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Awesome. I will go ahead and press. Start. Thank you. Everyone.

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Good morning, afternoon or evening, depending on which part of the world you are zooming into today.

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I'm Myisa Batello. I'm in a associate professor at Columbia University, and I'm delighted to welcome you to our June Lc.

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Friday Forum. Legal and policy challenges to privacy in the post-genomic and postdocs era the Forum is hosted by the center for Lc.

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Resources and analysis, and held on the second Friday of every month for 1 h, starting at 12 noon Eastern time.

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We also have a zoom room reserved for more informal discussion.

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Immediately after the panel for 30 min. For those of you who might be new to the center for Lc.

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Resources and analysis, or Sierra, we provide resources to support research on the ethical, legal, and social implications of genomics and genetics, and serves to connect scholars, scientists, policymakers, journalists, members of the public and others, to engage in lc issues, Sirira is funded by the national human genome research institute's

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Nhs at the National Institutes of Health, and is managed by teams at Stanford and Columbia Universities in partnership with the Hastings Center and Harvard University.

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I encourage you to visit Sarah online platform. Elsie, hop.org for the recording and transcripts of this one, and related references.

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Please use the link in the chat to learn more about how practices that create a news.

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Personal data, for surveillance purposes, challenge privacy rights and explore solutions with our newest. Lc.

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Hub, collection, data, valence and human Rights, curated by Jennifer K.

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Weagner. These also go to the website to join the Lc.

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Scholar Directory. Sign up for Newsletters and other events like this one at Lc. Hub.

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Org and get daily updates in news on Linkedin and Twitter.

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For before we begin this event, in a more formal way, some quick housekeeping information, if you wish to use close captioning, please turn on CC.

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At the bottom of your screen the Panelist presentation will be very brief.

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In order to conserve a significant portion of our time and discussion.

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Please use your button, which you will find at the bottom of your screen to write in questions for the panelists at any point during the session.

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You can register your entity as it's a question, and elevated up the list by using the update button.

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Button in the box, the chat box is available for further engagement.

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We will post links to resources referenced in today's discussion there as well.

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A portion of today's presentation is posted in the chat and will be available on Lc. Hub.

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Following, the Forum, if you have any questions, please also email info at Lc.

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Hop.org at anytime. It is now with a great pleasure that I want to introduce our sessions. Moderator, Dr.

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Leslie Francis, who is a distinguished Alfred Ca.

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Marie, endowed professor of law and distinguished Professor of Philosophy at the University of Utah.

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Dr. Francis writes widely on issues of justice and healthcare, public health and reproductive care.

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She's an elected fellow of the Hasty Center and a life member of the American Law Institute.

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Thank you very much. Maya, and let me add my delight in welcoming you to this wonderful session.

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On legal and policy challenges to privacy in the post, genomic and post-dobs era.

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Genetic information has been judged worthy of special protections for both defensible and potentially problematic reasons.

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Genetic information may enable identification of individuals with a high degree of accuracy.

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Genetic information may have health implications, not only for the individual to whom it directly pertains but also for their relatives.

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The use of genetic information may reach even to distant relatives who lack knowledge or the opportunity to consent.

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Genetic information also may be misinterpreted in ways that are essentialist or fatalist.

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People may mistakenly believe that their genes determine who they are, or set their fates on an inexorable path direct to consumer marketing of genetic tests, and even polygenic risk scores for matters such as suicidal suicidality have

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only complicated. These issues raised by the acquisition, use, and protection of genetic information.

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Many commentators have questioned what's been called genetic exceptionalism.

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The idea that genetic information is somehow different from other kinds of physiological information about people in assessing these arguments we should not forget that what matters for privacy is not just the significance of the information for individuals themselves, but also how the information will be understood and used by others the Supreme court's decision

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in jobs to remove Federal constitutional protection for reproductive choices has added new dimensions to these debates.

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There are, of course, the risks that medical records will be used in prosecutions or novel damage, revenues in abortion, restrictive states.

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But despite protestations to the contrary, in the majority, opinion in jobs, the rejection of constitutional protection for reproductive liberty has also thrown into question constitutional protection for other liberties that don't have explicit mention in the constitution, including rights

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to same-sex marriage and to contraception.

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Other rights may also be at increased risk, including the right to informational privacy, which has never been formally recognized by the court, but was only assumed for the sake of the argument in a decision upholding the permissibility of databases of controlled substance prescriptions the

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landscapes of these issues is vast. Today, we're very fortunate to have experts on 2 of the most exciting emerging and critical problem areas.

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The forensic use of DNA, including that in newborn screening samples and the potential for experimental use of pre-implantation or prenatal gene therapy.

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So our 2 speakers, Natalie RAM, is Professor of law at the University of Maryland, Francis King Carrie, School of Law, an adjunct faculty member at the Berman Institute of Biteics at Johns Hopkins, University, she Writes at the Intersection of Genetic Privacy and the

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criminal legal system. She was a 2021 Greenwall faculty scholar in Bioethics, and she's an elected member of the American Law Institute Altochaira is Professor Emeritus of Law and Bioethics at the University of Wisconsin She now

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works as a consultant on medical and agricultural biotechnology, ethics, and regulatory policy for industry, advocacy, groups and government agencies.

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She's being been elected to the triple-aas, to the American Academy of Arts and Sciences, and to the National Academy of Medicine, where she co-shared its reports on Stem cell Research and on Human genome editing and with that I'm turning the floor over

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to my colleague, Natalie, Rob.

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Thank you so much. Let me pull up my slides here, and I hope that you can see these. Now.

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Can we see the slides?

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Yes.

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Okay, great. Thank you. Alright. So I'm delighted to be with you today.

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I wanna note at the outset that the work that I'm describing in this talk was supported in part by a faculty scholars.

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Grant from the Greenwald foundation. So since the April 2018, arrest of the Golden State Killer pictured here, police have been eager to use non forensic genetic data in service of their forensic goals in the Golden State killer case, investigators developed a genetic profile from

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crime, scene evidence uploaded it to several consumer genetic sites and compared it with the profiles of millions of ordinary Americans exploiting connections to distant relatives to home, in on a suspect in the 5 years since the Golden State killers arrest investigators have undertaken hundreds of

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similar industations. Having discovered one traditional and one non-traditional DNA repository through which to develop investigative leads. Some law enforcement.

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Investigators have already set their sites on another. So first in December 2020, reporters uncovered that investigators in California had sought access to residual newborn blood spots for criminal investigative purposes and then last summer news broke of a lawsuit in new

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Jersey, seeking access to information about how frequently law enforcement there have used residual newborn blood spots for investigative purposes.

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The State office of the Public Defender has alleged that law enforcement in New Jersey used only 9 year old residual newborn blood spot to make a familial identification to the child's father, who is subsequently arrested and charged with a crime, this kind of use is only

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poised, to grow to date because we weren't screening hasn't involved extensive genetic sequencing it's the residual newborn screening samples.

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The dried blood spots that have been the target of law enforcement, access for such access to be efficient investigators typically have to have a specific suspect in mind.

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And while those blood spots could in theory be used to create a national DNA database, that law enforcement could use.

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That probably isn't practicable, at least at this time, for law enforcement to undertake that kind of sequencing effort, but his newborn screening programs seek to adopt or expand genomic sequencing public health entities engaged in newborn screening programs may effectively

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be doing law enforcement's work for them. So this map shows the results of research.

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I completed to survey State statutory and regulatory policies governing non-consensual law enforcement, access to newborn screening resources.

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As you can see, things are messy, and I would argue in need of reform, while most States have something on the books about the availability of newborn screening resources, samples and data for secondary use more than a quarter of states appear to have no clearly articulated policy that could govern law enforcement

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access, even among States, with a policy on the books of these policies range in their substance, coverage and specificity at a very high level of generality.

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Nearly a third of States permit Law enforcement, access to either newborn screening samples or data, while the remainder do not significantly.

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Many of the most permissive law enforcement provisions appear not in the newborn screening statutes or regulations at all, but rather in more general sources, like genetic pracy, statutes this is the case, for instance, in New Jersey, and so the landscape of policies that might affect law enforcement access

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to newborn screening resources is highly fragmented at times inconsistent, and, to be honest, often seemingly the product of initention.

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To this looming. I think this is a problem more precisely in my view, any law enforcement use of newborn screening resources is problematic.

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Let me briefly offer you 2 reasons why so? First, a policy excluding law enforcement access is likely essential for maintaining public trust in newborn screening programs, particularly as these programs evolve to consider greater swots of genetic sequence data as we all well know by now, public trust is

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essential for the success of public Health initiatives, including newborn screening, even law enforcement, has sometimes recognized the important relationship between trust and privacy.

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In addition to its databases of crime, scene samples and known past defenders and Austees, the FBI's official DNA database for law enforcement use also has databases pertinent to identifying missing persons these include databases of DNA

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profiles recovered from unidentified human remains, and, importantly, those voluntarily contributed from relatives of missing persons.

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These last sets of samples are known as family reference samples, and as relevant here according to the FBI itself, family reference samples are not utilized for ordinary crime detectection purposes, that is, they are not compared and may not be compared to DNA profiles

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from those drawn from DNA, left by perpetrators of unsolved crime.

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In other words, in order to encourage trust, and participate of family members of missing persons, the FBI has tied its own hands the same logic applies in the newborn screening context second law enforcement access to newborn screening samples are related data would raise thorny

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Constitutional concerns. To put it very briefly, the Fourth Amendment applies when the Government seeks to intrude upon an individual's reasonable expectation of privacy.

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Now newborn screening itself is for sure a fourth amendment search after all, it's a government mandated intrusion to the body to enable data collection.

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But don't worry yet. Newborn screening is not, therefore, unconstitutional.

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In fact, newborn screening is constitutional. Nonetheless, because its goal is public health rather than ordinary crime.

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Detectection and crime control and so newborn screening as a public health program serves what's called a special need separate from ordinary law enforcement.

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But that's special needs doctrine that justifies traditional newborn screening just doesn't apply to law enforcement access which would be precisely for ordinary law enforcement purposes and routine law enforcement access to newborn screening resources might well, come

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to imperil the constitutionality of newborn screening.

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In the first instance. Now, because newborn screening programs are operated at the state level, and because Congress has a hard time getting things done, most of the time, I'd like to suggest that state legislatures and regulators are the entities best positioned to act in this space and that they should

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adopt uniform, comprehensive, and explicit policies, governing and hopefully barring law enforcement, access to newborn screening resources.

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You might feel pessimistic that these rules might be made even at the State level.

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And so I want to highlight 2 examples that I hope will give you some optimism.

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So first, this is Hb. 2, 40, which became law in Maryland just over 2 years ago in May 2021 Hb.

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240, creates a comprehensive regulatory scheme governing Maryland law enforcement's use of consumer drugs, and as some colleagues and I have written about in science, Hb.

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240 includes several critical features identified on the slide for constraining launch enforcement use of consumer genetics platforms to its best and most justifiable use.

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Cases. Implementation of Hb. 200 fortys provisions hasn't been entirely smooth, but it's been pretty good, and I feel really lucky to live in a state that takes our genetic privacy.

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Seriously moreover, Maryland isn't the only State with a law like this on the books this year Utah enacted a similar, though not identical statutory regime.

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In other words, from both sides of the political aisle, privacy is making headway in this space.

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Second, I want to mention Iowa's policy regulating law enforcement, access to or use of newborn screening samples in a subsection entitled Prohibited Uses the I/O Administrative Code, Unequivocally States a Residual newborn Screening

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specimen shall not be released to any person or entity for commercial purposes or law enforcement purposes, or to establish a database for forensic identification.

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This policy couldn't be more clear it's my fault that more screening newborn screening programs will develop regulations or statutory provisions that use language like this.

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So. It would be even better if these provisions include a newborn screening data within the scope of their protection.

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To conclude our genetic, material and data now live in all sorts of places.

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And law enforcement is beginning to notice and take interest in particular.

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Law enforcement has come knocking for consumer genetic data and for samples and data held by newborn screening programs.

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Policymaking is possible in these fields, and there are good reasons to enact us.

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Thank you. I'm now going to hand things over to Alta.

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Thanks, very much, Natalie, and thank you also for having highlighted the importance of of newborn screening in the United States.

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That's exactly where I'm going to begin my presentation as well before I do that I should just reveal some significant bias conflict information.

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I'm the co-organized workshop with Tippy Mckenzie at Ucsf on this very topic, I'm going to talk about which is the prenatal use of gene therapy, and as a group along with others including literature who's

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on this call. We're going to be working toward developing a consensus standard on ethical issues surrounding this new area of application.

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Next slide, please. So event of newborn screening.

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We are looking at potential expansions in the range of genetic infections that will be collected in the future.

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With that comes opportunities to intervene far earlier than we do now.

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When it comes to genetically determined diseases. Typically, we work on these diseases after birth.

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But there are reasons why Hutero, Gene, therapy, and genome editing in particular, might be a particularly useful way to approach this.

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First, the fetal immune system does not present the same problems with immunogenicity that adults are even children would present, and since most gene therapy is now delivered through viral vectors, that issue of immunological reaction is significant it does mean also that we might allow

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redosing, which is currently a problem. After a first dose which we're seeing now with children in the early trials for muscular dystrophy.

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In addition, there are ways in which to access parts of the fetal body and fetal cells that are easier than would be the case if you are working with newborns, for example, the blood grain barrier is far more permeable which allows you to work on a range of diseases that are

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inaccessible. Once a child has been born, it's also easier to access certain kinds of key stem cells, particularly in the fetal liver, and that allows you to do therapy before they now settle into bone marrow, and finally, because the fetus is smaller it allows you to

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use lower doses in particular, of the vectors, which for the moment are a problematic aspect of gene therapy.

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Some issues with overreaction to the Aav doctor, and as a result, what we are thinking about now is a water range of gene.

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Gen genetically determined diseases that could be addressed.

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Now in the prenatal state, but because the diagnosis will still take a period of time.

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We're probably looking at confirmatory diagnosis of a phenotypic presentation and a development of a.

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Gene therapy taking place in the second trimester, and know earlier, as we're going to see very quickly the phenomenon of the Docs decision becomes a very important factor in figuring out whether to pursue these kinds of therapies next slide just to give this very quickly a very concrete

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example let's just talk for a moment about cystic fibrosis.

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Most people think of it only as a lung disease, but of course it affects other parts of the body as well.

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It affects the mucus membranes, and so can cause infertility.

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It can also create problems with digestion. In other words, it has toic effects, and being able to treat it early on, allows you to treat it systemically and prevent this kind of damage.

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In addition, in the fetal cell, sorry that fetal situation, the vectors are able to get deeper into the lungs than is typically possible with an already born child.

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So cystic fibrosis becomes an example of one of those areas where ideally we would love to be able to correct this problem before it has a chance to do damage damage that already occurs.

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Even before a child is born next slide. But if you're talking about the therapies for genetic disorders, we have a series of questions, some familiar, some a little bit different.

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The familiar question for any kind of prenatal therapy is, who are, or who is the patient you've got the pregnant woman as well as the fetus, and you're trying to treat the fetus while preserving the woman's own health and so risk and benefit is complicated because you're measuring

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risk and benefit for both the fetus and the child who would emerge, assuming the pregnancy, successful as well as risk, and benefit for the woman herself.

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But how does the availability of abortion affect this calculus potentially?

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It can affect it in enormous ways, because any kind of prenatal therapy gene, therapy, or otherwise, has the possibility of creating a situation in which you are.

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Pregnancy is now even at higher danger, or where the woman's and life are at risk.

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Ordinarily a miscarriage could be managed.

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Medically, or a termination could be chosen to liberately.

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If the gene therapy intervention goes badly, however, in light of the dots, decision that phenomenon now has changed miscarriage management has been affected by whether or not laws in states allow physicians to take measures that might affect the fetal viability in order to save the woman's

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health or manage what is a impending miscarriage?

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In other cases it is Hello, pregnancy that is already bound to fail.

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But there are certain key medical signals, such as degree of infection or of a fetal heartbeat that have not occurred, and so physicians have been prevented from managing those impending miscarries.

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The way they ordinarily would, in a manner that would preserve the woman's health.

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And fertility as much as possible. In addition, if abortion is not available as a choice, it does mean that in some cases, if gene therapy went awry and actually left the fetus worse off than termination would not be an option, so in the risk benefit analysis that ordinarily

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would go would be part of any kind of therapeutic discussion.

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The availability of abortion as a backup or the potential complexities of misscarriage management.

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In certain States would be now part of that conversation, and in some ways might actually make it more difficult to come.

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A sensible evaluation of what the options might be.

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For the war. If abortion is not yet available, then in some cases it may drive people to accept gene therapy options that otherwise they would have steered away from, because they fear that if the pregnancy proceeds without any kind of intervention and goes badly there would be no management through

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termination or miscarriage. In other words, this phenomenon of changing laws and their effect on misscarriage management, as well as termination decisions, could either drive people toward these therapies or complicate the risk benefit analysis once they've chosen them the second area has to do with

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who's going to give consent in this new era?

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We will. We should anticipate. There may be a revisiting of issues around the role of the paternal figure in these Prades and the control that this figure has on the kinds of choices that are made.

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And I'll come back to that in just a moment.

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If we can go to the next slide. I just want to give people a moment here to take a look at this map, which is probably out of date.

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I think I put it together about 12 days ago, but what you can see is a new pattern of developments in which there are some states and you'll see them in shades of blue and turquoise, hey? V.

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That are adopting laws that will preserve more, or even maximum decision-making authority for both a woman and their physician.

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When it comes to pregnancy management, and at the other end of the spectrum, in the darkest of red, we find the most restrictive laws, with a few that are now circling in between most of the in-between laws, are really there because they have, in terms of whether the limitations, on

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abortion access. So we'll kick in at 15 weeks versus 6 weeks.

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Some of them are done in terms of heartbeat laws, but because in the area of prenatal therapy so much happens in the second trimester, it's in some ways those differences don't matter, because even the more even the restrictive, but somewhat less restrictive

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rules would still wind up time. Of physicians and women when it came to decisions.

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In the second trimester about how to manage these complicated pregnancies.

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And what's really frustrating in some ways about this is that these are very much pregnancies that were wanted.

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There's that's the reason why we are seeing them.

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In the second trimester, with people contemplating ways to try to salvage what looks like a problematic situation we can go to the next slide.

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I wanna moment about the phenomenon of consent because there are Federal rules that govern in many, although not all situations, but in particular, when it comes to research, but in particular, when it comes to research it, these consent rules apply so interestingly, if you have a pregnant woman and I should say by the

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way, that when I say pregnant women, I'm including all people capable of getting pregnant, even if they don't.

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Those women. If a pregnant woman is asking for therapy for her own benefit.

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For example, you have people who have got cancer during their pregnancy or they're being treated for major depression during that pregnancy only the consent of the pregnant woman is needed, even though obviously there can be an effect on fetal development and the health of the of the newborn if on the other

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hand research it at the fetus, that it is not only the pregnant woman whose consent is needed, but also that of the father, and this particular provision, presumably the theory is that the fetus is of interest to both the parents, we parents you know kind of tentative way here because we don't know who's going

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to be rearing this child, but therefore the consent of the pregnant woman alone is not sufficient.

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There are a number of complications. This, and they become very much relevant when we're talking about fetal therapy as well as any kind of prenatal therapy.

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The first is when you ask Who is the father? Because in many, many cases the male progenitor, the person who provided the sperm is not, in fact, either the current rearing partner, what life partner of the pregnant woman?

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Nor is that the person who's intended to be the rearing partner in the future for the child.

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It could be that this is a pregnancy woman who is single and does not intend to co-parent.

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It could be that she is co-parenting with another woman. It could be.

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She's co-parenting with another man, but not one who is, in fact, the genetic father of.

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And these regulations are simply, completely unclear as to whose consent is really required.

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If one thinks about it, the logic would suggest it would be the intended rearing parent gender.

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We irregardless, who has the joint interest in whether or not to take a chance on doing therapy on the fetus?

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Since the risks to the fetus will be manifest in a newborn would be the responsibility.

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My parents, but that is simply not the case, and we have seen in the past, in the debates around abortion, a lot of effort to try and give male progenitors some degree of control in the decision around whether or not termination is possible.

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Even to the extent of where the male progenitor was a rapist, and so in this atmosphere, that we're in today, in which State legislatures, exploring all the ways in which they can express their views about the appropriate boundaries of women's reproductive

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autonomy, I would predict that we're going to see some new attention to the to the male progenitor who is going to be assumed in many ways to be the responsible co-parent, whether or not he is there are ways you can get around this due to unavailability there is

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actually a a limitation. These resulted from Rape. Princess.

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This is in the research context, not under the State laws, but these kinds of exceptions can often be difficult, for example, proving unavailability is like proving a negative and so can be difficult in the context of these therapies I simply want to conclude by saying that we're on the

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threshold of a really exciting and hell and valuable new therapeutic and at the prenatal stages of life something that avoids some of the ethical conundrums associated with trying to edit preconception or or pre-implantation that is germline editing

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and embryos, and also is capable of potentially giving us better results than doing it.

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Postnatally. And yet the current situation of the rather labile situation in law, postdocs is making this a lot more complicated, and area of therapeutic intervention even more complicated than it needs to be.

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Thanks very much. I'll turn it over to our hosts.

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Thank you so much. Both Natalie and Alta, and I'm been asked now to pose a few questions.

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I know that some are showing up in the but while we're talking I would encourage people to please put your questions in the, and we'll get to them in just a few minutes.

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So this is a question first for Natalie. When do?

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From newborn screening is used from the samples, that is, could you say a little bit more about who's rights, you think are violated, and why the parents, the child's, or both, or maybe even someone else's?

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That's a great question. So thank you. So, in my view, it is both the child's interest.

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In genetic privacy, and the parents interest in genetic privacy and potentially even a broader set of genetically identifiable individuals.

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Right so to me this stems from the fact that genetic relatedness, unlike most other kinds of relationships, we have, is involuntarily and immutably thrust upon us, as I like to say, nobody chooses their genetic parents.

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We don't choose our siblings. How many we have.

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We don't choose our aunts, uncles, cousins, how many we have, and in what arrangement?

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And yet all of those individuals have DNA that can be used.

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In what arrangement. And yet all of those individuals have DNA that can be used to learn about or identify us right?

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And so I've argued in my scholarship that familial DNA identification ought to constitute a search both of the person whose cells are analyzed and of the person or persons whom police learn about or identify or the government learns about or identifies through that analysis so

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I'm caping the web of genetic identifiability broadly, but that reflects the biological reality of the nature of our genetic relatedness.

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Thank you for Alta. Do you think a likely consequence actually is that after daub's the focus?

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Both in terms of research, development, and ultimate interest in clinical care.

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May shift back from in utero gene therapy to pre implantation, testing, and gene editing along with the user of Ivf.

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Would this be a good thing or a bad thing?

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You're on mute.

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You're muted. Yeah.

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Yeah. My apologies, as I think, probably most people online here know the date around germline editing has been going on since the advent of Crispr's announcements.

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Starting back in 2016 without real resolution, at this point there is absolutely no basis for believing that this point there is absolutely no basis for believing that it is safe to do embryo editing in order to affect the journeyline and try to correct a disorder before it even has a chance to manifest

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in the fetus, so regardless of the morality of that particular technique, safety issues are long from resolved, and indeed, at the genome editing summit that was held in March of this year in London, we saw more and more data suggesting problems with trying to use some of the current technologies to do

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the journal line editor to do editing, pre-conception as opposed to implantation would require that you're editing gametes that introduces a whole new other area of complexity because you can't edit an existing gamete what you have to do

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is edit a stem cell, and then differentiate the stem cell into a gamete.

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So you've now added yet another technological tour de force 2 sequence of events which adds yet another level of complexity and an opportunity for things to go wrong.

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And so for the moment I don't see much opportunity for using genome editing pre natively Pre, before you already have the fetus in Europe.

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Yes, we could go back to trying to use more.

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Genetic screening and more selective implantation of areas that have been diagnosed as free of a known genetic vari.

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But it's been shown that this is not yet a completely adequate solution.

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A lot of genetic disorders. Just do not become obvious at that embryonic stage, and you do need to wait development in order to realize that you need to therapeutic intervention.

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Thank you for, Natalie. What do you make of the data that suggests that people are in general more willing to let the information be used?

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What it might lead to the apprehension of someone who could be a significant danger to the public.

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An ongoing open set of continuing crimes, and whether we might want to use that sort of data as the default position to presume consent in this context.

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When you can't reach people.

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Yeah, so that data doesn't really surprise me. I mean, who is against catching serial killers?

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No one, not me, not anybody else catching really bad guys is good for public safety.

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Right, so so in the Maryland law, for instance, we have, you know, a actually enacted legislation that preserves, as I said, the use of law enacted legislation that preserves, as I said, the use of law enforcement use of consumer genetic data for its best and most justifiable

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use cases, and that includes for the most serious kinds of offenses right?

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And so that is one way we could go. But I would I would be remiss if I did not regale you with the history of law enforcement.

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Use of DNA for investigative purposes in the United States, which started by collecting DNA from a very small subset of individuals just those convicted of the most serious and violent sexual crimes, right and then over time, the aperture of investigation widens it becomes you know all violent

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felonies, then all felonies, then all you know.

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People arrested for felonies not yet convicted.

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And it's really hard to get your DNA in many States expunged.

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If you're not ultimately convicted now, some misdemeanors, some people arrested or convicted of misdemeanors.

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Some juveniles are having their DNA collected and added to the official law enforcement.

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DNA database. And so I think that we can only presume that though these these new technologies, these new uses, start with the best and most justifiable use cases, they rarely stay there narrowly.

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Cabin we're already seeing this kind of a widening of uses in law enforcement, use of consumer genetics.

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To identify, a suspect in a really terrible stocking case.

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It sounds like a terrible set of facts, but stalking is is not the same as murder and sexual assault, which is where most of these investigations have taken place.

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We've seen a lot of controversy surrounding the use of consumer genetics data to identify abandoned newborns in order to identify and and subsequently often arrest and charge the mothers of those abandoned newborns which are really tragic

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cases, but may not be the best use of public resources in this limited and expensive technology and technique.

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So so your public data, your public opinion data doesn't surprise me and can be informative.

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But I do. I am wary of trusting that once some use is permitted, that that use will not inevitably expand.

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Thank you. This is for Alta. Do you think that an upshot of jobs, and what you've just described is that we're gonna have a Federalist patchwork of the permissibility of research across the country so that we'll have research permissible in some States?

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Say Maryland, or Massachusetts. That's not permissible.

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In other States, say Missouri or Mississippi.

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Well, I think first, it's worth noting that we already have such a situation, although it doesn't cover very many areas of research research using fetal tissue.

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For example, is now impossible in certain States that have placed restrictions on that and in the 1970 S.

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There were States that test laws that would control or forbid certain aspects of research on embryos.

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So we have had such a situation in the past, and that kind of Federalist phenomenon is not uncommon in the Us.

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In this area. I don't think it would be as direct as laws in some States saying, you may not do prenatal therapy research, because, of course, the intent is therapeutic.

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However, I do think that the absence of a full range of options for the management of located and possibly failing pregnancies in the States with restrictive abortion, laws, states where physicians have already encountered difficulties in managing miscarries or in giving women the option to

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terminate when it looks like the pregnancy is going to result in a fetus or a new board that is inevitably going to die.

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I think research in those States might not happen not because it's illegal, but because it's not the best environment in which to recruit women and perform the research.

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So yes, you might find some of these prenatal therapy areas developing more rapidly in places like California that have passed legislation to protect reproductive rights and less of it happening in States with more restrictive rules.

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But I don't see an over prohibition on this particular research.

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Thank you. So there are several questions in the chat for Natalie.

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ROM! I see that she's typing an answer to one of them.

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But I'm going to ask her to actually answer it.

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Live? Which is the question of how could you say a little bit more about the numbers, or any data that you have about documented cases where law enforcement has actually used newborn screening blood spots?

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And and then maybe I'll just tack onto that.

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The question right below it, given the deletion of the spots after they've been used immediately, might seem to be the best privacy, protection.

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What would you think of that as a strategy?

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So those are both great questions. I was really excited to see them in in our and I'm happy to answer them. A live.

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So I will just read you what I had typed on how many documented cases we have of law enforcement uses of newborn blood spots.

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And the answer is simply, we don't know it's extremely hard to track this.

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It is, in part really hard to track this phenomenon, because this is a kind of step in an investigation that law enforcement is likely to omit or fuzzy up when they go to write a a subsequent search warrant affidavit or arrest

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warrant affidavit. We've seen this with a number of new techniques that might be controversial law enforcement doesn't really want people to know that they're using a certain technique either because they don't want controversy or they don't or they worry that

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maybe criminals out there will find ways to work around that technology.

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And so they just sort of omit it from the documents they F file and that are available to the public.

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So so the New Jersey Law suit actually stumbled upon this, and now has filed a lawsuit to say, Wait a second.

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We know this we, this appears to have happened in our one case, that we know of how many other cases like this are there, and, in fact, there's now an ongoing litigation about whether they're entitled to that information and how they're going to get that information so the answer is we don't

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know it's really hard to know right? As to the second question, you know, should we just destroy the samples and data?

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That is the strategy that has been adopted by some State.

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So Tennessee, I believe, has a destruction policy.

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That's again. Quite a short window. And so they don't have a policy on the books that can regulate law enforcement access after the fact to these newborn screening resources.

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But they don't really need one, because those samples aren't retained for a very long time, and then nor is the data.

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But and I think this gets to Amy's question also in the you know, newborn screening samples, and perhaps soon a newborn screenings sequence data can be a really powerful and epidemiologically valuable research tool and so there might be some interest in

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trying to balance privacy via destruction with retention for research purposes.

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One way you could do this. Try to have your cake and eat it too, would be to retain the sample and data on the kind of clinical state lab.

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Newborn screening side of things for just a very short period of time, and then seek consent from parents as they do frankly in Michigan, reasonably well to designate those samples for a Biotross specifically set up to facilitate research and that entity can have a certificate of

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confidentiality, which, as I am writing about with some colleagues, now appears to provide really robust protection, including vis-a-vis law enforcement.

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So I think there are ways to spl this circle. They're not necessarily straight forward, but they are important to try to try to identify.

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Thank you. So I'm gonna ask a question that I'm gonna ask alto to.

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Take the lead in answering, since Natalie's been talked, got the first round of questions.

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So this is a question from Jennifer, for both speakers.

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What are the constitutional arguments used in roe?

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Was the private relationship between doctors and patients. The to what extent can a case be brought?

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The demonstrates that this privacy is respected in any and all other exchanges between doctor and patient.

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And now because of jobs, not for women and their doctors.

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Is there a problem of equal protection and or discrimination based on gender?

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Here. So I read Jennifer's question.

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I might expand that to say, one of the points I made in the introduction is that the court is never fully recognized.

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Informational privacy as a constitutional right. It's been assumed for the sake of argument, and it's not mentioned as one of those other constitutional rights that the court is meaning to leave intact postdobs whether that will actually happen or not nobody knows but so this

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question, asks not the straight out protection of informational privacy as a constitutional due process, right?

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But whether they are equal protection questions. If the right is protected elsewhere, but not protected with women and doctors.

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So, Alta, take it away.

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Sure. Yes, let's do for an entire year, you know.

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2 semesters plus dance questions. So after and before I say that, by the way, I'm happy to listen to Natalie, for as long as she'll talk I listen to Natalie, so don't worry about that.

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I think that the privacy between physician and pregnant woman after the Row decision was probably one of the weaker bases on which that decision landed.

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And it's why, for example, you saw people like Justice Burg later, talking about the importance of thinking in terms of liberty and equal protection rather than thinking in terms of privacy as a grounding for this.

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Indeed! Contrary to what may be implicit in a professor. Merchants comment.

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I don't know that the privacy, the doctor, patient relationship, is that well protected in the United States these days across a number of topics.

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Now I will agree with you. They all tend to be hot button topics.

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Let's talk about, for example, gun control and doctors wanting to ask people about whether they have guns in their homes, and State laws that have been upheld, that prevented doctors from asking this question asking the question which would also seem to be a first amendment question about free speech

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you also have a history of State laws that have interfered with Dr.

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Choices in one case to offer conversion, therapy to gay teenagers.

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So, the idea being that the State was going to stop positions from offering this therapy, I'll put it in quotes to help gain teenagers become straight.

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But then there was another law in a different state that required that physicians offer end of life options to people, even when physicians didn't think it was in the patient's best interest.

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So again, we are examples of states that were interfering in the doctor-patient relationship in a fairly profound way.

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And now we have a whole host of states that are busily legislating restrictions on doctors, advising and performing of services.

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We that are related to gender transfer from, you know, male to female, or vice versa, especially for teenagers.

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So we have a more complicated patchwork of State law and judicial regard for the physician.

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Discretion in what to ask, to say and what to offer, with a very subtle set of distinctions made between physicians, speech and physician, performance of services.

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That can get very blurry at times, and as a result, I don't know that trying to isolate abortion from the stuff, position, care and say that this is an equal protection problem, because only an abortion.

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Our physicians winding up, restricted in their ability to have a private and consensual relationship with their patient.

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I don't think that's going to win here, because it's not as clear cut a distinctly carved out area of limitation, and one might at first believe.

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And I add one additional bit of cold water on this discussion, which is that in the jobs decision, despite overturning rafts of long-standing precedent from row onwards.

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Nonetheless justice, Alito's opinion in one sentence, disposed of the idea that restrictions on abortion could constitute an equal protection violation, because, after all, only people with child bearing capacity otherwise known colloquially as usually women right are affected by those laws by having

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their health, care, choices interfered with. He disposed of that by citing the good old decision that said discrimination, based on privacy or pregnancy isn't discrimination based on sex, because not all women are pregnant.

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All the time and so there are non-pregnant women who aren't affected by restrictions and discrimination, based on pregnancy and discrimination, based on pregnancy.

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So apparently that's still good. Law. But yeah.

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Yeah, just despite the fact that Dig led Congress to pass the pregnancy Discrimination Act.

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That's right. That's right.

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Right? Okay. So let me go back to Natalie for the 2 questions that are there.

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Are there any other quote from forensic uses like identifying missing children that you carve out?

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And would it be possible at the newborn screening event, to do something more by way of consent?

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I take it back on the model of a Michigan Bio bank, or some of the other options.

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Yeah, so are there forensic uses quote unquote forensic uses that ought to be allowed.

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Like identification, immediately missing children. I think the question that we want to ask here is if we're gonna open the door to law enforcement access to these resources at all.

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Is it absolutely necessary for that access to be had? And when we're talking about identification of missing children, of course we can do what the FBI already does with family reference samples, which is, get a DNA sample from a parent.

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And so I would be. I would look skeptically upon that use, though that use troubles me less than the use of of newborn screening samples and data for identifying suspects for investigation.

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Of course, I will also note it is sometimes really hard to differentiate identification of missing persons.

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Identification of unidentified human remain, say, an identification purpose, that's not targeted at a criminal prosecution from a use for criminal prosecution.

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We see those in those baby DOE cases that are quite controversial within the consumer genetics, genealogy, community.

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So so. And then there was a question about whether we should ramp a revamp consent for newborn screening.

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So so the typical way in which new or screening happens today is that parents are not asked to affirmatively consent to the newborn screening.

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In the first instance, the collection of the newborn screening blood sample in order to screen.

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For I, you know, a set of methods that have some modality of treatment that would be really important to know about consent is presumed in those instances has to do with the idea that if that's the state acting parents Patrick, in place of the parent that a reasonable parent would not decline

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to consent. In that case, right? So that's one of the justifications right now.

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Most States still adhere to that kind of presumed consent.

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There's often a permission or statutory way in which parents can opt out, but they are really counsel not to do that, because, after all, the medical benefit of newborn screening flows directly to their child's benefit and newborn screening is a is a really important and highly successful public

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health program. And, in fact, my work on Restraining Law Enforcement access to new ororn screening resources is all about preserving and reinforcing the importance of newborn screenening for its primary purpose, for the clinical benefit and public health of the child and the population as

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a whole in Michigan, right after the baby is born.

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So in that later period parents are presented with a pretty, robust, informed consent.

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Document asking if they will consent for the sample to be turned over.

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After the clinical screening is completed to the Michigan biotrust.

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There's some litigation ongoing on which I am not an expert, and will not speak about whether that informed consent is sufficient.

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If it's the right time, and those sorts of those sorts of questions.

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But you know there are ways to create more consent for those sort of non-individually beneficial to the child kind of uses for research and other uses.

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Thanks. So one last question for Alta. Do you think the Federal Regs need to be changed?

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Yeah.

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In ways other than this is the common rule in ways other than the 2. Parent consent.

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I mean, I take it, you think that the 2 parent consent for therapeutic research should be changed.

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Are there any other changes you have in mind?

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So how much time do we have left there, Leslie?

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Oh, a minute!

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Yeah, I think there's a whole host of things that we would benefit from changing in the current situation.

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I mean, for one thing, we have failed for decades.

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Now to come up with rule that adequately addressed research with people whose competence is either absent permanently or is intermittent.

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That is a very, very big topic. For a second. We have, I think, very cumbersome rules that govern the use of information, whether it's in form of biological samples, or it's in the form of the information that's been derived, and stored from the biological samples and

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we have relied for a very long time on notions of consent that are probably out of date.

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For one thing, they presume an ability to completely, anonymize things that may have gone away completely, and I was very tempted to break in several times to ask Natalie if she imagines that with current techniques in blockchain and photography and other things if there's any

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way we can imagine a day in which the information could be kept, but it could be appropriately, truly anonymized, because without that, in many cases some of our rules that depend on anonymous versus not anonymous or de-identified, really don't make a lot of sense we also depend on informed

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concerns a great deal more than we need to or should, because it is something that puts all responsibility on individuals to imagine everything that they could possibly care about, and effectively protect themselves.

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Having a system that tries to figure out how we protect all of ourselves.

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At the same time, but most radically, I would say that we have a system that hasn't figured out whether it wants to treat everybody who's being studied as a victim or somebody who is grasping for an opportunity, and because in some cases you're one in other cases, you're the

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other personally, I think we should all be available for study with appropriate protections, because we all benefited from study in the past, and we should be studied for the benefit of people in the future.

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But you can only do that in a system that has what Natalie was emphasizing earlier on in a different context, which is trust as well as a robust system of controls on youth, information that is just and equitable, so in my fantasy, yes, many many changes in my political reality.

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No, no, I don't think anything needs to be changed.

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With that, let me turn it back to Mya for closing, and any other questions. We'll go to the zoom room.

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Thank you so much. Everyone, I'd like to thank the panelists and the met for the presentations, and the moderator that was really fantastic for those who can please join us in our post.

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Event, discussion. The link is in the chat. We hope to see you on July fourteenth for a next Lc.

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Friday Forum, which focuses on population descriptors in genomic research.

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Applying the National Academies of Science and Journalism, recommendations, and it will be joined by panelists and Morning and monitors, and moderated by Dorothy Roberts, the registration Link is in the chat. Please visit Lc.

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Hub.org, and subscribe to our Newsletter for more details.

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Also you will receive a post event survey, and I encourage you to complete this, as our Organizing Committee takes your comments and suggestions seriously, it has informed us on how to improve the Forum and brings new topics and speakers to you so please do fill that out thank you

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very much, and I wish all of you a wonderful weekend.