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New regulatory paradigms for cellular therapy and regenerative medicine

Great successes in the prevention and treatment of a multitude of diseases have been achieved through the use of pharmacological drugs that target cellular receptors to alter human physiology. Breakthroughs in science of cell therapy and regenerative medicines have led to tremendously promising novel therapies that will likely change the paradigm of medicine and health for decades to come. However, unlike therapies commonly used today, these novel regenerative medicine therapeutics including stem cells and gene editing will likely permanently alter tissue structure and function. Consequently, the likely permanence of regenerative medicine therapeutics combined with the growing number of patients who choose to receive medical therapy outside of their home country (medical tourism) and increased accessibility of regenerative medicines for patients is ushering in a new era of challenges for bioethics and regulatory sciences. We need a new paradigm for collaboration involving all aspects of the production, manufacture, research and clinical application of gene and cellular therapies. In this presentation, we will discuss several paradigms and approaches for the design, development and implementation of a more collaborative, modern, holistic global regulatory framework. We will focus on the case study of the regulatory framework in The Bahamas as an example of an ethical model for evaluating, monitoring safety and efficacy of advanced cellular therapies. We argue that there is a need for more inclusive perspectives, broader adoptions, and swifter, more efficient implementation strategies in the interest of furthering improved educational bedrock and advancing the field. Our hypothesis and analysis suggest that a more integrative and unified regulatory landscape will likely require a multi-disciplinary approach that leverages advances in accelerating technologies and systems-thinking in order to capture and share clinical outcomes across many different geographies and regulatory jurisdictions. It will also require us to draw on diverse experiences and ethical models in order to overcome bureaucracy and make promising gene and cellular therapies more widely accessible and cost-effective.

Biography

Desiree Cox – Rhodes Scholar, educated at McGill University, Oxford University and Cambridge University. She has rightly earned her place as a Thought-Leader in healthcare and education and is highly respected health consultant internationally. Her focus is on health innovation, the regulatory aspects of the global stem cell and regenerative medicine, and medical tourism. Her experience in healthcare consulting includes consulting for biotech companies and major pharmaceutical companies including Amgen, GSK, and Novartis on pipeline therapeutic products and medical devices. Since 2015, she has been spearheading health innovation in The Bahamas and the development of the stem cell and regenerative industry in The Bahamas. She is the Founder and CEO of The HEALinc Health Innovation Incubator (www.thehealinc.com).

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