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Samera Ahmad [Date]

The Economy of Eyes: Examining the Ethical Status of For-Profit Entities in Eye Banking

By Samera Ahmad
Master of Arts

Bioethics

_____
Gerard Vong, DPhil
Advisor

_____
Yousuf Khalifa, MD
Committee Member

_____
Rebecca Pentz, PhD
Committee Member

Accepted:

_____
Lisa A. Tedesco, Ph.D.
Dean of the James T. Laney School of Graduate Studies
_____ Date

The Economy of Eyes: Examining the Ethical Status of For-Profit Entities in Eye Banking

By Samera Ahmad
B.S, Georgia Institute of Technology, 2015

Advisor: Gerard Vong, DPhil

An abstract of a thesis submitted to the Faculty of the James T. Laney School of Graduate Studies of Emory University in partial fulfillment of the requirements for the degree of Master of Arts in Bioethics 2020

Abstract

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By Samera Ahmad

Corneal transplant is the most common transplant performed in the United States, with more than 80,000 performed in 2018. The industry has grown rapidly in recent years thanks to the introduction of new processing techniques. Business changes have also occurred in the past few years, with the recent introduction of for-profit entities into the eye banking industry. These for-profit entities are participating not just in the traditional functions of an eye bank, such as the recovery, processing, and distribution of tissue, but also participating in corneal transplant research and development. For-profit entities in a human donation industry raise several ethical questions, and a dedicated examination of the ethical concerns with for-profits is essential to understand and evaluate their role in the eye banking industry.

To achieve this examination, I begin with an interview survey that was performed with corneal surgeons and eye bank leadership on their attitudes toward for-profit entities in corneal donation. There were several positive outlooks noted, such as the ability of for-profit entities to perform more research and innovation. There were also several ethical concerns, most frequent of which where the potential of for-profit to exploit donor generosity, the loss of local tissue with for-profit entity expansion, and loss of donor trust if notified of for-profit entities in corneal banking. I then focused on these three most frequent concerns to see if a more comprehensive ethical analysis could illuminate if these concerns were relevant to for-profits or offered any reason to reject for-profits in eye banking. I determine that none of the concerns in the interview actually provide an incontrovertible reason to reject for-profits, and that ethical differences between for-profits and non-profits might instead originate from the structural differences in

their business model. Most notably, for-profits allow for the participation of investors and shareholders in their business, which creates conflicts of interest between the duty to donors and the duty to investors. I conclude that for-profit entities in eye donation must address these conflicts of interest in their operations, and I suggest several interventions to help ensure the ethical management of conflicting interests to investors and donors.

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Chapter One: Introduction

As the organ and tissue donation arenas have evolved in the United States, ethical questions have continued to arise that challenge our traditional notions of how donation should be conducted. Organ donation organizations are coming up with ever new ways to maximize the donation rate to attempt to bridge the gap for the many patients waiting on transplant recipient lists, whereas tissue donation, including eye donation, faces a surplus of incoming donations, which has brought its own corresponding questions of how to manage a donation system with no scarcity (Chu 2000, Moshirfar et al. 2018). Eye donation, or more precisely corneal donation, rid itself of waiting lists more than a decade ago, and the industry has slowly shifted in several ways away from the original eye banking models. Previously, eye banks would recover tissue from local hospitals or morgues, place the tissue with local corneal surgeons, the surgeon would perform any pre-transplant tissue processing in the operating room, and then transplant the tissue. The first major shifts were that once the waiting lists were eradicated, corneal tissue could be placed with surgeons on a scheduled basis. In other words, a surgeon can freely schedule their transplant surgeries, notify the eye bank of their upcoming transplant surgeries, and the eye bank can promise tissue on the date of surgery (Chu 2000, Moshirfar et al. 2018). Additionally, eye banks began to have a surplus of tissue domestically, and many began to partner with foreign surgeons to export any excess tissue (Moshirfar et al. 2018, Gain et al. 2016). One additional change was that newer techniques of corneal transplant were being invented; these techniques promised improved success rates of the transplant graft but required a larger amount of pre-operative processing of the tissue (Mannis and Sugar 2018). The corneal tissue had to be carefully separated, such that only a few layers of the cornea would be transplanted, as opposed to the full thickness of the cornea (Rose, Kelliher, and Jun 2009). This processing was originally

performed by surgeons in the operating room, but as eye banks began to enjoy the financial benefits of having a surplus of tissue, some began to have the resources to process the corneal tissue within the eye bank itself (Richard L. Lindstrom 2017, Moshirfar et al. 2018). This meant that when surgeons would receive the tissue, it would already be ready for transplantation without the need for any additional operating room processing. This ability to process tissue within an eye bank meant that eye banks could now charge surgeons or surgery centers not just for the tissue, but also for the cost of processing the tissue (Richard L. Lindstrom 2017, Moshirfar et al. 2018, Mannis and Sugar 2018). This created a new form of revenue for eye banks and significantly increased the revenue capacity for eye banks that could offer this service. As some eye banks became more experienced in the processing of tissue, they sought to solicit additional partner surgeons in order to increase the revenue stream from processing and distribution (Richard L. Lindstrom 2017, Moshirfar et al. 2018, Mannis and Sugar 2018). With eye banks having an unprecedented capacity to bring in capital, the first for-profit eye banking entities emerged. These novel for-profit entities combined the traditional functions of an eye bank with a for-profit business structure, including investors and shareholders (Richard L. Lindstrom 2017, Moshirfar et al. 2018, Mannis and Sugar 2018).

For-profit entities seem like they would be discordant with the current National Organ Transplant Act (NOTA), which generally forbids any valuable exchange for human tissue (Champney 2016). But, NOTA makes an exception for the standard costs associated with the recovery, processing, and distribution of tissue (Champney 2016). In the United States, this is a necessary exception, otherwise the donation industry would have to be reliant on volunteers to function. Being able to recover some of the expended cost allows organ and tissue banks are able to employ support staff, have brick and mortar processing and quality control locations, and

provide more specialized processing techniques for surgeons and patients. The NOTA does not specify a limit for what a reasonable cost might be, which gives organ, tissue, and eye banks leeway in their setups and account for fluctuations in medical and operation costs over time. Similarly, the NOTA does not contain any language that mandates that donation banking entities must be non-profits. Through these policies, there is nothing to stop a for-profit entity from entering the donation marketplace. The flow of profits into a for-profit eye banking entity generally comes from processing and distribution of corneal tissue. To better illustrate this, I will describe the various steps in corneal banking, using a hypothetical corneal transplant scenario, and then describe the flow of money for a for-profit entity in corneal banking.

Donation Pathway

In exploring this topic, it is important to outline the donation pathway in detail, as it will be often referenced in the ethical analysis. Suppose there is a scenario where a person has just been declared deceased, and they died in such a manner that the hospital determined they may be a candidate for corneal donation. The next step is the hospital will alert the local eye bank, or sometimes a local organ/tissue procurement agency, and the eye bank will begin the process of vetting the donor tissue (Eye Bank Association of America , Liaboe et al. 2015) . If the donor is determined to be eligible for recovery, a recovery agent will go out into the field and recover the corneal tissue, while simultaneously performing in-person assessments of the donor that will assist in determining if the tissue is appropriate for transplant. The tissue is returned to the eye bank, where the tissue is assessed for quality. If the tissue quality and donor history, physical, and lab work suggest that the corneal tissue is eligible for transplant, the tissue is then matched to a surgeon who has placed a request for tissue for an upcoming scheduled surgery. The tissue is processed by a processing technician for the particular needs of the surgeon, and then rechecked

for a final quality checkpoint. Finally, the tissue is then packaged and shipped to the surgery center where the surgeon is affiliated (Eye Bank Association of America , Liaboe et al. 2015). The surgeon can then utilize the tissue for the transplant operation. It is important to note here that the activities covered in the donation pathway (i.e. recovery, quality control, processing, distribution) are not always performed by one singular entity. Corneal tissue may be recovered by one bank, then transferred to another for processing and distribution. Or, tissue may be recovered and processed by one bank, but then distributed via another entity.

After the corneal tissue has been placed with the surgeon, the up-front cost of the tissue is paid for by the surgery center or by the physician's practice (Bentley and Hanson 2014). Following the completion of the surgery, the surgery center or ophthalmology practice will file for reimbursement from the patient's insurance company. Insurance companies tend to follow the reimbursement patterns set by the Center for Medicare and Medicaid Services (CMS), which has currently granted corneal transplant a pass-through status (Bentley and Hanson 2014, Hayden, Kelly, and Rapuano 2012). What this means is that there is no set reimbursement rate for corneal transplant surgeries, and the insurance company will reimburse any reasonable amount of money that the surgeon or surgery center requests. The pass-through status of corneal transplant may make variations in corneal tissue cost less noticeable to surgeons or surgery centers, as they will be appropriately compensated even if the tissue is more expensive.

For-Profit Entities in Donation

For a for-profit entity in eye banking, the opportunity to make a profit comes from this initial charge to surgeons or surgery centers for their corneal tissue product. The for-profit eye bank can charge more than what they expended on the corneal banking activities (e.g. recovery, processing, quality control), which would allow them to accumulate a profit. This does not

necessarily mean though that they are charging more than other eye banks to garner this profit. If the for-profit is able to perform their eye banking processes at higher efficiency than the non-profit banks, then they may be able to charge the same amount as a non-profit eye bank while still making a profit. But, even if they are charging slightly more than a non-profit eye bank, there is unlikely going to be any resistance from surgeons or surgery centers, as their full reimbursement is still protected due to the insurance pass through status of transplant surgeries (Hayden, Kelly, and Rapuano 2012, Bentley and Hanson 2014). For-profit eye banks in the United States have also begun offering novel additions to their tissue, such as devices or media additives, which can only be accessed if a surgeon or surgery center agrees to purchase tissue from that eye bank (Mannis and Sugar 2018). The total cost charged at the time of surgery then includes both the tissue and the added device, and the eye bank can then garner profits from the device sales as well. Again, the cost of the tissue and device will have pass-through status when a surgery center files for reimbursement. The tissue transplant saw a shift to for-profit entities almost two decades ago, and the tissue industry has shown that the strategy of accumulating profits through deceased donation is extremely lucrative (Agnos 2003, Thompson and Kendall 2009). In 2013, the overall market value for the tissue banking was reported to exceed $2 billion (Fabregas and Conte 2013). Public data does not yet exist on the size of the eye banking market, but it is undoubtedly continuing to grow each year as eye banks expand in size and capacity.

The Ethical Challenge of For-Profits

The intersection of profit-making and human donation has been ethically examined in the past in the context of organ sale and for-profit tissue processing, and the conversation is with the changing landscape of eye banking. It is worth a dedicated review of the ethical status of profit making, and specifically for-profit entities in eye/corneal donation. This thesis will attempt to

address the ethical status of for-profit entities in corneal donation, in particular examining if there are any relevant ethical concerns that are unique to for-profit entities in corneal donation that might be ameliorated with adoption of new policy or regulation. For example, these for-profit entities in eye banking may be involved in any of the various activities of eye banking, including processing, distribution, or research, but any of the above may be referred to in this thesis as for-profit eye banks for shorthand. As for-profit entities in eye banking solely exist in the United States, the scope of this thesis will be limited to eye banks in the United States, as well as the markets and regulations within the United States.

