

Essays on Manufacturing Outsourcing

by
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ABSTRACT

JOHN VINCENT GRAY: Essays on Manufacturing Outsourcing.
(Under the direction of Wendell G. Gilland and Aleda V. Roth.)

The outsourcing of manufacturing resources has been occurring for many years, and is increasing in many industries. There exists some well developed theory under the headings of “make-buy,” “firm boundaries,” “economics of organization,” and “vertical integration.” Outsourcing, or the turning over of an activity to an outside vendor, is a subset of these vast literature streams. In this dissertation, we draw from the manufacturing strategy, economics, and business strategy literature to enhance the existing economic theory of outsourcing by incorporating an operations strategy lens. Specifically, we look how manufacturing outsourcing influences—and is influenced by—a firm’s cost and quality capabilities. We do this through three separate essays using multiple methods. All three essays arose from an iterative process of literature review and practitioner interviews. The essays are related both in their grounding in existing literature and theory and in their focus on the relationship between manufacturing capabilities and outsourcing decisions and outcomes.

In the first essay, “The Effect of Learning and Strategic Behavior on Manufacturing Outsourcing Decisions,” we analytically evaluate how the presence of learning-by-doing and strategic behavior by both parties affects a major outsourcing decision in a two-period game. Previous analytic work that has assessed the effect of learning on outsourcing neglected the possibility of opportunism by the supplier. To fill this gap, we analyze a two-period game involving a firm that has the opportunity to outsource some portion

of its volume to a contract manufacturer. Both firms can reduce their production cost through learning-by-doing. When the contract manufacturer is the Stackelberg leader, we obtain several interesting results. These include showing that the contract manufacturer's learning can benefit the buying firm, but only if the buying firm also learns. We also show that learning by the buying firm can either help or hurt the contract manufacturer. In addition, we find that below-cost transfer pricing by the contract manufacturer will occur. We also analyze alternative bargaining arrangements. This essay analytically shows the importance of considering both learning-by-doing and possible future opportunism when deciding whether or not to outsource.

In the second essay, "Outsourcing of Manufacturing Resources: The Effect of Manufacturing Capabilities and Priorities" we empirically analyze relationships between operations capabilities and priorities (quality and cost) and a firm's plans to outsource. This essay extends the existing research on antecedents of outsourcing in two ways. First, we make theoretical arguments about specifically which firm-specific operations capabilities and priorities relate to plans to outsource. This is different from the extant literature which looks at a single capability proxy, if capabilities are considered at all. Second, we develop operational metrics and test the hypotheses using structural equation modeling. We find, as expected, that cost capability and importance impact outsourcing plans. Surprisingly, we find that quality capability and importance do not matter.

The third essay is entitled "Buyer Beware? Quality Risk in Manufacturing Outsourcing." Here, linked to the second essay, we examine whether quality capability and importance should relate to outsourcing plans. We draw from literature in supply chain management, total quality management, and economics to argue that outsourcing pro-

duction to contract manufacturers does pose a quality risk. We draw from similar literature to also propose that ISO 9000 does little to mitigate this risk. We use eleven years of Food and Drug Administration (FDA) inspection results from the United States drug industry as a proxy for quality risk. We interview a panel of industry experts using the Delphi process to transform the raw data to a usable “quality risk” score. After classifying 154 plants from the database as either “contract manufacturer” or “internal plant,” we use ordered logit regression on our quality risk score to show that outsourcing to contract manufacturers does pose a quality risk; and that being ISO 9000 certified does not alter a firm’s quality risk.

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Chapter 1

Introduction

This dissertation investigates manufacturing outsourcing decisions, and their relationship to operations capabilities, particularly cost and quality. Outsourcing decisions are among the most strategic and fundamental that a manufacturing manager must make (Hayes et al., 2005). While the outsourcing of manufacturing resources is common in many industries, the past decade has witnessed an increase in the contract manufacturing of entire products or major subassemblies and systems. Decades of rigorous theoretical and empirical work have generated important insights as to the environmental conditions under which a firm should outsource. However, little is known about the relationship between a manufacturer's competitive capabilities and decisions to outsource; and, surprisingly little is known about the performance outcomes of decisions to outsource to contract manufacturers. In the strategy literature, only recently has the relationship between a firm's path-dependent capability development and outsourcing been explicitly studied (Barney, 1999). With few exceptions, the manufacturing strategy literature has not fully investigated the antecedents and consequences of outsourcing decisions, either empiri-

cally or analytically. There is little in the way of theory development in the operations management literature that pertains to outsourcing and contract manufacturing.

As further motivation for this dissertation, Kasra Ferdows, president of the Production and Operations Management Society (POMS), recently noted:

...the central circle of this debate [outsourcing] has been occupied by scholars in economics, public policy, strategy, and international business. These groups are notorious in treating production like a black box. For them, once you determine a few key external factors like wages, tax benefits you have determined the wisdom of the move....We, POM, ought to get into these debates and open these black boxes for our colleagues in other fields....Somehow in the last few years it has become fashionable to regard production as a non-core activity-a function you can supposedly unbundle surgically from the rest of the company and outsource. (Ferdows, 2006, p.2-4)

Outsourcing is a subset of “make-buy,” “vertical integration,” “firm boundary” and “economic organization” research. In their usefulness to manufacturing strategy and supply chain management, theories generated from these streams of research are generally lacking in two broad areas. First, there is much to be learned about the relationship between firm-specific capabilities and antecedents to outsourcing. The antecedents literature, primarily from strategy and economics, has theoretically and empirically shown how a number of product and market characteristics impact outsourcing decisions (e.g., Leiblein and Miller, 2003). However, this literature has yet to study the impact of detailed

firm-specific capabilities on outsourcing plans. Second, the literature on the operational consequences of outsourcing is much less mature, especially in the long term and with regard to difficult to measure capabilities. Much of the extant literature has focused primarily on outsourcing's short-term impact on relatively easily measured outcomes, such as cost (e.g., D'Aveni and Ravenscraft, 1994). None of the operations, strategy, and economics literatures has adequately addressed outsourcing's influence on factors like learning, opportunism, and quality.

In this dissertation, we use multiple methods to address gaps in the literature related to outsourcing. We employ logic from the operations strategy literature (e.g., Giffi et al., 1990) and the resource-based view (Barney, 1991) to extend the primary theoretical views of outsourcing: transaction cost economics (Williamson, 1979) and property rights (Hart and Moore, 1990). In so doing, we enhance these existing economic theories of outsourcing by adding an operations perspective. Each essay in this dissertation is a stand-alone essay. Some of the material in this introductory chapter is redundant with the introduction sections of each essay. The following research questions are answered: How does learning-by-doing impact manufacturing outsourcing decisions in the presence of a strategic supplier? (Essay 1) Which firm-specific operations capabilities have a significant impact on a business unit's outsourcing plans for manufacturing? (Essay 2) Does outsourcing present a quality risk? That is, does outsourcing production to contract manufacturers pose a quality risk to the buying firm? (Essay 3) Answering each of these questions improves the field's theoretical and practical understanding of the antecedents and consequences of outsourcing decisions in manufacturing. We note

that while the answers to these questions might also present some insights into service outsourcing, this is left for future research as the characteristics and cost structures of services are quite different. This dissertation research is expected to contribute to the manufacturing and supply chain literature by explicitly studying whether and how contracting out production affects various aspects of manufacturing performance, focusing on cost and quality. We draw from the operations strategy literature for our definitions of capabilities and our understanding of how those capabilities are developed and how they drive performance. We draw from the economics and business strategy literatures for the underlying theories on firm boundaries.

Each essay is a stand-alone document. This first chapter summarizes existing theories on outsourcing, documents the gaps this dissertation research is partially closing, and identifies future work that could further enhance our theory-building and testing of the antecedents and consequences of outsourcing decisions and contingent factors.

1.1 Scope of Research

Any theory must have boundaries (Bacharach, 1989). For this dissertation, all three essays share some common boundaries, which we discuss now. Most of the public controversy surrounding outsourcing involves “offshore” outsourcing (or simply “offshoring”), and the subsequent loss of domestic jobs. This is currently a prominent contemporary issue; and several prominent economists have broadly written on the topic from a macroeconomic perspective (e.g., Samuelson, 2005). The issue has also been prominent in the

popular press (e.g., Thottam, 2004). The majority of manufacturing outsourcing is, in fact, domestic (Casale, 2000). For semantic clarity in this research, we use the definitions in Table 1.1 to distinguish between 1) outsourcing, 2) offshoring, and 3) offshore outsourcing. The focus of our research is on manufacturing “outsourcing.” We do not focus on the location to which a firm has outsourced, but rather we consider the transfer of ownership and responsibility for the execution of the production task. We are interested in how this transfer influences and is influenced by a manufacturer’s operations capabilities, specifically quality and cost.

Table 1.1: Distinction between “outsourcing” and “offshoring”

Term	Definition
Outsourcing	“Turning over all or part of an activity to an outside vendor” (Barthelemy, 2003)
Offshoring	Relocating an operation to a foreign location, usually lower wage
Offshore Outsourcing	Turning over an activity to an outside vendor located in a foreign location, usually with a lower wage

We further restrict our attention to the outsourcing of the manufacture of final products and/or major systems/assemblies to contract manufacturers. This type of outsourcing of manufacturing resources has been occurring for many years. However, it has been growing in importance and little is known about its impact.

Our interest in manufacturing outsourcing stems from the belief that the manufacturing function generally possesses knowledge and capabilities directly related to competitiveness (as discussed in Schroeder et al., 2002). Thus, this type of outsourcing is inherently more interesting than the outsourcing of most other business processes, such as janitorial, payroll, etc., because the capabilities that reside in manufacturing will usu-

ally directly influence a firm’s ability to compete effectively (Giffi et al., 1990; Hayes and Wheelwright, 1984). Other “strategic” functions, such as marketing, research & development, and finance are rarely outsourced (Quelin and Duhamel, 2003).

Also, in this dissertation we do not consider specifically the characteristics of the ongoing outsourcing relationship. This relationship can range from close partnerships (e.g. in the Liz Claiborne case (Dalby, 1990)) to arms-length relationships, with many possible arrangements in between (Hayes et al., 2005). Many scholars have studied buyer-supplier relationships (e.g., Monczka et al., 1998; Liker and Choi, 2004; Kotabe et al., 2003) of which outsourcing relationships are a subset. We readily acknowledge that the structure of the outsourcing arrangement will affect capabilities, but it is outside the scope of this dissertation to explicitly deal with this added complexity in any of the three essays. Particularly in our empirical essays (2 and 3), the characteristics of the outsourcing relationship will manifest themselves as unexplained “noise.”

1.2 Prevalence of Manufacturing Outsourcing

While outsourcing has received much attention in the popular press over the last few years, much of the discussion has been focused on the steep rise in offshoring. The more general notion of outsourcing manufacturing resources is not new. Contract manufacturers have long been performing manufacturing for companies that have chosen to no longer perform some or all of their manufacturing in-house (Tully, 1994). Yet, the past decade has also witnessed a significant rise in contract manufacturing. In the electron-

ics industry, some of the contract manufacturers (e.g., Flextronics and Selectron) have grown quite large, and their growth has been rapid, outpacing the rest of the industry (Sturgeon, 2002). In the automobile industry, firms such as Magna Steyr and Karmann have begun producing complete cars for their customers (Edmondson, 2003). Prevalence and growth of contract manufacturers in FDA-regulated sectors, the subject of Essay 3, is also evident (e.g., Jeffries, 2003; Antonelli, 2005).

The growth in the use of contract manufacturers has occurred for some rational reasons. First, technology has made the management of a remote operation easier. Second, strong and competitive supplier bases have been created in many industries. Third, increased product variety and technological volatility have made it more difficult for a single entity to master all of the technology required to produce its product.

1.3 The Benefits and Risks of Manufacturing Outsourcing

Why outsource manufacturing? Outsourcing of manufacturing resources can carry benefits as well as risks. Several benefits and risks have been well-documented in the academic and practitioner literature. We utilize Tables 1.2 and 1.3 to highlight many of the commonly cited benefits and risks.

Table 1.2: Benefits of outsourcing

Benefits	Example Citations
Reduce short-term costs	Gilley and Rasheed (2000)
Lower costs due to economies of scale of supplier	Cachon and Harker (2002)
Reduce capital expenditures	Quinn and Hilmer (1994)
Reduce asset base, improve ROA, labor productivity	
Supplier faces market discipline, generally more efficient than hierarchical discipline	Williamson (1971)
Allow focus on remaining tasks	Prahalad and Hamel (1990)
Decrease product/process development time	Chesbrough and Teece (2002)
Option value of secondary source of supply (if partial outsourcing)	VanMieghem (1999)
Tap into supplier expertise	Quinn and Hilmer (1994)
Gain entry into foreign market (if offshore)	Deavers (1997)
Mitigation of price competition among competing buyers	Cachon and Harker (2002)
Overcome inertia of internal organizations	Goolsby (2003)
Avoid union difficulties	Abraham and Taylor (1996)
Allow rapid growth without hiring/large expenditures	executive interview
Potentially “easy” short-term career benefit	executive interview

Table 1.3: Risks of outsourcing

Risks	Example Citations
Opportunism: Suppliers act in their own interest	Bettis et al. (1992)
Opportunism: Loss of competency/credible threat to supplier	Quelin and Duhamel (2003)
Hidden costs: Coordination, contracting, observation, re-contracting (conflict resolution)	Barthélemy (2001)
Reduction in future learning-by-doing	Anderson and Parker (2002)
Lose opportunity for internal continuous improvement	Cant and Jeynes (1998)
Loss of “tacit” knowledge	Grant (1996)
Loss of informal interaction	Monteverde (1995)
Loss of ability to design manufacturable products	Bettis et al. (1992)
Loss of opportunity for accidental discovery	Parker and Anderson (2002)
Cost of learning new ways to manage interfaces	Novak and Eppinger (2001)
Remaining overhead spread over less value-added	Bettis et al. (1992)
Outsource “crown jewels” by mistake	Huber (1993)
Contract manufacturer shirks in quality or other hard-to-measure area	Kaya and Özer (2005)

1.4 The Link Between Manufacturing Outsourcing and Capabilities

A motivation for this research is the belief that internal operations provide an avenue for the development and improvement of competitive capabilities. Given this belief, once operations are out of a firm's control the majority of this capability development and learning now occurs at another firm, which presents risks for the firm that has outsourced. We justify this argument theoretically now.

Arrow (1962) stated that “one empirical generalization is so clear that all schools of thought must accept it:...Learning is the product of experience” (p.155). This learning-by-doing results in a learning curve, where production costs are reduced with volume. The economics literature (e.g., Spence, 1981) has long known that the learning curve can allow early movers to create high barriers to entry, and that learning rate can impact each firm's ability to gain market share. The learning curve has been shown to exist in many industries (Argote and Epple, 1990). The fairly consistent observation of the learning curve demonstrates that learning-by-doing exists in most industries, and that it should, therefore, be considered as a factor in major strategic decisions such as outsourcing. There are articles in economics that study the effect of a learning curve in various settings (e.g., Fudenberg and Tirole, 1983); but not in an outsourcing setting.

Also, there is an extremely large body of literature on internal knowledge creation, and how it can be a path to competitive advantage by accelerating organizational learn-

ing and innovation. One such area is the research on the manufacturing interfaces with other functions. This research indicates a synergistic affect on business performance. For example, manufacturing's important interface with marketing (Hausman et al., 2002) was the topic of a special issue in Management Science in 2004 (Ho and Tang, 2004). The importance of manufacturing's interface with new product development is well documented (Krishnan and Ulrich, 2001; Parker and Anderson, 2002; Sosa et al., 2004). Tight coordination and cross-functional feedback have been found to be critical success factors for organizational learning. Next we note some seminal theoretical research which supports the belief that manufacturing contributes to organizational knowledge.

Nelson and Winter (1982) developed the idea that organizational routines, developed through experience, are a source of competitive advantage. Cohen and Levinthal (1990) looked at organizational "absorptive capacity," and noted that "absorptive capacity may also be developed as a byproduct of a firm's manufacturing operations....Production experience provides the firm with the background necessary" to improve costs. Leonard-Barton (1992) ("The Factory as a Learning Laboratory") and Roth et al. (1994) ("Knowledge Factory") both provided examples and articulated the means by which a well-managed production system can provide competitive advantage for an entire organization.

Teece et al. (1997) discuss "dynamic capabilities," which "suggests that private wealth creation...depends in a large measure on honing internal technological, organizational, and managerial processes inside the firm" (p.509). Teece (1998) specifically discusses outsourcing and notes that the "boundaries of the firm, and future integration and out-

sourcing opportunities, must clearly be made with reference to learning and knowledge issues” (76). In the strategic decision-making literature, Hall (1992) specifically addressed the strategic analysis of intangible resources. Importantly for this dissertation research, Hall found that CEOs considered employee know-how as one of two resources (along with reputation) that were most important to business success. CEOs also felt that the operations function was the area where employee know-how was most important.

In the manufacturing strategy literature, Hayes et al. (1988) noted that “the organizational and technological skills required to produce products better than one’s competitors are extraordinarily difficult to duplicate, and therefore constitute one of the soundest bases for achieving a sustainable competitive advantage” (20). Ferdows and DeMeyer (1990) and Roth (1996) outlined a specific path for production facilities to build operational excellence by improving on all operations-critical capabilities. Stratman et al. (2004), in a case study and simulation of temporary workers in an assembly operation (i.e, outsourcing labor, not the entire production process), noted that “steady-state average productivity estimates and production standards may fall short” (p.692) as aids in decision-making, and in so doing they “demonstrate the importance of taking the dynamics of learning and forgetting into account when determining manufacturing strategy” (p.701). The particular case studied actually eventually led to the outsourcing of the entire manufacturing activity, as high costs and poor quality became unmanageable.

Wernerfelt (1984) took a “first cut at a huge can of worms” (p.180) by articulating the resource-based view (RBV) and arguing that it is productive to analyze a firm not just based on its products and market but on its “resources,” which may include technology

and capabilities. Demsetz (1988) “revisited” the theory of the firm, and noted “roughly” that “the vertical boundaries of a firm are determined by the economics of conservation of expenditures on knowledge” (p.159). Barney (1991), in his seminal work, noted that firms possess heterogeneous, non-perfectly mobile resources. And, if these resources are rare, inimitable (either due to causal ambiguity, social complexity, or a unique history), valuable, and non-substitutable, then the resources can lead to sustained competitive advantage. His emphasis of the path-dependent nature of the development of these resources is critical to this dissertation.

Several years later, Barney (1999) explicitly discussed how resource-based arguments had been neglected in firm-boundary decisions, noting simply that “conditions under which a firm’s decisions about how to manage its business activities should be affected by its capabilities and those of its potential partners” (p.138). Barney also called for the knowledge-based view (KBV) to be considered. Grant (1996) wrote about the “knowledge-based view” (KBV); knowledge here is really a subset of the resource-based view; the knowledge-based view emphasizes that knowledge is the key resource. Several studies (e.g., Leiblein and Miller, 2003) have shown that firm-specific capabilities do matter in the make-buy decision (earlier studies, e.g. Walker and Weber (1984) had already shown this but did not emphasize this result). In Leiblein and Miller (2003), the proxy for “firm-specific capabilities” at the operations level was “production experience.”

There are two key takeaways from this literature. First, it is well established that learning-by-doing is a key factor that influences dynamic capability building. Thus, it is relevant to consider learning-by-doing specifically and the path-dependence of capability-

building in general in any decision of such long-term importance as outsourcing. Second, there is growing support (both empirically and theoretically) that competitive advantage is obtained through the path-dependent development of internal capabilities; many authors consider manufacturing the most difficult capability to imitate. Therefore, capability development over time should be considered in outsourcing decisions.

1.5 Outsourcing Theory and its Neglect of Capabilities

We have established above that the development of competitive capabilities often occurs in the manufacturing function, and that the development of these capabilities is path-dependent and hard to imitate. We now review literature on outsourcing and firm boundaries.

1.5.1 Transaction Cost Economics (TCE)

The classic economic theory of firm boundaries dates back to at least to the 1930s, when Ronald Coase theorized about why firms exist at all (Coase, 1937), if markets are known to be an efficient mechanism to facilitate trade. His work was extended by Oliver Williamson in the 1970s and 1980s (e.g., Williamson, 1979). This “transaction cost economics” (TCE) view has been the leading explanation of firm boundaries in the strategy and economics literature ever since. TCE is based on several observations. First, con-

tracts, and their enforcement, are not costless. Second, it is usually impossible to contract for all contingencies. Third, partners in a market relationship may act opportunistically if given the chance. One relevant construct that will affect propensity to outsource is asset specificity, which relates to opportunistic behavior. Others include uncertainty and frequency of interaction, which relate to contracting difficulties and expense. Asset specificity refers to whether a costly asset is useful only in the specific arrangement. If an asset is specific to an agreement, then opportunism may occur once one firm has invested in the (now otherwise useless) asset. Environmental uncertainty may cause two firms engaging in a market-based transaction to have to often renegotiate the terms of their agreement. Similarly, if the nature of the activity to be outsourced requires frequent interaction between the parties, then the costs of this market-based interaction will tend to increase.

There is a large amount of empirical support for the asset specificity as a predictor of outsourcing decisions, and weaker support for the other two constructs. The vast empirical literature based on TCE has been recently reviewed in the OM literature by Grover and Malhotra (2003) and in the strategy literature by David and Han (2004). We now note, as Barney (1999) did, that nowhere in this theory do path-dependent capabilities (or even differences between firms) play a role, so that TCE provides only partial theoretical insights for addressing the research questions in this dissertation.

1.5.2 Property Rights

The “property rights” perspective utilizes the asset specificity construct from the TCE perspective, but uses a different theoretical framework to explain when firms should outsource. Hart and Moore (1990) documented the property rights view. They assumed costless recontracting and complete information, both of which are different than the assumptions of TCE. They also assumed that asset-specific investments must be made, and that all contracts are incomplete. The key difference between owning an activity and contracting for it in this view is this: when one owns a firm they can fire some, but not necessarily all, workers in the firm; whereas, when contracting, the only options are to continue dealing with an entire firm or to fire the entire firm. Because of this, when an activity is owned the owner has more control over the individual pieces of the activity than if he contracts for it. Key drivers, then, of vertical integration, are that highly complementary assets should be owned together, and that ownership should be given to agents who are indispensable. Grossman and Hart (1986) modeled these phenomena analytically. Grossman and Helpman (2002) determined an industry equilibrium where firm structure is endogenous, incorporating both the TCE and property rights views. Empirical testing of this theory has been scant. Novak and Eppinger (2001), based on the property rights view, empirically demonstrated the impact of product complexity on vertical integration in the automobile industry. Like TCE, the property rights approach to outsourcing decisions does not consider path-dependent capabilities.

1.5.3 Measurement

Alchian and Demsetz (1972) documented the importance of measurement difficulty on firm boundaries. They noted that when measurement difficulty is present, it is often best to have one owner who holds the residual claim to profits to monitor cooperative productive activity, as opposed to having multiple owners who will “shirk” in the presence of difficult-to-measure individual inputs. Poppo and Zenger (1998) provided theoretical arguments as to why measurement difficulties may have a stronger negative performance impact in markets than in firms, but get mixed empirical results. Again, the path-dependent nature of capabilities was not considered.

1.5.4 Summary

The three classic economic “views” of the firm discussed in the previous section (TCE, property rights, measurement) neglect the effect of capabilities on firm boundary decisions. The “resource-based” and “knowledge-based” views introduced capabilities into the strategic domain, but there are still many gaps in the manufacturing and supply chain strategy literature on how capabilities influence manufacturing outsourcing and vice versa. As noted by Langlois and Foss (1999), the capabilities view is offered “not as a finely honed theory but as a developing area of research whose potential remains largely untapped” (p.203). One of the ways the capabilities view is still untapped is in its explanatory power in the antecedents and consequences of outsourcing.

Recent work has tried to integrate these traditional views of firm boundary deter-

minants and the capabilities view. Even Williamson (1999), stated: “Rather, therefore, then ask the question ‘What is the best generic mode...to organize X?’ [we should ask] ‘How should firm A-which has pre-existing strengths and weaknesses (core competences and disabilities)-organize X?’ (p.1103). Some authors (e.g., Jacobides and Winter, 2005) have attempted to conceptually incorporate capabilities and transaction costs into firm boundary decisions.

1.6 Manufacturing and Supply Chain Strategy Links to Outsourcing

Classic manufacturing strategy texts generally devote a section or chapter to make-buy/vertical integration decisions (e.g., Hill, 1994; Hayes and Wheelwright, 1984; Buffa, 1984). These texts discussed the benefits and risks, and provided some guidance as to when production should be in-house vs. outsourced. Additionally, as previously mentioned, a large body of operations strategy literature examined supplier management for components, subassemblies, or products that are manufactured by different firms (e.g., Prahinski and Benton, 2004; Liker and Choi, 2004; Monczka et al., 1998). Also, there are bodies of analytic work on contracting between layers in a supply chain (Cachon, 2003), tactical issues between two firms in a supply chain (e.g., VanMieghem, 1999; Kouvelis and Milner, 2002), and stylized conditions when outsourcing makes sense (e.g., Grahovac and Parker, 2003). Some more recent manufacturing strategy research (Frohlich and Westbrook, 2001; Rosenzweig et al., 2003) has expanded operations strategy to the sup-

ply chain; and shown that integration across a supply chain (internally and externally) improves performance. As evidence to the lack of attention that the manufacturing strategy literature has paid to supply chain issues, just recently valid and reliable scales have been developed for measuring supply chain management practices (Li et al., 2005).

Surprisingly, there is no manufacturing or supply chain strategy literature that empirically investigates either the drivers or consequences of major outsourcing decisions to contract manufacturers. Schroeder et al. (2002) explained that manufacturing strategy has generally been focused on the adoption of practices to manufacturing performance, or on the relationship between manufacturing capabilities and firm performance, generally within the factory walls.

Manufacturing strategy has also only recently been explicitly linked to the resource-based-view, although much of manufacturing strategy research has always been consistent with the RBV. For example, manufacturing strategists have devoted much effort to the operationalization of capabilities (e.g., Miller and Roth, 1994; Ward et al., 1995; Roth, 1996), and shown that those capabilities can lead to improved performance (e.g., Vickery et al., 1991). But, Schroeder et al. (2002) asserted that the “manufacturing strategy literature critically needs to incorporate ideas from the RBV” (p.114). They note that manufacturing strategy literature does not address the inimitability of the implementation of practices.

1.7 Gaps in the Incorporation of Capabilities in Outsourcing Decisions

Given the relatively recent consideration of resources in the strategic management literature as a whole, it is not surprising that there are some broad gaps in the literature concerning the inclusion of capabilities into the manufacturing outsourcing decision. We discuss three specific gaps, which will be filled by our essays, now.

First, one significant gap in the normative analytic literature in manufacturing and supply chain management pertains to path-dependency. Here, models of outsourcing relationships are virtually all single-period, and do not consider the potential path-dependent nature of capability development. That is, they do not consider whether or not outsourcing today impacts a firm's capabilities to produce in the future. The lone exception (to our knowledge) comes from the operations literature. Anderson and Parker (2002) modeled how learning-by-doing impacts the outsourcing decision. However, they neglected the additional reality that a supplier may behave strategically in the future. Thus, there is a gap in the normative theory on outsourcing in that it neglects the combined effect of path-dependent learning-by-doing in the presence of a strategic supplier. Essay 1 addresses this gap.

Second, a gap occurs in the otherwise well-developed literature on the antecedents of outsourcing. Here, several theories predict which product and market characteristics should matter, as discussed in Section 1.5. Also, RBV proponents have recently argued

and demonstrated that firm-specific resources and heterogeneities do matter in outsourcing decisions (Leiblein and Miller, 2003; Barney, 1999). However, this literature does not look in any depth at which firm-specific characteristics matter from a functional manufacturing perspective. So far, what has been empirically shown is that a simple proxy (production experience in the case of Leiblein and Miller) for capability does have a significant impact on the decision. Essay 2 partially addresses this gap by studying both how a firm's cost and quality capability, and the importance that a firm places on cost and quality, affect its plans to outsource.

By design, the antecedents literature does not test performance (outcomes) of given decisions for manufacturing in general (Masten, 1993). There is less literature on performance "outcomes" area, primarily because data collection is challenging. David and Han (2004) noted in their review of the literature that "there was very little attention or support for TCE propositions regarding the relative performance of governance forms" (p.52). D'Aveni and Ravenscraft (1994) used the 1976 Federal Trade Commission "Line of Business Report" data to show that vertically integrated firms had marginally better profitability than their unintegrated counterparts (they had lower administrative and R & D costs but higher production costs). Leiblein et al. (2002) used a detailed semiconductor industry report to show both that firm-specific attributes affect decisions, and that fit between governance decisions and market conditions improve performance. Randall et al. (2004) studied the internet retailing industry and find that those that make the fulfillment choice (drop ship vs. internal fulfillment) that matches that which would be expected theoretically have less bankruptcies than those who do not. As for non-financial mea-

tures, very few studies have looked at outsourcing and innovation empirically (Armour and Teece, 1978) and analytically (Brocas, 2003; Plambeck and Taylor, 2005). Also, the effect of outsourcing on quality has been studied analytically (Economides, 1999; Kaya and Özer, 2005) and empirically in a few service industries. Essay 3 contributes to the outcomes literature by performing a large study which compares the quality risk posed by contract manufacturers and internal plants.

1.8 Summary of the Three Essays in this Dissertation

This dissertation fills three gaps in the academic literature on outsourcing discussed above, through three separate essays. These essays enhance the development of an economic theory of outsourcing behavior that brings in the perspectives of both manufacturing and supply chain management strategy. All three essays arose from an iterative process of literature review and practitioner interviews. Each essay addresses a particular gap in the academic literature. More details on each essay are given now.

In the first essay, “The Effect of Learning and Strategic Behavior on Manufacturing Outsourcing Decisions,” we incorporate learning and strategic behavior together in an outsourcing setting. Anderson and Parker (2002) had previously studied the effect of learning on outsourcing decisions, but in their model the supplier passed on any savings directly to the buyer. We incorporate a strategic supplier by analyzing a two-period

game theoretic model in which a firm has the opportunity to outsource some volume of its finished-product production to a contract manufacturer. Both firms can reduce their production cost through learning-by-doing. We show that the contract manufacturer's learning can benefit the buying firm, but only if the buying firm also learns. We also show that learning by the buying firm can either help or hurt the contract manufacturer. In addition, we find that below-cost transfer pricing by the contract manufacturer will occur. We also discuss alternative bargaining arrangements. This essay analytically shows the importance of considering both learning and a potentially strategic supplier when making an outsourcing decision.

In the second essay, "Outsourcing of Manufacturing Resources: The Effect of Manufacturing Capabilities and Priorities," we empirically analyze the effect of quality and cost capabilities and priorities on plans to outsource. We extend the existing research on antecedents of outsourcing decisions in two ways. First, we make theoretical arguments about how specific capabilities (cost and quality) relate to plans to outsource. Also, we make arguments about the importance that a firm places on specific manufacturing capabilities (cost and quality) affects plans to outsource. We then test the resulting hypotheses, and show that a firm's cost capability and importance drive its outsourcing decisions, and that its quality capability and importance do not relate to a firm's plans to outsource. This essay makes important contributions to the operations strategy literature by empirically linking a firm's operations strategy to its propensity to outsource, thus linking a firm's operations strategy to its supply chain strategy.

