Alliance for Human Research Protection (AHRP)

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August 6, 2001
Dr. Bernard Schwetz
Acting Commissioner
Food and Drug Administration

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: COMMENT ON: Docket #00N-0074 April 24, 2001 Interim Rule: "Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products

Dear Dr. Schwetz:

Thank you for the opportunity to comment on the interim rule published in the Federal Register on April 24, 2001 concerning 21 CFR Parts 50 and 56.

We SUPPORT FDA's decision to adopt HHS 45 CFR 46 Subpart D, EXCLUDING Section 46.408(c), pursuant to bringing FDA regulations into compliance with provisions of the Children's Health Act of 2000, which requires that all research involving children conducted, supported, or regulated by HHS be in compliance with HHS regulations to provide additional protections for children involved as research subjects. The rule applies to FDA's authority to regulate safety and effectiveness testing in children of such products as: human drugs and biologicals, medical devices, and dietary supplements, nutritionals, food additives, and foods

> 45 CFR Subpart D, 46.408 (c) states: "If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part ...provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and

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condition."

This language departs significantly from basic tenets of law and ethics--without any justifiable criteria specified. The issue of surrogacy, i.e., the appointment of a third party to represent the child's interests, is not relevant until and unless parental rights have been terminated. Thus, surrogacy should not be an option for researchers seeking human subjects. Clearly, there is no justification for waiving parental permission under any other circumstances. It is also clear that such rights are not waived even when the child has been deemed dependent and has been placed in state care as a ward.[1]

The FDA RIGHTLY chose NOT TO PERMIT the section 46.408 (c) waiver by IRBs of parental or guardian permission, as it leaves the specific circumstances for such a violation of parental rights to the discretion of local Institutional Review Boards (IRB). Given the stream of revelations of gross ethical and procedural violations at one after another of the nation's premier research institutions,[2] assumptions that "procedural safeguards are in place," or that IRBs can be relied upon to make decisions that protect the best interests of human subjects--adults and children--has been debunked. The fact is, there is no established "appropriate mechanism," no procedural safeguards, and no system of IRB accountability.

Children are being experimented upon without regard for their safety or the pain and suffering inflicted on them. For example, the Boston Globe[3] reported that experimental eye surgeries being conducted at the University of South Florida had caused "more than the usual complications, including transplants that slipped and wounds that broke open." A toddler was subjected to "a self-contained experiment" in which traditional surgery was performed on one eye, and a new technique on the other, resulting in "unusual bleeding into the eye." Children are unjustifiably exposed to pain and suffering for research.[4]

To recruit ever greater numbers of children for experiments involving risks of harm--some may prove to be long-term harm--without any demonstrable "appropriate mechanisms" in effect, is reckless endangerment, not "added protection."

Thus, we urge FDA to reconsider its recent adoption of a broad interpretation of the meaning of regulatory language related to recruitment qualifications.[5] Previously, the enrollment of children was restricted to studies that offered a potential benefit for a specific, identifiable medical condition. FDA redefined the terms "potential benefit" and "condition" in April 2000 to mean an unspecified risk or disposition to a common (even minor) condition: "any child has the potential to benefit from a treatment for otitis media" (ear infection).

The FDA RIGHTLY concluded that section 46.408(c) is NOT permitted under FDA law. Thus, pursuant to the requirements of the Federal Administrative Procedures Act, adoption by the FDA of the section 46.408(c) IRB waiver authority would require an act of Congress.

We further urge that the FDA resist any pressure to change its legislative authority in this regard for the following reasons:

1. Parental and guardian rights should not be waived except under the extraordinary circumstances wherein the courts adjudicate the existence of abuse or neglect and terminate parental rights. Permitting IRBs to exercise the Section 46.408(c) waiver authority is tantamount to abrogating the entire system of judicial protection of children whose life safety or morals are put into jeopardy. There is a very heavy burden of proof on those would argue for removal of the traditional court jurisdiction just because the child is desired as a research subject by some interested biomedical researcher to show how his/her prudential standard is at least as high as that of a proper court of jurisdiction.

Indeed, the only proper way to test the equivalence of IRB and court prudential standards would be for the interested biomedical researcher and supportive IRB to petition the appropriate court of jurisdiction to grant its request to waiver parental or guardian consent in the specific research circumstances. If the FDA were to adopt regulations that permitted IRBs to exercise the section 46.408(c) waiver authority, one could anticipate a swift and immediate test of its decision under the Federal Administrative Procedures Act and, that failing, an appeal to an appropriate federal district court of jurisdiction. One can also anticipate very messy news media and

political reverberations if children and adolescents were to be recruited into medical experiments without parental permission.