Structure of Thesis

As no prior empirical studies have been done to address ethical attitudes toward for-profits in cornea transplant, it was decided to perform an attitude study with corneal surgeons and eye bank leadership as foundation for this ethical examination. This not only serves as a launching point for discussion, but also gives a survey of the landscape that is useful for determining which discussions and concerns are of most interest to the corneal transplant community. I will describe this study in detail, including a full review of the results. I will then focus on three of the most prevalent concerns identified in the interview study, with the goal of determining if any of the concerns can provide an ethical reason to object for-profit entities in eye banking. I will particularly highlight that many of the concerns identified in the interview study apply to both for-profits and non-profits in corneal donation. Finally, I will argue that for-profit entities are not inherently an immoral part of the donation industry, but that their financial structure creates conflicts of interest between investors and donors/donor families. I will detail ways in which these conflicts of interest may be problematic throughout different stages of the donation pathway if not properly mitigated. I will conclude with recommendations for policy and

regulation reform that may help to create more transparency and alleviate some of the competitive pressures. Next, I will briefly review some of the ethical concerns that have arisen in related literature on organ or tissue transplant.

Concerns in the Literature

Previously, literature on profit making from organ donation has focused on the ability of donors to be able to make a profit through the sale of their organs. Arguments against such a practice note that the sale of organs may be exploitative and disproportionately impact those who are impoverished, as organ sale leverages monetary gain to induce people to undergo an unnecessary medical procedure (Greasley 2014, MacKellar 2014) . Others argue that organ sale is dehumanizing, as it places a dollar value on a human part (Greasley 2014, MacKellar 2014). The underlying argument here is that humans have an inherent value that cannot and should not be capitalized on (MacKellar 2014). Again, this literature is focused primarily on donors being allowed to make profit from their organs, which is not the scenario at hand in corneal donation, but it still highlights concerns and attitudes toward human parts that may be relevant here.

This literature on for-profits in tissue donation have noted that of for-profit entities in tissue banking may not be adequately covered in the consent process with donor families (Siminoff, Traino, and Gordon 2010). Moreover, some have suggested that knowledge of for-profits in tissue banking may dissuade people from wanting to participate in donation (Siminoff, Traino, and Gordon 2010, Agnos 2003). Some worry that profit making is disruptive, or possibly even exploitative, of the altruism that motivates people to donate (Kirby 2012, Wilkinson 2004). Other notable concerns include how research is conducted using donated research tissue, and if products created from something such as donated skin are ethically distinct than a product created from purely synthetic materials (Kirby 2012, Petrini 2012, Pirnay et al. 2015). Some

have also wondered if there should be a particular status for how to market products that originate from donated tissue, and if marketing that minimizes the role of donor altruism in developing such a product is disrespectful (Agnos 2003).

This is by no means an all-encompassing review of the transplant literature, but it introduces several of the ethical strands that might be relevant to corneal transplant. The previously identified concerns are a helpful starting point for discussions on corneal transplant and for this thesis, were particularly useful for creating salient interview questions for members of the corneal transplant community. Next, I will detail the qualitative interview study conducted with corneal surgeons and eye bank leadership, which attempts to describe the most prevalent attitudes toward for-profit entities in eye banking amongst these parties. The study will examine not only concerns with for-profits, such as the ones detailed above, but also assess positive attitudes toward for-profit entities to determine if people perceive any particular benefits from them. This interview study will provide useful insight into which of the previously mentioned concerns are salient to corneal transplantation.

Chapter Two: Interview Study on For-Profits in Corneal Donation

Chapter Two redacted due to copyright restriction. Chapter Two is published at:

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and

https://journals.lww.com/corneajrnl/Abstract/publishahead/Ethics_in_Eye_Banking__Understanding_Professional.96206.aspx

Chapter Three: Examining Ethical Concerns of Interviewees

Interviews with eye bank leadership and corneal surgeons in eye banking revealed several key ethical concerns amongst the community with the entry of for-profit entities (Ahmad et al. 2020). In order to better understand the ethical status of corneal transplant, it is vital to critically analyze these concerns against existing literature and evidence. Any intersection of human donation and business is bound to cause fear and concern, and some participants in the study indicated that they do agree that for-profit entities in eye banking raise ethical fears. Of the concerns raised in the empirical study, three were pervasive amongst both corneal surgeons and eye banking leadership to warrant a thorough ethical examination (Ahmad et al. 2020). In this chapter, I will aim to further assess these three prevalent concerns raised in the empirical study to examine if they are truly justifiable ethical reasons to reject the entry of for-profit entities into eye banking. The concerns I will focus on in this chapter are 1) profiting from donation is exploitative of a gift, 2) for-profit entities in donation may damage donor trust, and 3) for-profit entities in eye banking will lead to loss of local tissue supply.

Profiting from Donated Tissue

In the empirical study performed, participants from both groups tended to agree that profiting from donated eye tissue was exploitative of a donor gift, and many participants provided open-ended answers that mirrored this sentiment (Ahmad et al. 2020). The Likert-scale statement used for the interview study asked participants if "profiting from donated human tissue exploits the generosity of donors and the inherent monetary value of their donated tissue" (Ahmad et al. 2020). This statement is multifaceted, and there are several ethically relevant fragments within that must be assessed. The first phrase contains two key words worth separate examination: donated and human. I will begin by first examining the claim that it is ethically

objectionable to profit from gifted tissue and then move to assessing the claim that it is ethically objectionable to profit from human tissue.

Profiting from a Gift

The ethical claim in the statement included in the interview study intentionally included the word donated, in an effort to emphasize the gifted nature of corneal tissue, and 23% of participants in the study echoed the language of corneal tissue as a "gift" in their qualitative responses (Ahmad et al. 2020). Organ and tissue donation has been examined previously through the lens of gift giving, most famously via Titmuss's work on blood donation (Titmuss 2018, Rapport and Maggs 2002). Corneal donation could fit within the framework of gift giving as it is typically offered freely by the donor and donor family for no remuneration; the foundation of the motivation to donate is to promote the general good of society, as opposed to any material gain for oneself or for a business/corporation. In other words, donation is an altruistically driven process, and the ultimate goal of donors or donor families is to provide something of benefit to another person (the recipient). Donation is not dissimilar to the colloquial understanding of gift giving of any item, although analogous with charitable giving such as clothing donation, as donors do not have the opportunity to select the recipient of their gifted cornea, and that donors must rely on several other parties to facilitate the provision of their gift to the recipient. In the context of corneal donation, these parties include eye banking entities (performing recovery, quality assessment, processing, and distribution of the corneal tissue) and surgeons (performing the transplant of the corneal tissue).

Understanding that corneal donation may be understood as a gift raises the original question from the interview survey: is profiting from a gift fundamentally exploitative or unethical? Some may object to profiting from a gift as being unethical as such an act potentially

goes against the intended goals and motivations of the gift giver (Camenisch 1981). But, if we are assuming that gift giver is acting altruistically, then the gift giver must recognize that the transplant recipient has the right of self-determination over what to do with the gift. Stated another way, the giver must release control of the item to the recipient for it to be an altruistic act (Gill and Lowes 2008, Camenisch 1981).

In assessing the claim that the gift giver should allow the recipient to have self-determination over the gift, it is worth considering the larger impact on the gift-giver if the recipient does choose to profit from their gift. If the gift-giver has given something of extreme sentimental or personal value, they may expect that the recipient will treat the gift with the same reverence and value as the gift giver. If the recipient then chooses to profit from said gift, the gift-giver will likely not only be tremendously offended by the action, but if the gift was one that the giver valued tremendously, they may come to view the recipient as an undeserving and untrustworthy recipient of such a gift in the future. In the context of corneal donation, this is a noteworthy outcome, as people tend to assign a large importance to donated human tissue, and trust that others will give an appropriate amount of respect to their tissue after donation is an essential element of people's decision to donate. But, as described above, in corneal donation, the recipient is not the person who is making the decision to financially profit from the tissue; instead, the external parties responsible for stewarding the gift from the donor to the recipient are the ones who are profiting. This actually may circumvent the outcome described above then, as gift-givers will still likely view the recipients as worthy of the gift, although they may question then the external arbiters of the tissue.

But it is worth noting that there are ample alternate situations where gift giving may rely on some other party, and that external party's decision to profit does not damage the gift-giver's

decision to contribute. To use a commonplace example, gift givers often rely on mail or package delivery services to transmit the gift to the recipient, which could be analogous to a for-profit distribution system for corneal donation. Mail and package delivery services are by and large run as competitive, profit making entities. Although perhaps a reductive illustration, it does suggest that we already commonly accept that third parties should be allowed to garner a profit from a gift through facilitating the gift relationship, and we do not consider such an act to be exploitative of the gifter's generosity. Of course, this is contingent on appropriately stewarding the gift for its intended use as according to the wishes of the gift-giver, but assuming this to be true, then there is nothing inherently exploitative or unethical about such an action.

To conclude, although third party profiteering is theoretically ethically permissible, in the case of corneal donation, the practicality is much more complicated. Appropriate stewardship of human tissue is complex, as the expectations of donors/donor families for these stewards may vary widely and the balance of trust for donation entities can be particularly fragile. For some donors, an eye banking entity garnering a profit from their gift may be acceptable, as long as their gift still reaches the intended recipient and is able to provide some good, but others may view such an action as subverting the gift-relationship as they intended. This topic will be revisited in the next chapter, but this is simply to highlight that profiteering does not necessarily render third-party stewardship unethical. Other factors, such as appropriate stewardship of the gift, must be considered.

Profiting from Human Tissue

The second key component of the ethical statement in the original Likert-scale statement is that the donated item being profited from is obtained from a human body (Ahmad et al. 2020). On review of the literature against profit making from human tissue, many of the arguments are

based on objections to the commodification of human tissue, which often is reliant on the pretext that human bodies (and their component parts) belong in a sacred class of material objects (Wilkinson 2004). According to this line of argument, humans are uniquely complex, autonomous, self-sufficient beings, and allowing humans or human parts to be treated as a market good is objectifying and dehumanizing to the unique value of humans (Petrini 2012, Wilkinson 2004). The sanctity of the human body is a complex ethical topic which will not be discussed fully here, but suffice to say that those who perceive commodification to be immoral would thereby object to profit making from human tissue, as it is dehumanizing to equate a dollar value to the inherent value of humans and human bodies. Upon more critical evaluation of this claim, it is clear that this contention is inconsistent with currently accepted behaviors regarding humans and human tissue.

Although some may claim that commodification of human tissue is unethical or exploitative, the reality of the matter is that our current system is based on and allows for some amount of commodification. As a nation, it is accepted that some amount of money can be exchanged through the trade of human tissue, as written into the National Organ Transplant Act (Thompson and Kendall 2009). The National Organ Transplant Act does technically legally prohibit the purchase or sale of human organs or tissue, but it also contains an exception clause for the costs associated with the stewardship of the organ or tissue between the donor and the recipient. What this means, in practice, is that all eye, tissue, and organ banking entities request a reimbursement cost from a hospital or surgery center for the donated organ provided, as a medical device company would for a surgical implant or tool; in other words, they treat the human tissue as a medical commodity. It would seem that in the United States eye banking system, this revenue is necessary to allow for corneal transplant to occur at all, as organ and

tissue procurement, processing, and distribution could not operate on a purely volunteer basis; ergo, this is an ethically appropriate form of revenue generation in the aim of the larger good that organ, tissue, and eye transplant provide. Some may argue here though that the situation presented does not necessarily qualify as commodification of human tissue, as money is not directly made from the tissue, just from the associated operations needed to properly utilize the tissue. But there are current examples of human parts that are commodified more directly, and it is worth briefly exploring if relevant ethical differences exist between those parts and corneal tissue.