The third essay is entitled "Buyer Beware? Quality Risk in Manufacturing Outsourc-

ing.” In this essay, we use econometric techniques to empirically investigate the quality performance of contract manufacturers’ and branded manufacturers’ plants in regulated industries over multiple years. This essay links nicely to the second essay, which showed that firms do not consider quality in outsourcing decisions, by testing whether or not there is a quality risk. We utilize Food and Drug Administration (FDA) audits to test our hypotheses. We empirically demonstrate that contract manufacturers do pose a greater quality risk. Our results also support a growing body of academic literature that ISO 9000 has no impact on quality risk.

1.9 Conclusions

Through the three independent but related essays above, this dissertation enhances the existing economic theory of outsourcing, by explicitly bringing operations-based path-dependent capabilities into the conceptual, analytical, and empirical literature. In so doing, we accomplish two important things. First, with this dissertation we are heeding the call of Ferdows (2006) and Schroeder et al. (2002) (and the initial work of Frohlich and Westbrook (2001) and Rosenzweig et al. (2003)) to expand operations strategy’s focus beyond the existing factory walls. Second, we bring together existing economic and business strategy theories on capability development and firm boundaries to help managers better assess how the development of knowledge and capabilities impacts outsourcing decisions. The three essays in this dissertation are clearly only a start in that direction. A better articulated theoretical understanding of the effect of outsourcing on

path-dependent capabilities, along with empirical support, may help managers avoid the trap of focusing too much on short-term cost at the expense of long-term competitive capabilities.

Poppo and Zenger (1998), after an empirical study on firm boundaries in information services, noted “that a theory of the firm and a theory of boundary choice is likely to be complex, requiring integration of transaction cost, knowledge-based, and measurement reasoning” (p.853). We believe they are correct. Some authors have attempted to reconcile the views (e.g., Williamson, 1999), but all authors acknowledge that a “grand” theory of firm boundaries is complex. Very little contribution to the theory has been made by operations scholars. Our research incorporates more detailed aspects of the capabilities perspective than have been previously included into the outsourcing discussion, and also looks at consequences (lost capability improvement, quality risk) that are often ignored in the high-level strategy discussions of firm boundaries. Thus, our current and future research will enhance the emerging complex integrated theory of firm boundaries by bringing operations strategy’s detailed understanding of capabilities into the discussion of both the antecedents and consequences.

Chapter 2

The Effect of Learning and Strategic Behavior on Manufacturing Outsourcing Decisions

2.1 Introduction

In several industries, manufacturing companies have turned to outsourcing for the production of their finished products for more than a decade (Tully, 1994). For example, in the electronics industry, contract manufacturers (called electronic manufacturing services or EMSs) had penetrated 13% of the total market in 2000, with the top six players (including Selectron and Flextronics) growing at 43% per year from 1995 to 2002 (Sturgeon, 2002). After a brief slowdown in the industry, EMSs are again expected to grow at 15% per year through 2010 (Jorgensen, 2005). In the pharmaceutical industry, out-

sourcing accounted for 50% – 60% of production in 1998 (VanArnum, 2000). Even in the automotive industry, which has outsourced subassemblies for years, some firms are now outsourcing the production of entire model generations to companies like Magna Steyr (Edmondson, 2003). While the outsourcing of complete finished products can often offer lower production costs in the short term, the opportunity for the manufacturer to learn about his product is decreased. As Kenneth Arrow stated more than 40 years ago: “One empirical generalization is so clear that all schools of thought must accept it...: Learning is the product of experience” (Arrow, 1962, p.155). In an outsourcing relationship, one firm’s learning-by-doing does not necessarily benefit the other if both firms behave strategically in order to maximize their own profits. The simultaneous consideration of learning and strategic behavior in an outsourcing arrangement is the focus of this paper.

The increase in outsourcing mentioned above is occurring for many rational reasons. Information technology has eased remote management and reduced transaction costs (Williamson, 1979). Increasing volatility and product variety make it more and more difficult for one firm to do everything, forcing firms to define their “core competence” more narrowly than before (Prahalad and Hamel, 1990). As the trend continues, capable contract manufacturers are established in an industry; these contract manufacturers may enjoy economies of scale and employ best practices. Also, many firms outsource manufacturing to focus on higher-rent activities, such as product development and service.

However, accepting an offer by a contract manufacturer to produce a product for a lower price is not without risks. Broadly, the interaction of production and higher-rent activities is not well-understood; it is possible that the loss of production capability can

lead to losses in these areas. Within manufacturing, proponents of the resource-based view (Barney, 1991) and competitive progression theory (Rosenzweig and Roth, 2004) argue that capability development is path-dependent; that is, capabilities are developed over time and cannot be created (or recreated) overnight. This has two major implications for the outsourcing decision that we will model here.

First, a manufacturer’s own ability to continuously improve should not be neglected when making the production/sourcing decision (Cant and Jeynes, 1998). Scholars in many disciplines, from organizational behavior to economics, have observed that production costs tend to decrease with volume; i.e, that learning-by-doing occurs (e.g., Zangwill and Kantor, 1998). Furthermore, the supplier should not ignore its ability to learn when making its wholesale pricing decision. Learning (or the potential to learn) leads to complex interactions that must be considered when making outsourcing decisions.

Second, manufacturers must realize that the contract manufacturer may act opportunistically, especially at the completion of a contract period. As noted by Insinga and Werle (2000, p.58), “outsourcing at the operational level can easily lead to the development of dependencies that create unforeseen strategic vulnerabilities.” Rossetti and Choi (2005) described mechanisms by which manufacturers in the aerospace industry have inadvertently, through time, created monopoly sources with whom they have poor relationships.

Surprisingly, despite the relevance and importance of learning and strategic behavior, to the best of our knowledge these two factors have not been studied simultaneously in

the context of manufacturing outsourcing. In this paper, we investigate how these factors affect optimal strategies from the supplier’s and the buyer’s perspectives. We show how the optimal wholesale price, production, and sourcing decisions can change when path-dependent learning is considered in the relationship, and we provide descriptions of the new optimal strategies that emerge. Our results lead to several interesting insights. For example, we show that supplier learning can benefit the manufacturer if the latter is also learning, but that supplier learning does not benefit the manufacturer if he is not learning. We also show that an increase in the manufacturer’s learning rate can either help or harm the supplier, depending on which strategy is being optimally employed by the supplier.

The rest of this paper is organized as follows. The relevant literature is reviewed in Section 2.2. In Section 2.3, we introduce the model and assumptions. We consider the case in which the manufacturer does not have the option to outsource in Section 2.4 . In Section 2.5, we consider the case in which the manufacturer can outsource and the contract manufacturer is the Stackelberg leader of the game. We consider the case where the manufacturer is the leader in Section 2.6. In Section 2.7, we conclude. Proofs of all theorems, corollaries, and propositions can be found in the appendix.

2.2 Literature Review

Outsourcing is a type of “make-buy” decision. There is a vast conceptual literature on make-buy and vertical integration. Coase (1937) theorized about why firms exist,

given the benefits of market discipline. Williamson (1979) extended Coase’s work and popularized the transaction cost view—that is, firms exist when the costs of contracting, oversight, etc. of a separate profit-maximizing entity exceed the incremental costs of hierarchical control versus market control. Williamson presupposes the existence of opportunism (i.e, strategic behavior) in a vertical relationship. Grossman and Hart (1986) modeled the transaction cost view, spawning the incomplete contracts literature. Barney (1999) noted that while transaction costs have been a useful framework, current capabilities and capability development receive too little consideration. We, like Williamson, assume the presence of opportunism, or strategic behavior. Like Barney, we consider the capabilities—current and future—of both players in the relationship.

The learning curve literature is also well-established. As outlined by Argote and Epple (1990), documented observation of the learning curve first occurred in the 1930s. Since then, learning has been observed in many manufacturing and service industries, and different learning rates have sometimes been observed within industries.

The papers that investigate outsourcing and learning together do so in a non-game theoretic context; i.e, the suppliers are passive entities that pass on the cost-savings from learning. Kim (2003) showed the importance of considering the learning rates of potential suppliers when a buying firm chooses between possible suppliers. Anderson and Parker (2002) modeled longer term impacts of component outsourcing decisions on the buying firm’s capabilities. Their model incorporated learning and forgetting in both component cost and integration cost. They did not, however, incorporate strategic behavior by suppliers. In their model, the suppliers charged a constant markup.

There are many papers that study outsourcing in the presence of strategic behavior. To the best of our knowledge, such papers include only a single period of production, and thus ignore the path-dependent learning benefits of production. Kamien et al. (1989), in a “first attempt [to include subcontracting] in the economic theory of the firm” (Kamien and Li, 1990, p.1352) showed that for duopolists engaging in Bertrand competition, the possibility of subcontracting to one another affects the outcome in an auction setting. The incentive for subcontracting in their model is strictly convex costs. There are several papers that highlight the competitive benefits for duopolists of outsourcing to avoid overinvestment. McGuire and Staelin (1983), in a seminal paper from the marketing literature, showed that competing firms may prefer to outsource retailing to mitigate price competition. Cachon and Harker (2002) demonstrated the existence of contracts where competing firms will outsource to a subcontractor with no cost advantage, also to mitigate price competition. Gilbert et al. (2003) investigated competing Original Equipment Manufacturers (OEMs) with partially substitutable products and find that outsourcing may be beneficial to competing firms with opportunities to invest in lower costs to prevent overinvestment. Grahovac and Parker (2003) found a similar result for components, and added insight about how modularity, relevance, and development costs affect the likelihood of outsourcing. Shy and Stenbacka (2003) showed in a duopoly model that competition among suppliers makes inputs available at supplier average costs and achieves economies of scale, because in equilibrium both firms outsource to the same supplier. Corbett and van Wassenhove (1993) showed that in a bilateral monopoly, vertically integrated supply chains perform better than unintegrated supply chains, but that when more than one firm exists at each level of the chain, supply chain profits

increase with disintegration.

There are several papers in the economics literature that have studied learning curves and competition between horizontally competing duopolists with no outsourcing or subcontracting. Spence (1981) performed numerical work with the power learning function. Fudenberg and Tirole (1983) obtained analytic results, focused on welfare and tax policies, using a linear learning curve. Cabral and Riordan (1997, 1994) also used linear learning to show (among other things) how, in a duopoly setting, predatory pricing may be socially optimal and learning may be privately disadvantageous. None of these papers considered outsourcing.

We note that while we investigate the path-dependent effects of outsourcing on cost capability, Plambeck and Taylor (2005) studied the path-dependent effect of outsourcing on innovation. They show that outsourcing may lead to industry-wide underinvestment in innovation.

An operational motive for outsourcing, separate from the lower cost motive modeled here, is to subcontract part of production at a higher cost in the presence of uncertain demand. Several papers studied this type of outsourcing (Kamien and Li, 1990; Van Mieghem, 1999; Atamturk and Hochbaum, 2001; Tan, 2002; Kouvelis and Milner, 2002). We do not address this motive for outsourcing here.

The primary contribution of this paper to the outsourcing literature is that, to the best of our knowledge, it is the first to jointly consider the ramifications of learning-by-doing and strategic behavior on outsourcing decisions.

2.3 The Model

We consider a firm (the “manufacturer”), which faces a known linear price-dependent demand for its product in each of two periods, $d(p)=a-bp$. A period is best understood to represent a generation of a product. The manufacturer can, if he chooses to, purchase some or all of the volume of his complete finished product from a contract manufacturer (the “supplier”). The supplier offers a linear price-only, take-it-or-leave-it contract to the manufacturer. Each contract governs a single period in the model. This approximates reality in many contract-manufacturing arrangements, where contracts are written for a set period of time (Quelin and Duhamel, 2003).

The sequence of events in period $t = 1, 2$ is as follows. First, the supplier, with per-unit cost c_s^t , offers the manufacturer a linear wholesale price contract (w^t per unit). Then, the manufacturer chooses how much to produce in-house (q_m^t) at a cost c_m^t per unit, how much to purchase (q_s^t) at the wholesale price w^t , and how much to sell to the market (s_m^t). The supplier may also choose to produce more than it sells, a quantity we denote z_s^t , i.e, the quantity the supplier produces beyond what it sells to the manufacturer. We call production beyond the amount sold by either player “strategic overproduction.” Second-period profits are discounted by a factor δ , $0 \leq \delta \leq 1$. We note that because periods represent different generations of products, inventory cannot be carried from period 1 to period 2. We normalize disposal costs/salvage value at the end of each period to zero. Both players have complete information about all parameters. We note that our intent is not to identify coordinating contracts, as is the focus of the literature surveyed by

Cachon (2003), but rather to understand how learning and strategic behavior together influence the outsourcing decision.

If a firm produces in the first period, it benefits from learning-by-doing. Each unit produced in the first period reduces the second-period costs by the learning factor γ_i . We follow Fudenberg and Tirole (1983) and Cabral and Riordan (1997) by modeling learning as a linear function of production. These papers do not include a point where learning stops, although the learning-curve literature has discussed a “plateau effect,” which is defined as “the eventual lack of any improvement at all with additional output” (Muth, 1986, p.958). To model the plateau effect, we introduce a minimum attainable cost for each firm, \underline{c}_i , $i = m, s$. With this enhancement, the second period cost function becomes $c_i^2 = \text{Max}(c_i^1 - \gamma_i q_i^1, \underline{c}_i)$. Note that this function could also be considered an approximation of the power function, which is often used to represent learning. As shown in the economics literature, the power function itself will not allow analytic results in a two-period model (e.g., Fudenberg and Tirole, 1983). As in Fudenberg and Tirole (1983), a firm with positive production gains a cost benefit only in the second period. This benefit accrues for all first-period production until \underline{c}_i is reached; i.e. for q_i^1 up to \underline{q}_i , where \underline{q}_i equals $\frac{c_i^1 - \underline{c}_i}{\gamma_i}$. We restrict the manufacturer’s learning rate to not be excessively high. That is, we require $\gamma_m \leq \frac{2}{b\sqrt{\delta}}$, which preserves concavity of the manufacturer’s profit function.

Figure 2.1 graphically depicts the progression of the model.

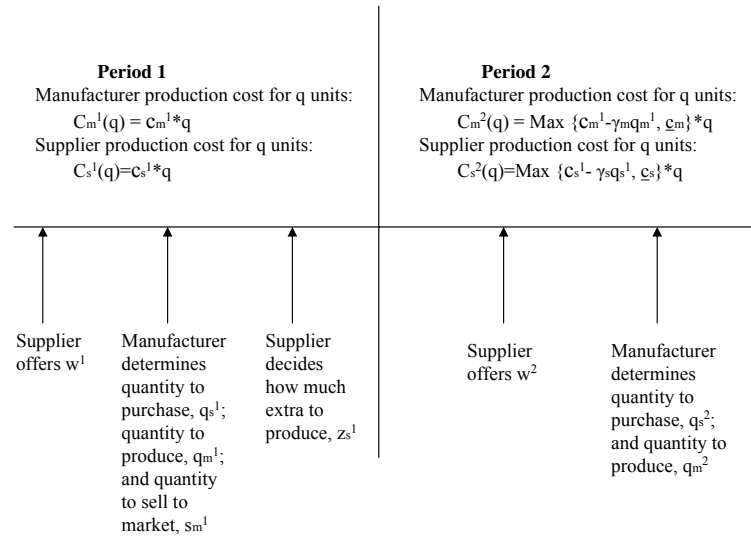


Figure 2.1: Progression of the model (except Section 2.6)

2.4 No Supplier Available

It is instructive to first consider the case where outsourcing is not an option for the manufacturer; i.e., no supplier exists. We note that if there were no learning in this setting, the manufacturer would produce $\frac{a-bc_m^1}{2}$ in both periods, resulting in a profit of $\frac{(a-bc_m^1)^2 + \delta(a-bc_m^1)^2}{4b}$.

We now turn to the case where learning occurs, i.e., $\gamma_m > 0$. We first consider whether it can be optimal for the manufacturer to produce more than he sells. While such a strategy is clearly suboptimal in the second period, it is not a priori obvious whether it is suboptimal in the first period. This is because production ($q_m^1 < \underline{q}_m$) in the first period leads to lower second-period costs, but selling extra units may not increase first period revenue. We now present Proposition 1, which rules out strategic overproduction by the manufacturer when no supplier is present:

Proposition 1 $q_m^1 = s_m^1$.

The intuition behind this result is as follows. First, we note that selling an additional unit to the market when total sales are less than $\frac{a}{2}$ increases revenue, so a manufacturer will always sell any production up to $\frac{a}{2}$. The reason that overproduction is never optimal in this case is that in order for q_m to be greater than $\frac{a}{2}$ (and thus overproduction possibly optimal), γ_m must be sufficiently small in terms of other parameters; so small, in fact, that strategic overproduction is not profitable.

With Proposition 1 in hand, we can now limit discussion to production quantities

with the understanding that the firm sells exactly what it produces each period when no supplier is present.

We now proceed to characterize the optimal production strategies for the manufacturer. The manufacturer may embark on one of three strategies. The particular strategy that is optimal is uniquely determined by the exogenous parameters.

Theorem 1 *When there is no supplier present,*

(i) there are three mutually exclusive and exhaustive optimal production/sales strategies (uniquely determined by model primitives). They are:

$$A1. q_m^1 = \frac{(2+b\delta\gamma_m)(a-bc_m^1)}{4-\delta b^2\gamma_m^2} \leq \underline{q}_m; q_m^2 = \frac{(2+b\gamma_m)(a-bc_m^1)}{4-\delta b^2\gamma_m^2}.$$

$$B1. q_m^1 = \underline{q}_m; q_m^2 = \frac{a-b\underline{c}_m}{2}.$$

$$C1. q_m^1 = \frac{a-bc_m^1}{2} \geq \underline{q}_m; q_m^2 = \frac{a-b\underline{c}_m}{2}.$$

Conditions on γ_m and profits (in terms of model primitives) for each of the three strategies are given in Table 2.1; the values of the breakpoints are given in Table 2.2.

(ii) As γ_m increases, the optimal strategies will follow the sequence A1-B1-C1.

Table 2.1: Manufacturer-only problem: strategies

Strategy	γ_m	Profit
A1	$< Bg$ OR $< Cg$	$\frac{(a-bc_m^1)^2(1+\delta+b\delta\gamma_m)}{b(4-b^2\delta\gamma_m^2)}$
B1	$< Ag$ AND $\geq Bg, Cg$	$\frac{4\gamma_m(a-bc_m^1)(c_m^1-\underline{c}_m)+\delta\gamma_m^2(a-b\underline{c}_m)^2-4(c_m^1-\underline{c}_m)^2}{4b\gamma_m^2}$
C1	$\geq Ag$	$\frac{(a-bc_m^1)^2+\delta(a-b\underline{c}_m)^2}{4b}$

Values of Ag, Bg, and Cg are given in table 2.2

First, we note that if there is no learning present ($\gamma_m = 0$), only Strategy A1 exists and the decision reverts to the no-learning solution. The new strategies emerge because learning changes the marginal benefit of production in the first period.

Strategy A1, which occurs when γ_m is low, represents the case in which the manufacturer does not produce enough to reach \underline{c}_m , but does produce more than he would with no learning. This is because when employing this strategy he is still gaining a second-period learning benefit for every unit he produces. Strategy B1, which occurs for moderate γ_m , represents the case in which the manufacturer produces enough to reach \underline{c}_m , but no more. Due to the plateau effect, the manufacturer has gained all of his learning benefit. He therefore does not find it worthwhile to produce beyond this amount just for first-period benefits. Strategy C1 represents the case in which γ_m is high enough (and therefore \underline{q}_m low enough) that the manufacturer produces beyond \underline{q}_m to the amount he would produce with no learning. This strategy arises when the manufacturer is still gaining a marginal first-period benefit for each unit of production when he reaches \underline{q}_m .

Figure 2.2 shows the first-period production quantity q_m^1 as a function of γ_m , and Figure 2.3 shows the manufacturer's profit as a function of γ_m for a set of parameters that will remain consistent throughout the paper ($a = 10, b = 1, c_m^1 = 1, \underline{c}_m = .8, \delta = .9$). The profit is increasing in γ_m throughout. For low γ_m , the manufacturer is in Strategy A1, and thus q_m^1 increases in γ_m . Then, as γ_m increases further, q_m^1 reaches \underline{q}_m , and the manufacturer enters Strategy B1. Within Strategy B1, q_m^1 begins to decrease in γ_m , because $q_m^1 = \underline{q}_m$ in this strategy and \underline{q}_m itself decreases as γ_m increases. Finally,

Table 2.2: Manufacturer-only problem: parameters

Parameter	Value
Ag	$\frac{2(c_m^1 - \underline{c}_m)}{a - bc_m^1}$
Bg	$\frac{bc_m^1 - a + \sqrt{(a - bc_m^1)^2 + 4\delta b(c_m^1 - \underline{c}_m)(a - b\underline{c}_m)}}{b\delta(a - b\underline{c}_m)}$
Cg	$\frac{2(c_m^1 - \underline{c}_m)}{a}$

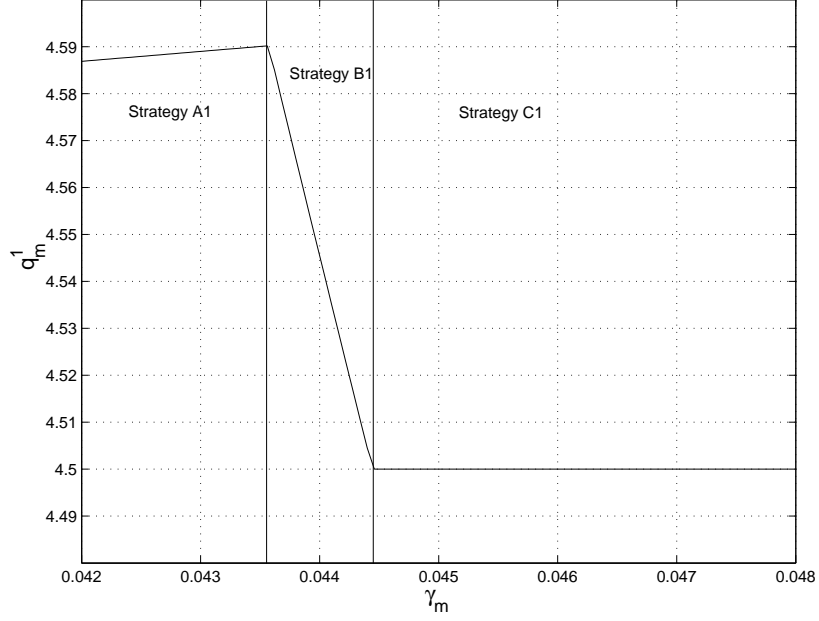


Figure 2.2: q_m^1 as a function of γ_m (no supplier)

the manufacturer reaches the point where he produces $\frac{a-bc_m^1}{2}$ and no longer benefits from learning; this is Strategy C1. The relatively small size of the region where the manufacturer produces exactly \underline{q}_m is typical of many numerical examples investigated. Note that we restrict the graphs to the relevant region of γ_m for clarity; profits and q_m^1 proceed linearly outside of the region.

2.5 Supplier Available

Having characterized the optimal production/sales strategy in the absence of a supplier, we now proceed to consider the case of a manufacturer that can outsource to a supplier. Throughout the paper, we assume that if the manufacturer is indifferent between outsourcing and producing in-house, he will outsource.

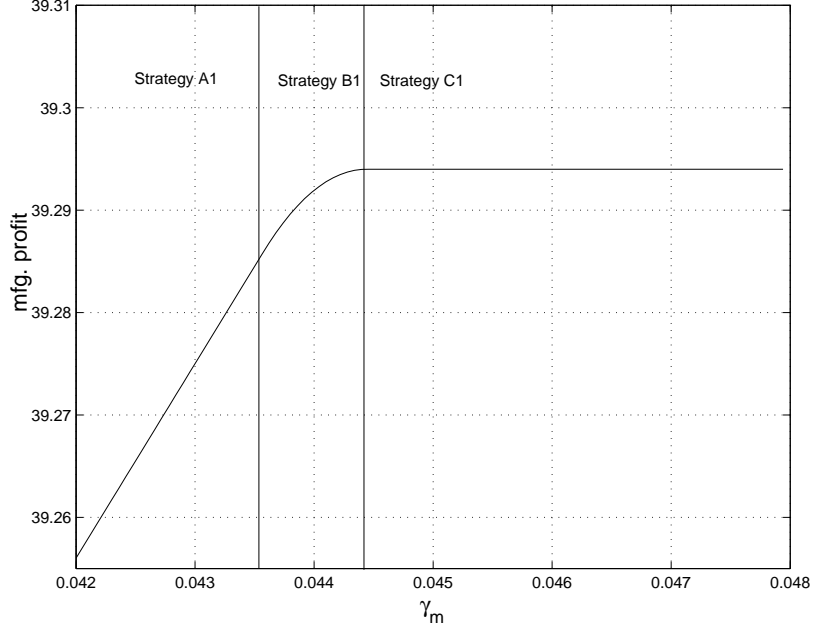


Figure 2.3: Manufacturer profit as a function of γ_m (no supplier)

In the presence of the supplier, a mild assumption is necessary for analytic tractability. This assumption is that $c_m^1 \leq \frac{a}{2b} + \frac{\underline{c}_s}{2}$. Fortunately, the majority of industries would operate within this assumption. For example, with $\underline{c}_s = 0$, we are restricted to cases where the absolute value of the price elasticity of demand is less than or equal to 3 at the optimal second-period monopoly price. This is true in the vast majority of industries (Gwartney, 1997). Further, as \underline{c}_s increases from zero, this assumption gets less and less restrictive. For example, if $\underline{c}_s = \frac{c_m^1}{2}$, i.e, the supplier's lowest cost is half of the manufacturer's period 1 cost, then we are restricted to cases in which the price elasticity of demand is less than 5. It is a very rare industry that exhibits such high elasticities (Gwartney, 1997). Thus, in spite of this assumption, our results apply to most industries.

Before proceeding to the general problem with learning, we first introduce three propositions that will be of use later.

Proposition 2 (i) *In the second period, the supplier always charges $w^2 = c_m^2$ if $c_s^2 \leq c_m^2$, and does not participate if $c_s^2 > c_m^2$.*

(ii) *The supplier's second-period profit is $(c_m^2 - c_s^2)\frac{a-bc_m^2}{2}$ if $c_s^2 \leq c_m^2$ and is zero if $c_s^2 > c_m^2$.*

(iii) *The manufacturer's second-period profit is always $\frac{(a-bc_m^2)^2}{4b}$. The manufacturer either produces or purchases $\frac{a-bc_m^2}{2}$. He purchases $\frac{a-bc_m^2}{2}$ if $c_s^2 \leq c_m^2$. He produces $\frac{a-bc_m^2}{2}$ if $c_s^2 > c_m^2$.*

A key result from Proposition 2 is that cost savings achieved by the supplier are not passed on to the manufacturer in the second period. These results are driven by the assumption above that $c_m^1 \leq \frac{a}{2b} + \frac{c_s}{2}$. We again note that the assumption driving this proposition still allows the results to apply to the vast majority of industries.

The fact that the manufacturer never benefits in the second period from the supplier's learning in the first period means that actions by the manufacturer specifically to reduce the supplier's second-period cost do not benefit the manufacturer. This leads to the following two propositions.

Proposition 3 *The manufacturer will never purchase product that he will not sell, i.e., he will never "strategically overpurchase."*

Proposition 4 $w^1 > c_m^1 \rightarrow q_s^1 = 0$.

We note that the above propositions do not imply that the manufacturer can never benefit from the supplier's learning, but only that he will not benefit in the second period

from supplier learning in the first period. Supplier learning, however, may drive changes in the first period that may benefit the manufacturer, as we will see later in Section 2.5.3.

Before proceeding to analyze the impact of learning on outsourcing, we first consider the simple case in which neither party learns. The manufacturer will completely outsource in both periods if he is at a cost disadvantage, and will produce all product in-house in both periods otherwise. That is:

Remark 1 *When $\gamma_m = \gamma_S = 0$,*

If $c_s^1 \leq c_m^1$, $w^t = c_m^1$, $q_s^t = s_m^t = \frac{a-bc_m^1}{2}$, $q_m^t = 0$ for $t = 1, 2$.

If $c_s^1 > c_m^1$, the supplier does not participate, $q_s^t = 0$, $q_m^t = s_m^t = \frac{a-bc_m^1}{2}$ for $t = 1, 2$

We now turn to cases in which learning is occurring. In Section 2.5.1, we examine the case where only the supplier learns. In Section 2.5.2, we study the case where only the manufacturer learns. Finally, in Section 2.5.3, we present results for the most general case where both learn.

2.5.1 Learning Only by the Supplier

In this section, we analyze the game with supplier learning (i.e., $\gamma_s > 0$), but no manufacturer learning, i.e., (i.e., $\gamma_m = 0$). This could represent a case when the manufacturer is far along its learning curve and the supplier is relatively new to producing the product; for example, an established manufacturer considering outsourcing something for which he has experience and the supplier does not.

Theorem 2 When $\gamma_m = 0$,

(i) Neither player strategically overproduces. That is, $z_s^1 = 0$ and $s_m^1 = q_m^1 + q_s^1$.

(ii) The supplier participates if and only if:

$$c_s^1 \leq c_m^1 + \delta(c_m^1 - \underline{c}_s) \text{ when } c_m^1 < \frac{a}{b} - \frac{2(c_s^1 - \underline{c}_s)}{b\gamma_s}$$

$$c_s^1 \leq c_m^1 + \delta \frac{\gamma_s(a - bc_m^1)}{2(1 + \delta)} \text{ when } c_m^1 \geq \frac{a}{b} - \frac{2(c_s^1 - \underline{c}_s)}{b\gamma_s}$$

(iii) If the supplier participates, her optimal strategy is to charge $w^1 = w^2 = c_m^1$. Furthermore, the manufacturer outsources in both periods. That is, $q_s^1 = q_s^2 = \frac{a - bc_m^1}{2}$, and $q_m^1 = q_m^2 = 0$.

(iv) If the supplier does not participate, the manufacturer produces everything in-house in both periods. That is, $q_s^1 = q_s^2 = 0$, $q_m^1 = q_m^2 = \frac{a - bc_m^1}{2}$.

Corollary 1 (i) The supplier's profit is non-decreasing in γ_s .

(ii) The manufacturer's profit is constant in γ_s .

As in the case with no learning (Remark 1), we again see that there are two possible manufacturer strategies—outsource everything or produce everything in-house. The main difference here is that outsourcing in both periods may occur even when the supplier is at an initial cost disadvantage.

One of the key insights from this theorem is that the supplier gets all of the benefit of her learning. The manufacturer sees no benefit from the supplier's learning. This is in contrast to the model of Anderson and Parker (2002), who explicitly assume that

the supplier will pass on any savings to the manufacturer, always charging a constant markup. While this insight is a result of the supplier's being the leader in this game, it shows that allowing for a strategic supplier substantially alters the effect of learning on outsourcing.

Another important result is that the supplier may charge less than her costs in the first period; i.e., she is potentially willing to lose money in the first period so as to learn and profit in the second period. Thus, in this environment it may be optimal for the supplier to engage below-cost pricing, analogous to “predatory pricing” discussed in a horizontal setting by Cabral and Riordan (Cabral and Riordan, 1997, 1994).

