4-2014

Impersonal Trust in Versus Dependence on FDA

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IMPERSONAL TRUST IN VERSUS DEPENDENCE ON FDA

Amanda C. Meyer, M.A.
Western Michigan University, 2014

This study emerged following an examination of the work by Susan Shapiro (1987) delineating the construct of impersonal trust, and Shapiro's analysis of trust was applied to an understanding of the impersonal trust relationship which Americans have with Food and Drug Administration (FDA). Few fields outside of organizational studies have undertaken efforts to operationalize impersonal trust and to distinguish it from other related constructs, so this exploratory study assessed whether variables associated with interpersonal trust as outlined by Meyer and Ward (2009) were also associated with impersonal trust in FDA. This study further examined whether measures of impersonal trust could be distinguished from a measure of the related construct of dependence. Lastly, as a practical concern, this study examined both trust in and dependence on FDA among a subset of older Americans. This study found that the majority of subjects expressed both trust in and dependence on FDA, that variables associated with personal trust were also associated with impersonal trust, and that measures of trust were empirically indistinguishable from measures of dependence. This study confirmed results obtained by Meyer and Ward (2009; 2013) which indicated that, while trust and dependence are theoretically distinct constructs, they often exist simultaneously under a given set of circumstances and are difficult to empirically demarcate.
ACKNOWLEDGEMENTS

I would first like to thank the members of my thesis committee, Dr. Barry Goetz, Dr. David Hartmann, and Dr. Greg Howard. Dr. Goetz asked a question which inspired me to change the direction of my research to the study of trust. Dr. Hartmann helped to refine the focus of this project and provided vital suggestions for methods of data analysis. I am grateful to both Dr. Goetz and Dr. Hartmann for their valuable feedback and assistance.

I would like to extend special thanks to my thesis chair, Dr. Howard. Dr. Howard offered sage advice and constant guidance, and this project would not have achieved its final form without his invaluable help and support.

Most remarkably, Dr. Howard answered every question which I asked him. Not only did he answer each question, but he did so with precision, depth, and tact, no matter how strange or off-base my inquiry. (He responded quickly, too!) I feel blessed to have worked with the best advisor one could hope to find.

I would like to thank my family for their continued support as I complete my educational journey. I would especially like to thank my husband and best friend, Robert, for putting up with me while I cloistered myself in the basement for a month to complete the writing on this project, for encouraging me to pursue my educational dreams, and for always loving me.

Amanda C. Meyer
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CHAPTER I

INTRODUCTION

Shapiro (1987) added a substantial contribution to the study of trust by presenting a detailed theoretical analysis of the social control of impersonal trust. She stated that trust is embedded in agency relationships, in which one person or organization (agent) works or functions on behalf of another (principal). Shapiro noted that agency relationships are increasingly common in modern society, as agents are employed to handle tasks which principals do not have the time or expertise to properly address. Agency relationships are built on trust, but not on interpersonal trust which develops between individuals who engage in face-to-face contact. Given social distance, combined with power and expertise differentials, between agents and principals, trust within agency relationships is based on a fiduciary responsibility rather than on a sense of obligation, and is therefore impersonal in nature.

Shapiro (1987) explained that the nature of the impersonal trust relationship leaves agents in a position of control over principals, and conversely leaves principals vulnerable to the misdeeds of agents. Principals, therefore, employ “guardians of trust,” often other organizations, to act as watchdogs to ensure that agents fulfill their fiduciary responsibilities. Shapiro noted that the employment of guardians of trust provides social organization of distrust, meaning that guardianship is a socially acceptable, systems-based channel through which principals may simultaneously express distrust in an agent.
while engaging in oversight of the agency. However, guardians of trust are subject to the moral and ethical failings of both principals and agents. Furthermore, given that guardians perform a service on behalf of principals which principals are unable to provide for themselves, guardians simultaneously function as agents. When problems manifest with guardians of trust, new guardians may be employed to oversee the present guardians, spurring an endless cycle of guardian-agent-principal relationships. Shapiro (1987) stated that, with the addition of each new party to trust-based relationships, trust itself becomes more diffuse and complex. Shapiro suggested that one option to avoid the problems of guardianship and agent-principal relationships would be to decline to participate in agency relationships, especially with strangers. However, while withdrawing from systems of agency would minimize risk for the individual, Shapiro noted that the refusal to extend trust leads to economic and social stagnation.

In sum, Shapiro affirmed that agency relationships often enrich the lives of principals and agents, but the necessity of such relationships in the modern world puts agents in a position of power over principals. In a refined statement of the difficulties for both agents and principals in establishing trust-based agency relationships, Shapiro stated:

> The paradox of trust is akin to the choice between Type I and Type II errors. Should the procedural constraints of trust be set so narrowly that desirable agency behavior is deterred or so flexibly that inappropriate behavior is tolerated? Most often, principals equivocate: they really hope that trustees do not take their instructions too literally yet simultaneously fear that they will not (Shapiro, 1987, p. 651).

This project extended the application of the construct of impersonal trust as outlined by Shapiro (1987) to the trust relationship which Americans have with FDA. It explored the
ways in which FDA functions as both agent and guardian of trust for Americans. Of note, there is a practical distinction between assigning a primary designation to an organization of “agent” or “guardian,” although all guardians also function as agents. According to Shapiro (1987), an agent in an original agent-principal relationship is contracted to perform a specific task, and the agency’s fiduciary responsibility to the principal is encased in the completion of the assigned task. Although fiduciary responsibility dictates that an agent should act prudently in the execution of a task and should work for the benefit of the principal, the principal has limited means to independently verify the fulfillment of these obligations. The principal-agent relationship is reduced to one in which principals hope, but cannot confirm, that agents are acting on their behalf, and one in which the higher-order responsibilities toward the principal implicit in the assignment of agent as true fiduciary are lost. In short, agents have incentive to complete tasks on behalf of principals only if they must, and have little personal interest, aside from how such investment otherwise benefits the agency and apart from fulfilling minimum duties of care, in the overall well-being of principals.

Whereas an agent is employed to complete some task on behalf of principals, the sole purpose of a guardian of trust is to function in a fiduciary capacity. The purpose of the agent is to do; the purpose of the guardian is to protect.

Shapiro (1987) stated that guardians, while still functional agents of trust, are held to a higher level of responsibility than original agents. In law, guardians are assigned to individuals who are unable to care for themselves. Embedded in the notion of guardianship is an understanding of powerlessness on the part of principals to make their
own effective decisions. Once principals make the choice to use medications, and therefore engage in the agent-principal relationship between pharmaceutical companies and Americans, they are essentially powerless to oversee the safety of the products of the pharmaceutical industry. FDA is employed as an arbiter of the safety of medications, and according to Shapiro (1987), officials within guardianships are expected to limit their own compensation, to make impartial decisions, to hold certifications and educational credentials which verify their competence, and to hold themselves to a overall higher standard of responsibility toward principals.

While guardians of trust are subject to the same moral and ethical dilemmas as other agents, the distinction between original agent and guardian is important because the designation of guardian implies that the guardianship agency should be held to a stricter set of ethical standards. Although guardians are often allowed to hold the same level of conflicts of interest, engagement in self-dealing, and other ethical concerns as other agencies, perhaps, given the great responsibility with which guardians are entrusted, policies which allow these ethical concerns to linger should be re-examined.

Furthermore, Shapiro's (1987) work was conceptual in nature, and she called on researchers to address a battery of questions about impersonal trust through continued conceptual and empirical development of the construct. This paper builds on the work of Shapiro (1987), while combining it with work conducted by Meyer and Ward (2009) and other researchers, to develop empirical measures of impersonal trust and dependence in an attempt to add increased operational value to the constructs.
CHAPTER II

BACKGROUND

The concept of trust has its origins in the fields of philosophy and religion and has been studied throughout history (Hardin, 1998). Hardin (1998) noted that ancient Greeks equated lawfulness with trustworthiness, and at the heart of the philosophical debate about human nature between Hobbes and Locke was the question of whether humans can be trusted to act civilly toward each other and, if so, under what conditions (Malinowski & Mazlish, 1960).

Rosseau et al. (1998) defined trust as a “fundamental construct” and sought to develop a cross-disciplinary view of trust. However one defines it, there is general agreement across academic disciplines that trust is a necessary condition for modern society. For example, we trust that strangers will not try to harm us without due cause, and as demonstrated by Garfinkel’s breaching experiments, we trust that people will respond to common social interactions in predictable ways (Darity, 2008; Garfinkel, 2011).

Although most disciplines which address the construct acknowledge that it is an integral part of modern society, there is less agreement about how to define and parameterize trust. In response to the myriad, overlapping, and occasionally contradictory definitions of trust scattered across academic disciplines, Susan Shapiro (1987) offered the following critique:
It's [trust's] conceptualization has received considerable attention in recent years, resulting in a confusing potpourri of definitions applied to a host of units and levels of analysis. Many of these definitions regard trust as a property either of individuals or of the emotional content, common understandings, or reciprocities of their interpersonal relationships (using “trust” more or less synonymously with feelings of faith, confidence, expectation, reliance, security, etc.) (Shapiro, 1987, p. 625).

In line with Shapiro's (1987) critique, some social theorists have made great strides in advancing the understanding of trust as it develops between and beyond the internal psyche and personal relationships (Frederiksen, 2012; Möllering, 2001; Messick & Kramer, 2003; Lewis and Weigert, 1985). However, less work has been done to examine and define impersonal trust-based relationships between principals and organizations, such as between the American public and FDA.

Contextualizing the Trust Relationship between Americans and FDA

Prior to delving into a discussion about the nature and definitions of trust, it is valuable to examine why FDA was chosen as a focus of this study and to explain why it is important to understand the type of trust relationship which Americans have with FDA.

First, the formation of FDA was the result of an iterative process directed toward stricter oversight of food and drug manufacturing processes. The practice of securing greater trust in food and drug corporations was necessitated by egregious acts of negligence on the part of such companies, resulting in sickness, death, and permanent disability for unwitting patrons. For example, Upton Sinclair's publication The Jungle epitomized pioneering journalism of the 1900s which exposed the despicable conditions of food processing in America. Increased awareness of unsanitary food-processing
practices led to the passage of the 1906 Pure Food and Drugs Act, a precursor to the present-day FDA. This 1906 act allowed the federal Bureau of Chemistry to regulate the safety of food and drugs used in interstate commerce by removing impure or misbranded products from the market. In 1930, the Bureau of Chemistry was renamed the Food and Drug Administration. While the Pure Food and Drugs Act was still in force in 1930, it was not powerful enough to prevent harmful substances from being sold on the market, and in 1937 the unregulated drug Elixir Sulfanilamide caused the rapid deaths of 105 people across America before the federal government took action to remove it from the market (Jarrell, 2012). Following public uproar, the passage of the 1938 Food, Drugs, and Cosmetics Act expanded the regulatory authority of FDA to include oversight of both prescription and non-prescription drugs and granted FDA the majority of the powers which it has today (Jarrell, 2012; Whittington, 2010). The government-backed regulatory authority of FDA drastically reduced the number of deaths and medical complications as a result of individuals consuming unsafe and unregulated foods and pharmaceuticals.

Presently, FDA has tremendous power to affect people's lives as it regulates 25% of GDP. FDA is the only agency in the United States which is authorized to grant approval to a company to market a new drug, to design the monographs from which over-the-counter (OTC) drugs are constructed, and to approve the sale of generic medications. FDA is also responsibility for overseeing the safety of alcohol, nicotine, and myriad food products and other substances. In practice, FDA is the only governmental institution guarding the American people from inadvertently consuming drugs with egregious health risks, and stopping the public from consuming food, cosmetics, and drugs in which the
negative health consequences outweigh the potential benefits. In brief, Americans have designated FDA as a guardian of trust in the safety of most foods and all pharmaceuticals.

However, FDA does not always perform its basic functions to the best of its ability. FDA has been subject to scandals and criticisms involving corruption, ineptitude, inaction, and inequality (Deyo, 2004).

For example, controversy surrounds FDA’s regulation of the drug dextromethorphan (DXM), an antitussive found in over 90% of OTC cough-and-cold medications. FDA has continuously refused to schedule DXM, despite concerns from numerous organizations regarding dangers associated with its abuse potential (FDA, 2010).

**Conflicts of Interest**

Lurie, Almeida, Stine, Stine, and Wolfe (2006) found that out of 221 meetings held by 16 FDA Advisory Committees, 73% of the meetings had at least one individual with a self-disclosed conflict of interest. As stated by Deyo (2004), these conflicts of interest are often in the form of “stock ownership, consulting fees, [and] research grants” (p. 142). Although Lurie et al. (2006) determined that removing the votes of individuals with conflicts of interest from the meetings would not have changed meeting outcomes, the researchers also determined that the exclusion of these votes produced less favorable reviews of the drugs in question. Additionally, Lurie et al. (2006) determined that for each person with a conflict of interest serving on an Advisory Committee, the odds of the committee voting for the index drug increased by 10%. Furthermore, the researchers
found that only 1% of the 221 members studied were recused due to conflicts of interest. Lurie et al. (2006) concluded that, despite the continuation of some inevitable conflicts of interest, it often would be possible for FDA to assemble high-quality Advisory Committees which were free of such conflicts.

The FDA allows conflicts of interest to exist in drug approval and review processes. Individuals applying for positions on FDA Advisory Committees are required to self-disclose financial conflicts of interest (Gieser et al., 2009); however, FDA does not take measures to ensure the accuracy of this reporting. Furthermore, provided that such information is disclosed, FDA does not find conflicts of interest in the following amounts problematic and does not consider them a bar to unbiased performance: < $10,000 in consulting fees; < $100,000 in investments; < $300,000 in grants, contracts, or Cognitive Research And Development Agreements (CRADAs); and < $10,000 in lecturing fees (Gieser et al., 2009). Lastly, even when conflicts of interest are present which exceed the acceptable dollar amounts, individuals may still sit on Advisory Committees provided they complete the appropriate waiver (Gieser et al., 2009; Lurie et al., 2006).

**Fraudulent Activities within FDA**

According to the Office of the Inspector General (OIG) (1992), corruption among FDA employees was a widely acknowledged concern within the federal government. The OIG pointed to a scandal in which FDA employees were convicted of receiving illegal bribes from the manufacturers of generic drugs. According to the OIG (1992), “over a 2-year period, three generic drug companies, five company officials, one industry
consultant, and five FDA employees were convicted and sentenced in this phase, in which companies paid to receive favorable processing of their generic equivalents” (p. 3). Following this, the OIG stated that two more companies were prosecuted and sentenced “on charges of fraud, false statements, and manufacturing malpractice” (1992, p. 3). The laboratory which allowed the manufacturing malpractice to occur was also sentenced and penalized, along with a company official who was convicted and sentenced to over two years in jail for his role in defrauding FDA. At the time of publication, the OIG (1992) stated that, “an additional 13 company representatives and 2 laboratory representatives have been charged” for charges of fraud against FDA (p. 3).

Following that series of scandals, FDA engaged in a campaign co-created with the OIG to increase awareness among its staff about bribery and to take measures to decrease its occurrence (OIG, 1992).

Unequal Treatment of Agencies Requesting FDA Approval

As stated by Deyo (2004),

Perhaps the biggest challenge and source of friction for the FDA is the speed of approvals for drugs and devices. Protecting the public from ineffective or harmful products would dictate a deliberate, cautious, thorough process. On the other hand, getting valuable new technology to the public – to save lives or improve quality of life – would argue for a speedy process (p. 145).

