Selling Clinical Biospecimens: Guidance for Researchers and Private Industry

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Abstract: The recently revised Common Rule requires that donors of biospecimens for research be informed if their specimens might be used for commercial profit. The Common Rule, however, does not apply to sharing or selling de-identified biospecimens that are "leftover" from clinical uses. As a result, many medical researchers remain uncertain of their legal and ethical obligations when a commercial entity expresses interest in these specimens.

Introduction

Health systems face numerous pressures to utilize patient data for research purposes and, in turn, to use the outcomes of research to improve patient care. Some advocates of "learning health system" models, where research and treatment take place simultaneously, argue that health care providers even have a moral duty to share patient data for research purposes.[1] Because providers "are uniquely positioned to seek, conduct, and contribute to learning activities that can advance health care quality, economic viability, and a just health care system," providers and the institutions they work for must "accept a responsibility to feed information into the system that increases our knowledge."[2]

A particularly controversial aspect of this push to blend research and care is the role of private industry. Even if clinicians have a duty to share patient data for research, one might think that such data should only be shared with certain trusted entities, perhaps only academic research institutions. Commercial entities, however, are a major recipient of patient data, both for research and clinical purposes. For example, Geisinger Health System in Pennsylvania partnered with Regeneron Pharmaceuticals to sequence the DNA of patients who agreed to participate in the MyCode Community Health Initiative, a precision medicine program with an affiliated systemwide biobank.[3] As of July 2023, over 184,000 patients' DNA have been sequenced, and more than 4,513 patients have received clinically actionable results.[4] In return, Regeneron received broad permission to use patient specimens and their associated genetic sequence for drug development and a wide range of other revenue-generating purposes.

This paper focuses on the sale of patients' biospecimens to private companies without patient consent and for unspecified uses, either research or non-research, and provides guidance to both researchers and commercial partners in navigating the associated ethical and legal issues. Unlike the Geisinger-Regeneron partnership, many health systems share patient specimens that are remnants or "leftover" from clini-

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cal tests. Because they are considered discarded specimens, they can legally be shared without patient consent, as long as they are de-identified. The recently revised Common Rule requires that individuals donating biospecimens for research should be informed if their specimens might be used for commercial profit.[5] However, this only applies to specimens acquired through the process of consent for research. The Common Rule does not apply to the question of whether health systems can share or sell de-identified specimens leftover from clinical testing, since they are generally regulated under the Health Insurance Portability and Accountability Act (HIPAA). As a result, many medical researchers are uncertain of their legal and ethical obligations when a commercial entity expresses interest in these specimens.

We begin by presenting a fictional case to illustrate sharing of leftover specimens with industry by academic medical centers. This case is an "easy" one, without some features that raise ethical and legal concerns that will be discussed later in the paper. We summarize relevant regulatory and legal debates about commercializing biospecimens, ultimately arguing that there is no strict legal or ethical restriction on selling leftover clinical specimens to industry, regardless of purpose. At the same time, possible types of agreements, such as ones where a healthcare institution is promised payment for providing leftover samples in the future, can raise important issues with conflict of interest. Even if all legal and ethical requirements are met, health systems could lose patients' trust by routinely sharing their specimens without informing and involving patients in such decisions, in some way. We conclude by proposing possible strategies for addressing the most significant ethical and legal concerns and for improving health systems' trustworthiness in using or sharing leftover biospecimens.

Even if all legal and ethical requirements are met, health systems could lose patients' trust by routinely sharing their specimens without informing and involving patients in such decisions, in some way.

Case: Commercializing Cervical Swabs

Consider the following fictional case: While conducting a Pap smear on one of her patients, Dr. Smith collects a cervical swab to test for chlamydia. The results come back positive. There is some leftover material from the swab, which may be valuable to the center for STD research on campus. Once the label has been removed from the tube containing the leftover specimen, it will satisfy the definition of a "de-identified" specimen, exempting it from federal laws that would otherwise require patient consent to use the specimen for federally funded research or research to support an application to the Food and Drug Administration. A researcher from the university working on treatments for chlamydia approaches Dr. Smith to ask whether she would be willing to share some of the leftover material. Sharing the specimen is costless to everyone involved, falls outside of regulations requiring institutional review, and contributes to important medical research, so Dr. Smith agrees to share the specimen.

