Natural Resources Defense Council

BACKGROUNDER ON PROPOSED HUMAN TESTING RULE
70 Fed. Reg. 53838 (Sept. 12, 2005)

1. The Proposed Rule Approves Systematic Testing of Pesticides on People.

EPA is proposing a rule that authorizes systematic testing of pesticides on human subjects for the first time. EPA has forbidden these studies in the past, but now gives a green light to the chemical industry to conduct laboratory experiments that intentionally expose people to pesticides. (70 FR 53843).

2. The Rule Expressly Permits Testing on Pregnant Women and Children.

EPA falsely claims that this rule would "categorically prohibit" intentional tests by industry on pregnant women or children as subjects. In fact, the rule allows intentional testing on pregnant women or children in at least three circumstances.

First, EPA will accept human studies if they are found to be "crucial to the protection of public health," expressly including an "*intentional dosing study involving pregnant women or children as subjects*." But "protection of public health" is not defined, and EPA could interpret it to mean protecting or increasing crop yield. For example, EPA might rely on an industry human test to increase the amount of a pesticide allowed to be used on a certain crop, by arguing that public health depends on a greater supply of that crop. Also, there is no way to know the outcome of a test until after the fact, so this loophole encourages industry to test on pregnant women and children with the hope that the results will qualify for the exception. (70 FR 53857)

Second, EPA will allow tests that expose pregnant women or children to food sprayed with pesticides up to the current legal limit. For example, even though industry could not dose toddlers with a certain pesticide directly, they would be allowed to dose toddlers with the same pesticide sprayed on apples up to the legal limit. This is so even though the "legal limit" is often not safe for all toddlers, because those limits are often set without all toddlers in mind, and because EPA often assumes that people will be exposed to less than the maximum possible amount. (70 FR 53864, at 26.201(b)).

Third, EPA will accept tests on pregnant women and children if the tests were not originally conducted with the "intent" of being submitted to EPA. This exception is discussed more below. (70 FR 53838).

Even if these three exceptions were justified, it is untrue for EPA to claim that its rule is a categorical ban on intentionally dosing pregnant women and children.

3. EPA Can Export Human Experiments Overseas to Avoid the Rule Entirely.

The proposal allows EPA to 'export' dangerous human tests that would otherwise be illegal under the rule – using children as the experimental subjects – in order to get around the limitations in the

rule. EPA can waive the entire regulation if EPA is conducting or funding chemical tests on children *outside* the United States. (70 FR 53864, at 26.401(a)(2)).

4. The Rule Allows "Neglected Or Abused Children" to Be Tested Without Parental Consent.

Under the proposal, EPA is generally required to get parental consent before it can test on children. However, EPA waives this parental consent requirement for "neglected or abused children." EPA's explanation is that it is not "reasonable" to require consent from an abusive parent – which may be true enough – but EPA's solution makes the problem worse. Rather than protecting abused children from chemical testing entirely, EPA goes out of its way to *allow* testing on abused children. (70 FR 53865, at 26.408(c)).

Testing pesticides on children is never appropriate to begin with, because: (a) children lack the legal capacity to consent, (b) children are especially vulnerable to the harms of pesticide exposure, which might not show up until years down the road, and (c) children will not benefit in any way from the tests. (See the discussion in point 12, below). Testing pesticides on neglected and abused children is inexplicable.

5. The Rule Allows Testing on Children of "Limited Capability" Without Their Consent.

The proposed rule generally requires that children provide consent – along with their parent or guardian – before being subjected to an EPA human test. However, if a child's capability is "so limited" that he or she "cannot reasonably be consulted," EPA allows testing on that child *even without his or her consent*, based on parental or guardian consent only. In other words, children who are either mentally disabled or too young to communicate consent can be tested without their approval. This clause would allow testing on orphaned newborns, for example, or institutionalized and severely mentally disabled children, with the permission of the institution or other guardian. (70 FR 53865, at 26.408(a)).

6. EPA Waives All Protections Unless the Human Tests Are Used "In Its Regulatory Decisionmaking."

EPA restricts its use of industry human studies only "in its regulatory decisionmaking," and then only under two laws. This means that EPA can accept and rely on human studies, even unethical ones, for any purpose other than "regulatory decisionmaking" under those two laws. The term is not defined in the rule, which gives EPA room to claim that "regulatory decisionmaking" does not include policy statements, guidance documents, risk assessments, or decisions *not* to regulate. EPA could therefore rely on unethical human tests for any of those purposes, or for regulatory decisions made under other laws. (70 FR 53864-65, at 26.221 & 26.421).