This section has shown that the supplier will always charge the manufacturer's costs to get all the business when learning. This leads to the supplier's gaining all of the benefit from her learning when the manufacturer is not learning.

2.5.2 Learning Only by the Manufacturer

Now, we turn to the case in which $\gamma_s = 0$ and $\gamma_m \geq 0$. This situation may exist with a mature supplier that has already reached a plateau. It also may exist if a supplier has a natural cost advantage but does not aggressively invest in cost improvement. This case also may be approximated when the manufacturer is in the early stages, perhaps even the startup phase, of a product, but the supplier has experience with similar technology. Another example may be when a manufacturer is considering bringing a product back in-house after several years of outsourcing.

The optimal first-period price w^1 charged by the supplier, and the resulting outsourcing strategy chosen by the manufacturer, are both largely determined by the relative cost structure of the two players. We say that the manufacturer has an *initial cost advantage* if $c_s^1 > c_m^1$, that he has an *attainable cost advantage* if $c_s^1 \leq c_m^1$ but $c_s^1 > \underline{c}_m$ (i.e., the manufacturer can attain a lower cost position through learning), or finally that he has a *definite cost disadvantage* if $c_s^1 \leq \underline{c}_m$.

The following theorem characterizes the optimal supplier pricing strategy and the resulting manufacturer production/purchasing/sales decisions in each period. Figure 2.4 characterizes a number of results from Theorem 3, as they relate to outsourcing occurring or not occurring in any given period.

Manufacturer Cost Structure	Strategy Label	Supplier Strategy	Resulting Manufacturer Outsourcing Strategy	
			Period 1	Period 2
<i>Initial cost advantage</i>	-	Supplier does not participate in either period.	Zero Outsourcing	Zero Outsourcing
<i>Attainable cost advantage</i>	A3	Supplier does not participate in either period.	Zero Outsourcing	Zero Outsourcing
	C3	Supplier obtains first-period residual business only, and does not participate in second period.	Partial Outsourcing	Zero Outsourcing
	E3	Supplier obtains all business in both periods.	Complete Outsourcing	Complete Outsourcing
<i>Definite cost disadvantage</i>	B3	Supplier obtains second-period business only (and gets all the second period business).	Zero Outsourcing	Complete Outsourcing
	D3	Supplier obtains first-period residual business and all the second-period business.	Partial Outsourcing	Complete Outsourcing
	E3	Supplier obtains all business in both periods.	Complete Outsourcing	Complete Outsourcing

Figure 2.4: Strategies, learning only by the manufacturer

Theorem 3 When $\gamma_s = 0$,

Neither player strategically overproduces. That is, $z_s^1 = 0$ and $s_m^1 = q_m^1 + q_s^1$. The optimal supplier prices and resulting manufacturer production/purchase strategies are as follows:

(i) When the manufacturer has an initial cost advantage (i.e., $c_s^1 > c_m^1$) the supplier does not participate and all results of Theorem 1 apply.

(ii) When the manufacturer has an attainable cost advantage (i.e., $c_s^1 \leq c_m^1$ and $c_s^1 > \underline{c}_m$) then one of three mutually exclusive and exhaustive supplier-manufacturer strategies emerges. The particular strategy is uniquely determined by model primitives.

A3. The supplier does not participate in either period. The manufacturer's production/purchase quantities are given by $q_m^1 = \underline{q}_m$ or $q_m^1 = \frac{(2+b\delta\gamma_m)(a-bc_m^1)}{4-\delta b^2\gamma_m^2}$, $q_s^1 = 0$ and $q_m^2 = \frac{a-bc_m}{2}$, $q_s^2 = 0$. Exogenous parameters (given in the proof) determine which q_m^1 is optimal.

C3. The supplier participates in the first period only and charges w^{1*} , where $w^{1*} = c_m^1$ or $w^{1*} = \frac{a}{2b} + \frac{c_s^1}{2} - \frac{c_m^1 - \underline{c}_m}{b\gamma_m} < c_m^1$ (w^{1*} is uniquely identified from model primitives). The manufacturer's production/purchase quantities are given by $q_m^1 = \underline{q}_m$, $q_s^1 = \frac{a-bw^{1*}}{2} - \underline{q}_m$ and $q_m^2 = \frac{a-bc_m}{2}$, $q_s^2 = 0$.

E3. The supplier participates in both periods, charging w_c in the first period and c_m^1 in the second period. The manufacturer's production/purchase quantities are given by $q_m^1 = 0$, $q_s^1 = \frac{a-bw_c}{2}$ and $q_m^2 = 0$, $q_s^2 = \frac{a-bc_m^1}{2}$, where w_c depends on exogenous parameters. The possible values and conditions for w_c are given in the appendix.

As γ_m increases, the strategies will follow one of the following progressions, depending entirely on model primitives: E3, E3-C3, E3-A3-C3.

(iii) When the manufacturer has a definite cost disadvantage (i.e., $c_s^1 \leq \underline{c}_m$) then one of

three mutually exclusive and exhaustive supplier-manufacturer strategies emerges. The particular strategy depends solely on model primitives.

B3. The supplier participates only in the second period, charging \underline{c}_m in that period. The manufacturer's production/purchase quantities are given by $q_m^1 = \underline{q}_m$ or $q_m^1 = \frac{(2+b\delta\gamma_m)(a-bc_m^1)}{4-\delta b^2\gamma_m^2}$, $q_s^1 = 0$ and $q_m^2 = 0$, $q_s^2 = \frac{a-bc_m}{2}$. Exogenous parameters (given in the proof) determine which q_m^1 is optimal.

D3. The supplier participates in both periods, charging w^{1*} , where $w^{1*} = c_m^1$ or $\frac{a}{2b} + \frac{c_s^1}{2} - \frac{c_m^1 - \underline{c}_m}{b\gamma_m} < c_m^1, > w_e$ or w_e ($w_e = w_c + \varepsilon$; ε is a very small positive number). w^{1*} is uniquely determined by model primitives. The supplier charges \underline{c}_m in the second period. The manufacturer's production/purchase quantities are given by $q_m^1 = \underline{q}_m$, $q_s^1 = \frac{a-bw^{1*}}{2} - \underline{q}_m$ and $q_m^2 = 0$, $q_s^2 = \frac{a-bc_m}{2}$.

E3. The supplier participates in both periods, charging w_c in the first period and c_m^1 in the second period. The manufacturer's production/purchase quantities are given by $q_m^1 = 0$, $q_s^1 = \frac{a-bw_c}{2}$ and $q_m^2 = 0$, $q_s^2 = \frac{a-bc_m^1}{2}$, where w_c depends on exogenous parameters. The possible values and conditions for w_c are given in the appendix.

As γ_m increases, the strategies will follow one of the following progressions, depending entirely on model primitives: *E3*, *E3-D3*, or *E3-B3-D3*.

For the case in which there is no manufacturer learning, we proved that one of two strategies can occur: zero-outsourcing in both periods or complete outsourcing in both periods. From Theorem 3 (and Figure 2.4), we see that a richer set of strategies emerges for the case of manufacturer learning. In particular, the outsourcing strategy can differ from period 1 to period 2, and in addition the manufacturer may engage in partial

outsourcing (that is, both produce and purchase) in the first period.

In strategies A3 and C3, when the manufacturer has an *attainable cost advantage*, the manufacturer produces in period 1 to lower his internal production costs for the second period, when he takes all the business. We call this *production for cost reduction*. Here, the manufacturer is losing money (relative to if he purchased at $w^1 < c_m^1$) in the first period in order to lower his actual costs of production in the second period. There is a similar interesting partial outsourcing case (strategies B3 and D3) that occurs when $c_s^1 < \underline{c}_m < c_m^1$. Note that in this case the manufacturer is at an *absolute cost disadvantage*—his lowest cost is higher than the supplier’s cost. In this case, the manufacturer is producing only for strategic reasons. He produces in the first period to force the supplier to charge a lower price in the second. We call this *production for leverage*. The important distinction between these two sets of strategies is that when the manufacturer is producing for cost reduction he keeps production in-house both periods, whereas when he produces for leverage he produces in-house in one period and outsources the next. The only benefit from learning in the production for leverage case is strategic; the manufacturer forces the supplier to reduce the price she can charge.

To induce the manufacturer to choose a complete outsourcing strategy (E3), the supplier must now offer a lower wholesale price (w_c) than was the case with no manufacturer learning. This is because the manufacturer now recognizes that he will benefit from producing in-house in the first period by lowering his second period costs. Figure 2.5 (with the same parameters as in Section 2.4 and $c_s^1 = 0.9$) demonstrates this. Observe that w^1 declines as γ_m increases while the supplier is employing strategy E3 to induce total

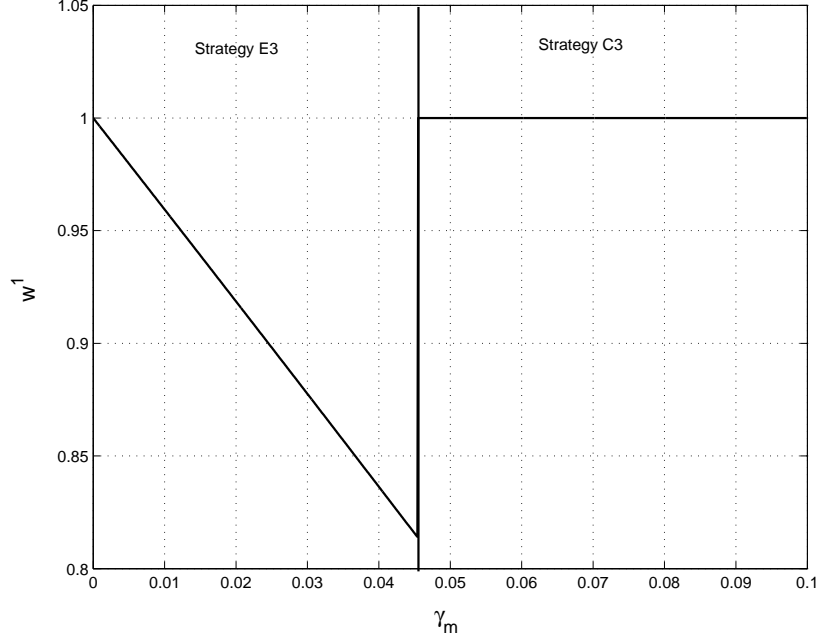


Figure 2.5: w^1 as a function of γ_m

outsourcing.

The existence of strategies that include both “partial outsourcing” and “complete outsourcing” leads to an interesting response of the supplier’s profit to changes in manufacturer learning. We denote supplier profit as a function of γ_m as $\Pi_s(\gamma_m)$:

Corollary 2 (i) $\Pi_s(\gamma_m) < \Pi_s(0)$ for $\gamma_m > 0$.

(ii) For $\gamma_m > 0$, $\frac{\partial \Pi_s}{\partial \gamma_m}$ can be > 0 or ≤ 0 .

There are two important things to note from Corollary 2. First, the supplier is never better off when the manufacturer has some learning as compared to none. But once the manufacturer has some learning, an increase in manufacturer learning can either help or hurt the supplier, depending on which strategy (zero outsourcing or partial outsourcing) is being employed. If the full outsourcing strategy (E3) is being employed, then as γ_m

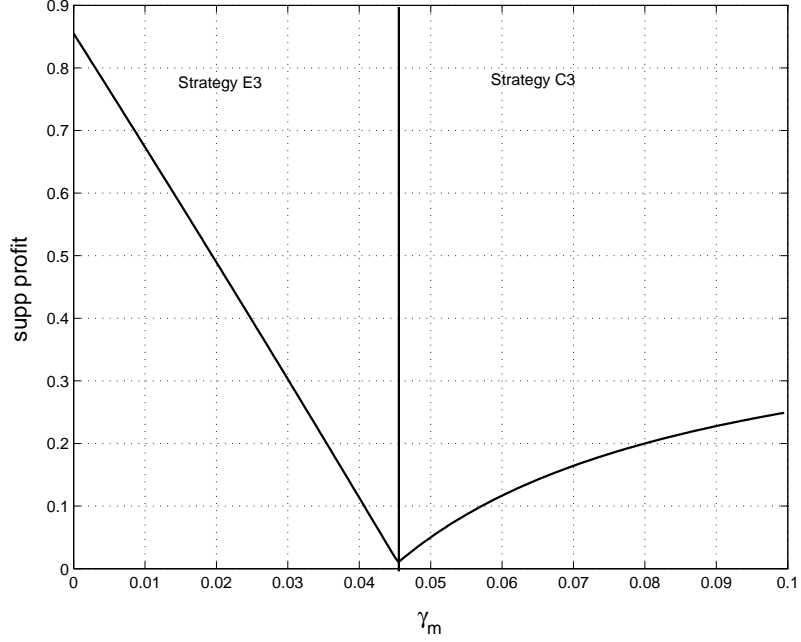


Figure 2.6: Supplier profit as a function of γ_m

increases the supplier must charge a lower price to get the business and thus earns less profit. If one of the partial outsourcing strategies is employed (C3 or D3), an increase in manufacturer learning leads to a lower \underline{q}_m . This results in more residual business, and hence an increase in profit for the supplier. Recall that in Corollary 1 we showed that the manufacturer never benefits from supplier learning when the manufacturer itself is not learning. Here, differently, we have shown that the supplier may benefit from increases in manufacturer learning, even when the supplier is not learning (see Figure 2.6). With no learning, the supplier is able to charge c_m^1 and get all of the business. However, with learning the supplier must charge a lower w^1 (reducing her profit) to get all of the business, until at one point the supplier decides to get only the residual business. If a supplier is employing a residual business strategy, an increase in the manufacturer's learning actually is helpful to the supplier, because there is more residual business to be had.

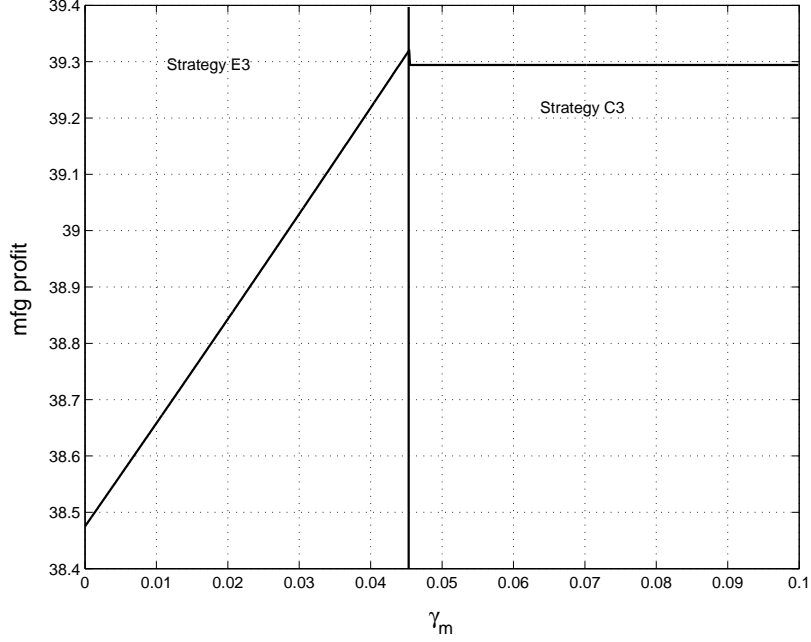


Figure 2.7: Manufacturer profit as a function of γ_m

Figure 2.7 illustrates the effect of γ_m on manufacturer profit. In general, the manufacturer benefits from his learning. The profit function increases with learning when Strategy E3 is being employed, because the supplier must continually charge lower w^1 in order to get the business. The profit function is constant in γ_m in the residual business case, because C3 (with $w_1 = c_m^1$) is employed in Figure 2.7. As shown in Figure 2.7, the profit function can undergo a slight dip when γ_m gets large enough that the supplier abandons her attempt to induce complete outsourcing in both periods. Since w_c is the point at which the manufacturer is indifferent between complete and partial outsourcing, charging anything greater than w_c will result in merely partial (i.e., residual) business for the supplier. Knowing this, the supplier charges the amount that maximizes her profit when getting residual business—almost always a step change up from w_c . This suddenly higher price causes the manufacturer's profit to dip. At the γ_m where the supplier switches her strategy, the supplier's profit is at its lowest point.

This section has shown that complex strategies emerge when the manufacturer is learning and both players are behaving strategically. The manufacturer will demand a lower w^1 to completely outsource to the supplier. The manufacturer may engage in production just for leverage in the second period, knowing it will eventually outsource. Also, the supplier can benefit or be hurt by increases in manufacturer learning. This result is in contrast to a result in Section 2.5.1, where we proved that when only the supplier learned, the manufacturer did not benefit from the supplier's learning.

2.5.3 Learning by Both Players

We now investigate learning by both players. We first note that (as a result of Proposition 2) the first-period choices for the manufacturer in period 1 are unchanged from the model in Section 2.5.2 in which just the manufacturer learns. Therefore, for a given wholesale price, the manufacturer will respond the same way he would have in section 2.5.2.

Due to the increased complexity, from this point forward in the paper we make a new restriction on γ_s for this section. Specifically, we assume $\gamma_s < \frac{2c_s^1}{\delta(a-bc_m)}$. This assumption allows us to a priori eliminate the possibility of strategic overproduction by the supplier, without carrying s_s^1 and z_s^1 through the proof as we did in previous sections. This assumption still allows virtually all realistic learning rates to be considered.

Supplier learning may make it optimal for the supplier to participate even if she is at an initial cost disadvantage; only when the manufacturer has a *significant initial cost advantage* will it be optimal for the supplier to not participate. Theorem 4 char-

acterizes the optimal supplier pricing strategies and the resulting manufacturer production/purchasing/sales decisions in each period. To save space, we do not present a table analogous to Table 2.4; the only things that would change would be the addition of the word “significant” to cost advantage, the labeling of the strategies (A3 would become A4, etc.), and the addition of Strategy C4’ (see Theorem 4). For this theorem, we introduce $\Delta_c \geq 0$. This represents the maximum value of the supplier’s initial cost disadvantage such that she will still participate. This value is analogous to the conditions given for supplier participation in Theorem 2, when only the supplier learned.

Theorem 4 *When $\gamma_s > 0$ and $\gamma_m > 0$,*

Neither player strategically overproduces. That is, $z_s^1 = 0$ and $s_m^1 = q_m^1 + q_s^1$. The optimal supplier prices and resulting manufacturer production/purchase strategies are as follows:

(i) When the manufacturer has a significant initial cost advantage (i.e., $c_s^1 > c_m^1 + \Delta_c$), the supplier does not participate and all results of Theorem 1 apply.

(ii) When the manufacturer has an attainable cost advantage (i.e., $c_s^1 \leq c_m^1 + \Delta_c$ and $c_s^1 > \underline{c}_m$), the results are the same as Theorem 3, section (ii), with the following differences:

(1) A fourth strategy emerges (C4’), in which the supplier participates in the first period and charges w^{1} , given in (2) below. Her first period production drives $c_s^2 < \underline{c}_m$. The manufacturer’s production/purchase quantities are given by $q_m^1 = \underline{q}_m$, $q_s^1 = \frac{a-bw^{1*}}{2} - \underline{q}_m$ and $q_m^2 = 0$ and $q_s^2 = \frac{a-b\underline{c}_m}{2}$.*

(2) There are three more possible values of w^{1} , in addition to the two given in Theorem 3, part (ii). These are $\frac{a}{b} - \frac{2}{b\gamma_m}(c_m^1 - \underline{c}_m) - \frac{2}{b\gamma_s}(c_s^1 - \underline{c}_s)$ and $\frac{a}{2b} + \frac{c_s^1}{2} - \frac{c_m^1 - \underline{c}_m}{b\gamma_m} - \frac{\delta\gamma_s}{4}(a - b\underline{c}_m)$ and w_e . w_e is defined in Theorem 3, part (iii)*

(iii) When the manufacturer has a definite cost disadvantage (i.e., $c_s^1 \leq \underline{c}_m$), then the possible strategies are the same as Theorem 3, part (iii).

One substantive difference between this theorem and Theorem 3 (i.e., no supplier learning) is that there are three new possible wholesale prices that result in the manufacturer's choosing partial outsourcing strategies when he has an attainable cost advantage. Another change, which also occurs when the manufacturer has an attainable cost advantage, is the addition of strategy C4'. This strategy arises because it now may be possible for the supplier's second-period cost to drop below \underline{c}_m via her first-period production. Thus, when the supplier learns, it is possible that although the manufacturer has an attainable cost advantage, he may not attain it.

Another key difference when both players are learning is that the presence of supplier learning has given the supplier more motivation to induce complete outsourcing. This is because supplier learning makes first-period production by the supplier more valuable (for $0 < q_s^1 \leq \underline{q}_s$). Figure 2.8 (using the same parameter values as in Section 2.5.2, plus $\underline{c}_s = 0.81$) shows w^1 as a function of γ_m for several values of γ_s . Note that for $\gamma_s = 0$, the graph is the same as in Figure 2.7. As γ_s increases (up to the point where $q_s^1 = \underline{q}_s$), the supplier is willing to charge a lower w_c for higher and higher values of γ_m . The fact that supplier learning motivates the supplier to charge w_c for more sets of parameters leads to the following corollary.

Corollary 3 *If $\gamma_m > 0$, then the manufacturer's profit is non-decreasing in the supplier's learning rate.*

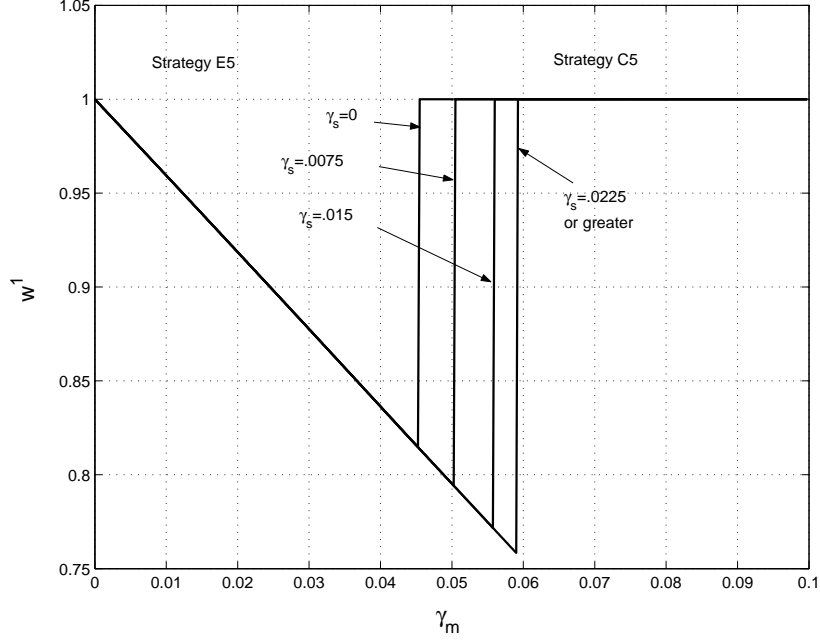


Figure 2.8: w^1 as a function of γ_m for several γ_s

Recall that when there was no manufacturer learning, the supplier always charged c_m^1 and therefore the manufacturer did not benefit from supplier learning. Importantly, we show here that when the manufacturer also learns, he can benefit from supplier learning. This is because the more the supplier learns, the more incentive she has to charge w_c to gain all of the business. Thus, there are cases where the supplier charges w_c if she is learning but would have charged a wholesale price greater than w_c if she were not learning. The manufacturer cannot be worse off (and can be better off) when faced with an offer of w_c instead of a higher wholesale price. The manufacturer's profit therefore can improve, for some parameters, as γ_s increases (Figure 2.9).

Thus, when both players learn, the form of the solution is similar to the case when only the manufacturer learns. The addition of supplier learning increases the likelihood the supplier will be willing to induce complete outsourcing and adds new w^{1*} values that

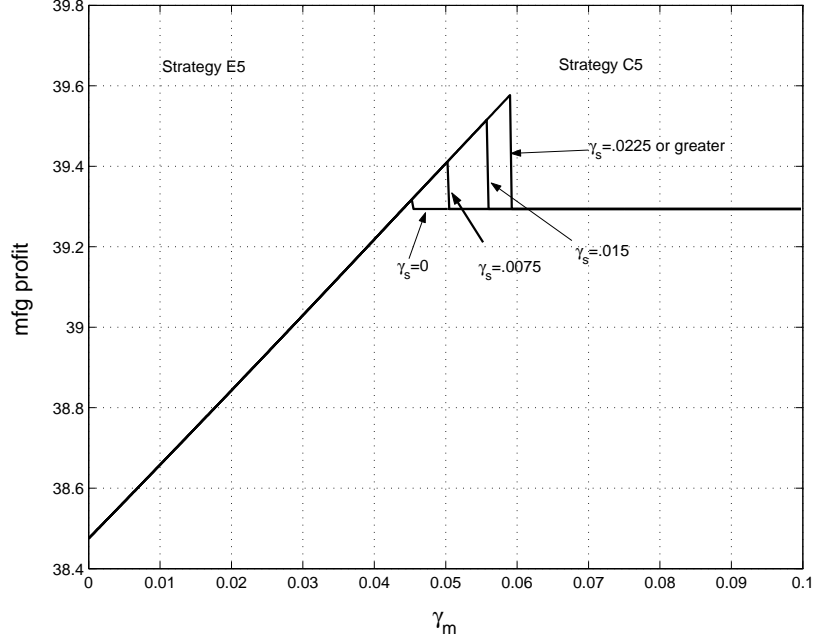


Figure 2.9: Manufacturer profit as a function of γ_m for several γ_s

the supplier may charge to obtain residual business. Finally, only when both players are learning can the manufacturer benefit from supplier learning; he never benefits from supplier learning when his learning rate is zero.

This section has featured the supplier as the leader of the game, making the first offer. In the next section, we investigate the outcomes if the manufacturer is the Stackelberg leader.

2.6 Manufacturer as Leader

Up to this point, the supplier has been the Stackelberg leader. This reflected situations in which she has all (or nearly all) of the power in the relationship. In this section, we investigate the case in which the manufacturer is the Stackelberg leader. With the

manufacturer as the leader, the sequence of the game changes. In each period, the manufacturer decides how much to produce in-house and how much to purchase from the supplier and also determines w^i , the per-unit price he offers the supplier. The supplier then accepts or declines the offer. If she declines, she earns zero profit. For this section, we make the assumptions on learning rates that a priori eliminate the possibility of strategic overproduction. That is, we assume $\gamma_i < \frac{2c_i^1}{\delta(a-b\underline{c}_i^1)}$, ($i \in m, s$). We also must assume that $\gamma_s \leq \frac{2}{b\sqrt{\delta}}$, analogous to the assumption made earlier on γ_m .

Because the supplier does not have to recoup any investment, it is optimal for the manufacturer to choose a wholesale price that is equal to the supplier's marginal cost; that is, for him to offer to pay $w^t = c_s^t$ per unit in each period. Therefore, the supplier earns zero profit in both periods. In essence, the problem reduces to a problem in which the manufacturer chooses the production quantities at both facilities to maximize the supply chain profit. Because of this, the problem is equivalent to one in which there is a single company with two facilities that differ in their costs and learning rates. The possible strategies are listed in Theorem 5. Note that, without loss of generality, we assign the superscript j to the facility with the higher first-period cost, and superscript i to the facility with the lower first-period cost. If the manufacturer is indifferent, he will choose facility i .

Theorem 5 *When the manufacturer is the Stackelberg leader, the following strategies emerge:*

(i) *When $\underline{c}_i \leq c_i^1 \leq \underline{c}_j$, facility i has an absolute cost advantage. The optimal strategy is to source product from facility i , following the strategies of Theorem 1.*

(ii) When $\underline{c}_i \leq \underline{c}_j < c_i^1$ or $\underline{c}_j \leq \underline{c}_i < c_i^1$, one of the following six production strategies may be optimal, depending entirely on exogenous parameters:

A5i. Facility j does not participate. Facility i follows production strategy A1 of Theorem 1.

B5i. Facility j does not participate. Facility i follows production strategy B1 of Theorem 1.

C5i. Facility j does not participate. Facility i follows production strategy C1 of Theorem 1.

A5j. Facility i does not participate. Facility j follows production strategy A1 of Theorem 1.

B5j. Facility i does not participate. Facility j follows production strategy B1 of Theorem 1.

D5. Facility j produces \underline{q}_j in the first period and $\frac{a-b\underline{c}_j}{2}$ in the second period. Facility i produces $\frac{a-bc_i^1}{2} - \underline{q}_j$ in the first period and nothing in the second period. The resulting profit is $\frac{(a-bc_i^1)^2 + \delta(a-b\underline{c}_j)^2}{4b} - \frac{(c_j^1 - c_i^1)(c_j^1 - \underline{c}_j)}{\gamma_m}$.

(iii) When $\underline{c}_j < \underline{c}_i = c_i^1$, strategies A5i and B5i are no longer feasible.

The conditions on parameters which lead to each of the different strategies are discussed in the proof. The possible production and sourcing strategies are not significantly different from the cases in which the supplier was the Stackelberg leader. Note that since facility j has a higher first-period cost, it will produce only if it will be the source of product in the second period.

In contrast to the supplier-as-leader analysis, here the manufacturer gains all benefits

from learning. Thus, he can benefit from the supplier's learning in any case in which $q_s^2 > 0$.

Corollary 4 *When the manufacturer is the Stackelberg leader, his profit is non-decreasing in both his own learning and the supplier's learning. The supplier's profit is always zero, and is therefore unaffected by learning rates.*

This corollary is a result of the fact that when the manufacturer has all of the power in the relationship, the supplier is forced to pass on all of her cost improvement to the manufacturer. Recall, differently, that when the supplier was the leader of the game in Section 2.5, she was not able to take all of the benefits of learning when both players were learning.

If the supplier has a reservation profit that she must earn to ensure her participation, then the following two-part tariff is optimal for the manufacturer: set the fixed fee equal to the reservation profit and the wholesale price in period t equal to the supplier's cost in period t . As an aside, we note that such a contract would coordinate the supply chain. We also note that because this is game of complete information and the gains from trade are known to both parties, that if the players behave cooperatively or bargain as in Nash (1953), then the optimal strategies will still be as in Theorem 5. However, in this case the two parties will divide the gains from trade evenly.

To conclude, making the manufacturer Stackelberg leader allows him to take all of the profits of both players, and thus benefit from either player's learning. The supplier

then makes no profit; her ability to behave strategically has been completely eliminated due to her lack of power.

2.7 Conclusion

This paper is based on three realities: outsourcing decisions have implications beyond the current time period, firms learn through experience, and independent firms will act in their own interest. Incorporating these facts into one model has led to several new and interesting insights about the longer-term effects of major manufacturing outsourcing decisions.

The purpose of this research was to study the effects of learning and strategic behavior on outsourcing decisions over multiple periods. Prior research that investigated the effect of learning on outsourcing assumed a passive supplier that would pass on its savings to the buying firm, e.g., Anderson and Parker (2002). We argue this is not realistic in many cases, as Rossetti and Choi (2005) have shown in the aerospace industry. Our research indicates that when the supplier behaves strategically, the manufacturer may maintain some in-house production even when he is at an absolute cost disadvantage. In addition, when the manufacturer is learning, he will demand greater savings to outsource from the supplier in order to protect himself from future strategic behavior. When only the supplier learns, only the supplier benefits from this learning. Differently, when only the manufacturer learns, the supplier may benefit from or be hurt by manufacturer learning, depending on which strategy is being employed in the given situation. When

both are learning, even more interesting dynamics arise. Whereas supplier learning does not benefit a non-learning manufacturer, it actually can benefit a manufacturer that is learning. Similarly, manufacturer learning can help or hurt the supplier when both learn.

