

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 30, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Children's Bureau Proposed Research Priorities for Fiscal Years 2006-2008.

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), HHS.

ACTION: Notice of proposed child abuse and neglect research priorities for Fiscal Years 2006-2008

SUMMARY: The Children's Bureau (CB) within the Administration on Children, Youth and Families (ACYF) announces the proposed priorities for research on the causes, prevention, assessment, identification, treatment, cultural and socio-economic distinctions, and the consequences of child abuse and neglect.

Section 104(a)(4) of the Child Abuse Prevention and Treatment Act (CAPTA), as amended by the Keeping Children and Families Safe Act of 2003, Public Law (Pub. L.). 108-36, requires the Secretary of the Department of Health and Human Services (HHS) to publish proposed priorities for research activities for public comment and to maintain an official record of such public comment. The proposed priorities are being announced for the two-year period required by CAPTA. Because the amount of Federal funds available for discretionary activities in Fiscal Years 2006-2008 is expected to be limited, respondents are encouraged to recommend how the proposed issues should be prioritized.

The actual solicitation of grant applications will be posted electronically each fiscal year and will be available online through <http://www.Grants.gov>. Solicitations for contracts will be announced, at later dates, online at FedBizOps. (FY 05 was

the last year that CB discretionary grants were published in the **Federal Register**.) No proposals, concept papers or other forms of application should be submitted at this time.

No acknowledgement will be made of the comments submitted in response to this notice, but all comments received by the deadline will be reviewed and given thoughtful consideration in the preparation of the final funding priorities for the announcements.

DATES: In order to be considered, comments must be received no later than April 4, 2006.

SUPPLEMENTARY INFORMATION:

I. Background

As noted above, Section 104(a)(4) of CAPTA requires the Secretary to publish proposed priorities for research activities for public comment every two years. In response to this legislative mandate, CB has undertaken a review of the current legislative language, the results of the CAPTA funded research since the last CAPTA announcement of research priority areas in 1997, findings from other relevant research, and input from the field. Based on this review, this notice of proposed research is being disseminated for comment. The FY 2005 budget appropriated \$31,640,000 for child abuse discretionary activities to support efforts designed to assist and enhance national, State and local efforts to prevent, identify and treat child abuse and neglect. The program funds projects to: Compile, publish and disseminate training materials; provide technical assistance; and demonstrate and evaluate improved methods and procedures to prevent and treat child abuse and neglect. Under discretionary funds, CB will continue to fund the following clearinghouse and technical assistance activities:

- The National Clearinghouse on Child Abuse and Neglect Information;
- The National Resource Center on Child Protective Services; and
- The National Child Abuse and Neglect Data System (NCANDS) technical assistance and technical support program.

In addition, the child abuse discretionary activities account funds a number of research and demonstration grants and contracts. The fourth National Incidence Study of Child Abuse and Neglect (NIS-4), is a Congressionally mandated, periodic research effort to assess the incidence of child abuse and neglect in the United States. Also, consistent with the legislation's preference for longitudinal research efforts related to child maltreatment, CB discretionary funds

continue to support the Consortium for Longitudinal Studies of Child Maltreatment (LONGSCAN).

For those members of the public interested in responding to this announcement, information on previous and continuing projects supported by CB are available through the following websites:

- The National Clearinghouse on Child Abuse and Neglect Information (<http://nccanch.acf.hhs.gov>);
- Children's Bureau Reports/Publications (<http://www.acf.dhhs.gov/programs/cb/publications/index.htm>);
- LONGSCAN (<http://www.iprc.unc.edu/longscan>);
- NIH Child Abuse and Neglect Working Group Neglect Consortium (<http://obssr.od.nih.gov>); and
- National Center for Children Exposed to Violence (<http://www.ncccev.org>).

II. Proposed Child Abuse and Neglect Research Priorities for Fiscal Years 2006-2008

A. Legislative Topics

A number of research topics are suggested in the 2003 reauthorization of CAPTA, Section 104. The legislation states that the Secretary shall, along with other Federal agencies and recognized experts in the field, carry out a continuing interdisciplinary program of research, including longitudinal research, that is designed to provide information needed to better protect children from abuse or neglect and to improve the well-being of abused or neglected children, with at least a portion of such research being field initiated. Suggested research includes:

- The nature and scope of child abuse and neglect;
- The causes, prevention, assessment, identification, treatment, cultural and socio-economic distinctions and consequences of child abuse and neglect, including the effects of abuse and neglect on a child's development and the identification of successful early intervention services or other services that are needed;
- Appropriate, effective and culturally sensitive investigative, administrative and judicial systems, including multidisciplinary, coordinated decision making procedures with respect to cases of child abuse;