7. The Proposed Rule Applies Only to New Tests Conducted After the Rule Is Finalized, Expressly Allowing Harmful and Unethical Tests Until Then.

EPA's proposed rule will apply only to *new* studies conducted after the rule is finalized. For the two dozen human tests already submitted and under consideration, and other industry tests that

might be underway right now, EPA would accept the results unless there is "*clear evidence*" that the tests were "*fundamentally unethical*" – for example, if "the research was *intended to seriously harm participants*."

EPA's proposed rule encourages industry to start additional unethical tests, up until the day before the final rule is published. EPA would accept those tests *even if they were intended to harm the test subjects*, as long as the harm was not deemed "serious." This permits the chemical industry to conduct *intentionally harmful* human tests. (70 FR 53866).

8. The Proposed Rule Only Applies to Tests "Intended" from the Outset to Be Submitted to EPA.

EPA's proposed rule creates a second big loophole based on "intent." Human tests – including tests on pregnant women and children – are exempt from the rule if they were not conducted with the *intent* of submitting them to EPA. This allows human tests to be 'laundered' by letting the chemical industry sponsor tests at a university or contract lab, and submit the results to EPA through another channel afterwards. (70 FR 53845).

9. The Proposed Restrictions on Industry Apply Only to Pesticides, Not to Any Other Toxic Chemicals.

EPA's proposed rule for the chemical industry is narrowly limited to tests of pesticides only. The chemical industry is therefore free to dose human subjects with other toxic chemicals with no restrictions. Indeed, the industry has conducted human tests of other chemicals to submit to EPA, including a human test of the rocket fuel chemical perchlorate. Perchlorate and other non-pesticide human tests are exempt from the proposed rule. The rule applies to industry tests only if they are submitted under one of two pesticide laws, but does not apply to any other industry human tests submitted to EPA. (70 FR 53838).

10. The Proposed Rule Narrowly Defines "Intentional Dosing" to Exempt Experiments that Encourage Risky Pesticide Use.

EPA's proposal applies only to "intentional" exposure tests, and exempts studies that unethically encourage ongoing exposure in order to collect data, even if the researcher knows it may cause harm to the subject. Specifically, the rule covers only studies "in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study." Studies that examine "existing" exposure – even if the experimenter knows that the exposure is harmful, but continues the test anyway – are exempt from the rule. (70 FR 53863, at 26.102(k)).

11. EPA's Rule Violates Congressional Restrictions on Human Testing.

In July 2005, Congress passed legislation requiring EPA to publish a rule governing human tests that followed certain ethical guidelines. In particular, the law requires that EPA's rule "shall not permit the use of pregnant women, infants, or children as subjects." EPA's proposal violates the law because it *does* permit the use of pregnant women, infants, and children in intentional industry tests, as noted above. (Public Law No. 109-54).

12. The Proposed Rule Is Not Consistent with the Nuremberg Code, Contrary to Congressional Mandate.

The human testing legislation passed by Congress also requires EPA to follow the stringent ethical standards of the Nuremberg Code in its human testing rule. The Nuremberg Code declares that the voluntary consent of test subjects is "absolutely essential," and in particular that the test subject must have "legal capacity to give consent" and must be "so situated as to exercise free power of choice." By allowing human tests on children of such limited capabilities that they cannot consent, as discussed above, EPA's proposed rule impermissibly allows testing on vulnerable subjects that lack free power of choice and the legal capacity to consent. (70 FR 53865).

The Nuremberg Code also declares that experiments must avoid *all* unnecessary physical harm and mental suffering. EPA's proposed rule violates this requirement by accepting existing human tests that cause anything short of "serious" harm. (70 FR 53866).

The Nuremberg Code also requires that "the degree of risk" in an experiment "should never exceed that determined by the humanitarian importance of the problem to be solved." Intentional human pesticide tests have no "humanitarian importance," because they are entirely unnecessary. EPA can regulate pesticides by conducting animal tests and then using safety factors to extrapolate the results to people, as it has for years. Therefore, *no* risk is acceptable, but some of the pesticide studies likely to be approved by EPA under this rule have caused documented harm to subjects.