A local biotech company also contacts Dr. Smith to request cervical specimens for its own purposes. The specimens technically belong to the university, which requires the involvement of university administrators to negotiate a contract to share these leftover specimens with the company. The company agrees to pay the university a reasonable and customary sum of money for the specimens. None of that money goes directly to Dr. Smith, but she is hopeful that the company will produce important research and treatments for chlamydia and other STDs, just like her colleagues at the university's center for STD research.

This case illustrates common dispositions of biospecimens after collection during clinical encounters: diagnosis, research at an academic center, and sharing with a private company, potentially for both research and non-research uses. Only the initial testing during a clinical encounter requires patient consent, and many patients will be completely uninformed of the other downstream uses. In the following sections, we discuss relevant regulatory, legal, and ethical considerations for cases of this sort, including ones that raise more questions.

Regulatory Context

The Common Rule is the primary federal regulation covering the commercialization of biospecimens collected for research. However, the Common Rule does not apply to the sorts of activities described in the case above, since the leftover biospecimen was collected

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for clinical purposes, not research. There is no regulatory requirement to inform patients that their leftover specimens might be sold to private companies.

Even in the research setting, where consent must be obtained for use of leftover specimens, the Common Rule imposes few limitations on commercialization. Changes to the Common Rule that went into effect in 2019 require that individuals be told during the consent process if their specimens could be sold to commercial entities, even if the specimens are de-identified.[6] However, no other details are required in consent materials to explain the nature of the commercialization. Thus, even when the Common Rule applies to sharing clinical samples with a private company, there is no obligation for hospitals or clinics involved in commercialization to name the companies, their intentions, or to describe future possible usage.

The Health Insurance Portability and Accountability Act (HIPAA) requires that covered entities de-identify specimens in accordance with certain standards, unless patients have signed a HIPAA waiver indicating that they permit the sharing of their protected health information.[7] In cases like the one described above, the institution would likely require a Material Transfer Agreement (MTA) stating that the university has ensured that protected health information, as defined by HIPAA, has been removed from the specimens. Because the biotech company is not a covered entity, and the specimen has been de-identified, HIPAA has no further applicability.

MTAs are a contractual tool for sharing biospecimens for research. There are no strict legal requirements for their use in cases like Dr. Smith's, but relevant guidance can be found in the widely recognized National Institutes of Health's (NIH) research tools policy, which strongly encourages the use of MTAs to promote prompt dissemination and sharing of NIH-funded research.[8] The NIH policy explicitly aims to facilitate sharing the data and technologies with commercial entities, reasoning that in some cases "private sector involvement is necessary or the most expedient means for developing or distributing the resource."[9] As long as commercial use does not reduce access for the broader scientific community, the NIH policy would in principle support the case above.

In short, current regulations are broadly permissive and offer little guidance when sharing remnant, de-identified specimens, either for research or for commercialization.

Legal Context

Two common legal debates concerning the acceptability of commercializing biospecimens involve claims about physicians' fiduciary duties and patients' ownership of their genetic information. Considering these debates indicates that Dr. Smith's actions are legally permissible in the case described above, but slight changes in the case could lead into murkier territory, raising important legal questions about ongoing commercialization of biospecimens.

Fiduciary Duties and the Patient-Physician Relationship

The cases of Henrietta Lacks and John Moore are often cited in arguments against commercializing patients' biospecimens. In both of these cases, physicians appeared to have violated their fiduciary duties to their patients because their personal interests influenced patient care. Both Lacks and Moore were subjected to clinical testing and biospecimen collection without being specifically informed that certain collections were unrelated to their diagnoses and treatment. Furthermore, neither was informed that their physicians (or their collaborators) could profit from selling the specimens.[10] The question here is whether there is a similar fiduciary duty for physicians like Dr. Smith in the case above that should prevent them from sharing their patients' biospecimens. We will focus only on Moore, as his case occurred more recently, under conditions more similar to the current regulatory environment, and his care was more evidently impacted by his doctor's conflict of interest.

In *Moore v. Regents of California*, Dr. Golde and another researcher, Shirley Quan, developed a cell line from John Moore's T-lymphocytes that had been initially removed during his clinical care. The cell line was then patented by UCLA. An agreement was negotiated with Genetics Institute, Inc., for the commercial development of the cell line, such that Dr. Golde received stock in the company and a consultant salary. Moore became aware of the commercialization of his specimens during follow-up visits in which revised consent forms asked him to waive ownership rights over his cell line and any related products. The Court ultimately held that while Moore was not entitled to any financial benefit from his profitable cell line, he was legally entitled to have been informed of Dr. Golde's financial interest in his biospecimens. That is, there was a legitimate legal claim for a breach of fiduciary duty. The case is frequently cited to support the proposition that patients have a right to be advised of a physician's economic interests to the extent those

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interests are unrelated to the patient's health and may affect the physician's professional judgment.

