

HHS REGULATIONS PROVIDE EMERGENCY ACCESS TO PROMISING THERAPIES

From U.S. Dept. of Health & Human Services

■(WASHINGTON) The Food and Drug Administration and the National Institutes of Health last Thursday announced measures designed to protect individuals who may benefit from emergency research.

The FDA issued final rules to make it easier for promising experimental drugs and medical devices to be studied in persons who are in life-threatening situations and unable to give informed consent for their use. As a companion document, NIH has published "Emergency Research Consent Waiver" applicable to all agencies of the Department of Health and Human Services.

These policies establish narrow limits for allowing research without informed consent in certain studies of emergency medical procedures, and harmonize these standards throughout the Department of Health and

Human Services.

HHS' new overall approach to emergency research situations may offer the best hope in cases when critically ill, unconscious, persons (with no readily available legal representative to give consent), cannot be successfully treated through conventional means, but might benefit from a promising experimental intervention.

FDA addressed this issue last September in a proposal that defined the main conditions under which patients could be enrolled in clinical trials without their consent, provided that an independent physician and an institutional review board (IRB) — a committee of experts and lay persons established to review research — agree that the clinical trial addresses a life-threatening situation and that other criteria are met.

These new policies were developed in response to growing concerns that the current

regulations were making high quality research in emergency circumstances difficult or impossible to carry out at a time when the need for such research is increasingly recognized.

The FDA proposal, which was broadly supported by 19 leading medical, patient advocacy, and industrial groups, received more than 90 comments. Based on these comments, FDA expanded, in final regulations, the procedures to be followed by IRBs and investigators in attempting to obtain informed consent from the patient's legal representative, or to inform the patient's family about the research.

FDA's final rule and the HHS Waiver Notice will be published in the Federal Register Oct. 2. The regulations become effective 30 days after the date of publication.

PAC CONTRIBUTIONS INCREASE \$17 MILLION

From Federal Election Commission

■(WASHINGTON) Political action committees (PACs) contributed \$126.5 million to federal candidates between January 1, 1995, and June 30, 1996, according to statistics released last Friday by the Federal Election Commission (FEC).

That total is an increase of almost \$17 million over the 18 month period in the 1993-94 election cycle. Of the \$126.5 million, PACs contributed over \$114.4 million to candidates seeking election in 1995-96, with the remaining \$12 million going toward debt retirement and future elections. In the previous cycle, \$100.9 million — from a total of \$109.9 million — went to candidates seeking election in 1993-94.

FEC analyses of statistics from 4,430 PACs show a total of \$311.5 million raised and \$264.7 million spent in the first 18 months of the 1995-96 election cycle. Cash on hand to begin the last six months of this election year was \$144.5 million.

Incumbents received \$98.3 million of the \$126.5 million contributed, while challengers were given \$12.5 million and candidates for open seats got \$15.8 million from PACs. In the previous election cycle, incumbents received \$91.1 million, challengers \$5.5 million, and candidates for open seats \$13.3 million. Republican candidates received \$71.6 million from PACs through June, 1996, while Democrats received \$54.7 million. Through June of 1994, Republicans had received \$37.8 million compared to Democrats' \$72 million.

NEW CHILD CARE FUNDS RELEASED

From US Dept. of Health & Human Services

■(WASHINGTON) Increased child care funds available to states under the newly enacted welfare law were released Tuesday, according to HHS Secretary Donna Shalala. She also announced new grants to help states improve the health and safety of child care programs.

The child care block grant funds for fiscal year 1997 will provide up to \$1.92 billion to states, a significant increase over the estimated FY 1996 level of \$1.35 billion.

Depending on states' decisions, HHS estimates this increase in funds will enable states to serve about 230,000 additional children in full-year, part-time child care slots.

Under the new welfare law, several federal child care programs were consolidated into the Child Care and Development fund, a single block grant to the states. This consolidation makes it easier for states to plan for and access federal funds, reduce administrative burdens, increase the number of children who can be served and improve the quality of child care programs.

Later this year, approximately \$1 billion in discretionary child care funds will also be released to the states.

HHS is also awarding \$2.5 million in grants to 42 states, the District of Columbia, Puerto Rico and the Republic of Palau this week to support and encourage the development of statewide strategies and planning for healthy, safe child care programs. The grants build upon the Healthy Child Care America Campaign launched by Secretary Shalala last year.

The activities of the projects include formation of statewide Healthy Child Care Campaigns, investments in systems and services to increase child care capacity, programs to address children with special needs and the training of child care providers in health and safety. The projects are funded for three years.

The changes in funding for Oklahoma and bordering states are:

	FISCAL 96	FISCAL 97	Increase
Arkansas	\$ 5,216,653	\$ 11,928,191	\$ 6,711,538
Colorado	11,935,519	20,458,829	8,523,310
Kansas	10,166,728	16,962,947	6,796,219
Louisiana	12,716,209	26,579,410	13,863,201
Missouri	27,599,568	38,926,173	11,326,605
Oklahoma	30,998,199	33,904,916	2,906,717
Texas	73,324,512	116,877,750	43,553,238
Total of all states	\$1,354,855,195	\$1,922,742,500	\$567,887,305