

Executive Summary of the Special Session on Law and Ethics of Nanotechnology Safety and Health: Nano Medicine Transforming Disability into Health

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1. Introduction

Dedicating a science conference session to the non-science topic of Law and Ethics represents an important opportunity for researchers to learn about and participate as stakeholders in nanotechnology law and ethics programming. The session's focus on safety and health represents a nod to the transversal implications of crosscutting law and ethics issues that have historically been undervalued by the scientific community. New interdisciplinary learning from this session will set the groundwork for important analytical breakthroughs across disciplines for Best practices and sound Nano regulatory policies. People have been giving birth since humanity began, and children of all genders have their life, health and well-being undermined by maternal mortality, defined as: death of moms during pregnancy, delivery or soon after live birth. And while death cannot yet be avoided ultimately, given the state of our current technology, the reality that children need their moms in order to survive the early years of life remains nonetheless true. Unfortunately, VMVLA is situated in a Legal desert and a maternity desert. VMVLA lawyers serve indigent and near poor clients with a wide variety of unmet needs.

Until the time in the near future when machines will bear our human offspring, the questions surrounding the tragedy of maternal mortality, reflecting thousands of preventable deaths, continue to plague humanity. Dr. Ilise L Feitshans JD and ScM and DIR and LLM student Georgetown University Law Center and President VMVLA, discussed the role of applied science and technology law to solve these tragic problems.

In her estimation, the absence of a cohesive packaging for a bundle of health rights undermines the ability of the USA'S federal infrastructure to use the law to advance public health. According to Dr Feitshans, the USA needs a Constitutional amendment providing the Constitutional Right to health protections of all, in order to tie a ribbon of protection around an inconsistent and wasteful patchwork of health care systems that are local, national, public, private and tied

to employment, with the resulting impact that pregnant women and their babies die falling through the systemic cracks. This problem is especially embarrassing in the USA, where the nation has a reputation for high quality of life, national wealth and leadership in advancing innovations in technology but is on a trajectory of increased maternal death with no improvements in sight under current laws. Instead, the problem of maternal mortality lingers as a bad air engulfing other efforts to improve our Nation's health. Too often ignored in policy meetings, in reproductive health seminars and case law that addresses abortion, and underfunded with insurance gaps that create a "maternity desert" in some parts of the USA, this problem is "the smelly dead cat in the middle of the table that no one wants to discuss" when they propose spending and programming for health care, nonetheless the presence of this undiscussed problem pollutes any efforts to advance public health. Robust data reflecting remarkably low maternal mortality in Northern Europe suggests that the technology to accomplish this protection already exists in civil society.

Political will is needed however, to operationalize our existing rights-based norms by using technology everywhere. The unresolved problems from the risks of maternal mortality throughout life are not answered by health equity arguments cobbled together from several different treaties and soft law. One important requisite for a robust discussion of programs to reduce maternal mortality is: collecting empirical information that reflects differences and then analyzing that data to determine whether root causes for differences are determined by race, class, gender, trauma, environmental conditions, and cultural norms enabling risk, misinformation, genetics or individual variability regarding immunoresponse to diseases or illness.

Health disparities are preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by socially disadvantaged populations [1]. The absence of such rights explains why the law is in turmoil about such crucial global health issues as abortion rights, reproductive health

and maternal mortality, child care, HIV treatments and testing, transgender issues, informational privacy or decisional privacy surrounding procreative decisions such as the decision whether to use contraception or to terminate pregnancy.

Therefore, Dr Feitshans proposed the following Constitutional language in her work:

All persons born or naturalized in the USA and subject to the jurisdiction thereof, shall have the right of access to preventive health care, the right to benefit from medical treatment and shall enjoy the protection of their health to the extent feasible and consistent with equal protections of the law. The federal government shall have the power to enforce by appropriate legislation the provisions of this Amendment [2]. This proposed framework language addresses the core issue that has been taboo in the underpinning of national laws: the right of moms and their babies to have health care that is not readily available and not a right in many nations although fundamental to respecting anyone's right to life. Neither moms nor their children can exist without sound preventive care and ongoing follow-up that ensures their well-being.

