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Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues

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Body

The EPA commissioned The National Academies to provide advice on the vexing question of whether and, if so, under what circumstances EPA should accept and consider intentional human dosing studies conducted by companies or other sources outside the agency (so-called third parties) to gather evidence relating to the risks of a chemical or the conditions under which exposure to it could be judged safe. This report recommends that such studies be conducted and used for regulatory purposes only if all of several strict conditions are met, including the following: The study is necessary and scientifically valid, meaning that it addresses an important regulatory question that can't be answered with animal studies or nondosing human studies; The societal benefits of the study outweigh any anticipated risks to participants. At no time, even when benefits beyond improved regulation exist, can a human dosing study be justified that is anticipated to cause lasting harm to study participants; and all recognized ethical standards and procedures for protecting the interests of study participants are observed. In addition, EPA should establish a Human Studies Review Board (HSRB) to evaluate all human dosing studies both at the beginning and upon completion of the experiments if they are carried out with

the intent of affecting the agency's policy-making.

- Chapter 4 presents A Risk-Benefit Framework for Assessing Intentional Human Dosing Studies & Chapter 5 the Ethical Considerations in the Review of Intentional Human Dosing Studies.

Read *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues*

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