Center for Regulatory Effectiveness

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October 2, 2000

Dr. Greg Koski
Director
Office of Human Research Protections
United States Department of Health and Human Services
6100 Executive Blvd
Rockville, MD 20892

Dear Dr. Koski,

The United States Environmental Protection Agency is taking action and planning future action on human testing in a manner that may conflict with, or duplicate, OHRP's actions and plans. Inter-agency coordination on the human testing issue is required by basic principles of good government and by Executive Order 12866. Expeditious inter-agency coordination is especially important because EPA's actions and plans on human testing, if continued, will probably be litigated. Litigation over the human testing issue would complicate and impede OHRP's efforts to reform the federal regulation and use of clinical human testing.

Background on EPA Human Testing Issue

Attached is CRE's letter to EPA discussing this issue. Briefly summarized, companies often submit to EPA clinical human test data in order to show that their pesticides and herbicides are safe. Companies may be subject to more stringent regulation if they cannot rely on clinical human test data. EPA's historical practice was to accept and consider these clinical human test data. However, EPA's Pesticides Office recently decided not to use or consider any clinical human test data during its regulation of pesticides and herbicides.

The Pesticides Office's current refusal to consider human test data does not depend on whether the tests were conducted in accordance with the Common Rule or the Declaration of Helsinki. The Pesticides Office is refusing to consider any clinical human test data, regardless of how the tests were conducted. The Pesticides Office's new ban on human test data is inconsistent with the practices of

other EPA offices, which still do use clinical human test data to regulate in various areas such as air pollution.

The SAB/SAP Human Testing Report and EPA's Human Testing Rulemaking

At EPA's request, a Joint Subcommittee of the Science Advisory Board and the FIFRA Scientific Advisory Panel studied and recently issued a report entitled, "Comments on the Use of Data from the Testing of Human Subjects." A copy of this Report is attached. The Report goes considerably beyond the issue of using human test data to regulate pesticide and herbicides. It recommends, for example, that "[a]ll research involving humans [regardless of funding source] should require prior review by an Institutional Review Board." It further recommends that "EPA should take whatever administrative action is necessary to extend the protections of ...the 'Common Rule' to all human research activities whose results will be submitted to the Agency," including privately funded studies. It also recommends various IRB reforms and a dramatically increased EPA enforcement posture. Report, p. 3

CRE has corresponded with EPA regarding the Pesticides Office's new ban on human test data. In response to one of CRE's letters, EPA stated in part, "The Agency will carefully consider the Joint Subcommittee's recommendations as it develops its policy regarding use of studies involving human subjects as the basis of regulatory decisions. We expect to release a proposed policy for public comment soon." A copy of this EPA letter is attached. Both as a legal and practical matter, EPA's public-notice-and-comment proceeding will be a rulemaking on federal regulation and use of human testing. Based on the SAB/SAP Joint Subcommittee Report, this rulemaking will have a broad scope.

Executive Order 12866 and Basic Principles of Good Government Require Coordination Between EPA and OHRP

EPA's current and proposed actions on human testing overlap OHRP's actions, authority, and plans. Coordination on this issue is, therefore, required by Executive Order 12866, Section 1(b)(10). This section of the Executive Order states that "[e]ach agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies." EPA's "proposed policy" on human testing will result in a "regulation" or "rule" as defined by Section 3(d) of the Executive Order. Coordination between EPA and OHRP is necessary to avoid "inconsistent, incompatible, or duplicative" regulations and rules.

More important, basic principles of good and efficient government require inter-agency coordination on this issue. EPA and OHRP should not be working at cross purposes with each other. CRE understands that part of OHRP's mandate and mission is to instill uniformity and consistency in federal regulation and use of clinical human test issue. That mandate and mission will be jeopardized if various agencies act independently and without coordination on this complex and important issue. Consequently, we recommend that you advise EPA of the importance of giving your office the

opportunity to review their new policy on human testing before it is released for public comment.

Thank you for your time and attention. We will call you in a few days to request a meeting on this issue.

Sincerely,

Jim J. Tozzi
Member, CRE Board of Advisors

cc: Ms. Susan Wayland, EPA

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