

Court hears arguments in case challenging EPA human testing rule

Pesticide and Toxic Chemical News

Monday January 28, 2008

EPA's February 2006 rule covering the use of human subjects in pesticide testing flatly contradicts congressional directives in the statute that required EPA to promulgate such a rule, and so it should be vacated, an attorney representing several environmental and labor groups argued in federal appellate court this month.

Michael Wall, an attorney with the Natural Resources Defense Council, presented arguments on behalf of NRDC, Pesticide Action Network North America, Migrant Clinicians Network and several other groups before a three-judge panel of the U.S. Court of Appeals for the Second Circuit on Jan. 17.

Section 201 of the FY 2006 Department of Interior, Environment, and Related Agencies Appropriations Act, which directed EPA to promulgate a new rule to protect human subjects in intentional dosing experiments, specified that such a rule must bar any testing on pregnant women, infants and children. Congress also ordered EPA to follow the principles of the Nuremberg Code as well as principles proposed in a 2004 National Academy of Sciences report on human testing.

But the rule only bars a subset of tests on pregnant women and children — those that are intended for submission to EPA under FIFRA or the Federal Food Drug and Cosmetic Act (FFDCA).

Congress's prohibition against testing on pregnant women and children is supposed to apply across the board, not just in the context of FIFRA and FFDCA, Wall told *Pesticide & Toxic Chemical News*, adding that none of the protections in the rule apply outside the context of those two laws. Pesticides are regulated pursuant to other statutes, such as the Safe Drinking Water Act, which may entail testing on humans, Wall noted.

In addition, EPA's rule allows things expressly forbidden by the Nuremberg Code, for example, permitting a person's "authorized representative," rather than only the potential test subject himself, to provide consent.

Department of Justice lawyer Alan Greenberg, who argued the case on behalf of EPA, told *PTCN* he basically reiterated the main points in the government's legal brief in the case and declined to elaborate beyond that. As with NRDC attorney Wall, he declined to discuss the judges' line of questioning.

The government's brief first argues that the petitioners lack standing to challenge the rule. The notion that the rule may influence the availability of information EPA relies upon in separate decisions to establish safe levels for pesticides "is not an actual or imminent injury sufficient for standing," the brief states. In addition, because the rule

"does not establish any less stringent safety levels for pesticides, it cannot be the cause of the petitioners' alleged injuries," the brief continues.

The brief goes on to attack the substance of the petitioners' case, arguing that EPA "reasonably interpreted the scope of the prohibition on using pregnant women, infants and children as concerning those studies submitted to it under FIFRA and FFDCA."

EPA's interpretation reflects the context and purpose of Section 201, "which was enacted against the backdrop of human studies that had been submitted for use in EPA's ongoing risk assessments pursuant to FIFRA and FFDCA," the brief states.

However, several members of Congress disagree with EPA's interpretation. "The plain language of the statute establishes that Congress wanted pesticide testing on pregnant women and children banned," a friend-of-the-court brief filed by California Democrats Sen. Barbara Boxer and Reps. Henry Waxman and Hilda Solis, along with Sen. Bill Nelson (D-Fla.), states.

"Congress did not limit its instruction to EPA to cover actions pursuant to only two of the many statutes that the agency administers" — FIFRA and FFDCA, their brief continues.

The government's brief also argues that the rule is consistent with the Nuremberg Code's principles, adding that "the phrase 'consistent with' is flexible statutory language and does not require an exact correspondence but only compatibility."

On the 2004 NAS report, the government's brief notes that Section 201 never specifically mentions the 17 recommendations, and EPA's reading of the phrase "principles proposed" in the report as referring to principles repeatedly referenced in the report, namely, respect for persons, beneficence, and justice, is not unreasonable. EPA contends its human testing rule need only be consistent with these three principles, which come from the 1979 Belmont Report and which NAS considered for its 2004 report. But Congress never mentioned the Belmont Report, Wall noted.

Real world impacts

Environmental groups claim industry is using human testing to help ease restrictions on pesticides. According to Earthjustice attorney Patti Goldman, when Food Quality Protection Act standards are poised to knock out pesticide uses due to the law's safety factors, registrants are paying for human tests to try and get rid of one of the factors — usually the one to extrapolate experimental results from animals to humans.

"I can't tell you how often it happens, but it's something you seem to see in a lot of these troublesome pesticides," she told *PTCN* last month.

In earlier court filings, the groups argued that EPA has used human testing data to increase or propose increases in tolerance levels in several pesticides, including aldicarb and DDVP.

But EPA and industry reject the notion that human testing inevitably leads to less protective pesticide tolerance levels.

"The data can come out in any number of ways," Bill Jordan, senior policy adviser in EPA's Office of Pesticide Programs, has previously told *PTCN*. "In some cases the data show that humans need greater protection, [in other cases] it won't show much of anything, and [in] others it will show less protection is needed."

If environmental groups prevail in the case, EPA will not be able to consider human tests until there is a valid rule, Goldman noted, adding that EPA would have to strengthen the rule with respect to both scientific validity and ethical principles. A decision is expected this spring.

— Larry Pearl

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