Major outsourcing decisions are complex, even if only near term costs and benefits are incorporated into the decision. This paper highlights two important, and often neglected, longer-term risks in outsourcing decisions. Learning and future strategic behavior are often neglected because their impact occurs at a future time and their effects are difficult to quantify. All of the strategies which emerged when learning was added to the model (e.g. keeping production in-house when at an absolute cost disadvantage, partial outsourcing, etc.) would be less likely to occur as δ gets smaller. Low δ can be thought of as a proxy for short term thinking. Short term thinking can exist for very “good” reasons (cash shortfall, company survival), or, too often, for the “wrong” reasons (short term incentives, short managerial assignments). This paper shows how short-term thinking can lead to a sub-optimal decision to outsource.

While this research has generated interesting insights, it is necessarily an abstraction of reality. It would be interesting to empirically investigate outsourcing arrangements in order to build a richer understanding of how the factors examined here influence decisions, contracts, and relationships. Specifically, how do manufacturers reduce the risk of supplier opportunism in future contract periods? How do they continue to learn about their product if they are outsourcing production? Also, do suppliers engage in below-cost wholesale pricing if they know their learning rate to be high? Finally, it would be interesting to see whether firms that do consider learning and future opportunism in

the relationship, and put plans in place to deal with them, outperform firms that seem to be thinking only in terms of the short-term impacts of outsourcing arrangements.

Chapter 3

Outsourcing of Manufacturing Resources: The Effect of Manufacturing Capabilities and Priorities

3.1 Introduction

In this study, we link a firm's operations capabilities and priorities to its outsourcing strategy. In doing so, we contribute to the literature in two ways. First, we extend the literature which has recently brought together firm boundaries and the resource-based view by showing which operations capabilities (cost and quality) impact outsourcing plans. Second, we extend the operations strategy literature by linking a firm's operations

strategy with its outsourcing strategy, which is a component of its supply chain strategy. We do this by studying the effect of individual manufacturing priorities on outsourcing plans.

While the relationship between product and market characteristics on outsourcing decisions is well studied (Grover and Malhotra, 2003; David and Han, 2004), the literature that relates a firm's heterogeneous operational characteristics and firm boundary decisions is in its infancy (Barney, 1999). The first major contribution of this paper is to answer the question: "How do operations capabilities (specifically quality and/or cost) affect outsourcing plans?" The strategy and economics literature have recently concluded that capabilities do matter in outsourcing decisions, but have only studied weak proxies for capabilities. To our knowledge, this paper is the first to provide insight the effect of specific operations capabilities on plans to outsource.

Additionally, to our knowledge, no one has linked the priority that a firm places on different competitive capabilities to its outsourcing plans. Doing so links a firm's operations strategy to a key part of its supply chain strategy. Thus, the next major contribution of this paper is to answer the question: "How does the importance that a firm place on a specific competitive capability impact its outsourcing plans?" Understanding this provides insight about how a firm's manufacturing strategy links to whether it plans to keep manufacturing in-house.

"Outsourcing" is a term that is often used loosely and in different contexts, so it is important to clearly define its meaning for this research. Our definition is adapted from

Barthélemy (2003) for manufacturing: “turning over all or part of [a manufacturing] activity to an outside vendor” (p.87). Implicit in this definition is that the company at one time performed the activity in-house. As such, outsourcing is one special type of “make-buy” or “firm boundary” decision.

While it has recently grown in prominence, “outsourcing” of manufacturing has been around for a long time. Henry Ford’s River Rouge production system was “integrated from the production of wood and steel through final assembly” (Hayes et al., 2005, p.116), and has clearly since disintegrated significantly. Although outsourcing is not new, there is a trend toward outsourcing of manufacturing resources over the last decade in many important industries, include electronics (Sturgeon, 2002), pharmaceuticals (VanArnum, 2000), biotech (Mirasol, 2004), and aerospace (Destefani, 2004). This trend is occurring for some rational reasons. Rapid technological change has made it difficult for corporations to maintain internal expertise on all components of their products. The Internet has made remote information sharing (and management) easier. Finally, the growth of the outsourcing practice itself has created a base of suppliers who are well along on the learning curve and may be benefiting from economies of scale. Outsourcing carries many documented benefits, but also many risks. In the introductory chapter to this dissertation (Tables 1.2 and 1.3), we document the commonly cited benefits and risks.

To make the decision to outsource versus keep in-house, a manager must trade off these benefits and risks. This is very difficult to do in practice, especially given that many benefits (e.g., focus on core competence) and costs (e.g., possible future losses in competences) are hidden and difficult to measure. Studying the factors that relate to

plans to outsource provides some insight about how managers weigh different capabilities and priorities when making a decision. As will be discussed below, antecedents of outsourcing decisions have been studied in terms of transaction costs, property rights, the resource based view, and other frameworks. We will investigate the effect of specific operations capabilities and priorities on a business unit's plans to outsource.

This research will contribute to existing research in two ways. First, we will contribute to the resource-based view by showing not only that some broad proxy for firm-specific capabilities matters in a firm's plans to outsource, but by showing which of these capabilities matter. Second, we will contribute to the operations strategy literature by being the first to explicitly link a firm's operations strategy—its priorities—to outsourcing decisions. For practicing operations managers, this research will provide guidance as to which capabilities impact their firm's plans to outsource.

The remainder of the paper is organized as follows. In Section 3.2, we provide theoretical background from both the manufacturing strategy and business strategy literatures as they relate to our study, as well as a review of closely related empirical literature. We present a conceptual model and hypotheses in Section 3.3. Data and methodology are discussed in Section 3.4. Results are given and discussed in Section 3.5. In Section 3.6 we conclude.

3.2 Theoretical Background

This paper enhances two literature streams, the literature on “firm boundaries” and the manufacturing strategy literature. We discuss the relevant aspects of those literatures, and the gaps which we will fill, now.

3.2.1 Firm Boundaries

In the strategy and economics literatures, firm boundaries have been studied since at least the 1930s. At that time, (Coase, 1937), in discussing the nature of the firm while developing the transaction cost economics (TCE) perspective, framed the outsourcing decision as one of minimizing transaction costs. Extended by Williamson (1985), TCE looks at make-buy decisions as a trade-off between governance costs and opportunism. Hierarchical governance is the management of internal production, whereas market governance directs a competitive supplier market. Market governance is considered to be generally more efficient, but the efficiency benefit must be weighted against the increased transaction costs and risks of opportunism caused by dealing with a separate firm. These risks will be increased if there exists asset specificity and uncertainty, the two main independent variable constructs in transaction cost analysis.

Asset specific investments are those that are only useful in production of a certain good, and therefore are not valuable for any other use. When such assets are involved in a transaction, then the possibility of “hold-up” exists by the firm that does not put the

up front investment into the assets. This possibility requires detailed contracts between the firms and/or may result in underinvestment by the firm that needs to make the investment. The presence of uncertainty can also increase the costs of market governance, as it is not possible to contract for a large number of possible outcomes; these may be dealt with by the presumably more flexible hierarchical control. We note here that some (e.g., Shelanski and Klein, 1995) have pointed out that the effect of uncertainty depends on competitive conditions; and as a stand-alone first-order construct may not predict outsourcing plans. Perhaps consequently, the empirical support for uncertainty as a predictor of outsourcing behavior has been mixed (David and Han, 2004). In summary, the TCE would expect, all else equal, that a firm's plans to outsource manufacturing would be decreased by the presence of high asset specificity and the presence of uncertainty. Reasonable proxies for asset specificity and uncertainty are included as control variables in our study. By including these, we acknowledge the importance of TCE constructs in explaining outsourcing plans.

Barney (1999) notes that in the TCE framework “never once do questions about the relative capabilities of a firm and its exchange partners arise. Firm capabilities simply do not play a significant role in traditional transaction cost analyses of firm boundaries” (p.140). As a tool to analyze firm boundaries and outsourcing decisions, this may be seen as a shortcoming of the traditional TCE approach. The resource-based view augments TCE by incorporating path-dependent capabilities.

The “resource-based view” (RBV) (Barney, 1991; Wernerfelt, 1984) has been embraced by strategy scholars as a complementary view to study not only the boundaries

of the firm, but the attainment of sustainable competitive advantage. Barney (1991) describes resources that are inimitable, rare, non-substitutable, and valuable as being the ones that lead to competitive advantage. The development of such resources is generally path-dependent and complex. RBVs main contribution to firm boundary antecedents research is to supplement the TCE view by noting that these path-dependent firm-specific characteristics play a major role in outsourcing decisions in addition to the characteristics of the product and the transaction. Recently, Ray et al. (2004) have condoned using dependent variables other than broad performance to test the value of different resources in a firm. Along this line, plans to outsource as a dependent variable can be considered an assessment of the value placed by top management on the resource of capabilities possessed by the manufacturing function.

The key takeaway from the above discussion is that while the boundaries of the firm have been studied for decades, only relatively recently have firm-level capabilities been studied as a key explanatory variable. While other papers have looked at the effect an overall firm-specific variable (e.g., Leiblein and Miller, 2003), this paper is the first that we know of to investigate the effect of specific manufacturing strategy variables (capabilities and priorities) on outsourcing decisions. In this research, we are both acknowledging the importance of TCE in firm boundary decisions and extending the resource-based empirical literature on determinants of firm boundaries.

3.2.2 Manufacturing Strategy

We discuss the ways in which manufacturing strategy has covered outsourcing in Section 1.6 of this dissertation. While much has been written, it is surprising that we know of no manufacturing strategy literature that empirically investigates the drivers of outsourcing decisions from an operations perspective. This work has been left to the strategy and economics literatures, which have generally treated operations capability as a single construct, if at all.

Manufacturing strategy has developed the definitions and has operationalized the constructs we use in this study. Classic manufacturing strategy defined four key manufacturing capabilities as quality, delivery, cost, and flexibility. The importance an organization puts on these different areas reveals manufacturing's priorities. An assessment of performance in each of these dimensions identifies manufacturing's capabilities (Miller and Roth, 1994; Roth, 1996; Ward et al., 1995). We focus in this study on the competitive dimensions of cost and quality.

In sum, manufacturing strategy has discussed vertical integration as a key decision, but most of the manufacturing strategy research either assumes control of the operation under study, or studies how to interact with suppliers for material not produced in-house. The manufacturing strategy literature has given us constructs to assess operations strategies, through the definitions and operationalizations of manufacturing capabilities and priorities. But, to our knowledge, no one in the manufacturing strategy literature has linked these fundamental operations strategy variables to a firm's outsourcing strategy.

3.2.3 Related Empirical Studies

There have been many empirical studies testing TCE's impact on firm boundaries. This body of work has been reviewed recently by Grover and Malhotra (2003) and David and Han (2004). Grover and Malhotra (2003) note that "most studies view the operations context as a black box" (p.465). Leiblein and Miller (2003) state that "existing research has largely followed the precepts put forth in transaction cost economics (TCE) and argued that the optimal form of organization is primarily a function of the characteristics underlying a given exchange" (p.839). They go on to note that while empirical support for TCE has been obtained, "the existing literature provides almost no discussion of the role of firm-level differences and how they might influence the boundaries of the firm in existing empirical transaction-based models of the firm" (Leiblein and Miller, 2003, p.840). The authors then provide evidence that operational characteristics (operationalized as fabrication experience) significantly impact sourcing decisions, along with some other variables predicted by the TCE literature.

Argyres (1996) performed a case study, to investigate "the capabilities approach to strategic management [which] has argued that the relative capabilities of buyers and suppliers are important factors in vertical integration decisions" (p.129). He investigates, in-depth, several make-buy decisions of a firm, and finds that in some cases transaction cost logic dominates, but that in others the relative capabilities dominate. Capabilities seem to matter when knowledge related to the activity is tacit and team-based; or when long-term goals to produce in-house outweigh a short-term cost disadvantage.

In addition to work done since the advent of the capabilities approach to strategic management, a couple of classical studies on TCE found evidence that interfirm capability differential makes a difference in the make-buy decision. For instance, the most important explanatory variable for the sourcing decision in Walker and Weber (1984) was “supplier production advantage”; it proved more important than supplier competition and environmental uncertainty; traditional TCE variables. Also, in Monteverde and Teece (1982), the most significant explanatory variable in their study of the auto industry was the dummy for the firm (a control variable). This was more significant than their proxies for asset specificity and supplier market competitiveness.

In short, it has been established that firm-specific capabilities do matter in firm boundary decisions. As Barney (1999) points out, if you ask a manager how he makes a sourcing decision, he will surely include capability differential, and will most likely consider that among the most important factors. Our interviews with managers support this assertion. Empirical evidence has shown that broad operationalizations of firm-specific variables (e.g., production experience, production advantage) do significantly impact outsourcing decisions. However, we do not know specifically which firm operational characteristics-capabilities and priorities-matter most to the firm’s decision to outsource manufacturing. That is the focus of this study.

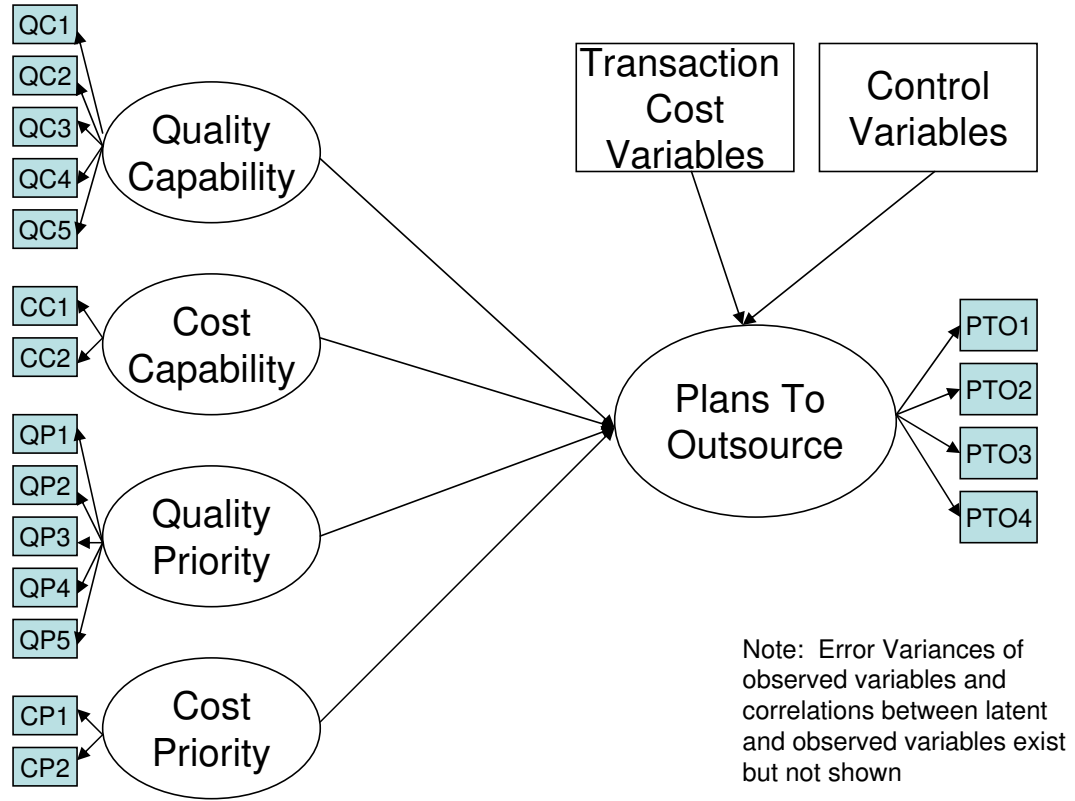


Figure 3.1: Path diagram of model to be tested

3.3 Conceptual Model

Figure 3.1 depicts the model to be studied. The relatively simple structure of the model, a test of first-order effects, is customary in research which studies the antecedents of a decision. We will discuss each of the relationships presented in the model in this section.

As discussed above, previous empirical studies have used such variables as “production

experience”-i.e, the cumulative number of similar products produced by a firm—as proxies for capabilities. In this research, we look at specific capabilities, relative to competitors, and study how these capabilities individually affect plans to outsource. We make specific, directional hypotheses on those capabilities and priorities-cost and quality—which we believe will have a significant, stand-alone effect in a known direction. At the end of the results section, we also test a competing model that includes the moderating effect of a competitive priority on a competitive capability’s influence on plans to outsource.

3.3.1 Plans to Outsource—The Dependent Variable

The dependent variable in this study is “plans to outsource.” Most empirical studies of outsourcing decisions have a dependent variable which identifies the level of outsourcing of an activity, either dichotomously or continuously. This approach works well when the objective is to look at how the characteristics of a single activity relate to whether that specific activity will be outsourced. Our intent here is to determine what role business-unit level operations capabilities and priorities play on a business unit’s outsourcing strategy. The outsourcing strategy is revealed based on whether a manufacturing business unit leader intends to increase or decrease its outsourcing activity, on a continuous latent variable. We call this intention to outsource a firm’s “plans to outsource.”

3.3.2 Competitive Capabilities—Cost and Quality

All else equal, if a firm has a higher level of manufacturing capability in a given dimension, one would expect that it would be less apt to outsource part or all of its manufacturing function. This is the premise of studies which link the resource-based view to firm boundaries, and also at the root of the debate in the strategy literature on whether the traditional transaction cost view of firm boundaries, which focuses only on market structure, is adequate. The strategy literature has shown that firm-specific capabilities do matter, but has not dissected which capabilities matter. We do that now.

The importance of capability should certainly be true in the area of overall quality. High quality capability is generally the end result of a time-consuming development of processes, routines, and skills. Successful quality leadership involves developing in-house intangible, behavioral capabilities that are valuable, hard to imitate, and rare (Powell, 1995). Inimitable, rare, value, and non-substitutable capabilities per the RBV are the key to long-term competitive advantage, as discussed above. In the TQM literature, it has been suggested that it is not the practices of quality but the hard to imitate “infrastructural” components of the programs that make the difference in performance. The infrastructural components of the programs are the “soft” parts—the tacit knowledge developed, the open culture, the empowerment of workers to perform improvement work, etc. (Flynn et al., 1995; Sousa and Voss, 2002). Further, an emerging belief in operations strategy is that quality capability serves as the basis for building capabilities in other areas (Ferdows and DeMeyer, 1990; Roth, 1996; Rosenzweig and Roth, 2004). Based on the above, it seems likely that firms that have achieved quality capability will be less

likely to outsource all or part of their manufacturing function.

Hypothesis 1 A firm's OVERALL QUALITY CAPABILITY will negatively affect its PLANS TO OUTSOURCE.

Another competitive capability that may affect a firm's outsourcing decisions is cost. Cost improvement is still frequently cited as the leading reason firms outsource (Casale, 2004). Our conversations with outsourcing decision-makers also indicate that short-term measurable costs are the main decision-driver. It is interesting that while cost is still given as the leading reason for outsourcing, much more attention in the academic and management literature has been on concepts such as "strategic outsourcing" (Quinn and Hilmer, 1994). Bounded rationality (Simon, 1979) has shown that managers cannot possibly understand all of the effects of their decisions, and thus are more likely to base their decisions on something readily measurable, like cost. Also, many managers are awarded on short-term profitability during their tenure. Given the expected supremacy of measurable costs in the decisions, a firm with low manufacturing costs will be less likely to seek to outsource manufacturing. This is simply because there will be fewer contract manufacturers who can effectively compete with them regarding manufacturing costs.

Hypothesis 2 A firm's COST CAPABILITY will negatively affect its PLANS TO OUTSOURCE.

3.3.3 Competitive Priorities—Cost and Quality

The priority a firm places on different manufacturing-based capabilities can give some insight into whether or not a firm will be likely to outsource. Quality is known to be difficult to contract (Kaya and Özer, 2005), and there is evidence from the franchise literature that vertically integrated firms have higher quality (Michael, 2000). Therefore, outsourcing may present a quality risk. Additionally, a firm for which quality is a high priority would tend to value continuous improvement, integration between manufacturing and other functions, and the development of tacit knowledge. Powell (1995) linked the tacit, casually ambiguous and difficult to imitate aspects of Total Quality Management to improved performance. These are capabilities that cannot be purchased on factor markets. Given this, we believe that a firm which places a high priority on quality will be less likely to outsource.

Hypothesis 3 A firm’s QUALITY PRIORITY will negatively affect its PLANS TO OUTSOURCE.

The analysis of possible cost savings in an outsourcing decision is difficult. If a firm looks long enough, and only looks at hard numbers and the “promised” results of a supplier vs. the actual, proven past performance of in-house production, it is likely it can find a “lower cost” supplier. In addition to survey data (Casale, 2004), our discussions with managers indicate that firms for whom cost is a priority may be more likely to seek the outsourcing option as a seemingly easy and rapid way to lower costs. Thus, firms who put a high importance on cost performance are more likely to be tempted by a “lower

cost” offer from a supplier. From this, the following hypothesis emerges:

Hypothesis 4 A firm’s COST PRIORITY will positively affect its PLANS TO OUT-SOURCE

3.3.4 Transaction Cost Variables

Asset Specificity TCE would predict that asset specificity would negatively affect outsourcing plans. Continuous flow and machine-paced lines are processes that would generally entail asset-specific investments. Having such a process is thus a proxy for asset specificity, and as such it may have a negative impact on plans to outsource (Grover and Malhotra, 2003; David and Han, 2004). Also, such assets represent significant investments, and structural inertia theory (Hannan and Freeman, 1984) would indicate that firms with such sunk investments may be less willing to outsource. Based on this, we expect our proxy for asset specificity to negatively impact plans to outsource, and include it as a control variable.

Technological Uncertainty TCE would predict that technological uncertainty would negatively impact plans to outsource, due to renegotiation/recontracting costs, especially in the presence of asset specificity. Empirical validation of this has been inconsistent (Grover and Malhotra, 2003; David and Han, 2004). However, because uncertainty is often included in studies on the antecedents of outsourcing, we include it as a control variable in this study.

3.3.5 Other Control Variables

The database is rich, but does not include some variables previously shown to be significant in firm boundary research. For example, the data set does not include usable information on the supplier market, such as competitiveness and number of suppliers (Walker and Weber, 1984; Leiblein and Miller, 2003). However, the data set does include several variables of interest, some that have been included as control variables in other studies and others that have not. The actual survey questions are included in Appendix 6.2.1. This list gives the control variables of possible interest, as well as some brief discussion of how they may affect a firm's outsourcing strategy.

Emerging Market Geography may impact plans to outsource. Other studies (e.g., Leiblein and Miller, 2003) have found location of firm (US, Japan, other Asian) to be non-significant in their study. Our database is unique in that we have many firms from emerging economies. Thus, we include emerging/non-emerging (based on the classification of Hoskisson et al. (2000)) as our 1-0 control variable for location.

Market Leader Market leaders may behave differently with regard to outsourcing. This is a 1-0 variable as to whether a firm assessed itself as a market leader.

Firm Size This is a control variable in most studies, and has been shown to increase outsourcing (Poppo and Zenger, 1998) and increase vertical integration (Leiblein and Miller, 2003). There are reasons to believe size would increase outsourcing (complex operations, outsource to support growth) and decrease outsourcing (resources available to do in-house). Buzzell (1983) found that larger firms benefited

more than small firms from vertical integration.

Life Cycle It has been proposed (Coming et al., 2003), that products follow a natural cycle from in-house early in the life cycle to significant outsourcing late in the life cycle. Grant and Gregory (1997) make an opposite argument-that outsourcing should decrease late in the life cycle. Given the possibility that life cycle plays a role in outsourcing plans, we include it in the study.

Highly Custom Producing a custom product (vs. standard) may require special skills that demand outsourcing, or, on the contrary, may warrant maintaining specialized skills in-house. Therefore, we include this as a control variable

Industry Although not reported for parsimony, we did run tests including six industry dummies in the model, accounting for the effect of seven industries (consumer products, pharmaceutical, high tech, aerospace, automobile, chemical, and general manufacturing/other). None of these dummies had a significant impact on the dependent variable, nor did their presence significantly alter other key substantive findings.

3.4 Data and Methodology

3.4.1 Database

The data are from the 1997 VIM survey, administered by Deloitte and Touche and Aleda Roth of Clemson University. Roth et al. (1997) describe the focus of this survey as “manufacturing strategies, including competitive capabilities, key action programs, and performance” (Roth et al., 1997, p.168). The unit of analysis of the survey is manufacturing business unit (MBU). This is where manufacturing strategy is formulated. MBU leaders would certainly play a major role in outsourcing decisions.

The VIM survey was administered in 35 countries. The Gallup Organization was used to administer the survey. The sample was administered to a wide variety of industrial sectors and regions. The surveys were administered by a professional research organization; they followed the procedures recommended by Dillman (1978). Professional translators, together with bilingual business people, ensured the surveys were acceptable to foreign respondents. The overall response rate was 10% (resulting in 867 companies); the response rate in emerging market countries was less than half of that from industrialized countries.

Single-respondent bias and common methods bias are common issues with survey-based research. Several aspects of the survey design and administration help to mitigate common methods bias, as discussed in Mitchell (1994) and Podsakoff et al. (2003). First, high level respondents (senior manufacturing executives), who were regular participants

in their manufacturing business unit's manufacturing strategy process, were the respondents for the survey. Second, the survey is complex, containing over 900 items. Third, most questions are of different forms. Fourth, the relevant questions are quite simple and unambiguous. As further evidence that bias is not an issue here, an earlier survey of similar design was found by field studies to exhibit minimal measurement bias. Common method bias is especially a concern if the independent variables and dependent variables exhibit correlation (and therefore a significant effect) due to common method bias instead of for theoretical reasons. Fortunately, when considering bias between the independent and dependent variables, none of the seven common causes of common rater effects listed in Table 2 of Podsakoff et al. (2003) apply in this case. This is partially driven by the fact that the dependent variable questions are both far away from the others in the survey and are in a different form. To test for method bias, we ran two commonly used tests: Harman's single-factor test and the inclusion of a method factor as discussed by Podsakoff et al. (2003). These tests as a whole indicate that some common method bias may be present among the independent variables, but, importantly, we have no evidence that a non-negligible amount of common method bias exists between the dependent variable (plans to outsource) and the independent variables. We partially deal with common method bias in the independent variables by freeing the covariance of the error terms of similarly worded capabilities and priorities. We discuss common methods bias in more detail in Appendix 6.2.3

3.4.2 Measures

To evaluate the model in Figure 3.1, structural equation modeling (SEM) will be employed. We know that measurement error will be present in the survey responses. Of the readily available alternatives, structural equation modeling allows the weakest assumptions regarding measurement error. The construct names and definitions of each latent variable used in the model of Figure 3.1 are given in Table 3.1.

Table 3.1: Constructs and definitions

Construct	Definition
Plans to Outsource(PTO)	A firm's plans to increase outsourcing of its manufacturing activities in the coming years
Overall Quality Capability (QC)*	The current ability of the company to deliver several dimensions of product quality
Overall Quality Priority (QP)	The current priority the business places several dimensions of product quality (same dimensions as above)
Cost Capability (CC)*	The current ability of the manufacturing function to support competing on price
Cost Priority (CP)	The current priority the business places on the ability to compete on price

*-same scale used in Rosenzweig et al. (2003)

3.4.3 Validity and Reliability

The measures used for each construct capture the essence of the underlying construct. Perceptual measures are used for all items in the analysis. In all, 26 items are used for this model. The number of questions per construct ranges from one (for most of the control variables) to five (for the quality capability and priority, and for the dependent variable; plans to outsource). The constructs are operationalized using the scales given in Table 6.2.1 in the appendix. Scale reliabilities for multi-item scales are also given in

Table 6.2.1. Content validity is assured by the tight linkage between the definitions and the manufacturing strategy literature. Many of the scales have been used in previous published research. As indicated in the appendix, all scales with more than two items have item reliabilities (Hair et al., 1998, p.612) greater than 0.70. The two cost items (priority and capability) are two item scales; the two items are strongly correlated.

Descriptive statistics for the variables are given in Table 6.2.2 in the appendix. Correlations were examined for all variables and are given in Tables 6.19 and 6.20 in the appendix. The correlations within a factor are in all cases significant to the $p < 0.001$. Additionally, inter-item correlations are in all cases greater than the correlation of an item outside of its factor, with one group of exceptions. In the cases where the same category of item is used to obtain the capability and priority of an item (e.g., see QC1 and QP1 in Appendix 6.2.1), the correlation between the two items is high. Because identical question wording may bias these correlations high for reasons beyond what theory would predict, we allow the error variances of these items to correlate in the model. We discuss common methods bias in this study in Appendix 6.2.3.

The scales were checked for unimodality and approximation of normality by viewing histograms and normal probability plots of the data. All of the capability and plans to outsource items exhibited reasonable approximations to normality. However, most of the priority items were skewed the high end of the scale. We do not use Shapiro-Wilk (or other) tests because of the categorical nature of our data. Given that the normality of each of the variables cannot be assumed (and therefore multivariate normality cannot be assumed), we examined bootstrapped standard errors in AMOS after completing the

analysis in LISREL and found no difference in key substantive results; we will discuss more in the results section.

We tested for discriminant validity of the scales by analyzing the difference in chi-square between pairs of multi-item constructs when they are allowed to correlate freely and when the correlation is fixed to one. A significant difference provides evidence of discriminant validity. All chi-square differences were highly significant, as indicated in Appendix 6.2.4.

We first performed an overall confirmatory factor analysis (CFA) using LISREL 8.54. LISREL was chosen for the CFA and the structural equation modeling tests of hypotheses because of its capabilities for handling missing data. The missing data was not excessive. In the observed variables used in the model above, there are a total of 9% missing values. However, due to the amount of variables (26) used in the analysis, listwise deletion with this model would have reduced the sample size to approximately 300 usable companies from the original number of 867 companies. Also, listwise deletion requires an assumption of missing completely at random (MCAR). Full Information Maximum Likelihood (FIML) allows us to make an assumption that the data are missing at random. “Missing at random” (MAR) means that a value’s missingness “may depend on observed values but not on missing ones” (Schafer, 1999). This is a weaker assumption than MCAR and therefore preferable. The model fit for the CFA of the multi-item scales is in Table 3.2.

First, note that LISREL does not give standard fit statistics (GFI, CFI, etc.) when

Table 3.2: Fit statistics for confirmatory factor analysis

	χ^2 (df=135)	p-value	RMSEA	All loadings sig?
CFA	249	.000	.031	YES

using FIML. This is because “the specification of a means structure (required for estimation) renders certain fit indexes undefined” (Enders, 2001, p.135). However, the low RMSEA, significantly less than 0.05, is the most important stand-alone measure of model fit. The “probability of close fit” in the LISREL output is 1.00. The significant chi-square is common in large sample sizes; the fact that χ^2/df is less than 2 indicates reasonable fit by the chi-square test (Carmines and McIver, 1981). As further evidence that the measurement model is acceptable, we note that all loadings were highly significant on their factors, with t-values ranging from 5 to over 20.

