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SEN. BOXER, REP. WAXMAN, AND REP. SOLIS DENOUNCE LEAKED BUSH ADMINISTRATION PLAN TO PROMOTE HUMAN PESTICIDE EXPERIMENTS

WASHINGTON, DC — Today, Senator Barbara Boxer, Rep. Henry A. Waxman, and Rep. Hilda L. Solis criticize a Bush Administration plan to promote pesticide experimentation upon humans. The plan, contained in a final draft rule, was leaked to the legislators by a concerned Administration official who requested that the original copy of the plan not be duplicated in its entirety and widely distributed out of concern for anonymity. According to the EPA's communications plan, the Administration will officially announce the pesticide experimentation plan later this week as a final regulation.

In August 2005, Congress enacted a moratorium upon EPA using human pesticide experiments until strict ethical standards were established. Senator Boxer championed the moratorium in the U.S. Senate. Representative Solis pushed the moratorium through the U.S. House of Representatives.

"The Administration plan is inconsistent with the law passed by Congress with bipartisan support. The loopholes which allow continued testing on pregnant women, infants and children are contrary to law and widely accepted ethical guidelines, including the Nuremberg code. The fact that EPA allows pesticide testing of any kind on the most vulnerable, including abused and neglected children, is simply astonishing," said Senator Boxer.

"The regulation is an open invitation to test pesticides on humans, which is the exact opposite of what Congress intended," said Rep. Waxman. "The Administration predicts that over 30 pesticide experiments will be submitted to EPA each year under the new rule. That's an enormous step in the wrong direction."

"This is yet another example of the Bush Administration choosing to ignore the letter of the law and going its own way. Congress passed legislation to curb the practice of unethical pesticide testing on humans, but with this rule the Bush Administration is authorizing systematic testing of pesticides on humans which not only fails to meet its congressional mandate but which will increase the number of unethical studies," said Congresswoman Solis. "Americans should be concerned about just how far the Bush Administration will go to allow pesticide testing on pregnant women and children and, the ease at which it chooses to ignore the law. The Bush Administration must revise this rule to meet its Congressional mandate and give Americans a policy which is moral, ethical, and safe."

"This rule has not been signed by EPA Administrator Stephen Johnson yet. It's within his power to fix this regulation, and we are calling on him to do so," said Senator Boxer.

If the rule is finalized as currently drafted, it would apply to studies in which humans are intentionally dosed with pesticides, as well as "observational" studies. Some of the serious flaws of the plan include the following:

- **The Administration plan is inconsistent with federal law.**
  Congress required that EPA ensure that pesticides are never tested upon pregnant women and children. But the final rule would allow manufacturers to conduct testing of pesticides upon both pregnant women and children so long as there is no "intent" at the outset of the study to submit the results to EPA. Additionally, the plan would allow pesticides to be tested upon pregnant women and children in studies intended for submission at exposure levels up to the current legal limits — even though the National Academy of Sciences found that in some cases this level of exposure could present acute risks to children.

- **The Administration plan is inconsistent with the recommendations of the National Academy of Sciences.**
  Congress required that EPA establish a Human Subjects Review Board (HSRB) as recommended by the National Academy of Sciences. The Academy urged that this Board review research protocols prior to consideration by an Independent Review Board (IRB). The Academy expected that the HSRB would have ethical and pesticide expertise that IRBs typically lack. This approach would allow an IRB to block unethical research or require modifications suggested by the Human Subjects Review Board prior to the initiation of a study. However, the Administration plan would establish a powerless Human Subjects Review Board that would consider research protocols after an IRB and EPA staff had already approved a study. Under the Administration plan, the HSRB would not have any authority to block or require modifications to unethical research.

- **The Administration plan would establish loopholes that could legally allow unethical experiments.**
  The Administration plan introduces new loopholes that will allow for ethical abuse. While the plan would require researchers to document their ethical compliance in the United States when the plan applies to them, it waives overseas researchers from having to prove a study was ethically conducted — even when the researcher intends to submit the study to EPA. Also, the plan would commendably subject EPA observational studies to the Common Rule. However, observational studies conducted by the pesticide industry would be bound by no specific ethical requirements. These loopholes were never suggested or even contemplated by Congress.