Finally, the Nuremberg Code requires that an experiment "should be conducted only by scientifically qualified persons." Yet EPA expressly reserves the right to consider data from a study "conducted at a disqualified institution." (70 FR 53866).

13. The Proposed Rule Does Not Comply With Basic Recommendations of the NAS, Contrary to Congressional Mandate.

The law passed by Congress also requires EPA to follow the recommendations of the National Academy of Sciences' 2004 human testing report, but EPA's rule fails to do so. NAS Recommendation 5-1 states that "*necessary conditions*" for acceptable human tests include, among other things: (a) prior animal studies; (b) a "*demonstrated need*" for the knowledge from the proposed human test; and (c) proof that the study has *adequate statistical power* to detect effects. EPA's proposed rule includes *none* of these necessary conditions.

EPA also ignores the NAS recommendation that human test subjects receive medical treatment if they are injured in experiments. NAS Recommendation 5-5 states that, "at a minimum," sponsors of human tests "should ensure that participants *receive needed medical care for injuries incurred in the study,* without cost to the participants." EPA gives no explanation in its proposed rule for ignoring what the NAS called a basic matter of "justice, fairness, and gratitude."

14. The Proposed Human Studies Review Board Offers No Guaranteed Protections.

EPA's rule creates an independent Human Studies Review Board to evaluate proposed human tests, but EPA does not give that review board any authority. EPA allows the Human Studies

Review Board to "review and comment on" proposed human tests, but not to disapprove or force changes to a test because of scientific or ethical flaws. EPA will also "solicit the views" of the Human Studies Review Board before relying on a fundamentally unethical test, but EPA is not bound by the review board's recommendations in response. (70 FR 53863 & 53866, at 26.124(b)(5) & 26.603(b)).

Also, EPA's proposal to rely on previously conducted human tests even if unethical (discussed above) violates the requirement of independent review *before* tests can be conducted or relied on. *See* NAS Recommendation 6-2; *see also* H7020 (July 28, 2005) (stating that the human testing amendment "requires the creation of a review board to evaluate the ethical and scientific propriety of intentional human dosing studies *before they can be conducted, considered, or relied on*") (statement of Rep. Solis). Studies completed and submitted before the Human Studies Review Board has been created obviously cannot meet this requirement. (70 FR 53866).

15. The Proposed Rule Has No Teeth, Because There Are No Mandatory Sanctions for Industry Non-Compliance.

EPA lists a number of potential consequences for entities that conduct or submit unethical human tests, including termination of ongoing studies, disqualification of the entity, and refusal to rely on the data. However, none of these sanctions will deter unethical human tests, because none are mandatory. EPA gives itself the discretion not to impose any of these sanctions at all, even for the most egregiously unethical human tests. As discussed above in point 12, EPA even reserves the right to rely on data "conducted at a disqualified institution." (70 FR 53865-66, at 26.501(b) & 26.502).

16. The Proposed Rule Allows Pesticide Testing on Prison Inmates.

EPA currently relies on some "third-party research with prisoner subjects." EPA deferred adopting any rules to protect prisoners, however, because such rules could "create as many problems as they solve." Despite the obvious problems of informed consent posed by testing chemicals on prison inmates, EPA dodges the issue in its proposed rule. EPA will therefore continue to rely on inmate experiments under this rule. (70 FR 53852).

17. The Proposed Rule Encourages Noncompliance with its Own Weak Standards.

Human tests conducted after the rule is finalized need only "substantially comply" with the rule. This encourages noncompliance and contravenes the express legislative history of the human testing law passed by Congress in July 2005. Representative Solis, a co-sponsor of the human testing amendment, expressed Congress' clear rejection of this provision in an earlier draft of the proposed rule, declaring in the legislative history: "This provision overtly undercuts the protections in the rule. The vague standard of substantial compliance wrongly sends the signal that EPA will not demand strict adherence to ethical standards in human pesticide experiments." H7021 (July 28, 2005) (statement of Rep. Solis). EPA is ignoring this direct rebuke from Congress. (70 FR 53866, at 26.602(d)).