3.5 Results

The complete structural model of Figure 3.1 was also tested using LISREL 8.54, and handling missing data with FIML. As indicated in the Table 3.3, the RMSEA is comfortably below the cutoff for “good” fit of 0.05; again, the “p-value for close fit” =1.00.

Table 3.3: Fit statistics of the SEM of Figure 3.1

	χ^2 (df=226)	p-value	RMSEA	All loadings sig?
SEM	414	.000	.030	YES

As in the CFA, commonly discussed fit statistics are not given by LISREL. However,

we ran the structural model using data sets formed by multiple imputation with missing data imputed in AMOS 6. The commonly used fit indices (CFI, GFI, IFI, TLI) all had values above .9, further indicating acceptable fit. Additional indications of acceptable fit include normal-looking standardized residual plots, very few residuals greater than 2.6, and relatively few modification indices greater than 4 (Jöreskog and Sörbom, 2001).

3.5.1 Tests of Hypotheses

Looking at the path values predicted by the hypotheses in Table 3.4, two of the four hypotheses—the two related to cost—are supported to the 0.05 level. This is a one-tailed test, so the critical t-value is 1.65.

Table 3.4: Tests of hypotheses

Hypothesis	Loading	t-value	Significant?	Hypothesis Supported?
(1) Quality Capability	.026	.427	NO	NO
(2) Cost Capability	-.119	-2.89	$p < .05$	YES
(3) Quality Priority	-.009	.093	NO	NO
(4) Cost Priority	.187	2.46	$p < .05$	YES

Some interesting things can be observed by the results. Surprisingly, neither quality capability nor priority appears to play a direct role in plans to outsource. This indicates that product quality does not have a strong, independent impact on the decision to outsource manufacturing resources. It is possible that firms that had already obtained high quality were embracing the core competence paradigm (Prahalad and Hamel, 1990) and strategically outsourcing non-critical operations. Also, quality is multi-dimensional.

The independent impact of cost capability and priority is telling. It indicates that cost is driving the manufacturing outsourcing decision. If low cost is a priority, then firms are more likely to outsource manufacturing. If internal cost capability was high, they were less likely to outsource manufacturing. It will be interesting to see if this capability continues to have such a large impact in the future relative to the other reasons to outsource. Our expectation is that it will, as recent interviews with manufacturing executives at world-class companies indicate that cost is still the main driver of their outsourcing decisions.

3.5.2 Impact of Control Variables

Next, we list the control variables tested, including our proxy for asset specificity. There are a couple of key things to note on Table 3.5. First, the most empirically robust construct from transaction cost theory has again withstood empirical validation-asset specificity reduces plans to outsource. Second, uncertainty has again not been shown to have a stand-alone first-order effect on outsourcing. (David and Han, 2004) and (Grover and Malhotra, 2003) showed that both of these results (support for asset specificity, mixed results for uncertainty) are common.

A surprising result is that operating in an emerging economy significantly increases plans to increase outsourcing. This could be because these countries are generally more collectivist (Hofstede, 2001) and more open to resource sharing. Further work based on this result is left to future research.

Table 3.5: Tests of the control variables

Variable	Loading	t-value	Significant?
Asset Specificity	-.140	-3.086	$p < .05$
Technological Uncertainty	.003	.019	NO
Emerging Market	.142	2.961	$p < .05$
Market Leader	.007	.152	NO
Large Firm	.072	1.67	NO
Early in Life Cycle	.042	.838	NO
Custom Product	-.048	-1.19	NO

3.5.3 Robustness Checks

To check the robustness of the model to the choice of methodology, some additional tests were performed. First, multiple imputation and regression (with collapsed scales) were performed in SAS. The key substantive results did not change. Second, standard errors were bootstrapped using AMOS with each multiply imputed data set. Bootstrapping the standard errors did not affect any of the key substantive results. Also, hierarchical regression (with collapsed scales) was performed in SAS using multiply imputed data sets to ensure that the four hypothesized variable explained a significant amount of variance over and above the control variables; they did. These checks ensure that the main results did not depend on the method chosen or how missing data was handled-they are robust and exist in the data set.

3.5.4 Competing Model

The first-order effect model presented above gives the effect of a given operations capability on plans holding priority constant and vice versa. It may be argued that the priority

a firm places on a competitive dimension would moderate the relationship between the realized capability and plans to outsource. For example, a firm that places a high priority on cost may be more likely to outsource due to low capability than a firm that places a low priority on cost. Thus, the priority a firm places on a competitive dimension may alter the effect of a capability on outsourcing plans. For cost, this possible interaction is represented conceptually in Table 3.6.

Table 3.6: Possible interaction of cost priority and capability

	Low Capability	High Capability
High Priority	HIGH	MED
Low Priority	MED	LOW

Impact on plans to outsource

We note that our theory for quality differed, in that we believed firms that place a high priority on quality may be less likely to outsource, all else equal. We conceptually present this in Table 3.7.

Table 3.7: Possible Interaction of quality priority and capability

	Low Capability	High Capability
High Priority	MED	LOW
Low Priority	HIGH	MED

Impact on plans to outsource

Moderation is generally modeled by including a product term between the two independent variables of interest with mean-centered data, as given in the equation below:

$$PTO_i = \beta_0 + \beta_1 QC_i + \beta_2 QP_i + \beta_3 CC_i + \beta_4 CP_i + \beta_5 (CP_i * CC_i) + \beta_6 (QC_i * QP_i) + \beta_j (Cont.Var.) \quad (3.1)$$

Because of the extreme difficulties of including interaction terms in such a large structural equation model with missing data, we included an interaction term in a regression framework using collapsed scales. This is justifiable as regression with collapsed scales and no interaction terms led to the same substantive results as the structural equation model presented above. When interaction terms are included, none of them have significant coefficients, meaning the first-order effects (when present) dominate. However, the inclusion of the interaction terms did slip cost priority to non-significance. More complicated relationships between capabilities, priorities, and plans to outsource will be the subject of future research.

3.5.5 Limitations

We now discuss some limitations of our study. First, the data are cross-sectional. This concern is somewhat minor in this study because we are studying how current operations strategy impacts current outsourcing plans, but it would be appealing to determine how a firm's operations strategy relates to actual outsourcing performed. Second, the survey was not designed to have multiple indicators of a single construct, so the constructs had to be gleaned from the available questions and are sometimes multi-dimensional. While the constructs reasonably reflect the questions used as indicators, a study designed explicitly for this purpose would probably have used slightly different, more unidimensional indicators of the underlying constructs. Third, the overall R-squared of the model was 14.1%, quite low but not unreasonable in research studying such a complex dependent variable. In spite of the above limitations, we have provided further evidence that capabilities do

matter and obtained new evidence about which specific manufacturing strategy variables matter most in outsourcing decisions. There is ample opportunity for future research to investigate more and different aspects of firm-specific characteristics that drive a firm to have a plan to outsource.

3.6 Conclusion

By linking a firm's operations strategy to its outsourcing strategy, this study makes several contributions to the academic literature. First, it adds further empirical evidence that firm-level attributes (capabilities and priorities) do matter in outsourcing decisions, lending support to the resource-based view as important in boundary decisions and reinforcing that firm boundary research that neglects firm-specific capabilities is lacking. Second, it looks at specific operations-based competitive capabilities and priorities, as opposed to a single variable such as "production experience" (Leiblein and Miller, 2003), and measures the influence of these individual priorities and capabilities on a firm's outsourcing plans. Third, this study provides a first step in utilizing operations strategy concepts not just to predict plant or business performance, but also to predict the health of the production function within the firm.

From a practitioner perspective, this research is not prescriptive-it does not provide guidance as to the conditions under which outsourcing should be undertaken. However, we can make statements of interest to managers. First, for practicing operations managers, this study reiterates the importance of attaining and articulating leadership in cost

to avoid being outsourced-the “soft stuff” does not seem to have great influence to high level managers’ plans to outsource. For higher-level managers, we suggest that difficult-to-measure, longer term criteria should perhaps be given a larger weight in outsourcing decisions, as opposed to a focus on costs.

Chapter 4

Buyer Beware? Quality Risk in Outsourcing

4.1 Introduction

Pan Pharmaceuticals was a large contract manufacturer in the Australian pharmaceuticals industry in early 2003. But, in mid-2003 a travel sickness pill it produced on contract resulted in 19 hospitalizations. Investigations of Pan's operations revealed such serious violations as the fabrication of test results and the substitution of raw materials. In the end, 1650 export products were recalled (Nowak, 2003; Schmetzer, 2003). For the firms who outsourced production of those 1650 products to Pan Pharmaceuticals, outsourcing certainly posed a quality risk. Although outsourcing has been on the rise over the past decade, the extent to which the case of Pan Pharmaceuticals is an isolated event is unknown. More generally, this research aims to subject to empirical scrutiny the degree to which outsourcing production to a contract manufacturer poses a quality risk to the

buying firm relative to producing in-house.

The research question we ask is: “Do contract manufacturer’s plants pose a higher quality risk than internal plants, on average?” For semantic clarity in this dissertation essay, we operationally define the three main variables associated with this question. A *contract manufacturer’s plant* is an establishment that manufactures finished or nearly finished products to another company’s specifications. An *internal plant* is an establishment that manufactures products under the brand name and specifications of its own company. *Quality Risk* is the propensity for product shipped from a given establishment to fail to perform as intended, due to manufacturing-related issues.

To address our research question, we develop theoretical arguments and an empirical model to enable us to test hypotheses concerning the influence of contract manufacturing relative to maintaining production in-house, as well as ISO 9000 certification, on quality risk. We included ISO 9000 certification because many practitioners consider it a process-based factor in an outsourcing decision that should act to lower quality risk. To develop a valid measure of quality risk at the plant level, we employed a Delphi approach using a panel of experts and eleven years of Food and Drug Administration (FDA) inspection reports. Using a systematic approach, we developed a sample of contract manufacturers and internally owned plants. We apply our research in a sample of 154 plants in the over-the-counter (OTC) and pharmaceutical drug industry.

Evaluating the potential quality risk posed by outsourcing production to contract manufacturers is important to operations management. The practice of outsourcing pro-

duction to contract manufacturers is common in many industries (Tully, 1994), including the prescription drug, over-the-counter drug, and regulated cosmetic industries which we study here (VanArnum, 2000; Jeffries, 2003; Antonelli, 2005). In fact, the global pharmaceuticals outsourcing market is predicted to reach \$53 billion by 2010 from \$24 billion today (Anonymous, 2006). Given that off-quality drugs can be harmful to humans, it is important for firms to understand whether or not outsourcing to contract manufacturers poses an added quality risk. While manufacturing outsourcing continues to increase in many industries, the theoretical underpinnings of the quality risk implications of using contract manufacturers are lacking.

In this paper, we make several contributions to the academic literature and practice. First, we draw from the economic incentives and measurement literature, the supply chain literature, and the total quality management (TQM) literature to propose a theory on the effect of outsourcing on quality, as it pertains to contract manufacturing. Second, we create an innovative measure of plant-level quality risk from publicly available FDA inspection reports. We do this utilizing the Delphi process with a diverse panel of experts. Next, using our summary metric, we provide empirical support that the use of contract manufacturers poses a greater quality risk than producing in internal plants. We control for several potentially relevant variables in this analysis. Finally, counter to conventional wisdom, our empirical results show that ISO 9000 certification does not mitigate quality risk. This is relevant to outsourcing decision-makers because ISO 9000 is often used to signal low quality risk.

The remainder of this essay is organized as follows: In Section 4.2, we review the

related literature and present our theoretical model. We discuss our database and measurement in Section 4.3. In Section 4.4, we present the results of an ordered logit regression analysis of the data. In Section 4.5, we discuss limitations and future research, and give our theoretical and managerial conclusions.

4.2 Theoretical Model

Our research seeks to improve our understanding of the quality risk implications of outsourcing production to contract manufacturers by empirically studying the model in Figure 4.1. This model demonstrates that we will test two plant-level characteristics—production source and ISO 9000 certification—to see how they impact quality risk. We also consider the effect of several potentially relevant control variables, including the continuous variables of company size, plant size and plant age, and three dummy variables. These indicate whether plant produces primarily regulated products, whether the company has any credit issues, and whether the company is public or private.

4.2.1 Source of Production

The primary focus of this study is on the effect of source of production on quality risk. In this section, we draw upon the supply chain literature, the total quality management literature, and the literature on measurement and incentives to make an argument that, in general, outsourcing to contract manufacturers can pose a quality risk. Outsourcing can

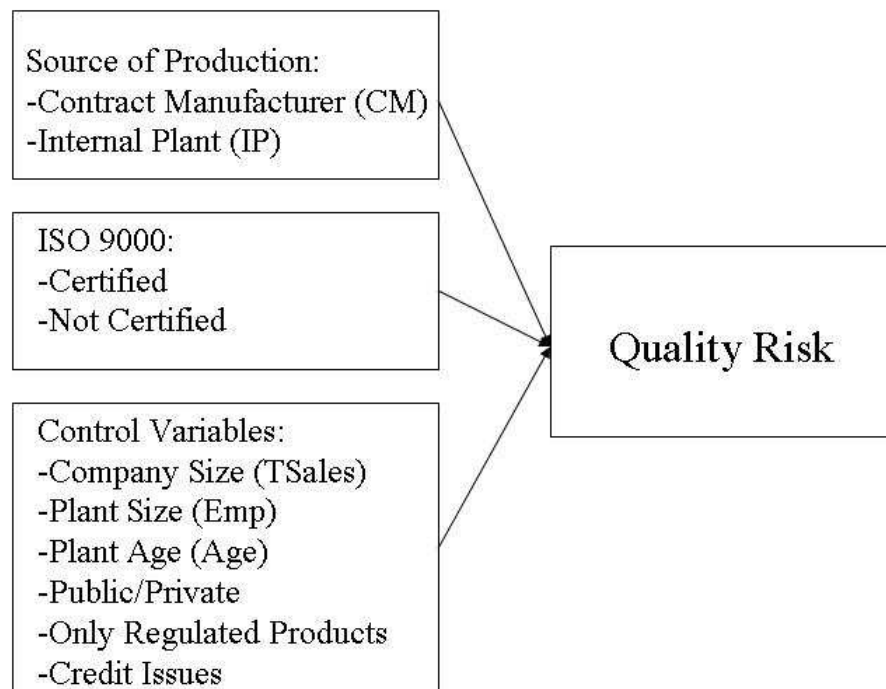


Figure 4.1: Conceptual model

range from components to complete products. Here, we focus on contract manufacturers who make finished or nearly finished products. Focusing on finished product outsourcing to contract manufacturers allows us properly measure quality risk, as an undetected quality failure at either type of plant will be shipped to the consumer. In terms of vertical integration, the distinguishing characteristic of the two types of plants is forward vertical integration. They may have varying levels of backwards integration. Internal plants are vertically integrated in the sense that they are manufacturing product with their own brand name for a retail or distribution center. Contract manufacturers are disintegrated in that they are transferring ownership to another firm who then ships to distribution or retail. This distinction is important to the theoretical discussion below.

4.2.1.1 Supply Chain Management

The supply chain literature has documented a quality risk in outsourcing, particularly in the special case of a monopoly market, with one buyer and one contract manufacturer. In these papers, “quality” is operationalized as perceived quality to the consumers; higher quality products are valued more by consumers. While this is a different type of quality than our “quality risk,” these papers provide insight to our study as defect-free products will clearly be more valued by customers. Economides (1999) shows that outsourcing, as opposed to vertical integration, leads to lower quality. He explains, “because of double marginalization, the impact of marginal improvement in quality on price is higher under dual ownership....[dual, disintegrated] monopolists can achieve the same strategic effects while providing lower quality and saving on costs” (p.904). Kaya and Özer (2005), who

also utilize the term quality risk, specifically define quality as “product attributes for which the customers prefer more to less” (p.2). They state that difficulty in contracting on quality and lack of information by the OEM about the CM’s costs to achieve quality are the factors that lead to a quality risk. They show that “the CM exerts less effort on quality than what a vertically integrated OEM would have exerted” (p.3) due both to double marginalization and the fact that the OEM cannot through contracts enforce his desired quality level. Sheopuri and Zemel (2005) assume a contract manufacturer who will shirk on quality, and look at the effect of buyer quality auditing costs on the actions of the buyers and suppliers. Thus, there is limited but consistent normative theory from the analytic supply chain literature that quality performance will be lower in the presence of outsourcing than in vertical integration in a simplified setting due primarily to double marginalization and the difficulty of contracting on quality.

We found no empirical research on quality in manufacturing outsourcing in the supply chain literature, but a few studies in the service management literature lend some insights. Harris and Winston (1983) found that service quality was higher in railroads after vertical mergers. Their results indicate that “insourcing” of railroad operations improved quality.

Michael (2000) found that in the hotel and restaurant industries, that firms with more franchised outlets had lower quality performance (measured by Consumer Reports data), due to the difficulty in contracting for quality and resultant “free riding” by franchisees. Franchises are like contract manufacturers in that they are producing a clearly defined product on contract. There are some differences, however. Franchisees interact directly with the customer and perform some level of local marketing activities, whereas contract

manufacturers do not. Also, in many contract manufacturing arrangements, contract manufacturers retain the right and responsibility to the detailed process, whereas this would normally be dictated in a franchise relationship. Thus, while the theory and results of this study are aligned with ours, the results of this study do not directly relate to outsourcing production to a contract manufacturer.

Finally, Hsieh et al. (2004) show that outsourcing lowers delivery reliability in several segments of the international courier services industry. The authors assert that “vertical integration, while costly to employ, provides advantages over outsourcing for designing and tailoring the production process to improve reliability by avoiding under-investment in product and process design” (p.3).

We found one study that proposed that outsourcing would improve quality. Benson et al. (1991), in a larger study on organizational context’s effect on quality management, hypothesized that a high proportion of products purchased (i.e., outsourced) would correlate to higher quality due to less internal complexity. This hypothesis was not supported.

In summary, the supply chain literature has provided both analytical and empirical evidence that there is a quality risk in outsourcing. The context for the analytic models is generally for simple settings; the empirical studies have been mostly in services. We now turn to the TQM literature to motivate the theoretical argument underpinning our study in the drug manufacturing industry.

4.2.1.2 Total Quality Management (TQM)

The literature on total quality management provides an important part of our theoretical arguments. The literature has demonstrated that rote implementation of TQM practices does not consistently improve performance; a change in “tacit” culture is required, as we discuss now.

In their review of the TQM literature, Sousa and Voss (2002) found that quality practices alone do not drive quality performance. Rather, it is the infrastructural (Flynn et al., 1995) components of TQM that more consistently drive performance than implementation of the practices (Anderson and Rungtusanatham, 1994; Dow et al., 1999; Giffi et al., 1990; Handfield, 2004; Powell, 1995). The infrastructural practices are more tacit and cultural than the core practices. The infrastructural practices include “softer” components of TQM such as executive commitment, open organization, employee empowerment, and zero defects mentality. These “intangibles” are a necessary component for a TQM program to successfully improve quality performance (Powell, 1995; Giffi et al., 1990).

In a contract manufacturing setting, the fact that the infrastructural practices are those that drive quality performance and that they are difficult to observe can present problems for the buying firm. For example, a buyer could observe, through audits or surveys, that a contract manufacturer utilizes written procedures, performs validations, etc. However, these systems would matter only if they are rigorously followed. For example, do employees take the extra effort to stop production to report observed defects?

Does line management ensure that all process changes are reviewed and revalidated? Do key decision-makers ensure that out-of-specification results are thoroughly investigated? Table 4.1 lists several quality “risk-reducers,” clearly spelled in the regulations which the FDA audits, which will be difficult for buyer audits to detect. FDA inspectors have the legal authority to pull records, interview employees, etc. to observe the robustness of the quality systems. It is likely that even careful buyers will have difficulty assessing their supplier’s “infrastructural” quality programs.

Thus, while one could argue that a buyer could enforce the implementation of certain practices (e.g. written procedures, documented training program) on a contract manufacturer, it is more difficult to argue that a buyer can enforce a contract manufacturer’s “tacit” culture. In fact, it will be difficult to even observe such a culture in a typical negotiation.

4.2.1.3 Measurement and Incentives

Holmstrom and Milgrom (1991) discuss how when multidimensional incentives are present, shirking can occur in the harder-to-measure dimension. As discussed above, it is difficult for a buyer to compare quality risks posed by different contract manufacturers when negotiating a contract. However, it is relatively easy to compare cost, delivery time promises, etc. Recall, the second essay of this dissertation showed that neither a firm’s self-assessed quality capability nor the importance it placed on quality affected whether it planned to outsource; while costs did. Similarly, a recent Gartner survey showed that costs are still the main driver of outsourcing decisions in process manufacturing (Woollacott, 2006).

Table 4.1: Examples of systems to lower quality risk

Term	Definition
Prior to Startup	<ul style="list-style-type: none"> -Training: Assuring all production and laboratory personnel know proper operating procedures, process conditions, and what to do in unusual circumstances -Process Validation: testing and ensuring the production and laboratory processes will perform as intended, including under unusual conditions -Raw Material Qualification: Ensuring vendor knows acceptable range of raw material specifications, and has capability and systems to continuously meet those specifications -Computer System Qualification: Ensuring all automatic systems are validated across the range of scenarios they may possibly face
During Normal Production	<ul style="list-style-type: none"> -Following Procedures: Ensuring written procedures are continuously followed and any deviation is justified -Calculation of Yield: Ensuring two individuals independently account for all materials -Addition of Materials: Ensuring two individuals independently confirm the proper amount and type of ingredient is added -Testing of Product: Ensuring proper items tested at proper intervals; ensuring two individuals test that product meets specifications -Hygiene: Ensuring personnel and plant are clean and sanitary; including free of pests. -Release Authority: Ensuring only trained quality control personnel are authorized to release product to the trade
During Changeover and Shutdown	<ul style="list-style-type: none"> -Ensuring that proper cleaning and sanitization procedures are in place and followed for transition from Product A to Product B or extended shutdown -Ensuring maintenance procedures are consistently followed and documented
Change Management	<ul style="list-style-type: none"> -Ensuring all changes are reviewed by qualified QA personnel; and validations, procedures and retraining are done as needed
Out of Specification Product	<ul style="list-style-type: none"> -Ensuring proper procedure followed after the discovery of any out-of-specification results -Ensuring QA has the power to prevent release of product until cause of out-of-specification is determined

Source: Code of Federal Regulations, 21 CFR-Parts 210 & 211

Contract manufacturers are aware of the supremacy of costs in outsourcing decisions, and therefore may tend to focus on those capabilities that earn the business, possibly at the expense of quality.

Similarly, once the contract manufacturer is producing product for the customer, they will see immediate benefit (or cost) from any decrease (or increase) in production costs. They will also feel immediate pain for late deliveries. However, quality must just be "acceptable." Thus, if existing systems have yet to lead to a known problem, the contract manufacturer is less likely to invest in improving the robustness of its quality systems, due to the conventional wisdom that managers are rewarded more for providing immediate benefits (cost, delivery on time) more than for preventing an infrequent failure.

There is also some classic work on the effect of measurement capability on firm boundaries (e.g., Alchian and Demsetz, 1972). This work shows that hierarchical organization may be superior in cases where measurement is difficult. Grossman and Hart (1986), modeling the property rights view of firm boundaries, show that vertical integration may be preferred in cases where all possible outcomes cannot be specified in the contract.

4.2.1.4 Mitigation of Risks

We have documented several reasons why contract manufacturers may operate with less robust quality systems (and thus pose a higher quality risk) than internal plants, due to lack of investment in robust quality systems. Unfortunately, these contracting hazards are not mitigated by a strong understanding of how to manage quality at contractors.

While the practitioner literature have given anecdotal advice (Watkins, 2005), there is little rigorous understanding of how to mitigate these quality risks. Phelps (1998) noted that “managers are frustrated in their efforts to transfer quality concepts directly to their contracting activities. This frustration has been largely unaddressed by management educators” (p.464). More recently, Robinson and Malhotra (2005) observe that few studies examine quality management and supply chain management jointly. An exception is a recent paper by Fynes et al. (2005), which shows that communication, trust, and adaptation among supply chain partners leads to improved quality performance. Activities between buyers and contract manufacturers to mitigate quality risk are not explicitly studied in this paper. While certain practices may mitigate quality risk, we believe that, on average, there will be a quality risk in outsourcing manufacturing.

4.2.1.5 Counter-Arguments

One could argue that for contract manufacturers, manufacturing is a core competency (Prahalad and Hamel, 1990). Also, contract manufacturers may benefit from economies of scale and/or scope by producing similar product for several customers. Both of these factors could lead one to expect contract manufacturers to, in fact, pose a lower quality risk. We believe that the factors described in the preceding sections will overwhelm these arguments, on average.

Therefore we hypothesize:

Hypothesis 1 Contract manufacturer’s plants will pose a higher quality risk than in-

ternal plants, all else equal.

4.2.2 ISO 9000 Certification

ISO 9000 is a quality management certification. As of December 2004, almost 700,000 certificates have been issued worldwide in 154 countries. In the United States, there have been approximately 37,000 certificates issued (Helberling, 2005). ISO 9000 certification fees can be thousands of dollars, and that does not include the time, labor, and (often) consultants required to implement the systems. And, many registrars seem to be giving certifications without assurance that requirements are being met, hindering ISO 9000's credibility (Dalglish, 2003). Despite ISO 9000's broad reach and high costs, the evidence regarding performance improvement due to ISO 9000 certification is still inconclusive.

ISO 9000 certification is intended to provide assurance that a certified plant has strong systems that will lower quality risk. As discussed in the previous section, practices that can be described and easily audited do not always relate to quality performance improvements; “infrastructural,” “soft,” or “tacit” behaviors matter (Giffi et al., 1990; Powell, 1995). Perhaps because of this, the empirical research on the ISO 9000-quality performance link has been mixed.

A few studies have found a link between ISO 9000 certification and quality performance, but usually with some qualifiers. For example, Naveh and Marcus (2004) note the performance improvement depends upon how much an organization “goes beyond” the base standard. Voss and Blackmon (1998) showed no link between ISO 9000 and im-

provements in quality when the use of TQM is controlled for. Interestingly, some authors have shown financial improvements correlated to ISO 9000 certification (Corbett et al., 2005; Wayhan et al., 2002; Sharma, 2005).

Given our theoretical belief that easily documented practices cannot alone drive quality performance, the apparent inconsistent enforcement of registration standards, and the mixed previous literature, we do not expect that ISO 9000 will lower quality risk.

Hypothesis 2 ISO 9000 certification will not independently affect plant-level quality risk.

4.3 Database and Measurement

In this section, we will document the empirical methodology used to measure the dependent variable, quality risk. The resultant measure is a key contribution of this work. We first document other methods of measuring quality risk in operations management. Then, we provide details about our FDA database, which provides the raw data for the measure. Finally, we review the process we used to convert the raw FDA data into a valid measure of quality risk.

4.3.1 Other Methods of Measuring Quality Risk

Quality risk is approximately the reverse of conformance quality capability. Conformance quality is defined as “the degree to which a product’s design and operating characteristics meet established standards” (Garvin, 1987, p.105). Since few have used the term “quality risk” in empirical studies, in this subsection we discuss approaches that researchers have used to measure conformance quality capability.

A few studies have directly measured conformance quality by observing defects in multiple plants (e.g., Garvin, 1983). While theoretically appealing, this approach would be prohibitively time-consuming and costly for a large scale empirical study such as ours. For example, Garvin (1983) thoroughly investigated the internal and external defects of 18 room air conditioner plants over two years. To perform a similar study with 154 plants with diverse products, we would need to clearly define failing to perform as intended for each product. This would include contaminations, mislabeling, high/low active ingredient level, etc. Then, we would need to sample from the trade and test each product for each sample. One can see why, except in small, focused studies, the actual measurement of defects is rarely done in large-scale research projects.

Partially because of this difficulty, the vast majority of previous research which measures quality has utilized survey data, usually managers self-assessments of their quality capability relative to others. Surveys ask managers about quality performance either at the plant-level (Adam, 1994; Dow et al., 1999; Flynn et al., 1999; Maani et al., 1994; Shah and Ward, 2003; White, 1996) or the firm or business-unit level (Cleveland et al., 1989;

Forker and Vickery, 1996; Frohlich and Dixon, 2001; Kaynak, 2003; Miller and Roth, 1994; Rosenzweig and Roth, 2004; Ward et al., 1995). A tremendous amount of theoretical knowledge has been gained by these studies. However, perceptual survey research is not without problems. First, surveys are time-consuming and expensive to administer. Second, it is difficult for managers to assess their performance relative to others, as discussed in Ketokivi and Schroeder (2004) and Podsakoff and Organ (1986). An indication of the difficulty of self-assessing performance is that average scores on “performance” relative to others are often much higher than the average on the scale, as in Safizadeh and Ritzman (1996), even in studies not explicitly focused on “high performing companies.” As Boyer et al. (2005) have noted, “identifying alternative, innovative sources of data is becoming increasingly important” (p.446). Aside from assessing outsourcing’s quality risk, a key contribution of this research is the utilization of an innovative source of plant-level data on quality risk, which we introduce now.

4.3.2 FDA Inspection Database Description

Regulated industries are subject to inspection by governmental organizations. In the case of FDA-regulated industries, these inspections are relatively frequent and thorough, and thus provide a detailed look at the quality risk posed by manufacturing facilities. The inspections generally last from three days up to two weeks, and usually involve spot checks of records, conversations with random employees, and tours of manufacturing facilities. The FDA has the authority to ask for any information related to any production of a regulated product. We know of no better assessment of establishment-level quality risk

in manufacturing that is available in large quantities.

FDA inspection data are available via the Freedom of Information Act; although obtaining data can be expensive and time-consuming. We obtained a large database from the FDA, which contains every establishment inspection in the drug industry in the United States from January, 1994 to April, 2006. The beginning date of the data follows a major legal decision involving Barr Laboratories which greatly increased the FDA's regulatory authority (Farley, 1993). The drug database contains information on over 5000 plants and more than 15,000 audits.

