# Make Or Buy Decisions And Strategic Problem Solving:
# A Knowledge-Based Examination in Medical Device Manufacturing

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**Abstract**: This paper examines how the knowledge-based view (KBV) can be applied to firm boundary decisions and the performance implications of those decisions. At the center of the paper is a theoretical and empirical examination of how firms efficiently organize manufacturing in a regulated industry. We find that distinct organizational approaches are advantaged in the terms of performance, depending on technological complexity and product novelty. We make theoretical and empirical contributions to KBV research that examines organization and performance related to knowledge development and transfer. The medical device manufacturing industry serves as the empirical setting.

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## INTRODUCTION

The knowledge based view (KBV) of the firm emphasizes the role of knowledge in shaping organization and affecting performance. Knowledge develops within firms from experiential learning facilitated by organizational routines and problem solving activities, and creates values from its effective application (Grant, 1996). Early KBV research emphasizes the virtues of internal organization in both limiting knowledge transfer (Conner, 1991; Conner & Prahalad, 1996) and facilitating knowledge transfer (Kogut & Zander, 1992, 1996). More recent KBV research emphasizes the importance of external linkages (Leiponen & Helfat, 2011; Love, Roper, & Vahter, 2013), external interactions (Chatterji & Fabrizio, 2013; Foss, Laursen, & Pedersen, 2011), and external technology markets (Arora, Fosfuri, & Ronde, 2013) in developing new knowledge. A developing research stream in the KBV attempts to reconcile this incongruity by examining how knowledge development and transfer differs between organizational modes and offering comparative performance implications (Nickerson & Zenger, 2004).

This paper examines the performance of manufacturing products of varying technological complexity and novelty within and between firms, which can entail significant knowledge development and transfer. The efficiency and quality of manufacturing is a primary arena of competition and source of competitive advantage in many industries (Wheelwright, 1984). We utilize the medical device industry as our empirical setting, where products (i.e., medical devices) manufactured vary in terms of technological sophistication and novelty. After medical devices are approved by the Food and Drug Administration (FDA) for their safety and efficacy, the processes for those medical devices are inspected by the FDA (at least) every two years to insure proper design, monitoring and control are present in the manufacturing facility. Considerable emphasis is placed by FDA on process control via current Good Manufacturing Practice (cGMP) requirements. Regulatory noncompliance can lead to escalating FDA sanctions on manufacturing facilities, from warning letters to product recalls and withdrawals, penalties and disgorgements.

Following previous research (Nickerson & Zenger, 2004), we assume that firms' primary objectives in manufacturing are to create valuable knowledge. But because this knowledge does not typically exist, firms must instead solve particular problems that yield valuable knowledge. Our problem solving approach to knowledge development is particularly germane in environments that entail varying technological sophistication and product novelty, given the

inherent uncertainties and complexities (Fleming, 2004). Depending on problem characteristics, certain organizational modes are argued superior for problem solving relative to other organizational modes. We add to this research by unpacking the effects that technological sophistication and product novelty have on problems, problem solving organization, and the subsequent performance (i.e., regulatory compliance) of alternative organizational approaches.

We make several contributions to the KBV literature. We find that problem complexity (via technological sophistication) and problem structure (via product novelty) affect firms' subsequent performance. Firms improve (regulatory) performance from insourcing the manufacturing of more technological sophisticated and novel products—given the knowledge integration advantages within the firm and the difficulty of knowledge transfer between firms—and incur no performance degradations from outsourcing the manufacturing of less technologically sophisticated and follow-on products—given the specialized resources available via external knowledge sources and the ease of knowledge transfer between firms. We thus add to empirical research that examines the performance implications of alternative organizational modes (Leiblein, Reuer, & Dalsace, 2002; Poppo & Zenger, 1998), and find support for the importance of organizational alignment in firms' knowledge development and transfer activities in a manufacturing setting. Our dependent variable also adds to the extant make-versus-buy literature by examining a relatively understudied measure of firm performance (i.e., regulatory compliance) that is nevertheless commonplace across a wide range of industries.

The next section provides a review of the KBV organization and performance literature, and then develops comparative hypotheses from it. The following section sets the empirical context, highlighting the role of contract manufacturing in the medical device industry. The following section describes the data and variables, presents the econometric and robustness results, and discusses the main findings and limitations. The final section makes concluding comments.

## HYPOTHESES DEVELOPMENT

### Theoretical Background

The knowledge based view (KBV) of the firm conceptualizes organizations as institutions for developing and integrating knowledge. Knowledge develops within firms from experiential learning facilitated by internal rules, organizational routines and problem solving approaches. Knowledge transfers within and across firms, allowing for value creation (Grant, 1996). Early

KBV research predominantly underscored the benefits of internal organization due to its abilities to not only avoid knowledge transfer by exercising authority (Conner, 1991; Conner & Prahalad, 1996), but also promote knowledge transfer by facilitating communication (Kogut & Zander, 1992, 1996). More recent KBV research recognizes the role of external knowledge sources (i.e., markets) in developing knowledge, given readily available markets for technology (Arora, Fosfuri, & Gambardella, 2001; Arora *et al.*, 2013), wide breadth of external linkages (Leiponen & Helfat, 2011; Love *et al.*, 2013) and numerous external constituent interactions (Chatterji & Fabrizio, 2013; Foss *et al.*, 2011).

As control and communication, incentives, and property rights differ across organizational modes, a developing KBV research stream attempts to reconcile this incongruity by discriminately comparing alternative organizational arrangements and subsequent performance around knowledge development and transfer. A knowledge-based theory of the firm is proposed based on the problem solving and solution search efficiencies of distinct organizational arrangements (Nickerson & Zenger, 2004). Problems represent systems that correspond to decisions that potentially interact in complex and non-simple ways (Simon, 1962). Problems are accompanied by sets of potential solutions termed 'landscapes,' each of which relates to unique combinations of decisions made (Hsieh, Nickerson, & Zenger, 2007). Kauffman's NK framework is typically used to conceptualize solution landscapes, whereby N represents the number of knowledge sets applicable to a problem and K represents the degree of interdependence among knowledge sets (Kauffman, 1993). Given a particular N and K, firms attempt to search the landscape for high-value solutions by combining (potentially dispersed) knowledge sets (Levinthal, 1997). Theoretical and empirical discriminating alignment arguments are made between problems, which vary in their complexity and structure, and organizational modes, which vary in their abilities to effectively support solution search.

Research that takes a comparative approach to problem solving and organization has predominantly been set in the context of technological development (Macher, 2006; Macher & Boerner, 2012) or innovation (Afuah & Tucci, 2012; Baldwin & Hippel, 2012; Van de Vrande, Vanhaverbeke, & Duysters, 2009). Attributes of the technological development or innovation "problem" reveal the requisite knowledge sets, define the organizational approaches, and shape subsequent performance (Felin & Zenger, 2013). We emphasize firms' 'knowledge production' activities related to manufacturing, which entail the development of and/or access to different

knowledge sets within and across firm boundaries. Manufacturing is characterized not only as a process of solution search that utilizes different and interdependent knowledge sets (Ethiraj & Levinthal, 2004), but also as a trial-and-error exercise in which particular knowledge set parameters are altered, learned about, and improved upon. Depending on the problems presented, manufacturing can range from relatively simple—given the known number and interactions among knowledge sets—to being relatively complex—given the unknown number and interactions among knowledge sets.

The degree of problem complexity and problem structure in the manufacturing environment thus suggests that particular organizational approaches are more efficient in developing and/or transferring knowledge than other organizational approaches. Internal and external incentives that reward and encourage knowledge development and transfer are also necessary for efficient (i.e., regulatory compliant) manufacturing. We hypothesize that firms determine in a discriminating way how best to organize manufacturing that varies in technological sophistication and product novelty by simultaneously considering efficiency demands and integration requirements. As we compare the performance of knowledge-based sources between and within firms, our approach represents an ideal setting in which to theoretically and empirically add to KBV research that examines firm boundary decisions.

**Problem Complexity**

Problems can be characterized according to their complexity, defined as the number of knowledge sets involved and the degree of interaction among these knowledge sets. Simple problems are composed of relatively few knowledge sets with limited knowledge set interactions. In NK models, simple problems are characterized by relatively low N and relatively low K (Kauffman, 1993). These types of problems are considered decomposable, because decision-making and control can be easily sub-divided and partitioned among different actors. Complex problems are composed of relatively many knowledge sets with extensive knowledge set interactions (Funke, 1991). In NK models, these problems are characterized either by a relatively high N (i.e., a large number of knowledge sets) or a relatively high K (i.e., a large number of interactions) (Levinthal, 1997). These types of problems are considered non-decomposable, because the myriad requisite knowledge sets and knowledge set interactions make sub-division difficult.