2.Those who argue that IRBs are capable of developing a mechanism of review to assure that the child or adolescent is capable of making the decision to participate in specific research and to provide appropriate procedural safeguards to protect his/her welfare in the research process are deluding themselves in so far as the system is unraveling in public view. A steady stream of investigative reports and research shut downs[6] has revealed that the IRB system as constituted under existing law and regulations is demonstrably dysfunctional and fundamentally flawed--even the nation's most prestigious biomedical research institutions are violating basic safeguards. Gross violation of ethical standards and regulatory procedures to ensure the safety of people in research are not the exception, they are sad everyday reality.

3. Those who are promoting the adoption of 46.408 (c) to lift safeguards such as the involvement of parents in the protection of their children are in fact arguing to weaken safeguards for children, not to improve them. **Informed consent for adults can be waived for adult subjects only if "the research involves no more than minimal risk to the subjects."** 45 CFR 46.116. (d) We note with profound concern that the language of HHS Subpart D, section 46.408 (c) blithely dismisses this restriction with the unfounded assurance that:

> "The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition."

The clear implication of this deviation from the standards for adult research protections is that dependent children and adolescents merit even less protection and concern than do adults.

4. We SUPPORT FDA's retention of the terms "permission", "guardian" and "informed consent" -- so as to distinguish children from other participants in clinical investigations who can exercise the right to informed consent. Children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations." Thus, by definition, children cannot give informed

consent. "Because children are unable, due to age, to give consent themselves, permission is provided by a parent or guardian on their behalf. The term informed consent under Section 50.20 applies to other participants in clinical investigations."

5. Those who argue that Section 46.408(c) waiver authority is needed to permit biomedical and behavioral researchers to enroll children and adolescents with a propensity for risky behaviors involving sexually transmitted diseases, for experimental research projects, carry a very heavy burden of proof. They must demonstrate that the research they envision does not put children at undue risks of harm, and that the research offers benefits to the children and adolescents that outweigh the basic right and duty of parents and guardians to intervene to protect them from these illnesses and risky behaviors--as well as to choose appropriate medical interventions. For government agencies to permit IRBs to exercise the Section 46.408(c) waiver of parental authority would be regarded as an unacceptable intervention by the federal government. For such an intervention undercuts the responsibility of parents and guardians to safeguard the welfare and morals of children and adolescents--in order to facilitate their recruitment for research purposes.

Most responsible parents will recoil at the suggestion that biomedical researchers and their supporting Institutional Review Boards are more able than the parents or guardians to decide what is in their best interests. What is more, the courts with jurisdiction to intervene to protect children from abuse and neglect at the hands of parents or guardians, will surely take a dim view of such a claim by government--especially in view of widespread evidence of unethical conduct by researchers in the nation's most prestigious biomedical research institutions.

6. We DISAGREE with the unpredictability of current criteria for the assessment of risks and the inconsistencies that have been shown to arise as a result. The National Bioethics Advisory Commission (NBAC) recommendations, if endorsed and adopted, would improve research safeguards for adults and children. First, we concur with NBAC's analysis [ch 3, p. 25] about the inherent flaw in current regulations that has encouraged IRBs to designate risks into categories such as "minimal risk"-- without first examining both the probability and degree of severity of risks. This lack of clarity has fostered misrepresentation about the nature of the risks involved to prospective subjects

and IRBs--thereby undermining the latter's ability to both evaluate and minimize all aspects of the risks involved.

The NRAC recommended framework for analyzing risks is on a two-dimensional continuum: (a) the probability (likelihood) of harm, from zero to certainty of harm, and (b) the magnitude (severity) of potential harm, from trivial to fatal. This approach is scientifically appropriate and facilitates improvement of safeguards for human subjects, including children. It also leads to standardized full disclosure of risks to patients with the eventual creation of a database for use by future researchers.

We STRONGLY DISAGREE with FDA's deference to IRB discretion even the approval process of "Clinical Investigations Involving Greater than Minimal Risk and No Prospect of Direct Benefit to Individual Subjects, But Likely to Yield Generalizable Knowledge About the Subjects' Disorder or Condition." That process has been shown to have resulted in preventable harm--including deaths--even in experiments deemed potentially beneficial.