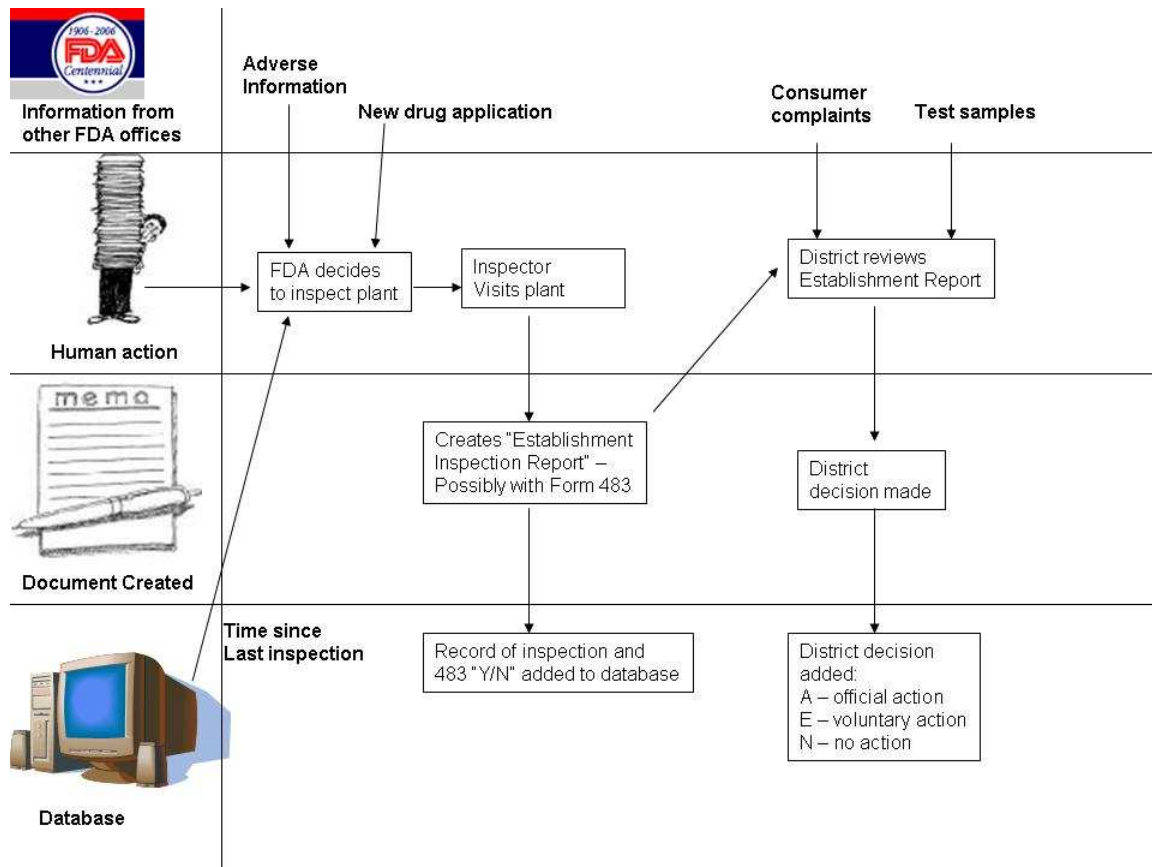


Figure 4.2: Flow chart of FDA inspection process

Figure 4.2 gives a flow chart of the process by which the FDA creates and codes the

data into the database. The database contains the company name and establishment location, the date of the audit(s) at each establishment, and (for every audit), two different indicators of quality risk. First, there is “Yes/No” variable that indicates whether or not a Form 483 was issued by the auditor. A Form 483 is issued to the firm if at the conclusion of the inspection the auditor believes there is a quality risk (that is, a deviation from “Good Manufacturing Practices”) significant enough to warrant formal documentation. A single Form 483 may contain many observations, but the database does not contain information about the number of observations on each Form 483. In 56% of the audits in the total drug database, a Form 483 was issued. The complete inspection report, including a Form 483 if issued, is then sent to the district office. The district office reviews the Establishment Inspection Report (EIR), as well as other information related to the plant, and makes a district decision on the inspection. The district office indicates one of the actions in Table 4.2. Together, the Form 483 decision and district decision provide plant-level evidence of quality capability.

In addition, although not included in the database, we obtain from the Enforcement section of the FDA website information about establishment inspection related seizures, injunctions, and recalls related to any companies in our study.

4.3.3 Delphi Process to Operationalize Quality Risk

Given this data source, some difficulties emerge. It is obviously desirable to utilize the FDA inspector’s decisions (483 Yes/No), the District Decision for each audit, and any

Table 4.2: Coding of FDA district decisions

District Decision Code	% of data	District Decision Description	Explanation
N	39.1%	No Action Indicated	Establishment has no objectionable conditions; or objectionable conditions found during the inspection were so minor that routine reinspection is the only action indicated. Automatically entered by the computer when inspection conclusion is NAI.
E	41.4%	Voluntary Action Indicated	Objectionable conditions are found but the District is not prepared to take or recommend any administrative or regulatory action. The District may advise the establishment following the inspection of findings that should be corrected, but the findings are not significant such to warrant warnings of administrative or regulatory actions or to request a response. Any corrective action is left to the establishment to take voluntarily.
A	18.0%	Official Action Indicated	Regulatory or administrative sanctions will be recommended.
I	0.1%	Referred to State (for Action)	The findings of the inspections were such that any action towards correction should be taken by a state or other local or federal authority.
P	0.4%	Pending—Referred to Center	Inspection conclusions will be correction indicated. Inspectional information has been forwarded to a Center for decision; or The District Decision has not yet been made.
Un	1.1%	Unknown—not yet reported	District Decision is Unknown or has yet to be reported.

Source: FDA coding in response to Freedom of Information Act Request

audit-related seizures, injunctions, or recalls, but how? Also, since we want to perform our study at the establishment level, we need to know how to assess a plant with multiple audits. We decided to form a panel of experts to help us decide how to use the data. To rigorously draw out the expertise of the panel, we chose to use the Delphi method.

Anderson and Rungtusanatham (1994) described the Delphi process as “a technique, developed by RAND corporation in the early 1950s, intended for systemically soliciting, organizing, and structuring judgments and opinions on a particularly complex subject matter from a diverse panel of experts until a consensus is reached” (p.478). We asked our panel to help us determine how we can mathematically transform the raw spreadsheet data into a valid measure of quality risk. The Delphi method is ideally suited for situations in which there is a question with a clear objective, but for which finding an answer requires subjective reasoning by people with expertise in the area (Linston and Turoff, 1975); our question certainly fits that description.

We utilized four experts for this study. The experts all had experience both with manufacturing in regulated industries and FDA inspections. All experts voluntarily participated in the research, and were willing to spend the time necessary to complete the process. Brief biographies of each of the four experts are given in Appendix 6.3.1. Our experts have diverse backgrounds, no history of communication, and have heterogeneous knowledge and experience which we wish to preserve. Also, it was important for us to understand why each expert believes what he/she does, and we did not wish group dynamics/confrontation to lead to a forced consensus or suppression of some experts’ ideas. Per Linston and Turoff (1975), the Delphi process is ideal for an expert panel with

the above characteristics.

Following the Delphi process, we did the following in each of three rounds: (1) created an interview script, (2) interviewed each expert individually, following the script, and (3) sent a summary of the round to the expert panel. After three rounds, we conducted a fourth “wrap-up” conference call. The average interview lasted about an hour. Calls were recorded and reviewed each round prior to sending out summaries. While the experts expressed some concern about the “coarseness” of FDA audits as a proxy for quality risk, they felt that FDA inspections provided a reasonable assessment of a plant’s quality risk. They compared our approach favorably to both perceptual surveys and actual measurement of defects in different processes. The expert solicitation letter, as well as interview scripts and summaries for all three rounds are presented in Appendix 6.3.2. The process did lead to a consensus mathematical transformation of the available components into a measure of quality risk, which we document now.

4.3.4 Operationalization of “Quality Risk” Using FDA Inspection Data

As discussed earlier, there are seven possible audit outcomes when the FDA enters a facility. There are two possible decisions by the inspector (483 issued-“Yes”; No 483 issued-“No”). In addition, there are three meaningful district decisions which we can use (No Action-“N”, Voluntary Action-“E”, Official Action-“A”). Finally, and only in cases where official action is indicated, the FDA could take enforcement ac-

tion (Seizure/Injunction/Recall) during or as an immediate result of the audit. For each of these possibilities, Table 4.3 shows the single audit consensus “Quality Risk” scores determined by the expert panel; Table 4.4 gives the distribution of outcomes by audit.

Table 4.3: Single audit “quality risk” score based on audit outcome

483	District Decision	Quality Risk Score
No	N-No Action	0
No	E-Voluntary Action	0.5
No	A-Official Action	3
Yes	N-No Action	1
Yes	E-Voluntary Action	1.5
Yes	A-Official Action	3.5
Enforcement	A-Official Action	10

Table 4.4: Distribution of outcomes (n=972 audits of 154 plants)

483	District Decision	% of Inspections
No	N-No Action	39.4%
No	E-Voluntary Action	6.7%
No	A-Official Action	1.1%
Yes	N-No Action	1.9%
Yes	E-Voluntary Action	37.0%
Yes	A-Official Action	12.9%
Enforcement	A-Official Action	1.0%

We note that the database from the FDA did not have information about seizures, injunctions, and recalls. To get these we included all FDA Enforcement Reports found on the FDA website that were manufacturing-related, and within the following time-frame: 2 weeks prior to the end of the inspection up to 3 months after an inspection which was classified official action. The reason for linking seizures, injunction, and recalls to audit timing is that major problems uncovered during an inspection would lead to enforcement during or shortly after the completion of the audit. Items on the enforcement report that could not be attached to an objectionable audit were not included, for two reasons.

First, our data source for all other quality risk information is audits, so this remains consistent. Second, the number of firm-initiated recalls may confound both the quality risk presented by the plant and the firm's caution and care for protection of the public.

Note on Table 4.3 that the panelists put much more weight on an official action (A) than a voluntary action (E) by the district. The authors had no idea a priori that official action would carry so much weight and voluntary action so little. Similarly, the panelists put significant weight on seizures/injunctions/recalls.

With single audit scores determined, the panel discussed the difficulties presented by multiple audits for a single plant. One option, of course, is to simply average the quality risk scores. The key questions discussed were: (1) does the fact that the FDA chose to do multiple audits indicate an increased quality risk?, and (2) does the trend of the audit scores affect the quality risk? On question (1), the most FDA-experienced panelist educated the panel (through the Delphi summaries) that the majority of inspections are either part of annual work plans or for pre-approval inspection. And, "for cause" inspections (which are done due to a perceived quality risk) will often be the result of, or result in, official action. Thus, the panel was convinced that raising quality risk due to the number of audits was not appropriate. On question (2), the panel agreed that a company that has shown the ability to improve its quality systems over time presented a lower quality risk than one that did not or was getting worse. Thus, the panel felt the need to adjust the average quality risk for trend, but not frequency. After much discussion, the final quality risk score that resulted from the work is given now (QR=Quality Risk score from Table 4.3, n=number of audits, i=indicator for a specific audit):

$$\frac{\sum_{i=1}^n QR_i}{n} + \frac{\sum_{i=1}^{n-1} QR_{i+1} - QR_i}{n+1}$$

The first term is simply the average of the quality risk scores from the individual audits. The second term is a straightforward trend adjustment. Note that it is divided by $n+1$, when there are only $n-1$ terms in the numerator. This is to ensure that quality risk scores for plants with few audits are not modified excessively for their improvement or decline in an audit scores. As a validity check, the panelists reviewed the resulting quality risk scores for a selection of companies and felt that the numbers matched the “subjective” quality risk, based on audit results. The audit histories and resulting quality risk scores used for this check are also given in Appendix 6.3.2.

4.3.5 Plant Classification—Contract Manufacturer or Internal Plant

Aside from transforming the dependent variable, another key task of this research was to search the database for contract manufacturers and internal plants. This search was partially semi-random, and partially convenience. The semi-random portion was a methodical search of one of every four plants (alphabetically by establishment name) in the database. Each plant was given one of eight classifications, two of which were “contract manufacturer” and “internal plant.” This search utilized company websites, industry websites, SEC reports (if public), and occasionally even phone calls. Separately, published lists of contract manufacturers and brands in the OTC, regulated cosmetics, and

pharmaceutical industries were used to find possible candidates. Also, news alerts and news searches led to the classification of some firms. Finally, local store shelves were searched as a source for some of the "internal plants."

After a first round of classification, we rigorously rechecked all plants that were classified either contract manufacturers or internal plants in the first round. For all of these plants, news searches were performed in Lexis-Nexis to find more detailed evidence of the exact operations of the establishment. Appendix 6.4 discusses in more detail the process by which plants were selected for the study. We ended up with a sample size of 154 firms, 77 of which were contract manufacturers and 77 of which were internal plants. It is purely coincidence that the sample was balanced between contract manufacturers and internal plants.

4.3.6 ISO 9000 Certification

The Quality Digest database was searched in the spring of 2006 to see if plants were ISO 9000 certified. The database is searchable on Quality Digest's website by company name. The database is maintained by Quality Digest. The data come from the registrars, who send information to Quality Digest which is then incorporated into the database.

We coded plants as "ISO 9000 certified" if they were registered in the database, and more than half of their inspections had occurred after the estimated beginning of their registration process (15 months prior to the certification date (Meyer, 1998)). This left with only ten plants which we classified as ISO 9000 certified, so any results should be

interpreted with caution.

4.3.7 Other Control Variables

In addition to our dependent variable (quality risk) and our two key independent variables (contract manufacturer/internal plant dummy and ISO 9000 dummy), we felt it necessary to obtain control variables. Data at the plant-level are difficult to obtain for any firm; and many of the firms in our study are private, further compounding the problem (Ojala, 2004). After an extensive search, we decided to purchase Harris's Company Reach, a Dun and Bradstreet database. This was our primary source of data for plant age (age), plant size, total company sales, and whether plant was part of a public or private firm. We also used ReferenceUSA, an InfoUSA database. We utilized ReferenceUSA for "credit rating" score; ReferenceUSA has a 1-5 scale for this score, but virtually all plants had a score of "5." Thus, we created a 1-0 variable ("credit") where "0" indicates a credit rating of 5, and "1" indicates anything else. Since ReferenceUSA did not have information on all plants, we have some missing data with this variable. Because of the low frequency of missing data, we used single imputation with logistic regression to fill in the missing values. In addition, by examining company websites and other available information, we created a dummy variable to distinguish between companies that made almost exclusively regulated products and those that made non-regulated products.

By examination of bivariate plots of the continuous independent variables (Total Sales, Employees, and Age), we determined that three independent variables should be

transformed. Transformations are appropriate if there is a reason to believe that there is a nonlinear effect that can be made linear and/or there are a small number of large values that could be overly influential. In the cases of Total Sales, Employees, and Age, it is likely that the strength of the association decreases as the value gets large. For example, will the impact of size on quality risk be four times as much for an 8000 employee operation vs. 2000 person operation; or the plant of a \$40 billion company vs. \$10 billion. We choose the log transformation, one of the most common. This transformation reduces the effect of very large independent variables to a more realistic effect. In addition, the significant bivariate second-order (non-linear) effects that existed prior to transformation were eliminated.

4.3.8 Descriptive statistics

Descriptive statistics for all variables measured are given in Table 4.5. Correlations of relevant variables in the database are given in Table 4.6. Note from the correlations that there is a significant positive correlation between the quality risk (Qrisk) and process choice (CM for contract manufacturer). As shown in Table 4.7, simple t-tests show that contract manufacturers and internal plants differ in all control variables. This underlines the importance of controlling for plant characteristics when assessing quality risk.

Table 4.5: Descriptive Statistics

Name	Description	N	Mean	StDev	Min	Max
QRisk	Quality risk	154	1.08	.84	0	3.5
CM	1=Contract manufacturer	154	.50	.50	0	1
ISO9000	1=plant in Quality Digest ISO9000 database	154	.08	.27	0	1
TSales	Total company sales, \$mil-lions	154	9,213	16,926	.069	56,741
Emp	Plant employees	154	363	769	1	8000
Age	Age of plant, in years	154	43.5	40.1	2	200
OnlyReg	1=plant makes primarily regulated products	154	.40	.49	0	1
Credit	1=evidence of credit issues (4 or less in R-USA)	148	.14	.34	0	1
Public	1=public	154	.32	.47	0	1

Table 4.6: Pearson correlations (n=154)

	QRisk	CM	ISO9000	TSales	Emp	Age	OReg	Credit	Public
QRisk	1								
CM	.29***	1							
ISO9000	-.03	-.19**	1						
TSales	-.27***	-.52***	-.10	1					
Emp	-.06	-.27***	.05	.25***	1				
Age	-.10	-.34***	.01	.23***	.25***	1			
OnlyReg	.02	-.32***	-.14*	.22***	.11	.03	1		
Credit	.13	.17**	-.12	-.20**	-.14*	-.20**	.06	1	
Public	-.17**	-.55***	-.04	.68***	.34***	.35***	.25**	-.28***	1

Table 4.7: Differences in means between CMs and IPs

Name	Mean-CM	Mean-IP	t-stat	$Pr > t $
QRisk	.832	1.32	-3.79	.00
ISO9000	.026	.130	2.44	.02
TSales (\$mill)	499	1790	7.44	.00
Emp	159	568	3.42	.00
Age	30	57	4.45	.00
OnlyReg	.247	.558	4.13	.00
Credit	.195	.078	-2.139	.03
Public	.065	.584	8.22	.00

4.4 Results and Discussion

4.4.1 Multicollinearity and Leverage

We first assess the independent variables for multicollinearity, utilizing PROC REG in SAS 9.2. The variance inflation factors (vif) are all below 4, whereas a commonly used indication of multicollinearity is a vif above 10. In addition, the highest condition index in the variance-decomposition matrix is 4.1, a commonly used threshold value for this is 15 to 30. There are also no rows in the variance-decomposition matrix with two variables having a proportion of variance above 0.5, where 0.9 is the accepted threshold values. Threshold values are based on Hair et al. (1998). We can strongly conclude that multicollinearity does not present a major problem in our data set.

We also check for leverage using only the independent variables. The Hat Matrix is checked against a commonly used threshold (Hair et al., 1998). There are no observations with high leverage in the data set, indicating that no observations are highly distinct from others in terms of their overall set of independent variables. This indicates that it is unlikely that an individual observation will have too much influence over the results of any analysis.

4.4.2 Estimation Method

It is reasonable to expect that the concept of “quality risk” would have an underlying normal distribution. At the extreme left tail of the distribution are plants for which there is almost no risk of nonconforming product being released to the trade. At the extreme right of the distribution are plants knowingly and willingly releasing product that is defective (e.g., Pan Pharmaceuticals in 2003). However, our quality risk score does not capture this normal distribution for two reasons. First, our quality risk score censors true quality risk at zero. Second, the distribution of plants’ quality risk scores do not follow a normal distribution; the distribution is “lumpy.” Both the censoring and “lumpiness” can be seen in Figure 4.3. These two issues, censoring and “lumpiness,” must be dealt with in the econometric method.

The first issue is censoring. When an FDA inspector does not issue a Form 483, and the district indicates that no action is required, we score the quality risk of the plant (for that audit) as 0. However, there is considerable differentiation in actual, unobserved quality risk below this point. Said differently, plants with low levels of true quality risk would, if measured, have a negative score on our scale. These plants have quality systems that are robust enough that the FDA does not issue any action but they still have some propensity for quality problems. Reviews of inspection reports where no 483 or district action was warranted indicates that there are still often varying levels of minor quality issues observed in these “clean” audits. Thus, the dependent variable is censored at a fixed quality risk, zero. In addition to being censored, the distribution of the dependent variable is not normally distributed. A single audit can only result

in one of the seven scores on Table 4.3. And, as shown in Figure 4.4, four of those seven measures rarely happen. While averaging and adjusting for trend at the plant level helps alleviate this coarseness, Figure 4.3 shows our risk score for multiple audits does not capture an underlying normal distribution; it is a “lumpy” measure of quality risk, particularly for plants with few audits. There is a clustering of observations around the most common single-audit results (0, 1.5, 3.5). In summary, we assume that there exists a true, unmeasurable quality risk and that the FDA audits and our scoring system are imperfectly measuring a plant’s quality risk, due to censoring and “lumpiness.”

The method that can best deal with both “lumpy” measures and censoring is ordered logit. To perform this regression, we must first divide the sample into discrete categories, ordered in the dependent variable. We have created 5 categories of companies, as described in Table 4.8. Categories 2,3,4 each contain .75 units of “quality risk,” and are clearly ordered. Table 4.8 shows that there are far more very low-risk internal plants (17) than contract manufacturers (5); and, that there are far more high-risk contract manufacturers than internal plants (15-8 high risk and 11-1 very high risk). In the low and moderate risk categories, there is no statistically significant difference between the groups.

4.4.3 Econometric Specification

The econometric specification, adapted from Verbeek (2004), of the ordered logistic model for this analysis is given now (γ_j is an unknown, estimated parameter, QR_i is the quality

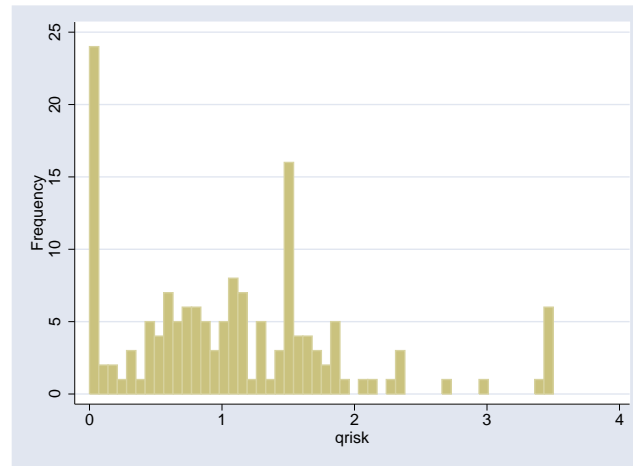


Figure 4.3: Histogram of dependent variable, quality risk (n=154)

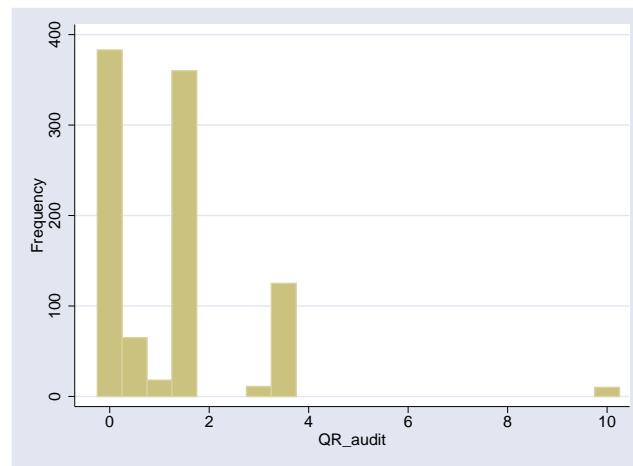


Figure 4.4: Histogram of audit-level quality risk (n=972 audits)

risk score for plant i , $i = 1$ to 154):

$$QR_i^* = \beta_1 CM_i + \beta_2 \log(Age_i) + \beta_3 \log(TSales_i) + \beta_4 \log(Emp_i) +$$

$$\beta_5 ISO9K_i + \beta_6 OReg_i + \beta_7 Public_i + \varepsilon_i$$

$$QR_i = 1 \text{ if } QR_i^* \leq \gamma_1$$

$$QR_i = 2 \text{ if } \gamma_1 < QR_i^* \leq \gamma_2$$

$$QR_i = 3 \text{ if } \gamma_2 < QR_i^* \leq \gamma_3$$

$$QR_i = 4 \text{ if } \gamma_3 < QR_i^* \leq \gamma_4$$

$$QR_i = 5 \text{ if } QR_i^* > \gamma_4$$

Table 4.8: Discrete categories for use for ordered logistic regression (qr=Qrisk)

Cat.	Qrisk Range	Description	# Plants (mean Qrisk)	#CM (mean Qrisk)	#IP (mean Qrisk)
1	$qr = 0$	Plants with all clean inspections (lowest risk)	22(0)	5(0)	17(0)
1	$0 < qr \leq .75$	Plants with generally clean inspections (low risk)	38(.49)	19(.48)	19(.50)
3	$.75 < qr \leq 1.5$	Plants which, on average, receive a 483 but no official actions	59(1.18)	27(1.21)	32(1.15)
4	$1.5 < qr \leq 2.25$	Plants with at least one official action (high risk)	23(1.77)	15(1.76)	8(1.77)
5	$qr \geq 2.25$	Plants that average close to official action (highest risk)	12(3.09)	11(3.05)	1(3.50)

The descriptions of the variables are given with the descriptive statistics in Table 4.5.

4.4.4 Results

To perform the ordered logit regression, we employed STATA 8.2’s “ologit” procedure. We used the “cluster” option to adjust the standard errors to account for correlation among plants from the same company. There are 120 companies represented by the 154 plants. The estimators are determined by maximum likelihood. Because the maximum likelihood estimators are asymptotically normally distributed, and our sample size is 154, we bootstrap the standard errors using 200 repetitions. The results are given in Table 4.9.

Table 4.9: Results of ordered logit regression (n=154)

Parameter	Estimate	StdError	t-Value	$Pr > t $	Odds Ratio
CM	1.17**	.49	2.39	.02	3.23
ISO9000	.21	.71	.30	.77	1.24
log(Age)	.20	.21	.94	.35	1.22
log(TSales)	-.20**	.10	-2.13	.03	.816
log(Emp)	.21	.15	1.39	.16	1.24
OnlyReg	.98***	.40	2.44	.02	2.67
Credit	-.04	.44	-.09	.92	.96
Public	.73	.58	1.25	.21	2.06

Wald $\chi^2 = 24.74(8)$ $p = .00$ Pseudo $R^2 = 6.2\%$

The significant Wald chi-square indicates that the omnibus effect of all variables in the model is statistically significant from zero; this indicates reasonable model fit. The McFadden’s pseudo- R^2 is 6.2%, but we note this is not comparable to that obtained in

an ordinary least squares (OLS) regression and should be interpreted with caution. For example, SAS 9.2 PROC LOGISTIC calculates a different pseudo- R^2 with a value of 16.8%. As noted in Borooah (2002), there is no natural interpretation to the values of R^2 in logistic regression.

We utilize Table 4.10 to show the marginal probability of the effect of being a contract manufacturer on quality risk. The table gives the marginal probability of being in a specific category for a plant which is average on all variables except contract manufacturer or internal plant. As further explanation, the model predicts that a plant which is average on all other variables in the analysis has a 7% chance of being in category 1 if it is a contract manufacturer, and a 20% chance of being in category 1 if is an internal plant.

Table 4.10: Marginal probability of being in category X (all other variables average)

Category	CM	IP
1	.07	.20
2	.18	.32
3	.44	.30
4	.21	.15
5	.10	.03

4.4.5 Discussion

The first thing to note from Table 4.9 is that Hypothesis 1 is supported. That is, there is a quality risk in outsourcing. Even after controlling for basic plant characteristics, being a contract manufacturer does significantly influence the quality risk of a plant. This result provides empirical support to our theoretical arguments that, due to difficulty of observing quality risk and the resulting incentives, contract manufacturers take on more

risk than internal plants, on average. The odds ratio of 3.23 for the contract manufacturer indicates that a being a contract manufacturer significantly increases the odds of ending up in the higher category of any subset of the five categories (Borooah, 2002). For example, the ratio of the probabilities of being in categories 4 or 5 over the probability of being in categories 1, 2, or 3 for a contract manufacturer is 3.23 times the same ratio for an internal plant. This odds ratio is true for any continuous subset of categories (e.g. (1), (2345); (12),(345); etc.).

Thus, due to misaligned incentives derived from the unobservability of robust quality systems, contract manufacturers pose a quality risk, even after controlling for several potentially relevant plant and firm characteristics. Firms considering outsourcing are faced with a difficult task with regard to quality. The same factor that leads to quality risk—difficulty of observing robust quality systems—makes it hard to mitigate.

The second notable result is that Hypothesis 2 is also supported. As predicted, but counter to the conventional wisdom of many, ISO 9000 certification does little to improve actual quality risk. On average, companies that have obtained the certification have not reduced their quality systems any more than those that have not. Note that this finding holds across the sample, for both internal plants and contract manufacturers.

These two results are quite tightly linked theoretically. They both result from the fact that the implementation of relatively easy-to-observe practices do not correlate directly to quality risk. The fact that ISO 9000 does not relate to quality risk indicates that cursory methods of assessing quality systems are not enough.

Not surprisingly, large companies (those with high total sales) have lower quality risk. These companies generally have the means to invest in quality assurance departments that can help create a culture of reduced risk. We note that this control variable has a relatively small coefficient and odds ratio (.82, comparable to 1.22 if direction reversed) but also a small standard error. The other control variable (only regulated products) that became significant in the regression is quite surprising, for two reasons. First, its univariate correlation with quality risk is very low and insignificant. Second, it seems producing primarily regulated products increases quality risk. One would hope the effect would be opposite; those plants producing exclusively regulated products would have better systems to reduce their quality risk. One possible explanation is that the FDA has more to observe (and therefore find) when they enter a plant with only regulated products; or, it may be possible that auditors are more stringent with these plants. This result is an opportunity for further study.

4.5 Conclusions

In this section, we first discuss limitations and some opportunities for future research. Next, we review the implications and key contributions of the research.

4.5.1 Limitations and Future Research

This study was innovative in its use of publicly available secondary data to research a question very important to operations management. We were innovative both in obtaining the data and utilizing experts and the Delphi process to transform it for use in research. The data source and approach both have some limitations, some of which can be addressed with future work. While FDA audits are thorough, standard, and designed to assess quality risk, the data available to use on the spreadsheet are a coarse filter, with essentially seven quality risk “scores” possible for a given inspection. In addition, there is variability in FDA auditors, and many audits are either focused on a specific item or for pre-approval; and therefore do not inspect an entire facility. While the regulations have been reasonably consistent since 1994, auditors may interpret them differently depending on their assessment of the risk of different drug products. Also, in determining a plant level quality risk using experts, it is possible that a different set of experts would have scored the audits differently, but this risk is somewhat reduced by the similarity of the independent panelists’ scores. Another limitation is that the reliability of most of the control variables cannot be assessed. And, even if perfectly reliable, the data are from spring 2006 but the audits date back as far as 1994; some firms and plants have changed during that time. Another limitation is that other drivers of quality are neglected in this research. For contract manufacturers, these drivers include customer expectations and practices, as well as internal practices. The theory developed in this paper may aid in designing an empirical study to assess the success of practices that mitigate quality risk in outsourcing relationships. Finally, because of the nature of the data, only industries

regulated by the Food and Drug Administration could be included in the study; and only the drug industry was included in this particular study. While a limitation, we note that the presence of regulations makes our finding of a significant difference in quality risk between contract manufacturers and internal plants more robust, as regulation should reduce the variance of quality capability across the industry.

Some of the limitations lead to opportunities for future research. The most logical next step would be to survey contract manufacturers to see what internal systems and customer behaviors seem to lower quality risk. This would fill in some of the missing explanatory variables in our model. Another opportunity is to repeat this study in other regulated industries; we have data on medical devices and biologics, and are awaiting data on food plants to possibly perform replication studies. These would assess the robustness of the results. Future work in different industries would enhance the generalizability of the findings, but a new dependent variable would need to be created.

Another area of future research is to more deeply study the dynamics of outsourcing in the drug industry. In this industry, there is a great amount of variance in the manufacturing strategies of firms. Many have outsourced all of their production; many others have maintained production in-house, many produce some product in-house and outsource other product. This study will hopefully spur future research on the implications of outsourcing in this industry.

4.5.2 Implications

This research has made several contributions to the research community. First, we have introduced an innovative plant-level measure of quality that is available in FDA-regulated industries. We hope more studies will utilize our measure of quality risk. Also, we hope this data usage spurs other creative uses of available plant-level data for research.

We have linked the quality management literature to the measurement and incentives literature, explaining the mechanisms by which outsourcing can pose a quality risk. We then tested the resulting hypothesis in a regulated industry. Detailed regulation should force both the mean and variance of quality risk to be lower than in an unregulated industry. In spite of this, we have provided evidence that outsourcing poses a quality risk in this industry. It is quite plausible that industries without rigorous external regulation may have an even more significant quality risk.

Also, we have supported theory developed in the TQM literature by showing that easy to observe practices, like those required by ISO 9000, do little to independently reduce quality risk.