There are several human parts that are excluded from the National Organ Transplant Act, such as human sperm or human plasma (Thompson and Kendall 2009). In the United States, tissue and blood banking institutions have less restrictions on the acceptable transactions with these tissues; for example, people are often compensated for providing sperm or plasma, and various medical or biotech companies may freely utilize these human tissues to garner revenue and profit. The products may be processed and sold to another person to be used for its original biological purpose, as in the case of sperm donation for artificial insemination. Alternatively, the human tissue may be sold for research and medical device creation; altogether, these practices drive a massive domestic market via the profits they incur (Grand View Research 2018). This is a clear instance of human commodification, but unlike corneal tissues, this commodification is ubiquitous, legal, and commonly accepted as ethically sound (Grand View Research 2018, Farrugia, Penrod, and Bult 2010, Wilkinson 2016).

There are a few notable distinctions between the group of human parts that are an established part of the marketplace and corneal tissue that should be considered. The list of human parts accepted as ethically sound to sell and make profit from described here is by no

means an extensive list, but it is amply representative for the ethical analysis necessary. The first distinction of note is that as opposed to corneal tissue, the tissues listed above are all renewable parts of the human body. In other words, people are able to produce more plasma, blood, or sperm to replace those that have been donated. Ethical arguments that favor commodification in particular for renewable tissues typically are that they risk less physical harm to the donor, their renewability lessens the risk of regret, and they by nature are less scarce than other human organs (Dworkin 1993, Sobota 2004).

Corneal donation may only occur post-mortem, unlike the renewable tissues mentioned above. I will not aim to detail arguments of why living versus deceased humans may hold different ethical value but will note that commodification of tissue from post-mortem donors may actually be more ethically sound than living donors based on current literature. There is no risk of physical or psychological harm to the donor with post-mortem corneal transplant donation, as opposed to something like blood or sperm donation which each carry small but still relevant risks to the person donating. Moreover, there is a lower risk of inducement to donate in post-mortem donation, as they are not receiving any sort of reimbursement (MacKellar 2014). Altogether, corneal tissue is not necessarily ethically distinct from tissues that are directly commodified in the current market, and arguments against for-profits for this reason are ethically inconsistent with current practice in the United States.

Some may argue that there is an ethically relevant difference between revenue and profit in their acceptability. Revenue here is referring to any income that is accrued from some exchange or some action. Profit alternatively refers to revenue that is earned in excess of the expenditure necessary to complete said exchange or action. Although an eye bank's tax designation may be either "for-profit" or "non-profit", both entities may actually accrue some

amount of profit in the traditional sense as defined above. The designation of non-profit does not mean that the eye bank cannot or does not earn revenue greater than its expenditure, but simply that any excess revenue (i.e. profit) must be routed back into the functions and missions of the eye bank.

Non-profit entities are structurally designed to serve some charitable purpose, and as such they enjoy tax exemption for their entity. Moreover, they can be given a 501(c)(3) designation, which means that allows for tax deductible charitable donation to the organization (Malani and Posner 2007). But, to maintain such a status, non-profits and their leadership must commit themselves to their charitable mission, and any accrued revenue must reflect such a commitment. All revenue is to be reinvested back into the mission of the charity, and individuals (including non-profit leadership) may not gain any financial advantage through their contribution, financial or not, to the non-profit. To ensure such a fact, there are legal limits on the amount of profit that may be accrued by a non-profit, and non-profits must disclose publicly their finance sheets at the end of each fiscal year, detailing how their revenue and profits were utilized for the year (Hofmann and McSwain 2013). For a non-profit eye banking entity, this means that they are typically operating with fairly narrow or negligible profit margins, as they may only be recouping revenue equal to their costs in recovering, processing, and distributing the tissue. For-profit entities are structured to support a profit-making operation, and as such, they are permitted to engage in activities to promote such a mission that would be forbidden to non-profit entities. For example, they may offer reciprocal ownership stake in their entity, where if a person contributes financially to a company, they are able to expect some form of financial re-compensation if the company experiences financial success; this is to incentivize a larger influx of capital into the for-profit entity to finance their operations as they establish themselves and

their business (Malani and Posner 2007). Additionally, they do not have the same limitations on how much profit they may accrue or how such profit should be used. In exchange for these business freedoms, they are not given any tax exemptions and are also not expected to maintain the same level of transparency of their finances (Malani and Posner 2007). Knowing the key differences between for-profits and non-profits, it is possible that some participants may have been objecting to excess accumulation of profit from human tissue or use of profit for non-cornea transplant related activities, which is a topic to be revisited in the next chapter.

Participants in the interview study were asked to reply to a complex ethical statement, and by and large voiced their concern that profit making from donated corneal tissue would be exploitative of donors and their generosity (Ahmad et al. 2020). On a further examination, it can be seen that several different ethical interpretations of this statement are possible, but that all fail to stand up as a singular reason that for-profit entities in donation must be ethically rejected. It may be unfavorable to profit from a gift, but it is not necessarily unethical; similarly, profiting from human tissue, either directly or indirectly, may be disturbing to some, but it would be ethically inconsistent with current practice to claim that for-profits should be ethically rejected for that reason. Analysis of this concern though has elicited several ethically salient points worth further examination, such as the issues of competition, consolidation, and consequences of increased profit making on the practices of the corneal transplant community. These will be further addressed in future chapters, with the important note that these ethical issues implicate both non-profit and for-profit eye banks.

Damage to Donor Trust

The results of the interview study show that the majority of participants in both the eye bank leadership group and the corneal surgeon group hold the ethical concern that widespread

public knowledge of for-profit entities in eye banking may disrupt donor or donor family trust (Ahmad et al. 2020). This ethical concern is predicated on the notion that donor and donor family trust in donation institutions is paramount to people consenting to donation. As already detailed above, in donation, people must rely on third parties to carry out their altruistic goals; they must trust that this system will honor the altruistic goals that they hope for, or they may not participate in the system at all. This is obviously quite a precarious situation, as loss of public trust then risks people choosing to not participate in donation, decreasing the overall number of corneal donations in this country. Much work has been put into ensuring the eradication of the waiting list for corneal transplants in the United States, and regression from this achievement could be seen as quite catastrophic for both surgeons and patients.

In assessment of this ethical concern, a historical review of the literature is useful for understanding why this fear is so prevalent, as well assessing if there is any evidence to suggest for-profit entities in eye banking may damage trust in eye banking entities. First, I will begin by looking at studies that may suggest that loss of donor trust may result in a decline in donation rates. The PANAORAMA scandal is one of the earliest examples of how widespread public mistrust can hurt donation rates. In 1980, the BBC aired a primetime news special that called into question how physicians determine brain death in advance of donation, with the program insinuating that physicians are procuring organs from people who are not actually dead – that they are killing people or letting them die in order to obtain their organs (Matesanz 1996). This program was viewed by many in the United Kingdom, and although disputed by the National Health Service, the program still created public outrage and mistrust in the donation industry. Donation rates fell in the subsequent months, taking more than a year for the rates to return to their prior levels (Matesanz 1996).

More recently, a report from Shaw, Neuberger, and Murphy (2013) details the consequences of a public scandal in four donation/ transplant agencies in Germany. The agencies were found to have been manipulating recipient lists and creating fraudulent medical records in order to move certain patients to higher priority status for receiving a liver transplant. The issue was first discovered in 2011, and over the next year, knowledge of the agencies' misconduct became widespread amongst the German public. Donor rates of organ dropped more than 20% over the next two years, with donation of other organs, corneas, and tissues similarly declining in this period (Röck et al. 2017, Shaw, Neuberger, and Murphy 2013). These examples illustrate the potential harm that may arise from a loss of public trust in donation and transplantation entities, especially in the age of mass media and social networking. With this historical background in mind, it is important to now look to existing literature on for-profit entities in donation to see if they may elicit a similar effect on donation rates.

Siminoff, Traino, and Gordon (2010) conducted an interview study of families who had recently made a decision whether or not to donate a loved ones' tissue in order to assess what factors may have been important to their consent decisions. Participants were asked if they agreed or disagreed with the Likert-scale statement that it is "acceptable for tissue to be processed and distributed by for-profit companies" (Siminoff, Traino, and Gordon 2010, 12). The majority of families, including ones who consented to donation and ones who did not, did not agree with that statement, and the authors concluded that for-profit entity involvement in donation may be one of several key factors in a family's decision whether or not to consent to tissue donation (Siminoff, Traino, and Gordon 2010). Unfortunately, no formal data exists to show that knowledge of for-profit entities in eye banking prior to donation may actually deter donation consent from families, and this is a vital missing piece of the current literature. In lieu, I

will examine how existing laws on for-profits has been received by the public. These may suggest a pattern of attitudes amongst the public with regards to for-profit entities, but do not replace the need for formal analysis.

In certain parts of the country, informed consent procedures already include information on the potential use of tissue by for-profit entities. For example, as of 2003, California state law mandates that informed consent for tissue donation in California must make clear that for-profit entities may be involved in the processing of the tissue (Katz 2005). This came in the wake of an investigation by the Office of the Inspector General (OIG), who conducted interviews with donors in order to determine their attitudes toward tissue banking companies becoming for-profit and utilizing donated tissue for cosmetic products (Agnos 2003). The investigation concluded that donors may not object to profiteering from tissue processing, but objections arise when this profiteering occurs in excess (Agnos 2003). In response to the OIG's recommendations, California chose to adopt a policy of allowing for-profits to operate within the state but mandated that informed consent procedures must include information on for-profits and provide families an option to donate without processing by for-profit entities (Agnos 2003, Katz 2005). This study demonstrates two important points; first, donors and donor families do not find profiteering from donated tissue to be entirely unacceptable but do have standards for how much profit is acceptable. It is possible that this reflects a feeling amongst some donors that a for-profit entity is not disruptive to their altruistic donation goals, so long as someone is appropriately being aided at the end of the process. Second, this law has now been in effect for many years, but has not had the outcome of significantly lowering the tissue donation rate in California (Vertanous et al. 2016). Again, this data is particular to tissue donation and cannot necessarily be applied to eye

banking but may be a supportive indicator that the public would not necessarily distrust for-profits in corneal donation.

