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CPR White Paper Proposes Innovative Solutions to Gaps in Data on Toxic Chemicals

Applegate: 'Americans would be appalled to know just how many of the chemicals used today in commerce have never been adequately tested for safety. It's long past time to fix the data gap.'

Washington, DC --- A new white paper from Center for Progressive Reform Member Scholar John Applegate offers a series of new proposals for defeating what has come to be known as the "data gaps" problem – that neither industry nor the government have gathered the data necessary to be confident that the majority of high-production toxic chemicals used in commerce in the United States are in fact safe.

"We lack any toxicity information on about 40 percent of the 3,000 chemicals produced or imported in amounts over one million pounds annually," said white paper author and CPR member scholar John Applegate, the Dean for Academic Affairs and a Professor of Law at the Indiana University School of Law – Bloomington. "For example, hydrazines are used in a range of applications – including agricultural pesticides, rocket fuel, photography chemicals, and spandex. EPA describes it as a probable human carcinogen, and acknowledges that acute exposure can cause temporary blindness, seizures, pulmonary edema, and coma. But it also acknowledges that 'information is not available on the chronic [non-cancer] effects' of exposure, that 'information is not available on the reproductive or developmental effects,' and that 'adequate information is not available on the carcinogenic effects.' We're well past time when we need to have such answers."

Congress attempted to address the problem in 1976 with the passage of the Toxic Substances Control Act, which called for a series of regulatory approaches for gathering needed data. But several studies since have made clear that TSCA has fallen far short of fixing the data-gap problem. In deciding whether chemicals may be used in commerce, the law leaves the burden of proof on government to demonstrate that the chemical is unsafe, rather than requiring the manufacturer to demonstrate that its product will do no harm. Indeed, some chemicals were on the market for years before TSCA, and were "grandfathered." The result is that manufacturers have little incentive to conduct toxicity studies, while Congress has not allocated funding so that the government could sponsor needed research.

"Americans would be appalled to know just how many of the chemicals used today in commerce have never been adequately tested for safety. There's far too much we don't know. It's time for new approaches to filling or bridging the data gaps," Applegate said in releasing the white paper. The paper, *Strategies for Closing the Chemical Data Gap*, written with CPR policy analyst Katherine Baer, offers a series of recommendations:

- *Create a New Institutional Design for Toxicity Testing.* Research on toxic substances currently occurs in many parts of the federal government. The National Toxicology Program (NTP), EPA, and others perform toxics testing, but there is little government-wide coordination. There are several ways to remedy this situation, including, for example, the creation of a centralized National Agency for Toxicity Testing.

- *Establish Incentives for Information Production*. The most powerful such incentive would be to shift the burden of proof from the government (to prove that a chemical is unsafe) to the manufacturer (to prove that it is safe).

- *Reinvent TSCA*. Congress should amend TSCA to facilitate EPA's ability to require testing of existing chemicals.

- *Increase Research Funding*. The political challenge aside, the inescapable reality is that the government must fund more research and data-generation about the toxicity of chemicals in commerce. By funding more basic research and clearinghouse activities, government spending can increase the effectiveness and efficiency of research by others.

- *Reinvigorate IRIS*. EPA's Integrated Risk Information System is missing values for many chemicals, and the addition of new values is slowed by an ossified peer review process, lack of resources, increasing political meddling, and a priority list that omits many statutory needs. Although the IRIS process generates synthesis assessments and not raw toxicological data, the program should be coordinated with other federal testing programs and used to generate research priorities to simultaneously close the gaps in basic data and IRIS chemical assessments.

- *Encourage Development of Emerging Technologies*. Although new technologies are not magic bullets, emerging technologies like toxicogenomics (changes in expression of genes in cells or tissues in response to toxic exposure) should continue to be developed as a potential method to understand chemicals' health effects.

- *Prohibit non-disclosure contracts* between industry and university scientists for research supported by federal funds.

- *Extend disclosure requirements for publicly funded research to private research used in regulatory processes.* The government should be able to see and review industry data if it is to be used in any regulatory process or government database, including the data that underlies forms and other industry submissions. For example, because EPA

cannot demand industry data, the IRIS program has relied on industry models and tolerance values without being able to evaluate or reanalyze the supporting data.

- *Decrease and penalize overuse of confidential business information (CBI) claims.* The widespread industry practice of submitting scientific data to the government, but gratuitously stamping it "Confidential Business Information" prevents agencies from releasing information to the public and fellow scientists.

- *Create a registry of studies and study results*. Existing studies should be added to a registry or clearinghouse of studies to increase the availability of existing information. Registration could be required as a condition of using the information in rulemakings or other government functions. Furthermore, notification of the start of the study should be required for inclusion in the registry and use in decision-making, to ensure that the public receives all studies, not just ones favorable to the proponent of the chemical.

- *Require corporate data disclosure.* Congress should enact a Sarbanes-Oxley-type requirement that CEOs, subject to personal liability, certify the accuracy of submissions related to environmental issues to the Securities and Exchange Commission.

- *Require industry to furnish EPA with data it submits to foreign governments.* Under TSCA, EPA should require chemical producers to provide to EPA environmental and health effects data that have been submitted to foreign governments – a requirement that will have significant impact with the implementation of the European REACH program.

Strategies for Closing the Chemical Data Gap draws on a forthcoming book written and edited by CPR scholars, Rescuing Science from Politics, to be published by Cambridge University Press this summer. In March, CPR cosponsored a symposium at Indiana University School of Law – Bloomington to compare the data gap in the chemical and natural resources areas of environmental law.

Strategies for Closing the Chemical Data Gap is available for download on CPR's website, http://www.progressivereform.org/articles/Closing_Data_Gaps_602.pdf.

The Center for Progressive Reform is a nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. For more information, contact Matthew Freeman at 301-762-8980 or at mfreeman@progressivereform.org. Visit CPR on the web at www.progressiverform.org.