It is generally agreed that physicians have fiduciary duties to their patients.[11] Patients are in a position of vulnerability and dependence. They entrust doctors with power over their health, including control over their personal information. As a result, physicians must avoid significant conflicts between their personal interests and their patients' health. This includes not receiving a profit from their patients' treatment, beyond employment compensation. They also should not put themselves in a position where their personal interests prevent them from informing their patients about what might be done to them — including what might be done to their specimens.

In Dr. Smith's case, however, patient care appears unaffected. The doctor is not personally profiting from sharing specimens, nor is she altering her patients' care as a result of any commercialization interests, so it does not appear that she broke her fiduciary duty to her patient. In this case, at least, it does not appear that commercializing biospecimens in itself directly violates the physician's fiduciary duty to her patient.

Ownership of Specimens

Some have argued that, ultimately, patients should always be allowed to decide what happens to their body, including specimens they provide as part of clinical care.[12] Although the law has tended not to see things this way, we will discuss one argument for patients having greater power over their biospecimens than has been recognized.

The standard legal view is that patients lose ownership of their biospecimens once the specimens are discarded.[13] However, Jessica Roberts has recently proposed that patients can claim ownership over their genetic information contained in biospecimens.[14] Patients can make a claim of conversion to the effect that they own a portion of their discarded specimens (the DNA) which has been stolen from them. This is similar to the argument made in *Moore,* but such a right to genetic ownership could allow patients to take legal action to limit commercial use of their biospecimens to a greater extent than has been previously allowed.

Roberts's review of recent legal rulings on genetic ownership highlights problems that could occur in situations like Dr. Smith's. In the case of *Peerenboom v. Perlmutter* (2017), a private forensic testing company collected Isaac Perlmutter's genetic material from items he handled at a deposition, in order to place him at the scene of a crime.[15] Perlmutter sued and won, with a Florida circuit court concluding that the genetic information was stolen property. The court reasoned that there are important privacy interests in genetic information, and that previous cases (like *Moore*) had not ruled decisively against the idea that one's DNA constitutes property. The degree of deception involved and the fact that Perlmutter had contributed his DNA involuntarily also led the Court to conclude that a claim of conversion was appropriate.

Analogously, patients could claim that healthcare systems' sharing their de-identified specimens with private companies amounts to stealing their property. Although patients give their clinical specimens voluntarily, they arguably have not voluntarily given their specimens to private companies. If a biotech company sequenced the DNA of a de-identified specimen, they would be engaging in an activity similar to the forensic company in *Perlmutter*. They would be able to identify the patient based on this data, and the patient could make a claim that their privacy had been violated. Because they have not undergone a standard consent process, patients could argue that they were deceived into allowing such use of their specimens.

Currently, this possibility is speculative and the recent case of *Dinerstein v. Google, LLC* 484 F. Supp. 3d 561 (N.D. Ill. 2020) suggests the hurdles for patients attempting to make such arguments will be substantial. Specifically, while the Court in *Dinerstein* found that the plaintiff had standing to bring his breach of contract claim, he could not use a purported breach of HIPAA as a vehicle for doing so. Further, the plaintiff was required to show actual economic damages in order to satisfy his claims. Ultimately in that case, the Court granted defendant's motions to dismiss, confirming there is not much appetite from Courts for expansion of either HIPAA or contract law to cover issues related to patient privacy in the context of health data.

Even if such approaches became more standard, however, healthcare institutions might respond by pointing to the standard agreements that patients sign before receiving care, which often outline a wide range of possible uses of patient data and specimens, including commercialization.[16] Sometimes these agreements also include an agreement to participate in research, but since they do not specify the research project, such agreements would not satisfy the requirements of informed consent under the Common Rule. Such agreements might more accurately be described as contracts. There are good reasons to doubt that the included agreements in such contracts regarding the use of patient data and samples would be upheld in court, since patients have no choice but to accept the proposed terms in order to receive treatment.

