



BEYOND PESTICIDES

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April 4th 2011

Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington DC 20460-0001

Re: Revisions to EPA's Rule on Protections for Subjects in Human Research Involving Pesticides. Docket Number: EPA-HQ-OPP-2010-0785

Dear Sir/Madam:

Thank you for the opportunity to comment on the revisions to the agency's rule regarding protections for subjects involved with human testing with pesticides. First, Beyond Pesticides would like to express that conducting experiments on human subjects, intentionally exposing them to chemicals that can cause both short and long-term adverse effects, is unproductive, unethical and lacking in scientific integrity. These clinical trials using human subjects are attempts by chemical companies aiming to avoid additional regulations set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA) which were designed to limit their pesticides' use because of the toxicity of the agent and possible threats they pose to human and environmental health. Even though the agency in 2001 stated that it will not consider or rely on human studies in its regulatory decision making, subsequent industry pressure resulted in EPA invoking the Common Rule (40 CFR 26 - Protection of Human Subjects) for third-party intentional dosing studies. This being the case, the agency has promulgated new rules and has made revisions to these rules, stemming from the lawsuit and settlement by the Natural Resources Defense Council (NRDC) et al., to broaden and refine rules relating to human research involving pesticides.

Beyond Pesticides is committed to pesticide safety and the adoption of alternative pest management strategies which reduce or eliminate a dependency on toxic chemicals. We believe that the agency's consideration of data collected from human subjects in pesticide trials

will continue poses serious threats to public health despite recent amendments set forth in the proposed rule. However, the agency believes that these 'tougher' new rules will decrease the number of systemic intentional dosing toxicity studies conducted for pesticides, and expects the number of systemic toxicity studies submitted to drop to as few as zero or one per year.¹

According to the agency, it significantly strengthens and expands the protections for participants in third-party research. Beyond Pesticides agrees that the new amendments have the potential to hinder a proliferation of human test scenarios, but given the agency poor performance in being stringent in its registration process and the collection and review of data, we expect that many human studies will be allowed into EPA's regulatory process.

New Rule Applicable to All Statutes

EPA proposes that instead of covering substances under FIFRA alone, the proposed amendments would apply to pesticide substances under all statutes. We agree that this proposal is best to close any loopholes and discrepancies regarding the data and the regulation of substances which fall under multiple environmental statutes. That is, data involving human subjects submitted for FIFRA and FFDCFA consideration would also have to abide by these rules even if human data is to be submitted for consideration under another statute. EPA does not believe this amendment would lead to an increase in the number of human studies reviewed and is not aware of any cases where studies involving human subjects were submitted in accordance to laws other than FIFRA/FFDCFA.

Protection for the Most Vulnerable, Others Still at Risk

EPA proposes (Subpart K) to disallow consent by a "legally authorized representative." This would mean individuals who may be unable to consent for themselves, e.g. the mentally disabled or incapacitated, are protected. This of course will also include minors such as infants and children. EPA states that it does not anticipate any research that could be justified to enroll subjects lacking the capacity to consent for themselves. Given that recent revisions to the Common Rule have banned testing on nursing and pregnant women, then it is reasonable to expect the infants and unborn children would be protected.

However, Beyond Pesticides is concerned about the financial pressures a particular subject might feel to be involved in a study. While we recognize the right to self-determination and realize people are free to make their own decisions, for some populations circumstances exist that severely restrict a person's liberty and ability to evaluate risks and rewards in an objective manner. People in stressful economic situations, such as low income groups, or even students,

¹ USEPA. Expanded Protections for Subjects in Human Studies Research. February 16, 2011. Available at <http://www.epa.gov/oppfead1/guidance/human-test.htm>

might be more willing to put themselves at risk for a certain amount of financial compensation. These people risk exploitation. It has been suggested that the relevant review boards should ensure that payments to participants “are neither so high as to constitute undue inducement nor so low as to be attractive only to individuals who are socioeconomically disadvantaged.” Also recommended, “proposed levels of and purposes for remuneration (*e.g.*, time, inconvenience, and risk) should be scrutinized in light of the principles of justice and respect for persons.” The agency must seriously address the issue of remuneration so as to protect those who may be recruited to becoming a subject for human dosing studies. The agency must also define what constitutes payments as being considered too high or too low. Nevertheless low-income and other financially disadvantaged populations will be disproportionately affected, especially since payment for research participation can be perceived as a potential income source among participants.^{2,3} Thus, financial remuneration for participating in human studies should be reconsidered, and be done on a strictly volunteer basis⁴ with non-monetary incentives.

Lax Oversight of Human Studies Expected

Subpart K would also require the submission to EPA and the newly created independent Human Studies Review Board (HSRB) proposals for new research before the research is initiated and review after completion, before the research would be considered. The information to be submitted would include information concerning the ethical conduct of the human research, including copies of relevant records, and copies of records relevant to the key ethical considerations. According to the agency, only after an external, rigorous review including opportunities for public involvement, will EPA reach decisions on whether to rely or not rely on a human study. Ideally, this proposed rigorous review, recordkeeping and independent oversight would discourage submissions of intentional dosing studies. However, EPA has a history of lax oversight when it comes to reviewing data and holding industry accountable for missing or questionable data prior to the registration and/or review of pesticides. The FIFRA registration process is fraught with data gaps which often persist for years, putting the public and environment at risk for unknown and understudied risks. It is inevitable that although this proposal theoretically sets a higher standard for the review of human studies, EPA’s lax oversight and review process would lead to the unconditional approval of many questionable human studies.

Conclusion

² Slomka J. et al. 2007. Perceptions of financial payment for research participation among African-American drug users in HIV studies. *J Gen Intern Med*;22(10):1403-9.

³ Stones M, McMillan J. 2010. Payment for participation in research: a pursuit for the poor? *J Med Ethics* ;36(1):34-6.

⁴ Russell ML, Moralejo DG, Burgess ED. 2000. Paying research subjects: participants' perspectives. *J Med Ethics*. 26(2):126-30.

The agency expects, with these new amendments and “tougher new rules will decrease the number of systemic intentional dosing toxicity studies conducted for pesticides.” These amendments have addressed some serious concerns since the last proposal in 2003 which include a ban on testing involving pregnant and nursing women, and children. Beyond Pesticides maintains that intentionally dosing human subjects with potentially toxic chemical substances is unproductive and unethical. The new proposal would place more checks and balances in place to increase oversight for these studies, however given EPA’s poor and limited enforcement and lax registration process, many questionable practices may fall through the cracks. We believe that the agency’s continued consideration of data collected from human subjects in pesticide trials will continue poses serious threats to public health despite these new amendments. We therefore urge the agency to be vigilant in the application of these rules so as to truly decrease the number of human studies.

Sincerely,

Nichelle Harriott
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