

DEBATE ON EPA'S USE OF HUMAN DATA FLARES AGAIN

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The longstanding debate over whether human data should be used to assess potential risk from chemical products, and in particular pesticide products, is flaring yet again. On July 26, 2005, the Conference Committee for H.R. 2361, the fiscal 2006 spending bill that includes appropriations for the U.S. Environmental Protection Agency (EPA), the Department of Interior, and other related agencies, reached agreement on compromise legislation. Section 201 of the compromise measure imposes a moratorium on EPA's ability to consider human testing for pesticides. It provides in full:

None of the funds made available by this Act may be used by the Administrator of the Environmental Protection Agency to accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject. The Administrator shall allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule. Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and shall establish an independent Human Subjects Review Board. The final rule shall be issued no later than 180 days after enactment of this Act. *See* H.R. Rep. No. 109-188, at 34 (2005) (Conf. Rep.), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_reports&docid=f:hr188.109.pdf.

The House of Representatives and Senate approved the compromise bill, respectively, on July 28, 2005, and July 29, 2005. The appropriations bill was signed by President Bush on Aug. 2, 2005.

This moratorium is one of the latest in a series of events dictating the ability to use human data to assess the risk of pesticide products.

- The current controversy over EPA's review of human data has its roots in the release of the Environmental Working Group's 1998 report entitled *The English Patients: Human Experiments and Pesticide Policy*, which criticized human studies conducted with pesticide products. A copy of the report is available at <http://epa.gov/scipoly/sap/1998/december/english.pdf>. EPA convened a Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in 1998 to provide advice on the ethical and scientific acceptability of human data. The SAP issued a report in September 2000, which though presenting an agreement of the Panel on broad principles, also contained minority views divergent with other views stated in the main report.
- EPA then, in December 2001, issued a press release stating a moratorium on its consideration of human studies and announcing that it had asked the National Academy of Sciences (NAS) to review the ethical issues of studies involving third-party intentional dosing of human subjects.
- The pesticide industry challenged EPA's issuance of the moratorium through its press release in early 2002, and the D.C. Circuit Court of Appeals, in 2003 issued a decision vacating the moratorium because EPA had not issued it through notice and comment rulemaking. The decision stated that "the agency's previous practice of considering third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide, is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation." *CropLife America v. EPA*, 329 F.3d 876, 884-85 (D.C. Cir. 2003).

- The NAS issued its report in response to EPA's request in February 2004. This report contained numerous recommendations with regard to EPA's consideration of human data, both those data that might be generated prospectively and those already existing data. With regard to the latter, the NAS stated that "EPA should accept scientifically valid studies conducted before its new rules are implemented unless there is clear and convincing evidence that the conduct of those studies was fundamentally unethical." National Research Council of the National Academies, *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues* (2003) at 19-20.
- On Feb. 8, 2005, EPA published a notice announcing its plan to establish a framework for deciding when to use human studies.
- Following the passage of the appropriations amendment in August, EPA's not-yet-published proposed rule on its consideration of human studies was leaked to the press. The leaked proposal would address only pesticide products.

These events make it clear that the debate over the appropriate use of human studies is far from over, particularly as it relates to data addressing pesticide products. Some of the debate centering on pesticide products has relied on what many in industry believe are simply incorrect and inflammatory assumptions. For example, the debate often is premised on the underlying presumption that pesticide products are without societal benefit, when many believe that the world food supply and public health would be tremendously and adversely impacted without them. Likewise, the debate many times presumes that humans would not be exposed to these products if the studies were not conducted, when many of the products at issue are in widespread use already. As another example, there are assumptions that pesticide chemicals are somehow different than other chemicals, when often chemicals developed are used for multiple purposes and/or evolve from one purpose to another.

There are numerous instances, by way of illustration, of pharmaceutical chemicals that are also the active ingredient in pesticide products. Other erroneous assumptions go to whether the protections afforded humans in tests using pesticides are different than those afforded humans in testing using drugs. In fact, many in industry assert, Food and Drug Administration (FDA) guidelines for conducting Phase I clinical drug experiments and clinical trials involving pesticide chemicals are nearly identical and are often done by the same laboratories.

These are just a few of the issues that have framed the debate over the years, and EPA's forthcoming proposed rule raises many others. The resolution of this debate will have a profound impact not only on pesticide products, but on risk assessment principles generally, especially regarding the appropriateness of tests conducted using children or other sensitive subpopulations. Complicating the situation will be the need for applying ever-changing risk assessment principles to the evaluation of possible risks in a variety of emerging fields such as biotechnology, toxicogenomics and nanotechnology. As regulators will be expected to evaluate these emerging technologies for their potential impacts on human health, there may be some artificial constraints placed on certain kinds of testing (*e.g.*, how to evaluate the potential for allergenic response in children to biotechnology food products). It thus is a debate that requires significant attention.



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