Indeed, the evidence of high-risk experiments that have harmed children demonstrates their vulnerability and need of protection from exploitation. The following unethical experiments are discussed and documented in Sharav VH:[4]

- 100 children and babies with gastroesophageal reflux were subjected to a fatal Propulsid drug trial after the drug was linked to deaths;

- 68 children with hypertrophic cardiomyopathy were subjected to a NIH pacemaker experiment under coercion, some died others' condition worsened;

- Preschool children are being recruited into an NIMH sponsored psychotropic drug trial that offers parents $645 above expenses if the children--some not even toilet trained-- complete the 45 week experiment to test the effects of methylphenidate;

- Soon after Eli Lilly's powerful antipsychotic drug, olanzapine (Zyprexa) was approved for adult schizophrenia patients, 6 to 11 year old children were recruited for a clinical trial--despite the drug's documented serious adverse effects. ALL children

experienced adverse effects, such as sedation, weight gain up to 16 pounds, extreme restlessness (akathesia)--none of the children were helped. The study was terminated before 6 weeks.

- 100 inner city minority children, aged 6 to 11, were exposed to a toxic drug that was subsequently withdrawn from the market, Fenfluramine. Thirty-four of the children were not diagnosed with ANY medical condition, the experiment was conducted to prove these children's predisposition to violence on the researchers' undocumented assumption that siblings of incarcerated brothers are "at risk" of a non-defined, non-medical condition-- violence in the future;

- 45 children (6 to 12 years old) were subjected to methylphenidate / dextroamphetamine / pemoline and the pain and risks of spinal taps for non-therapeutic research purposes

We STRONGLY DISAGREE with FDA's willingness to waive public review of the Commissioner's decision in cases in which a high risk clinical investigation may proceed "that is not otherwise approvable but presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children." Section 50.54(b) (consistent with 45 CFR 46.407) requires that "The Commissioner is to consult with a panel of experts...following public review and comment on the Commissioner's pending decision." FDA's April 24, 2001 statement in the Federal Register [FR, 20594] indicates that public review may be denied if "the sponsor is unwilling to publicly disclose necessary information" is **ethically and politically untenable.** FDA is putting business interests ahead of child protections. Only national security considerations would warrant the proposed cloak of secrecy for unwilling sponsors.

The NBAC recommendation proposes that research studies "with risks falling on the extreme upper end of the continuum--very risky or unknown risks--" should not be left to the discretion of one local IRB, but rather should be reviewed by "a national review panel, with public input into the review process." [Ch.3, p 25, L 19] NBAC's recommendation better serves the public interest and should be adopted.

Attached is our letter of dissent with NHRPAC's draft recommendation, which provides greater detail about child welfare law.

Thank you very much for your consideration. We would be happy to meet with FDA staff to discuss these matters in greater depth.

Sincerely,

Vera Hassner Sharav
John H. Noble, Jr., Ph.D
Howard Fishman, MEd, MSW

Alliance for Human Research Protection (AHRP)

Footnotes:

[1] It is important to note that such legal and ethical niceties are frequently ignored by spokespersons for the child abuse industry. The risks attendant to being in State care will be discussed elsewhere in this statement, but are raised here to underscore the fact that a great deal of research is currently ongoing with this population that is both illegal and unethical.

[2] "I did not expect, or want, to complete my tenure as secretary of health and human services by raising questions about the safety of patients in clinical research. However, recent developments leave me little choice." Shalala D, "Protecting Research Subjects--What Must Be Done," NEJM, Sept. 14, 2000, vol 343:

[3] Dembner A, "Who's protecting the children?" The Boston Globe, March 25, 2001, front page

[4] Children are being recruited aggressively to be test subjects in psychotropic drug trials that were approved for conditions the children do not have. In the process they are suffering severe adverse effects in trials intended to expand the pediatric market, not to benefit them. Sharav VH, "Evidence Demonstrating the Need for A National Human Subject Protection Act," 2001, under publication review.

[5] FDA adopted on April 19, 2000 the recommendation of its "Ethics Working Group Consensus Statement on the Pediatric Advisory Subcommittee's November 15, 1999 Meeting. http://www.fda.gov/cder/pediatric/ethics-statement.htm

[6] Since 1998, Federal investigations have made clear that non-compliance with ethical standards and Federal regulations was widespread. Research at six institutions was shutdown: *Rush-Presbyterian-St. Luke's Medical Center; *Friends Research Institute, Inc., West Coast Division; *Veterans Affairs Greater Los Angeles Health Care System; *Duke University Medical Center; *Virginia Commonwealth University; *University of Oklahoma, Tulsa Campus [See OHRP website, letters of determination].
At three other institutions, all federally funded research was suspended: *University of Illinois, Chicago; *University of Alabama, Birmingham; *University of Texas Medical Branch at Galveston. [see OHRP website, letters of determination] From January 1, 1999, to June 2000, approximately 60 institutions, including some of our most prestigious universities, were found non-compliant.