Of final note, many participants were concerned about how donors might react to for-profit entities but expressed very little concern for other potentially controversial factors in eye banking. For example, excess corneal tissue in the United States is often exported and placed with a foreign recipient; this is a widely accepted practice done by both non-profit and for-profit entities, but one that may also have the effect of hurting donor trust (Martin et al. 2017). For example, a local Las Vegas newspaper reported in August 2019 on a mother who was incredibly upset to discover that her son's corneas were exported to a foreign recipient (Hynes). The mother in the article felt her son's donation was exploited, and she took to social media to attempt to warn other potential donors of this possibility (Hynes 2019). There are no statistics to show exactly what her social media reach was, but the article suggests her intention was to alert a wide audience to her concerns. Although for-profit entities may be a novel introduction to the eye banking system, it is inconsistent to treat for-profit entities in eye banking as something uniquely dangerous to the donation rate, as this article clearly illustrates that foreign export of tissue may be just as damaging to donor trust as the inclusion of for-profits. It is not to suggest one is particularly worse than the other, but just to show that for-profits are not the singular concern in maintaining corneal donation rates; issues of maintaining donor trust implicate the entire eye banking community, including non-profit entities as well.

Although there are some historical instances of donation scandals or donation misinformation causing drops in donation rates, there is evidence to suggest that for-profit entities in donation have already been reported on and publicized, and that no resulting scandal has followed and no fall in donation rates ensued. Moreover, there are other currently accepted

practices in eye banking that could pose the same threat, although the practices are deemed to be ethical. There is a need for further research in this area to fully characterize how the general American public may feel about the issue of eye banking, but critical examination of this ethical fear suggests that it may not be as drastic as some worry about.

Loss of Local Tissue

In the interview study conducted, there was no closed ended question pertaining to the issue of local tissue, but fears about the impact of for-profit entities on local banks and the local tissue supply they provide was identified in the qualitative answer set by 23% of participants (Ahmad et al. 2020). Traditionally, eye banks operated based on their local geography, with local recovery and local distribution; the original EBAA constitution dictated that eye banks should respect this local sovereignty and that new eye banks should not open unless there is unfilled need geographically (Holt 1965, Moshirfar et al. 2018). Typically, locality was indicated for eye banks at the state-level, with at least one eye bank per state; rarely more than one eye bank existed within a state if such a need existed. But, in recent years, some eye banks have begun moving into other states and other geographic regions to perform recovery of tissue and will subsequently distribute tissue to surgeons in other states, or even in other countries.

In our study, for participants who extrapolated on their ethical concerns with losing local tissue, the justifications can be grouped into two different arguments. The first were justice-focused objections to the distribution of donated tissue to recipients outside of the location where the donor was based on local sovereignty. The second were concerned about the damaging outcomes that may result for recipients without a local bank, such as a decline in the amount of donated tissue or the unavailability of emergency tissue for urgent transplant surgeries. I will explore each of these concerns, with the aim of understanding their validity as a specific

objection to for-profit entities in corneal tissue banking. A review of non-local eye banking systems is a useful starting point for understanding why this fear was pervasive amongst the participants.

Justice and Non-Local Distribution

The ethical issue of sending tissue to a recipient who may not be locally related to the donor is one that the organ and donation community is facing at large, and it is worth considering how corneal donation may relate to the literature written on this topic for other types of donation. Those who favor a local model for organ and tissue distribution claim an ethical obligation of governments to arrange their donation systems such that they can provide adequate tissue for those within their population. As was briefly covered in the last chapter, this claim suggests that being able to adequately provide for the population within one's borders is vital to an area's sovereignty; in other words, if suddenly, interaction with other locations was impossible, a local area should be able to maintain self-sufficiency of tissue donation and placement. Delmonico et al. (2011) and McHale (2013) wrote on this subject as proponents of local tissue autonomy, with much of their foundational reasoning being based on an argument of justice. McHale (2013) cites instances of wealthy persons in the European Union being able to travel across borders to obtain organ transplants in other cities or countries as fundamentally unethical, as it unjustly allows some people to exploit regional variations in donation rates to bypass the waiting list to obtain an organ transplant. This is one part of a larger phenomenon known in the literature as medical tourism, and it is widely considered as a form of social injustice that must be combated by those who help to regulate organ and tissue donation policy (Hanefeld et al. 2014). The solution proposed by McHale (2013) is to legislate policy that more directly outlaws medical tourism. Delmonico et al. (2011) echoes these sentiments, but also argues that in the goal of governments

must take efforts to eradicate the diseases that necessitate transplant and should create nationalized donation networks, such that there would be no need for medical tourism to occur. Although these claims are sound for the issue of something like kidney transplant, corneal donation in the United States has not relied on a waiting list due to the excess of tissue being recovered each year (Moshirfar et al. 2018). If ethical arguments based in injustice are not applicable to corneal transplant, then objections to a non-local system in the United States are less compelling.

There are still some who may claim self-sufficiency is important due to issues of local sovereignty, but in this context, overemphasis on state borders may actually create more injustice than allowing non-local distribution to occur. There may be areas of the country where donation rates are comparatively lower or areas where there are less resources to perform corneal tissue recoveries. Just as socioeconomic status should be a morally neutral feature in a person's ability to receive a transplanted organ, location of residence should similarly be a neutral feature of a recipient. To create a system where parts of the country may be living with a waiting list while others do not would be unjust and may actually perpetuate medical tourism domestically.

Donor and Recipient Outcomes in Non-Local Tissue Distribution

The second group of ethical concerns was founded on the potentially catastrophic outcomes if a local eye banking system is abandoned (Ahmad et al. 2020). In addressing this concern, I will subgroup into the donor-focused outcomes and the recipient-focused outcomes. The donor-focused outcome of concern here is a potential drop in donation rates if people's tissue is not being retained within a local recipient population, as people may be less motivated to donate if they feel that the recipient of their tissue might not be someone from their local area (Long and Krause 2017). This speaks to a general social psychological theory that people tend to

feel more willing to assist others who they feel are similar to themselves; as such, people may feel a stronger altruistic drive to donate if they know that the recipient is someone who is associated with them (Long and Krause 2017). The article referenced above regarding the mother who was distressed to find her son's corneas is a good example of such a phenomenon, where she only wanted to donate in order to held "a kid in the United States" (Hynes 2019). In other words, she wanted to donate to help someone like her son, but when she found out someone other received the gift, she regretted her decision to donate. But, studies examining determinants of altruism found that social relationships, as opposed to geographical relationships are typically more important for determining a person's altruistic drive (Long and Krause 2017). For example, a person in Georgia may be more inclined to a person who they personally know that lives in Alabama over an unknown, arbitrary person in Georgia. In the absence of personal relationships, perhaps geographic location may be more pertinent.

Moreover, in the specific instance of corneal transplant, a non-localized eye banking system doesn't particularly mean that tissue cannot be distributed in the same area where it was donated. The current preservative lifespan of corneal tissue in sterile media is about 14 days, which is ample time for the tissue to be safely transported for processing at a secondary location before being placed with a recipient in the original location of recovery. If corneal donation did become increasingly centralized, corneal donors and donor families could reasonably be given an option in their informed consent to if they would prefer local distribution. This could help mitigate the potential outcome of losing donors if the increase in non-local eye banking continues.

It is also important to note here that, similar to the other ethical issues discussed in this chapter, this concern poorly explains why for-profit entities in eye banking are uniquely a risk

factor for the ethical concerns related to the loss of local distribution. Non-local distribution is not exclusive to for-profit agencies in eye banking, as non-profits also engage in the practice of recruiting surgeons from outside their local area and exporting corneal tissue, similarly diverting tissue from local populations to non-local recipients (Martin et al. 2017). Participants are clearly connecting for-profit entities with this behavior, but perhaps this ethical concern speaks more to larger objections of competitive practices amongst all eye-banking entities, as opposed to specifically against for-profit entities.

The general recipient-focused argument amongst our participants was that some amount of corneal transplants occur emergently, typically following a trauma, and that surgeons might need tissue within hours of their request in order to salvage the eye (Ahmad et al. 2020). Surgeons in a service area that no longer have a local eye bank may be unable to serve these patients with urgent needs, which is damaging and regressive compared to the typical model of local eye banks. It is entirely possible that this concern may actually be eradicated in the near future, with the rapid evolution of processing and shipping ability for corneal tissue; but even in the status quo, this argument against for-profit eye banks is not particularly compelling as the heart of this ethical argument is against eye bank consolidation, not for-profit entities. In the United States, both for-profits and non-profits have engaged in consolidative behavior; it is possible that the expansion of for-profits may have spurred more intensity in the practice, but it seems unlikely that this is simply a result of their tax status as opposed to their increased reliance on competitive business practices (Richard L. Lindstrom 2017, Moshirfar et al. 2018, Mannis and Sugar 2018).

Conclusions

Corneal banking is an incredibly unique system of human tissue donation, as the lack of corneal scarcity exempts it from many of the standard concerns that may come with a donation system, such as issues of waiting lists or increasing donation rates. The concerns voiced by the interview participants are important in establishing what the majority opinion is in the eye banking community, which has utility in guiding further collaborative discussion. But none of the major concerns expressed actually provide a foundational ethical reason for why the eye banking community must reject for-profit institutions in eye banking. Profiting from a donated item, or from a part of the human body, is not inherently an unethical practice, and is importantly a commonplace part of the current American organ, tissue, and eye banking industry. This practice has allowed donation systems in this country to increase the overall efficiency of donation systems in this country, improving the national supply and providing incentives for donation systems to successfully utilize their supply. Unequivocal data is lacking to fully know if donors or donor families may refuse to consent to donation if they are informed about for-profit entities in eye banking, but a brief review of current state law and previous government investigations suggests that perhaps it is not a particularly influential factor in consent decisions. Concerns of distributive injustice from a loss of local tissue do not apply to the corneal banking system, and there is potentially an argument that a non-local system may be actually more just for a nation that is operating with national level excess in tissue. Loss of local eye banks and local tissue may have the potential to negatively impact emergency tissue supply, but these concerns are similarly applicable to non-profit eye banks, as consolidation and competitive business practices are not unique to one type of tax status.

Chapter Four: Conflicts of Interest and Corneal Donation

The intersections of commercial businesses and human bodies in modern society are becoming ever more complex, which makes it all the more vital to carefully scrutinize the various ethical challenges that arise with these interactions. The involvement of for-profit entities into the eye banking industry has come during a time of rapid, large scale changes in the industry as a whole, and with it, numerous questions and concerns from those who work within the eye donation field (Mannis and Sugar 2018). In the interview study, eye bank leadership and corneal surgeons were identified to be most frequently concerned about loss of donor trust, loss of local tissue, and exploitation of donor generosity; but upon a more thorough analysis the most prevalent issues do not particularly indict for-profit donation as uniquely less ethical than non-profit donation. One must then return to the key structural and operational differences between non-profits and for-profits to determine if any of these differences carry an ethical implication. As previously discussed, one of the key differences between for-profits and non-profits is that for-profits have the ability to form reciprocal financial relationships with other persons or entities, where a person can make an upfront investment in a for-profit to support their operational capacity in exchange for a percentage of the profits that are earned from those operations. These relationships constitute an alternate duty that for-profit entities must attend to in addition to their duty to donors and donor families, and this conflict of interest carries ethical weight due to the influence it may impart of on the decisions and operations of a for-profit donation entity. In this chapter, I will investigate conflicts of interest within the context of for-profit entities in eye banking, first by defining conflicts of interest in a biomedical context, including donation, and next by describing why the burden of conflicts of interest are unique to for-profit entities in donation. Next, I will aim to illustrate how conflicts of interest can disrupt

ethical conduct of corneal donation and transplant from recovery to distribution, particularly by fueling completive activities amongst eye banks, and use these identified potential weak spots to propose interventions that may help to mitigate the ethically damaging impacts of conflicts of interest.

