

LETTERS

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Trade-Secret Model: Privacy Rights

IN THEIR POLICY FORUM “GENOMICS, BIOBANKS, AND THE TRADE-secret model” (15 April, p. 309), R. Mitchell and his colleagues suggest that trade-secret law could be applied effectively to manage the use of human genomic information. It would be productive to assess

the potential application of two other legal models as well: the individual’s right to control his or her name and likeness, and the right to control public disclosure of private facts.

Jurisdictions that recognize a right of personal privacy commonly include within that right the ability of an individual to control the use of his/her name and likeness for commercial advantage (1). An individual’s name and visual image are deemed

to be unique and highly personal qualities that each person should have the right to control. This right is viewed by the law as part of the individual’s ability to protect the key aspects of his/her personality. Name and likeness have been interpreted to include other characteristics of an individual’s personality, including the sound of his or

her voice (2). It seems reasonable that the legal framework designed to help the individual to protect the integrity of his/her personality should also include the most intimate aspect of an individual’s personality—personal genomic information.

Personal privacy rights also frequently include the ability to control public disclosure of private facts about an individual (3). Arguably, genomic information includes the most private and personal facts associated with any individual. The right to control public disclosure of private facts appears to provide another legal vehicle for management of use of personal genomic information.

Application of these traditional privacy rights can supplement legal approaches such as the trade-secret model proposed by Mitchell *et al.* There may also be circumstances in which the trade-secret model would not be appropriate but the traditional privacy rights could be applied. For example, it is unclear whether an individual can effectively assert a trade-secret claim when the secret he or she possesses is not actually understood by the individual asserting the protection. No such complications arise when a traditional personal privacy right is applied.

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3. California State Constitution, Article I, Section 1B and Florida State Constitution, Article I, Section 23.

Trade-Secret Model: Potential Pitfalls

IN THEIR POLICY FORUM “GENOMICS, BIO-banks, and the trade-secret model” (15 April, p. 309), R. Mitchell *et al.* submit that donating genetic samples for medical research is like selling a confidential commodity of potentially lucrative value, warranting individual licensing arrangements to secure acceptable benefit outcomes. We disagree with this approach to building cancer research biorepositories.

Trade secrets derive value from being unknown and not readily ascertainable (1). By contrast, the value of human subject biospecimens contributed for cancer research

increases with widespread dissemination for use in approved studies, accompanied by open sharing of data. (2–5). Whereas trade-secret doctrine recognizes the necessity of preserving confidential information to further personal gain, research participants contributing samples and associated data are primarily motivated by altruistic, not compensatory, desires (2, 3, 6, 7).

Moreover, the trade-secret model is not practical from the perspective of biobanking operations and governance. How might cancer biorepositories accurately track and implement the diverse licensing preferences of multiple research participants with respect to such issues as determining future research uses of biospecimens, or returning research

results? What if participants wanted to negotiate profit distributions for successful products developed in part based on their contributions? How can the numerous, incremental research advances that precede product development be quantified in order to determine a fair distribution of commercial profits among research participants? Progress in scientific research, particularly in the accelerating world of cancer genomics, is not typically attributed to single biospecimen contributors [Henrietta Lacks (8) notwithstanding]. Heralded by the authors as furthering individual autonomy, the trade-secret model has the potential to foment suspicion and distrust among research participants as they compete for the highest-profit dividends.



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difficult reactions

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In lieu of evaluating the biospecimen contributions of cancer research participants under a trade-secret model, we advocate a custodianship model as set forth in the National Cancer Institute's Best Practices for Biospecimen Resources (9). The custodianship model supposes that biorepositories accept responsibility for ensuring the long-term quality and security of contributed biospecimens and protect the confidentiality of participant data. This model promotes equitable and continuous access to biospecimens for research in accordance with scientifically vetted public priorities, maintaining trust through accountability, transparency, and justice (10).

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7. L. Beskow, E. Dean, *Cancer Epidemiol. Biomarkers Prev.* **17**, 1440 (2008).
8. R. Skloot, *The Immortal Life of Henrietta Lacks* (Crown, New York, 2010).
9. National Cancer Institute, Office of Biorepositories and Biospecimen, 2010 Revised NCI Best Practices (<http://biospecimens.cancer.gov/practices/2010bp.asp>).
10. Custodianship and Ownership Issues in Biospecimen Research Symposium/Workshop, Rockville, MD, 4 to 5 October 2007; <http://biospecimens.cancer.gov/global/pdfs/CaOsumm.pdf>.

Letters to the Editor

Letters (~300 words) discuss material published in *Science* in the past 3 months or matters of general interest. Letters are not acknowledged upon receipt. Whether published in full or in part, Letters are subject to editing for clarity and space. Letters submitted, published, or posted elsewhere, in print or online, will be disqualified. To submit a Letter, go to www.submit2science.org.

Trade-Secret Model: Legal Limitations

THE POLICY FORUM "GENOMICS, BIOBANKS, and the trade-secret model" (R. Mitchell *et al.*, 15 April, p. 309) introduces a new way to promote the autonomy of research participants in genomic biobanks. However, the proposed trade-secret model suffers from socio-ethical and legal flaws.

First, Mitchell *et al.* conflate the "value" of an individual's genetic information with a "secret." Rather than articulating a case for such a link, the authors simply posit that "information encoded by an individual's DNA" is "something of unique value for a certain kind of 'business' (biomedical research)." However, unique values do not necessarily have to be secrets.

Second, the trade-secret model will diminish, not enhance, the autonomy of research participants. Enabling biobank contributors to obtain legal ownership (not mere possession) of their genetic information and set the parameters of its use will not permit them greater self-control, free from external interference. Rather, participants will be subjected to contractual negotiations with biobankers. Because the biobankers will unilaterally draft the "limited menu of options," the trade-secret model could increase the possibility of a power imbalance (1).

Third, the model contains legal and policy flaws. Trade-secret information, by definition, must confer an economic benefit on the holder, deriving specifically from the fact that the information is not generally known (2, 3). Genetic information is financially worthless absent outsourced scientific interpretation and technological application (and even then, there is no guarantee of its financial worth). Trade secrets presuppose that the holder knows the confidential information; here, individuals do not know most of their own genetic information, but the researcher will (4). Also, trade secrets do not ameliorate power balance, autonomy, or compensation issues. They are not instrumental legal tools to serve (bio)ethical ends. They are solely means to obtain an eco-

nomical advantage over others. Do we want to foster a research environment in which biobankers and contributors compete against each other to obtain the most favorable economic terms?

Ultimately, to reap the promised medical benefits of genomic research for all of society, we must eschew the individualistic, procedural vision of research that falsely assumes all actors possess conflicting agendas irrevocably irreconcilable outside a legal forum. We should focus instead on developing robust, transparent, and collaborative research models that will truly benefit humanity (5).

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3. American Law Institute, *Restatement of the Law (Third), Unfair Competition*, § 39.
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Response

IN OUR POLICY FORUM, WE PROPOSED A trade-secret model that would enable greater autonomy for individuals who contribute to genomic biobanks by contesting elements of the informed consent regime. We thank Matsuura, Weil and Compton, and Dove, Joly, and Knoppers for their thoughts on the potential of this model.

Matsuura proposes that personal privacy rights could strengthen recognition of research participant autonomy. Personal privacy rights enable individuals to control public use of personal or private information or characteristics, and are thus a solution to the problem of unwanted public disclosure. Yet whether guided by current human subjects research protections or recent exemption guidelines, researchers generally promise not to make public any link between individuals and their DNA. Our proposal aims to enhance participant autonomy whether or not unwanted public disclosure becomes an issue.

Our model does not require that individuals understand their secret, as both Matsuura and Dove, Joly, and Knoppers suggest. The information qualifies as long as it "derives economic value, actual or potential, from not being generally known" (1).

We do not oppose the custodianship model advocated by Weil and Compton, although we find it legally complex and indeterminate. We do disagree, however, with several of their claims. We do not “submit that donating genetic samples for medical research is like selling a confidential commodity of potentially lucrative value.” Rather, we believe that prospective participants view their DNA as confidential property, and often consider the terms and conditions—which may include financial compensation—upon which they might permit its use. Liking a participant’s DNA to a trade secret does not imply that its primary value is personal gain, nor does it preclude “widespread dissemination for use.” On the contrary, the licensing of trade secrets often encourages widespread dissemination. Researchers working on “approved studies” can, if inclined, include in their menu options a provision for open sharing.

With respect to practicalities, we do not propose recognizing the “diverse licensing preferences” of participants. We propose that biobanks offer participants a limited menu of licenses that differ, for example, in the nature of the compensation and the extent of the permitted use. Just as sharing biospecimens motivated creation of material transfer agreements, licensing needs can drive creative approaches to track permitted options. We also wish to clarify that although Weil and Compton (understandably) refer frequently to cancer research, we think that our model should be tested first among healthy volunteers.

Weil and Compton’s claim that our model may “foment suspicion and distrust among research participants” seems inconsistent with their claim that research participants “are primarily motivated by altruistic, not compensatory, desires.” Our research suggests that participants are motivated by both altruism and money, with the respective contributions varying among individuals (2)—a reality that our model recognizes. We feel that the current interpretation of human subjects regulation is more likely than our proposal to alienate many among the large populations necessary for biobanking, given that informed consent often serves as a quasilegal device to ensure that an institution retains rights to whatever is derived from a biospecimen yet absolves itself of liability. Our model, by contrast, offers a way for individuals to be actual partners, rather than simply “subjects,” in biobank research.

Dove, Joly, and Knoppers are concerned that we conflated “value” with “secret.” However, we described these terms as the

two distinct elements of the legal definition of a trade secret: It must have economic value to its proprietor, and it must not be generally known. The avid interest of medical science in obtaining DNA samples seems to be conclusive evidence that a person’s genetic information has economic value. Likewise, it seems self-evident that DNA information cannot be generally known unless and until the person chooses to make it available.

We do not see why a menu of options would in principle promote a power imbalance, as Dove, Joly, and Knoppers suggest, given that a menu could be developed in cooperation with likely participants. Such an imbalance seems more likely in the present system of informed consent. Currently, the prospective participant has two choices—take it or leave it—and all terms are dictated by the researcher, and are probably legally unenforceable by the participant (3).

The fact that “genetic information is financially worthless absent outsourced scientific interpretation” is not relevant. Many trade secrets cannot be exploited without third-party expertise and resources—that is why their proprietors license them out.

Finally, Dove, Joly, and Knoppers suggest that increasing contributor autonomy may run counter to “robust, transparent, and collaborative research models.” We disagree that autonomy and collaboration are opposed, given that true collaboration seems to require that each participant retain autonomy. The idea that the trade-secret model necessarily facilitates rampant individualism is a misunderstanding of the concept of intellectual property. Contrary to what Dove, Joly, and Knoppers contend, trade secrets—and intellectual property generally—can indeed be “instrumental legal tools to serve (bio)ethical ends.” Intellectual property owners use their rights to promote the public interest all the time; for example, PXE International holds and uses a patent (which could just as well be a trade secret) not for profit but to promote its health agenda.

If our proposal were given a trial among healthy volunteers, we suspect that many if not most of them would seek the same eleemosynary ends for which Dove, Joly, and Knoppers argue. However, our proposal would let participants make that choice, rather than deferring to scientific and academic elites who speak for them.

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3. Greenberg v. Miami Children’s Hospital Research Institute, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

CORRECTIONS AND CLARIFICATIONS

Reports: “Adipose triglyceride lipase contributes to cancer-associated cachexia” by S. K. Das *et al.* (8 July, p. 233). Fig. 1G shows normalized white adipose tissue (WAT) weight of gonadal, retroperitoneal, and visceral WAT. In Fig. 1, G to J, descriptions of “epididymal WAT” actually refer to retroperitoneal WAT. In addition, the last complete sentence on p. 235 should read, “To assess the contribution of adipose tissue loss to the tumor-induced weight loss, we determined white adipose tissue (WAT) mass by visual inspection, weighing surgically removed adipose depots (gonadal, retroperitoneal, and visceral adipose tissue) and in vivo nuclear magnetic resonance (NMR) WAT quantitation.”

Research Articles: “Scale for the phase diagram of quantum chromodynamics” by S. Gupta *et al.* (24 June, p. 1525). The corresponding author’s e-mail address was incorrect. It should be bmohanty@vecc.gov.in. The address has been corrected in the HTML version online.

TECHNICAL COMMENT ABSTRACTS

Comment on “A Test of the Snowball Theory for the Rate of Evolution of Hybrid Incompatibilities”

Daniel A. Barbash

Matute *et al.* (Reports, 17 September 2010, p. 1518) tested the theory that the number of genes involved in hybrid incompatibility increases faster than linearly. However, the method they used is inappropriate because it detects genes that are haploinsufficient in a hybrid background but that would not contribute to lethality in wild-type hybrids, thus overestimating the frequency of hybrid inviability.

Full text at www.sciencemag.org/cgi/content/full/333/6049/1576-b

Response to Comment on “A Test of the Snowball Theory for the Rate of Evolution of Hybrid Incompatibilities”

Daniel R. Matute, David A. Turissini, Jerry A. Coyne

Barbash claims that deficiency mapping of inviability regions cannot distinguish hybrid lethality from haploinsufficiency, the phenomenon whereby a single functional copy of a gene cannot maintain normal function in a hybrid genetic background. Although we acknowledge that his hypothesis deserves careful experimental testing, we argue against his conclusions and provide evidence that our methodology is suitable to study the evolution of Dobzhansky-Muller incompatibilities.

Full text at www.sciencemag.org/cgi/content/full/333/6049/1576-c