Since July 2000, OHRP has suspended Federally funded clinical trials at seven additional research centers: University of Texas Medical Branch at Galveston (July 10, 2000 letter); *University of Miami (July 31, 2000 letter); *Northeast Georgia Medical Center (August 4, 200 letter; *Brook Army Medical Center (October 3, 2000 letter); *National Institute of Health (November 3, 2000); suspension of a single NICHD intramural research project involving children); *University of Texas Southwestern Medical Center (January 23, 2001); *Florida Department of Health (February 16, 2001 letter). And on July 19, 2001 all federally funded research was suspended at Johns Hopkins University.

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Cong. Constance Morella
Cong John Peterson
Cong Steve LaTourette
Cong Ed Whitefield
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July 25, 2001
Mary Faith Marshall, Ph.D, Chairperson,
National Human Research Protections Advisory Committee
Dept. of Health and Human Services

Dissenting opinion of Vera Hassner Sharav, President and founder, AHRP, member, Children's Workgroup of the National Human Research Protections Advisory Committee, Department of Health and Human Services (HHS)

Re: Specific Comment on FDA's Decision to Adopt HHS 45 CFR 46 Subpart D, EXCLUDING §46.408 (c)

First, the language used in the Children's Workgroup letter recommending that FDA adopt 45 CFR Subpart D, 46.408 (c) **misapplies** the well defined legal concept of **"informed consent"** throughout the document. For example, "the informed consent of the adolescent is solicited and accepted as sufficient to proceed with research." "Research protocols went forward based on the informed consent of the adolescent." **HHS regulations preclude children from giving valid "informed consent."** Under HHS 45 CFR Subpart D, 46.402 (a) specifically defines "children" as "persons who have not attained the legal age for consent to treatments or procedures involved in the research..." Under 45 CFR Subpart D, 46.402 (b) children are limited to giving "assent."

Second, the proposed language "strongly" endorsed by the Workgroup for FDA adoption **departs so significantly from basic tenets of law and ethics** that questions must be raised regarding the possible motives and ideology of those who propose to broaden its application to FDA regulated clinical trials, and the integrity of the process that led to its adoption by HHS. These concerns will inevitably be reflected in the following discussion

neglected or abused? Given that more than 80% of the approximately three million reports of child abuse registered annually are ultimately determined to be false, one could hardly be sanguine about any such process. Furthermore, there is abundant evidence that self-reports are subject to massive distortion either because the child anticipates the rewards of victim status or because of manipulation by caseworkers and other child protection professionals.

The Workgroup proposal fails to provide any specific recommendations that would even approximate "an appropriate mechanism for protecting the children," an unmet requirement under HHS 45 CFR Subpart D, 46.408 (c). Indeed, the statement acknowledges the absence of any IRB "mechanism of review of these protocols" or the existence of "a system of IRB accountability." Nevertheless, the Workgroup statement "STRONGLY" urges FDA to adopt this illegitimate policy, allowing waiver of parental permission without valid legal cause. By waiving parental rights, this Government intervention severs parental responsibility for children and puts the burden of protection from undue risks of harm on the fragile shoulders of children--even before any safeguards have been contemplated. Yet, sweeping statements based on assumptions that contradict the evidence, are made arguing that "consent of the adolescent, without parental involvement, IS SUFFICIENT to permit research to proceed as long as procedural safeguards are in place to protect the interests of the subjects."

The assumptions that "procedural safeguards are in place," or that IRBs can be relied upon to make decisions that protect the best interests of human subjects--adults and children--has been debunked as the practices at one after another prestigious institution are exposed to public scrutiny. **The fact is, there is no established "appropriate mechanism," no procedural safeguards, and no system of IRB accountability.** To recruit ever greater numbers of children for experiments involving risks of harm--some may prove to be long-term harm--without any demonstrable "appropriate mechanisms" in effect, is reckless endangerment, not "added protection." (2)

3. Research cannot be valid or reliable until and unless baseline data has been established. One of the many controversial questions that must be answered prior to undertaking research on "neglected and abused children" is whether or not they manifest characteristic differences — both physiologically and psychologically — from

control groups (i.e., children who have not been neglected or abused).

Certain elements within the child abuse industry maintain that such children almost invariably suffer from severe — and sometimes irremediable — injuries. No reliable baseline data is available regarding the specific nature, source, or even presence of such characteristic differences (3,4). Thus, any research based on this population of subjects would be compromised.