Because simple problems are easily subdivided, high-value solutions are more efficiently realized through organizational arrangements that operate under directional search. Market forms of organization represent ideal approaches. The high-powered incentives of markets motivate actors to not only develop specialized knowledge (Felin & Zenger, 2013), but also provide it through markets for technology (Arora *et al.*, 2001). Outsourcing affords relatively weak support for knowledge sharing, however, given the limited communication and control, differing incentives, and overlapping property rights. Extensive knowledge sharing is largely unnecessary for simple problems, due to their decomposability (Nickerson & Zenger, 2004). Insourcing is comparatively disadvantaged for simple problems because of its low-powered incentives and additional bureaucracy. For simple problems, low-powered incentives constrain knowledge development while bureaucracy adds unnecessary costs and complexities to knowledge transfer.

Because complex problems cannot be easily subdivided, high value solutions are more efficiently realized through heuristic search. Organizational arrangements that offer extensive communication and control, provide incentives that support knowledge sharing, and recognize property rights offer particular advantages. Outsourcing impairs the adaptive, sequential and interrelated changes that are often necessary in the solving of complex problems, given the more limited control and communication and weaker incentives for knowledge sharing that exist. Organizational arrangements with low-powered incentives that allow information to be shared without risk of appropriation are instead required. Insourcing is advantaged for the solving of complex problems in comparison because it better facilitates the dissemination of new knowledge through the formation of firm-specific languages and communication codes (Kogut & Zander, 1996; Monteverde, 1995). Insourcing is also better able to alter search strategies as information unfolds and is revealed (Williamson, 1985)—a likely scenario with complex problems. While both insourcing and outsourcing should face greater solution search challenges with increasing problem complexity, insourcing is better able to manage the extensive knowledge sets and interdependencies through more formal administrative control and superior communication related to information exchange.

A definable attribute of problem complexity relates to technological sophistication, or the degree to which a product is considered (near) state-of-the-art in its design, development or manufacture. Greater technological sophistication engenders problems that are more complex in terms of knowledge sets (N) and knowledge set interactions (K). The solving of these more

complex problems benefits from organizational arrangements that offer extensive control and communication and support knowledge transfer. Masten (1984) finds that greater component design complexity in the aerospace industry benefits from internal organization because of coordination difficulties presented between successive production stages. Macher (2006) similarly finds performance advantages accrue to vertically integrated semiconductor firms over pure-play foundries (i.e., contract semiconductor manufacturers) when greater technological sophistication is required in manufacturing process development. More recently, Afuah and Tucci (2012) suggest the probability of crowdsourcing (i.e., outsourcing a task to a 'crowd' rather than designated 'agent') decreases with the difficulty of problem tacitness and complexity.

We add to this empirical research by examining the effects that technological complexity has on problem complexity and subsequent solution search in a manufacturing environment. The manufacturing of products that are considered technologically simple is more explicit and unequivocal, with minimal performance concerns. Because outsourcing offers higher-powered incentives and greater competitive pressures in comparison to insourcing, performance benefits should be realized between firms rather than within firms. The manufacturing of products that are considered technologically complex is more ambiguous and equivocal, however, and subsequently creates performance difficulties between firms both administratively and contractually. Because insourcing is better able to adapt to changing circumstances as information is revealed, the adverse performance effects from technological complexity should be more effectively reduced within firms than between firms. Firms should therefore realize performance benefits from outsourcing manufacturing that presents technologically simple problems and from insourcing manufacturing that presents technologically complex problems. The following hypothesis is examined:

> *H1: Firms that insource (outsource) manufacturing that entails more technological complexity are more (less) regulatory compliant than firms who outsource (insource) such manufacturing, ceteris paribus.*

**Problem Structure**

Problems can also be characterized according to their structure, defined as the degree of understanding of the problem domain or availability of problem solving mechanisms (Fernandes & Simon, 1999; Simon, 1973). Well-structured problems have well-defined initial states and known elements, documented approaches to solving, and accepted end states and solutions.

These types of problems have knowledge sets and interactions that are documented and well understood. Complex problems have ill-defined initial states and known elements, indefinite approaches for solving, and poorly understood end states and solutions. These types of problems have knowledge-sets and interactions that are undocumented or poorly understood.

Because well-structured problems have well understood knowledge sets and interdependencies, solution search is more transparent. High-value solutions are more efficiently realized under markets, given the directional search requirements (Nickerson & Zenger, 2004) of these problems and the high-powered incentives, decentralized control and competitive pressures in place (Williamson, 1991). While outsourcing affords relatively weak support for knowledge sharing, it is largely unnecessary for well-structured problems given the depth of understanding of the problem domain and problem solving mechanisms available. Insourcing is comparatively disadvantaged for well-structured problems. Although these organizational approaches facilitate knowledge sharing and transfer, well-structured problems neither require nor benefit from these features (Macher, 2006). The low-powered incentives and additional bureaucracy of hierarchies further slow the speed and efficiency with which problem solutions to well-structured problems can be examined.

Because ill-structured problems have ill-defined knowledge set interdependencies, solution search is imprecise and more ambiguous. High value solutions are more efficiently realized through organizational arrangements that promote communication and control and share knowledge with minimal risk of appropriation and accumulation (Nickerson & Zenger, 2004). Outsourcing impairs the adaptive and sequential changes that are often necessary in ill-structured problem solving, given the limited control and communication and weaker knowledge sharing incentives that exist. Organizational arrangements with low-powered incentives that allow for greater control and coordination and for information to be shared without risk of appropriation and accumulation are instead required. Insourcing is advantaged for ill-structured problems in comparison because of firm-specific languages and communication (Kogut & Zander, 1996; Monteverde, 1995). While both insourcing and outsourcing should face greater solution search challenges with ill-structured problems, insourcing is better able to manage the indeterminate knowledge sets and interdependencies through superior administrative control and coordination.

A definable attribute of problem structure relates to product novelty, or the degree to which a product is “new to the market.” Greater novelty similarly engenders problems that are more

complex in nature and easier to solve via organizational arrangements that not only offer extensive control and communication, but also support knowledge sharing and transfer. Heiman and Nickerson (2004) find the degree to which new knowledge is expected to result from an alliance is associated with more hierarchical approaches. Weigelt and Sarkar (2012) define product complexity according to the degree to which new and nontraditional Internet banking products and services are offered to customers, and find performance advantages from insourcing over outsourcing. Macher (2012) similarly finds more novel pharmaceutical drug products (i.e., compounds that are the first in a drug class within a therapeutic area) benefit from an internal clinical trial posture in comparison to outsourcing to specialized contract research organizations (CROs).

We add to this empirical research by examining the performance effects that product novelty has on problem complexity and subsequent solution search in a manufacturing environment. Manufacturing that entails limited product novelty presents problems that are relatively easy to solve and with minimal performance concerns. Because outsourcing offers more high-powered incentives and competitive pressures in comparison to insourcing, superior performance in manufacturing should be achieved between firms than within firms. Manufacturing that entails substantial product novelty presents problems that are relatively more difficult, however, given the more ambiguous and equivocal knowledge-intensive activities required. Given the control and communication benefits related to knowledge transfer from insourcing, the adverse manufacturing performance effects from greater product novelty should be lessened within firms than between firms. Firms should therefore realize performance benefits in manufacturing from outsourcing less novel products and from insourcing more novel products. The following hypothesis is therefore examined:

> *H2: Firms that insource (outsource) manufacturing that entails more (less) product novelty are more regulatory compliant than firms who outsource (insource) such manufacturing, ceteris paribus.*

## EMPIRICAL SETTING

### The Market Environment

Medical devices is a large—estimated at $266 billion in 2011—and growing industry, given the life-sustaining and life-improving benefits of these healthcare products. In past years, the medical device industry maintained a low level of outsourcing given concerns over quality,

delays and regulatory compliance. In recent years, many medical device firms have actively embraced outsourcing, given the needs to reduce costs and accelerate time to market of new products. Similar to consumer electronics, semiconductors, and pharmaceuticals, contract manufacturing organizations (CMOs) have flourished in the medical devices industry by offering viable manufacturing service alternatives to medical device firms. Many CMOs have bolstered their own capabilities and are able to provide a full range of services—from product design to engineering, packaging and distribution. Given these developments, the medical device contract manufacturing market is large—estimated at nearly $34 billion in 2011—and growing. The U.S. is currently the largest market for contract manufacturing services, but China and India represent increasingly attractive options to medical device firms considering outsourcing, given the lower cost structures and potential for accelerated commercial expansion. The structure of the medical device CMO market is highly fragmented with thousands of firms competing for market share, but is expected to consolidate over time via acquisition.

Medical device manufacturing not surprisingly ranges from relatively simple to extremely complex. Some medical devices are low-volume and predominantly utilize human labor as the main manufacturing input, while other medical devices are high-volume and require automated assembly systems and advanced robotics. Some medical devices present no technical difficulties in manufacturing, while others present a continuous flow of technical challenges related to product design changes (e.g., reductions in size, weight and power—and interactions among these factors) and process manufacturing changes. Some medical devices are relatively old and established, while others are brand new and bring associated manufacturing challenges.

The importance of manufacturing is reflected in the time and resources medical device manufacturers commit to this value chain activity. Medical device manufacturing can account for more than 50 percent of costs, with costs increasing over time from additional regulatory requirements, increased development scope, and greater technological complexity in the products manufactured. Many medical device firms rely—in part or in total—on the knowledge, capabilities and cost structures of CMOs for manufacturing. CMOs allow medical device manufacturers to not only outsource some manufacturing and thereby save costs, but also gain access to specialized manufacturing knowledge that might not be resident in their own manufacturing facilities.

**The Regulatory Environment**

The Food and Drug Administration (FDA) is an agency of the U.S. Department of Health and Human Services (HHS), and is responsible for regulating the food, dietary supplements, drug (pharmaceutical and biological) products, blood products, medical and radiation-emitting devices, veterinary products and cosmetics that are sold in the United States (US). FDA has mandated goals of ensuring the safety of the general public and the effectiveness of marketed products that fall under its regulatory umbrella. FDA is organized into six centers with separate responsibilities related to health and safety, depending upon the product or end-user.[2]

The regulation of medical device products falls under the Center of Devices and Radiological Health (CDRH), which oversees the design, development, manufacturing, repackaging, relabeling, and/or importing of all medical devices sold in the US. CDRH seeks to ensure that medical devices used for the treatment and prevention of diseases are proven safe and effective. CDRH oversees the evaluation of new medical devices before approval, the safety and efficacy of medical devices during (and after) approval, and the manufacture and distribution of medical devices after approval. Our focus is on the latter (i.e., the regulation of manufacturing for approved medical devices), as opposed to the former (i.e., the review and approval of new medical devices).

FDA is required by the Federal Food, Drug and Cosmetic Act of 1938 to inspect all registered manufacturing facilities that sell medical devices within the U.S., regardless of facility location. Federal statutes mandate that medical device firms operate under compliance standards termed “current Good Manufacturing Practices” (cGMPs). These standards seek to ensure that the products manufactured consistently meet applicable quality and safety specifications and requirements, and are generally consistent with international standards on quality systems.[3] cGMP regulation generally takes an “umbrella approach” in that it does not prescribe in detail

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[2] These six centers are: (1) the Center for Food Safety and Applied Nutrition; (2) the Center for Drug Evaluation and Research (CDER); (3) the Center for Biologics Evaluation and Research (CBER); (4) the Center for Veterinary Medicine (CVM); (5) the Center for Devices and Radiological Health (CDRH); and, (6) the National Center for Toxicological Research. The Office of Regulatory Affairs (ORA) oversees the general regulatory affairs for each center.

[3] cGMP regulation is consistent, to the extent possible, with quality system requirements contained in applicable international standards, primarily the International Organization for Standards (ISO) 9001:1994 "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing,” and the ISO committee draft (CD) revision of ISO/CD 13485 "Quality Systems--Medical Devices--Supplementary Requirements to ISO 9001.”

how manufacturers must produce medical devices, but rather provides an overall framework to be followed. Supplementary information—referred to as "guidances"—provide additional specificity only when is necessary and around manufacturing requirements, quality control and documentation, or process and methods validation updates. In short, cGMP regulation requires manufacturers develop and follow procedures and fill in the details that are appropriate to a given medical device according to current state-of-the-art manufacturing. Operating within this flexibility, it is each manufacturer's responsibility (1) to establish requirements for each type (or family) of medical devices to ensure safety and effectiveness; and (2) to establish methods and procedures to design, produce, and distribute devices that meet quality system (QS) requirements. Because QS regulation covers a broad spectrum of medical device products and processes, it allows for leeway in details. Medical device manufacturers determine the necessity for, or extent of, some quality system elements and develop and implement specific procedures tailored to their particular processes and products. FDA does identify the essential elements that a quality system must embody in its regulation, however, but does not prescribe specific ways to establish these elements.

FDA maintains an active cGMP compliance and enforcement program. The Office of Regulatory Affairs sets the overall enforcement budget and is the organizational unit in which most investigators are housed. Twenty FDA district offices have inspection and enforcement responsibility for domestic manufacturing facilities, while the Office of Regulatory Affairs (ORA) and CDRH share responsibility for international manufacturing facilities. From one to several FDA investigators take part in individual cGMP inspections, depending upon the type of manufacturing facility and types of medical devices manufactured.

After cGMP inspection, manufacturing facilities are notified of any violations. Formal inspection outcomes determine whether manufacturing facilities are cGMP compliant or cGMP non-compliant—the latter requiring some response by these facilities. Minor cGMP violations generally fall under the responsibility of the FDA district office conducting the original inspection. A period of time in which to address and correct violations is provided to manufacturing facilities before additional FDA regulatory actions are taken. If outstanding violations are left unaddressed, FDA can and does escalate the severity of penalties, including but not limited to controlled distribution, limited marketing, and/or legal sanctions (e.g., fines, seizures, disgorgements, injunctions and prosecutions). FDA can and will propose such

regulatory actions to the U.S. Justice Department and file cases with the U.S. District Court, if and when necessary.

## EMPIRICAL ANALYSIS

### Data

Data for this paper were obtained from the Food and Drug Administration's (FDA) Center for Medical Devices and Radiological Health (CDRH) via confidentiality and non-disclosure agreements.[4] These data come principally from two proprietary FDA databases. The first is the FDA Registration and Listing (R&L) database. Medical device manufacturing facilities selling products within the US are required to register with FDA and list the products manufactured or to be manufactured. The R&L database records the medical device firm (or firms) that own each manufacturing facility; the location of each manufacturing facility; the number, regulatory classification, medical specialty classification, and market submission classification of products within each manufacturing facility; as well as any changes that occur in this information over time. The second is the Field Accomplishments and Compliance Tracking System (FACTS) database. Medical device manufacturing facilities are inspected by FDA on average every two years. The FACTS database is a repository of information on completed current Good Manufacturing Practice (cGMP) inspections of domestic and foreign manufacturing facilities selling medical devices within the US. The FACTS database provides detailed information on each cGMP inspection, including inspection date; FDA district responsible; and inspection outcome (i.e., regulatory compliance or non-compliance). Data are assembled on cGMP inspections conducted by CDRH of medical device manufacturers over a 13-year period (2000-2012 inclusive).

### Measures

*Dependent Variables*

*Organization* – How firms organize medical device manufacturing is expected to have performance effects. The variable *Contract Manufacturer (CM)* is coded one if the

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[4] The author is a Special Government Employee (SGE) of the Food and Drug Administration, and has worked with the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) on issues related to regulatory inspection, regulatory compliance and technological investment.

manufacturing facility provides contract manufacturing services and zero otherwise. The variable *Integrated Manufacturer* (IM) is coded one if the manufacturing facility provides integrated manufacturing services (i.e., medical device firm's manufacturing facility) and zero otherwise.

*Performance* – Superior performance is ultimately measured through competitive standing as demonstrated in firms' revenue, profitability, market share or market value. The use of such measures to explore manufacturing performance is somewhat problematic. As manufacturing is an (albeit important) input into firms' overall performance, it is difficult if not impossible to determine the effect of manufacturing on the measures above. We instead examine one measure of performance—the regulatory performance of medical device manufacturing facilities via cGMP inspections related to quality systems (QS) and "good manufacturing practice." Our dataset provides the regulatory outcome of these cGMP inspections. cGMP inspection outcomes range from a certification of complete compliance [No Action Indicated (NAI)], to partial compliance [Voluntary Action Indicated (VAI)] and complete noncompliance [Ordered Action Indicated (OAI)].[5] Each dependent variable represents a dummy variable equal to one if the respective inspection outcome obtains and zero otherwise. Given the qualitative differences between complete compliance, partial compliance and complete noncompliance, Ordered Action Indicated (OAI) is used as the main dependent variable (a measure of poor performance) but other measures are examined in the robustness analysis.

*Independent Variables*

*Problem Complexity* – Problem complexity is measured using the regulatory classification of medical devices in the manufacturing facilities. The FDA classifies medical devices based on the level of regulatory control necessary to assure safety and effectiveness. Regulatory classification depends on the intended use and indications for use of the medical device,[6] as well as the risks posed to the patient and/or user. Three regulatory classifications of medical devices exist. Class I

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[5] An NAI inspection outcome occurs when no objectionable conditions or practices are found during the inspection or the significance of the documented objectionable conditions found does not justify further actions. A VAI inspection outcome occurs when objectionable conditions or practices are found but do not meet the threshold of regulatory significance. An OAI inspection classification occurs when significant objectionable conditions or practices are found and regulatory action is warranted to address the manufacturing facility's lack of compliance with statue(s) or regulation(s).

[6] For example, the intended use of a scalpel is to cut tissue. The indications for use of a scalpel vary, however, from making relatively simple incisions into the skin to making more exacting incisions into the heart, the cornea, etc.

medical devices present minimal potential for harm to the user and are generally simple in design. These devices are not intended to help support or sustain life, are not substantially important in preventing impairment to human health, and do not present unreasonable risks of illness or injury. These medical devices nevertheless still fall under FDA general control requirements related to adulteration, labeling, registration and listing, and good manufacturing practice, among others. Class I device examples include bedpans, elastic bandages, tongue depressors, thermometers, disposable gloves, etc. Class II medical devices present some potential for harm to the user and are generally more complex in design. These devices also fall under FDA general control requirements, but include additional control requirements—such as special labeling, mandatory performance standards and post-market surveillance—to ensure safety and effectiveness. Class II device examples include infusion pumps, surgical drapes, surgical needles, suture material, etc. Class III medical devices are generally those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential or unreasonable risk of illness or injury. These devices are generally the most technologically sophisticated in design and manufacture. Class III devices includes automated external defibrillators, stents, implants, prostheses, etc.

Given their myriad technological inputs, stringent product design requirements, and multiple process manufacturing steps, our measure of problem complexity is derived from Class III devices in operation in the manufacturing facility. *Problem Complexity* is defined as the percentage of Class III medical devices relative to the total number of medical devices manufactured in a facility in a given year. This measure captures the overall technological sophistication of medical devices manufactured in the facility, and by construction is bounded between zero and one.

*Problem Structure* – Problem structure is measured using the market submission classification of medical devices in the manufacturing facilities. After regulatory classification the FDA classifies medical devices based on market submission. Three market submissions—in order of increasing application submission requirements—are most common: 510(k) Exempt, 510(k) and PMA. A 510(k) Exempt submission is made to FDA by a medical device manufacturer to indicate that the medical device to be manufactured is exempt from premarket notification [510(k)] requirements (explained below), subject to certain limitations on exemptions. While 510(k) approval is not required, medical device manufacturers must still meet other marketing requirements for the

medical device, including manufacturing under a quality assurance program, be suitable for the intended use(s), be adequately packaged and properly labeled, and have establishment registration and device listing information on file with FDA. 510(k) exempt submissions apply to most Class I medical devices, as well as some Class II and Class III medical devices. A 510(k) submission is made to FDA by a medical device manufacturer to demonstrate that the medical device to be marketed is not exempt from regulation, but is at least as safe and effective (i.e., substantially equivalent) to an already legally marketed medical device not subject to pre-market approval (explained below).[7] The 510(k) applicant must compare the medical device to one or more similar legally marketed medical devices (a.k.a., a predicate) and make and support substantial equivalency claims. The applicant must receive FDA approval of the 510(k) market submission prior to marketing the medical device. 510(k) submissions apply to Class II and Class III medical devices, as well as some Class I medical devices. A premarket approval (PMA) submission is made to FDA by a medical device manufacturer to demonstrate that the medical device to be marketed is not exempt from regulation, is not substantially equivalent to a predicate, and has met scientific and regulatory review requirements around safety and effectiveness. As applicants must receive FDA approval of PMA applications prior to marketing their medical devices, PMAs are considered the most stringent market submissions. PMA approval is based on an FDA determination that the submission contains sufficient valid scientific evidence to assure that the medical device is safe and effective for its intended use(s).[8] PMAs apply to nearly all Class III medical devices, as well as many Class II medical devices.

Given their originality and newness, our measure of problem structure is derived from PMA devices in operation in the manufacturing facility. *Problem Structure* is defined as the percentage of premarket approval medical devices relative to the total number of medical devices manufactured in a facility in a given year. Given premarket approval devices have no close substitutes, this measure captures the overall product novelty of all medical devices manufactured in the facility. It is bounded between zero and one by construction.

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[7] A medical device is considered substantially equivalent (in comparison to a predicate) if either (1) it has the same intended use as the predicate, and has the same technological characteristics as the predicate; or (2) it has the same intended use as the predicate, has different technological characteristics as the predicate, and the information submitted to FDA (a) does not raise new questions of safety and effectiveness and (b) demonstrates that the device is at least as safe and effective as the legally marketed device.

[8] An approved PMA is considered a license granting the applicant (or owner) permission to market the device.

*Control Variables*

Several control variables are included to capture FDA-, manufacturing facility-, and product-specific characteristics. At the FDA level, we control for the FDA district conducting the cGMP inspection. There are twenty unique FDA district offices (including headquarters) located regionally throughout the U.S., as well as several regional offices.[9] A series of FDA district indicator variables are included (essentially FDA District fixed effects) that take the value one if that FDA district conducted the inspection and zero otherwise. These variables also capture information related to the geographic locations of manufacturing facilities.

At the manufacturing facility level, we control for the number of medical devices manufactured by regulatory class. *Class I CNT*, *Class II CNT* and *Class III CNT* represent respective counts of the number of Class I, Class II and Class III medical devices manufactured in a facility in a given year. We also control for the number of medical devices by market submission. *510(k)e CNT*, *510(k) CNT* and *PMA CNT* represent respective counts of the number of 510(k) exempt, 510(k) and PMA medical submissions in a facility in a given year. We aggregate the above measures to examine the total number of medical devices manufactured. *Device CNT* is a count of the total number of medical devices manufactured by a facility in a given year. We utilize the disaggregated measures in the baseline empirical examination, but consider the aggregate measure in the robustness analysis. We also control for the number of activities undertaken by a manufacturing facility.[10] *Activity CNT* is a count of the number of unique activities provided by a manufacturing facility in a given year. The regulatory class and market submission count variables represent measures of manufacturing facility scale, while the manufacturing activity count variable represents a measure of manufacturing facility scope.

We control for the medical specialty classifications of medical devices manufactured in each facility via indicator variables. There are 19 unique "medical specialty panels" that FDA uses to

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[9] The FDA district offices are located in Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Diego, San Francisco, Seattle and San Juan. FDA also maintains a number of regional offices in the Central, Pacific and Southwest of the U.S.

[10] There are nine manufacturing facility activity categories: contract manufacturing, contract sterilizer, foreign exporter, manufacturer, remanufacturer, repackager/relabeler, reprocessor, specification developer, and U.S. exporter.

classify medical devices.[11] Each medical specialty indicator variable is coded one if the facility manufacturers at least one device of a particular classification and zero otherwise. As scope (dis)economies in manufacturing devices across multiple medical specialties might exist, we also control for the number of unique medical specialties within a manufacturing facility. *Medical Specialty CNT* is a count of the number of unique medical specialties manufactured in a facility in a given year.

We control for two important medical device characteristics. The R&L database indicates whether medical devices are implantable or life-sustaining, among other factors. Implantable devices are those that replace a missing biological structure, support a damaged biological structure or enhance an existing biological structure (e.g., pins, rods, screws, plates). *Implant Flag CNT* is a count of the number of implantable medical devices manufactured in a facility in a given year. Life-sustaining devices are those that are essential to the restoration or continuation of a bodily function important to the continuation of human life. *LS Flag CNT* a count of the number of life-sustaining medical devices manufactured in a facility in a given year.

We finally control for unmeasured variation that might exist from differences in cGMP inspections of manufacturing facilities over time, using yearly fixed effects.

**Summary and Correlation Statistics**

Table 1 provides summary statistics of the unlogged variables for the entire sample and the integrated manufacturer (IM) and contract manufacturer (CM) subsamples. FDA district, year and manufacturing facility medical specialty classification indicator variables are not included due to space constraints. The sample includes nearly 9,000 unique cGMP inspections of more than 3,000 medical device manufacturers over 2000-2013. OAI outcomes (i.e., regulatory noncompliance) result in roughly nine percent of inspections on average, but are correspondingly higher (lower) for integrated (contract) manufacturers. NAI outcomes (i.e., complete regulatory compliance) occur in roughly 46 percent of inspections on average, but are correspondingly lower (higher) for integrated (contract) manufacturers. The remainder of inspection outcomes is VAI outcomes (i.e., partial compliance).

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[11] The medical specialty panels are anesthesiology; cardiovascular; clinical chemistry; clinical toxicology; dental; ear, nose and throat; gastroenterology-urology; general and plastic surgery; general hospital; hematology; immunology; microbiology; neurology; obstetrics and gynecology; ophthalmic; orthopedic; pathology; physical medicine; and radiology.

Thirty percent of the medical device manufacturing facilities are contract manufacturers, while 89 percent of the manufacturing facilities are integrated manufacturers. As several integrated manufacturers provide contract manufacturing services, we therefore compare the organization and regulatory performance of purely contract manufacturers (i.e., those only providing contract manufacturing) to purely integrated manufacturers (i.e., those only providing integrated manufacturing) in our main empirical analysis. We consider the performance effects of "hybrid" manufacturing facilities in the empirical robustness section.

Class I and Class II medical devices represent the vast majority of regulatory classifications in the average manufacturing facility. Contract manufacturers produce more devices on average, in comparison to integrated manufacturers, across all regulatory classifications. 510(k) exempt and 510(k) devices similarly represent the majority of market submissions in the average manufacturing facility. Contract manufacturers again have more market submissions on average than integrated manufacturers across all market submissions. The average manufacturing facility is engaged in roughly 1.6 unique activities and nearly two medical specialties, with integrated manufacturers below and contract manufacturers above this average.

--- Insert Table 1 here ---

Table 2 provides correlation statistics of the unlogged variables indicating pair-wise correlation significance (at .05 p-levels) in bold. OAI inspection outcomes are negatively correlated with contract manufacturing facilities, while NAI inspection outcomes are positively correlated with contracting manufacturing facilities and negatively correlated with integrated manufacturing facilities. OAI inspection outcomes are negatively correlated with problem complexity (i.e., manufacturing facility technological sophistication). NAI inspection outcomes are positively correlated with problem complexity and problem structure (i.e., manufacturing facility product novelty). Table 2 also indicates significant pair-wise correlations between several of the regulatory class and market submission count variables. In particular, Class I and 510(k) exempt variables, Class II and 510(k) variables, and Class III and PMA variables show high pair-wise correlations, respectively.

--- Insert Table 2 here ---

Table 3 illustrates in greater detail the relationship between regulatory classification and market submission classification for all medical device products under FDA regulation. 86 percent of 510(k) exempt submissions are Class I devices; 89 percent of all 510(k) submissions are Class II devices; and 99 percent of all PMA submissions are Class III devices. At the same time, 91 percent of all Class I devices are 510(k) exempt submissions; 89 percent of all Class II devices are 510(k) submissions; and 78 percent of all Class III devices are PMA submissions. PMA market submissions therefore represent a subset of Class III devices.

--- Insert Table 3 here ---

**Econometric Model**

Firms should improve regulatory performance in manufacturing medical devices by aligning problems, which differ in their attributes, with organizational modes, which vary in their abilities to support knowledge development and transfer (Nickerson & Zenger, 2004). If $P_O$ represents the expected regulatory performance of outsourcing manufacturing and $P_I$ the expected regulatory performance of insourcing manufacturing, firms should outsource manufacturing when $P_O > P_I$ and insource manufacturing when $P_I > P_O$. Firms that do not appropriately align problem attributes with problem solving organizational approaches are presumed to suffer performance consequences.

The empirical estimations utilize ordered action indicated (OAI) as the main dependent variable. Given the dichotomous construction of this variable, logit or probit estimation is most appropriate. Variables that lead to better (worse) regulatory performance have negative (positive) coefficients. We employ probit estimation as our baseline estimation, and adjust standard errors for robustness and within-firm clustering (by medical device manufacturing facility) if and when possible.[12] Maximum likelihood estimation is utilized in all models. Other dependent variable permutations of regulatory performance outcomes (e.g., NAI) as well as other estimation approaches (e.g., ordered probit) are explored in the robustness analysis.

[12] Our results are robust to logit estimation.

**Econometric Results**

Table 4 presents the empirical results with all count variables natural log transformed. As the regulatory class variables and market submission variables are nearly collinear, separate empirical estimations must be implemented. The left hand side of Table 4 presents the regulatory classification results and the right hand side of Table 4 presents the market submission classification results in identical formats. Model 1 provides a baseline estimation using the control variables and the (unreported) FDA district, year and manufacturing facility medical specialty classification indicator variables. Model 2 adds the direct variables of interest to Model 1. Model 3 add the interaction terms to Model 2. Likelihood-ratio statistics reject zero slope coefficient hypotheses (.01 p-values) in all models. We focus our discussion on the Model 3 results for the regulatory class and market submission estimations.

We report coefficients and standard errors following standard practice, but caution against determining statistical or economic significance from this information for two reasons. First, the reported coefficients do not represent marginal effects (Hoetker, 2007; Zelner, 2009), and the reported standard errors do not convey direct information about the statistical significance of these effects because of model nonlinearity (Ai & Norton, 2003; Huang & Shields, 2000). Second, the interaction terms do not represent cross-partial derivatives (Hoetker, 2007) and do not indicate the economic significance of the conditional effects of interest. It is thus not possible to determine direction or statistical and economic significance by simply examining the magnitude and standard error of a single coefficient when moderating effects are included in nonlinear models. We instead use an approach developed in political science by King, Tomz and Wittenberg (2000) and tailored to strategy research by Zelner (2009). We show the results of this approach graphically not only to facilitate intuition, but also to demonstrate statistical and economic significance over different variable ranges, using the CLARIFY suite of Stata commands (King *et al.*, 2000). This estimation approach simulates a distribution of coefficient estimates by repeatedly drawing new estimate values from a multivariate normal distribution. Each figure uses simulations of coefficient parameters, preset values for the explanatory variables, calculated expected values, and 95 percent confidence intervals to present the results. All other variables are held at their respective means.

We briefly mention the direct effects of our main variables of interest in Table 3. In terms of the control variables, facilities engaged in manufacturing medical devices across multiple

medical specialties ($p<0.01$) face increased likelihoods of regulatory noncompliance. Scope diseconomies thus appear to exist in manufacturing medical devices across a broad medical specialty space. None of the other independent variables achieves statistical significance.

We next examine the interrelationships between problem complexity and manufacturing organization and between problem structure and manufacturing organization using the Model 3 results of Table 4 and Figures 1 and 2. Contract manufacturers are less likely ($p<0.05$) regulatory noncompliant in comparison to integrated manufacturers, *ceteris paribus*. Increasing technological sophistication introduced in the manufacturing facility is moderately associated ($p<0.10$) with decreasing cGMP regulatory noncompliance. Increasing product novelty into the manufacturing facility is strongly associated ($p<0.01$) with decreasing cGMP regulatory noncompliance. These results are somewhat counterintuitive, but are easily explained by the interactive effect between these problem attribute measures and organizational approach. Contract manufacturers face increased regulatory noncompliance as problem complexity increases ($p<0.05$). Class III medical devices substantial technological challenges and require increased levels of control to assure safe and efficient manufacturing. The increased technological sophistication present from a greater percentage of these products increases the complexity of problems in the manufacturing facility. Contract manufacturers face greater problem solving difficulties from this increased problem complexity, in comparison to integrated manufacturers. These results provide support for Hypothesis H1. Contract manufacturers similarly face increased regulatory noncompliance as problem structure increases ($p<0.01$). Premarket approval (PMA) submissions are those medical devices that are relatively novel and must first meet scientific and regulatory review requirements around safety and effectiveness. As many of these medical devices are *de-novo* products, the depth of understanding all of the associated manufacturing requirements is more limited. As a greater percentage of PMA medical devices pervade the manufacturing facility, the associated problems introduced are more ill-structured, and problem solving is made more difficult. Contract manufacturers face greater problem solving hurdles as the problem solving environment becomes more difficult, in comparison to integrated manufacturers. These results provide strong support for Hypothesis H2.

--- Insert Table 4 here ---

Figures 1 and 2 better illustrate our empirical findings and hypotheses support by providing a detailed examination of statistical and economic significance. Figure 1 plots the probability of regulatory non-compliance for contract manufacturers and integrated manufacturers across the range of manufacturing facility technological sophistication (*Problem Complexity*). Figure 2 plots the probability of regulatory non-compliance for contract manufacturers and integrated manufacturers across the range of manufacturing facility product novelty (*Problem Structure*). Superior regulatory performance is exemplified in lower vertical axis values. Three findings are noteworthy and common across the figures. First, contract manufacturers and integrated manufacturers obtain nearly equivalent regulatory non-compliance outcomes at "low levels" of manufacturing facility problem complexity (i.e., low technological sophistication or low product novelty). Second, contract manufacturers' regulatory performance increases with more complexity and less structure while integrated manufacturers' regulatory performance decreases with more complexity and less structure. In short, the cGMP non-compliance slopes are opposite in sign for contract manufacturers (positive) and integrated manufacturers (negative). Third, the regulatory performance differences between these organizational modes increases with greater problem complexity and greater problem structure. While the same directional result obtains for both problem complexity and problem structure, statistical and economic significance only obtains for product novelty (percentage of PMA market submissions) in comparison to technological sophistication (percentage of Class III medical devices).

--- Insert Figures 1 and 2 here ---

**Robustness Results**

Table 5 presents several empirical robustness tests. Model 1 replaces the regulatory classification variables (*Class I CNT*, *Class II CNT* and *Class III CNT*) and market submission variables (*510(k)e CNT*, *510(k) CNT* and *PMA CNT*) with *Device CNT*—a measure of the total number of medical devices manufactured in a facility in a given year. The Model 3 estimation of Table 4 is rerun, with the results nearly identical in terms of magnitude, sign and statistical significance of the main variables of interest.

Model 2 alters the dependent variable used in the baseline empirical analysis. As cGMP inspection outcomes vary from complete non-compliance (OAI) to complete compliance (NAI),

we recode the dependent variable from OAI to NAI and rerun the empirical estimation.[13] This new dependent variable is thus an indicator of regulatory compliance performance. The results indicate more Class III medical devices ($p<0.01$) and more PMA submissions ($p<0.01$) increase the likelihood of NAI regulatory inspection outcomes. Contract manufacturers are more likely ($p<0.05$) to be found regulatory compliant in comparison to integrated manufacturers, *ceteris paribus*. This performance advantage is unaffected when greater problem complexity or problem structure is introduced into the manufacturing facility, in comparison to integrated manufacturers.

Model 3 alters the empirical approach from probit estimation to ordered probit estimation, given the natural compliance-to-noncompliance ordering of the dependent variable (i.e., from NAI to VAI to OAI). The results are markedly similar to the Model 3 results in Table 4. Contract manufacturers are less likely ($p<0.05$) to have increasingly noncompliant regulatory outcomes in comparison to integrated manufacturers, but this performance advantage wanes as problem complexity—via technological sophistication ($p<0.05$)—and problem structure—via product novelty ($p<0.05$)—increases in the manufacturing facility.

Model 4 includes "hybrid" manufacturing facilities (i.e., integrated manufacturers that also provide contract manufacturing services) in the empirical estimation. These facilities are "reclassified" as integrated manufacturers, as they first-and-foremost serve the needs of internal customers. The results are again markedly similar to the Model 3 results of Table 4, which makes intuitive sense. Hybrid manufacturing facilities are demonstrated better off in managing the complexities of increased technological sophistication and product novelty, in comparison to contract manufacturers. As some portion of their capacity is already dedicated to the internal manufacturing of medical devices, the experiential learning, communication codes and control mechanisms already in place likely provide spillover benefits to manufacturing medical devices for the market.

--- Insert Table 5 here ---

[13] Note that OAI inspection outcomes are not the opposite of NAI inspection outcomes, given a third inspection outcome (voluntary action indicated – VAI) represents mild compliance/non-compliance.

## Discussion

Our empirical results confirm that problem complexity and problem structure have notable organization and regulatory performance effects. As more difficult problems are introduced into the manufacturing environment—either in terms of increasing technological sophistication or increasing product novelty—greater control and/or coordination is required to efficiently solve them. Firms who insource more complex and ill-structured problems are found to outperform those who outsource these types of problems, given the hierarchical efficiencies. Less complex and well-structured problems in the manufacturing environment require correspondingly less control and/or coordination to efficiently solve, as either the knowledge sets or interactions are fewer in number or the knowledge sets and interactions are better understood. Firms who outsource less complex and well-structured problems outperform those who insource these problem types, given market-based efficiencies. These results therefore support KBV arguments that firms improve performance by discriminatingly aligning knowledge attributes and organization (Macher, 2006; Nickerson & Zenger, 2004).

Our empirical results importantly suggest that an internal manufacturing posture provides certain performance benefits. Insourcing manufacturing fosters control and facilitates communication in ways that outsourcing manufacturing has difficulty matching. Knowledge development and transfer related to complex and ill-structured problems is thus more efficient within rather than across firm boundaries. While it has been suggested that virtual organizations are indeed virtuous (Chesbrough & Teece, 1996), the complete "hollowing out" of firms is indeed unlikely (Foss, 2003).

An important question is why some medical device firms take arguably underperforming approaches in organizing manufacturing. We believe that some medical device firms are not strategic in their organizational approaches toward manufacturing. Instead of considering the manufacturing requirements for the entire medical device product portfolio, some firms quasi-randomly assign internal manufacturing resources (when available) to the "next" medical device, irrespective of its particular problem-solving requirements. Our findings instead suggest that medical device firms must balance their product portfolios (Wheelwright & Clark, 1992), and maintain some amount of manufacturing slack according to the problem solving requirements of the medical devices currently manufactured or soon to be manufactured (via pre-market approvals) in the foreseeable future.

Our analysis has obvious implications for firms competing in the medical device industry. As medical device firms allocate significant resources to manufacturing, how well they organize this value chain activity has a substantial impact not only on regulatory performance, but also on economic returns. We also believe our results have important implications beyond medical devices, and are relevant to managers and firms engaged in the production of technological knowledge within and across value chain activities and within and outside of firm boundaries. Relevant industry examples are likely to include, but are not be limited to, biopharmaceuticals, chemicals, consumer electronics, semiconductors and software. We finally believe that our empirical setting has important implications for managers and firms competing in regulated industries where inspection and compliance concerns are part of day-to-day operations. Survey analysis suggests that the average total costs associated with a single non-compliant investigation by a health agency are on between several hundred thousand to several million dollars (PDA, 2012). Regulatory compliance thus has important implications for firm profitability.

Certain limitations and caveats in our empirical analyses and results are noteworthy. First, we examine a single and somewhat idiosyncratic industry. While our narrow focus potentially limits generalizability, it nevertheless allows for greater precision in our measures and a more direct link between these factors and firm performance differences. Second, we examine only FDA-approved medical devices that are sold in the United States. An arguably more complete picture would consider medical devices distributed and sold around the world. Third, due to data availability we are unable to examine the organizational decisions of manufacturing individual medical devices. In particular, we can only determine whether the manufacturing facility overall provides contract manufacturing services, provides integrated manufacturing services, or provides both services and whether the manufacturing facility is cGMP-compliant or cGMP-noncompliant. Fourth, we do not control for the breadth and depth of medical device firm-contract manufacturer partnerships. While we question whether partnerships achieve the same level of success as internal organization, relationship breadth and depth likely impact regulatory performance. Fifth, medical device firms are unlikely to choose contract manufacturing organizations randomly. A myriad of (potentially confounding) factors—including but not limited to geographic proximity, availability, prior relationships and costs—likely influence the contract manufacturing selection process. The effect of this potential on regulatory compliance performance, however, is difficult to determine. Some factors (e.g., experience, capabilities)

should clearly improve regulatory compliance performance and bias medical device firms toward greater contract manufacturing, while other factors (e.g., proximity, relationships) could potentially reduce regulatory compliance performance while still biasing medical device firms toward greater contract manufacturing.

## CONCLUSION

This paper utilizes the knowledge based view (KBV) to examine how problem complexity and problem structure affect regulatory performance in manufacturing at the boundaries of the firm. Firms' 'knowledge production' activities in manufacturing are highlighted and examined from a problem solving perspective. Several theoretical contributions to existing KBV research are put forth, and a comparative examination of the organization and performance of knowledge development and transfer within and between firms is conducted. Performance implications around the complexity and structure of problems and the choice of manufacturing organization are proffered and supported, which subsequently adds to KBV research that examines boundary decisions.

Problem complexity and problem structure are found to have performance effects on firms' regulatory performance. Problem complexity—the number of knowledge sets and the degree of interaction among knowledge sets—has a significant effect on the performance realized between insourced and outsourced manufacturing. Problem structure—the breadth and depth of understanding the knowledge sets and interactions—has similar organization and performance effects. The difficulties associated with developing and integrating knowledge across firm boundaries rather than within firm boundaries become especially acute with more complex and ill-structured problems. We therefore argue that problem complexity and problem structure are important determinants of organization and performance across firms' value chain activities.

Using the medical device manufacturing industry as the empirical setting and current Good Manufacturing Practice (cGMP) regulatory performance—a measure of manufacturing and quality systems effectiveness—as our performance measure, we add to empirical KBV research that examines the performance implications of alternative organizational modes and provide support for the importance of organizational alignment in firms' knowledge development and integration activities. Because manufacturing is an activity that (1) can often be characterized by complex and ill-structured problem solving and (2) can require regulatory oversight, our analysis has important implications for firms competing in a wide range of industries. As firms allocate

significant resources to “quality systems” manufacturing, especially in regulated industries, how they organize this value chain activity determines whether and when the products developed will achieve commercialization and provide economic return.

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**Table 1 – Summary Statistics**

| | ALL MANUFACTURERS | | | | INTEGRATED MANUFACTURERS | | | | CONTRACT MANUFACTURERS | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **VARIABLE** | **MEAN** | **STD DEV** | **MIN** | **MAX** | **MEAN** | **STD DEV** | **MIN** | **MAX** | **MEAN** | **STD DEV** | **MIN** | **MAX** |
| *NAI* | 0.46 | 0.50 | 0.00 | 1.00 | 0.45 | 0.50 | 0.00 | 1.00 | 0.51 | 0.50 | 0.00 | 1.00 |
| *VAI* | 0.45 | 0.50 | 0.00 | 1.00 | 0.45 | 0.50 | 0.00 | 1.00 | 0.42 | 0.49 | 0.00 | 1.00 |
| *OAI* | 0.09 | 0.29 | 0.00 | 1.00 | 0.09 | 0.29 | 0.00 | 1.00 | 0.07 | 0.26 | 0.00 | 1.00 |
| *Contract Manufacturer (CM)* | 0.30 | 0.46 | 0.00 | 1.00 | 0.21 | 0.41 | 0.00 | 1.00 | 1.00 | 0.00 | 1.00 | 1.00 |
| *Integrated Manufacturer (IM)* | 0.89 | 0.32 | 0.00 | 1.00 | 1.00 | 0.00 | 1.00 | 1.00 | 0.62 | 0.49 | 0.00 | 1.00 |
| *Problem Complexity* | 0.02 | 0.13 | 0.00 | 1.00 | 0.02 | 0.13 | 0.00 | 1.00 | 0.02 | 0.12 | 0.00 | 1.00 |
| *Problem Structure* | 0.01 | 0.10 | 0.00 | 1.00 | 0.01 | 0.10 | 0.00 | 1.00 | 0.01 | 0.08 | 0.00 | 1.00 |
| *Device CNT* | 7.40 | 20.62 | 1.00 | 620.00 | 7.18 | 19.99 | 1.00 | 620.00 | 10.45 | 25.62 | 1.00 | 620.00 |
| *Class I CNT* | 4.44 | 15.06 | 0.00 | 597.00 | 4.55 | 15.24 | 0.00 | 597.00 | 5.83 | 18.58 | 0.00 | 597.00 |
| *Class II CNT* | 2.79 | 8.60 | 0.00 | 169.00 | 2.49 | 7.59 | 0.00 | 169.00 | 4.35 | 11.51 | 0.00 | 154.00 |
| *Class III CNT* | 0.17 | 0.83 | 0.00 | 16.00 | 0.14 | 0.73 | 0.00 | 13.00 | 0.25 | 1.07 | 0.00 | 16.00 |
| *510(k)e CNT* | 4.62 | 15.87 | 0.00 | 620.00 | 4.71 | 15.98 | 0.00 | 620.00 | 6.06 | 19.39 | 0.00 | 620.00 |
| *510(k) CNT* | 2.68 | 7.76 | 0.00 | 140.00 | 2.38 | 6.75 | 0.00 | 115.00 | 4.23 | 10.81 | 0.00 | 140.00 |
| *PMA CNT* | 0.09 | 0.58 | 0.00 | 15.00 | 0.08 | 0.48 | 0.00 | 10.00 | 0.14 | 0.77 | 0.00 | 15.00 |
| *Activity CNT* | 1.61 | 0.90 | 1.00 | 9.00 | 1.66 | 0.92 | 1.00 | 9.00 | 2.12 | 1.12 | 1.00 | 9.00 |
| *Medical Specialty CNT* | 1.91 | 1.83 | 0.00 | 17.00 | 1.86 | 1.72 | 0.00 | 17.00 | 2.43 | 2.32 | 0.00 | 17.00 |
| *Implant Flag CNT* | 0.70 | 3.58 | 0.00 | 83.00 | 0.51 | 2.92 | 0.00 | 83.00 | 2.20 | 6.65 | 0.00 | 68.00 |
| *LS Flag CNT* | 0.11 | 0.65 | 0.00 | 15.00 | 0.09 | 0.55 | 0.00 | 11.00 | 0.26 | 1.16 | 0.00 | 15.00 |

**Table 2 – Correlation Statistics**

| | *(1) NAI* | *(2) VAI* | *(3) OAI* | *(4) Contract Manufacturer* | *(5) Integrated Manufacturer* | *(6) Problem Complexity* | *(7) Problem Structure* | *(8) Device CNT* | *(9) Class I CNT* | *(10) Class II CNT* | *(11) Class III CNT* | *(12) 510(k) Exempt CTN* | *(13) 510(k) CNT* | *(14) PMA CNT* | *(15) Activity CNT* | *(16) Medical Specialty CNT* | *(17) Implant Flag CNT* | *(18) LS Flag CNT* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (1) | 1.00 | | | | | | | | | | | | | | | | | |
| (2) | **-0.83** | 1.00 | | | | | | | | | | | | | | | | |
| (3) | **-0.29** | **-0.28** | 1.00 | | | | | | | | | | | | | | | |
| (4) | **0.06** | **-0.04** | **-0.04** | 1.00 | | | | | | | | | | | | | | |
| (5) | **-0.06** | **0.05** | 0.02 | **-0.55** | 1.00 | | | | | | | | | | | | | |
| (6) | **0.05** | **-0.04** | -0.02 | 0.00 | **-0.03** | 1.00 | | | | | | | | | | | | |
| (7) | **0.05** | **-0.04** | **-0.03** | **-0.02** | **-0.01** | **0.75** | 1.00 | | | | | | | | | | | |
| (8) | **0.02** | -0.01 | **-0.02** | **0.10** | **-0.03** | **-0.01** | **-0.01** | 1.00 | | | | | | | | | | |
| (9) | 0.01 | 0.00 | -0.02 | **0.06** | **0.02** | **-0.04** | **-0.03** | **0.92** | 1.00 | | | | | | | | | |
| (10) | 0.02 | -0.01 | -0.02 | **0.12** | **-0.10** | 0.00 | 0.00 | **0.76** | **0.44** | 1.00 | | | | | | | | |
| (11) | **0.08** | **-0.07** | **-0.02** | **0.07** | **-0.09** | **0.53** | **0.35** | **0.27** | **0.09** | **0.39** | 1.00 | | | | | | | |
| (12) | 0.01 | 0.00 | -0.02 | **0.06** | **0.02** | **-0.03** | **-0.03** | **0.94** | **0.99** | **0.50** | **0.11** | 1.00 | | | | | | |
| (13) | **0.02** | -0.01 | -0.02 | **0.13** | **-0.11** | **0.01** | **0.01** | **0.72** | **0.41** | **0.97** | **0.43** | **0.43** | 1.00 | | | | | |
| (14) | **0.09** | **-0.07** | **-0.03** | **0.05** | **-0.08** | **0.38** | **0.48** | **0.24** | **0.07** | **0.37** | **0.82** | **0.07** | **0.40** | 1.00 | | | | |
| (15) | 0.00 | 0.01 | -0.02 | **0.37** | **0.17** | **-0.01** | 0.00 | **0.23** | **0.19** | **0.21** | **0.07** | **0.19** | **0.21** | **0.07** | 1.00 | | | |
| (16) | 0.01 | 0.00 | -0.02 | **0.19** | **-0.07** | **-0.07** | **-0.05** | **0.70** | **0.61** | **0.60** | **0.22** | **0.62** | **0.58** | **0.22** | **0.28** | 1.00 | | |
| (17) | **0.04** | **-0.03** | -0.02 | **0.12** | **-0.15** | **0.07** | **0.06** | **0.48** | **0.29** | **0.59** | **0.50** | **0.28** | **0.66** | **0.42** | **0.09** | **0.37** | 1.00 | |
| (18) | **0.05** | **-0.05** | -0.01 | **0.09** | **-0.08** | **0.12** | **0.11** | **0.33** | **0.16** | **0.47** | **0.46** | **0.18** | **0.47** | **0.46** | **0.10** | **0.31** | **0.27** | 1.00 |

**Bold** indicates pair-wise correlation significance at 0.05 level.

**Table 3 – Product Characteristics**

| | | *MARKET SUBMISSION* | | | |
|---|---|---|---|---|---|
| | | **510(k)e** | **510(k)** | **PMA** | |
| ***REGULATORY CLASS*** | **1** | 86% | 7% | 0% | |
| | **2** | 13% | 89% | 1% | |
| | **3** | 1% | 4% | 99% | |
| | **TOTAL** | 100% | 100% | 100% | |

| | | *MARKET SUBMISSION* | | | |
|---|---|---|---|---|---|
| | | **510(k)e** | **510(k)** | **PMA** | **TOTAL** |
| ***REGULATORY CLASS*** | **1** | 91% | 9% | 0% | 100% |
| | **2** | 11% | 89% | 0% | 100% |
| | **3** | 3% | 19% | 78% | 100% |

## Table 4 – Empirical Results

| | OAI MOD 1 | OAI MOD 2 | OAI MOD 3 | | OAI MOD 1 | OAI MOD 2B | OAI MOD 3 |
|---|---|---|---|---|---|---|---|
| *Contract Manufacturer (CM)* | | | -0.228** (0.096) | *Contract Manufacturer (CM)* | | | -0.242*** (0.094) |
| *Problem Complexity (PC)* | | -0.163 (0.172) | -0.274 (0.177) | *Problem Structure (PS)* | | -0.215 (0.185) | -0.425** (0.191) |
| *CM X PC* | | | 0.861** (0.408) | *CM X PS* | | | 1.335*** (0.419) |
| *Class I CNT* | | -0.019 (0.033) | -0.023 (0.033) | *510(k)e CNT* | | -0.019 (0.032) | -0.025 (0.033) |
| *Class II CNT* | | 0.012 (0.040) | 0.004 (0.040) | *510(k) CNT* | | 0.014 (0.039) | 0.008 (0.039) |
| *Class III CNT* | | 0.022 (0.081) | 0.032 (0.081) | *PMA CNT* | | -0.046 (0.084) | -0.026 (0.084) |
| *Activity CNT* | 0.011 (0.027) | 0.013 (0.028) | 0.006 (0.029) | *Activity CNT* | 0.011 (0.027) | 0.014 (0.029) | 0.005 (0.029) |
| *Medical Specialty CNT* | 0.384*** (0.147) | 0.370*** (0.141) | 0.386*** (0.142) | *Medical Specialty CNT* | 0.384*** (0.147) | 0.373*** (0.141) | 0.389*** (0.142) |
| *Implant Flag CNT* | -0.031 (0.045) | -0.030 (0.047) | -0.026 (0.047) | *Implant Flag CNT* | -0.031 (0.045) | -0.009 (0.045) | -0.003 (0.045) |
| *LS Flag CNT* | 0.080 (0.070) | 0.082 (0.067) | 0.091 (0.068) | *LS Flag CNT* | 0.080 (0.070) | 0.099 (0.068) | 0.108 (0.068) |
| *Constant* | -1.183*** (0.177) | -1.178*** (0.167) | -1.151*** (0.168) | *Constant* | -1.183*** (0.177) | -1.182*** (0.168) | -1.150*** (0.168) |
| Estimation | PROBIT | PROBIT | PROBIT | Estimation | PROBIT | PROBIT | PROBIT |
| Fixed Effects | D Y RMS | D Y RMS | D Y RMS | Fixed Effects | D Y RMS | D Y RMS | D Y RMS |
| Observations | 7115 | 7115 | 7115 | Observations | 7115 | 7115 | 7115 |
| Wald Statistic | 264.1*** | 268.3*** | 280.4*** | Wald Statistic | 264.05*** | 267.2*** | 288.6*** |
| Pseudo-$R^2$ | 0.063 | 0.063 | 0.065 | Pseudo-$R^2$ | 0.063 | 0.064 | 0.067 |

*** $p$<0.01 ** $p$<0.05 * $p$<0.10

D = FDA District, Y = Year and MS = Regulatory Medical Specialty Fixed Effects

## Table 5 – Robustness Results

| | OAI | NAI | INSP OUTCOME | OAI | | OAI | NAI | INSP OUTCOME | OAI |
|---|---|---|---|---|---|---|---|---|---|
| | MOD 1 | MOD 2 | MOD 3 | MOD 4 | | MOD 1 | MOD 2 | MOD 3 | MOD 4 |
| *Contract Manufacturer (CM)* | -0.226*** (0.095) | 0.257*** (0.063) | -0.253*** (0.060) | -0.215 (0.164) | *Contract Manufacturer (CM)* | -0.239** (0.094) | 0.269*** (0.062) | -0.266*** (0.059) | -0.347* (0.192) |
| *Problem Complexity (PC)* | -0.234* (0.132) | 0.007 (0.116) | -0.071 (0.105) | -0.222** (0.092) | *Problem Structure (PC)* | -0.464*** (0.154) | 0.138 (0.126) | -0.190* (0.112) | -0.236*** (0.091) |
| *CM X PC* | 0.859** (0.406) | -0.277 (0.286) | 0.450 (0.329) | 0.716** (0.357) | *CM X PS* | 1.347*** (0.420) | -0.488 (0.313) | 0.759** (0.375) | 1.144*** (0.377) |
| *Device CNT* | -0.011 (0.041) | | | | *Device CNT* | -0.011 (0.041) | | | |
| *Class I CNT* | | 0.037 (0.024) | -0.032 (0.021) | -0.054* (0.030) | *510(k)e CNT* | | 0.036 (0.023) | -0.032 (0.021) | -0.050* (0.029) |
| *Class II CNT* | | -0.046* (0.028) | 0.035 (0.026) | 0.025 (0.036) | *510(k) CNT* | | -0.028 (0.027) | 0.024 (0.025) | 0.025 (0.035) |
| *Class III CNT* | | 0.168*** (0.054) | -0.121*** (0.050) | 0.044 (0.070) | *PMA CNT* | | 0.176*** (0.058) | -0.146*** (0.053) | 0.004 (0.077) |
| *Activity CNT* | 0.005 (0.029) | -0.017 (0.021) | 0.014 (0.019) | -0.022 (0.022) | *Activity CNT* | 0.004 (0.029) | -0.019 (0.021) | 0.015 (0.019) | -0.023 (0.022) |
| *Medical Specialty CNT* | 0.395*** (0.141) | -0.099 (0.107) | 0.168* (0.097) | 0.344*** (0.128) | *Medical Specialty CNT* | 0.394*** (0.141) | -0.103 (0.108) | 0.174* (0.097) | 0.341*** (0.128) |
| *Implant Flag CNT* | -0.014 (0.041) | 0.053 (0.033) | -0.045 (0.030) | -0.057 (0.042) | *Implant Flag CNT* | -0.002 (0.041) | 0.048 (0.033) | -0.036 (0.029) | -0.039 (0.041) |
| *LS Flag CNT* | 0.102 (0.066) | 0.038 (0.050) | -0.008 (0.047) | 0.051 (0.061) | *LS Flag CNT* | 0.108* (0.065) | 0.038 (0.050) | -0.004 (0.047) | 0.061 (0.061) |
| *Constant* | -1.145*** (0.168) | -0.417** (0.174) | | -1.230*** (0.174) | *Constant* | -1.134*** (0.168) | -0.810*** (0.149) | | -1.210*** (0.174) |
| */cut1* | | | -0.182 (0.114) | | | | | -0.197 (0.114) | |
| */cut2* | | | 1.316 (0.115) | | | | | 1.302 (0.115) | |
| Estimation | PROBIT | PROBIT | OPROBIT | PROBIT | Estimation | PROBIT | PROBIT | OPROBIT | PROBIT |
| Fixed Effects | D Y RMS | D Y RMS | D Y RMS | D Y RMS | Fixed Effects | D Y RMS | D Y RMS | D Y RMS | D Y RMS |
| Observations | 7115 | 7115 | 7115 | 8861 | Observations | 7115 | 7115 | 7115 | 8861 |
| Wald Statistic | 278.5*** | 635.3*** | 606.3*** | 308.4*** | Wald Statistic | 287.0*** | 640.9*** | 615.9*** | 314.4*** |
| Pseudo-$R^2$ | 0.063 | 0.065 | 0.046 | 0.057 | Pseudo-$R^2$ | 0.067 | 0.065 | 0.047 | 0.058 |

*** $p<0.01$ ** $p<0.05$ * $p<0.10$

D = FDA District, Y = Year and MS = Regulatory Medical Specialty Fixed Effects

**Figure 1: Class III Percentage and Regulatory Non-Compliance**

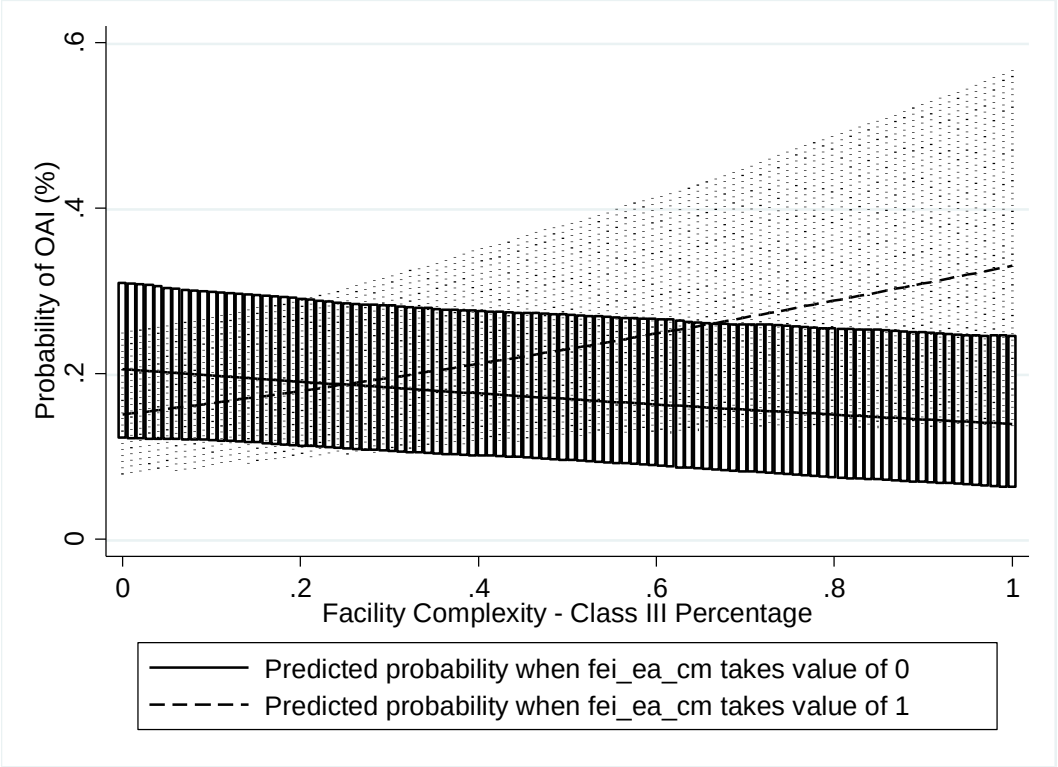


**Figure 2: PMA Percentage and Regulatory Non-Compliance**