

## **EPA's Human Studies Review Board: Assessing Scientific and Ethical Validity of Human Studies or Commenting on Regulatory Decisions?**

*By Kenneth D. Morris, Esq.*

On January 26, 2006, EPA's Administrator signed the Agency's final rule entitled "Protections for Subjects in Human Research." In summary the rule (i) prohibited new research involving intentional exposure of pregnant women or children related to studies for submission to the EPA, (ii) extended the provisions of the Federal Policy for the Protection of Human Subjects of Research (the "Common Rule") to other human research related to intentional exposure of non-pregnant adults, (iii) requires submission to EPA of protocols and related information about covered human research at the outset of studies, and (iv) establishes a new and independent Human Studies Review Board (HSRB) to review proposals for new research, as well as reports of completed human research which the EPA intends to use in its decision-making.

The issuance of this Rule followed considerable study by the EPA. Initially, the Agency convened an advisory committee under the auspices of the Scientific Advisory Board and the FIFRA Scientific Advisory Panel to consider issues related to scientific and ethical appropriateness of such studies. The Agency also asked the National Academy of Sciences to review these issues in December 2001 and in February, 2004 the committee established by the NAS for this purpose issued its report entitled, "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues." EPA's final rules implements NAS' recommendation.

Of relevance to the activities of the HSRB is the fact that pursuant to the provisions of the 1996 Food Quality Protection Act (FQPA), the EPA has until *August 3, 2006* to review and relicense all pesticides. Review of these human studies will be an important consideration as the Agency reviews individual pesticides and develops risk assessments for key classes of chemicals. It is therefore not surprising that the activities of the HSRB are already the subject of serious concern with both environmental and industry communities.

Even at the time the final rule was issued in January 2006, lawsuits were filed alleging the inadequacy of the protections adopted by the EPA. In the Second Circuit Court of Appeals Forest Products Research Laboratory filed an action challenging the Agency's rule. The Natural Resources Defense Council and other environmental organizations also filed lawsuits contending that the EPA's rule violated Congress' 2005 law mandating strict ethical and scientific protections for pesticide testing on humans. Lawsuits are also pending in the Fourth and Sixth Circuits. All of the cases are likely to be consolidated into the jurisdiction of the Second Circuit.

While it will be several months before the litigation has run its full course, the current activities of the HSRB are already raising the concern of stakeholders. The EPA had asked the Board to review eleven human studies and it is now clear based on a draft report released during the week of May 22, 2006 that the HSRB will likely recommend that EPA not use two studies in light of its conclusion they were scientifically or ethically deficient: one involving azinphos methyl which is a pesticide used on

fruits, nuts, and other crops, and a second study concerning amitraz which is contained in products used on pears, certain stone fruits, livestock, and cotton. It is believed there are approximately ten other human exposure studies which the EPA could also ask the HSRB to review. The Agency is not obliged to accept the HSRB's recommendations, but the fundamental point here is that it is not yet clear whether the HSRB will strictly follow its mandate to analyze the ethical and scientific merits of studies which the EPA submits to it, or whether the HSRB will venture to comment on the regulatory decision-making process. The HSRB is scheduled to finalize its report on June 8. Nor is it clear how the EPA will eventually come to use and rely on the recommendations of the HSRB. With the August deadline looming, the significance of the HSRB and its potential impact on the registrability of key chemicals cannot be understated.

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