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Spector-Bagdady highlights a similar imbalance of power and knowledge in contractual agreements between patients and companies offering direct-to-consumer health services.[17] If challenged in court, health care providers would likely have to demonstrate that they attempted to ensure that patients understood the terms of their consent, including that the biospecimens could be sold to commercial entities. The chaotic nature of many clinics, where there are other competing priorities, makes it doubtful that institutions regularly satisfy such a requirement. As the law currently stands, however, healthcare institutions do not need to rely on these agreements to justify their sharing of unidentified samples that are left over from clinical testing.

Conflicts of Interest Raised by Financial Expectations

We argued that within a legal context there do not appear to be any fiduciary conflicts in Dr. Smith's case described above. However, the ethical and legal issues become more complex if Dr. Smith starts conducting tests on her patients with some expectation of selling their biospecimens or if her institution has an ongoing agreement to sell such specimens. Such arrangements may still be ethically and legally permissible, but the potential conflicts should be carefully examined.

The most straightforward conflict would come from Dr. Smith or her healthcare institution signing a prospective agreement to share her patients' de-identified biospecimens in exchange for money. For example, imagine that the biotech company and the university negotiate a contract that will require Dr. Smith to share 100 specimens over the next year in exchange for $5,000. Such an agreement would alter Dr. Smith's motivations for treating her patients. She would be extracting biospecimens from patients knowing these samples would make her more money. As empirical studies on conflicts of interest (COI) show, it is difficult for people to resist changing their behavior in response to such incentives.[18] A COI exists even if Dr. Smith intends to ignore the incentive in her treatment decisions.

Additionally, COIs can be present even without the promise of payment. Social and professional relationships also alter incentives. For example, Dr. Smith may expect to rise in status on campus or simply to cultivate good will from sharing the specimens. Such benefits can be as potent as financial compensation in leading physicians to change their patients' care.[19] Of course there are many such possible incentives as physicians grow and modify their clinical programs, and they are hard to track, but they nonetheless remain important when considering the ethics of commercialization. In one recent case, researchers in the VA San Diego Healthcare System agreed to share leftover specimens from clinical liver biopsies with a research study, but then regularly removed extra liver tissue during biopsies specifically to provide them to the research project.[20]

Another possibility is that any financial compensation will go only to the university, not Dr. Smith. There has been very little attention paid to whether academic medical centers also have fiduciary duties to their patients. The fiduciary relationship is thought to exist primarily between the patient and their physician. However, it is clear that the university could introduce a COI for Dr. Smith — for example, by suggesting that Dr. Smith's employment is dependent on her helping meet the contractual agreement with the biotech company. Such a suggestion could lead Dr. Smith to change her treatment decisions, which would threaten her fiduciary duties to patients. An analogy might be made to the opioid crisis, where certain healthcare institutions and universities pressured clinicians and researchers to take actions that would attract funding from the opioid industry.[21]

Even if there is no formal agreement to share specimens, a COI can also arise merely from clinical investigators and healthcare institutions knowing that the specimens have commercial value. Suppose that Dr. Smith has previously negotiated lucrative agreements with private industry. She may expect that any leftover specimens she collects from clinical tests will eventually be able to be sold, even without a standing contract. Collecting leftover specimens while *planning* to sell them is enough to raise concerns that a COI exists. It is ethically problematic if clinical tests are based on the possibility of selling patient specimens rather than patients' needs.

All of these COIs are worth considering in cases where biospecimens are shared without patient consent. Typically, physicians are not allowed to have financial COIs, while non-financial COIs are allowed but routinely evaluated (e.g., by institutional COI review committees). The mere existence of these COIs does not alone make such sharing impermissible, but they do require oversight. The permissibility of the arrangement depends on the exact role of the physician, the university, and the terms of the agreement with the company.

Patient Attitudes Toward Commercialization

Some commentators have worried that commercialization of biospecimens, whether from patients or research participants, would damage trust in medical

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research and ultimately lead to a generalized reluctance to share specimens and other data for research.[22] Caulfield and colleagues argue, based on a review of the literature up to 2014, that people trust biobanks less when commercialization is involved.[23] In a recent survey with over 800 participants, Spector-Bagdady et al. found that more than 75% would be uncomfortable if their university hospital benefited financially from sharing leftover biospecimens.[24] Two-thirds of the participants also wanted explicit notification if their biospecimens were used by commercial entities. That is, they were concerned with both commercialization and sharing specimens without consent. Many other studies with potential biobank donors have confirmed that people object to sharing their specimens and associated data with commercial entities.[25] These finding stand in contrast to studies showing a wide range of support by patients for sharing data and leftover specimens for research in general,[26] even in some cases where they did not give consent.[27]

These findings suggest that patients may respond negatively to finding out that their leftover specimens are being sold to commercial entities. While there is some evidence that patients will accept commercialization when the specimens are used for medical research aimed at benefiting everyone,[28] allowing commercial entities to use specimens with no expected benefit for patient care could damage patient trust in medical research and healthcare institutions more generally. Such a response does not imply, necessarily, that sharing the specimens is unethical, but it does indicate a problem that should be anticipated and addressed pro-actively.