Topol (2004) pointed out that drug companies stand to gain enormous profits with “blockbuster” drugs (p. 1708), and Deyo (2004) added that in order to expedite the process of drug approval, in 1992 Congress authorized FDA to accept “user fees” from pharmaceutical manufacturers (p. 145). These “user fees,” as of 2004, accounted for
approximately half of FDA’s then-budget of $1.3 billion. Therefore, according to Deyo (2004), FDA may have difficulties controlling conflicts of interest related to the acceptance of these fees, and may face pressure to approve drugs without allowing time for adequate clinical trials and review.

Olson (2004) found that firms which had larger research and development (R&D) departments received faster approval times for NDAs than firms which were less research-intensive. The researcher theorized that FDA was not as critical of firms with larger R&D departments because those firms were assumed to have properly completed their pre-clinical and clinical trials based on their previous experiences with similar experiments. The end result was that firms with smaller R&D departments typically experienced longer waiting times for the approval of new products compared to firms with more resources dedicated to R&D (Olson, 2004).

In 1992, the OIG found that one of the primary problems with the functioning of FDA was its lack of “equitable and fair treatment of applicants” (p. ii). Carpenter (2002) noted that the approval times for drugs varied widely based on the wealth of the organization requesting FDA approval, the media coverage given to the disease, and the number of organizations with interests in treating the disease. To fix this problem the OIG suggested, “the development of ‘first-in, first-out’ policies, and standard operating procedures and guidelines for reviewers” (1992, p. ii). Although this criticism was raised by the OIG in 1992, as of 2006, FDA had yet to implement such ‘first-in, first-out’ procedures (OIG, 2006).

In short, FDA is susceptible to corruption, controls the knowledge which it both
intakes and releases, and at times makes controversial, or even incorrect, regulatory decisions.

FDA has been accused and convicted of serious breaches of trust, yet based on previous research about levels of trust in FDA (Dickinson, 2007), the public appears unconcerned (or at least unaware of these controversies). Therefore, a primary purpose of this project was to evaluate the levels of trust toward FDA as held by older individuals. Older subjects were chosen because they are less trust in FDA than other age groups and who, as a cohort, are less likely to extend blind trust than younger people (Dickinson, 2007).

The question of to what extent individuals trust FDA is pertinent because, while some amount of trust in government is necessary for government to function, it is also necessary for individuals to remain somewhat critical of governmental institutions in order to question the knowledge they produce and to remain alert to the potential for corruption and abuse of power.

Furthermore, examining the nature of the trust relationship with FDA is important because, framed in the context of impersonal trust as outlined by Shapiro (1987), it allows for the understanding that the balance of power in the relationship is overwhelmingly in favor of FDA. Unlike an interpersonal trust relationship between equals, in which both parties may attempt to manipulate each other’s actions, in the case of the impersonal trust relationship between FDA and the American public, the flow of information and direction of action is almost exclusively one-sided. While FDA can directly affect the lives of Americans, it is only through tremendous collective action that
individuals can successfully endeavor to affect or change FDA.

Furthermore, at what point does extreme difficulty in negotiating the parameters of the trust relationship with FDA turn into dependence on FDA? When subjects are in a state of impersonal trust they perceive that they have a choice about whether to trust, but with dependence subjects feel they have no choice in the matter – they must trust, meaning that they are dependent on FDA. The practical distinction between trust and dependence has important psychological consequences for individuals who feel they have no choice but to trust FDA, as these individuals may feel powerless to meaningfully act to control their own medication-related healthcare decisions, and also has important consequences of FDA itself. If people feel they are fully dependent on FDA to ensure the safety of their medications, it is reasonable to argue that any conditions which may compromise the ability of FDA to perform this great fiduciary responsibility without unreasonable bias, such as the existence of conflicts of interest and favoritism toward certain pharmaceutical companies, should be re-examined and perhaps removed, thereby holding FDA and its actors to a higher ethical standard associated with guardian of trust as outlined by Shapiro (1987).

**Elements of Trust**

Prior to discussing definitions of trust, this paper offers an outline of the basic elements of trust as discussed and often accepted within sociology. First, there is widespread agreement that trust is a social construct. Möllering (2001) emphasized “the relational quality of trust” (p. 407) as necessary to understanding the development of
trust. There is also general agreement that a second element of trust is that it must be directed toward some future outcome (Luhmann, 2000; Shapiro, 1987).

Barber (1983) noted another general component of trust, stating that trust involves a willingness to rely on another person, social group, or institution or their symbolic representation. Hawley (2012) argued that while reliability is an important component of trust, interpersonal trust cannot be reduced to reliability. Hawley (2012) provided the example that, while people rely on inanimate objects, the failure of the objects to perform as expected does not constitute a breach of trust (e.g. if a chair collapses under a person, the individual likely does not feel as if the chair has somehow wronged him or her). Hawley (2012) also argued that when people rely on individuals who are unaware that they are being relied upon, this also does not constitute a trusting relationship. Hawley (2012) therefore concluded that engaging in a trusting relationship with another “has something to do with your heightened expectations in trusting, and your reaction if the trustee lets you down. Researchers from different disciplines share this basic view of trust, but they can't agree about what exactly these heightened expectations and reactions are” (p. 5).

Luhmann (2000) also emphasized that trust involves expectation, and framed the difference between simple expectation and trust as a question of confidence versus trust: “The distinction between confidence and trust thus depends on perception and attribution. If you do not consider alternatives (every morning you leave the house without a weapon!), you are in a situation of confidence. If you choose an action in preference to others in spite of the possibility of being disappointed by the action of others, you define
the situation as one of trust” (p. 96).

The “possibility of being disappointed” as noted above assumes that trust also carries an element of risk (Luhmann, 2000, p. 96). In fact, Luhmann outwardly acknowledged that extension of trust carries risk, and an individual must have something to lose, however small, in order to extend trust. Although several researchers agree that trust necessarily involves an element of risk, the literature is not clear on what situation exists if a person engages in trust-like behavior while he or she has nothing to lose. In a mode similar to risk, trust involves uncertainty. If there is either no chance or a 100% change that something will happen, we have knowledge, not trust.

Meyer and Ward (2009) specified that the expected outcome of trust must be positive. Hawley (2012) echoed this sentiment by stating that if people expect an individual to fail to follow through on obligations, then people can hope that the individual will follow through but cannot be said to properly trust that the individual will follow through, at least until present expectations change direction.

In addition to the element of expectation, other theorists have argued that trust supposes that “the other person or persons will abide by ordinary ethical rules that are involved in the situation” (Messick & Kramer, 2003). This assumption can be applied to both personal and impersonal trust. Messick and Kramer (2003) define trust as “a form of shallow morality,” meaning that the acquisition of trust is associated with ethical behavior and those who are trusted thereafter acquire honor, which is a desirable form of social capital (p. 89).
Importance of Trust

At its most basic level, trust functions to reduce complexity in decision-making processes. Rational choice theory dictates that a person will ponder every plausible option and will then take whatever course of action maximizes benefits while reducing personal costs (Aronson, 1999). However, several theorists (Hawley, 2012; Luhmann, 2000; Möllering, 2001) have noted that it is not possible for human beings to realistically consider every possible course of action prior to making a decision about whether to extend trust. Furthermore, rational choice theory ignores that people are not purely rational actors and sometimes make decisions based on emotions rather than logic (Collins, 2004). Even if humans could take every possibility into account on a singular occasion, it would be impossible to account for all future contingencies. As stated by Möllering (2001), the extension of trust involves the “suspension of disbelief” in certain possible but unlikely possibilities (e.g. an individual trusts that the person he hired to fix his television will not rob his house); therefore, trust is used as a mechanism of reducing the complexity of decision-making by acting as if certain possible social outcomes will not occur (Möllering, 2001). Suspension of the beliefs that everyone in the government is corrupt or that all repair persons are also thieves, for example, is crucial to the functioning of a civilized society and democracy (Darity, 2008). If suspension of these possible but improbable situations was not possible, people may stop trusting each other, and “forgoing these agency relationships considerably constrains efficiency, affordability, richness of experience, and protection from risk. Carried to an extreme, it produces paralysis” (Shapiro, 1987).
The above-mentioned elements of trust, including its relational quality, direction toward some future outcome, involvement of multiple social actors, involvement of risk and uncertainty, inclusion of positive expectations related to outcome, and use as a decision-making heuristic, are not often explicitly included in definitions of trust; instead, they are assumptions which underlie the understanding of trust as a general concept.

Definitions of Trust

In an effort to explore impersonal trust in FDA, this paper first considers a definition of personal trust which was created specifically for the study of health sociology. Meyer and Ward (2009) examined factors which predicted patients' trust in their general healthcare practitioners, and defined trust as, “the optimistic acceptance of a vulnerable situation which is based on positive expectations of the intentions of the trusted individual or institution” (p. 3). Although applied to personal relationships, this definition of trust is an adequate starting point for understanding impersonal trust in persons and organizations related to healthcare. This is because Americans who need FDA-approved medications are in a vulnerable situation, FDA is expected to perform according to statutory guidelines, and when Americans feel that FDA will perform as expected they have trust in FDA.

However, based on the work of Shapiro (1987), Meyer and Ward's (2009) definition of trust is not alone sufficient to understand the impersonal trust relationship which Americans have with FDA.

First, Meyer and Ward's work does not take into consideration the importance and
existence of “generalized interpersonal trust,” defined as the expectation of positive or neutral interactions with total strangers. Möllering (2001) quoted Simmel as saying that, “without the general trust that people have in each other, society itself would disintegrate' (1990:178)” (p. 405).

Both background trust and generalized interpersonal trust are extended without prior knowledge about the specific individuals in question. Instead, both types of trust are forms of depersonalized trust, that is, “trust based on category, not personal information or experience” (Cook, 2003). Even if we do not know the engineers who personally constructed a particular bridge, we know that engineers as a class must take rigorous coursework and hold specific credentials and degrees to hold the title of “engineer.” In this case, we trust experts and categories of competent (or at the very least, non-hostile) others to fulfill their social and occupational obligations (Powell, 2011). Depersonalized trust may also be referred to as “impersonal trust” (Shapiro, 1987; Schoenfeld, 2005), which is a primary focus of this research project.

To understand the trust relationship which Americans have with FDA, it is necessary to first understand that relationship as impersonal. Average Americans do not personally know the individuals who are in control of regulating medications at FDA, and may not know a single member of FDA or even how FDA is operated. This level of social distance between Americans and FDA is one element which makes this trust relationship impersonal rather than personal.

Susan Shapiro offered the following definition of impersonal trust:

Impersonal trust arises when social-control measures derived from social ties and direct contact between principal and agent are unavailable, when faceless and
readily interchangeable individual or organizational agents exercise considerable
delegated power and privilege on behalf of principals who can neither specify,

It is through this lens of impersonal trust that American's relationship with FDA will be
conceptualized and empirically examined.
CHAPTER III

LITERATURE REVIEW

Functional Accounts of Impersonal Trust

One of the primary purposes of this project is to detail how pharmaceutical companies are engaged in an impersonal agent-principal relationship with the American public, how FDA has been employed as a guardian to oversee that relationship, and how in being so employed, FDA itself has become an impersonal agent. Susan Shapiro's (1987) theory of impersonal trust is used as a template to explain these relationships, and the formation and implications of these agent-principal-guardian relationships are detailed in the remainder of this section.

Shapiro (1987) offered a functionalist analysis of impersonal trust built on models of trust grounded in economics and examined the role and production of trust between agents and impersonal principals. The present study reviews Shapiro's (1987) insightful analysis of impersonal trust and explains how it applies to the impersonal trust which Americans (principals) have in pharmaceutical companies (agents) and FDA (guardians of trust).

Shapiro (1987) began her analysis of impersonal trust by asking the question, “How do societies control trust relationships that are not embedded in structures of personal relations?” (p. 623). She first stated that close social proximity is not a necessary prerequisite for trust because people may enter into “agency relationships,” in which
“agents” (defined as individuals or organizations which act on behalf of others), take care of business which “principals” (the people on whose behalf the agents act) cannot or do not want to take care of on their own. Shapiro noted that agents are often employed to handle tasks for which principals lack sufficient expertise.

Shapiro (1987) agreed with Niklas Luhmann that increased opportunities to foster societal trust through agency relationships add complexity to social interactions. This complexity can be good in that it allows for individuals who may otherwise never interact in a less complex culture to meet and exchange goods, services, and ideas.

However, Shapiro (1987) mentioned that agents are often in a position of power to abuse principals. A large amount of the power of agency comes because, “Agents create and disseminate information that cannot be verified by its recipients because of their lack of expertise or access to data sources” (p. 629). Other problems plague agent-principal relationships, such as social and physical distance between agents and principals; the faceless bureaucratic structure of many agencies, inaccessibility of company reports due to concerns about protecting proprietary information; and the lack of “mechanisms to deter and, if necessary, to punish unacceptable agent performance” (p. 632). Shapiro stated that:

Agents therefore hold structural opportunities to 'take the money – in all its manifest forms – and run' while unwitting principals, blinded by distance, organizational structure, secrecy, and lack of expertise, idly await the future dividends of symbolic promises made by faceless strangers. Hence, the problem of trust (Shapiro, 1987, p. 630).

Shapiro (1987) noted that there are some actions which principals may undertake to protect themselves against abusive agents, such as entering into legal contracts, only
using agents with whom they have personal relationships; becoming lay experts; diffusing risk (as with insurance policies, banks, stocks), and at an extreme, refusing to enter into principal-agency relationships altogether. While the last coping mechanism provides a good amount of certainty that individuals will not be abused by agents, it may also be nearly impossible for those individuals to function normally and effectively in modern-day society, and employment of the other coping mechanisms may have negative effects on social and economic development.

Agents may take action to self-regulate by abiding by a set of procedural norms or voluntarily seeking independent certification or approval to shield against the possibility of abuse of power; however, Shapiro (1987) stated that there are problems inherent in both of these techniques. She pointed out that procedural norms can be violated and that unethical but commonplace practices may be ignored, and companies which provide independent certification may commit financial suicide by providing a low rating to a well-paying customer.

Schoenfeld (2005) elaborated on the role of norm violation within the agent-principal relationship in understanding the consequences of misconduct by agencies, specifically, by prosecutors. The researcher argued that in order to understand the reasons for prosecutorial misconduct, it is vital to examine both the social and organizational structure which surrounds the office of the prosecutor, and the nature of the trust-based agent-principal relationship between prosecutors and the public.

Borrowing from Shapiro (1987), Schoenfeld (2005) constructed a theory to explain prosecutorial misconduct which, “builds from the characterization of prosecutors
as agents of trust and prosecutorial misconduct as violations of the norms of trust” (p. 125). Schoenfeld (2005) argued that tremendous power on the part of the prosecutor to act on behalf of principals (the public) without consultation from principals; the withholding of information from principals in the interest of protecting privacy or ensuring secrecy; the lack of discrete and enforceable procedural norms unique to the position of prosecutor; and other factors create a power imbalance between principals and prosecutors. Schoenfeld argued that these situations are ripe for the abuse of power; however, principals trust that prosecutors will not fall to the temptation. Therefore, if prosecutors fail to restrain themselves and engage in acts of misconduct, then, “Prosecutors' acts of misconduct are essentially violations of the norms of trust” (p. 127).

The crux of Schoenfeld's (2005) argument is that the unfair balance of power and resources within the agent-principal relationship which prosecutors have with the public, coupled with the motivation of many prosecutors to act in a self-interested manner for the sake of job security, a work environment which allows for a great degree of autonomy with little oversight, and the unwillingness of professional organizations and courts to act as guardians of trust by imposing sanctions or penalties upon individuals guilty of prosecutorial misconduct, create a situation in which prosecutorial agents may act unscrupulously with little fear of negative repercussions of formal or informal social control.

How do principals address these concerns? As an alternative to the coping mechanisms to deal with impersonal trust relationships, Shapiro (1987) argued that principals may turn to “trustees or guardians of trust, a supporting social-control
framework of procedural norms, organizational forms, and social-control specialists, which institutionalize distrust” (p. 635). Guardians of trust are necessary because, “by definition, the principals of impersonal trust are vulnerable and impotent” (Shapiro, 1987, p. 635), and may otherwise either forgo the benefits of agency relationships or may suffer unacceptable losses at the expense of unscrupulous agents (Gilbert, 2004).

However, Shapiro (1987) stated that guardians of trust are subject to the same moral and ethical problems in managing the trust relationship as principals. Shapiro concluded that, “Ironically, the public and private guardians of trust also stand in a trust relationship with those whom they hope to reassure. Guardians of trust are agents” (1987, p. 645). The notion that guardians of trust also function as agents can be applied to the trust relationship which Americans have with FDA. FDA has been appointed by democratically elected officials to oversee the pharmaceutical industry, which makes the organization a guardian of trust in medications and other FDA-regulated products. However, FDA functions as an agent because it performs services such as monitoring the safety of medications, foods, and nicotine products, which Americans are unable to provide for themselves. FDA functions more specifically as an impersonal agent because its decision-makers are socially removed from average Americans, the flow of communication between FDA and Americans is primarily unidirectional, and FDA performs functions and releases information which most individuals lack the ability to independently verify.

Guardians of trust are expected to “place the interests of those they represent over their own, to deal at arm's length and disqualify themselves from agency relationship that
create conflicts of interest, to limit their compensation and other position-related benefits, and to refrain from self-dealing” (Shapiro, 1987, p. 637).

Examples of guardians of trust include governmental organizations which oversee the actions of corporations; private testing firms which assess intelligence levels, substance abuse profiles, and psychological well-being; and fact checkers for magazines and newspapers. Guardians of trust also serve as “gatekeepers” of trust, meaning that there are special requirements which must be met, such as the completion of specific training programs or levels of education, in order for an individual to serve as a guardian. These restrictions keep unqualified individuals from serving in high-level positions; however, they also act as barriers to allowing principals to access guardians of trust. In this sense, Luhmann (2000) was correct: trust breeds trust which breeds increasingly complex social relationships.

Shapiro (1987) argued that the added level of complexity introduced by employing guardians of trust may not be worth the associated risks. First, guardians of trust struggle with the same issues as principals with regard to ensuring access to and cooperation from agents. Secondly, guardians of trust are subject to the same potential for moral failing as agents. For example, guardians can be bribed, conflicts of interest can be tolerated beyond an acceptable measure, and grievances can be overlooked (Gilbert, 2004; Schoenfeld, 2005). Therefore, corrupt guardians of trust could greatly decrease the quality of the relationship between agent and principal rather than enhance it.

Furthermore, Shapiro (1987) argued that the employment of a guardian of trust implies distrust of the agent. This assumption of distrust of the agent can contagiously
spread to distrust of the guardian to properly oversee the principal-agent relationship. The principal may then seek additional trustees to oversee the guardian which oversees the agent. In this cycle, trust becomes progressively diluted and distrust becomes increasingly widespread. Shapiro argued that in some instances, it is an open question as to whether it is preferable to have a guardian of trust or whether it is better for trust to exist simply between principals and agents despite the potential problems involved with this arrangement.

Shapiro (1987) also stated that if principals do not trust an agent but do trust a guardian, the above-mentioned cycle may not start and the relationship may be satisfactory for all parties.

In sum, Shapiro (1987) argued that principals employ agents to perform tasks which principals cannot or do not wish to complete for themselves. The development of agent-principal relationships may lead to social and economic growth; however, agents are often in positions of power and hold considerable opportunities for abuse of principals. To protect themselves from abuse of power by agents, principals may employ guardians of trust to oversee the activities of retained agents. While use of guardians of trust may provide an added level of security in the original agent-principal relationship, it may also add an unanticipated layer of complexity as a result of moral and ethical failings on the part of guardians. This complexity is amplified by the fact that guardians of trust themselves function as agents which have been employed to oversee the execution of fiduciary responsibility on the part of the original agent. The ultimate problem stems from the fact that there is no one to oversee the guardian, so principals may employ yet
more guardians to oversee the first guardian, leading to an endless cycle of agent-guardian relationships and an overall diffusion of trust.

Shapiro’s theory of impersonal trust involving the use of guardians within agent-principal relationships was applied to the relationships which exist between pharmaceutical companies, the American public, and FDA. According to Shapiro’s logic, trust in FDA would imply that agents are ostensibly satisfied with the use of FDA as guardian of trust in the safety of pharmaceuticals and other regulated products, whereas lack of trust in FDA would mean that agents are not satisfied with FDA as guardian and may therefore be reluctant to take the agency’s advice or to use products regulated by FDA. Too much distrust of FDA could lead to individuals rejecting medications and other life-saving interventions because they do not trust the ability of FDA to oversee the safety of the products. Therefore, the present study asked the following question: Is FDA, a guardian of trust, trusted by Americans?

**Impersonal Trust and FDA**

In the case of the present study, it is argued following the thoughts of Shapiro (1987) that an impersonal agency-principal relationship exists between Americans and pharmaceutical companies, and that Americans employ FDA as a guardian of trust to oversee this relationship.

It may be helpful to delimit the role relationship between Americans and pharmaceutical companies and between Americans and FDA. Using Shapiro’s (1987) work, it can be argued that an impersonal principal-agent relationship exists between
pharmaceutical companies and Americans. First, a quasi-formal agreement between pharmaceutical companies and taxpayers dictates that the companies (agents) agree to accept tax breaks in exchange for making concerted efforts to provide safe and effective medications for the American public (principals). An underlying informal agreement states that if the companies provide a safe and effective pharmaceutical product, Americans will use that product to treat their medical conditions. Evidence of this can be seen in commercial advertisements for presumably safe medications which are directed toward the public which Americans then request from their physicians by name, and in the incentives provided to physicians by pharmaceutical companies for offering prescriptions for their products when their professional judgment leads them to believe the product may potentially be helpful.

Using Shapiro's (1987) framework of impersonal trust, the impersonal nature of the trust relationship between pharmaceutical companies and Americans becomes clear. First, the decision-makers within pharmaceutical companies are socially and physically removed from average Americans by great distance. CEOs of large pharmaceutical companies commonly report multimillion dollar salaries and have the ability to approve or deny advancement on research projects of tremendous importance. Furthermore, pharmaceutical companies provide services (creation and testing of current and new medications) which the vast majority of individual Americans lack the knowledge and resources to provide independently. Pharmaceutical companies also have bureaucratic structure, as websites of large drug manufacturers direct principals toward contact persons who perform administrative duties, have mid-level researchers who design
experiments and analyze data, and have CEOs and board members who oversee day-to-day operations. Furthermore, pharmaceutical companies have been accused of being unnecessarily secretive with their data, of refusing to allow independent verification of data, of withholding non-significant results and concentrating alternatively and exclusively on significant positive findings, and by one scientist, of using the judicial system to harass researchers who sought to report more information than one Canadian pharmaceutical company desired to release (Hailey, 2000).

In short, pharmaceutical companies are in a situation to abuse their power, and Hailey (2000) reported that at least in some instances, they do. Yet, average Americans have little recourse. First, pharmaceutical companies have the resources to address many conflicts internally and discretely so they are never revealed to the public. When problems are revealed, although individuals may write letters in public forums, seek legal recourse, talk to local news sources, report the agency to the Better Business Bureau, or write to legislative representatives, the resources of the large company far outnumber the resources of an average American to the point where a fine of nearly one billion dollars is a manageable loss for Merck, a prominent American pharmaceutical manufacturer (Gagnon, 2013).

As a result of great potential, exercised or otherwise, for the abuse of power by pharmaceutical companies, and as a result of the lack of good alternatives, Americans have designated FDA as a guardian of trust to ensure both compliance with ethical standards on the part of drug manufacturers and to safeguard the safety and effectiveness of all American medications. However, as stated by Shapiro (1987), the same factors
which both positively and negatively affect impersonal trust relationships with pharmaceutical companies have the ability to affect impersonal trust relationships with FDA. This is because, once FDA is given the responsibility of guardian of trust, it assumes the social position of agent, too.

For example, just as pharmaceutical companies have an obligation to provide innovative and effective medications in exchange for taxpayer dollars, FDA also shares a set of reciprocal obligations with the American public. FDA has an obligation to ensure that all medications which enter the United States market are “safe and effective,” and the American public has a duty to vote for legislative representatives who will properly oversee the organization and who will provide FDA with the resources necessary to do its job. It is only through this indirect effect that the American public has the ability to interact with FDA. In terms of behavior, differential status, and privilege (Straus, 2000), FDA outweighs almost all individual members of the American public, and has greater influence in certain areas than even institutional powerhouses such as Drug Enforcement Administration and American Medical Association.

In terms of behavior, FDA is expected to dictate instructions to the public about the proper use of medications and the public is expected to follow these instructions. Here, as with pharmaceutical companies, Americans are expected to trust the information coming from FDA with little ability to independently verify the facts. Physicians have more flexibility in how they interpret FDA guidelines and have the ability to use professional judgment to make atypical recommendations for medication usage; however, FDA guidelines are the “gold standard” and physicians must have good justification for
prescribing medication outside FDA recommendations.

FDA is also filled with bureaucratic structure and makes extensive efforts to channel all materials through necessary sub-committees, committees, and hearings, and to document the results in detail. Likewise, social distance separates most Americans from FDA, and only few selected members of the American public are allowed to attend decision-making meetings. Even fewer are allowed a chance to speak at those meetings or to have a spot designated for a consumer on an important FDA committee.

Shapiro (1987) stated that, “impersonal trust should be thought of as a continuous variable. The placement of an agency relationship on this continuum is determined by the availability to discrete principals of alternative mechanisms of social control that they can exercise to regulate their agents” [original emphasis] (p. 634). In the case of both pharmaceutical companies and FDA acting as agents, the American public has very little control over the workings or direction of either type of organization. To complicate matters, FDA also functions as the gatekeeper of approval to sell and manufacture medications in the United States. FDA approval ostensibly means that humans may consume the medication without irrational fear of disability or death.

Overall, FDA serves an important function as guardian of trust in overseeing the principal-agent relationship between Americans and pharmaceutical companies, and there is little doubt or argument that medications are safer now, as a result of FDA intervention, than they were 100 years ago. However, as stated by Shapiro (1987), FDA may be vulnerable to the same problems inherent in impersonal trust relationships which plague pharmaceutical companies. If this is the case, individuals may drop out of the agent-
principal relationship and fail to take necessary medications for fear that the medications are not safe for consumption. For example, in some situations FDA may relax its guardianship and approve a vaccination for use prior to full FDA-approval if FDA feels that the benefits of doing so outweigh the possible negative effects. The downside to this is individuals may be less likely to trust vaccinations, especially when those vaccinations are administered to their children, if they know that their appointed guardian, for whatever reason, has not fully tested the safety and effectiveness of the vaccine.

Therefore, it is important to understand how Americans feel about FDA in order to assess whether action is necessary to shore up trust in the institution because Americans view FDA as just another impersonal agent, or whether Americans are satisfied with the guardians who they have chosen to oversee the safety of their potentially life-saving medications.

It is useful to define the trust relationship with FDA as impersonal because this both provides a theoretical framework for understanding how FDA interacts with the public, and it allows this study to test the hypothesis that variables associated with personal trust will also be associated with impersonal trust. Lastly, as trust is an amorphous concept, it is useful to carve out recognizable distinctions in an effort to provide the concept of impersonal trust, at least from one vantage point, with one more concrete application and increased definition.

**Measures of Impersonal Trust**

The majority of research which has focused on measurement of impersonal trust
has concentrated on impersonal trust in organizations. This is a narrow application of impersonal trust compared to Shapiro's (1987) broader expansion of the construct to include impersonal trust relationships between most classifications of agents and principals. For example, Vanhala, Puumalainen, and Blomqvist (2010) found that the perceived capability and fairness of an organization were the two dimensions which predicted impersonal trust in an organization. As opposed to what is being measured in this project, the dimensions identified by Vanhala et al. (2010) were characteristics of the organization, not of the individual extending trust. The researchers also stated that, “impersonal trust refers to trust in impersonal organizational factors such as vision and strategy, top management, the management group’s goals and capability, technological and commercial competence, justice, fair processes and structures, roles, technology and reputation and HRM policies” (p. 486). Additional applications of impersonal trust to the understanding of organizational structure and management defined impersonal trust in similar ways (Tyler, 2003; Whitener, 1997; McCauley & Kuhnert, 1992; Perry & Mankin, 2007).

While the prediction of impersonal trust using factors which affect business output and functioning is valid for theorists of organizational design and human resource management, these factors do little to explain impersonal trust in FDA following the framework of Shapiro (1987).

Less empirical work on the study of impersonal trust has been conducted in the field of sociology. This study made an effort to determine whether predictors associated with impersonal trust as outlined by Shapiro (1987) were also associated with personal
trust in general physicians as outlined by Meyer and Ward (2009). These variables are outlined in detail in Chapter 3. This effort was undertaken to determine to what extent interpersonal trust and impersonal trust are two different constructs. Impersonal trust has stricter parameters, but do we have to look at the way in which people trust impersonal institutions as different from the way in which they trust those with whom they have personal interactions? One way to explore this question is to determine whether the variables associated with personal relationships also are associated with trust in impersonal relationships. If the associations persist, it might only be necessary to draw a conceptual distinction between the constructs. If similar associations are not found, it might be necessary to further flush out the dimensions which separate trust from impersonal trust.

Impersonal Trust versus Dependence

In an attempt to add definition to the construct of trust, a secondary focus of this study is to add to work which has been done to distinguish the constructs of trust and dependence (Meyer & Ward, 2009). This distinction is important is because a subjective state of dependency on the part of principals indicates a greater need for stricter ethical practices on the part of related agents and guardians. Furthermore, teasing out differences between constructs adds to their theoretical and operational values.

As a note, it has been argued that trust often has been conflated with similar but distinct constructs (Luhmann, 2000; Meyer & Ward, 2009; Gilbert, 2005). Lukes (2005) drew a distinction between trust and power, Möllering (2001) between trust and weak
inductive knowledge, Simmel between trust and confidence (Möllering, 2001), and Luhmann (2000) between trust and hope, faith, and confidence.

Trust is also not dependence. Meyer and Ward (2009) expanded on the conceptual framework established by Luhmann and juxtaposed the constructs of trust and dependence. First, Meyer and Ward (2009; 2013) established that two primary types of trust exist – interpersonal trust and institutional trust. This study blended the work of Shapiro (1987) and Meyer and Ward (2009) and therefore juxtaposed the constructs of (inter)personal trust versus impersonal trust. Allowing for rare exceptions, while impersonal trust as described by Shapiro (1987) would always have to be a form of institutional trust, institutional trust could be, but would not necessarily have to be, impersonal. The remainder of the present study uses the terms “interpersonal” and “personal” trust interchangeably.

Meyer and Ward (2009) based their work on that of Luhmann and attempted to create a semantic distinction between trust and dependence in much the same fashion that Luhmann differentiated trust from confidence and trust from familiarity. According to Meyer and Ward (2009), Luhmann stated that trust differed from confidence regarding the attribution of blame for the failure of the relationship. According to Luhmann, because the extension of trust involved a thoughtful decision to take a risk, individuals attributed blame to themselves for a failed trust-based relationship. However, as the assumption of confidence involved no consideration of alternatives apart from general positive expectations, failure of confidence was attributed to external factors. Regarding the construct of familiarity, according to Luhmann as cited in Meyer and Ward (2009),
familiarity is a necessary pre-requisite to extend trust but is not alone a sufficient condition for trust.

To tease apart the constructs of trust and dependence, Meyer and Ward (2009) first identified the factors which affect an individual’s willingness to trust, including level of negotiation of trust, past history of trust in the person or organization, demographic variables such as age and sex, and the amount of risk involved in choosing to extend or deny trust. The researchers then conducted interviews with individuals with coronary heart disease to determine their willingness to trust their general practitioners, and at what point their willingness to trust their doctors became or converged with dependence on their doctors.

The researchers conducted 13 interviews with eight males and five females who ranged from 32 to 80 years old. Patients with coronary heart disease were chosen as subjects because of their high-risk medical condition, meaning that their choice to trust in or to ignore medical advice from their general practitioners had amplified consequences for the subjects. Subjects were questioned on a variety of issues, including their current levels of trust in elements of the healthcare system, the level of risk they perceived in not listening to pertinent medical advice about their health condition, demographic information, and the quality of their present relationship with their general practitioner. Data were analyzed using thematic analysis.

Meyer and Ward (2009) found that subjects had an overall high level of trust in their general practitioners but not in all doctors. Subjects were hesitant to trust a doctor who they have never used before. However, when subjects were asked if they would trust
any doctor who was available to treat them in a life-threatening emergency, the subjects overwhelmingly indicated that they would. Meyer and Ward (2009) concluded that in the presence of a high risk situation, individuals defaulted to dependence on doctors rather than trust in them, as evidenced by their lack of reflexivity in deciding whether to extend trust.

Meyer and Ward (2013) conducted a larger study, which included 22 males and 15 females with coronary heart disease, a few years later on the same topic and using very similar methods and found similar results.

Meyer and Ward (2009) concluded that the extension of trust must involve some element of choice on the part of the trustor. If the trustor has no choice but to trust an individual or an organization, then the individual is in a state of dependence, not trust.

The present study employs the following conceptual definition of dependence: “the quality or state of being influenced or determined by or subject to another” (Dependence, 2013). Trust involves risk that the other party will fail to follow through on their obligations or will misuse trust to betray the other. When trust is extended, it means that this risk has been assessed and overridden based on reasoned calculation or emotion. In contrast, dependence does not involve the free extension of trust despite the knowledge of risk. The state of dependence is one of helplessness and subordination, in that the dependent individual is “subject to the authority or control of another” (Subordinate, 2014). In the state of dependence, the individual has no choice but to take a risk and place their health and well-being in the hands of another, whereas the extension of trust involves choice about whether to risk the loss of one's possessions, time, and overall
The distinction between trust and dependence can be extended to include a
distinction between impersonal trust and dependence. To some degree both impersonal
trust and dependence may exist simultaneously in a social relationship, and to some
degree the definitions and constructs overlap. For example, decisions about the safety of
medications are determined by FDA and not by principals - there is little debate about
that. This indicates that there is necessarily some degree of dependence in this principal-
agent relationship. However, the important question was: do Americans feel they have a
choice in the matter of extending trust to FDA? This question was answered by
examining responses to measures of impersonal trust and dependence. Furthermore,
logistic regression was used to see if variables associated with impersonal trust also were
associated with dependence on FDA. If the same variables are positively and
significantly associated with both constructs, trust and dependence might be difficult to
empirically distinguish. If the same patterns of association are not found, a measure of
dependence might have been identified, and there may be hope to empirically distinguish
dependence from trust.

**Trust in FDA**

In addition to adding operational value to the construct of impersonal trust, this
study also provides another look at trust attitudes toward FDA, an understudied yet
highly influential organization. In 2007, American University’s Center for Congressional
and Presidential Studies (CCPS) engaged in a series of conversations about FDA and its
role in ensuring drug safety, entitled, “A Dialogue: Seeking Common Ground on Drug Safety” (Financial Content, 2007). As a part of the dialogue series, the CCPS released results of a national survey conducted to measure the levels of trust and confidence which the public had in prescription drug safety and management. The survey was underwritten by the pharmaceutical company Pfizer. According to Dickinson (2007), the CCPS found that 82% of Americans trusted the FDA to oversee the safety of prescription drugs. Additionally, according to Dickinson (2007), younger Americans (18-34) were more likely than older Americans to trust FDA to regulate the safety of drugs, and senior citizens were the least trusting of FDA. However, Dickinson (2007) stated that only 53% of Americans felt that the performance of FDA was “excellent” or “good,” whereas 47% of Americans rated the work of the agency as “fair” or “poor.” Lastly, Dickinson (2007) stated that, “FDA is the most trusted organization on prescription drug issues (82%), followed by patient advocacy groups (74%), drug companies (67%), and Congress (53%). Half of those surveyed said they were skeptical of Congress' ability to pass “common-sense” laws governing how the FDA approves drugs” (webpage).

In a different study, the Pew Research Center released a statement in 2010 that 58% of the public expressed trust in FDA (Pew Research Center, 2010). This result stands in contrast to the results found by American University's CCPS 2007 study, which found that 82% of Americans trusted FDA more than any other organization to make decisions about prescription drug issues, and that 53% of Americans rated the performance of FDA to be “excellent” or “good.”

Few studies have examined public opinion toward FDA, its functions, or the
safety of the products it regulates. Furthermore, no studies have framed the relationship between FDA and the public as an impersonal trust-based relationship between guardian of trust and principal. Given the few studies which have been conducted to measure trust of the American people in FDA, and given their conflicting results, more research must be conducted to measure the level of trust which the American people have in FDA while taking into consideration the impersonal nature of the trust relationship.

**Statement of the Question**

The questions which this study seeks to answer are, 1) are variables associated with interpersonal trust also associated with impersonal trust, 2) is it possible to distinguish measures of impersonal trust from measures of dependence, and 3) on a practical note, what trust attitudes do a subset of Americans have toward FDA?

To date, trust has largely been measured as an undifferentiated concept. Although many efforts have been made through theoretical development to differentiate types and forms of trust, few efforts have been undertaken to operationalize and empirically distinguish various forms of trust. This study made an effort to provide a concretized example of impersonal trust as described by Shapiro (1987) as applied to the agent-principal relationship which exists between FDA and the American public. Additionally, few studies have made attempts to distinguish not only different versions of trust, but also to distinguish trust from other related concepts, such as dependence. Lastly, trust in FDA and other large-scale organizations is understudied, and there is theoretical reason to believe that at least some measures of trust in such studies may be measures of other
similar but distinct concepts.

Why do these questions matter? The questions of how to define and parameterize trust break down the ambiguities inherent in understanding a multidimensional concept and allow for the development of clearer and more precise definitions. Adding clarity to the understanding of a concept such as trust creates better operational definitions, which leads to greater ease in studying the concept and ultimately to increased knowledge and understanding. Furthermore, contextualizing concepts such as impersonal agent-principal relationships and guardians of trust by using them to explain the trust-based relationships among pharmaceutical companies, the American public, and FDA, adds value to the concepts because it demonstrates that they can be successfully applied to real-world problems. Lastly, the question of how much trust Americans have in FDA is of practical concern as very high levels of trust in FDA may discourage diligent monitoring of the activities of the organization, and very high levels of distrust may discourage the acceptance of life-saving medical advice and medications. This question also has practical concern for FDA, which can take action to increase or maintain its perceived trustworthiness based on the results of this and similar studies.
CHAPTER IV

METHODOLOGY

Participants

Prior to data collection, approval to conduct this study was received from the Human Subjects Institutional Review Board (HSIRB) of Western Michigan University. Approval to conduct this research was also received from the site supervisor and from the city attorney for the city in which the data was collected. A copy of the HSIRB approval form is located in Appendix A.

One hundred and fifty five subjects were recruited to take part in this study, and a total of 150 individuals chose to participate. Subjects were recruited from a large senior center in the Midwest. The senior center is open to individuals aged 50 and above and offers classes, activities, meal programs, and volunteer opportunities intended to enhance the lives of senior citizens in the local community. Programs and activities are directed toward individuals of sound mind and body. The facility is non-residential, and participants are free to arrive and leave at their leisure. Only individuals who were aged 55 or more and who were not part of a protected population were asked to participate in this study. Following HSIRB guidelines of Western Michigan University, individuals in protected populations included children, prisoners, pregnant individuals, individuals with diminished cognitive capacity, blind individuals, and active duty military personnel.

Older individuals were selected to participate because older individuals are more
likely than other age groups to use medications (Kaufman et al., 2002); therefore, older individuals may have more interest in and knowledge about FDA than other age groups. Likewise, older individuals are more likely to have medical complications than other age groups, and may therefore have more vested in the decisions of FDA, as FDA is also responsible for overseeing the safety of medical devices. Furthermore, in order to meaningfully extend or deny trust, subjects must have some exposure to or knowledge of the institution in question. Younger individuals tend to default to a position of trust in an institution until they have enough knowledge to make a more informed decision (McKnight, Cummings, & Chervany, 1998). It is possible that a more experienced population would have a larger pool of accumulated knowledge to inform their decisions and feelings about FDA. Therefore, older individuals were recruited as subjects in an attempt to avoid measuring ignorance rather than trust.

Individuals in protected categories were not asked to participate in this study because the investigators lacked the necessary tools to ensure that they could freely provide informed consent. Three individuals in protected categories were excluded from participation. In one instance an individual was excluded due to diminished cognitive capacity, and in two cases the researchers were unable to establish informed consent with individuals with a combination of partial blindness and hearing loss. Individuals who fell into protected categories were offered refreshments as were all survey recruits and participants.

Subjects were recruited after they participated in classes and activities offered by the senior center. Once HSIRB permission was received to collect data, the investigators
attended 100% of classes and activities offered by the senior center in an attempt to expedite the process of data collection. Activities attended included card playing groups, walking programs, board game playing groups, exercise courses, organized lunch programs, writing clubs, reading clubs, choral groups, and pool leagues. Some activities met at scheduled times, such as choral groups and reading and writing clubs, and others, such as the walking clubs, pool leagues, and some card groups, were open to all seniors to participate in throughout the day. In classes with formal starting times, seniors were recruited at the beginning of class to participate in the study at the end of the class, and in activities with variable or informal starting times, seniors were approached at the beginning of their engagement in the activity about participating in the study when they concluded their involvement in the activity. After two days of data collection in early 2014, the investigators obtained 150 completed surveys and thus concluded data collection at the senior center.

A document of informed consent was reviewed with each group, a copy was distributed to each individual, and all subjects were asked to carefully consider whether they wished to participate in the study. Voluntariness of participation in addition to the lack of repercussions for refusing to participate were emphasized multiple times, as were the rights of the subjects to refuse to answer any questions and to withdraw consent to participate for any reason at anytime. Recruits who indicated that they wanted to participate were handed surveys and informed that the return of their surveys to the investigators indicated their consent for use of the answers provided.

Refreshments were provided to all recruits regardless of whether they chose to
participate in the study. Study recruits were informed that if they chose to participate, they would receive a gift card worth five dollars for a local grocery store. Recruits were informed that they would receive the gift card as long as they returned their surveys to the investigators, even if they refused to answer any questions.

**Survey Instrument**

A survey instrument was created to measure whether the variables associated with interpersonal trust as indicated by Meyer and Ward (2009) were also associated with impersonal trust in FDA, whether variables associated with impersonal trust in FDA were also associated with dependence on FDA, and overall trust attitudes toward FDA among older Americans. A copy of the survey instrument is located in Appendix B.

A balance was reached between the number of survey items to include and the desire to obtain as much valuable information as possible from the subjects. It is unrealistic to expect individuals to answer lengthy surveys with quality answers unless extenuating circumstances are in order (Sherman & Straus, 2002). Additionally, Moser and Kalton (2004) strongly advised against including all potentially relevant or interesting information, as this may lead to greatly decreased response rates and to an overall waste of time.

A great deal of caution was exercised in creating the questions. Moser and Kalton's (2004) guide to creating a questionnaire was followed, and each question was checked for compliance with the guide to ensure appropriate wording and content.

Survey Questions 1-7, which asked the subjects to provide demographic
information, were modeled on the design of the survey instrument of SAMHSA (2008), a national study on substance abuse. These questions provided information about the sociodemographic characteristics of the sample, and the questions used in SAMHSA studies have been shown to be reliable (SAMHSA, 2006). It was not known if demographic characteristics would affect responses, so only minimal data was collected in this area in an attempt to establish preliminary findings.

Survey Questions 8, 10, and 11 were designed to measure variables associated with trust in FDA. Meyer and Ward (2009) indicated that the following variables were associated with personal trust in general healthcare practitioners: “the negotiation of trust between individuals, the level of trust one has in the system or institution, and the level of risk in trusting (Giddens 1990; Giddens 1994; Luhmann 1979; Luhmann 1988; Luhmann 2005), and personal experience and social factors (socioeconomic status (SES), age sex) (Meyer et al., 2008)” (p. 6).

The question asking about the number of alternatives which participants felt they had to FDA was asked to determine the ability of individuals to turn to other sources for guidance on the safety of medications. Alternatives to FDA were viewed as a tool of negotiation in the ability of subjects to refuse to extend trust in FDA.

A question was asked about whether individuals would be more willing to trust an FDA-approved medication or a non-FDA-approved medication to treat a common cough in order to gauge present levels of trust in FDA, and a question was asked about whether an individual would take any medication given by a certified healthcare professional in an emergency as a measure of the willingness to extend trust in a high-risk situation.
Questions 9, 12 and 15 were designed to measure the level of trust which the subject had in FDA, and Questions 13 and 14 were designed to measure level of dependence on FDA. Questions 9, 12 and 15 were modeled after the questions included in the American National Election Studies (ANES) 2010-2012 Evaluations of Government and Society Study (EGSS). The ANES EGSS is designed to measure attitudes toward the President, Congress, and various features of the current political climate (ANES, 2010). As the EGSS asked questions about attitudes toward the government, and as FDA is a governmental institution, only slight modifications had to be made to EGSS questions to make them pertain to FDA. Furthermore, ANES questions were used as models for the questions in this survey because some of the questions contained in the ANES have been used for years to produce reliable results about attitudes toward government and politics in the general population (DeBell, Wilson, Segura, Jackman, & Hutchings, 2011).

Questions 13 and 14 were based on the results of Meyer and Ward (2009), in which they found that dependence existed rather than trust when subjects indicated that they “had no choice but to trust” their doctors (p. 6). The idea of having “no choice but to trust” was extended to FDA by asking subjects if they had no choice but to accept that medications listed on a label are the same as the medications in the bottle (a quality standard which FDA is responsible for upholding), and if they “have to trust” FDA to make the right decisions about medications.
CHAPTER V

RESULTS

Instrumentation

All data were sorted, cleaned, coded, and analyzed using IBM SPSS Statistics Grad Pack Plus Version 22.

Missing Data

Table 1 contains a list of all acronyms of variables used in the remainder of this paper. Missing data were handled using pairwise deletion. Multiple imputation was considered as the first method of choice for handling missing data; however, it was not performed as the variables grossly violated the assumption of normality. Missing values analysis indicated that one variable had 10% missing data (ALTTOFDA) and another had 6.7% missing (INCOME); however, all other variables had 5% or less missing data. ALTTOFDA may have had greater than 5% missing data due to the fact that the variable was phrased as an open-ended question, and INCOME may have had greater than 5% missing due to the fact that some individuals may have been uncomfortable disclosing sensitive information about their earnings. There appeared to be no distinguishable pattern to the missing data based on examination of missing values analysis as performed in SPSS; therefore, data were assumed to be missing completely at random. There also did not appear to be any significant differences in measures of central tendency and
standard deviations of variables when using listwise versus pairwise deletion. Therefore, to retain statistical power, pairwise deletion was selected as it retained a high number of cases ($n = 138$) versus listwise ($n = 113$). Pairwise deletion was also chosen given the exploratory nature of this study and the comparison of analyses is not as important as first discovering what types of relationships exist between the independent variables and each measure of trust and dependence.

Table 1

<table>
<thead>
<tr>
<th>Variable Acronyms and Related Survey Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name</td>
</tr>
<tr>
<td>SEX</td>
</tr>
<tr>
<td>AGE</td>
</tr>
<tr>
<td>INCOME</td>
</tr>
<tr>
<td>RACE</td>
</tr>
<tr>
<td>FDAVNONFD</td>
</tr>
<tr>
<td>CONINFDA</td>
</tr>
<tr>
<td>ALTTOFDA</td>
</tr>
<tr>
<td>LIFETHREAT</td>
</tr>
<tr>
<td>TRUSTFDA</td>
</tr>
<tr>
<td>NOCHOICE</td>
</tr>
<tr>
<td>TRUSTDEC</td>
</tr>
<tr>
<td>SAFEMEDS</td>
</tr>
</tbody>
</table>

Independent Variables

Sex (SEX), income (INCOME), age (AGE), race (RACE), number of alternatives to FDA (ALTTOFDA), present level of trust in FDA (FDAVNONFD), and willingness to
take any medication in the event of a health-related emergency (LIFETHREAT) were included in this study as independent variables.

Out of the 150 individuals who returned the survey, 100% (n = 150) reported being over the age of 55 and 100% (n = 150) also identified as “white.” Once it was discovered that these two variables were more precisely constants, they were excluded from further analyses.

Regarding the remaining demographic variables, 64% of subjects identified as female (n = 96) and 36% (n = 54) identified as male. Out of the 140 subjects who reported income, the subjects reported a median income of “between $25,001 and $50,000” when the primary breadwinner is/was working (42%, n = 59). The addition of “is/was working” to the phrasing of this question was added because the researchers wanted to know the general income which subjects had within their families over their lifetimes as opposed to income levels from Social Security benefits, pensions, or other sources of income in later life. Approximately 21% of subjects reported an income of “less than $25,000” (n = 29), meaning that 63% (n = 88) of total subjects reported an income while working at or below $50,000. An income of “between $50,001 and $75,000” was reported by 24% (n = 34); income of “between $75,001 and $100,000” was reported by 10% (n = 14); and income “over $100,000” was reported by 3% (n = 4) of subjects. Following this analysis, income was collapsed to a dichotomous variable in order to reduce the number of cells with small ns (1 = “$50,000 or below”, 2 = “over $50,000”).

Three independent variables were designed to measure levels of impersonal trust
in FDA. One asked subjects how many alternatives they had to FDA (ALTTOFDA); another asked subjects whether they would more likely trust an FDA-approved medication or a non-FDA-approved medication to treat a common cough (FDAVNONFD); and the third asked whether they would take any medication issued by a healthcare professional in a life-threatening emergency (LIFETHREAT).

An open-ended question asked subjects to specify the alternatives which they had to FDA (ALTTOFDA). In SPSS, this question was coded as two different variables. The first variable, ALTTOFDA, was coded in binary fashion, with a code of “0” indicating that the subject had no alternatives to FDA and a code of “1” indicating that the subject specified at least one alternative. The second variable derived from this question, ALT2FDA, contained a list of the alternatives specified by the subjects.

For ALTTOFDA, 135 subjects answered the question. Out of those individuals, 84% (n = 113) stated that they had no alternatives to FDA, and 16% (n = 22) stated that they had at least one alternative. The subjects who reported alternatives to FDA were allowed to list multiple options, and 13 of the 23 subjects reported one alternative to FDA, four reported two alternatives, and five reported three alternatives. Twelve different types of alternatives were found among the 32 alternatives collectively mentioned by the subjects. The most commonly recommended alternative to FDA was “doctor” (n = 6), followed by “pharmacist” (n = 4), “Consumer Reports” (n = 4), and “the internet” (n = 3). Two sets of two subjects indicated “spiritual leader” and “personal recommendation” as alternatives to FDA, and six subjects listed additional alternatives as detailed in Table 2.
Table 2

List of reported alternatives to FDA

<table>
<thead>
<tr>
<th>Alternative</th>
<th># of subjects which mentioned alternative (% which mentioned)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>6 (26%)</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>Consumer Reports</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>Internet</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>Spiritual Leader</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>Personal Recommendation</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>Local Health Food Store</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Pharmaceutical Industry</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Hospital/Clinic</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Centers for Disease Control</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Self-testing Medications</td>
<td>1 (4%)</td>
</tr>
</tbody>
</table>

One hundred and forty three subjects answered the question of whether they would be more likely to trust an FDA-approved or a non-FDA-approved medication to treat a common cough (FDA VNONFD). FDA VNONFD was coded in a binary fashion, with “0” indicating that the subject would rather trust a non-FDA-approved medication. Out of the 143 respondents, 11% (n = 16) stated that they would rather trust a non-FDA-approved medication, and 89% (n = 127) indicated that they would rather trust an FDA-approved medication to treat a common cough.

Regarding the last of the three variables, LIFETHREAT was also binary coded, with “0” indicating that a subject checked either “no” or “unsure” to the question of whether he or she would take any FDA-approved medication in an emergency (“yes” = 1). A total of 148 subjects answered this question, with 19% (n = 28) answering “no/unsure” and 81% (n = 120) answering “yes.” Summary information for all of the independent variables is available in Table 6.
Dependent Variables

Measures of Trust

The dependent variables were designed to measure either impersonal trust in FDA or dependence on FDA. The first variable was designed as a 3-point Likert scale to measure confidence in individuals who run FDA (CONINFDA), and had answer choices of “low confidence (coded as “1”),” “some confidence (“2”),” and “high confidence” (“3”). The choice to use a variable with the term “confidence” to measure trust was made because the terms are often used interchangeably by the general public, and because similarly phrased questions were included in the ANES (2010) survey on trust in government.

The remaining two measures of trust were collected using 5-point Likert scales (1 = “strongly disagree”). The first question asked subjects whether they trusted FDA to ensure that their medications are safe (TRUSTFDA), and the second asked for agreement with the statement that, even if some FDA-approved medications are proven to be unsafe, you have to trust that all other FDA-approved medications are still safe (SAFEMEDS).

The four variables which were collected using a 5-point Likert scale were collapsed to 3-point Likert scales to ease the process of interpretation and to reduce the number of cells with low frequencies (1 = “strongly disagree/disagree”; 2 = “neither agree nor disagree,” and 3 = “strongly agree/agree”).

Overall, regarding the three measures of trust, 73% (n = 108) and 78% (n = 110) of subjects chose “strongly agree/agree” as answers to TRUSTFDA and SAFEMEDS,
respectively. Conversely, only 27% of subjects (n = 40) reported having high confidence in the people who run FDA. The majority of subjects (64%, n = 95) reported having some confidence in the people who run FDA and 9% (n = 14) reported having low confidence.

Measures of Dependence

Two questions were designed using 5-point Likert scales to measure dependence on FDA, and were coded in the same fashion as the measures for trust. The first question asked subjects for levels of agreement with the statement that they have no choice but to trust that the medication listed on the label is the same as the medication in the bottle (NOCHOICE), and the second asked subjects for their agreement with the statement that they have to trust FDA to make the right decisions about the safety of their medications (TRUSTDEC).

Regarding the measures of dependence, the vast majority of subjects agreed/strongly agreed with NOCHOICE (87%, n = 124) and TRUSTDEC (84%, n = 120). Overall, for all but one variable for measures of both dependence and trust, the vast majority of subjects expressed agreement with statements measuring trust in and dependence on FDA.
Table 3

*Table of Dependent Variables, Percentages, Frequencies, and Coding.*

<table>
<thead>
<tr>
<th>Measures of Trust</th>
<th>TRUSTFDA</th>
<th>Frequency</th>
<th>Valid Percent</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>11</td>
<td>7.4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Neither agree nor disagree</td>
<td>29</td>
<td>19.6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>108</td>
<td>73.0</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>148</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| SAFEMEDS          |          |           |               |        |
| Disagree          | 14       | 9.9       | 1             |
| Neither agree nor disagree | 17       | 12.1      | 2             |
| Agree             | 110      | 78.0      | 3             |
| Total             | 141      | 100.0     |               |

| CONINFDA          |          |           |               |        |
| Low confidence    | 14       | 9.4       | 1             |
| Some confidence   | 95       | 63.8      | 2             |
| High confidence   | 40       | 26.8      | 3             |
| Total             | 149      | 100.0     |               |

| Measures of Dependence | NOCHOICE |          |           |        |
| Disagree              | 4        | 2.8       | 1         |
| Neither agree nor disagree | 14       | 9.9      | 2         |
| Agree                 | 124      | 87.3      | 3         |
| Total                 | 142      | 100.0     |           |

| TRUSTDEC            |          |           |               |        |
| Disagree            | 13       | 9.1       | 1             |
| Neither agree nor disagree | 10       | 7.0      | 2             |
| Agree               | 120      | 83.9      | 3             |
| Total               | 143      | 100.0     |               |

**Bivariate Correlations**

Prior to performing categorical principal components analysis (CATPCA) to determine whether the data clustered on two components, bivariate correlations were obtained for the five dependent variables. Kendall's tau_b coefficient was used to assess relationships between the variables, because, according to Chen (2002), it is the appropriate coefficient to use when the data are ordinal, the assumption of normality is violated, and there are many tied ranks.

The results are summarized in Table 4.
Table 4

**Bivariate Correlations Among Measures of Trust and Dependence**

<table>
<thead>
<tr>
<th>Measures</th>
<th>TRUSTFDA</th>
<th>SAFEMEDS</th>
<th>TRUSTDEC</th>
<th>NOCHOICE</th>
<th>CONINFDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUSTFDA</td>
<td>--------</td>
<td>.595*</td>
<td>.699*</td>
<td>.454*</td>
<td>.563*</td>
</tr>
<tr>
<td>SAFEMEDS</td>
<td>--------</td>
<td>--------</td>
<td>.627*</td>
<td>.469*</td>
<td>.487*</td>
</tr>
<tr>
<td>TRUSTDEC</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
<td>.505*</td>
<td>.492*</td>
</tr>
<tr>
<td>NOCHOICE</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
<td>.371*</td>
</tr>
<tr>
<td>CONINFDA</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
</tbody>
</table>

Note: Correlations marked with an asterisk (*) were significant at the 0.01 level (2-tailed).

The results of the bivariate correlation matrix warrant further discussion as thorough examination of results in addition to reexamination of the survey questions modified the course of data analysis.

First, two variables predicted to measure trust, TRUSTFDA and SAFEMEDS, were significantly and moderately correlated, as hypothesized (0.595, \( p < 0.01 \)). CONINFDA, the third specified measure of trust, was positively and more weakly but still moderately correlated with TRUSTFDA (0.563, \( p < 0.01 \)) and with SAFEMEDS (0.487, \( p < 0.01 \)).

Unexpectedly, one measure of dependence, TRUSTDEC, was, although significantly, less strongly associated with the other measure of dependence, NOCHOICE (0.505, \( p < 0.01 \)), than it was with the two of the three measures of trust. TRUSTDEC was significantly and strongly correlated with TRUSTFDA (0.699, \( p < 0.01 \)), and was significantly and moderately correlated with SAFEMEDS (0.627, \( p < 0.01 \)) and CONINFDA (0.492, \( p < 0.01 \)).

Following closer inspection of the phrasing of the question for TRUSTDEC, it was determined that although TRUSTDEC was intended as a measure of dependence, the phrasing of the question resulted in little practical distinction between TRUSTDEC and
the trust measures. Given that the phrasing of the question for TRUSTDEC closely resembled the phrasing of the question for TRUSTFDA; and given that, upon further reflection, it was determined that subjects would most likely not draw a significant distinction between the two questions, it was decided that TRUSTDEC was misspecified as a measure of dependence and should have been either re-worded to more distinctly align with the other measure of dependence or classified as a measure of trust. Pilot testing would have likely caught this error; however, budget and time constraints prevented the researchers from performing additional analyses.

Categorical Principal Components Analysis

The assumptions that the specified measures of trust (CONINFDA, TRUSTFDA, and SAFEMEDS) and dependence (TRUSTDEC and NOCHOICE) actually measured the constructs of trust and dependence were based on information derived from current sociological theories (Meyer and Ward, 2009; Shapiro, 1987) and on present psychometric formats for measuring trust (SAMHSA, 2008; ANES, 2010). CATPCA was used to explore whether there was empirical evidence to support the existence of two components, trust and dependence, among the five variables. CATPCA was used rather than linear principal components analysis because the data were both ordinal and highly skewed.

All variables were categorized as ordinal for purposes of CATPCA analysis. Two components were retained in this analysis, as it was hypothesized that the measures of trust and dependence would be reducible to two dimensions. Please refer to Table 3 for
descriptions of the five variables.

A two-dimensional CATPCA yielded an eigenvalue of 3.164 for the first component, indicating that the first component accounted for approximately 63.28% \((3.164/5 = 63.28\%)\) of the variance in the transformed variables. The second component yielded an eigenvalue of 0.929 and accounted for 18.58% \((0.929/5 = 18.58\%)\) of total variance. As the eigenvalue for the second component was below 1.0, there was not enough evidence to support the acceptance of two different components.

The finding that measures of trust could not be empirically distinguished from measures of dependence reflected the difficulties which Meyer and Ward (2009) had in distinguishing between the presence of trust within individuals versus the presence of dependence. The researchers found instead that both trust and dependence often exist simultaneously within subjects. Furthermore, the inability to distinguish between measures of trust and dependence highlights the difficulties encountered earlier with creating measures specific to the study of either trust or dependence.

Table 5

Summary of Component Loadings for CATPCA

<table>
<thead>
<tr>
<th>Item</th>
<th>Dimension</th>
<th>Trust</th>
<th>Dependence</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUSTFDA</td>
<td>.874</td>
<td>-.073</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOCHOICE</td>
<td>.383</td>
<td>.923</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRUSTDEC</td>
<td>.929</td>
<td>-.189</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAFEMEDS</td>
<td>.864</td>
<td>-.181</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONINFDA</td>
<td>.802</td>
<td>.052</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Eigenvalues | 3.164 | .929 | 4.093 |
| % Variance  | 63%   | 19%  | 82%   |
| Cronbach's alpha | .855 | -.095 | .945 |
A series of ordered logistic regression models were used to examine the associations between the independent and dependent variables. The original intention of this research project was to combine the measures of dependence into one scale and the measures of trust into another. However, given that CATPCA did not support that the data
formed two components, each of the five variables were analyzed individually in the absence of established theory exploring scaling techniques for a unified component of trust and dependence.

A series of ordered logistic regression models with different dependent variables was performed to determine whether the independent variables shared the same associations with each of the five dependent variables. Although these models cannot be mathematically compared, general trends in association between the independent variables and the various measures of trust and dependence can be assessed across the models. As this study is exploratory, this information could be constructive in determining whether the variables associated with interpersonal trust as outlined by Meyer and Ward (2009) are also associated with impersonal trust. Lastly, one binary logistic regression was conducted to determine whether the variables associated with measures of trust are also associated with a measure of dependence. This information is valuable in building the substantial grounds necessary to determine whether an empirical distinction can be drawn between measures of impersonal trust and measures of dependence.

Ordered logistic regression was used because it takes into account the ordered nature of the dependent variable. One assumption of ordinal logistic regression is that there are no problems with multicollinearity in the data. Bivariate correlations for the independent variables (SEX, INCOME, FDAVNONFD, ALTTOFDA, and LIFETHREAT) were obtained to make an initial assessment of the correlations present in the data. Only one pair of variables (ALTTOFDA and FDAVNONFD) were significantly
and weakly correlated (-.344, p < .001). The rest of the variables were not significantly correlated, so there were assumed to be no problems with collinearity in the data, and no further collinearity diagnostics were applied.

The independent variables retained in the models were INCOME, FDAVNONFD, ALTTOFDA, and LIFETHREAT. All models initially included the variable “SEX” as a predictor; however it was removed from all models because it did not function as a significant predictor and removing the variable did not significantly affect model fit. Furthermore, removing the variable SEX made the models more parsimonious. No covariates were specified, given that only one set of variables was weakly correlated and that there were no theoretical reasons to specify interaction terms. The independent variables used in the analyses are summarized in Table 6, and the dependent variables used in the analyses are summarized in Table 3.

Table 6

Table of Independent Variables: Percentages, Frequencies, and Coding.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency</th>
<th>Valid Percent</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCOME</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$50,000 or less</td>
<td>88</td>
<td>62.9</td>
<td>0</td>
</tr>
<tr>
<td>Over $50,000</td>
<td>52</td>
<td>37.1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>140</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>FDAVNONFD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-FDA-approved</td>
<td>16</td>
<td>11.2</td>
<td>0</td>
</tr>
<tr>
<td>FDA-approved</td>
<td>127</td>
<td>88.8</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>143</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>ALTTOFDA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>113</td>
<td>83.7</td>
<td>0</td>
</tr>
<tr>
<td>One or more</td>
<td>22</td>
<td>16.3</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>135</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>LIFETHREAT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>28</td>
<td>18.9</td>
<td>0</td>
</tr>
<tr>
<td>Yes</td>
<td>120</td>
<td>81.8</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>148</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Model for TRUSTFDA as Dependent Variable

The first model examined whether the independent variables were associated with trust in FDA (TRUSTFDA). The results of the ordinal logistic regression are shown in Table 7. First, the model with the independent variables gave significantly better predictions for outcome categories than the baseline model, indicating that the final model provided a significantly better fit for the data than the intercept-only model ($\chi^2 = 32.487(4), p < .001$). Pearson ($\chi^2 = 15.735(22), p = .829$) and Deviance ($\chi^2 = 18.438(22), p = .680$) goodness-of-fit statistics were both not significant, indicating that the null hypothesis that the observed data are a good fit for the model was not rejected. The test of parallel lines was not significant ($\chi^2 = .806(4), p = .938$), indicating that there was not enough evidence to reject the assumption that slope coefficients were the same across response categories. Nagelkerke pseudo R-square indicated that the final model explained 31% of the variation between subjects in their levels of trust in FDA.

The ordered logistic regression model with TRUSTFDA as a dependent variable showed that willingness to take any medication in the event of a life-threatening emergency (LIFETHREAT), income (INCOME), and willingness to take an FDA-approved medication over a non-FDA-approved mediation (FADAVNONFD) were associated with trust in FDA. The odds of subjects who would take any medication in a life-threatening emergency agreeing that they trust FDA were 6.773 times that of people who would not/were unsure if they would take any medication in a life-threatening emergency. Therefore, willingness to take any medication in a life-threatening emergency was positively and significantly associated with trust in FDA. The odds of people who
prefer to take an FDA-approved medication agreeing that they trust FDA were 5.518 times that of people who would prefer to take non-FDA-approved medications, meaning that FDAVNONFD was also positively and significantly associated with trust in FDA. Lastly, the odds of individuals with income over $50,000 agreeing that they trust FDA were 3.892 times that of individuals with incomes at $50,000 or below.

Table 7

<table>
<thead>
<tr>
<th>Response</th>
<th>Coef.</th>
<th>Std. Err.</th>
<th>P value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCOME</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$50,000 or below</td>
<td>-1.359</td>
<td>.529</td>
<td>.010</td>
<td>0.257</td>
<td>-2.398 to -.321</td>
</tr>
<tr>
<td>Over $50,000</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
<td>3.892</td>
</tr>
<tr>
<td>FDAVNONFD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not FDA-approved</td>
<td>-1.708</td>
<td>.648</td>
<td>.008</td>
<td>.181</td>
<td>-2.977 to -.438</td>
</tr>
<tr>
<td>FDA-approved</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
<td>5.518</td>
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<tr>
<td>LIFETHREAT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>-1.913</td>
<td>.549</td>
<td>.000</td>
<td>.148</td>
<td>-2.988 to -.837</td>
</tr>
<tr>
<td>Yes</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
<td>6.773</td>
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<tr>
<td>ALTTOFDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1.009</td>
<td>.573</td>
<td>.078</td>
<td>2.743</td>
<td>-.114 to 2.131</td>
</tr>
<tr>
<td>One or more</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
<td>0.365</td>
</tr>
</tbody>
</table>

Model for SAFEMEDS as Dependent Variable

A second model was fitted with the same independent variables but with SAFEMEDS as the dependent variable. The final model was significantly better at predicting outcome categories than the intercept-only model ($\chi^2 = 28.876(4), p < .001$). Non-significance of the Pearson ($\chi^2 = 16.343(22), p = .799$) and Deviance ($\chi^2 = 22.404(22), p = .436$) goodness-of-fit statistics indicated that there was not enough evidence to reject the null hypothesis that the observed data were a good fit for the model. The test of parallel lines was not significant ($\chi^2 = 7.010(4), p = .135$), indicating that there was not a statistically significant difference in the location parameters across
response categories. Lastly, Nagelkerke pseudo R-square indicated that the model explained 30.4% of the variation in the responses to SAFEMEDS.

The model for SAFEMEDS indicated that FDAVNONFD, LIFETHREAT, and INCOME were positively and significantly associated with agreement that one has to trust that most medications are safe even if some are proven to be unsafe (SAFEMEDS). The odds of people who would rather take an FDA-approved medication agreeing that they have to hope that most medications are safe even if some are proven unsafe (SAFEMEDS) were 13.545 times that of people who would rather take a non-FDA-approved medication. The odds of people who would take any medication in a life-threatening emergency agreeing with SAFEMEDS were 3.743 times that of people who would not/were unsure if they would take any medication as part of a life-saving effort. Lastly, individuals with income over $50,000 were 4.191 times more likely to agree with SAFEMEDS than individuals with income at $50,000 or below. The results of this ordered logistic regression are summarized in Table 8.

Table 8

<table>
<thead>
<tr>
<th>Response</th>
<th>Coef.</th>
<th>Std. Err.</th>
<th>P value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCOME</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$50,000 or below</td>
<td>-1.433</td>
<td>.611</td>
<td>.019</td>
<td>0.239</td>
<td>-2.631 to -.235</td>
</tr>
<tr>
<td>Over $50,000</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>4.191</td>
<td></td>
</tr>
<tr>
<td>FDAVNONFD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not FDA-approved</td>
<td>-2.606</td>
<td>.703</td>
<td>.000</td>
<td>0.074</td>
<td>-3.983 to -1.229</td>
</tr>
<tr>
<td>FDA-approved</td>
<td>Ref.</td>
<td></td>
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<td>13.545</td>
<td></td>
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<td>LIFETHREAT</td>
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<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>-1.320</td>
<td>.596</td>
<td>.027</td>
<td>.267</td>
<td>-2.488 to -.151</td>
</tr>
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<td>Yes</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>3.743</td>
<td></td>
</tr>
<tr>
<td>ALTTOFDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>.533</td>
<td>.636</td>
<td>.384</td>
<td>1.738</td>
<td>-.693 to 1.800</td>
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<tr>
<td>One or more</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>0.575</td>
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</tbody>
</table>
Model for TRUSTDEC as Dependent Variable

Another ordered logistic regression model was completed with TRUSTDEC as the dependent variable. The final model was significantly better at predicting outcome categories than the intercept-only model ($\chi^2 = 25.174(4), p < .001$). The Pearson ($\chi^2 = 14.905(22), p = .866$) and Deviance ($\chi^2 = 19.683(22), p = .603$) goodness-of-fit indices were not significant, indicating that the observed data did not differ significantly from the frequencies expected by the model. The test of parallel lines was not significant ($\chi^2 = 2.788(4), p = .594$), meaning that the slope coefficients were not significantly different from each other across categories of the dependent variable. Lastly, Nagelkerke pseudo R-square indicated that the model explained 29.1% of the variance in the data.

The results of this ordered logistic regression can be found in Table 9. LIFETHREAT and FDAVNONFD were positively and significantly associated with trust in the decisions made by FDA. The odds of individuals who prefer to take an FDA-approved medication agreeing that they trust the decisions of FDA were 8.551 times that of individuals who prefer to take a non-FDA approved medication to treat a common cough. The odds of individuals who would take any medication in the event of a life-threatening emergency trusting the decisions of FDA were 8.142 times that of individuals who would not/were unsure if they would take any medication in a medical emergency.
Table 9

Ordered Logistic Regression with TRUSTDEC as Dependent Variable

<table>
<thead>
<tr>
<th>Response</th>
<th>Coef</th>
<th>Std. Err</th>
<th>P value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCOME</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>$50,000 or below</td>
<td>-.779</td>
<td>.611</td>
<td>.202</td>
<td>.459</td>
<td>-1.978 to 0.419</td>
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<tr>
<td>Over $50,000</td>
<td>Ref.</td>
<td>2.179</td>
<td></td>
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</tr>
<tr>
<td>FDAVNONFD</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not FDA-approved</td>
<td>-2.146</td>
<td>.730</td>
<td>.003</td>
<td>0.117</td>
<td>-3.577 to -0.715</td>
</tr>
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<td>FDA-approved</td>
<td>Ref.</td>
<td>8.551</td>
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<td>LIFETHREAT</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>-2.097</td>
<td>.609</td>
<td>.001</td>
<td>.123</td>
<td>-3.291 to -0.904</td>
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<td>Yes</td>
<td>Ref.</td>
<td>8.142</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>None</td>
<td>.551</td>
<td>.696</td>
<td>.429</td>
<td>1.735</td>
<td>-.814 to 1.916</td>
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<tr>
<td>One or more</td>
<td>Ref.</td>
<td>.576</td>
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<td></td>
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</tr>
</tbody>
</table>

Model for CONINFDA as Dependent Variable

A fourth model was constructed with CONINFDA as the dependent variable. The final model provided a significantly better fit than the intercept-only model ($\chi^2 = 17.382(4), p = .002$). The Pearson ($\chi^2 = 24.764(22), p = .308$) and Deviance ($\chi^2 = 19.794(22), p = .596$) goodness-of-fit statistics were not significant, indicating that the observed data were a good fit for the model. The assumption of parallel lines was not rejected ($\chi^2 = 9.077(4), p = .059$). Lastly, the Nagelkerke pseudo R-square indicated that the final model explained 15.0% of the variation in responses to CONINFDA.

Only FDAVNONFD was positively and significantly associated with CONINFDA. Individuals who would prefer to take an FDA-approved medication were 6.706 times more likely to have high confidence in FDA than individuals who would prefer to take a non-FDA-approved medication. The results are summarized in Table 10.
Table 10

*Ordered Logistic Regression with CONINFDA as Dependent Variable*

<table>
<thead>
<tr>
<th>Response</th>
<th>Coef.</th>
<th>Std. Err</th>
<th>P value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
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<tr>
<td>INCOME</td>
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<td></td>
<td></td>
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</tr>
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<td>$50,000 or below</td>
<td>-.471</td>
<td>.363</td>
<td>.661</td>
<td>.624</td>
<td>-1.182 to .240</td>
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<td>Over $50,000</td>
<td>Ref.</td>
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<td></td>
<td>1.602</td>
<td></td>
</tr>
<tr>
<td>FDAVNONFD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not FDA-approved</td>
<td>-1.903</td>
<td>5.93</td>
<td>.001</td>
<td>.149</td>
<td>-3.066 to -.740</td>
</tr>
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<td>FDA-approved</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>6.706</td>
<td></td>
</tr>
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<td>LIFETHREAT</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>-.828</td>
<td>.481</td>
<td>.085</td>
<td>.437</td>
<td>-1.771 to .114</td>
</tr>
<tr>
<td>Yes</td>
<td>Ref.</td>
<td></td>
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<td>2.289</td>
<td></td>
</tr>
<tr>
<td>ALTTOFDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>.213</td>
<td>.484</td>
<td>.661</td>
<td>1.237</td>
<td>-.737 to 1.162</td>
</tr>
<tr>
<td>One or more</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>.808</td>
<td></td>
</tr>
</tbody>
</table>

**Binary Logistic Regression**

*Model for NOCHOICE as Dependent Variable*

The final logistic regression model was constructed for NOCHOICE. As opposed to the previous three of four dependent variables which were used as measures of trust in FDA, NOCHOICE was designed to be a measure of dependence on FDA. Ordinal regression was performed, and the final model was not significantly better at predicting outcomes than the intercept-only model ($\chi^2 = 5.740(4), p = .219$), and the assumption of parallel lines was not met ($\chi^2 = 20.365(4), p = < .001$). One of the three categories of the dependent variable had a very low count (“Strongly disagree/disagree,” $n = 1$), and as low ns can cause problems with ordinal regression, NOCHOICE was collapsed into two categories (“agree” = 1; “neither agree nor disagree/disagree” = 2) and binary logistic regression was performed.

Prior to running the logistic regression, a bivariate correlation matrix revealed that LIFETHREAT was weakly, positively, and significantly correlated with NOCHOICE.
(.341, \( p < .001 \)), but no other independent variables were correlated with NOCHOICE. It is important to observe correlation matrices prior to running logistic regression to check for potential problems with multicollinearity in the data, and no issues with multicollinearity were detected in this model.

The first binary logistic regression model included all four predictors, but the omnibus test of model coefficients was not significant (\( \chi^2 = 6.023(4), \ p = .197 \)), meaning that none of the independent variables helped to explain variation within the dependent variable. Therefore, the least significant predictor, FDA VNONFD, was removed from the model to make the model more parsimonious and to attempt to obtain a better fit for the observed data.

The omnibus test of model coefficients in the second binary logistic regression model indicated that at least one predictor significantly helped to explain variation in the dependent variable (\( \chi^2 = 13.849(4), \ p = .003 \)). Furthermore, the Hosmer and Lemeshow test (\( \chi^2 = 1.882(3), \ p = .597 \)) indicated that the model was a good fit for the observed data. The Nagelkerke pseudo R-square indicated that the model explained 21.2% of the variation in the dependent variable. The final results are summarized in Table 11.

The only variable which was positively and significantly associated with NOCHOICE was LIFETHREAT. Individuals who were willing to take any medication in a life-threatening emergency were 6.711 times more likely to agree that they had no choice but to trust that the medication written on the label of a bottle is the same as the medication inside the bottle as opposed to individuals who would not/were unsure if they would take any medication in a life-threatening emergency.
Table 11

*Binary Logistic Regression with NOCHOICE as Dependent Variable*

<table>
<thead>
<tr>
<th>Response</th>
<th>Coef.</th>
<th>Std. Err</th>
<th>P value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCOME</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$50,000 or below</td>
<td>1.333</td>
<td>.816</td>
<td>.102</td>
<td>3.793</td>
<td>.766 to 18.782</td>
</tr>
<tr>
<td>Over $50,000</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>.264</td>
<td></td>
</tr>
<tr>
<td>LIFETHREAT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/Unsure</td>
<td>1.904</td>
<td>.616</td>
<td>.002</td>
<td>6.711</td>
<td>2.005 to 22.462</td>
</tr>
<tr>
<td>Yes</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>.149</td>
<td></td>
</tr>
<tr>
<td>ALTTOFDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>.478</td>
<td>.866</td>
<td>.581</td>
<td>1.614</td>
<td>.295 to 8.815</td>
</tr>
<tr>
<td>One or more</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>.620</td>
<td></td>
</tr>
</tbody>
</table>

**Reliability and Validity**

Due to lack of sufficient time and resources, this survey was not pilot tested. All questions were subjected to a test for face validity. Although face validity has been referred to as “armchair validity” and some researchers doubt whether it is a form of validity at all, a test for face validity forces the researcher to critically examine whether the questions appear to measure what they are designed to measure (Baker, 1999, p. 110). This further encourages the researcher to re-examine whether the concepts under study are well-defined. Face validity is subject to greater error that other forms of validity and evidence of its fallibility may be found in the conflation within this paper of a measure of trust with a measure of dependence.

The content validity of this survey is uncertain. Some questions, such as those measuring demographics and attitudes toward trust, were heavily based on questions from large-scale and reputable surveys (SAMHSA, 2008; ANES, 2010) and likely contain the appropriate items to study the content under investigation. However, questions about predictors of trust were designed based on ideas put forward by Meyer...
and Ward (2009) and have not previously been tested.

Criterion-related validity is not an immediate concern for this assessment. As few measures of impersonal trust exist, there are few tests with which to compare the assessment at hand. Additionally, the nature of this study is exploratory, and as such, this study is interested in describing possible measures of impersonal trust as opposed to using survey results to make predictions.

Construct validity is a concern for the survey items which measure impersonal trust in FDA. As stated by Westen and Rosenthal (2003), construct validity is a primary concern when measuring something which is not otherwise directly observable. While it is important to establish all types of validity, it is beyond the scope of this project to conduct the necessary experiments to begin to measure the construct validity of this survey instrument.

The principal components analysis functioned as a test of internal consistency reliability, given that subjects consistently scored in the same direction on all measures of trust. Again, due to time and budget constraints, no other measures of reliability were undertaken.
CHAPTER VI

DISCUSSION

This study found variables associated with interpersonal trust, as indicated by Meyer and Ward (2009), were also associated with measures of impersonal trust in FDA. Income (INCOME), level of trust in the current system (FDAVNONFD), and extension of trust in high-risk situations (LIFETHREAT) were all positively and significantly associated with trust in FDA on two measures of impersonal trust (TRUSTFDA and SAFEMEDS); FDAVNONFD and LIFETHREAT were associated with trust in FDA on one measure of impersonal trust (TRUSTDEC), and FDAVNONFD was associated with trust in FDA on one measure of impersonal trust (CONINFDA). LIFETHREAT was associated with trust in FDA on the measure of dependence (NOCHOICE). For no measures was number of alternatives to FDA (ALTTOFDA) significantly associated with either impersonal trust in or dependence on FDA. Furthermore, the study found through CATPCA that measures of impersonal trust were not statistically distinguishable from measure of dependence, supporting the difficulty encountered by Meyer and Ward (2009) in trying to empirically examine dependence and trust as two different constructs. Lastly, this study found that, for three measures of trust in FDA (TRUSTFDA, SAFEMEDS, and TRUSTDEC), the vast majority of subjects either agreed or strongly agreed that they trusted FDA. Regarding the measure of trust in FDA as assessed by a measure of confidence in FDA, the majority of subjects reported some confidence in people running
FDA. Regarding the measure of dependence on FDA (NOCHOICE), the vast majority of subjects either agreed or strongly agreed that they have no choice but to trust the decisions of FDA.

Theme: Deeper Understanding of Impersonal Trust Relationship with Americans and FDA

Impersonal trust is fundamental to understanding how individual Americans interact with not only FDA but also with other similar large-scale organizations and in understanding how those organizations interact with individuals. Chapter One demonstrated how the relationship which Americans have with FDA can be framed as a relationship based on impersonal trust, and this framework is crucial to understanding why Americans do not do more to monitor actions of FDA or to otherwise hold FDA accountable for its occasional wrongdoings. This thesis topic was initially undertaken to understand why FDA has allowed an OTC medication with known abuse potential to remain on the market and to understand why there has not been more backlash from individuals and organizations demanding that the medication be removed from the hands of at-risk individuals. This may be, as supported by this and previous research, because FDA is viewed as a trusted guardian in the pharmaceutical industry, and according to Shapiro (1987), the extension of trust to FDA means that Americans may view the decisions of FDA as correct and in their best interests and likewise may not view additional monitoring of the organization as necessary.

The work on impersonal trust by Shapiro (1987) and its application to the understanding of FDA as guardian of an impersonal trust relationship can be extended to
other watchdog government organizations and private monitoring services. The understanding of these agencies as both guardians and agents of impersonal trust is fundamental to understanding how Americans react to their misdeeds. If Americans look the other way when these agencies do not hold themselves to normative ethical and moral standards, it may be because they do not see the problems due to social distance, or it may be because they have already extended trust to a second order and they wish to protect their understanding of guardians of trust as faithful and morally elite. As stated by Shapiro (1987), “one of the ironies of trust is that we frequently protect it and respond to its failures by bestowing even more trust. In the jargon of investment, we sometimes throw good money after bad” (p. 649).

The implication of this understanding is that it may take more than singular exposure to misdeeds for Americans to call for change when a guardian of trust fails to fulfill its fiduciary responsibilities. If Americans wish to protect their investment, they may either write off issues or they may employ more guardians to oversee the current guardians, resulting in an increasingly complex and diffuse distribution of trust.

The idea that Americans view FDA in a positive light as a faithful guardian of trust is supported by this and previous research which found that Americans, for the most part, trust FDA (Dickinson, 2007). In this study, subjects indicated that they strongly agreed/agreed that they trusted FDA on three out of four measures of impersonal trust in FDA. According to Shapiro (1987), it may be desirable for principals to have trust in guardians of trust, such as FDA, because relationships based on trust allow principals to leave the decision-making matters which they have little knowledge about to
professionals and experts entrusted with their care. However, while it is necessary for the public to retain some amount of trust in government in order for government to function (Goldwin, 1987), it is wise for the public to remain reasonably skeptical of governmental activity in order to remain alert for abuse and corruption of power. Measuring trust in FDA provides a gauge of where the public falls along the spectrum of too much and not enough trust in the organization.

Theme: Better Understanding of Measures of Impersonal Trust

The measures of impersonal trust in this study were heavily based on measures of trust taken from ANES (2010). Only slight modifications to survey questions had to be made to make the questions suitable for measuring trust in FDA. CATPCA provided evidence that one component derived from the four dependent trust variables explained over 63% of the variance in the variables. This provided evidence that the four measures of trust either measured highly correlated related variables or measured the same underlying construct. The fact that ANES (2010) research has consistently pointed to these variables as measures of trust provides strong evidence that the four measures of trust indeed measured trust in FDA.

While three measures of trust were moderately to strongly, positively, and significantly correlated, a fourth measure was not as strongly correlated with the other three measures. Confidence in people running FDA (CONINFDA) was included as a measure of trust in FDA based on trust-based questions from ANES (2010) which used similar wording to measure trust in government. Luhmann (2000) and other researchers
have drawn distinctions between trust and confidence; however, while conceptually different the two concepts are colloquially interchangeable. Yet, given that only one predictor of trust as stated by Meyer and Ward (2000) predicted CONINFDA, and as CONINFDA did not cluster as tightly around the trust component as the other three trust variables, it may be possible to draw an empirical as well as a theoretical distinction between confidence and trust. Another possibility for the difference in responses between CONINFDA and the other trust variables is that, as CONINFDA was initially measured using a three-point Likert scale and the other three measures of trust were obtained using a five-point Likert scale, it is possible that the 3-point Likert scale caused responses to gravitate toward the middle answer. A task for future research would be to conduct a similar study using the same scale of measurement for each dependent variable and to examine whether the concentration around the middle category for measures of confidence still holds when more answer choices are offered.

Yet another possibility for the distinction between measures of trust which use the language of “confidence” rather than trust might be that subjects hold a distinction wherein “confidence” in an organization applies to individuals who hold specific positions, and “trust” is reserved for overall trust in the system or systems-based process under consideration. This explanation appears powerful given the general knowledge which most people have about the existence of FDA coupled with little, if any, knowledge about the individuals and particularities within the system. In this situation, trust would be extended to FDA but not confidence, as subjects have trust in the system which oversees their medications but have no way to establish confidence in FDA
through interpersonal interactions with representatives of the organization. The further
consideration of the difference between confidence and trust should be a subject of future
research aimed at distinguishing trust from similar yet distinct constructs.

Theme: Better Understanding of Variables Associated with both Impersonal Trust and
Dependence

Little work has been done in the field of sociology to operationalize the construct
of impersonal trust. This study found that three out of four measures of interpersonal trust
advanced by Meyer and Ward (2009) also functioned as measures of impersonal trust in
FDA. This means that more work is necessary to further distinguish measures of personal
and impersonal trust, although this also means that there is evidence to support the
acceptance of “level of trust one has in the system and the level of risk involved in
trusting” (FDAVNONFD and LIFETHREAT, respectively) as measures of both personal
and impersonal trust (Meyer and Ward, 2009, p. 6).

One of the complications of this study was situated in the difficulty in establishing
causal relationships between the variables. While it might be appropriate, based on the
series of ordered logistic regressions included in this study, to suggest that a causal
relationship exists between income and trust, it is likely not appropriate to say that “trust
in the safety of medications caused trust in FDA,” or that “trust in medications in a high
risk situation caused trust in (and dependence on) FDA”. Although for the purposes of the
regression analyses variables had to be specified as “independent” and “dependent,” it is
difficult to say which form of trust preceded the other. Income, however, functioned as a
predictor of trust given that hypothetical manipulation of income would likely have a
direct effect on willingness to extend trust (McClendon, 1994). It is more difficult to envision manipulation of the variable “trust in the safety of medications” and subsequent results of that manipulation on overall levels of trust in FDA. Therefore, while it is interesting to determine whether there is an association between past levels of trust in an institution and current willingness to extend trust in it, as predicted by Meyer and Ward (2009), it is likely not correct to claim with relative certainty that trust in one form caused trust in the other.

According to Meyer and Ward (2013), Luhmann suggested that trust at the micro level is first necessary for trust to exist in related macro-level institutions, whereas Giddens argued that trust in institutions is a necessary prerequisite for trust in related micro-level actors. If Luhmann’s theory is correct, it might make sense to claim that trust in tangible objects which are regulated by FDA, such as medications, is a necessary prerequisite for trust in the overall institution of FDA, and it might make sense to claim that “trust in the safety of medications causes trust in FDA.” However, even if this is true, it does not remove the difficulty of including a measure of an abstract construct as a measure of another abstract construct. If Gidden’s theory is correct, then trust in FDA as an institution must necessarily precede trust in safety of the objects which is regulates, which would reverse the hypothetical direction of causality.

Given the difficulties with establishing causation and direction of effect between the variables in the models included in this study, future research on the nature of trust may include one or more of the following changes: exclusive use of variables such as income, race, age, sex, and other variables subject to hypothetical manipulation to predict
trust attitudes rather than use of dependent variables which measure abstract constructs; use of variables which measure abstract constructs as dependent variables; use of Chi Square and other tests which are designed to measure association rather than use of logistic regression; or use of qualitative methodology to study impersonal trust and related constructs.

As predicted by Meyer and Ward (2009), willingness to trust in a high-risk situation, as measured by willingness to take any medication administered by a healthcare professional in a life-threatening emergency (LIFETHREAT), was associated with increased trust in FDA. Because high risk situations place subjects in predicaments where they lack other options, high risk situations may encourage reliance on impersonal trust. As it can be difficult to distinguish necessary trust from dependence, and as there is certainly overlap between the two constructs, it could be argued that guardians of trust should be held to an even higher ethical standard than other agents of trust. This is especially true with regard to FDA as guardian of trust, as FDA is the only governmental agency with the power to approve or deny medications for market and most of its regulatory oversight has been legislated back to the agency itself. When an individual needs life-preserving and life-saving medications, it is only in the rarest of circumstances that such an individual has the opportunity to independently verify that the medication being administered is “safe and effective,” per the motto of FDA. Instead, the individual must rely on FDA to make that decision for him or her, and willingly allow FDA to be a guardian of that trust. Given that FDA has such a high level of trust and subsequent responsibility, and given that subjects were so willing to take any medication in an effort
to survive, it may be worth examining whether FDA should be held to a higher ethical standard than other governmental organizations to ensure its utmost fulfillment of fiduciary responsibility to the American public.

Not surprisingly, the level of trust which subjects currently had in FDA, as measured by their preference to take an FDA-approved medication versus a non-FDA-approved medication to treat a common cold (FDAVNONFD was associated with willingness to trust FDA. It is well known that if a trust relationship is already established, it is easier to extend trust in the future and to extend it to a greater degree (Misztal, 1996). This finding supports the hypothesis of Meyer and Ward (2009) that past and present levels of trust are associated with further extension of trust. While it is difficult to establish which forms of trust in FDA, such as trust in medications, directly affect the establishment of other forms of trust in FDA, such as trust in the institution as a whole (or whether both types of trust are built simultaneously), the positive association between trust in one area and trust in another may mean that the development of trust in one area has the potential to produce a positive effect on trust in another area. More research must be done to establish the possibility of causal relationships between the development of primary and recent trust in an organization. If such relationships can be established, FDA could focus on advancing public trust in the areas most amenable to community outreach while simultaneously experiencing the benefits of increased trust in protected areas involving impersonal interactions. Even if it is not the case that some forms of trust may predict other forms of trust, the associations between different forms of trust may be further examined and theoretical explanations for the associations can be
developed and tested in the interest of advancing understanding of trust as a construct.

Surprisingly, the number of alternatives which individuals provided for FDA (ALTTOFDA) was not significantly associated with trust in FDA. This question was provided as a measure of the number of trustworthy people and institutions to whom subjects could turn for advice about medications. It is possible that this question was not phrased to reflect the underlying factor mentioned by Meyer and Ward (2009). As this was the only non-significant independent variable as outlined by Meyer and Ward (2009), it would be worth re-examining this relationship in the future using a differently designed measure of ability to negotiate trust.

Although ALTTOFDA was not significantly associated with either trust in or dependence on FDA, it was interesting to note that only four out of the 12 different alternatives to FDA as suggested by the subjects (Centers for Disease Control, the internet, pharmaceutical companies, and Consumer Reports) has the same large-scale structure and impersonal relationship to the subjects as FDA. The remaining eight types of alternatives were people or organizations with whom the subjects were likely to have close personal contact. It is interesting that a subject would list “doctor” as an alternative to FDA, given that a general practitioner likely does not have the resources or the time to rigorously test medications in the same way as FDA. It could be possible that subjects are unaware of FDA responsibilities; however, these responsibilities were explained in layman’s terms in a question on the survey. It is also possible that subjects are aware that their physicians cannot perform the same types of testing and monitoring of medications as FDA, yet they choose to extend trust to their physicians as substitutes for FDA because
of the relationship of personal trust which subjects have with their doctors. If this is the case, it brings up interesting questions about whether the benefits of interpersonal trust have the ability to trump the benefits of impersonal trust, even if the benefits of impersonal trust may objectively appear to be more appealing.

Lastly, income functioned as a positive predictor of trust in FDA, as individuals with incomes over $50,000 were significantly more likely to trust FDA than individuals with incomes at $50,000 or below. This finding supports research conducted by Elgar and Aitken (2011) and others indicating that the factors often associated with lower income, specifically increased susceptibility to acts of crime, make it more difficult for individuals to extend trust than for individuals who do not have to deal with those circumstances. Furthermore, when individuals have higher incomes, the relative costs associated with a breach of trust are not as high as they are for lower income individuals. Alternatively, individuals with lower income may also feel that they are not treated as fairly as individuals with higher incomes and may therefore be more reluctant to extend trust in organizations (Leigh, 2006).

Overall the factors which were positively associated with personal trust were also positively associated with impersonal trust, making it difficult to say that impersonal trust can be measured as a construct distinct from personal trust. On another note, the Nagelkerke pseudo R-squares explained between 21-31% of the variation in the data among the five models. While this accounts for a good amount of the variation in the data, researchers caution about interpreting pseudo R-squares with too much rigidity. Furthermore, even 30% of explained variance leaves 70% unexplained. It is possible that
the 30% explained is the 30% of similarity which exists between the constructs of personal and impersonal trust. There are research possibilities in the remaining 70% to explore dimensions which are unique to impersonal trust.

Theme: Distinction between Trust and Dependence

Through CATPCA, this study found that the measures of trust were statistically indistinguishable from measures of dependence. While it would take another type of study to determine whether there were two different underlying factors, trust and dependence, this study provides evidence that additional research is necessary to solidly distinguish the construct of dependence from the construct of impersonal trust. Furthermore, only one variable associated with impersonal trust, a measure of whether the subject would be willing to take any life-saving medication in the event of an emergency (LIFETHREAT), was also positively associated with a measure of dependence on FDA. This makes sense, considering that individuals in high-risk situations must extend trust, in addition to accepting dependence upon, the individual or organization providing the aid. However, as with the variables mentioned earlier in this chapter, it is difficult to say that “trust predicts dependence” or vice versa without much more theoretical and empirical development of the relationships between the two constructs.

Exploration of Additional Explanations

While this study focused on the application of Shapiro’s (1987) construct of
impersonal trust and Meyer and Ward’s (2009) construct of dependence to the relationship which Americans have with FDA, and this thesis posited that Americans trust FDA because they view the institution as a guardian of trust, there are other possible theoretical explanations for verification of the finding that Americans trust FDA.

First, FDA may possess cultural characteristics which increase or decrease its perceived trustworthiness, making Americans more or less likely to extend trust in it (Bruhn, 2001). For example, Americans may be attracted to the self-proclaimed “core values” of FDA, such as commitment to overseeing the safety of medications. Affirmation of these values through the delivery of medications which are indeed safe and effective may encourage continued trust in FDA (Bruhn, 2001, p. 37). If the public approves of the actions and decisions of FDA, then it is possible that a cultural ideology exists which washes FDA with idealized qualities, causing the public to disregard criticism of the institution. Alternatively, or perhaps concurrently, it is possible that knowledge about these issues is not being adequately communicated to the public.

Another explanation for trust in FDA may be that individuals are encouraged to trust in people and organizations in positions of authority. Meyer and Ward (2013) found evidence based on interviews with patients with coronary heart disease that some subjects were willing to extend trust to any individual who appeared to be in a position of authority within the medical field. The subjects who expressed this view noted that they had been raised to blindly trust all individuals who occupied the positions of teachers, doctors, and other experts.

Another possible theoretical explanation for the findings of this study is that
Americans view FDA as a third-party in a system of exchange between pharmaceutical companies and themselves (Coleman, 1990). Using the logic of Coleman (1990) as advanced in his outline of third-parties in exchange-based relationships, neither the pharmaceutical companies nor the American public have a considerable amount of trust in the other party. For example, the public may not trust pharmaceutical companies to strictly oversee manufacturing processes or to deliver medications which are both safe and effective, and the pharmaceutical companies may not trust the public to purchase the medications which they produce. FDA may be employed as a third-party which is trusted by both pharmaceutical companies and the American public in which both original parties may place their trust. Under this arrangement, FDA may provide a level of security for the public by disallowing substances which are neither safe nor effective from entering the market, while simultaneously providing the pharmaceutical industry with a channel through which to verify its good intentions and legitimacy to the public and through which to obtain a market for its products. In this system, trust in FDA is born out of repeated positive exchanges between itself and the two other parties in the relationship.

A key part of Coleman’s argument is that individuals or companies who use third-party trust relationships want something from both the other party with whom they are directly involved and from the third-party. Americans erode pharmaceutical companies from the trust relationship and instead trust FDA to make sure the medications are safe, and pharmaceutical companies do not trust that the public will purchase medications of their own accord, but instead trust that FDA-approval will provide the license for them to sell their medications with legitimacy to doctors who will then prescribe the medications
with the authority and backing of FDA-approved. The pharmaceutical companies want to both sell their drugs to the American public and to receive official permission from the government to market their medications in the United States, the public wants to purchase safe and effective medications and also wants guarantee that those medications are safe and effective, and FDA wants to both spur the sale of medications in the interest of economic growth, stemming from its position as a governmental institution, and wants to keep its citizenry safe from harm. As pharmaceutical companies, FDA, and the American public experience positive effects as a result of their placement of trust in each other, they grow to trust each other increasingly more over time. The growth of trust in the third party is especially valuable to the continued stability of the network.

Cook and Whitmeyer (1992) also advanced the concept of exchange theory. Cook and Whitmeyer offered the following definition of exchange theory: “a configuration of social relationship among actors (both individual and corporate), where the relations involve the exchange of valued items (which can be material, informational, symbolic, etc.)” (1992, p. 110). The researchers argued that interpersonal interactions may enforce common values in a given system. In the case of FDA, positive interpersonal interactions between doctors, pharmacists, dieticians, nurses, and other individuals involved in the medical field may encourage the public to build trust in larger-scale healthcare-related organizations such as FDA.

Limitations

First, the independent variables which measured risk in trusting (LIFETHREAT),
level of negotiation in trust (ALTTOFDA), and history of trust (FDAVNONFD) were formed in response to literature by Meyer and Ward (2009) which indicated that these three factors were associated with trust in general healthcare practitioners. Association does not equal prediction, and perhaps these variables would have been better off either excluded from the analysis or specified as dependent variables in a different model. The underlying constructs may be useful as independent variables, but they should be re-specified to grant stronger predictive power.

Additionally, this study was conducted on subjects selected from a senior center in a small Midwestern town, and the generalizability of these results is likely limited. Also, the race (Caucasian) and age (over 55) of the population was homogeneous, and this study should be tested on a more heterogeneous population to see if the results still stand.

This study was not pilot tested due to budgetary and time constraints. If it had been pilot tested, it is likely that the issue of confusing a question based on trust with a question based on dependence (TRUSTDEC) would have been addressed and corrected before the survey was administered to subjects. Furthermore, after further consideration, it is possible that LIFETHREAT is a measure of trust in medications rather than trust in healthcare professionals.

Furthermore, additional tests are necessary to confirm the validity and reliability of study results.

The categorical nature of the predictors means that pseudo R-squares had to be used to estimate the amount of variance explained, and these statistics should be interpreted with caution, considering that several of the independent variables are better
suited for determining association rather than prediction.
CHAPTER VII

CONCLUSION

This paper applied the construct of impersonal trust as put forward by Shapiro (1987) to the relationship which Americans have with FDA. This study then measured impersonal trust in FDA and found that older Americans in a small Midwestern town overwhelmingly agreed that they trusted FDA. Known variables associated with trust, such as exposure to a high-risk situation, income, and current trust in the organization, were positively and significantly associated with trust in FDA in this study as well. As the variables associated with interpersonal trust were also associated with impersonal trust, and levels of trust were roughly equivalent to those provided in previous studies on trust in FDA, there was not enough evidence to support that impersonal trust needs to be measured differently than personal trust. However, over 70% of variation in responses remained unexplained in each of the five logistic regression models, so it is possible that impersonal trust can be empirically distinguished from personal trust on a dimension which has not yet been taken into consideration. Also, the CATPCA model indicated that trust and dependence were statistically indistinguishable which highlighted the difficulties involved with using quantitative methods to tease apart two constructs which are closely related.

The author would like to disseminate the results of this study in a peer-reviewed publication. The most interesting results, namely that subjects showed both trust in and
dependence on FDA, and that INCOME functioned as a significant predictor of trust, would likely be the focus of the paper. Although LIFETHREAT and FDAVNONFD may not be measured in a way which enables the establishment of causality between themselves and the dependent variables, the fact that these variables were positively associated with trust in FDA provides confirmatory evidence for theory put forward by Meyer and Ward (2009) about the types of variables which affect an individual’s decision to extend trust.

It would be very interesting to publish work in a similar fashion as Schoenfeld (2005), who showed that the construct of impersonal trust could be applied to an understanding of prosecutorial misconduct. It would be stimulating to answer a similar type of question regarding ethical concerns in FDA by using the theoretical framework of rational choice theory and Shapiro’s development of impersonal trust in FDA. This would show that Shapiro’s theory has utility at multiple levels of analysis, and would help to frame the understanding of difficult ethical problems in a large-scale organization.

Also, while this study did not find that the constructs of impersonal trust and dependence were statistically distinguishable, the graphical representation of the components trended toward distinction. It is very possible that there is something unique to questions which measure whether subjects have a choice to trust which functions as a measures of dependence. There was only one question included in this study which was phrased as a question about choice in trusting, so this may have contributed the difficulty in distinguishing trust from dependence. Future research could concentrate on developing more refined ways of asking about levels of choice in trusting as measures of dependence
and examining whether those results can be distinguished from the results of questions which ask about trust. The further these two constructs can be teased apart, the clearer the definitions which will emerge for the concepts of both trust and dependence.

Future research could include examination of any of the following questions: How do we create measures of dependence which are empirically distinguishable from measures of trust? What are the other variables which predict trust in FDA? Specifically, does pre-existing knowledge about FDA predict trust in FDA? Why do people trust FDA? How do we further distinguish interpersonal trust from impersonal trust? How do subjects view FDA – as guardians, third-party brokers, total authority figures, or in some other way or in some combination of those ways? Are confidence and trust empirically distinguishable constructs? Why did this study find that people had a high degree of trust, but not confidence in, FDA? To what degree should we seek to expose corruption in FDA? Would the negative consequences of potential decreased trust in the organization outweigh the benefits of increased knowledge about it? What is the “right” amount of trust for the public to have in governmental organizations? Are governmental organizations perceived to be more trustworthy than private organizations? Overall, while this thesis made a small advance in distinguishing interpersonal trust from impersonal trust and impersonal trust from dependence, much work remains to be done to operationalize and distinguish trust in all its forms from other related constructs.
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Appendix A

HSIRB Approval Form

Date: January 15, 2014

To: Gregory Howard, Principal Investigator
   Amanda Meyer, Student Investigator for thesis

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 14-01-11

This letter will serve as confirmation that your research project titled “Trust in Versus Dependence on the FDA” has been approved under the exempt category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may only be conducted exactly in the form it was approved. You must seek specific board approval for any changes in this project (e.g., you must request a post approval change to enroll subjects beyond the number stated in your application under “Number of subjects you want to complete the study”). Failure to obtain approval for changes will result in a protocol deviation. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

Reapproval of the project is required if it extends beyond the termination date stated below.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: January 15, 2015
Appendix B

Copy of Survey Instrument

Survey Instrument

Directions: For Questions 1-4, please circle the answer which best describes you.

Question 1: What is your sex?
Answer 1: Male
Female

Question 2: Are you over the age of 55?
Answer 2: Yes
No

Question 3: How much did/does your household make per year when the primary breadwinner was/is working?
Answer 3: Less than $25,000
Between $25,001 and $50,000
Between $50,001 and $75,000
Between $75,001 and $100,000
Over $100,000

Question 4: Please classify your race:
Answer 4: White
Non-white (please specify) ______________________________

Directions: For Questions 5-6, please write the correct answer in the blanks provided.

Question 5: How many total prescription medications do you currently take?
Answer 5: Please write the number of prescription medications you currently take: ___________
Question 6: How many total over-the-counter (OTC) medications (examples: aspirin, ibuprofen, Pesto-Bismol) do you currently take?

Answer 6: Please write the number of OTC medications you currently take: ________________

Directions: For Questions 7-11, please circle the answer which best describes how you feel.

Question 7: Would you be more likely to trust an FDA-approved medication or a home remedy to treat a common cough?

Answer 7: FDA-approved medication
Home remedy

Question 8: Would you be more likely to trust an FDA-approved medication or a non-FDA-approved medication to treat a common cough?

Answer 8: FDA-approved medication
Non-FDA-approved medication

Question 9: How much confidence do you have in the people running the FDA?

Answer 9: A great deal of confidence
Some confidence
Hardly any confidence

Question 10: One of the jobs of the FDA is to ensure that medications in the United States are safe. How many alternatives do you have to the FDA to ensure that your medications are safe?

Answer 10: None
One or more (please specify) ____________________________, ____________________________, ____________________________

Question 11: In a life-threatening emergency, would you take any medication given to you by trained healthcare professionals with the purpose of helping you to survive?

Answer 11: Yes
No
Unsure
Directions: For Questions 12-15, please circle your level of agreement with the following statements.

Question 12: I trust the FDA to ensure that my medications are safe.

Answer 12: Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree

Question 13: When you purchase an over-the-counter medication, you have no choice but to trust that the medication you receive in the bottle is the medication listed on the label. (For example, you have to trust that the pills in a bottle of aspirin are actually aspirin and not sugar pills, Tylenol, or anything else other than aspirin).

Answer 13: Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree

Question 14: You have to trust that the FDA will make the right decisions about the safety of medications.

Question 14: Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree

Question 15: Even if an FDA-approved medication turns out to be unsafe, you have to trust that all other FDA-approved medications are still safe.

Question 15: Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree