PhysiciansCommittee
for Responsible Medicine
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The Right Honourable Mark Carney
Prime Minister of Canada
80 Wellington Street
Ottawa, ON
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Sent via email (mark.carney@parl.gc.ca)

RE: Please Embrace Human-Based Research and Testing Methods

Dear Prime Minister:

We are writing on behalf of the nonprofit Physicians Committee for Responsible Medicine and our nearly 1 million supporters, many of whom reside in Canada. We commend the Government of Canada for its recent passage of Bill S-5, which amends the Canadian Environmental Protection Act (CEPA), and the launch of the 2023 national strategy to replace, reduce or refine vertebrate animal testing. Building on these milestones, the purpose of this letter is to position Canada as a world leader by prioritizing human-based research and testing methods and reducing the use of animals in projects funded or regulated by federal agencies. We would welcome the opportunity to serve as a resource as you explore this issue.

It is crucial that human health research be innovative, reliable, and reproducible, and the best way to meet all those needs is using nonanimal, human-based methods. Innovative tools like organ chips, organoids, and bioprinting are already being used to replace animals in a variety of applications, including disease modeling, precision medicine, and regulatory toxicology. They use human cells, tissue, and data to replicate human-specific biology and disease characteristics and have enormous potential to revolutionize medical research and testing.

These human-based methods also save money. A 2022 economic analysis estimated that the use of more predictive preclinical nonanimal technologies instead of animal tests could generate over **US $24 billion** in increased research productivity, resulting in streamlined drug development and potential cost savings for patients. While that analysis reflects U.S. data, a comparable assessment conducted in Canada could help to evaluate the potential for cost savings and efficiency gains for your country's healthcare and innovation sectors.

U.S. agencies are now realizing the need for change. In April, both the U.S. Food and Drug Administration (FDA) and U.S. National Institutes of Health (NIH) made groundbreaking announcements to reduce and replace animals in drug testing and disease research. The FDA stated, "there is growing scientific recognition that animals do not provide adequate models of human health and disease." NIH Director Jay Bhattacharya, MD, PhD, wrote, "For decades, our biomedical research system has relied heavily on animal models. With this initiative, NIH is ushering in a new era of innovation."

We encourage the Government of Canada to also embrace these changes. Here are some specific ways it could do so:

1. **End the federal requirement that drugs be tested in animals.** While the strategy to replace, reduce or refine vertebrate animal testing under the modernized CEPA marked an important step toward minimizing animals in chemical safety assessments, a comparable commitment is needed to advance human-based approaches in the development and safety testing of pharmaceuticals. More than 90% of drugs found to be safe in animal studies fail during human clinical trials. This slows down the public's access to important therapies, takes an expensive toll on industry, and causes unnecessary suffering to an untold number of animals. In comparison, human-based technologies are generally cheaper, faster, and more predictive of human outcomes than traditional animal tests.

2. **Invest in the development, validation, and acceptance of nonanimal research and testing methods.** Canada can build on the CEPA strategy by supporting Canadian-led innovation and cross-agency coordination of nonanimal approaches, ensuring Canadian science remains at the forefront globally. The FDA recently made permanent its Innovative Science and Technology Approaches for New Drugs (ISTAND) program, which will "support innovative, science-driven approaches that improve drug development and regulatory decision-making, ultimately helping to make therapies available to address patients' unmet needs." Similarly, the NIH's new Office of Research Innovation, Validation and Application (ORIVA) will "coordinate NIH-wide efforts to develop, validate and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection." Both could be models for Canadian agencies.

3. **Direct Canada's major funding agencies, such as the Canadian Institutes of Health Research (CIHR), to identify specific research areas where animal-based studies have demonstrably failed to translate to patients and to transition funding in those areas to nonanimal methods**. This effort would align with the CEPA strategy mentioned above and seek input from the Canadian scientific community. Coordination of this effort across the federal Health Portfolio—including Health Canada, CIHR, and the Public Health Agency of Canada (PHAC)—would help ensure a comprehensive and unified national approach. The CIHR should prioritize an examination of these areas. Criteria for prioritization could include clinical failure rates, evidence of greater human relevance and translational success with non-animal methods, and harm to the animals involved (e.g., the number of animals used and the severity of procedures). Key areas to target include oncology, neuropsychiatric diseases, cardiovascular disease, neurology, HIV, sepsis and burn injury, hepatitis C, Alzheimer's disease, and Parkinson's disease.

We appreciate you considering these recommendations and would be happy to discuss them in greater detail with your staff and agency directors.

Thank you for Canada's recent progress in modernizing chemical safety policy and for your ongoing commitment to the health of your nation.