Introduction

Good afternoon and thank you to Representatives Earl Blumenauer and Ken Calvert along with White Coat Waste Project and Johns Hopkins University's Toxicology Policy Research Team for organizing this event. My name is Rebecca Critser. I am lawyer and post-doctoral fellow at Johns Hopkins University but today I am here to speak in my capacity as a leader in the Animal Law Committee, which is part of the TIPS section of the American Bar Association. Please note that I am not employed by the ABA and am here only to speak on ABA Resolution 502, which was passed in February of this year and originated out of the Animal Law Committee. Also, my remarks do not necessarily represent the views of Johns Hopkins University where I am a fellow.

I want to acknowledge the hard work of my colleague Monica Englebretson (from Cruelty Free International) who deserves much of the credit for putting together both the resolution and accompanying report language. Many ABA Animal Law Committee members contributed to the success of this resolution, but I think they would all join me in recognizing Monica's central role in this endeavor.

I also want to thank TIPS, the International Law, and the Environment, Energy, & Resources Sections of the ABA for cosponsoring the resolution AND the Science & Technology as well as the Health Law Committees for their support of the resolution.

The American Bar Association is a membership organization for legal professionals. The organization is committed to setting the "legal and ethical foundation of the American nation . . . [and to a] mission of defending liberty and pursuing justice." The American Bar Association regularly reviews 25-45 resolutions at their twice-a-year House of Delegates Meeting. Resolutions that successfully pass the House of Delegates represent official positions of the association.

ABA Resolution 502

I am thrilled to be able to speak with you today about Resolution 502, which passed the ABA House of Delegates this past February. ABA Resolution 502 calls on Congress and US federal agencies to promote the development and use of non-animal methods by removing barriers and creating incentives for alternatives. *I want to repeat want I just said: The American Bar Association has called on our federal government to remove the legal barriers that currently exist and to create new incentives to promote the development and use of non-animal testing methods.*

If you are interested in reading this resolution language you may do so using the QR code on the poster. It will take you to an ABA website where you can access both the resolution language along with the accompanying report language. The resolution language itself is short so I am going to read it to you directly:

RESOLVED, That the American Bar Association urges national governments, the U.S. Congress, and U.S. federal agencies to promote the development and use of methods that aim to replace, reduce, and refine the use of animal models in research and testing; and

FURTHER RESOLVED, That the American Bar Association urges national governments, the U.S. Congress, and U.S. federal agencies to remove barriers to, and create incentives for, the use of non-animal model research and testing methods in regulatory testing and federally sponsored research.

As identified by a member of the ABA International Law Section during the February House of Delegates meeting, the passage of ABA Resolution 502 is not a trivial matter. The ABA is one of the largest voluntary organizations of legal professionals and is comprised of over 1 million members. So I want to take a minute to draw your attention to the key reasons the ABA passed this resolution – much of which is reflected in the report language you can access using the QR code I referred to earlier.

If you will indulge me, I would like to read two paragraphs directly form the introduction of the Resolution's report language:

(Paragraph 1) *This Resolution is based on the scientific principle of the Three Rs—Replacement, Reduction, and Refinement—which have been the foundation of better science and of improved conditions for animals used in research for over 60 years and which underpin laws worldwide, including in Europe and the United States. Further, this Resolution is consistent with a bi-partisan federal legislative initiative [known as the HEARTS Act] that seeks to further implement the Three Rs with particular emphasis on the 1st R, by accelerating the development and use of non-animal alternatives to replace the use of animals. In short, this Resolution provides a balanced approach to advance science, promote human health, protect the environment, and spare animals' lives.*

(Paragraph 3) *Although U.S. law is based on the principles of the Three Rs, there is no [statutory obligation] to apply any of them. There are also barriers that act as obstacles to achieving replacement, including lack of funding, shortcomings in existing law governing how research projects are funded, and outdated regulatory requirements have been cited as obstacles to achieving replacement. Moreover, the current legal regime in some cases may discourage replacement—if not prevent it—where regulations may require the use of animal methods even when more effective replacement alternatives exist. In 2019, the United States Government Accountability Office (GAO) recommended that federal agencies better monitor and report on their efforts to develop and promote replacement alternatives and decrease animal use.*

The report goes on to identify public health, environmental safety, and animal well-being as beneficiaries of the use of alternatives in lieu of outdated animal models. It notes that human-cell based tests can detect 90-95% of human carcinogens compared to animal models estimated at just 42%. And that alternatives can provide human-relevant data about the safety of chemicals with greater predictability and less time, making it clear that the time to invest in these technologies is now. It is predicted that global chemical production will only increase – some estimates forecast production will double by 2030. Our current animal-based models cannot keep up with demands and unless we invest in alternative tests we will only fall farther behind creating increased risk for adverse outcomes.

Federal Legislation

Earlier I made reference to a bill known as the HEARTs Act. Thank you to Representative Ken Calvert for cosponsoring this bill. This bill calls for an amendment to the Public Health Services Act in ways that would incentivize alternatives and remove barriers, just as ABA Resolution 502 urges Congress and federal agencies to do. Among other things, the bill would remove barriers by ensuring critical resources such as a reference librarians are available to researchers looking to implement non-animal alternatives and directly create incentives for scientists and researchers that actually use these alternatives. There are other bills that have also been proposed: both the CARE Act and the After Act (or Violets Act) seek to secure the resources necessary to ensure animals used in testing are rehomed when feasible. Rehoming has often been called the 4th R in reference to the aforementioned 3Rs (replacement, reduction, refinement). I want to thank our hosts, Representatives Ken Calvert and Earl Blumenauer who have sponsored and/or cosponsored one or more of these bills. The bills I've mentioned here would primarily impact work being done at the NIH and/or by NIH grant recipients. But it is my hope that we can look forward to similar federal legislation that would guide the work at EPA.

Agency Authority

I also want to address agency authority in this space. Consider these two points: first, in many cases agencies are directly responsible for animal testing and second, in many other cases agencies are indirectly responsible for animal testing. Let me explain. On the one hand, federal agencies – including but certainly not limited to the EPA – conduct their own research or testing using animal subjects. The use of animal subjects here is clearly under the control of the respective agency.

On the other hand, federal agencies are authorized and obligated to review submissions (whether those be new drug applications, requests for grant funding, or chemical safety approval) and in these scenarios federal agencies may require animal testing through regulation, guidance documents, or unofficial agency policies. Here too, the use of animal subjects is under the control of the respective agency – though indirectly.

Therefore, for any real, substantive change to take place, our federal agencies must be committed to the development, promotion, and use of human relevant, non-animal testing methods. Agencies must be proactive in this space, or they will continue to be a barrier to the adoption and use of the best scientific methods available.

ABA Goals & Takeaway

I want to conclude my remarks by emphasizing that the ABA passed Resolution 502 because it was understood that the call for non-animal alternative test methods was and is consistent with the ABA's goals. Those goals include (1) "working for just laws," (2) promoting quality of life, and (3) "applying the knowledge and experience of the profession to the promotion of the public good." At the end of the resolution's report language, you find the following sentence: "Prioritizing the use of human-relevant replacement alternatives and adequately investing in them will foster innovation in science – which will in turn, lead to safer products, better-quality

medicines, and new tools for confronting future challenges. . . .” For all of these reasons, the ABA has called on Congress and federal agencies to promote and develop alternatives to the use of animals in research and testing.