Managers can learn several key things from this study. First, in spite of the efforts by some companies to ensure quality production by their contract manufacturers, contract manufacturers still pose a higher quality risk, on average. Second, we found no empirical evidence that ISO 9000 reduces this risk. Third, because the underlying mechanisms that cause the risk are difficult to eliminate, potentially costly measures must be taken to avoid taking on a higher quality risk when outsourcing. When choosing a contract

manufacturer, buying firms must thoroughly investigate potential contract manufacturers to attempt to assess the robustness of their quality. However, prior to signing a contract, full knowledge of the quality risk is not possible to observe. Some effort to reduce quality risk will be necessary on an on-going basis. As an example, one quality-conscious company sends full-time employees to observe every unit of production produced by many of its contract manufacturers. Even with careful selection and monitoring, when making an outsourcing decision, firms must understand that they are likely accepting higher quality risk, *ceteris paribus*, when they outsource than could be obtained internally.

In summary, we have shown that outsourcing to contract manufacturers results in a quality risk, on average. While extremely poor quality systems are rare even for contract manufacturers, there is more of a tendency for contract manufacturers to operate with a high quality risk than there is for internal plants. Unfortunately, evidence of documented quality systems provides little assurance of reduced quality risk.

Chapter 5

Dissertation Conclusion

This dissertation has investigated the interface between manufacturing outsourcing and plant-level operations characteristics. As most literature on outsourcing has originated from economics and strategy, plant-level characteristics are often ignored (Ferdows, 2006). We studied the interface in three distinct essays. Essays 1 and 3 showed how the consideration of important plant-level characteristics affects outsourcing decisions and outcomes. These plant-level characteristics included manufacturing plant learning rate (Essay 1) and the robustness of quality systems (Essay 3). Essay 2 studied how the importance and current capability of two classic operations competitive dimensions affects outsourcing decisions. Together, these three essays have shown various ways that the failure to consider operations characteristics in outsourcing decisions can lead to suboptimal decision-making.

The first essay focused on two path-dependent aspects of outsourcing decisions in a two-period model. One path-dependent aspect of outsourcing decisions is the presence of learning-by-doing. That is, we make the common assumption that when a plant produces

product it may lower its per-unit costs; and, when a plant does not produce a product it cannot lower its costs. The second path-dependent aspect is the presence of a strategic supplier who will not necessarily pass on production cost reductions to the buyer in future periods. Together, these factors greatly change the analysis for an outsourcing decision-maker. If not considered together, the decision-maker would be more likely to outsource, and will do so at a higher per-unit price. We also show that is often optimal under reasonable circumstances for a manufacturer to keep production in-house even when he can never reach the supplier's costs, for purely strategic purposes. We also find that partial outsourcing is optimal in reasonable circumstances. And, we observe many interesting dynamics about the effect of each player's learning rate on strategies.

The second essay looked at how current operations strategy at a business-unit level impacted plans to outsource manufacturing resources. Here, we study the characteristics (cost and quality) of operations function as an antecedent to outsourcing decisions. As noted, studies have only relatively recently explicitly considered competitive capabilities at all in outsourcing decisions. The most well-developed theories look only at product and market characteristics. In this essay, we show using structural equation modeling on a sample of 867 business units, that cost considerations drive decisions, not quality. Both the importance that a company puts on cost and its current capability significantly affect a firm's plans to outsource. Counter to conventional wisdom, quality has no affect. This is consistent with practitioner literature that has shown cost to be the driver of outsourcing decisions.

The third essay builds on the second essay by showing that quality should matter

in outsourcing decisions. Why? Because outsourcing poses a quality risk. We show this using Food and Drug Administration inspection data of internal plants and contract manufacturers. Further, we showed that ISO 9000 certification did not mitigate this risk. We argue that no simple inspection or "checklist" type system will, by itself, fully mitigate the quality risk in outsourcing. The results of this essay tell managers that they must be sure to incorporate the cost of quality risk into any outsourcing decisions.

We started this dissertation by noting that outsourcing decisions are among the most challenging and important that managers must make. We finish this dissertation hoping that we have shed some light on some of the more difficult aspects of the decision: learning, quality, and capabilities. Managers can easily assess an outsourcing decision's likely impact on per-unit cost, return on assets, etc. But, we believe that short-term metrics are not the ones that lead to sustained competitive advantage in healthy companies. We have demonstrated that some important and often taken for granted benefits of internal production (learning-by-doing, quality) may be lost if outsourcing is pursued carelessly.

We have contributed to the economic theory of outsourcing by explicitly incorporating vital operations capabilities into the discussion and, therefore, have begun to open the "black box." Key gaps in the current theories of firm boundaries are the inclusion of firm-specific characteristics in the antecedents (Essay 2), and the consideration of longer-term (Essay 1) and harder-to-measure (Essay 3) consequences of outsourcing decisions. Hayes et al. (2005) posed the question: "Under what conditions should an organization vertically integrate, and under what conditions should it outsource?" (p.116). We've shown that, while cost considerations are the key decision drivers in practice (Essay 2),

companies should outsource with caution if the supplier may gain power in the relationship or internal learning rate is high (Essay 1). We have also shown that they should also be careful if exposure to quality risk is important (Essay 3).

Limitations were discussed in each essay, but we discuss broad limitations now. The environment faced by managers is far more complicated than that modeled in Essay 1. However, the lessons from Essay 1 should ring true. It is a good starting point for assessing the temporal impacts of outsourcing in a game theoretic setting. Essay 2 showed what managers *actually* plan to do, but does not tell us what they, in fact, should do. Essay 3's empirical results indicate that a quality risk is more prevalent in contract manufacturing plants versus internal plants. However, we did not get to the depth necessary to understand the variance within the groups. Finally, each essay looked at a piece of an outsourcing decision. A complete theory would allow managers to understand how each characteristic of their firm, product, and market impact their decision. While we are a long way from that point, we will continue to strive to completely understand the conditions under which firms should outsource. As many outcomes of firm boundary decisions take years to manifest themselves, detailed longitudinal data would likely be necessary to empirically test a complete economic theory of outsourcing.

Using this dissertation as a starting point, we plan to continue to fill gaps in the economic theory of manufacturing outsourcing with a focus on outsourcing's impact on manufacturing competitiveness. An important gap in our understanding is in the area of innovation. Conventional wisdom has companies outsourcing manufacturing to focus on innovation, but we believe that in many industries manufacturing knowledge

is essential for innovation. We hope to study outsourcing's impact on innovation in the future. Additionally, we plan to utilize our quality risk metric to study the impact of outsourcing on quality in other industries, and we hope to obtain foreign audit data to study how offshoring differs from outsourcing. Also, we hope to supplement Essay 3 with surveys of contract manufacturers to determine what buyer behaviors lead to reduced quality risk. Finally, we hope to combine our longitudinal quality data with other available longitudinal data to understand the long term effects of outsourcing on all manufacturing capabilities. These are ambitious goals, but understanding the conditions when firms should outsource is critically important.

Chapter 6

Appendix

6.1 Essay 1 Appendices

6.1.1 Proof of Proposition 1

In the second period, $\Pi(q_m^2, s_m^2) = (s_m^2)(\frac{1}{b})(a - s_m^2) - c_m^2 q_m^2$, subject to $s_m^2 \leq q_m^2$. We see that $\frac{\partial \Pi}{\partial q_m^2} = -c_m^1 < 0$ for all $q_m^2 > s_m^2$. Thus, $q_m^2 = s_m^2$ and the production and sales problem therefore collapses to a single variable (e.g. production) maximization problem with a concave objective function. Solving, $q_m^{2*} = \frac{a - bc_m^2}{2}$ and the period 2 profit is $\frac{\delta}{4b}(a - bc_m^2)^2$ where $c_m^2 = \text{Max}(c_m^1 - \gamma_m q_m^1, \underline{c}_m)$. The manufacturer's total profit is given by:

$$\Pi(s_m^1, q_m^1) = \begin{cases} (s_m^1)(\frac{1}{b})(a - s_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2, & q_m^1 < \underline{q}_m \\ (s_m^1)(\frac{1}{b})(a - s_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2, & q_m^1 \geq \underline{q}_m \end{cases}$$

For any $q_m^1 > 0$, $\Pi(s_m^1, q_m^1)$ is concave in s_m^1 , and $s_m^{1*} = \text{Min}(q_m^1, \frac{a}{2})$. It is now necessary to show that $q_m^1 \leq \frac{a}{2}$. Substituting s_m^{1*} into $\Pi(s_m^1, q_m^1)$, we obtain:

$$\Pi(q_m^1) = \begin{cases} (q_m^1)(\frac{1}{b})(a - q_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2 & \text{if } q_m^1 < \underline{q}_m \text{ \& } q_m^1 < \frac{a}{2} \\ (q_m^1)(\frac{1}{b})(a - q_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2 & \text{if } q_m^1 \geq \underline{q}_m \text{ \& } q_m^1 < \frac{a}{2} \\ \frac{a^2}{4b} - q_m^1 c_m^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2 & \text{if } q_m^1 < \underline{q}_m \text{ \& } q_m^1 \geq \frac{a}{2} \\ \frac{a^2}{4b} - q_m^1 c_m^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2 & \text{if } q_m^1 \geq \underline{q}_m \text{ \& } q_m^1 \geq \frac{a}{2} \end{cases}$$

The restriction $\gamma_m \leq \frac{2}{b\sqrt{\delta}}$ makes $\Pi(q_m^1), q_m^1 < \underline{q}_m \text{ \& } q_m^1 < \frac{a}{2}$ concave. Across all q_m^1 , $\Pi(q_m^1)$ is continuous but not necessarily concave.

If $\frac{a}{2} > \underline{q}_m$, then $\Pi(q_m^1)$ is concave and $\frac{\partial \Pi}{\partial q_m^1} |_{q_m^1 \geq \frac{a}{2}} < 0$; this proves that $s_m^1 = q_m^1$ for this case. If $\frac{a}{2} < \underline{q}_m$, then $\Pi(q_m^1)$ is not concave in q_m^1 . For $q_m^1 < \frac{a}{2}$, the function is concave in q_m^1 . For $\frac{a}{2} \leq q_m^1 \leq \underline{q}_m$, the function is convex in q_m^1 . For $q_m^1 \geq \underline{q}_m$, the function is strictly decreasing in q_m^1 . To prove that $s_m^1 = q_m^1$, we only need to show that $\frac{\partial \Pi}{\partial q_m^1} < 0$ for the region $\frac{a}{2} \leq q_m^1 \leq \underline{q}_m$. Due to convexity, $\frac{\partial \Pi}{\partial q_m^1} < 0$ in this region if $\frac{\partial \Pi}{\partial q_m^1} |_{q_m^1 = \underline{q}_m} < 0$. It is if $c_m^1 > \frac{\delta \gamma_m a}{2} - \frac{\delta \gamma_m b \underline{c}_m}{2}$. But, for this profit region to exist, $\underline{q}_m > \frac{a}{2}$, or $c_m^1 > \frac{a \gamma_m}{2} + \underline{c}_m$. Since $\frac{a \gamma_m}{2} + \underline{c}_m > \frac{\delta \gamma_m a}{2} - \frac{\delta \gamma_m b \underline{c}_m}{2}$, then the existence of the profit region $\underline{q}_m > q_m^1 > \frac{a}{2}$ implies the condition that profit is decreasing throughout it. Hence, $s_m^1 = q_m^1$, always.

6.1.2 Proof of Theorem 1

(i) Given Proposition 1, we can restrict attention to $q_m^1 \leq \frac{a}{2}$. In this region, the manufacturer's profit function is:

$$\Pi(q_m^1) = \begin{cases} (q_m^1)(\frac{1}{b})(a - q_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2, & q_m^1 < \underline{q}_m \\ (q_m^1)(\frac{1}{b})(a - q_m^1) - q_m^1 c_m^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2, & q_m^1 \geq \underline{q}_m \end{cases}$$

Given $\gamma_m \leq \frac{2}{b\sqrt{\delta}}$, we see that $\Pi(q_m^1)$ is strictly concave in q_m^1 . The relevant interior optima are $q_m^1 = \frac{(2+b\delta\gamma_m)(a-bc_m^1)}{4-\delta b^2\gamma_m^2} \leq \underline{q}_m$ and $q_m^1 = \frac{a-bc_m^1}{2} > \underline{q}_m$. Other possible optima are boundary conditions. Basic assumptions on parameters make $\frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=0} > 0$ and $\frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=\frac{a}{2}} < 0$. The necessary and sufficient conditions to determine the optimal strategies are listed in Theorem 1, Tables 2.1 and 2.2.

(ii) We first observe that $Ag > Cg > 0$, by inspection. Also, $Ag > Bg$ since $\frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=\underline{q}_m^-} > \frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=\underline{q}_m^+}$. That is, it takes a smaller value of γ_m to make $\frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=\underline{q}_m^-} = 0$ than it does to make $\frac{\partial \Pi}{\partial q_m^1} \big|_{q_m^1=\underline{q}_m^+} = 0$. Thus, Strategy A1 is always employed when $\gamma_m = 0$. Strategy C1 is always employed for large γ_m . And, since $Ag > Bg$ and $Ag > Cg$, Strategy B1 is always employed in between.

6.1.3 Proof of Proposition 2

(i) The supplier's second period profit function is $\Pi(w^2) = (w^2 - c_s^2)(\frac{a-bw^2}{2})$ subject to $w^2 \leq c_m^2$. This function is concave in w^2 and the optimal is $w^{2*} = \text{Min}(c_m^2, \frac{a}{2b} + \frac{c_s^2}{2})$. We have assumed that $c_m^1 \leq \frac{a}{2b} + \frac{c_s}{2}$. Since $c_s^2 \geq \underline{c}_s$ and $c_m^2 \leq c_m^1$, we know that $c_m^2 \leq w^{2*}$. Thus, $\frac{\partial \Pi}{\partial w^2} > 0$ for the entire relevant range up to c_m^2 , and therefore c_m^2 is optimal.

(ii) Substituting c_m^2 into the profit function from (i), $\Pi(c_m^2) = (c_m^2 - c_s^2)(\frac{a-bc_m^2}{2})$. The first term is negative if $c_m^2 < c_s^2$ and non-negative otherwise. The second term is always non-negative given prior assumptions. The supplier will therefore participate if and only if $c_m^2 \geq c_s^2$ so she will earn non-negative profit.

(iii) Faced with $w^2 = c_m^2$, and our assumption that, if indifferent, the manufacturer will buy, the manufacturer's second period profit function is: $(a - q_s^2)(1/b)(q_s^2) - c_m^2 q_s^2$ subject to nonnegativity. The manufacturer's optimal decision is $q_s^2 = \frac{a-bc_m^2}{2}$ and the resulting profit is $\frac{(a-bc_m^2)^2}{4b}$. In the case where the supplier does not make an offer, the optimization is the same, except q_m^2 replaces q_s^2 .

6.1.4 Proof of Proposition 3

Purchasing a unit to dispose will have no first-period benefit for the manufacturer and cost $w^1 > 0$. By (iii) in Proposition 2, this purchase will also have no second-period benefit.

6.1.5 Proof of Proposition 4

As a result of Proposition 2, the manufacturer's profit function in the first period is $\Pi(q_m^1, q_s^1, s_m^1) = (s_m^1)(1/b)(a - s_m^1) - c_m^1 q_m^1 - w^1 q_s^1 + \delta \frac{(a-bc_m^2)^2}{4b}$ subject to $s_m^1 \leq q_m^1 + q_s^1$ where $c_m^2 = \text{Max}(c_m^1 - \gamma_m q_m^1, \underline{c}_m)$. Thus, the manufacturer's total profit function is given

by:

$$\Pi(s_m^1, q_s^1, q_m^1) = \begin{cases} (s_m^1)(\frac{1}{b})(a - s_m^1) - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2, & q_m^1 < \underline{q}_m \\ (s_m^1)(\frac{1}{b})(a - s_m^1) - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2, & q_m^1 \geq \underline{q}_m \end{cases}$$

One can show $s_m^{1*} = \text{Min}((q_m^1 + q_s^1)\frac{a}{2})$. Substituting s_m^{1*} into $\Pi(s_m^1, q_s^1, q_m^1)$, we obtain:

$$\Pi(q_m^1, q_s^1) = \begin{cases} (q_m^1 + q_s^1)(\frac{1}{b})(a - q_m^1 - q_s^1) - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2, \\ \quad \text{if } q_m^1 < \underline{q}_m \text{ \& } (q_m^1 + q_s^1) < \frac{a}{2} \\ (q_m^1 + q_s^1)(\frac{1}{b})(a - q_m^1 - q_s^1) - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2, & q_m^1 \geq \underline{q}_m \text{ \& } (q_m^1 + q_s^1) < \frac{a}{2} \\ \frac{a^2}{4b} - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - bc_m^1 + b\gamma_m q_m^1)^2, & q_m^1 < \underline{q}_m \text{ \& } (q_m^1 + q_s^1) \geq \frac{a}{2} \\ \frac{a^2}{4b} - q_m^1 c_m^1 - q_s^1 w^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2, & q_m^1 \geq \underline{q}_m \text{ \& } (q_m^1 + q_s^1) \geq \frac{a}{2} \end{cases}$$

For all four of the above profit functions, $\frac{\partial \Pi}{\partial q_m^1} > \frac{\partial \Pi}{\partial q_s^1}$ if $w^1 > c_m^1$ for any possible value of q_m^1 or q_s^1 . Therefore, the manufacturer will never buy in period 1 if $w^1 > c_m^1$.

6.1.6 Proof of Theorem 2

(i) The manufacturer is not learning so clearly he will not engage in strategic overproduction, and so $s_m^1 = q_m^1 + q_s^1$. $z_s^1 = 0$ is proven in section (iii).

(ii) The supplier will only participate if $\Pi_s(w^1) > 0$. We will show in (iii) that $w^{1*} = c_m^1$.

Therefore, the supplier's profit function is:

$$\Pi_s = \begin{cases} (c_m^1 - c_s^1)(\frac{a-bc_m^1}{2}) + \delta(c_m^1 - c_s^1 + \gamma_s \frac{a-bc_m^1}{2})(\frac{a-bc_m^1}{2}) & \text{if } c_s^1 - \gamma_s \frac{a-bc_m^1}{2} > \underline{c}_s \\ (c_m^1 - c_s^1)(\frac{a-bc_m^1}{2}) + \delta(c_m^1 - \underline{c}_s)(\frac{a-bc_m^1}{2}) & \text{if } c_s^1 - \gamma_s \frac{a-bc_m^1}{2} \leq \underline{c}_s \end{cases}$$

Simply setting each of these profit functions equal to zero and solving for c_s^1 yields the result.

(iii) Given Proposition 2, we know $w^2 = c_m^1$. Therefore, the manufacturer's profit function is $\Pi_m(q_m^1, q_s^1) = (a - q_m^1 - q_s^1)(1/b)(q_m^1 + q_s^1) - w^1 q_s^1 - c_m^1 q_m^1 + \delta \frac{(a-bc_m^1)^2}{4b}$ subject to non-negativity of q_m^1 and q_s^1 . It can be shown that the optima are $q_m^1 = \frac{a-bc_m^1}{2}$, $q_s^1 = 0$ if $w^1 > c_m^1$, and $q_m^1 = 0$, $q_s^1 = \frac{a-bw^1}{2}$ if $w^1 \leq c_m^1$.

If $w^1 > c_m^1$, then the supplier gets no business in the first period per Proposition 4. Since all conditions will be the same in the second period, she will also get no business in the second period. If the supplier gets all of the business in the first period, she also gets all of the business in the second period. In the second period, the manufacturer will be maximizing a single period profit function. Therefore, $q_s^2 = \frac{a-bw^2}{2}$ if $q_s^1 > 0$. Also, because of Proposition 2, $w^2 = c_m^2 = c_m^1$. Thus, the supplier's profit function (given $w^1 \leq c_m^1$) is $\Pi_s(w^1, z_s^1) = (w^1 - c_s^1) \frac{a-bw^1}{2} - c_s^1 z_s^1 + \delta(c_m^1 - c_s^1) \frac{a-bc_m^1}{2}$ where $c_s^2 = \text{Max}(c_s^1 - \gamma_s(\frac{a-bw^1}{2} + z_s^1), \underline{c}_s)$. Therefore, for $w^1 \leq c_m^1$:

$$\Pi_s(w^1, z_s^1) = \begin{cases} (w^1 - c_s^1) \frac{a-bw^1}{2} - c_s^1 z_s^1 + \delta(c_m^1 - c_s^1 + \gamma_s(\frac{a-bw^1}{2} + z_s^1)) \frac{a-bc_m^1}{2} \\ \text{if } w^1 > \frac{a}{b} - 2 \frac{c_s^1 - \underline{c}_s}{b\gamma_s} + \frac{2z_s^1}{b} \\ (w^1 - c_s^1) \frac{a-bw^1}{2} - c_s^1 z_s^1 + \delta(c_m^1 - \underline{c}_s) \frac{a-bc_m^1}{2} & \text{if } w^1 \leq \frac{a}{b} - 2 \frac{c_s^1 - \underline{c}_s}{b\gamma_s} + \frac{2z_s^1}{b} \end{cases}$$

We first note that:

$$\frac{\partial \Pi_s(w^1, z_s^1)}{\partial z_s^1} = \begin{cases} -c_s^1 + \delta \gamma_s \frac{a-bc_m^1}{2}; \text{ if } w^1 > \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s} + \frac{2z_s^1}{b} \\ -c_s^1 \text{ if } w^1 \leq \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s} + \frac{2z_s^1}{b} \end{cases}$$

Given the above, we solve this problem under two exhaustive and mutually exclusive situations, (1) and (2).

(1) $\delta \gamma_s \frac{a-bc_m^1}{2} \leq c_s^1$, thus $\frac{\partial \Pi(w^1, z_s^1)}{\partial z_s^1} < 0$; and the optimal z_s^1 is always equal to 0; the profit function becomes:

$$\Pi(w^1) = \begin{cases} (w^1 - c_s^1) \frac{a-bw^1}{2} + \delta(c_m^1 - c_s^1 + \gamma_s \frac{a-bw^1}{2}) \frac{a-bc_m^1}{2} \text{ if } w^1 > \frac{a}{b} - \frac{c_s^1 - \underline{c}_s}{b\gamma_s} \\ (w^1 - c_s^1) \frac{a-bw^1}{2} + \delta(c_m^1 - \underline{c}_s) \frac{a-bc_m^1}{2} \text{ if } w^1 \leq \frac{a}{b} - \frac{c_s^1 - \underline{c}_s}{b\gamma_s} \end{cases}$$

(1a) $c_m^1 \leq \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s} \Rightarrow w^1 \leq \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$; this implies the profit function above is increasing in w^1 and $w^{1*} = c_m^1$.

(1b) If $c_m^1 > \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$, then the above profit function is continuous and concave in w^1 . We prove $w^{1*} = c_m^1$ by showing that $c_m^1 > \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$, along with our assumption $c_m^1 < \frac{a}{2b} + \frac{\underline{c}_s}{2}$, implies $\frac{\partial \Pi}{\partial w^1} |_{w^1=c_m^1} > 0$. We can rewrite $c_m^1 > \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$ as $c_s^1 > \gamma_s \frac{a-bc_m^1}{2} + \underline{c}_s$. We can rewrite $c_m^1 < \frac{a}{2b} + \frac{\underline{c}_s}{2}$ as $\underline{c}_s > 2c_m^1 - \frac{a}{b}$. Therefore, $c_s^1 > \gamma_s \frac{a-bc_m^1}{2} + 2c_m^1 - \frac{a}{b}$. This implies $c_s^1 > \delta \gamma_s \frac{(a-bc_m^1)}{2} + 2c_m^1 - \frac{a}{b}$, (since $0 \leq \delta \leq 1$) which is our condition for $\frac{\partial \Pi}{\partial w^1} |_{w^1=c_m^1} > 0$.

(2) $\delta \gamma_s \frac{a-bc_m^1}{2} > c_s^1$. The optimal z_s^1 may not necessarily equal to zero. Here, if

$c_s^1 < \delta \gamma_s \frac{a-bc_m^1}{2}$ (which defines this situation), then $c_s^1 < \gamma_s \frac{a-bc_m^1}{2} + 2\underline{c}_s$ (since $0 \leq \delta \leq 1$ and $\underline{c}_s \geq 0$); this is just $c_m^1 \leq \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$ rewritten. Since $w^1 \leq c_m^1$, the condition that makes $z_s^1 > 0$ possible, also means that the profit function where $\frac{\partial \Pi}{\partial z_s^1} > 0$ is possible cannot happen. We have already shown that for the profit function when $w^1 \leq \frac{a}{b} - 2\frac{c_s^1 - \underline{c}_s}{b\gamma_s}$ that $w^1 = c_m^1$ is optimal. Thus, $w^1 = c_m^1$ is the optimum if the supplier can participate.

(iv) In this case, neither party is learning. The problem separates into two single-period problems. It is straightforward to show that the results of remark 1 apply.

6.1.7 Proof of Corollary 1

Follows immediately from Theorem 2; the supplier always charges $w^1 = w^2 = c_m^1$. Therefore, (i), she gets weakly lower costs in period 2 with more learning; and, (ii) the manufacturer's profit is the same whether the supplier participates or not, and regardless of the value of γ_s .

6.1.8 Proof of Theorem 3

(i) Since the supplier is not learning, if $c_s^1 > c_m^1$, then for the supplier to make money w^1 or w^2 will need to be greater than c_m^1 . But, the manufacturer will not buy if this is the case, as shown in Proposition 4.

(ii) & (iii) We first solve for the manufacturer's response (i.e., production and purchase quantities) for any given wholesale price w^1 . In solving for the manufacturer's response, we first solve $q_m^1(q_s^1)$, which is the optimum production quantity given a purchase quantity.

Table 6.1: Possible optima: Only manufacturer learns

$q_m^{1*}(q_s^1)$	q_s^1 condition
0	$q_s^1 \geq \frac{a-bc_m^1}{2}(1 + \frac{b\delta\gamma_m}{2})$
k	$\frac{a-bc_m^1}{2}(1 + \frac{b\delta\gamma_m}{2}) - (b^2\delta\gamma_m^2 - 4)\frac{c_m^1 - \underline{c}_m}{4\gamma_m} \leq q_s^1 < \frac{a-bc_m^1}{2}(1 + \frac{b\delta\gamma_m}{2})$ & $\frac{a}{2} - q_s^1 > \underline{q}_m$
k	$\frac{a}{2} - \frac{2c_m^1}{b\delta\gamma_m^2} + \frac{1}{b\gamma_m}(a - bc_m^1) \leq q_s^1 < \frac{a-bc_m^1}{2}(1 + \frac{b\delta\gamma_m}{2})$ & $\frac{a}{2} - q_s^1 \leq \underline{q}_m$
\underline{q}_m	$\frac{a-bc_m^1}{2} - \frac{c_m^1 - \underline{c}_m}{\gamma_m} \leq q_s^1 < \frac{a-bc_m^1}{2}(1 + \frac{b\delta\gamma_m}{2}) - (b^2\delta\gamma_m^2 - 4)\frac{c_m^1 - \underline{c}_m}{4\gamma_m}$ & $\frac{a}{2} - q_s^1 > \underline{q}_m$
\underline{q}_m	$q_s^1 < \frac{a}{2} - \frac{2c_m^1}{b\delta\gamma_m^2} + \frac{1}{b\gamma_m}(a - bc_m^1)$ & $\Pi(\underline{q}_m) > \Pi^*(q_m^1 < \frac{a}{2} - q_s^1)$ & $\frac{a}{2} - q_s^1 \leq \underline{q}_m$
$\frac{a-bc_m^1}{2} - q_s^1$	$q_s^1 < \frac{a-bc_m^1}{2} - \frac{c_m^1 - \underline{c}_m}{\gamma_m}$ & $\frac{a}{2} - q_s^1 > \underline{q}_m$
$k = \frac{(a-bc_m^1)(2+b\delta\gamma_m)}{4-b^2\delta\gamma_m^2} - \frac{4q_s^1}{4-b^2\delta\gamma_m^2}$	

The manufacturer's profit function is given in Proposition 4.

We first solve for $q_m^{1*}(q_s^1)$ as in Proposition 4. $\Pi(q_m^1, q_s^1)$ is again continuous but not necessarily concave. If $\frac{a}{2} - q_s^1 > \underline{q}_m$, then $\Pi(q_m^1, q_s^1)$ is continuous and concave in q_m^1 . Relevant $q_m^{1*}(q_s^1)$ are given in Table 6.1. In this case, $\frac{\partial \Pi}{\partial q_m^1} < 0$ if $q_m^1 > \frac{a}{2} - q_s^1$, so $s_m^1 = q_m^1 + q_s^1$. If $\frac{a}{2} - q_s^1 < \underline{q}_m$, then $\Pi(q_m^1, q_s^1)$ is continuous but not concave in q_m^1 . For $q_m^1 < \frac{a}{2} - q_s^1$, $\Pi(q_m^1, q_s^1)$ is concave in q_m^1 . For $\frac{a}{2} - q_s^1 < q_m^1 < \underline{q}_m$, the profit function is convex in q_m^1 . For $q_m^1 > \underline{q}_m$, the profit function is strictly decreasing in q_m^1 . The possible $q_m^{1*}(q_s^1)$ are given in Table 6.1.

Note that s_m^1 is zero in all cases above except when $q_m^1 \leq \underline{q}_m$ & $q_m^1 > \frac{a}{2} - q_s^1$, in which case s_m^1 is equal to $q_m^1 - (\frac{a}{2} - q_s^1)$. We note that if $w^1 > c_m^1$, then $q_s^{1*} = 0$ and q_m^1 is determined by Theorem 1. The remainder of this proof covers the case where $w^1 \leq c_m^1$, $\Pi(q_s^1)$ is continuous but neither concave nor convex.

Having solved for $q_m^{1*}(q_s^1)$, we now solve for the optimal q_s^1 . This will then completely characterize the manufacturer's response function for a given w^1 . $\Pi_m(q_s^1)$, which is continuous but neither concave nor convex, is given now (k is defined in Table 6.1).

$$\Pi_m(q_s^1) = \begin{cases} (q_s^1)(\frac{1}{b})(a - q_s^1) - q_s^1 w_1 + \frac{\delta}{4b}(a - bc_m^1)^2 \text{ if } q_{m1}^*(q_s^1) = 0 \\ (q_s^1 + k)(\frac{1}{b})(a - q_s^1 - k) - kc_m^1 - q_s^1 w_1 + \frac{\delta}{4b}(a - b(c_m^1 - \gamma_m(k)))^2 \\ \text{if } q_{m1}^*(q_s^1) = k \\ (q_s^1 + \underline{q}_m)(\frac{1}{b})(a - q_s^1 - \underline{q}_m) - q_s^1 w_1 - \underline{q}_m c_m^1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2 \\ \text{if } q_{m1}^*(q_s^1) = \underline{q}_m \& \frac{a}{2} - q_s^1 \geq \underline{q}_m \\ \frac{a^2}{4b} - \underline{q}_m c_m^1 - q_s^1 w_1 + \frac{\delta}{4b}(a - b\underline{c}_m)^2 \text{ if } q_{m1}^*(q_s^1) = \underline{q}_m \& \frac{a}{2} - q_s^1 < \underline{q}_m \\ \frac{a-bc_m^1}{2}(\frac{1}{b})\frac{a+bc_m^1}{2} - (\frac{a-bc_m^1}{2} - q_s^1)c_m^1 - q_s^1 w_1 + \frac{\delta}{4b}(a - b(c_m^1 - \gamma_m(\frac{a-bc_m^1}{2} - q_s^1)))^2 \\ \text{if } q_{m1}^*(q_s^1) = \frac{a-bc_m^1}{2} - q_s^1 \end{cases}$$

We first consider case (1) where $\frac{a-bc_m^1}{2} - \underline{q}_m > 0$, or where $\frac{a-bc_m^1}{2} - \underline{q}_m \leq 0$ but $\frac{a}{b} - \underline{q}_m > 0$ and $w_{c1} \leq \frac{a}{b} - \underline{q}_m$. We use c1 to denote the conditions that lead to this case. We now solve for the optimum q_s^1 for a given w^1 for this case. Recall that $q_m^1(q_s^1)$ has already been specified above. There are three mutually exclusive and exhaustive sets of parameters that need to be considered within this case (1a, 1b and 1c).

