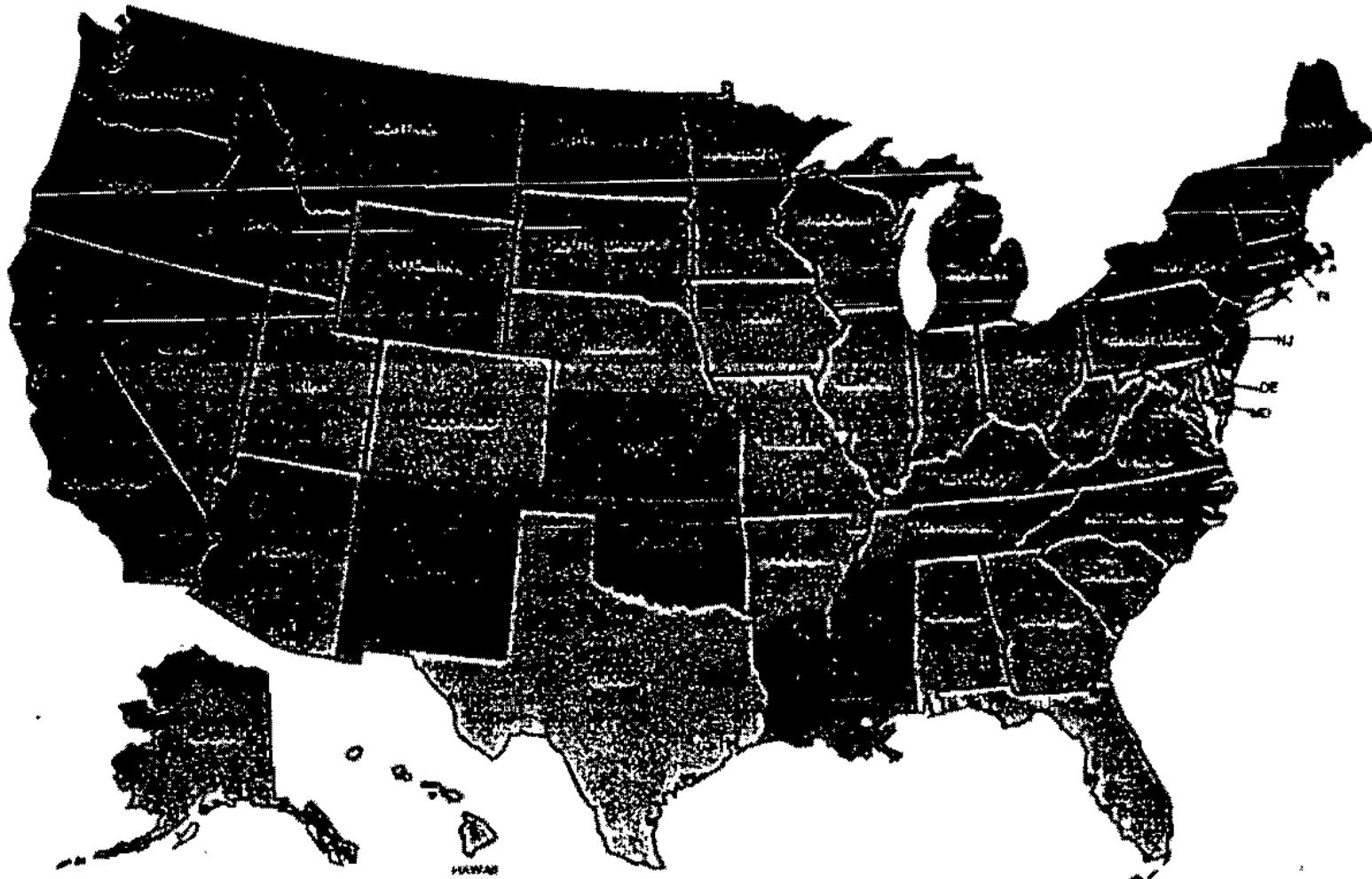


Chart 4: Increased Resource/Vehicle Limit



 Increased resource and/or vehicle limit

 As under former AFDC program

Chart 7: Time Limit Choices

