Center for Regulatory Effectiveness

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October 2, 2000

Ms. Susan H. Wayland
Acting Assistant Administrator
Office of Prevention, Pesticides
and Toxic Substances
United States Environmental Protection Agency
1200 Pennsylvania Ave., N.W. (7101)
Washington, D.C. 20460

Dear Ms. Wayland:

The Center for Regulatory Effectiveness has on several occasions presented its views on the Pesticides Office's position on the use of human test data. In your September 15th letter to me, you stated that EPA expects soon to release a proposed policy on this issue for public comment. Prior to doing so, EPA should coordinate its efforts on this issue with the Department of Health and Human Services' new Office of Human Research Protections ("OHRP"). EPA should not develop its own policy and establish new rules on this issue independent of OHRP's efforts to establish uniform Federal Government policy and rules on human testing

Attached is a CRE letter to OHRP on this issue.

The OHRP Is Charged with Reforming and Overseeing Government Regulation and Use of Human Testing

The OHRP was established this summer as a new office within the Office of the Secretary of DHHS. Its functions and delegations of authority include "overseeing human research subjects protections functions and related functions where research involves the use of human subjects." 65 Fed. Reg. 37136 (June 13, 2000). The OHRP's responsibilities include "conducting programs of clarification and guidance for both the Federal and non-Federal sectors with respect to the involvement

of humans in research...." Id. at 37137.

The predecessor to DHHS was the Department of Health, Education, and Welfare (DHEW). It was DHEW that promulgated the "Common Rule," 40 CFR Part 46, governing human testing. At the behest of the White House Office of Science and Technology Policy, sixteen other federal agencies, including EPA, adopted the Common Rule. See 40 CFR Part 26 (EPA regulations codifying the Common Rule).

Given HHS' historical and current prominence in the regulation of human testing, it is not surprising that OHRP personnel chair the National Science and Technology Council's ("NSTC") Human Subjects Research Subcommittee. EPA is represented on this Subcommittee.

Dr. Greg Koski is Director of the OHRP. Dr. Koski set forth a detailed and comprehensive agenda for the OHRP at a September 28th congressional hearing. agenda includes establishment of an HHS inter-agency working group charged with the task of eliminating inconsistencies and inefficiencies with the agencies' differing regulatory approaches toward human testing. He explained, "Greater cooperation among the federal departments subscribing to the Common Rule is a desirable and achievable goal, and the creation of OHRP affords an opportunity for leadership in this area." Dr. Koski wants to spearhead reform of the Common Rule. To achieve that goal, an inter-agency working group will review current regulations and guidance as part of an ongoing effort to identify and eliminate inconsistencies and inefficiencies within the federal government.

Executive Order 12866 Requires Coordination

The OHRP is reexamining federal regulation and use of human testing in close collaboration with the NSTC. Revision of the Common Rule and federal regulation of private testing are under consideration. Dr. Koski and OHRP are in the process of implementing inter-agency cooperation in these reforms in order to insure uniformity and consistency among the federal government agencies. Basic principles of sound and efficient government require EPA to coordinate with OHRP in order to avoid conflict and duplication, and in order to avoid EPA action that impedes OHRP's efforts at regulatory reform.

Executive Order 12866 also requires that EPA coordinate any proposed changes in its policy and regulations regarding human test data with OHRP. The Pesticide Office's current ban on human test data is a rule or regulation as defined by Section 3(d) of the Executive Order. EPA's imminent human testing rulemaking will produce new rules and regulations as defined by the Executive Order. Failure to coordinate could produce EPA "regulations that are inconsistent, incompatible, or duplicative with [EPA's] other regulations or those of other Federal agencies" in violation of Section 1(b)(10) of Executive Order 12866.

The Pesticides Office's Current Ban on Human Test Data Could Result In Litigation that Would Affect the Comprehensive Reforms Planned by OHRP and NSTC

If the Pesticides Office regulates based on its current ban on human test data without first conducting a rulemaking on the issue, then the ban could be challenged in court. The litigation could affect the regulatory reform efforts planned by OHRP. Obviously, EPA should coordinate with OHRP before it takes actions that would complicate and impede the government-wide regulatory reforms planned by them.

Conclusions and Recommendations

EPA should coordinate with OHRP before it takes any new action or establishes any new policies on human testing. In the interim, EPA should retain its long-standing policies and rules on this issue which allow use and consideration of human test data by all EPA offices and programs, as long as the tests conform to stringent national or international standards.

Thank you for your time and attention.

Sincerely,

Jim J. Tozzi
Member, CRE Board of Advisors

cc: Dr. Greg Koski, OHRP