- The evaluation and dissemination of best practices consistent with the goals of achieving improvements in child protective services systems of the States in accordance with CAPTA, Section 106(a), Grants to States for Child Abuse and Neglect Prevention and

Treatment Programs, paragraphs (1) through (14), which include:

- i. The intake, assessment, screening and investigation of reports of abuse and neglect;
- ii. Creating and improving the use of multidisciplinary teams and interagency protocol to enhance investigation, and improving legal preparation and representation;
- iii. Case management, including ongoing case monitoring and delivery of services and treatment provided to children and their families;
- iv. Enhancing the general child protective system by developing, improving and implementing risk and safety assessment tools and protocols;
- v. Developing and updating systems of technology that support the program and track reports of child abuse and neglect from intake through final disposition and allow interstate and intrastate information exchange;
- vi. Developing, strengthening and facilitating training;
- vii. Improving the skills, qualifications and availability of individuals providing services to children and families, and the supervisors of such individuals, through the child protection system, including improvements in the recruitment and retention of caseworkers;
- viii. Developing and facilitating training protocols for individuals mandated to report child abuse or neglect;
- ix. Developing and facilitating research-based strategies for training individuals mandated to report child abuse or neglect;
- x. Developing, implementing or operating programs to assist in obtaining or coordinating necessary services for families of disabled infants with life-threatening conditions;
- xi. Developing and delivering information to improve public education relating to the role and responsibilities of the child protection system and the nature and basis for reporting suspected incidents of child abuse and neglect;
- xii. Developing and enhancing the capacity of community-based programs to integrate shared leadership strategies between parents and professionals to prevent and treat child abuse and neglect at the neighborhood level;
- xiii. Supporting and enhancing interagency collaboration between the child protection system and the juvenile justice system for improved delivery of services and treatment, including methods for continuity of treatment plans and services as children transition between systems; or

xiv. Supporting and enhancing collaboration among public health agencies, the child protection system and private community-based programs to provide child abuse and neglect prevention and treatment services (including linkages with education systems) and to address the health needs, including mental health needs, of children identified as abused or neglected, including supporting prompt, comprehensive health and developmental evaluations for children who are the subject of substantiated child maltreatment reports.

- Effective approaches to interagency collaboration between the child protection system and the juvenile justice system that improve the delivery of services and treatment, including methods for continuity of treatment plans and services as children transition between systems;
- An evaluation of the redundancies and gaps in services in the field of child abuse and neglect prevention in order to make better use of resources; or
- The nature, scope and practice of voluntary relinquishment for foster care or State guardianship of low-income children who need health services, including mental health services.

B. Other Topics

Prevention Practices: CB is interested in research that builds on existing knowledge about child abuse and neglect prevention. CB initiated the Emerging Practices in the Prevention of Child Abuse and Neglect project as a collaboration between the agency and the professional community to describe the current landscape of prevention programs and generate new information about effective and innovative approaches to the prevention of child maltreatment. Through a national nomination process, several strategies and features of child abuse prevention programs were identified as holding promise for reducing the incidence of child maltreatment. Next, a grant competition to fund replications of effective prevention programs was held. Funds were awarded to eight sites nationwide to replicate the University of Maryland's "Family Connections" project. While this work is contributing to the body of knowledge about the type and range of problems in the U.S. for the prevention of maltreatment, it is clear that much more can and must be learned about the effectiveness of prevention programs in terms of what works and for whom. Research interests may include: The efficacy of prevention in the field of child maltreatment; rigorous study on all the major prevention models and strategies; and

integrating child abuse and neglect research into prevention practices.

Child Protection Systems: CB is interested in research that examines effective State-level strategies employed to improve child protection systems. Questions may include: the degree to which changes in *Child Protection Systems* (CPS) systems policy and practice are tied to better outcomes; determining the variations in local agencies that result in different outcomes; and whether or not child safety and well-being are improved by privatizing part or all of the child welfare system. Other research interests may include: Effective responses for children at risk of being harmed; barriers to consistency in CPS operations, such as differences in the level of resources; lack of clear laws and policy and the competing desire for local autonomy in government functions; the means by which CPS agencies try to understand the standards of the community they serve through outreach to additional panels and review teams (fatality review team, citizen review panels, external case reviews); and collaborations between CPS and other agencies. In addition, CB continues to be interested in building on previous research to explore over-representation of minorities in the child welfare system, particularly research to identify and disseminate lessons learned from promising practices that have been effective in reducing the rates of over-representation of children of color in the child welfare system.

Services: CB is interested in research focused on the assessment of service needs and services provided. Research questions may include: What services are children and families receiving; to what degree are services responsive to the needs of the target population; and what are the outcomes that result from various services. Other research may focus on case planning and intervention such as examining the development and implementation of comprehensive family assessment, safety planning, engaging families and monitoring risk assessment over the life of CPS cases, as well as increasing knowledge of parent and child engaging in the case planning process.

The findings from the initial Child and Family Service Reviews (CFSR) of all 50 States, the District of Columbia and Puerto Rico, identify strengths and needs within State programs, as well as areas where technical assistance can lead to program improvements. CB encourages research on areas in which States were found to be weak based on the CFSRs. State performance on identifying and responding to children's

mental health issues, in particular, was found to be one of the weakest in the CFSRs. Areas of interest for research may examine CPS procedures for identifying and responding to children's mental health issues as well as the prevalence, type and severity of mental health problems among children identified in State child welfare systems. In addition, findings from the National Survey of Child and Adolescent Well-Being (NSCAW) show that high rates of mental health problems among parents, coupled with low rates of identification and referral, is a serious issue. CB is interested in research that examines mental health services to parents.

Program Evaluation of Priority Area Initiatives (or Evaluation of Programs Addressing Administration Priorities): The current Administration has focused funding in areas of healthy marriage promotion, fatherhood initiatives, community and faith-based organizations and youth development in ensuring the healthy development of children. CB is interested in research to evaluate programs employing these strategies to prevent child abuse and neglect. Research topics may include the evaluation of the effectiveness of these programs as well as the dissemination of promising practices.

Secondary Data Analysis: CB encourages the utilization of existing data sources particularly the use of service data through the National Child Abuse and Neglect Data System (NCANDS). CB is interested in secondary data analyses using NCANDS focusing on service utilization, recurrence and perpetrators.

Service utilization: While not all States provide complete service data to NCANDS, for those States that do provide complete service data, the following areas could be examined: The services that are most often provided to victims of maltreatment; differences in service patterns that exist between children who are first-time victims and children who are repeat victims; differences in service patterns that exist between child victims who remain in their homes and those who are removed; and the variations in service patterns within States according to county characteristics.

Recurrence: To date, recurrence has largely been examined for six-month periods using NCANDS data. The Office of the Assistant Secretary for Planning and Evaluation undertook a longitudinal analysis of NCANDS data examining repeated CPS involvement. Using a multiyear dataset of 1,396,998 children, this research examined the proportion of reported children who re-reported,

the proportion of child victims who had a recurrence of maltreatment and the factors associated with these repeated events. The findings showed that re-reporting was relatively common—about one-third of children had at least one repeated report of maltreatment within a five-year period. For the most part, the same factors were related to both re-reporting of all reported children and recurrence among victims of maltreatment. Findings were also similar when analyses examined only the presence of a single subsequent event or the number and type of multiple subsequent events. Both re-reporting and recurrence occurred more frequently among younger children. Re-reporting and recurrence were more likely to occur in a short time following the initial maltreatment report, usually within a few months. Most children who experienced more than one re-report or re-victimization experienced these events within a short time after the initial event. Areas for further research might examine: Factors that are predictive of a second investigation; report sources that are the most likely to be associated with a second investigation; services that decrease subsequent investigation; and services that decrease subsequent victimization.

Perpetrators: CB continues to be interested in perpetrators, with the notion that understanding who this group is and what their characteristics are, can help to inform more effective intervention and prevention efforts. The Office of the Assistant Secretary for Planning and Evaluation undertook an analysis of NCANDS data examining some of these questions. The analysis focused on male perpetrators of child maltreatment and identifies clear subgroups of male perpetrators. The findings suggest that interventions of all types may need to be more highly differentiated for these different groups. Follow-up of interest includes research to gain a clearer picture of how the various categories of perpetrators fit within households to provide insights into the service and recidivism outcomes.

C. Field Initiated Research on Child Abuse and Neglect

The generation of new knowledge for understanding critical issues in child abuse and neglect improves prevention, identification, assessment and treatment. Research areas to be addressed may be those that will expand the current knowledge base, build on prior research, contribute to practice enhancements, inform policy, improve science and provide insights into new approaches to the assessment,

prevention, intervention and treatment of child maltreatment (i.e., physical abuse, sexual abuse, emotional maltreatment or neglect) on any of the topics listed in (A) Legislative Topics, (B) Other Topics, above, or any other child maltreatment topic.

In addition to the topics cited above, practitioners and researchers are encouraged to propose other relevant subjects for research topics in child abuse and neglect.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P-0023]

Determination That TEQUIN (Gatifloxacin) Injection, 10 Milligrams per Milliliter (200 Milligrams), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that TEQUIN (gatifloxacin) injection, 10 milligrams (mg) per milliliter (mL) (200 mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for gatifloxacin injection, 10 mg/mL (200 mg).

FOR FURTHER INFORMATION CONTACT:

Elaine Tseng, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Pub. L. 98-417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise