Feature Article

The Genetic Privacy Carousel: A Discourse on Proposed Genetic Privacy Bills and the Co-Evolution of Law and Science

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Abstract: In 2011, genetic privacy bills were introduced in two US states proposing that genetic information and material are an individual's exclusive property. Using the bills as a catalyst for broader discussion, the author introduces several themes. On a primary level, the scientific, medical, and broader community should be cognizant of the bills as they may be precursors to new legislation with potential future impact on genomics and personalized medicine. Their privacy-through-property approach contains definitional ambiguities (such as using the legal phraseology of "real property"), erects barriers to research and innovation, differs conceptually and procedurally from current genetic privacy legislation, and could herald a return to reductionist genetic exceptionalism. Since genetic research and personalized medicine operate in a borderless (transnational) world where natural and social system divisions are highly porous, patchwork legislation can impede advancement of knowledge transfer, health outcome delivery, and international harmonization and coordination. While these are US bills, they can set precedence with potential traction in globally networked innovation ecosystems that share, and are shaped by, legislation and international norms. Too often, law and science are artificially situated in silos. Yet law is not a disembodied system of ideas; it is a corpus embedded in a larger social structure that includes science and personalized medicine. Broader elements of society must be engaged and educated from the earliest stage of legal reform so that future legislation that impacts genomics and personalized medicine can be steered in a form more closely tuned to social values and the lessons learned from the past history of genetic/genomics research.

Keywords: Bill, culture, discrimination and genetic privacy, genomics and public policy, law and science, law and society, legislation, upstream engagement in law, science and personalized medicine.

1. INTRODUCTION: GENETIC PRIVACY'S PAST AND PRESENT

During the nascent Human Genome Project era of the 1990s, genetic exceptionalism was a prominent topic, coinciding with the media and scientific community-led push to publicize the potential benefits and risks of human genome sequencing [1]. Among those identified risks, commentators most often cited privacy and discrimination. Advocates of genetic privacy harnessed the underlying beliefs of genetic exceptionalism – namely, that genetic information is more sensitive, personal and potentially damaging than other types of personal health information – to advocate for genetic privacy-specific legislation, particularly in the United States (US) [2].

While attempts to enact a federal Genetic Privacy Act failed numerous times [3-7], many states succeeded in passing far-reaching genetic privacy laws, often in the midst of heated debate by privacy advocates, researchers and the biotechnology industry. Several states, namely Alaska [8], Colorado [9], Florida [10], Georgia [11], and Louisiana [12], passed laws that explicitly define genetic information as personal property. Alaska's law states that both "a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed" [8]. The model for such a privacy-through-property approach was the proposed Genetic Privacy Act, which provided at section 104(a) that "an individually identifiable DNA sample is the property of the sample source" [3]. As discussed below, in 1995, Oregon passed the first and one of the strictest genetic privacy laws in the country. It originally granted a property right in genetic information and later extended it to cover DNA samples [13-15]. In 2001, however, the legislature repealed the property rights clause.

Since this flurry of legislative activity more than a decade ago, we have witnessed a genetic privacy quiescence. Yet, perhaps in response to recent case law, decreasing DNA sequencing costs and the development of direct-to-consumer genetic testing, large-scale biobanks, and personalized medicine (*i.e.*, a perceived "new era of medicine" based on the democratization of genomics), genetic privacy legislation has recently been proposed in Massachusetts [16] and Vermont [17]. Texas has also recently introduced a bill that would grant an individual an exclusive property right in a DNA sample provided by that individual [18] (this article addresses the bills in Massachusetts and Vermont, which are more broadly drafted and expansive in scope than the Texas bill). This proposed legislation may reignite the debate

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around privacy protection and rights to and control of genetic information and material. The potential impact on genomics research and personalized medicine is vast.

It is imperative that the scientific and medical community (and broader public) be cognizant of these new bills. Too often, law and science are artificially situated in silos, existing as separate and distinct from one another. Yet law is not a disembodied system of ideas; it is a corpus embedded in a larger, co-evolving social structure that includes science, technology, and personalized medicine [19, 20]. The creation of new laws should not be viewed as a reflection of isolated work by policymakers (*i.e.*, law architects), legislators (*i.e.*, law makers) and jurists (*i.e.*, law scholars) operating in a vacuum. They are often the cause and effect of some wider social reform that in turn impacts science and its conduct both inside and outside the laboratory space. Consequently, the broader elements of society and the scientific community must be educated and engaged from the earliest discussions of legal reform. In the genetic privacy context, this certainly would include the public, research participants/patients, scientists, researchers, and clinicians.

Indeed, these recent privacy bills present a favorable opportunity for the scientific community to partake in upstream engagement in the legislative process. By becoming aware of the types of policies advocated by members of legislative chambers – and members of the lay public – the scientific community can usefully engage in the process of law-making while at the embryonic drafting and discussion stage. Such upstream engagement would assist in breaking the artificial silos between law and science and encourage much-needed dialogue between the two systems. The immediate goal of this article, therefore, is to make the broader personalized medicine and pharmacogenomics community aware of proposed legislation that, if passed (whether in this current session or in future ones), might significantly impact their work. But it bears stressing that although the ensuing discussion stems from bills in the US, it also has global relevance. Faris *et al.* have noted the importance of clear communication between all constituencies (*e.g.*, scientists, researchers and policymakers and the general public) to enable an effective data-intensive science [21]. Developing countries are increasingly contributing to the knowledge of the data-intensive omics sciences. In return, developed countries are increasingly relying on their contributions. The result is progressively more globally networked innovation ecosystems that contribute to the development of, and are influenced and actuated by, legislation and international norms.

The bills discussed in this article matter not just to American scientists, therefore, but to scientists around the world. Bills can be precursors to new legislation with potential future impact on international genomics research and personalized medicine. We have seen in India, for instance, how reactionary concerns over "biopiracy" led to legislation in 2002 heavily restricting foreign scientists' access to its wealth of diverse biological resources [22]. China has prohibited individuals and institutions from sampling, collecting, trading, exporting human genetic resources or taking them outside the territory, or providing them to other countries, without government permission [23]. Many biobank laws in Europe, such as Sweden [24] and Norway [25], restrict the transfer of genetic material outside the home country. In Germany [26] and Portugal [27], individuals retain property rights in their genetic material, even after being permanently extracted from the body. Estonia's Human Genes Research Act stipulates that no tissue samples may leave the country [28]. Undeniably, genetic-specific laws that create a property right in one's genetic material affect *all* persons interested in accessing that genetic material. In short, no law is an island.

This article is organized in five parts. First, it presents synopses of the main features of this emblematic (potential) return to genetic "property" by dissecting the key provisions of genetic privacy legislation proposed in the two US states. Second, it critically analyzes the bills and posits that they are likely not the best means of serving the stated end goals, namely, balancing the interests of the public regarding privacy while simultaneously fostering a climate conducive to innovation. On the contrary, these bills might create more confusion than clarity and potentially erect barriers to research, innovation, and effective privacy protection. Third, the article introduces the notion of upstream engagement and how it might be applied to law and science; it then illustrates this through the example of a new emergent subfield of personalized medicine – vaccinomics – that aims for customized, safe and effective use of vaccine-based public health interventions. Last, the article concludes that law must not be viewed as a domain separate from science; rather, the interests of researchers, scientists and clinicians will be better served if they proactively engage in the political, social and legal debates surrounding genomics and its various branches so that whatever legal reform is enacted represents a policy crafted with input from all significant stakeholders.

2. THE MASSACHUSETTS AND VERMONT BILLS

2.1. The Context

In January 2011, the Forum on Genetic Equity (a Massachusetts-based activist group formed in February 2010) introduced via a sponsoring State Senator, Bill S01080, the "Massachusetts Genetic Bill of Rights", before the General Court of the Commonwealth of Massachusetts. The Forum states that the bill addresses perceived privacy weaknesses at the federal level (*viz.*, HIPAA [29] and the 1999 *Gramm-Leach-Bliley Act* [30]) and the state level (*viz.*, the genetic privacy legislation passed in Massachusetts in 2000, which only addressed employment law and health insurance).

Further, the Forum claims that the post-genomic era environment "where public health realities superseded the existing regulatory apparatus has evolved [*sic*] throwing the public policy regime into a state of ambiguity" [31]. No elaboration of this claim is provided. The bill would "deepen and broaden the progress Massachusetts made a decade ago in balancing the interests of the public, while simultaneously fostering a climate conducive to innovation and prosperity for those engaged in important research" [31].

Several months later, in March 2011, the Forum introduced via a sponsoring State Representative, Bill H. 368

("An act relating to privacy of genetic information", also known colloquially as the "Vermont Genetic Bill of Rights") in the Vermont General Assembly [17]. The two bills are largely similar in substance and therefore their main privacy-related components are analyzed in parallel.

2.2. Genetic Material and Information as One's Property

The first clause of the Massachusetts bill declares genetic information to be "the exclusive property of the individual from whom the information is obtained" and that "genetic material shall be considered real property subject to one's individual control and dominion in accord with generally held precepts of property law in the Commonwealth" [16]. The term "real property" is intriguing for reasons discussed below, and it is unclear if it is used as a legal term or a synonym for "veritable." "Genetic material" is not defined, while "genetic information" is defined as:

> any written or recorded individually identifiable result of a genetic test as defined by this section or explanation of such a result about a gene, gene product or inherited characteristic derived from the individual or a family member of the individual. For purposes of this section, the term genetic information shall not include any information about an identifiable person that is taken:
>
> (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins;
>
> (2) as a blood sample solely for blood banking;
>
> (3) as a newborn screening pursuant to section 110A;
>
> (4) as information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol [16].

Further, the bill defines a "genetic test" as:

> a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying genes, inherited, genetic mutations or acquired genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. Genetic tests shall include those taken in the course of a physical medical exam or a family history analysis. For the purposes of this section, the term genetic test shall not include tests given for drugs, alcohol, cholesterol, or HIV [16].

Even though blood samples taken "solely for blood banking" are carved out from the definition of genetic information, this would appear to only exempt entities such as the Red Cross blood bank. It would not exempt biobanks that store not only blood samples, but also varying types of biological samples, including urine and tissue. Under current Massachusetts law, "genetic information" does not include individually identifiable confidential research information for use in epidemiological and clinical genetic or pharmaceutical research [32]. In contrast, this bill would remove this carve-out, likely disincentivizing the biotechnology industry and universities from conducting critical genetic research. Further, the removal of the carve-out will likely drive researchers to anonymize data to avoid being caught by the definition ("individually identifiable"), hindering the utility of the research and limiting the ability of research participants to receive individual results or withdraw from the research project.

The Vermont bill would amend the state's current statute on genetic testing and health. The general purpose provision declares "genetic information the exclusive property of the individual from whom the information is obtained" and prohibits the disclosure of genetic information without the informed written consent of the person to whom the information pertains [17]. Genetic information is defined as:

> ...with respect to any individual, information about such individual's genetic tests, the genetic tests of members of the individual's family, and the manifestation of a disease or disorder in members of the individual's family. The term includes any request for or receipt of genetic services by or on behalf of an individual and any participation by an individual or his or her family member in clinical research that includes genetic services. The term does not include information about the sex or age of an individual [17].

Notwithstanding the general purpose provision, the bill itself, like the Massachusetts Genetic Bill of Rights, extends the property right to not only genetic information, but also genetic material: "...genetic material shall be considered real property subject to one's individual control and dominion in accordance with generally held precepts of property law in Vermont" [17]. "Genetic material" is not defined. A property right carve-out is created for information derived from "the sequence of the human genome"; such information is considered part of the public domain [17]. It is unclear what is meant by "the" sequence of the singularly defined human genome that remains in the public domain, and "genome" is undefined.

The omni-accordance of property rights to genetic material – that is, unqualified, absolute ownership principles [33] – may achieve the opposite goals from those which the bills aim to accomplish. Genetic material could in theory be accorded certain characteristics of ownership – what the civil law calls *usus*, *fructus*, and *abusus* (*e.g.*, an individual possesses genetic material in his body and has the right to its use, the material can be alienated only by the individual in whose cells the genetic material resides and has a right to any of its revenue, the individual has exclusive use of the genetic information in his cells) – but it does not follow that it should be accorded an unqualified, full property right in law.

Most confusing in both the Massachusetts and Vermont Genetic Bill of Rights is why genetic material has been deemed "real" property, rather than "personal" property as is the case in Alaska, Colorado, Florida, Georgia, and Louisiana [8-12]. Real property generally consists of subsets of land that have been legally defined and improvements permanently attached to it made by human efforts. Examples include buildings, warehouses, factories, offices, machinery,

wells, dams, roads, and leasehold improvements. Personal property (both tangible and intangible), on the other hand, generally consists of anything that is not real property: clothes, money, books, securities, livestock, etc. It is possible that the drafters of the bills used "real" as a synonym for "veritable" and thus wished to emphasize that genetic material is enduring and durable property that remains one's own, but this is a philosophical and metaphorical assertion – not a literal, scientific, medical, or legal assertion.

Not only does classifying genetic material as real property violate basic property law principles, it opens the door to a multitude of unforeseen issues, including tax (real property is taxed differently than personal property), enforcement (real property generally has a longer statute of limitations period), registration (real property usually must be registered in a land registry office) and finance (real property can be mortgaged). This is to say nothing of the problems associated with vesting full property rights, real or personal, in genetic material (*e.g.*, financing by way of a security interest in or other lien on the property, potential value added taxes, abandoned property like cheek cells left on dental floss at a dentist's office or clipped hair at a barber shop becoming the property of the dentist or barber who then sells it, *etc*.).

2.3. Genetic Information as Containing an Inherent Monetary Value

Both bills declare that genetic information contains an inherent monetary value. Prior to entering into a contract to share one's personal health information, genetic material or genetic information, the individual must be notified, orally and in writing, that "their donation is a commodity and is of some material value" [16, 17]. Further, if the collecting entity intends to resell, license, or transfer genetic material for collateral gain in the future, the individual donor "must be made aware and compensated at a fair market value." No formula or procedure is mentioned to determine the fair market value of genetic material or genetic information.

These provisions seem to particularly address biobanks. Indeed, the Forum explains that "biobankers must tell individuals contributing genetic material that their individual genetic material has a monetary value" [34]. It is unclear what the provisions hope to accomplish; they perhaps reflect a belief that an obligation of disclosure will cause potential donors to think more carefully about participation. Nevertheless, it is perplexing to require a biobank (*i.e.*, the receiver of genetic material) to inform the donor of the attributes of the donation, especially when those attributes (a commodity of some monetary value) are not settled in commerce or law (and may never occur as few genes are sufficiently "unique" to be interesting from a commercial point of view). In fact, such a requirement could lead to misrepresentation and expose a biobank to tortious and contractual liability (*e.g.*, negligent misrepresentation and breach of contract).

2.4. Reports and Records as One's Exclusive Property

Reports and records pertaining to any genetic information from an individual would be the "exclusive property" of that person [16, 17]. That record or report would not be considered part of the public record and the contents cannot be divulged by any person having charge of or access to the report or record without informed written consent, unless there was a judicial order or if the data were used as part of confidential "epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease" [16, 17].

The latter thus seems to provide a carve-out for biomedical/clinical research. It is unclear how this provision would conform to HIPAA requirements, though, which state that "covered entities" are not required to obtain prior consent for certain uses and disclosures (*e.g.*, treatment, payment and health care operations) of protected health information, including genetic information. The prior consent requirement, which was in the initial HIPAA Privacy Rule adopted in December 2000, was removed in August 2002 due to its unintended effect of preventing "timely, quality health care to individuals in a variety of circumstances" [35]. Similar concerns regarding the unintended effects of preventing quality and timely healthcare must be considered here if reports of DNA analysis are the "exclusive property" of the individual.

2.5. Required Disclosure of Options to Participants when Seeking Consent

Entities holding genetic information and samples (presumably this includes biobanks) will be required to offer options to participants when seeking written informed consent regarding the use of any genetic material remaining after the purpose for which the material was obtained, including storing the material, donating the material to another individual or for research, and discarding the material [16, 17]. It is unclear how these options are to be actually managed (realistically) over time, and the ensuing open-ended ethical and legal obligations are not discussed. Such obligations and issues include the transfer of and access to information and samples, whether it would be lawful to waive consent where a person holds property rights over a sample, whether de-identification would extinguish the rights of the person from whom the sample was taken, return of results to the individual or family members, and the treatment of vulnerable populations.

It is furthermore unclear how this requirement applies to entities that receive federal funding and therefore must comply with the Common Rule requirements for informed consent [36]. Entities following the Common Rule requirements are afforded various exemptions, including those for research. A federally funded biobank operating in Vermont or Massachusetts could, therefore, face conflicting state and federal requirements for informed consent.

Table **1** below summarizes the salient aspects and putative impacts of the bills discussed above.

3. SITUATING THE BILLS IN HISTORICAL AND THEORETICAL CONTEXT

It remains to be seen whether these state bills are a harbinger of additional genetic privacy legislation, or simply

Table 1. Key Aspects and Putative Impacts of the Genetic Privacy Bills in Massachusetts and Vermont

Key Attributes	Putative Impacts on Genomics Research and Personalized Medicine
• Genetic information/material is exclusive property of the individual from whom the information is obtained • Any report or record of DNA analysis produced using a biological sample from an individual is exclusive property of that individual • Entities holding genetic material/information required to offer options to participants when seeking written informed consent regarding secondary use • Individual providing genetic material/information must be made aware that donation is a commodity and is of some material value	• Increased research and transaction costs • Barriers to commercialization and innovation • Barriers to secondary use of genetic information/material • Potential conflict between state and federal law requirements for informed consent • Hindrance of international sharing of data and samples

an aberration of an otherwise relatively quiescent period of genetic exceptionalism. Vermont and Massachusetts' bills, however, reintroduce genetic material property rights that were first proposed in the 1990s, albeit with a bewildering "real property" twist. It is unclear whether these bills will become laws as they are currently gestating in legislative committees. But there may be political groundswell. The Vermont House of Representatives declared April 25, 2011 to be "Genetic Equity Awareness Day", reflecting in part the belief that "an individual's genetic information and material are the product of that specific individual and should be treated in accordance with the provision of Vermont's civil and criminal codes" [37].

As noted, the bills suffer from serious drafting errors and administrative complexities. They do not specify how to determine the fair market value of genetic material. They claim genetic material and genetic information to be real property subject to one's individual control and dominion, opening a Pandora's box of problems. They also treat property ownership as an absolute concept, which arguably it is not. They demonstrate the quixotic attempt to draft a lucid, workable definition of "genetic information." They introduce what may be unintended barriers to genetic research. Lastly, neither specifically identifies how vulnerable populations – if not everyone – will be affected by the legislation. Granting a property right to each person's genetic material opens the door to commodification of the human body and its tissues, potentially conflicting with current laws prohibiting the purchase and sale of human tissue for valuable consideration [38, 39]. It also leads to misinterpretation, misapplication and unintended consequences in several common contexts, such as a child's participation in a pediatric biobank. Among the myriad questions raised in the latter scenario, can the child demand fair market value payment of his or her genetic material? If so, is such a payment to be sent to the parents? Will it be held in trust until the child reaches the legal age of majority?

The concerns associated with granting property rights in genetic material are not new. During the genetic privacy legislation heyday, several states declined to adopt the privacy-through-property approach. A Maryland bill modeled on the federal Genetic Privacy Act was voted down in 1995 after the Maryland Chamber of Commerce and medical and insurance industry lobbyists argued that its privacy-through-property approach would detrimentally impact research, medical records preservation and the biotechnology industry [40]. New Jersey's proposed 1996 Genetic Privacy Act was vetoed by the state governor because of concerns regarding the potentially negative effect it would have on scientific research. In particular, the governor noted that scientists would be forced to obtain permission to use genetic information and engage in royalty and compensation negotiations with donors [41]. The final version signed into law later that year replaced the property right with a privacy right, acknowledging that an individual's genetic information contains "uniquely" private information about the individual, and offered various protections against disclosure (the current version of the statute states that an individual's genetic information is "personal" information) [42]. Therefore, the essential elements of privacy protection were preserved. Michigan adopted cautious, conservative genetic privacy protections in 2000; its Commission on Genetic Privacy and Progress favored protecting genetic information just like other health data and expressly opposed a property rights approach because it believed that well-crafted informed consent requirements for all health information would more effectively balance individual interests and the public good of promoting research [43].

Several jurisdictions beyond the US have opted to forgo the privacy-through-property approach or genetic privacy-specific legislation altogether. Canada, for example, relies on general federal and provincial privacy laws to safeguard personal and health information [44, 45]. Some of its provinces also recognize a common law or statutory invasion of privacy tort, or both [46, 47]. A recent court decision has noted that, "[w]ith advancements in technology, personal data of an individual can now be collected, accessed (properly and improperly), and disseminated more easily than ever before. There is a resulting increased concern in our society about the risk of unauthorized access to an individual's personal information" [48]. The increasing societal concern, however, has not translated into legislation specifically targeting genetic information or material. Instead, the focus continues to rest on providing adequate safeguards through balanced, up-to-date statutes and methodically evolving case law.

Similarly, the Australian Law Reform Commission and Australian Health Ethics Committee (the Inquiry) comprehensively analyzed its federal, state and territorial privacy legislation in 2003 in the context of protecting genetic information. It concluded that the best means of privacy protection was the harmonization of its information and health privacy legislation and the incorporation therein of human genetic information and material. The possible use of property rights in genetic material as a means of protecting genetic privacy was also discussed – and ultimately rejected. The Inquiry found that a property approach would be difficult to adopt and that its drawbacks outweighed its benefits. There could be unforeseen consequences of extending property law to cover genetic samples, largely due to the strength of the rights that property law provides. Consequently, property law was viewed as a rather "blunt instrument" for protecting a person's interest in his or her genetic material [49].

As the Inquiry noted, there are some benefits to a property approach in regulating genetic information and material. Advantages include: 1) a clarification of the gift relationship between donors and researchers by defining which rights regarding the sample may be transferred, when, and how; 2) an enablement of donors to partake in benefit sharing by way of rights to the possible income and capital of their information or material; and 3) the creation of rights *in rem* (*i.e.*, rights enforceable against all), asserted against those who do not have a right to the information or samples or who have not acted in accordance with the terms stipulated by the individual [49].

Much of the academic literature contemplates the idea that a property right to one's genetic information is the most viable means of protecting the confidentiality of that information [50, 51]. Legal scholar Graeme Laurie argues that a personal property paradigm could complete the picture of adequate protection for one's personality in tandem with other protections such as autonomy, confidentiality and privacy, empower individuals and communities, and provide the crucial continuing control over samples or information through which ongoing moral and legal influence may be exerted [52]. Certain international norms and guidelines also favor reform of property law to provide individuals with better means of protecting the privacy of their genetic information and material. A 2003 World Health Organization report on human genetic databases, for instance, suggests that "[s]erious consideration should be given to recognising property rights for individuals in their own body samples and genetic information derived from those samples" [53].

It may be true that a property right vested in human biological material is the surest means of giving someone autonomous control over the information – thereby making full privacy protection possible. Indeed, it is axiomatic that a property right will protect patients, donors or research participants. That is what property rights do: they act as barriers against any undesired intrusion. But, like the Australian Inquiry concluded, this does not mean that recognizing a property right in law is appropriate. Many conceptual and practical obstacles counter such recognition, as the analysis of these bills has demonstrated.

Though a case may be made from a purely legal perspective that property rights (if not a full ownership right, then a bundle of quasi-ownership rights) can potentially exist in biological human material, there are many conceivable policy and socio-ethical reasons for not recognizing such a right [49, 54, 55]. These are summarized in Table **2** below.

Discussions about a privacy-through-property approach are not simply theoretical; several jurisdictions have adopted it, and therefore we can empirically observe its strengths and weaknesses. Oregon's legislative history provides the most empirically instructive lessons. Several concerns were identified in 2000 by the Genetics Research Advisory Committee (GRAC), a group comprised of "health care consumers," government, biotechnology, pharmaceutical and medical representatives created by the Oregon legislature in 1999 to explore the link between privacy and property. GRAC noted that (1) there had been no attempts to use the property clause in a court action to enforce genetic privacy rights, possibly due to practical difficulties; (2) by making

Table 2. Conceivable Policy and Socio-ethical Reasons for *Not* Recognizing a Property Right in Genetic Material and Information

• Offending notions of human dignity
• Concerns about the commodification/commercialization of the human body
• The undermining of the traditional notion of altruistic participation in research for the benefit of society at large
• The contention that donations of biological material do not warrant special control rights distinct from participation in non-genetic research
• The potential for anyone involved in the research and development process to stake a claim to end results
• The undermining of the principle of solidarity that underpins healthcare systems (this is more true outside of the US context)
• Belief that concerns about informed consent and autonomy are better addressed through other means than affording a proprietary interest
• The ability to copy and reproduce genetic material, undermining a property rights application
• The undermining of the current system of ethical approval for research, where consent to use can sometimes be waived by a research ethics committee
• The increase in research costs (and thus costs to downstream consumers) and time delays due to (negotiated) sales of genetic information and material
• The potential for a "tragedy of the anti-commons" (*i.e.*, individual ownership of human biological material will cause high transaction costs and underuse, thereby thwarting a socially desirable outcome)

genetic privacy an alienable right since it is tied to property, a person giving away a DNA sample simultaneously signs away their ordinarily inalienable privacy rights; and (3) property rights would have a chilling effect on genetic research and the nascent Oregonian biotechnology industry. GRAC ultimately concluded that a property right would not be essential for protecting genetic privacy, but that a law explicitly addressing penalties, discrimination, and obtaining informed consent would sufficiently protect privacy [56].

Moreover, one of the original authors of the 1995 privacy law admitted that the property clause was not created to determine rights to compensation for the use of genetic samples; rather, it was a "metaphor" for privacy [56]. Unsurprisingly, this drafter later recognized the unforeseen danger in transmogrifying this metaphorical language into law, acknowledging in testimony before the Oregon Senate Judiciary Committee that "the property clause... lacks a well-understood meaning and could give rise to a variety of interpretations and unpredictable damages", was "ambiguous", and did not accurately reflect the drafters' true intention of protecting genetic privacy [56]. The Oregon legislature took note, repealing the property clause in 2001 [57]. The foregoing reasons were not state-specific and lobbyist-driven. The Oregon legislative story illustrates well the universal problems associated with conceptualizing and legislating "genetic information as the individual's exclusive property."

4. THE RISKS OF MISMATCHING, DISHARMONIZED PRIVACY PROTECTIONS IN AN INCREASINGLY COLLABORATIVE AND NETWORKED WORLD

Given the policy concerns, Oregon's past experience, and the decision by several states to forego property provisions, it is not clear why certain legislators in Massachusetts and Vermont have decided to return to the privacy-through-property approach. Perhaps the bills reflect petitioning by a narrow polity and will be defeated or significantly amended at the committee stage. Or perhaps they reflect wider, emerging anxieties about large-scale biobanks, the democratization of access to genetic testing made available through new platforms like direct-to-consumer companies and next-generation sequencing, jurisprudence restricting donors' interest in their samples [58, 59], increasing requirements to publicize research data, personalized medicine, and documented concerns about abilities to maintain privacy and anonymity [60-63].

Regardless, at the present time, the bills risk creating a greater patchwork of mismatching privacy protections and tilt too strongly in favor of granting individual rights in genetic data and samples (without addressing vulnerable populations), at the expense of future commercial, clinical and scientific genomic research and innovation that can benefit society. Furthermore, while the privacy-through-property approach in these bills may fail to secure legislative passage, this may not dispel future bills that espouse the same approach (as recently witnessed in Texas) or dim the activism of genetics rights advocates such as the Forum on Genetic Equity, who will continue to push for a privacy-through-property approach.

With the advent of direct-to-consumer genetic testing and next-generation sequencing, investing in the genetic property approach may well prove to be a mostly symbolic gesture as the information (largely indecipherable) of each person's entire genome will be revealed [64]. While a strict reading of property law (*e.g.*, property equates to a bundle of rights) could allow one to confer only a limited right of use upon the owner, as opposed to the full set which includes the right to sell, such legal restrictions may be lost on legislators and citizens. Indeed, the right of use confers control over what is done with one's samples and data, which is exactly what respect for autonomy through the requirement of consent for their use already achieves. The Vermont and Massachusetts bills are unfortunately awash in definitional ambiguities and "biological" exclusions and are thus unworkable. They also herald a return to the reductionist genetic exceptionalism that considered persons the equivalent of their genetic "code." At a time when genomics is operating in a borderless world, where the divides between natural and social systems are highly porous, mismatching legislation can only impede advancement of knowledge transfer, health outcome delivery and international harmonization and coordination.

Because genetic research and personalized medicine are now operating in a borderless and (socially) networked world [65, 66], and no law is an island, it must be stressed that the ramifications apply not only to the particular US context, but also internationally. The legislative disharmony that could erupt with these and other possible future bills risks isolating parts of the US due to its perceived over-extended privacy law protections, and therefore could also jeopardize its currently strong position in international genomics research. It bears repeating that property rights would very likely have a chilling effect on data intensive omics science research and the biotechnology industry, which is already struggling for profits and growth [67].

Privacy policy is increasingly viewed from a broader, global social or public perspective, rather than a local, individual perspective [66, 68]. The bills discussed in this article do reflect traditionally American notions of individual liberty, private property, and scribed bills of rights, yet the implications also transcend political boundaries. They signal a need to address social, political and economic relationships. Science and technology, in particular, are domains less subject to direct or indirect temporal and spatial confinement. The contemporary globalization of research, medicine, biotechnology, bioinformatics, genomics and related omics disciplines may well cause policymakers in other jurisdictions to consider the ideas proposed in the bills in the states – often a hotbed for legislative innovation – as suitable precedence for safeguarding individual rights in a new era of science and medicine. Just as science and technology operate largely free of spatial and temporal constraints, so too law is increasingly penetrating jurisdictional, systemic constraints and acquiring global relevance.

5. BREAKING THE SILOS WITH UPSTREAM ENGAGEMENT

Taken together, mismatching, disharmonized and uncoordinated legislation would be a misstep, given the

conceivable doubts about the merits and legitimacy of these policies and the current absence of fuller inclusion and engagement. Broader elements of society should assume ownership of the bills while they are still in their embryonic period. In particular, the scientific and medical communities should engage in all stages of the lawmaking process to de-monopolize the expertise that is bestowed upon the traditional actors, *viz*., policymakers, jurists, and politicians. Such engagement can vary from becoming informed about proposed legislation and publicly responding (via media, peer-reviewed journals, or conferences), to calling local legislators to voice an opinion, to actively participating in committee hearings. Engagement could also take the form of advocating for the reincarnation of a state or federal-level Office of Technology Assessment, a valuable and productive agency of the US Congress that existed from 1972 until 1995 (coincidentally, the same year that Oregon's genetic privacy law was passed).

Upstream engagement – that is, dialogue and deliberation among the various parties at an early stage, before decisions are locked in, and in advance of social controversies – would contribute to an improved discourse of effective governance and legitimacy and consequently extend existing democratic structures. In fact, it may prevent the kind of *ex post facto* legislative amendments that Oregon undertook after consulting with various stakeholders in GRAC. The scientific community has recently made a concerted effort to foster upstream engagement in a variety of emerging fields, such as nanotechnology [69-71], to "democratize science" and build trust in science policymaking [72, 73]. Policy-makers, jurists, and politicians should likewise be open and participative, at the nascent stage of the process, in the dialogue and deliberation surrounding proposed legislation. Indeed, Hagendijk and Irwin refer to this as a shift from "discretionary governance" (intense reliance on technical and other forms of expert advice) to "deliberative governance" (organized public involvement that responds to and informs the political agenda) [74].

In the present scenario, the shift of discretionary governance to deliberative governance would entail less reliance on the advice of privacy-through-property focused expert policymakers and jurists at the drafting, subcommittee, and debate stages, and greater involvement of various stakeholders (especially the medical, science, and biotechnology communities) at the foundation of reform to respond to and inform the agenda. This model could conceivably mimic to a large extent the processes of the now defunct US Office of Technology Assessment. Even if the Massachusetts and Vermont bills fail to become law, the application of upstream engagement to their legislative genesis would have been well-served, and would also well-serve future similar bills that are likely to enter the public forum. In particular, upstream engagement in this context would encourage informed discussion among various stakeholders in the legislative process (which in genetic privacy or similar bills most certainly includes physicians and scientists). This would produce regulations or laws in the science and technology domain that are not only appropriately drafted and sufficiently broad to anticipate possible future events, but that are also an accurate reflection of consensus among all community members. Thus, the likelihood of a bill's passage is secondary to the main point of upstream engagement: community-wide dialogue and deliberation at an early level is an intrinsically good element of sound governance.

Supportive evidence of this participatory gentrification of lawmaking is seen in the United Kingdom [75] (which has unequivocally endorsed upstream engagement), Australia [49], France [76], and also the US. In the US, the 2003 federal *21st Century Nanotechnology Research and Development Act*, for example, requires public input and outreach to be integrated into the National Nanotechnology Program by "the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate" [77].

It is important to qualify this supportive evidence with the observation that upstream engagement should be viewed as a vital *tool* – not a panacea – to break the present impasse of public participation and legislative estrangement [78]. There is no guarantee that it will lead to greater ownership of any given topic or that its implementation will cause a confined polity to cede major governance and control. Further, one must acknowledge that a confined polity of legal experts, policymakers and special interest groups may not exhibit heterogeneity of opinion and voice; indeed, there can be just as much heterogeneity among the confined polity as there is among the broader community of stakeholders. Nonetheless, upstream engagement offers a promising path to law and science interaction and enlightened policy and governance. It can be applied to a variety of fields, including vaccinomics – a rapidly emerging subfield of personalized medicine as explained below.

6. AN EXAMPLE OF APPLIED LAW AND SCIENCE UPSTREAM ENGAGEMENT: VACCINOMICS

Upstream engagement, from the outset of a knowledge-based innovation, among the science, technology, and medical community is crucial in order to secure fully deliberated and robust legislation in science and technology and related domains (*e.g.*, privacy and discrimination). In the vaccine field, for example, there is currently a gap in available vaccine legal frameworks. With the arrival of the hybrid field of vaccinomics – the integrated use of data-enabled multi-omics approaches to understand biological heterogeneity in vaccine responses [79, 80] – it is crucial that law and science work together to develop effective policies, regulations, and laws.

Whereas vaccinology has been historically rooted in the "second paradigm" of science (*i.e.*, trial-and-error experimentation), leading to limited and underwhelming development of vaccines for major infectious pathogens, recent genomics diagnostics geysering from the fourth paradigm of science (*i.e.*, data-intensive science) are changing the folklore of R&D in the field of classical vaccinology [81]. Scientists are now making important strides understanding the variable vaccine responses within and across human populations that will radically change the use of vaccines [82] and offer unprecedented benefits to global health, including more customized and rational use of vaccine-based health interventions [83].

Vaccinomics is still in its infancy, allowing room for cross-discipline engagement to steer its technology design and innovation trajectory in ways that are attuned to social values [82]. From both a law and science perspective, this is critical. Absent concerted efforts at public education and information and effective use of communication strategies, which are underpinned by broad stakeholder-deliberated policy and legal regulatory frameworks that instill ongoing public trust [84], vaccine deployment and implementation and expansion through vaccinomics may face a contested future, resistance, mistrust, and ultimately, potential risk of failure.

Science and law each offer benefits to the other. As vaccinomics legislation and regulations are debated by policymakers, legislators, and jurists, scientists can offer their unique insights into this highly dynamic technical and conceptual field. For instance, scientists can help these stakeholders in crafting suitable legal definitions of vaccines and related terminology. This should not be undervalued. Taylor *et al*. have discussed how river science and law in Australia are disconnected from one another because of the exclusion of scientific research in legislation (*e.g*., the legal definition of "river") and judicial decisions [85]. This has profound social and economic implications as it influences what activities can be undertaken in and adjacent to these waters. Additionally, in the dynamic and emerging omics fields, the law needs to be responsive and adaptive to the nuances of new sciences. Scientists can engage upstream with those shaping future law; they can offer their insight in coping with inherent sociotechnical uncertainties in vaccinomics by making the co-production of scientific knowledge by technology and social systems explicit [82]. Scientists therefore should actively engage themselves from the earliest stage of law and policy development so that laws and policies accurately reflect the science.

At the same time, law has much to offer science. Ozdemir *et al*. and other commentators have written how data-enabled knowledge-based innovations like vaccinomics depend on new ways of knowledge co-production and coordination of collective action in cross-functional teams, beyond access to novel health technologies [83, 86-88]. Working towards a shared language and learning from other perspectives will help resolve the lack of a common knowledge or language often present in professional disciplines for representing and interpreting the knowledge of other disciplines [89]. It will also foster the creation of extensive vaccinomics knowledge platforms and innovations. For instance, by deeper knowledge and recognition of the dynamic nature of the new post-genomics personalized medicine fields like vaccinomics, and by better historical recognition of the problems associated with previous genetics legislation, the law can extinguish genetic determinism and exceptionalism discourse or policies that may otherwise influence or be influenced by scientists. In the dawn of this post-genomics and personalized medicine era, such discourse or policies disjointed from law and science would not be feasible or recommended, given that vaccine responses (and the infectious agent genomes and the microbiome) are highly plastic, adaptive, and shaped by both genes and the environment. Thus, future vaccine bills and legal frameworks are prime candidates for such law-science upstream engagement.

CONCLUSIONS AND OUTLOOK

Avoiding the Carousel Effect and Moving Upstream to a Co-constructed Law and Science Knowledge Ecosystem

As the example of vaccinomics illustrates, the adoption of an upstream engagement process would do much to break the silos – and myths – of law and science. Traditionally, law and politics are viewed as value-laden sources of ideas (though, fundamentally, law is expected to be impartial), whereas science is seen as a value-neutral, fact-driven source of information that enables policymakers to craft rational legislation that represents truth [90, 91]. Critics of this viewpoint stress that science is neither a uniformly objective, fact-driven and value-neutral discipline [92, 93], nor is law devoid of rationality and legitimacy absent the illumination of science [94].

Oonagh Corrigan has recently written for the CPPM about how post-genomics personalized medicine, science and technology are "co-produced" with, and shaped by, culture, politics and economics in relation to one another [95]. The same co-production may be found in law and science, which regularly operate in a seamless, but sometimes latent, relation to one another. Indeed, as science and technology studies scholar Sheila Jasanoff illustrates [96] and as argued in this article, law and science regularly interact and often mutually constitute each other, though they may blend normative and epistemic considerations in different ways [97]. They are different, but not incompatible, fields. An acknowledgement by legislators and policymakers that legitimacy and authority are not derived *ipso facto* from science, but that the inclusion of science and the science community in the policymaking function is critical for sound governance, would significantly improve laws that reflect a corpus of ideas embedded in a larger social structure that includes science and personalized medicine.

Absent such discourse, ill-conceived and illegitimate legislation will result. This is not to say that broader participation and upstream engagement will – or should – prevent the adoption of a privacy-through-property approach or genetic-specific legislation. If various stakeholders, including the biotechnology, medical and research community, support property rights as a means of privacy protection, then there is consensus, legitimacy and avenues for legal reform that reflect societal norms – though, as this article has discussed above, it could also create international legislative disharmony and potentially disrupt valuable international research collaboration.

Accordingly, while this article details reservations about the privacy-through-property approach, genetic-specific legislation and the proposed bills, this is, in effect, an immediate, "micropolicy" critique. The "macropolicy" critique focuses on the democratic deficit witnessed in the proposed bills and many other aspects of lawmaking. Participation by the broader polity may well influence a recalibration of the current form of these bills to create equilibrium in the desire for social reform that reflects input from a variety of

stakeholders. The recalibration may even lead to reform of ethics, medical, and scientific practice, rather than legislative enactment, to address underlying privacy concerns [98, 99]. Either way, equilibrium does not currently exist since the discussion has been monopolized by policymakers, legislators, and activist groups. The result, as this article has argued, is a poorly conceived and disembodied corpus of ideas. Legislators and citizens alike would be wise to avoid getting on this genetic privacy carousel, which is but the latest manifestation of recurrent concepts presented by a confined polity, and instead engage in upstream dialogue with the extended community about the most effective and balanced, novel means of simultaneously advancing knowledge and privacy protection.

At this early stage of these new bills, in what might be a signal for future legislation impacting genomics, there is ample room for a broadly based dialogue among the legal, science, biotechnology, and general community. While further research and policy experimentation should be undertaken in the US and elsewhere to determine the effectiveness and suitability of upstream engagement, this article proposes that such engagement will help steer future legislation in a way that avoids dangerous pitfalls such as a defectively formulated privacy-through-property approach. Accordingly, communication among all constituencies and across all jurisdictions may help transform isolated, ill-conceived, unworkable policies into an effective, just, socially aware and internationally coordinated 21st century law and science knowledge ecosystem.

ABBREVIATIONS

GRAC = Genetics Research Advisory Committee

HIPAA = Health Insurance Portability and Accountability Act

US = United States

CONFLICT OF INTERESTS

None declared/applicable.

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