One possible response in the clinical context would be to obtain patients' informed consent before sharing or selling their leftover specimens, and to do so in a way that does not bury the information during the general consent to care, as discussed above. However, the empirical evidence suggests that people often do not understand what it means to share specimens for secondary uses, even when explicitly informed of this possibility in consent forms. For example, Garrett and colleagues found that only 19% of biobank participants understood that pharmaceutical and biotechnological companies could receive their information, and only about half understood that government agencies and other researchers might receive their information.[29] Similarly, in a previous study, our research team found that less than 10% of participants understood that information was being shared outside the biobank at all, including for commercial purposes.[30] These misunderstandings persist despite numerous attempts to make the relevant information clear and easy to understand in informed consent materials.

As mentioned in the introduction, the distinction between research and care is increasingly unhelpful in making decisions about sharing specimens and associated data. Because of this traditional distinction, the laws, regulations, and ethics governing consent take a largely situational approach to specimen collection (Are you in a clinic or a research lab? Is the person collecting specimens a clinician or a researcher?).

In short, obtaining more explicit patient consent to use leftover specimens is unlikely to significantly affect patient understanding. Patients will likely continue to misunderstand who is using their specimens and for what purposes. One further option would be to educate patients in some ongoing way, separate from their consent to care. They could be informed, for instance, when one of their leftover specimens is sent to a commercial entity. Such disclosure would not be to obtain their consent but to make sure the institution is acting in a fully trustworthy and transparent way. The idea here is that given the lack of strong regulation over sharing leftover biospecimens, the goal for institutions is to answer to a high standard of trustworthiness. They should proactively do more than the legal minimum to protect patient specimens and data, rather than waiting to see whether current practices lead to patient distrust.

From this perspective, there would be a presumption in favor of disclosing commercial agreements to patients, including details about likely downstream uses of patient specimens. There are many difficult questions involved with this (e.g., How will such information be communicated? Should the company's name be shared?), but the general approach is worth exploring.

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More transparency about the details of how specimens will be used could help improve patient understanding of why such partnerships exist, thereby hopefully avoiding many of the issues discussed here. For example, Michigan Medicine requires disclosure of specific industry collaborators in consent forms, if those collaborators are known at the time of consent.[31] Similar disclosures could also be provided outside of the process of informed consent for either care or research.

Conclusion

There are multiple legal and ethical arguments that support the permissibility of sharing leftover clinical specimens with industry. Selling such specimens does not inherently violate the legal or ethical fiduciary responsibilities of doctors and their institutions or currently conflict with legally recognizable ownership claims over discarded specimens.

At the same time, sharing samples in certain ways can raise important issues of COI for healthcare systems and providers and may reduce patient trust in clinical care and research. In response, some institutions may wish to pursue a higher standard of ethical behavior, or focus on assuring trustworthiness, through steps such as providing ongoing disclosures to patients about use of their leftover clinical samples.

As mentioned in the introduction, the distinction between research and care is increasingly unhelpful in making decisions about sharing specimens and associated data. Because of this traditional distinction, the laws, regulations, and ethics governing consent take a largely situational approach to specimen collection (Are you in a clinic or a research lab? Is the person collecting specimens a clinician or a researcher?). However, we have reached a point where the context of collection does not determine how the data are used. It is not just that materials collected for patient care are routinely used for research. Sometimes specimens studied for research are also used in clinical care, which is essential to learning health systems, as health systems like Geisinger have implemented in returning actionable genetic test results to patients. What matters is what is collected (e.g., whole genome information vs. billing information) rather than why it's being collected. We need to move to a more realistic model that takes into account what is being collected and what we reasonably understand to be the potential destination of the specimen. Better transparency around these downstream uses will be essential for operating in the legal and ethical gray zone that exists for commercializing biospecimens.

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