Drug development stakeholders call for improved pharmaceutical testing

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Drug development stakeholders from private and public sectors, including researchers, academics, and representatives from the pharmaceutical industry and advocacy groups, have joined together to call for a significant and urgent shift to prioritize predictive, human-based nonclinical tests. Published in Drug Discovery Today, "Advancing Nonclinical Innovation and Safety in Pharmaceutical Testing" identifies the necessary steps that will lead to safer and more effective medicines, guided by a greater focus on human-based in vitro and in silico methods, which allow scientists to observe human cells, tissues, and biological processes, and their interaction with potential medications.

Participants of the Nonclinical Innovation and Patient Safety Initiative call for increased funding for human-based approaches, new and improved guidelines for preserving human cells and tissues for research, additional training for scientists to use human-based tools, and regulation that does not favor animal-based research. Complementing the FDA's Predictive Toxicology Roadmap, the authors affirm that using human-relevant tests earlier in the testing process would result in reduced waste, cost, and animal use, as unsafe or ineffective treatments would fail sooner and potentially safe and effective drugs would not be abandoned as a result of falsely appearing to be toxic.

"The status quo of pharmaceutical testing is tragically wasteful, in terms of time, cost, and lives lost," says lead author Elizabeth Baker, Esq., pharmaceutical policy director with the Physicians Committee for Responsible Medicine. "This paper—and the ensuing

collaboration—lays out thoughtful recommendations that have the potential to greatly improve drug development and save lives.."

More information: Elizabeth J. Baker et al, Advancing nonclinical innovation and safety in pharmaceutical testing, *Drug Discovery Today* (2018). DOI: 10.1016/j.drudis.2018.11.011

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