The absence of a cohesive, clearly articulated US Constitutional health right may explain why leading cases about health problems dance around informational privacy or decisional privacy surrounding procreative decisions such as the decision whether to use contraception or to terminate pregnancy, while maternal mortality is rising in the USA. Maternal mortality is higher in the USA than in any parallel industrialized nation--- higher than it was before Covid19-- and on a trajectory to rise even higher. For this reason, this article argues that the root cause of our maternal mortality problem is the absence of a core value for implementing the health protections, preventive strategies and followup delivery of health care embodied in the Right to Health. Such articulated core values are found in the Constitutions of many of our partner nations and in several binding international obligations that the USA has not ratified. Several nations in Africa serve as a useful model for the USA regarding what works to reduce maternal mortality.

Dr Cagri Zeybek Unsal Medical Ethics and History of Medicine-Bioethics Center, Hacettepe University, Faculty of Medicine Nanomedicine: Technology Challenges the Old Ways, Does it Challenge Traditional Ethics? When a cancer patient has not been informed of the possibility of preserving her eggs by freezing them prior to chemotherapy that removes or destroys her ovaries, it may be claimed that medical discretion to undertake his procedure without consent or without informing her about freezing her eggs exceeds the scope of standard informed consent. Whether the failure to inform her of this choice violates principles of informed consent, thereby rendering consent invalids a hot new area for litigation, Nano medicine regulation and reproductive health policy, raising the question whether there is a duty to inform patients of these options and to create a specific new discussion of unanticipated options that offer choices for patients, during the process of obtaining the patient's informed consent. Since there is close interaction between life sciences and engineering, sophisticated diagnostic and treatment

methods have emerged. In particular, new techniques in Nano medicine arise new questions to the fore which need to be addressed in terms of traditional ethics and whether there is a need of a new form of ethics, especially the need to discuss the scope of informed consent. In this regard, when a cancer patient has not been informed of the possibility of preserving her eggs by freezing them prior to chemotherapy that removes or destroys her ovaries, it may be claimed that medical discretion to undertake his procedure without consent or without informing her about freezing her eggs exceeds the scope of standard informed consent. Whether the failure to inform her of this choice violates principles of informed consent, thereby rendering consent invalids a hot new area for litigation, Nano medicine regulation and reproductive health policy.

This dilemma represents but one example where nanotechnology offers opportunities for patients that they may not know about, raising the question whether there is a duty to inform patients of these options and to create a specific new discussion of unanticipated options that offer choices for patients, during the process of obtaining the patient's informed consent. For this purpose, it becomes essential to question the applicability and adequacy of existing ethical approaches and principles in addressing the challenges posed by nanotechnologies in biomedicine. In this respect, this session explores the purposes and limits of informed consent and the role or duty of health care providers to ask patients about new developments rather than presuming they have made a choice with full knowledge of Nano medicine. In her second presentation for this session, Dr Ilise Feitshans JD and ScM and DIR, also spoke about "Returning to Life: Nanomedicine Developments that May Upend Guardianship and End of Life Directives" When nanomedicine offers new medical breakthroughs, such as the reduced impact of Parkinson's Disease explored by the Michael J Fox Foundation, patients with degenerative terminal diseases will have a new opportunity to live a highly functional life. Thanks to nanomedicine, previously incapacitated people may get well. Yet the law is unclear: what happens to directives, power of attorney authorizations and instructions for guardians who never expected the patient to live without being sick? Can the guardian refuse such care? Can someone intervene to authorize care and overturn the guardianship? How do we know what the patient really wanted assuming they did not know nanomedicines could make them well?

This problem is not hypothetical: as directives are being written today, the possibility of recovery may not be included in the text of the patient care plan or underlying trust to fund such care. Nanomedicine breakthroughs will pose these real life questions for people with Parkinsons disease in the next 3 to 5 years. Trusts and guardianship being written now probably don't foresee the patient becoming healthy... but the researchers at NANOTECHNOLOGY surely do! This session describes the changing role of guardians in light of these new discoveries not contemplated when patient protections were set up and offers practical approaches to anticipating these developments in nanomedicine

Prof Rikin Mehta, Pharm.D., J.D., LLM Adjunct Professor

Georgetown University Law Center spoke about “Law and Procedures in US FDA and WHO regarding Commercialized Nanomedicines”. Drawing upon personal professional experience as first, in house staff at the US Food and Drug Administration (FDA), then on secumdemment from FDA to the World Health Organization (WHO) and now as an entrepreneur in developing new pharmaceuticals, this wonderful and informative presentation based on real time professional experience will walk through the maze of regulatory hurdles facing nanomedicine. This presentation will provide the basics of the US FDA timeline, WHO efforts to align drug regulatory frameworks around the world and the joys and perils of walking through these regulatory systems in order to create and market new drugs.

Dr Chrisa Vassara, Cardiologist, Aristotle University of Thessaloniki Greece presented her views about “Nanomedicine in Cardiology: Transforming Disability into Health” Nanomedicine is a rapidly growing field that involves the use of nanotechnology for medical purposes. By utilizing materials at the nanoscale, researchers are able to create innovative solutions for diagnosing, treating, and preventing various diseases and conditions. One of the most exciting aspects of nanomedicine is its potential to transform disability into health. By developing targeted drug delivery systems, nanomedicine can deliver medications directly to the affected cells or tissues, minimizing side effects and improving treatment outcomes. This targeted approach is particularly beneficial for individuals with disabilities, as it can help manage symptoms and improve quality of life. Overall, nanomedicine has the potential to revolutionize the way we approach disability and health. By harnessing the power of nanotechnology, researchers are able to develop innovative solutions that can improve the lives of individuals with disabilities and ultimately transform their health outcomes.

Dr. Vasiliki Papadouli, LLM, LLB, Post-Doc Researcher at Vrije Universiteit Brussel, Adjunct Lecturer International Hellenic University Balancing AI and modern medical practice: perspectives and ethical challenges. The First view of Legal Issues for Artificial Intelligence applied to medicine! 1.intro to ai (key features) 2. Ai applications to modern medicine 3. Ai inherent limitations-black box 4. EU ai act and ai systems used in modern medicine 5. Responsibility of modern physicians: consideration in the light of the new disruptive technology

About the VMVLA: The VMVLA was honored to receive a 2024 Award of Merit from the Conference of Local and Specialty Bar Associations of the Virginia State Bar. VMVLA was recognized for its efforts to protect and preserve the legacy of Josephine City, a community founded by emancipated slaves in Berryville. In support of this Blue Ridge Mountain community, VMVLA launched the Josephine City Project to clear property titles, protect historic buildings from demolition, and establish a foundation dedicated to the preservation and restoration of historic structures. As a specialty bar association committed to the practice of law in the Mountain/Valley region, VMVLA is proud to play a part in preserving a crucial piece of Virginia's heritage while demonstrating the powerful role that lawyers can play in community preservation.

2024 is the second consecutive year that VMVLA has won a Merit Award. VMVLA received a 2023 Merit Award for service projects supporting Wills for Veterans and partnering with local civics and government teachers to create educational classroom materials on the function of the rule of law in American society. Both of these efforts were spearheaded by women lawyers seeking restorative justice and promote womens equality. Additionally, VMVLA hosted several CLE events regarding womens rights, especially the Keynote speech at International Law Days May 1 2024, regarding the urgent need to reduce maternal mortality and the pathbreaking description of new avenues for using science and technology law to curb this epidemic.

Diversity and inclusion efforts also propel women to leadership roles in VMVLA. VMVLA is a specialty Bar Association whose nearly 2000 members serve rural areas of Southern Virginia from Roanoke to West Virginia's border. Within the local context of the Shenandoah Valley served by VMVLA, there lies the state's strongest farm region; agriculturally rich, but an underserved Legal Desert where, believe it or not, there are too few lawyers to serve the needs of the population. Despite covering more than 50% of the Commonwealth's land area, there are more Virginia-licensed attorneys with addresses of record in Washington DC than in the VMVLA Region. Globalization has also increased the demand for knowledge about legal issues well beyond traditional academic borders; VMVLA fills this void, because Bar Associations in the USA require annual training for lawyers and judges updating their knowledge, applying criteria set forth by the Bar but do not require that the subjects discussed in CLE track traditional narrow law school subjects. Experts from ancillary professions, such as doctors, librarians, forensic experts, and administrators in key programs where law is in the hands of non-lawyers turned regulators, are also welcomed by VMVLA to educate practitioners about important aspects of their work in daily legal practice. Most of what the VMVLA does, it does for free or at very low cost, offering CLE programs live and on Zoom throughout the year. For this reason, VMVLA CLE offerings include Science and Technology, Access to Justice, and DEI and a host of pathbreaking topics that impact the daily life of lawyers and their clients in practice.

Reference

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