



AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES, AFL-CIO

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December 7, 2005

Mr. Steven L. Johnson
Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW, Room 3000
Washington, DC 20460

Dear Mr. Johnson

Members of the AFGGE reviewed the "**Protections for Subjects in Human Research: Proposed Rule**," (Federal Register Vol. 70; No. 175; 9-12-2005). Our review revealed so many potential problems for EPA's Bargaining Unit members that I am compelled to write to you directly, in addition to submitting this letter to the public docket (ID #OPP-2003-0132).

EPA's web site asserts that this proposed rule will "establish stringent enforceable ethical safeguards governing the conduct of third-party intentional dosing human studies intended for submission to EPA under the pesticide laws."

Unfortunately, the proposed rule has so many loopholes and exceptions that, if adopted, it could force EPA's Bargaining Unit members to accept data from third-party human studies that were conducted in an unethical manner.

Specific provisions that are a concern:

- (1) Applicability of the rule is confusing: The proposed rule would only apply to "intentional dosing studies" (i.e., studies where humans have been deliberately exposed to pesticides or other chemicals) *where the researcher intended to submit the resulting information to EPA*, or to hold the information for later inspection by EPA, under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); or the Federal Food, Drug & Cosmetic Act (FFDCA)."

The italicized wording is of particular concern, because it will require EPA scientists to prove that the third-party researcher (pesticide companies, for instance) "intended" to submit the research to EPA for regulatory consideration under FIFRA or the FFDCA.

With this wording, a pesticide company could submit to EPA data from an intentional dosing human study that had been conducted five years ago, and make the assertion that "We never

intended this study to be used for regulatory purposes.” Under this rule’s definition, EPA scientists might have to accept the data, even if the study had been conducted in an unethical manner.

- (2) Too many exemptions: The proposed rule also has far too many exemptions to make it an effective “ethical safeguard” for human studies. Some, but not all, of these exemptions are described below:
- Even though the proposed rule allegedly bans testing on pregnant women, fetuses, or newborn children, Section 26.603 makes an exception for this ban. It allows EPA to *accept* data from “intentional dosing” studies done on pregnant women, newborns and fetuses if the data from the studies are “*crucial to regulatory decisions that would be more protective of public health than could be justified without relying on the data.*” AFGE believes that under no circumstances should EPA accept data from studies where pregnant women, newborn infants, or fetuses have been **deliberately exposed** to pesticides or other chemicals.
 - The proposed rule explicitly states that EPA will “defer” adoption of rules that provide “additional protection of prisoners” who might participate in deliberate-dosing studies. Other Federal agencies have already adopted these additional protections for prisoners. Why is EPA hesitating to do so?
 - The proposed rule only applies to those human deliberate exposure studies that are conducted **after** the rule’s effective date. This wording implies that EPA scientists **may accept** data from unethical human studies, if those studies were completed **before** the effective date of the rule:
 - Subpart D of the rule establishes “additional protections for children involved as subject in all human studies research, whether funded or directly conducted by EPA.” However, this subpart contains two glaring exceptions:
 - (1) Section 26.401(a)(1) allows that, when children’s intentional dosing studies are conducted by EPA employees, the “head of an Office of the Agency may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.” This exception could result in different offices within EPA having different sets of procedures for children’s intentional dosing studies. AFGE strongly believes that any “ethical safeguards” adopted by EPA should be **uniformly enforced** across all offices within the Agency.
 - (2) Section 26.401(a)(2) states that, for human studies “conducted or supported by EPA outside of the United States,” **the EPA Administrator may waive some or all of these**

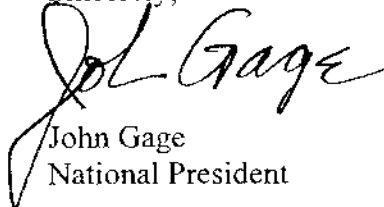
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children's special protections, on a case-by-case basis. AFGE firmly believes that the EPA Administrator should not be given this unilateral authority.

The proposed rule, as currently written, provides for too many loopholes and exemptions to provide any sort of "enforceable ethical standards" for intentional dosing human studies. And the "burden of proof" for reviewing and arguing against these numerous exemptions will fall to EPA's Bargaining Unit scientists.

AFGE represents approximately 6,500 of EPA employees. AFGE will submit comprehensive comments on the proposed rule on December 12th. I hope that you will give our comments serious consideration when revising the rule before final publication.

Sincerely,

A handwritten signature in black ink that reads "John Gage". The signature is written in a cursive style with a large, looping initial "J".

John Gage
National President