The Ethics of Conflicts of Interest

To begin scrutinizing the ethical issue of conflicts of interest, first a foundational understanding of conflicts of interest must be established. The classic definition of conflict of interest is understood as a situation where some agent holds some interest, be it financial, legal, or personal, that compromises their duty to appropriately make decisions or carry out actions on behalf of another person or entity (Luebke 1987). This conflicting duty may be a duty to another party, such as when the care of one patient may come at the expense of another patient, but it may also be a personal conflict, such as in the case of financial incentives for physicians prescribe particular pharmaceuticals. Conflicts of interest are not in and of themselves ethically objectionable; many people may find themselves in the aforementioned described situation where they have a conflict of interest, but it is the reaction to and outcomes of inappropriately managing a conflict of interest that may lead to moral challenges (Field and Lo 2009). For example, mismanagement of a conflict of interest may lead the agent to make decisions that could be potentially harmful to a vulnerable party, or if the conflict of interest is discovered, it may cause people to lose trust in the agent. Conflicts of interest are often a topic of discussion in medical settings, as physicians and other persons who work in healthcare must be trusted to conduct actions in a way that will be in the best interest of the patient. The majority of ethics literature had focused on financial conflicts of interest in medicine, but there can also be non-

financial conflicts of interest that arise from competing duties to two different patients or between one patient and the greater utilitarian good (Field and Lo 2009).

It is important to note that conflict of interest does not solely occur at the level of individual interactions. Medical corporations and institutions can also have financial conflicts of interest stemming from their streams of revenue or profits, which can lead to systemic changes in business operations that damage the underlying mission that a medical institution may hold toward patients or physicians (Emanuel and Steiner 1995). Emanuel and Steiner (1995) define this type of conflict of interest as an "institutional conflict of interest", with a large focus on conflicts of interest in biomedical research. They claim that when conflicts of interest exist at the system level, the implications can be larger than any one individual's conflict of interest, as the employees and other shareholders of the institution might all carry out unethical judgments based on the institutional conflict of interest. There is typically an extreme power asymmetry between employees and their employers, and in the scenario of an institutional conflict of interest, employees will be compelled to conduct themselves in whatever manner best ensures their continued employment (Emanuel and Steiner 1995). Employees may also not be aware of the conflicts and how they are impacting the institutional policies and procedures. This can create large institutions where a multitude of people, from the highest leadership to the everyday worker are making compromised decisions due to inappropriate institutional relationships, and the entirety of the institution's work risks losing validity.

Duty to Donors in Corneal Donation

People who work in corneal donation and eye banking institutions may be subject to conflicts of interest, both at the individual and institutional level. As was briefly described in the previous chapter, donors and donor families must trust and rely on several third-party entities to

appropriately act as an arbiter of their tissue and ensure that tissue is used in a way that respects their interests. Similarly to physicians and other healthcare workers, those who work in eye banking can be thought of as entering into an agreement with donors and donor families to act in their best interest, and this fiduciary duty is essential to building mutual confidence between donors and eye banks (Margolis 2015, Boyd 1989). The parties who must act as arbiters of donor eye tissue include the leadership of an eye bank, such as the board of directors or the executive staff that guide an eye bank's mission and operations, as well as various employees of an eye bank, such as the person performing the informed consent process with the families, the person who recovers the tissue, the person performing quality control, the person analyzing and processing the tissue, and the person distributing the tissue to surgeons. The surgeon is the other party of note that is an intermediary between the donor and the recipient. Donors and donor families have very little to no control over what happens to their corneal tissue once it is donated, so there must be an appropriate trust in these various actors, as well as donation institutions, to carry out the donor's altruistic goals in order for people to feel motivated to consent to donation. With an understanding of the duty between donors/donor families and eye banks, one can now look to how a for-profit entity may compromise that duty.

Conflicts of Interest and For-Profit Eye Banking Entities

For-profit entities are relatively novel in eye banking but are particularly worrisome for creating conflicts of interest in donation. Interestingly, in interviews of eye bank leadership and corneal surgeons, the issue of conflicts of interest with for-profits was infrequently raised, but there was ample concern for certain competitive business behaviors, such as the eradication of local eye banks and lack of appropriate informed consent (Ahmad et al. 2020). As covered in the last chapter, these competitive tactics have outcomes, such as the loss of emergency tissue, that

can hurt donors, but are not restricted to a for-profit entity simply based on their tax status. But, for-profit entities do maintain particular structural and operational elements that are make them particularly susceptible to conflicts of interest with their fiduciary duty to donors, the impact of which may already be seen in the current eye banking field and that may actually induce several of the ethical concerns explored in the survey. There are numerous examples of potential conflict of interest in donation, but particular focus here will be paid to financial conflicts of interest, as this is most salient to the issue of for-profit entities in eye banking.

The legal and functional differences between for-profit and non-profits have been covered briefly elsewhere in this work, but a quick review of the relevant features will be included here. First, for-profit companies, as suggested by their name, are allowed to accumulate profits, whereas non-profits must keep narrow to negligible profit margins to maintain their tax-exempt status. Secondly, due to their ability to generate profits, for-profit companies allow for a reciprocal shareholder relationship, where investors can inject some amount of capital into a company in exchange for ownership of a percentage of the eventual assets of the company, with the investor understanding that the fundamental mission and duty of for-profit entities is to maximize assets via the creation and exchange of some valued goods or services (Horwitz 2005, Margolis 2015). Not all shareholder benefits come in the form of profits; more and more shareholders claim their benefits in stock holdings, which climb in valuation as the company utilizes its earned profits to expand in some way. It is also true that in more recent times, companies are diversifying their missions, for example with the rise in popularity of corporate social responsibility (Moriarty 2017). One instance of this in recent history is the founding and subsequent success of shoe company Toms, which gained a large following as a shoe merchant due to its mission to provide one pair of shoes to a person in need for every pair of shoes

purchased (Lee and Jay 2015). This mission of providing shoes to those in need does not necessarily serve to bring any direct monetary benefit to the company but is simply something that can provide general social benefit for people (Moriarty 2017, Lee and Jay 2015). Even eye banks have begun to promote corporate social responsibility, with one of the most major eye banks claiming that the profits from their tissue are fundamental to their mission to cure corneal blindness by 2030 (Moshirfar et al. 2018). But having a socially conscious mission does not negate that for-profit companies are still have a legal fiduciary duty to provide shareholder benefits in some way and often will accumulate wealth regardless of their mission to promote social good. Additionally, corporate social responsibility may actually aid in company profit-making by increasing consumer favorability (Wigley 2008). This wealth accumulation and profit making is not an immoral act, but I highlight it here simply to note that social missions do not necessarily negate the for-profit obligation to investors.

Non-profits alternatively rely on non-reciprocal financial relationships, such as grants or donations, as they do not legally have the ability to sell any ownership of their entity (Margolis 2015). In the absence of the guiding hand of owners/stakeholders, non-profit entities rely on guidance from a board of directors who have no financial interest in the organization to act as leadership. There are typically thought to be various benefits to each approach, but as noted in the interview study, one of the primary benefits of for-profit entities is the ability to generate large amounts of capital, which can be channeled not just to stakeholders, but also to other endeavors such as research, innovation, or education (Chen 2013, Moore 2000).

As already noted, for-profit entities allow for additional persons to purchase some amount of control over the company and future profits in exchange for an upfront injection of cash for the company. To understand how it relates to the particular issue of donation, one can

return to the idea of the gift relationship and the donation pathway. In a for-profit entity in eye banking, the inclusion of these additional persons can be viewed as adding additional intermediaries to the donor-recipient pathway, in the form of investors, shareholders, and venture capitalists. These additional persons may or may not have any medical background or interest, and by and large, their role in the donation pathway is simply to help generate initial capital in order to initialize operations. But, unlike someone who is a financial donor to a non-profit, their continued support for donation efforts is contingent on reciprocity for their initial investment, which requires the donation entity to build profits, assets, and operations to provide such a reciprocity (Moore 2000). Certainly, companies with a social footprint, like the shoe company Toms described above or perhaps an eye donation entity, may obtain angel investments from people who are willing to accept a lower financial return due to the social good being promoted by the company, but there is still an expected reciprocal financial relationship when a person chooses to invest in a for-profit endeavor as opposed to a non-profit endeavor. Notably, the leadership of a for-profit company actually has a legal duty to pursue the most financially beneficial strategy for their investors and shareholders as part of their fiduciary duty to those stakeholders, and these stakeholders may also be given some amount of requires decisional capacity in dictating the organization and operations of the for-profit entity as part of that relationship (Goodpaster 1991). This risks a significant conflict of interest, as it creates a competing, legally binding fiduciary duty to shareholders that may compromise the informal fiduciary duty that eye banking entities and their employees have to donors and recipients. Financial conflicts of interest, especially those of a large sum such as those possible in for-profit entities, tend to be quite powerfully influential, and with the competing duty present in for-profit eye banking entities, the entire institution risks a motivational drift from supporting the altruism

of donation to supporting the profitability of the company (Emanuel and Steiner 1995). Building profitability primarily on the bodies of the deceased is an extremely tenuous ethical position, as appropriate treatment of the deceased is a daunting duty with many complexities to ensure donor families feel well cared for, and for-profit entities must adapt strategies to faithfully meet these conflicting duties, lest outcomes deteriorate for donors or recipients. Some may argue that regardless of the conflicting duty to shareholders and donors, if the central mission of a for-profit is one that serves the greater good, this is a justified utilitarian effort despite the potential impact of the conflicts of interest (Moshirfar et al. 2018). But, as will be outlined later in the chapter, the effect of such an altruistic goal may be diminished by pursuit unilaterally via for-profits, especially since in eye banking, the profitability of the for-profit relies on continued trust from donors and their families. This trust is predicated on the trustworthiness, or perceived trustworthiness of the donation entity, and the conflicting interests of for-profits, regardless of if appropriately managed, may erode on that trust. Moreover, it is an empirically false claim to suggest that in the medical world, social good corresponds with market success, and there are numerous instances where medical outcomes seem to decline when comparing a for-pro versus a non-profit system. For example, for-profit rehabilitation centers and hospitals carry a significantly higher readmission risk than non-profit rehabilitation centers (Li et al. 2018, Kind et al. 2010). These results were particularly shown for Medicare and Medicaid patients, respectively, which suggests a troubling effect of for-profits on the healthcare of vulnerable populations in the United States (Kind et al. 2010, Li et al. 2018). This is not to suggest that there is not the ability for medical good to arise from for-profit funded endeavors. There are certainly benefits to having a larger cash source, but this does not negate the need to address the ethical

concerns that come with building this cash source via a for-profit entity that holds conflicting duties to donors and shareholders.

In understanding why for-profits are uniquely damaging for eye banking, another important consideration is the potential downstream pathway of a for-profit entity in corneal banking. Many for-profit entities will eventually seek to become publicly traded companies, as this tends to exponentially increase the available capital for the company, and it is entirely possible that a for-profit eye bank may seek the same path. The process of becoming a publicly traded company involves an early fundraising period, where the company attempts to reach the initial capital requirements and build out the company foundation necessarily to qualify for an initial public offering (IPO) (Barry et al. 1990, Ellis, Michaely, and O'Hara 1999). Once approved to hold the IPO, the company then can sell shares of the company to the general public, allowing the company to build more capital as shares are bought and sold. If this occurs with a for-profit entity in eye banking, it means that even more people will now have an investment hold in the company, and these people, by and large, will have chosen to seek this investment for the purpose of financial gain. Sure, there may be people seeking to promote social responsibility through stock purchases, but a study of investor behavior suggests that the financial promise of an investment, more so than the social promise, motivates investor interest (Døskeland and Pedersen 2015). Returning to the donor-recipient pathway, if a for-profit entity in eye banking becomes a public entity, they have invited numerous new intermediaries that must be accounted for when appropriately stewarding a person’s donation. This public interest constitutes a massive new fiduciary duty that an eye bank must accommodate, and as it grows, its influence may be impossible to overcome. Eye bank leadership must now serve the interests of every public stakeholder as well, and they may not even have the option to retain practices that best serve the

donor or recipient if the majority of shareholders believe that practice is profit losing. If a situation occurs where participating in corneal donation is no longer considered to be the most profitable company strategy anymore, the public shareholders may push the controlling board and executives to move the company away from corneal donation, which is only needed in finite numbers for transplant each year, to something more profitable like tissue transplant, which is needed in much larger quantity for more expensive cosmetic or reconstructive procedures. This is especially troubling if the pattern of consolidation continues, as the larger these for-profit entities become, the more potentially disruptive any transition away from corneal donation may be. This outcome comes as a direct result of the conflicts of interest that come with the expansion of for-profit entities in eye banking; and it highlights how their involvement in the field may present an obstacle to progress in corneal transplant.

Although conflicts of interest are possible in many types of relationships, the donation sphere particularly faces discord when judgments made based on behalf of donors/donor families are corrupted by interests from entities other than donors/donor families. In the case of for-profit entities in donation, these alternate influences come in the form of the fiduciary duty to stakeholders to maximize their profit. This situation poses a unique conflict of interest, one that can have wide reaching implications throughout the donation pathway and lead to unethical actions and erosion of the altruism that motivates donors. To further illustrate this point, I will discuss three realms of the donation pathway where conflicts of interest can erode at donor's rights and potentially lead to less ethical conduct.

Conflicts of Interest in the Pathway from Donor to Recipient

When faced with a conflicting duty to shareholders and profit making at a systems level, people at an individual level may act in ways that are unethical. This may happen out of concern

for maintaining their jobs or potentially for their own financial gain. There are many ways this may play out on a day-to-day basis, and throughout the various responsibilities of an eye bank. Traditionally, the pathway from donor to recipient consists of various steps, with the eye bank being responsible for the recovery (including consent of donor families), processing, and distribution steps. Research arms have become integrated into several eye banks in the country, and there are relevant conflict of interest considerations for these research components as well. I want to briefly cover how conflicts of interest can play out in unethical ways through each of these steps, as well as how it may negatively influence the larger interactions between eye banks.

Recovery

Companies who build their profit on deceased donation have an invested interest in maximizing their recovery rates, as this provides more tissue that can potentially be distributed and sold. In conducting the consent, there may be motivation to withhold information that might dissuade the donor family from consenting to donation, or potentially to use a leading style of questioning that may undercut the validity of the informed consent by presuming the family's intent to donate. This has actually been documented as true in tissue donation, where tissue recovery agencies often would not mention potential interactions with for-profits during consent conversations with donor families (Siminoff and Traino 2013). This lack of transparency would risk hurting donor family trust in eye banking institutions, as was discussed in the prior chapter.

When considering recovery of corneal tissue, a for-profit bank may seek to maximize profitability from the process. Maximizing profitability from the recovery process means maximizing the amount of corneal tissue in the country that is routed to that particular eye bank; of course the corneal tissue must also subsequently be sold to a surgery center, a surgeon, or a research group in order for the profits to be realized, but that will be covered in a later section.

The drive to recover more tissue may lead to several different downstream actions that can have ethical implications. First, eye banks that have a large desire to bring in a larger amount of tissue may be more lenient in setting their standards for donation, such as accepting a wider range of ages or causes of death, which may result in a net increase in the amount of tissue obtained; but, this judgment doesn't necessarily represent action that is best for donors or recipients. Although there is some guidance from the Food and Drug Administration on donor standards, eye banks assume the bulk of responsibility for maintaining appropriate standards that ensure safety for recipients and respect for donor families. Of course, there is only a small risk that an eye bank would ever compromise its safety by not maintaining incredibly strict donor standards. But, in such a scenario, a sudden increase in donor infection or rejection would be likely. This could lead to numerous transplant related morbidities for recipients, including the strong likelihood of being permanently blinded.

Other mechanisms of increasing recovery rates include expanding one's geographic recovery zone beyond the traditional standard of only recovering within one's local area. This can be achieved by one of two methods. First, an eye bank could attempt to acquire another local eye bank, which would allow for the outside eye bank to now own that eye bank's recovery locations and hospital contracts. The second method, if acquisition of the eye bank is unfavorable or not possible, is the outside eye bank could directly seek contracts with non-local hospitals to perform their deceased corneal recoveries. This might also be done via organ procurement organizations, where a for-profit may contract with an organ procurement organization to ensure that when the OPO is called to perform a recovery, that the for-profit entity will be the prioritized call over a local entity. As for-profit eye banks have more flexible capital, they may be able to negotiate contracts that offer financial advantages for the hospital system and OPOs, which is a

phenomenon already seen in the tissue donation industry (Katz 2005). Taking hospital and OPO recoveries away from a local bank risks choking off the corneal tissue supply to a local bank, which may create a relative local scarcity despite the national surplus. It also risks closure of local banks, the ethical impact of which was covered in the prior chapter, or deterioration of a bank's operations to the extent that the non-local eye bank could pursue the first method of acquiring the local eye bank. The consolidation of eye banks similarly has its own ethical implications that have been covered elsewhere, but in brief, increasing consolidation of eye banks would allow for eye banks to operate with less accountability from alternate eye banks, and also risks national level destabilization of eye banking if anything occurs to damage the one central eye bank.

The notable point here is that although some may argue that recovery can help to provide better, more standardized corneal tissue nationally, these practices involve the deterioration of the operations of local eye banks, which means damaging the ability of the local eye bank to help donors and recipients as a larger eye bank begins to encroach on its recovery area. This is certainly not in line with the eye bank's duty to serve donors and to serve their altruism, and it reduces donated corneal tissue to a means to an end for capitalistic expansion. Moreover, it is dubious at best to claim that the only path to improving struggling eye banks is to acquire them directly; there are obvious other methods for assisting an eye bank that may not be as advanced other than consolidation. It is important to note here that the behaviors mentioned here are not a hypothetical; there are eye banks that have already sought out non-local recovery locations and that have worked to acquire other eye banks (Moshirfar et al. 2018). This represents a massive shift from the prior conduct of eye banking entities, and it is not unreasonable to tie this behavior to the growing conflicts of interest that are present for eye banks. There is no data beyond

anecdote available right now to tie this behavior directly to for-profits or non-profits, which might be useful for better understanding if profit status motivates consolidative effort, but as has been already outlined, the presence of significant external financial influences is certainly something that can push an eye bank toward these types of competitive behaviors.

Processing/ Distribution

Looking to other areas where conflicts of interest may provoke unethical behavior, one can examine how tissue is managed and processed after recovery. For the purposes of this analysis, the steps of processing and distribution will be grouped together, as distribution goals can heavily influence management of corneal tissue processing. Typically, tissue once recovered can be handled in one of three ways. First, it can be used for transplantation, second, it can be used for research and development, or third, it can be discarded. Typically, the most ideal outcome for tissue is to be utilized for transplantation, and tissue is first placed with the surgeons who practice in the United States. This is also the most financially beneficial use of the tissue from the eye banking perspective, as the compensation rate for surgical corneal tissue domestically is much higher than for research tissue or for internationally exported corneal tissue. Discarding tissue is the least desirable outcome, as it means that the recovery cost for that tissue is a sunk cost for the eye bank, but also as it squanders the altruistic desires of the donor and donor family when they agreed to donate.

As already covered, it may be financially advantageous for an eye bank seeking to maximize profits to recover larger amounts of tissue, but only if that tissue is actually utilized. To maximize profits, the ideal would be to have the majority of the tissue placed with surgeons for transplant surgeries, as this would bring in the highest reimbursement rates. This requires having a large collection of partner surgeons to potentially distribute tissue to, more so than

might be possible if the only surgeon partnerships were those that were geographically local. There may then be a motivation to try and solicit surgeons who are outside of the typical service area and create incentives for surgeons to switch from their local bank to an alternate partner eye bank. Again, I want to emphasize here that there may be a much larger incentive for a for-profit entity to pursue such an action than a non-profit. It is important to consider how exactly surgeons might be incentivized into partnering with an alternate eye bank.

The surplus of corneal tissue has created an environment where surgeons can theoretically pick and choose amongst the various tissue options that exists, as opposed to simply relying on whatever their local recovery site brings in. To entice a surgeon to their tissue, as opposed to another eye bank's, an eye bank must create some sort of novelty around a product (i.e. corneal tissue) that is typically fairly standardized at a national level. One way to do this is to simply more aggressively market one's tissue than other eye banks to create an aura of novelty, by directly contacting surgeons or hospital systems to promote their product; this may have ethical implications if the marketing is conducted in such a way that erases the donor's contribution from the corneal tissue being offered to surgeons. This is a concern that has previously been noted in tissue transplant, where tissue distributors would offer some human-based product without any mention in the marketing material of the person who donated the tissue (Agnos 2003). This is already occurring in eye banking as well. The product catalog for the largest corneal processor in the United States lists several types of corneal tissue products with no mention that these products originate from a donated human (CorneaGen , Moshirfar et al. 2018). Not acknowledging the role of the donor and the donor's altruism in the creation of these products risks making donor families feel disrespected and also disregards the fundamental altruistic motivation behind donation (Agnos 2003).

An alternate approach for creating novelty around a corneal product is to actually treat the donor tissue in some original way, which similarly comes with its own implications. One such strategy already being used is packaging tissues with various inserter devices or other transplant technology devices and selling those devices with the tissue prepackaged within. This reignites questions regarding corneal tissue sale, as well as the ethical implications behind repackaging a human product as a component part of a medical device.

Recent years has seen the advent of corneal tissue insertion devices to assist in the transplantation of certain types of thinly cut donor tissue. The inserter devices that exist currently are typically single-use, and more often, they are now coming pre-loaded, so the tissue is delivered already prepared and in the device for insertion into the recipient eye. What this means then is that when an eye bank is supplying tissue for a surgery, they are now charging for the tissue and the device together, and often this represents an increase in the charge compared to the tissue alone. This upcharge is unlikely to raise concerns amongst surgeons and surgery centers, as the charge still would maintain a pass-through status with insurance. These inserters can be incredibly beneficial for surgeons, helping them to successfully complete the surgery at hand and allow them to more rapidly complete a challenging surgery. Moreover, with preloaded devices, there is less risk that a surgeon might be in a position where the tissue is unusable or damaged in the operating room, as the processing is completed by the eye bank before the patient even arrives. The ethical questions arise though of when these devices are used as a competitive edge by eye banks to try and solicit more surgeon partners. For example, some eye banks have placed a patent on their devices, such that any eye bank that desires to use the devices has to pay a licensing fee. Other eye banks will completely protect their devices, never allowing any other eye bank or non-partner surgeon to have access. Historically, eye banks tended to widely share

their techniques and abilities; for example, when endothelial keratoplasty was gaining popularity, eye banks often would share their processing strategies with one another, in order to help create uniformity amongst the eye banking community and to help make sure every community had easy access to novel transplantation advances (Mannis and Sugar 2018, Moshirfar et al. 2018). Giving limited access only to potentially beneficial technology for the purpose of creating a more favorable market for certain eye banks may allow them to build a fund for future endeavors, but it also deprives many patients from potentially sight-saving technology. The judgment to package tissue and devices as a novel product to be marketed seems one that is driven less by the goals of donors and more by the goal of making profits.

Research

An important component of the conversation around these innovations and devices now being utilized by eye banks is that the research that may lead to the development of these innovations was built on donated tissue. Research in human donation is necessary to stimulate new knowledge discovery in the areas of transplant, but research work with donated human tissue must be conducted with care to avoid misuse or exploitation of the donor's generosity. In the United States currently, the amount of academic or government support for medical research by non-profit entities is relatively low, which can slow or even altogether halt the process of medical invention. But, as profits begin to accumulate for larger eye banks, mixed eye banking entities have arisen that both perform the cardinal functions of an eye bank (recovery, processing, and distribution), but that also have incorporated an in-house research branch. Such a situation is notably distinct from an eye bank providing tissue to an outside researcher and carries distinct ethical implications.

Adding an in-house research branch to an eye bank may allow for the creation of additional institutional conflicts of interests. As covered earlier, it may be to an eye bank's profit to be able to distinguish themselves as better than other eye banks, and this may involve offering novel additives or devices that other eye banks might have access to. Some eye banks have now decided to pursue this research and development in-house, which allows them further control over any intellectual property that may be created. By retaining these products as solely their own, as opposed to sharing them with other eye banks, an eye bank which can give themselves a financial edge in the corneal transplant market. But, this sort of relationship actually creates another institutional conflict of interest, as now the financial success of the eye bank is not only contingent on the success of its typical operations, but also on its research outcomes (Emanuel and Steiner 1995). This may also cause an individual conflict of interest for researchers employed by the eye bank, as their jobs and financial stability may be contingent on conducting research and reporting outcomes that the executives find favorable. These types of research conflicts of interest have previously been reported to erode neutrality in research. A systematic review by Bekelman, Li, and Gross (2003) found that publications of research funded by industry were three times as likely to publish pro-industry results. There have also been numerous instances of funding conflicts of interest compromising the judgement of researchers, even so far as to have resulted in research related deaths (Abramson and Starfield 2005). It is important to note that these are not concerns necessarily restricted to for-profits who seek to perform research. But, the profit-making motivations behind for-profit research, as well as the larger sums of money involved in a for-profit eye banks versus a non-profit, may make the magnitude of the secondary interest more difficult to overcome.

Interventions to Help Mitigate Conflicts of Interest

Due to their multiple priorities, for-profit entities in eye banking face a large conflict of interest between their duty to their shareholders and their duty to donors, recipients, and surgeons. This conflict of interest poses the danger of unethical behavior throughout the donation cycle that may compromise the intentions of donors or recipients. The reality of the current eye banking system is that a blanket ban on any for-profit entity in eye banking is not only incredibly unlikely, but also is not a particularly effective strategy at managing conflicts of interest. For-profit entities are not inherently an unethical component of the donation pathway; the ethical challenges with for-profits primarily arise when responsible stewardship of donor tissue is eroded due to the desire to maximize profits. The eye banking community needs strategies to may mitigate the influence of these conflicts of interest and help to better protect the integrity of the donation process, with the important note that many of these strategies also apply to non-profit eye banks. To conclude this discussion of conflicts of interest, I will suggest three regulatory interventions that may assist to this end.

Improving Informed Consent and Transparency

One primary improvement that can be adopted is a uniform minimum standard for transparency in informed consent procedures. Currently, recovery agencies are allowed to formulate their own personal scripts for consent conversations, but these scripts vary in their content and transparency about the various entities that are involved in the donation process. Currently, there is no mandate for an eye bank to provide information about for-profit entities in their consent conversations. If a donor's tissue might be transported to or utilized by a for-profit entity, informed consent conversations with families should include information about this. Moreover, information should be sufficiently detailed to allow for greater disclosure of the conflicts of interest that may exist, including information on what the for-profit entity will

specifically be doing with the tissue (processing, distribution, etc.), and information about the logistics of a for-profit eye banking entity, including their financial structure, should be provided if the family inquires. There must also be transparency about tissue being potentially distributed away from the region of donation, including international distribution. In the status quo, the quality and outcomes of for-profit and non-profit tissue is essentially identical, and so families should be given clear notice that they can elect to donate without the corneal tissue interacting with a for-profit entity. Additionally, if possible, they can elect for the tissue to be retained locally if they feel these requirements are an essential component of the donor's goals. If a non-profit bank might have an institutional conflict of interest arising from some other etiology, that should be disclosed as well.

During the informed consent process, there should be a secondary consent process for corneal tissue to be allocated for research if unable to use for transplant. In brief, the consent conversation should mention if the tissue would only be used for research relating to corneal transplant, or if it might be used for other research purposes, noting what those purposes are or making it clear that future research projects cannot be known now, but all will need careful oversight and review. Again, it should be made clear that the tissue may be used for academic or commercial research, and that any innovations that result from research that uses their donated tissue may be used commercially and sold for profits (but that the family should not expect to share in any of the profit made from the product). Explicit clarification should be made, if the family asks, of who exactly might profit, being sure to note that shareholders and venture capitalists may also profit if they provided monetary support to the research. Finally, if an eye bank has a financial relationship with a research entity, such that they might also receive a financial benefit from any profitable innovations from research, this should be disclosed in the

informed consent. Some may object here, saying that relationships with for-profits are becoming too complex or that donor families may not fully understand what this means. But ethically, these are not reasons that would justify the withholding of information from families; if anything, the increasing complexity highlights the need to begin integrating safeguards for families more urgently.

By more completely informing families prior to donation about the potential commercial interactions that corneal tissue may encounter, it allows for families to have the knowledge that for-profit entities exist in corneal donation, which is the fundamental foundation for disclosure of the conflicts of interest that for-profit entities pose. By providing more information and options surrounding the issue of for-profits, both in transplant and in research, it gives families more control in making donation decisions that would otherwise be made by eye bank employees, such as who will process the tissue and where it might be distributed. Families can indicate which entities they feel most comfortable having their loved one's tissues interact with, be it for-profit or non-profit, or local or non-local. By putting this choice in family's hands, it may help to mitigate the for-profit incentive to solicit recovery locations outside one's service area, as there is no guarantee that families will allow their tissue to interact with a for-profit entity. This approach also gives families greater control and knowledge over research uses of tissue, again helping to overcome some of the effects of conflicts of interest on decisions of how tissue is used. Moreover, it allows donors and donor families to ensure that whatever happens to their tissue is within their wishes, and that the altruistic goals of the donor are being carried out as they hoped.

A final point of note here is that hand in hand with improved informed consent should come a shift to transparency for eye banks, specifically for for-profit eye banks who are likely to

have more complex business models and who do not have the same legal obligation as non-profits to divulge their finances at the end of each fiscal year. This would allow for the widespread disclosure of the any conflicts of interest that may exist for a for-profit bank, and donors/ donor families would be able to review this information in order to make a more informed donation decision. Additionally, this may act as a deterrent for eye banks to hold conflicts of interest that are likely to be publicly viewed as problematic by donors, surgeons, or recipients.

Limiting Eye Bank Size

The topic of expansion by eye banks has been discussed here in two different ways: first, expanding the eye bank's recovery, processing, and distribution geographic locations by acquisition of other eye banks, and second, expanding the eye bank's distribution locations by solicitation of surgeons from across the nation, as opposed to within the local area. Both of these are particularly complex for for-profit entities that may be motivated to pursue such actions more aggressively to maximize their profit margins. And, these two actions go hand-in-hand, as acquisition of another eye bank's surgeons might destabilize that bank's operations and finances, making it easier for the larger eye bank to acquire the smaller eye bank. As covered earlier in this chapter and the last, these acquisitions can hurt local emergency tissue supply, which risks leaving patients in need of emergency sight-saving surgery without needed tissue and propagate competitive practices amongst eye banks that might damage operations. These competitive practices include marketing schemes in order to draw in surgeons. These advertisements treat the tissue as a surgical product as opposed to a human part, which as discussed, disrespects the sacrifice of donors/donor families and negates the donor altruism that is necessary for human based products to exist. Marketing in such a way creates a buyer-seller relationship with the

corneal tissue, which runs against the gift relationship central to donation motivation. The ability for an eye bank to market themselves at all is thanks to the gifts of thousands of donors, and to erase them from product catalogs or marketing materials is not only disrespectful, it is an unethical misrepresentation.

In order to confront the ethical issues that arise with some eye banks moving to a non-local model, stricter regulation is needed to guide acquisition of new eye banks locations or surgeons. First, the eye banking community should make all good faith efforts possible to prevent non-uniformity amongst eye banks. This is necessary to minimize the many unethical and negative effects that come from competitive practices in corneal donation, as previously covered. Moreover, it is the best way to ensure that all patients can access the highest quality of corneal tissue when receiving a transplant, regardless of their location, the surgeon they have, or the hospital they are at. For example, if an eye bank does not have sufficient donors to provide for their surgeons, other eye banks can provide supplemental tissue to bridge them, but should also provide any proven strategies they may know for increasing donation rates in the local population with the goal of eventually making the eye bank self-sufficient (e.g. public service announcements, donor drives, etc). Additionally, if an eye bank does not offer a processing technique that other eye banks may have access to, other eye banks should make an effort to help that eye bank acquire the necessary skills to perform the technique. Research reforms will be addressed in more detail in a separate section, but this additionally means that eye banks should not be seeking patents or other protections for processing techniques or for transplantation devices, as this promotes divisiveness and inequity amongst eye banks. If all good faith efforts have been made to salvage an eye bank, but the eye bank still faces closure and there is still a demonstrable need for corneal tissue in that area, then and only then should an alternate, non-

local eye bank be allowed to expand and acquire the recovery, processing, and distribution in that area. This sort of regulation gives a compromise that acknowledges the potential need and utility for non-local eye banks to supply areas that are lacking, but disincentives competitive and consolidative behaviors. There should be additional regulation to prevent any one eye bank from controlling too much of the eye bank market through consolidative processes, as centralization of all eye bank processes is too precarious a situation for corneal transplant in this country. If one eye bank controls all corneal donation in this country, any disruption to that company's operations has massive ramifications for the corneal tissue supply in the United States, whereas a non-monopolized model prevents any one eye bank's dysfunctions from having national repercussions. Some may argue that in this scenario, an eye bank could be bailed out as financial banks were in 2008. But this safety net meant that financial banks, by and large, did not face repercussions for their abuses in the years prior that led to the need for a bailout and did nothing to discourage such activity in the future. Experts from the Federal Reserve have recommended that breaking up the big banks is one of the key actions to prevent a repeat financial crisis, although political and lobbying forces make this difficult to carry out after the fact (Kashkari 2016). For the donation industry, if actions and regulations can be put into place before monopolies that are too big to fail are created, this could help curtail the need for ever having a bailout of the eye banking industry at all.

By limiting the ability to which a company can expand its abilities or geographic reach beyond other eye banks, one may also in tandem be able to stem other competitive actions that are ethically problematic, such as dehumanizing marketing techniques, by both non-profits and for-profits. Additionally, it restricts the impact of conflicts of interest that for-profit eye banks face, as they would be barred from making certain business or financial decisions that they might

otherwise choose to, and it also lessens how lucrative it might be to operate as a for-profit eye bank in the first place. By limiting certain competitive practices, one inherently limits the amount of profit that can be expected in the first place, and perhaps may set expectations with venture capitalists or other shareholders on how much return they should seek for their investment. Tampering the expectations of shareholders then lessens the magnitude of the conflict of interest for the eye bank and its leadership, who otherwise face the expectation to make as much profit as feasible, without any regulation aside from the NOTA. Finally, it could help prevent full consolidation of the eye banking system occurring in tandem with a for-profit IPO, which as mentioned risks losing control of the corneal transplant industry altogether.

It is worth mentioning here that consolidative processes are already ongoing at a national level, and that if regulatory bodies truly want to make a commitment to ensuring non-competition amongst eye banking entities, limiting eye bank size might involve the breakup of some currently existing eye banks to reduce their magnitude. This would be a massive policy decision but might be one of the few steps that can radically slow the consolidative and competitive processes now ongoing before they are non-reversible.

Research

Improving the informed consent processes for research based on corneal tissue was covered in the informed consent section, but there are a few other regulations that may help to stem the effect of conflicts of interest in the research sphere. One such conflict of interest is how research findings are managed, as those who are motivated by profits may be inclined to limit access to the transplant products they develop as a mechanism to become more competitive or to garner additional profits from the sale of these innovations. As mentioned in the last section, limiting access to innovations can contribute to a culture of competition and inequality amongst

eye banks, which can lead to inequality of healthcare for recipients. If an eye bank has sight-saving technology but is not allowing other eye banks to have access simply for the purpose of perpetuating a market for corneal tissue, this is not a fair or just reason for recipients to be blinded. As such, patenting for eye banking techniques or devices that originate from donated tissue should not be permitted, and eye banks should commit to sharing innovations in eye banking broadly throughout the community. Some people might say this is an unreasonable standard, as the people who spend time and effort pursuing this research should be appropriately compensated for their efforts. But, there's no ethical reason to restrict access to vital healthcare simply to allow for someone to be compensated. Some might argue that without compensation, people won't be motivated to research in eye banking or corneal transplant, but this is historically untrue. There has been research and development in the corneal transplant field that has arisen from collaborative efforts between academic centers or eye banks, and a committed effort to this effort could still allow for the field to move forward without a large investment from private entities or venture capitalists (Mannis and Sugar 2018). It is worth acknowledging that the status quo of federal funding is lower than it has been historically, with more and more money being diverted away from scientific grants. This may mean that there is a role for private funding into the future, but these funding sources should be carefully vetted by eye banking organizations and should be operating independently from the eye banks to minimize the potential for conflicts of interest in research allocation decisions. And again, if private entities are involved, this should be explicitly disclosed to donor families prior, and they should have a full understanding of who will be using the tissue, what it will be used for, and who might eventually benefit from any research arising from their tissue.

Conclusion

Identifying the ethical relevance of for-profit entities in corneal donation can be aided by identifying the relevant differences between non-profit and for-profit entities, then exploring if these differences may hold some type of ethical relevance. For-profit entities in and of themselves are not unethical, and so objections to them should be based in how their particular business or operations may compromise typical eye bank functions. In the initial interview survey conducted, the participants held concerns about losing donor trust, disruption of local tissue supply, and exploitation of generosity. None of these concerns, on further exploration, illuminate a particular difference between for-profits and non-profits based on their structure, and many of the concerns apply to both for-profit and non-profit entities. Regarding donation, the key differences between for-profits and non-profits are the ways in which they are able to raise capital and the presence of financial relationships that eye bank leadership must attend to when conducting their business. These relationships are reciprocal in nature, unlike those in non-profit entities, and the continuation of these investments requires that there is some financial benefit for the investors. There is additionally a legal fiduciary duty that the for-profit company will operate in a way that is in the best financial interest of the shareholders. In donation, this financial duty must compete with the duty to donors and donor families, creating a conflict of interest that for-profit entities must address. Considering the magnitude of other donation industries, such as the $2 billion tissue donation industry, the financial conflict of interest may be very large, making it more difficult to overcome for for-profit entities. Appropriate management of these conflicts of interest are important for keeping donor and donor family trust intact, and strategies must be adopted to stop or prevent unethical erosions to the donation process. Many of these concerns have either already been realized in eye-banking or have been seen in the for-profit tissue donation industry, and regulatory change to ensure that conflicts of interest can be

appropriately addressed would be useful for curbing these concerns. For-profit entities can bring benefits to the eye banking industry, such as increased research capacity and increased efficiency in processes, but they must ensure that they are addressing their conflicts of interest in a proactive way. This can be accomplished by standardizing and regulating various aspects of corneal donation, such as increasing transparency in informed consent and limiting the size/geographic reach of any one eye bank. Taking some of these steps may help to alleviate the concerns that were shared in the interview section and may protect the eye banking mission of restoring sight and helping patients.

Chapter Five: Conclusions

Corneal donation has enjoyed great successes in the United States, as recipients no longer have to wait on transplant lists to receive a cornea, and new processing techniques are making transplant easier and safer than ever. Concurrent business changes in eye banking have created many new questions for the corneal donation industry, with many people in the field uncertain of what the future may hold for corneal donation and transplant. The status of for-profit entities into eye banking has been a fundamental question in assessing the many changes ongoing, with the challenge arising from the many distinct features of corneal banking that distinguish it from other forms of tissue donation where this topic may have been explored. Understanding the ethical significance of for-profit entities can help to guide future deliberations on if for-profit entities truly hold unique ethical significance as part of the corneal donation system, and if so, how should said ethical concerns be addressed.

The current literature and research are lacking is defining what ethical topics may be relevant for the unique situation of corneal donation, which due to its current structure may carry different areas of concern and areas of benefit than other types of transplant. To provide a launching pad for this ethical analysis, I chose to take an empirically driven approach, using prior literature and the expertise of ethicists and ophthalmologists to help guide the creation of an attitude survey for eye bankers and corneal surgeons. Through their responses, many points of interest were identified for further discussion. The majority of participants did hold ethical concerns with a for-profit entity in eye banking, but many also acknowledged that there are benefits to their involvement, as their larger capital availability allows for research and innovation to occur more rapidly. The most common concerns noted were the loss of local eye banking, exploitation of the donor's gift, and loss of donor trust.

Following the identification of frequent concerns, it was important to assess whether these concerns held up to more critical analysis, with a focus on determining 1) if the concern held ethical validity, and 2) if the concern was specific to for-profit entities. On examination of the three major concerns held by the group, it was clear that none of them held weight in explaining why a for-profit entity is uniquely ethically problematic. Many of the concerns mentioned could apply to both non-profits and for-profits and have already been ongoing in the eye banking system. One consistent thread was that these ethical concerns all were associated in some way with the larger issue of increasing competition in eye banking, which then posed the question of why for-profits are particularly being linked with such behavior. Examining the differences in the structure of a for-profit business in donation, versus a non-profit business, was a useful strategy for seeing if any of the other concerns from the literature or interview study might be salient to explore further as well. The presence of investors in a for-profit entity, as well as the much larger sums of money that a for-profit is able to raise, are structural differences that may introduce ethical challenges due to the presence of conflicts of interest with their duty to donors and their duty to investors.

It is not unethical for an eye bank to have donors, investors, or shareholders, but competing interests between donors and shareholders presents a conflict of interest that might compromise the ability of eye banks and their employees to act as a neutral steward of donor tissue. For eye banks that have a priority to maximize profits, such as for-profit entity, there may be an influence to make decisions that are best for shareholders, as opposed to best for donors, donor families, recipients, or the eye banking community at large. For-profit eye banks specifically must reckon with their fiduciary duty to their investors and their duty to donors/ donor families, and acknowledge that these interests compete with each other, especially as for-

profit eye banks are entities that rely on the trade of donated, gratis human tissue to build their company's profits. If these competing duties are not appropriately managed, there are several potentially damaging outcomes, many of which have already emerged in the for-profit tissue banking industry. This includes taking actions to maximize their recovery and distribution rates, including promoting uncontrolled consolidation and competition between eye banks, which can hurt local tissue supplies. Research and development arms of eye banks are also becoming more popular, but if there is an incentive to have research outcomes that are financially favorable for an eye bank, this might compromise the neutrality and safety of any produced works.

Trust in eye banking entities is necessary to maintain our corneal donation system, lest donors fear that their tissue is being exploited or misused due to other influences. This means that not only should conflicts of interest in corneal banking be transparent and freely disclosed to the larger public, but that stronger regulation and policy are needed to disincentivize actions that are unethical, that may damage donation, that or run contrary to the altruism at the heart of deceased donation. This includes limitations on competitive behaviors by eye banking entities, which might constrain the possible profitability of any one eye bank, improved informed consent processes for donor families, and freer access to research that may benefit the corneal transplant community at large. At the heart of all of these regulations is a call for a renewed commitment to collaboration of corneal banking entities and tempering the shift toward competitive business techniques.

Calls for collaboration may sound hollow, but leadership and regulation that enhances cooperative relationships between eye banks can mitigate abuses from competing external influences, while stimulating the corneal transplant community to form relationships internally that can provide the benefits of having a larger capital base for research and innovation. Careful

consideration should be given by guiding bodies of how to best reconcile the many voices currently present in eye banking, acknowledging that donors and recipients should always remain central to any deliberation on these issues, as this industry exists to serve patients first and foremost. Policy decisions may be assisted by the amplification of donor and donor family opinions, and future research that assesses the perspectives of this population may be helpful in that effort.

Finally, it is worth noting that the trajectory of current research in corneal transplantation suggests that in the future, the need for corneal tissue may actually decline significantly. These new techniques may need only one donor cornea to create 100 transplantable tissue grafts, or there's the potential for no donor corneal tissue need at all if stem-cell based technologies are successfully implemented. These innovations mean that change in the corneal transplantation field is an inevitability, and the traditional functions of eye banks may not be the best for patients or surgeons into the future. As eye banks and the eye banking community continue to change and adapt to incoming research and development, the goal of keeping patient's interests first should continue to guide the industry. Even if the need for donated tissue declines into the future, efforts must still be taken to protect remaining donors from exploitation and harm. Proactive efforts to manage conflicts of interest in corneal transplant may help to prevent future abuses and can lay the groundwork for a culture of transparency and collaboration in a changing industry.

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