4. Informed consent for adults can be waived for adult subjects only if "the research involves no more than minimal risk to the subjects." [45 CFR 46.116. (d) (1)]
I note with profound concern that the language of HHS Subpart D, section 46.408 (c) blithely dismisses this restriction, by assuring that:
"The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, statutes, and condition."

The clear implication of this deviation from the standards for adult research protections is that dependent children and adolescents merit even less protection and concern than do adults.

Indeed, the evidence of abusive, high-risk experiments that have been conducted on children demonstrates their vulnerability and need of protection from exploitation. The following unethical experiments are discussed and documented in my paper: (2)

- 100 children and babies with gastroesophageal reflux were subjected to a fatal Propulsid drug trial after the drug was linked to deaths;

- 68 children with hypertrophic cardiomyopaty were subjected to a NIH pacemaker experiment under coercion, some died others' condition worsened;

- Preschool children are being recruited into an NIMH sponsored psychotropic drug trial that offers parents $645 above expenses if the children--some not even toilet trained-- complete the 45 week experiment to test the effects of methylphenidate;

- Soon after Eli Lilly's powerful antipsychotic drug, olanzapine (Zyprexa) was approved for adult schizophrenia patients, 6 to 11 year old children were recruited for a clinical trial--despite the drug's documented serious adverse effects. ALL children experienced adverse effects, such as sedation, weight gain up to 16 pounds, extreme restlessness (akathesia)--none of the children were helped. The study was terminated before 6 weeks.

- 100 inner city minority children, aged 6 to 11, were exposed to a toxic drug that was subsequently withdrawn from the market, Fenfluramine. Thirty-four of the children were not diagnosed with ANY medical condition, the experiment was conducted to prove these children's predisposition to violence on the researchers' undocumented assumption that siblings of incarcerated brothers are "at risk" of a non-defined, non-medical condition-- violence in the future;

- 45 children (6 to 12 years old) were subjected to methylphenidate / dextroamphetamine / pemoline and the pain and risks of spinal taps for non-therapeutic research purposes.

Whereas evidence--now and historically--demonstrates the need to protect children by restricting their availability for potentially harmful experimental research, HHS, its agencies and advisory panels are attempting to undercut existing safeguards, such as they are, in the name of "protecting children." Furthermore, the arguments made about "life prolonging" research studies suggest a "therapeutic misconception" about the distinction between treatment and research.

(5) The logic behind the language in the HHS 45 CFR 46.408 can be best described as "in loco parentis run amok." This conclusion is based on a review of the government's track record in assuring the welfare of, for example, "neglected and abused" children. There are currently approximately 600,000 children in state care. A significant majority of those children have not been physically or sexually abused by their parents. They are, however, subject to extraordinary risks thanks to the dubious beneficence of state intervention into their lives. It has been estimated that children in state custody, when

compared with children who reside with their parents, are at six times the risk of severe physical injury, fifteen times the risk of sexual abuse, and twenty-six times the risk of death.

An examination of the record of human casualties of medical research, demonstrates the combined failure of local IRBs and Government oversight agencies to protect adults and children from undue risks of harm in clinical trials. The nation's premier research centers have been found in gross violation of ethical standards that undermined patient safety. (5)

I cannot, therefore, subscribe to a recommendation that would ADD ADDITIONAL RISKS for children.

Conclusion

The specifics addressed in this statement are imbedded in a far more complex and controversial topic: the role of the government as it supports or undermines the integrity of the family. The cavalier treatment afforded parental rights in the HHS language suggests profound indifference to this focal social problem. Many other perspectives have been ignored. Thus, I have taken the liberty of attaching a list of readings that might help to identify and elucidate many of the issues that have been given short shrift by the proponents of this regulatory proposal. Howard Fishman, MED, MSW, an expert in the field who is a member of our organization compiled the list.

An argument made in the Workgroup statement is that FDA's decision NOT to adopt section 46.408 (c) "will potentially result in an incongruous system where the HHS regualtion and the FDA regulation are in conflict." Our organization agrees and recommends, therefore, in the interest of increased protections for vulnerable children of all ages, that HHS eliminate that ill-advised clause permitting waiver of parental consent.

Regrettably, the Workgroup proposal does not qualify as a regulatory improvement for the protection or best interests of children, but rather an accommodation to researchers who have difficulty recruiting children of responsible parents. This proposal is an invitation to exploitation of children as research subjects.

Some recommended readings:

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Lindsey, D. The Welfare of Children, Oxford Univ. Press, 1994.

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Wexler, R. Wounded Innocents: The Real Victims of the War Against Child Abuse, Second Edition, Prometheus, 1995.

Young, A. The Harmony of Illusions: Inventing Post-Traumatic Stress Disorder, Princeton, 1995.