(1a) If $c_m^1 > \frac{\delta\gamma_m}{2}(a - b\underline{c}_m)$, then $s_m^1 = q_m^1 + q_s^1$ because this condition directly implies that for $q_m^1 = \underline{q}_m > \frac{a}{2} - q_s^1$ $\frac{\partial \Pi(q_m^1, q_s^1)}{\partial (q_m^1)} < 0$. In this case, the profit function is continuous and has concave and convex regions. It is strictly decreasing as $q_s^1 \rightarrow \infty$ and increasing at $q_s^1 = 0$ with two local maxima in between. The two local maxima occur at $q_s^1 = \frac{a-bw^1}{2} - \underline{q}_m$ and $q_s^1 = \frac{a-bw^1}{2}$. One can show that if $w^1 \leq w_{c1}$ then $q_s^1 = \frac{a-bw^1}{2}$ is optimal, and if $w^1 > w_{c1}$ then $q_s^1 = \frac{a-bw^1}{2} - \underline{q}_m$ is optimal. Table 6.2 gives the value of w_{c1} . (1b) If $\frac{\delta\gamma_m}{2}(a - bc_m^1) < c_m^1 \leq \frac{\delta\gamma_m}{2}(a - b\underline{c}_m)$, the same two maxima with the same condition on w^1

Table 6.2: w_c values: only manufacturer learns

w_c name	value
w_{c1}	$c_m^1 - \frac{\delta}{2\gamma_m}(a - \frac{bc_m^1}{2} - \frac{b\underline{c}_m}{2})$
w_{c2}	$\frac{a}{b} - \sqrt{c_m^1 - \underline{c}_m} \sqrt{(-4c_m^1 - 4bc_m^1\gamma_m - b(-2a + b(c_m^1 + \underline{c}_m))\delta\gamma_m^2 + 4(\underline{c}_m + a\gamma_m))}$
w_{c3}	$\frac{a}{b} - \frac{\sqrt{-(a-bc_m^1)^2(2+b\delta\gamma_m)^2(-4+b^2\delta\gamma_m^2)}}{b(4-b^2\delta\gamma_m^2)}$

result, but the proof required additional steps. To prove this, we showed by contradiction that the conditions on q_s^1 that made the profit with strategic overproduction greater than that without, could not exist where they would be relevant. Details are available.(1c)

$c_m^1 \leq \frac{\delta\gamma_m}{2}(a - bc_m^1)$; in this case, the function is concave with one interior maximum, $q_s^{1*} = \frac{a-bw^1}{2} - \underline{q}_m$.

(2) Next, we consider $\Pi(q_s^1)$ for the case where $\frac{a-bc_m^1}{2} - \underline{q}_m \leq 0$ and either $\frac{a}{b} - \underline{q}_m \leq 0$ or $w_{c1} > \frac{a}{b} - \underline{q}_m$. In this case, there is only one positive (i.e., $q_s^1 > 0$) local maximum in $\Pi(q_s^1)$. This maximum occurs at $q_s^1 = \frac{a-bw^1}{2}$. However, this needs to be compared to the profit at $q_s^1 = 0$. At $q_s^1 = 0$, $q_m^1(q_s^1)$ will be either \underline{q}_m or $\frac{(a-bc_m^1)(2+b\delta\gamma_m)}{4-b^2\delta\gamma_m^2}$ depending on the conditions given in Table 6.1 at $q_s^1 = 0$. We use c2 to denote the conditions where $q_s^1 = 0$ results in $q_m^1(q_s^1) = \underline{q}_m$, and we use c3 to denote conditions where $q_s^1 = 0$ and $q_m^1(q_s^1) = \frac{(a-bc_m^1)^2(1+\delta+b\delta\gamma_m)}{b(4-b^2\delta\gamma_m^2)}$. Under conditions c2, it can be shown that for $w^1 \leq w_{c2}$, $q_s^1 = \frac{a-bw^1}{2}$ and for $w^1 > w_{c2}$, $q_s^1 = 0$. Under conditions c3, then for $w^1 \leq w_{c3}$, $q_s^1 = \frac{a-bw^1}{2}$ and for $w^1 > w_{c3}$, $q_s^1 = 0$

Having solved for the manufacturer's response, we now solve for the supplier's optimal

wholesale price, w^1 . Given the above, the supplier's total profit function is as follows:

$$\Pi_s(w^1) = \begin{cases} (w^1 - c_s^1)(\frac{a-bw^1}{2}) + \delta(c_m^1 - c_s^1)(\frac{a-bc_m^1}{2}) & \text{if } w^1 \leq w_c \\ (w^1 - c_s^1)(\frac{a-bw^1}{2} - \underline{q}_m) + \text{Max}(0, \delta(\underline{c}_m - c_s^1))(\frac{a-b\underline{c}_m}{2}) & \text{if } w_{c1} < w^1 \leq c_m^1 \text{ and } c1 \text{ applies} \\ 0 & \text{if } w^1 > c_m^1, \text{ or } w^1 > w_{c2} \text{ and } c2 \text{ applies, or } w^1 > w_{c3} \text{ and } c3 \text{ applies} \end{cases}$$

Conditions ci $i=(1,2,3)$ refer to the conditions used to determine the manufacturer's response function earlier in this proof. This profit function is discontinuous at $w^1 = w_c$. For $w^1 \leq w_c$, the optimal w^1 is always w_c due to similar arguments as in Theorem 2. Thus, under conditions $c2$ and $c3$ the supplier charges w_{c2} and w_{c3} if she can profitably do so.

Under conditions $c1$, for $w^1 > w_{c1}$ residual business is obtained. Within each region ($w^1 \leq w_{c1}$ and $w_{c1} < w^1 \leq c_m^1$), the supplier profit function is concave in w^1 . For $w_{c1} < w^1 \leq c_m^1$, there is one interior optimum, $w^1 = \frac{a}{2b} + \frac{c_s^1}{2} - \frac{1}{b} \frac{c_m^1 - \underline{c}_m}{\gamma_m}$ and the two boundaries ($w_e = w_{c1} + \varepsilon$ and c_m^1). The optimum of this region can be found using boundary conditions, and then must be compared to the profit at $w^1 = w_c$ when all business is obtained. When $\underline{c}_m < c_s^1$, it is straightforward to show that the supplier will never charge w_e to get only residual business. But, when $\underline{c}_m \geq c_s^1$, the supplier may charge w_e to get only residual business.

Note that $w_{c1} \leq c_m^1$ always. Also, note that $w_{c1} < 0$ if $c_m^1 < \frac{\delta\gamma_m}{2}(a - \frac{bc_m^1}{2} - \frac{\underline{c}_m}{2})$. If this is the case, if the supplier can participate, $w^{1*} = c_m^1$ if $c_s^1 > 2c_m^1 - \frac{a}{b} + \frac{2}{b}(\frac{c_m^1 - \underline{c}_m}{\gamma_m})$

Table 6.3: Possible w^{1*} , only manufacturer learns (conditions c1)

w^{1*}	conditions
w_{c1} (all business)	$c_m^1 > Dc$ and $((c_m^1 > Cc) \text{ or } (\Pi(w^{1*}, res) < \Pi(w_c, all)))$
w_e (residual)	$(c_m^1 > Ec \ \& \ c_m^1 \geq Dc \ \& \ \Pi(w_c, res) > \Pi(w_c, all))$
$\frac{a}{2b} + \frac{c_s^1}{2} - \frac{1}{b}(\frac{c_m^1 - c_m}{\gamma_m})$	$c_m^1 > Ac \ \& \ c_m^1 < Ec \ \& \ c_m^1 < Gc \ \& \ \Pi(w^{1*}, res) > \Pi(w_c, all)$
c_m^1	$c_m^1 < Ac \ \& \ c_m^1 < Gc \ \& \ \Pi(c_m^1, res) > \Pi(w_c, all)$

Table 6.4: c_m^1 breakpoints and derivations (conditions c1)

Name	$c_m^1 =$	if $c_m^1 <$
Ac	$\frac{a\gamma_m + c_s^1 b\gamma_m + 2c_m}{2 + 2b\gamma_m}$	Profit incr. at exit Reg. 2
Dc	$\frac{2\delta\gamma_m a - \delta\gamma_m b c_m}{4 + \delta\gamma_m b}$	Reg. 1 no exist
$Ec(> Ac)$	$\frac{2a\gamma_m + 2c_s^1 b\gamma_m + 2\delta\gamma_m^2 ba + (4 - \delta\gamma_m^2 b^2)c_m}{4 + 4b\gamma_m + \delta\gamma_m^2 b^2}$	Profit incr. at entry Reg. 2
Gc	$\frac{4a\gamma_m + 8c_m + (2b\delta\gamma_m^2 a - \delta\gamma_m^2 b^2 c_m)}{8 + 4b\gamma_m + \delta\gamma_m^2 b^2}$	Poss. Prof. in Reg. 2, given Reg. 1 exists
Reg. 1 is $0 < w^1 < Min(0, Min(w_c, c_m^1))$; Reg. 2 is $Max(0, w_c) < w^1 < c_m^1$		

and $w^{1*} = \frac{a}{2b} + \frac{c_s^1}{2} - \frac{1}{b}(\frac{c_m^1 - c_m}{\gamma_m})$ otherwise. For the more complicated case with $w_{c1} > 0$, the supplier's choices and conditions under conditions c1 are given in Table 6.3; the breakpoints referenced, in terms of c_m^1 are given in Table 6.4.

PROGRESSION: If $\gamma_m = 0$, and $c_s^1 \leq c_m^1$, then strategy E3 is employed. At low γ_m , the supplier must charge less than w_{c3} to get all of the business (Strategy E3), and there is no residual business available if the supplier cannot profitably charge w_{c3} (Strategy A3 or B3). At moderate γ_m , the supplier must charge less than w_{c2} to get all of the business (Strategy E3), and no residual business is present if the supplier cannot profitably charge w_{c2} (Strategy A3 or B3). Finally, at high γ_m , the supplier must charge less than w_{c1} to get all of the business (Strategy E3), or gets residual business for charging $w_{c1} < w^1 < c_m^1$ (Strategy C3 or D3). As γ_m increases, there will eventually be residual business as \underline{q}_m gets smaller. γ_m is limited by assumptions, thus strategies beyond E3 may not be reached.

6.1.9 Proof of Corollary 2

(i) We compare the profit $\gamma_m = 0$, $\Pi_s = (c_m^1 - c_s^1)(\frac{a-bc_m^1}{2}) + \delta(c_m^1 - c_s^1)(\frac{a-bc_m^1}{2})$ to the two cases when $\gamma_m > 0$. First, $\Pi_s = (w_c - c_s^1)(\frac{a-bw_c}{2}) + \delta(c_m^1 - c_s^1)(\frac{a-bc_m^1}{2})$ when strategy E3 is employed. Since $w_c < c_m^1$, and from Proposition 2 we know that $(w_c - c_s^1)(\frac{a-bw_c}{2}) < (c_m^1 - c_s^1)(\frac{a-bc_m^1}{2})$. Thus, in this case the supplier is worse off. Second, $\Pi_s(w^{1*}) = (w^{1*} - c_s^1)(\frac{a-bw^{1*}}{2} - \underline{q}_m) + \delta(\underline{c}_m - c_s^1)(\frac{a-bc_m^1}{2})$ when strategies C3 or D3 are employed. This can be rewritten as: $\Pi_s = (w^{1*} - c_s^1)(\frac{a-bw^{1*}}{2}) - (w^{1*} - c_s^1)(\underline{q}_m) + \delta(\underline{c}_m - c_s^1)(\frac{a-bc_m^1}{2})$. By Proposition 2, we know that $\frac{\partial((w^1 - c_s^1)(\frac{a-bw^1}{2}))}{\partial(w^1)} > 0$ for all $w^1 < c_m^1$. Therefore, since $c_m^1 \geq \underline{c}_m$, and $w^{1*} \geq c_s^1$, the profit function with no manufacturer learning is greater than that with some manufacturer learning.

(ii) For $\gamma_m > 0$, we have two possible profit functions for the supplier. Using the notation in (i) in this proof, and recalling that $w_c = c_m^1 - \frac{\delta\gamma_m}{2}(a - \frac{bc_m^1}{2} - \frac{bc_m}{2})$, and that $\underline{q}_m = \frac{c_m^1 - \underline{c}_m}{\gamma_m}$, we can see that when strategy E3 is employed, $\frac{\partial\Pi_s}{\partial\gamma_m} \leq 0$; this can be shown analytically but it is easier to note that second period profit is unchanged, and since $w_c < c_m^1$, first period profit is less by Proposition 2. For strategies C3 and D3, $\frac{\partial\Pi_s}{\partial\gamma_m} = \frac{(w^1 - c_s^1)(c_m^1 - \underline{c}_m)}{\gamma_m^2} \geq 0$.

6.1.10 Proof of Theorem 4

First, we observe that both players' period 2 profit functions and optimal decisions are unchanged. And, the manufacturer's first period profit function and optimal decisions for a given w_1 are also unchanged from Theorem 3. What does change is the supplier's

Table 6.5: Possible w^{1*} , both learning	
w^{1*}	value
w_c, w_e	$c_m^1 - \frac{\delta\gamma_m}{2}(a - \frac{bc_m^1}{2} - \frac{bc_m}{2})$
wef	$\frac{a}{2b} + \frac{c_s^1}{2} - \frac{1}{b}(\frac{c_m^1 - \underline{c}_m}{\gamma_m}) - \frac{\delta\gamma_s}{4}(a - b\underline{c}_m)$
wf	$\frac{a}{b} - \frac{2}{b\gamma_m}(c_m^1 - \underline{c}_m) - \frac{2}{b\gamma_s}(c_s^1 - \underline{c}_s)$
wfc	$\frac{a}{2b} + \frac{c_s^1}{2} - \frac{1}{b}(\frac{c_m^1 - \underline{c}_m}{\gamma_m})$
c_m^1	c_m^1

period 1 problem. As in Theorem 2, the supplier's period 1 function is discontinuous at $w^1 = w_c$.

First, we will show that she will never charge less than w_c if employing the strategy to get all of the business. We need to define the w^1 where the supplier achieves \underline{c}_s in this situation. That $w^1 = \frac{a}{b} - \frac{2(c_s^1 - c_s)}{b\gamma_s}$. If $\frac{a}{b} - \frac{2(c_s^1 - c_s)}{b\gamma_s} \geq w_c$, then the supplier has already achieved \underline{c}_s by charging w_c and will achieve no benefit by charging lower. If $\frac{a}{b} - \frac{2(c_s^1 - c_s)}{b\gamma_s} < w_c$, it may be beneficial for the supplier to charge less than w_c to get the learning benefit. This proof now follows the same steps as in Theorem 2, part (iii), replacing c_m^1 with w_c in the appropriate places. Thus, the supplier's profit if she charges $w^1 = w_c$ is $(w_c - c_s^1)\frac{a-bw_c}{2} + \delta(c_m^1 - c_s^2)\frac{a-bc_m^1}{2}$, where c_s^2 is either \underline{c}_s if $\frac{a}{b} - \frac{2(c_s^1 - c_s)}{b\gamma_s} \geq w_c$ and $c_s^1 - \gamma_s\frac{a-bw_c}{2}$ otherwise.

Next, we turn our attention the "residual business" case. We first note that if $\underline{c}_m < \underline{c}_s$, then $q_s^2 = 0$ for the supplier if they get only residual business. Therefore, her learning does not matter in the residual business case and she optimizes the first period profit exactly as in Theorem 3.

However, if $\underline{c}_s \leq \underline{c}_m$, then in the residual business case, the supplier's second period

profit depends on her first period actions. The supplier profit function in the relevant region ($w_c < w^1 < c_m^1$) is continuous but not necessarily concave. There are two possible boundaries where the profit function may change. The first is where the supplier achieves \underline{c}_s with just residual business; this point is $w^1 = \frac{a}{b} - \frac{2}{b\gamma_m}(c_m^1 - \underline{c}_m) - \frac{2}{b\gamma_s}(c_s^1 - \underline{c}_s)$, which we call w_f . If $w_c < w^1 < w_f$, then $c_s^2 = \underline{c}_s$. The second new boundary is the w^1 value above which the supplier gets no business in the second period, $w^1 = \frac{a}{b} - \frac{2}{b\gamma_m}(c_m^1 - \underline{c}_m) - \frac{2}{b\gamma_s}(c_s^1 - \underline{c}_m)$, which I call w_g ; $w_g > w_f$. If $w_f < w^1 < w_g$, then $c_s^2 = c_s^1 - \gamma_s(\frac{a-bw^1}{2} - \underline{q}_m)$. Note the profit function is concave from $w_c < w^1 < w_g$. If $w_g < w^1 < c_m^1$, then the supplier gets no second period business. It may be possible that the profit function is decreasing as w^1 approaches w_g , but then is increasing after w_g (if the second period profit, which hits zero at w_g , was decreasing in w^1 faster than the first-period profit was increasing). The interior optimum for the region $w_g < w^1 < c_m^1$ is the same as resulted from Theorem 3. Thus, only two new optimal w^1 values emerge, w_f and the new interior optimum in the region $w_f < w^1 < w_g$. These are added to the possible residual business optima from Theorem 3. We list the possible optima here on Table 6.5 but do not enumerate the conditions for when each is optimal; these conditions are tremendously tedious. The conditions are available from the lead author. Once the residual business optimum is obtained, the resulting profit must be compared with the relevant complete outsourcing profit, as in Theorem 3.

6.1.11 Proof of Corollary 3

There exist sets of parameters in which the supplier is willing to induce strategy E3 when she is learning, where she would not if she were not learning. This is because the presence of learning provides a greater marginal benefit for the supplier of first period sales to the manufacturer. To induce strategy E3, the supplier must charge w_c . $w_c < w^{1*}$, which is used to induce strategies C3 or D3. Since the manufacturer is receiving a lower price, he can only benefit. Also, the numerical example (Figure 2.9) demonstrates that both cases exist.

6.1.12 Proof of Theorem 5

(i) As facility i has strictly lower costs in both periods for any possible strategy, and the manufacturer is optimizing supply chain profits, clearly only facility i should be used and j should be ignored. Since learning is present, the strategies of Theorem 1 are relevant.

(ii) As before, in the second period the manufacturer will use the lower cost source for all production, and $q^2 = \frac{a-bc^2}{2}$, where $c^2 = \text{Min}(c_i^2, c_j^2)$. As leader, the manufacturer will always pay the supplier's marginal cost for purchased product, as he will be strictly worse off paying more. Thus, the manufacturer's optimization problem becomes maximizing the following profit function: $\Pi_m = (a - q_j^1 - q_i^1)(\frac{1}{b})(q_j^1 + q_i^1) - c_i^1 q_i^1 - c_j^1 q_j^1 + (\frac{\delta}{4b})(a - bc^2)^2$ where $c^2 = \text{Min}(c_i^2, c_j^2)$, and $c_j^2 = \text{Max}(c_j^1 - \gamma_j q_j^1, \underline{c}_j)$ and $c_i^2 = \text{Max}(c_i^1 - \gamma_i q_i^1, \underline{c}_i)$. If $\underline{c}^i < c^i < \underline{c}^j < c^j$, then clearly this function is minimized by using the results of Theorem 1 for firm $i = m, s$ and not using firm j.

If (a) $\underline{c}^i < \underline{c}^j < c^i < c^j$ or (b) $\underline{c}^j < \underline{c}^i < c^i < c^j$, then the profit function is neither convex nor concave in q_i^1 or q_j^1 . Solving one decision variable at a time, we note that while $\Pi_m(q_j^1)$, treating q_i^1 as constant, is neither convex nor concave, $\Pi_m(q_j^1)$ where $q_j^1 > \frac{c_j^1 - c_i^1}{\gamma_j} + \frac{\gamma_i}{\gamma_j} q_i^1$ is concave; we also note that if $q_j^1 < \frac{c_j^1 - c_i^1}{\gamma_j} + \frac{\gamma_i}{\gamma_j} q_i^1$, then in an optimal solution, $q_j^1 = 0$. Also, as q_i^1 reaches $\frac{c_i^1 - \underline{c}_j}{\gamma_i}$ in both cases (a) and (b), in an optimal solution $q_j^1 = 0$. In case (b) $q_i^1 = \frac{c_i^1 - \underline{c}_j}{\gamma_i}$ is less than $\frac{c_i^1 - \underline{c}_j}{\gamma_i}$; when $\frac{c_i^1 - \underline{c}_j}{\gamma_i}$ is reached the point below which we know q_j^1 is zero becomes $\frac{c_j^1 - \underline{c}_j}{\gamma_j}$. We call the smallest relevant critical q_j^1 below which we know $q_j^1 = 0$ λ . We proceed to optimize the concave region in q_j^1 for a given q_i^1 , given $q_j^1 > \lambda$. This solution gives critical q_i^1 values, in terms of exogenous parameters. The possible optimal q_i^1 values, given $q_j^1 > \lambda$, include $\frac{a - bc_i^1}{2} - \frac{c_j^1 - \underline{c}_j}{\gamma_j}$ and zero. Conditions can be obtained when $q_i^1 = 0$ and q_j^1 equals either $\frac{c_j^1 - \underline{c}_j}{\gamma_j}$ or $\frac{(a - bc_j^1)(2 + b\delta\gamma_j)}{4 - b^2\delta\gamma_j^2}$. Whichever optimum arises in the case where $q_j^1 > \lambda$ must be compared with the appropriate optimum when $q_j^1 = 0$; the appropriate optimum q_i^1 given $q_j^1 = 0$ is determined using the conditions of Theorem 1. Thus, the conditions arise from first determining the optimum q_i^1 and q_j^1 given $q_j^1 > \lambda$, then determining the optimum given $q_j^1 = 0$, then comparing the two possible optima. A list of mutually exclusive and exhaustive conditions, and their derivations, which result in each strategy being optimally employed is available (in a format similar to Table 6.3 and Table 6.4, but with many more parameters and conditions).

(iii) Here, facility i cannot benefit from learning. Therefore, strategies that arise from its learning benefit cannot happen.

6.1.13 Proof of Corollary 4

The manufacturer's profit function given in the proof of Theorem 5 is clearly non-decreasing in both player's learning.

6.2 Essay 2 Appendices

6.2.1 Essay 2: Variable Definitions

Table 6.6: Propensity to outsource (item reliability=.71)

PTO1 uses this question	Over the next 3 years, how important will the following strategies be for improving your overall supply chain performance? (1=much less important, 3=same, 5=much more important)
PTO1	Contracting with others to manufacture/assemble for you
PTO2-5 use this question	Which directions do you expect to change over the next 3 years regarding outsourced goods? (1=Decrease, 3=No Change, 5=Increase)
PTO2	Outsourced (purchased) finished products (from contract manufacturers-such as private labeling)
PTO3	Outsourced (purchased) basic materials/components
PTO4	Outsourced major assemblies
PTO5	Outsourced manufacturing processes

Table 6.7: Quality capability (item reliability=.84)

QC1-5 use this question	Listed below are critical success factors for competing in an industry. Please indicate how strong you feel your business unit currently is for each capability relative to your primary competitors in the same markets. (Relative current capability: 1=Lower, 3=Average, 5=Market Leader)
QC1	Conformance (degree to which products meet industry standards)
QC2	Durability (product life)
QC3	Product reliability (reduced probability of breakdown or failure)
QC4	Performance (functionality of design/engineering)
QC5	Overall product quality as perceived by customers

Table 6.8: Quality priority (item reliability=.78)

QP1-5 use this question	Listed below are critical success factors for competing in an industry. Indicate how important you feel each capability will be to your business unit in order to successfully compete over the next three years (Importance, Next 3 Years: 1=Not Important, 3=Moderate, 5=Very High)
QP1	Conformance (degree to which products meet industry standards)
QP2	Durability (product life)
QP3	Product reliability (reduced probability of breakdown or failure)
QP4	Performance (functionality of design/engineering)
QP5	Overall product quality as perceived by customers

Table 6.9: Cost capability (item reliability=.69)

CC1-2 use this question	Listed below are critical success factors for competing in an industry. Please indicate how strong you feel your business unit currently is for each capability relative to your primary competitors in the same markets. (Relative current capability: 1=Lower, 3=Average, 5=Market Leader)
CC1	Manufacture products at lower internal cost than competition
CC2	Offer lower-priced products than competitors

Table 6.10: Cost priority (item reliability=.55)

CP1-2 use this question	Listed below are critical success factors for competing in an industry. Indicate how important you feel each capability will be to your business unit in order to successfully compete over the next three years (Importance, Next 3 Years: 1=Not Important, 3=Moderate, 5=Very High)
CP1	Manufacture products at lower internal cost than competition
CP2	Offer lower-priced products than competitors

Table 6.11: Asset specificity

	Which of the following categories best describes the dominant production flows of your business unit's primary products?
AUTO	1=Continuous flow or machine-paced line 0=Worker-paced lines or disconnect flows through independent work centers or no dominant flows or production organized around a project

Table 6.12: Technological uncertainty

	How much will the following factors and market conditions likely affect your business over the next 3 years? (1=Very Low, 3=Moderate, 5=Very High)
TU	New manufacturing technology

Table 6.13: Emerging market

EMRG=1	China, Vietnam, Taiwan, Malaysia, Indonesia, Philippines, Mexico, Brazil, Chile, Argentina, South Africa, India, South Korea, Thailand, Poland, Czech Republic, Hungary, Portugal
EMRG=0	United Kingdom, Sweden, Denmark, Netherlands, Germany, Belgium, France, Switzerland, Italy, Singapore, Australia, Japan, Hong Kong, USA, Canada

Based on Hoskisson (2000) classification of countries

Table 6.14: Large company

	What is the approximate number of personnel employed at the company and/or in your business unit, worldwide?
BIG	1=Over 500 employees; 0=Less than 500 employees

Table 6.15: Early in life cycle

	What percent of your business unit sales revenues would you attribute to each of the following stages of product life cycle?
EAR	1=greater than 40% Introductory Stage/Growth Stage 0=greater than 60% Maturity Stage/Decline Stage

Table 6.16: Market leader

	How would you assess your position in your primary markets-the products and markets you focus on most?
MKLD	1=Market Leader-Clear Number 1 or 2 0=One of the top 3 or 4 in the market, but not the clear leader or Second tier-not as high as the market leaders but a strong competitor or A minor player in the market-serving a small niche or modest share of the market

Table 6.17: Customized product

	Overall, how extensively are most products customized in your business unit or operation?
CUS	1=Engineered to order (100% custom) or Assembled to order/made to customer 0=Make to stock (inventory) or Varies

6.2.2 Essay 2: Descriptive Statistics

Table 6.18 gives the descriptive statistics.

Table 6.18: Descriptive statistics for all items

Variable	N	Mean	StDev
PTO1	785	3.33	1.15
PTO2	702	3.33	.86
PTO3	771	3.41	.76
PTO4	640	3.25	.82
PTO5	711	3.24	.87
CC1	834	3.38	1.02
CC2	804	2.93	1.11
CP1	817	4.29	.83
CP2	801	3.66	1.14
QC1	849	4.12	.79
QC2	755	4.00	.87
QC3	803	4.06	.81
QC4	767	3.93	.82
QC5	840	3.98	.82
QP1	828	4.47	.74
QP2	748	4.18	.88
QP3	783	4.48	.71
QP4	754	4.35	.75
QP5	818	4.58	.66
AUT	793	.46	.50
TU	840	3.22	1.11
EMRG	860	.31	.46
BIG	805	.52	.50
EAR	701	.27	.45
MKLD	847	.43	.50
CUS	867	.47	.50

See Tables 6.6 to 6.17 for variable descriptions

Table 6.19: Pairwise pearson correlations

	PO1	PO2	PO3	PO4	PO5	CC1	CC2	CP1	CP2	QC1	QC2	QC3	QC4	QC5	QP1	QP2	QP3	QP4	QP5
PO1	1																		
PO2	.29	1																	
PO3	.23	.32	1																
PO4	.30	.39	.28	1															
PO5	.21	.41	.32	.49	1														
CC1	-.02	-.12	-.01	-.02	-.04	1													
CC2	-.02	-.08	.01	-.04	-.06	.48	1												
CP1	.03	.02	.13	.04	-.03	.37	.26	1											
CP2	.08	.03	.14	.11	.07	.18	.53	.37	1										
QC1	-.03	.01	.02	-.01	-.01	.09	-.04	.06	-.05	1									
QC2	.02	.03	.03	.06	.06	.05	-.07	.09	.07	.54	1								
QC3	-.00	.05	.07	.07	.07	.15	-.03	.10	.02	.59	.58	1							
QC4	-.01	-.02	.03	.04	.02	.08	-.06	.07	.01	.45	.44	.50	1						
QC5	-.04	.03	.01	-.05	.02	.15	.04	.12	.02	.51	.43	.56	.41	1					
QP1	-.01	-.00	.02	.02	.00	.05	-.02	.14	.04	.47	.27	.30	.28	.27	1				
QP2	.03	.00	.06	.09	-.01	.10	.01	.17	.14	.33	.66	.36	.30	.29	.36	1			
QP3	.02	-.00	.08	.10	.02	.02	-.04	.19	.09	.37	.41	.49	.33	.31	.43	.51	1		
QP4	.07	-.00	.06	.04	-.01	-.00	-.04	.18	.08	.32	.34	.28	.55	.24	.37	.40	.49	1	
QP5	-.03	.02	.06	.05	.02	.01	.01	.19	.09	.29	.27	.26	.25	.42	.39	.29	.42	.41	1
AU	-.14	-.11	-.06	-.10	-.02	.08	.02	.10	.14	.00	.06	.01	-.05	.00	.03	.04	.01	-.05	.02
TU	.08	.02	.06	.01	.02	.08	.09	.15	.19	-.02	-.01	-.04	.01	.03	.05	.01	.03	.05	.10
EM	.06	.02	.18	-.00	.14	.00	.07	.07	.16	-.02	.06	.06	.02	.03	.01	.10	.06	.08	.04
BG	.06	.04	-.02	.04	.04	.01	-.07	-.01	-.07	.01	.05	.01	.01	.01	-.05	-.02	-.02	-.01	-.04
ER	.05	-.02	.04	.03	.02	.03	.03	.00	.04	.03	.01	.03	.11	.04	-.02	-.00	.02	-.02	-.04
MK	-.05	.03	-.02	-.00	.02	.05	-.10	.00	-.10	.24	.15	.19	.22	.22	.13	.09	.05	.10	.06
CS	-.06	-.10	.01	-.02	.00	-.01	-.03	-.04	-.01	.01	.10	.03	.08	.04	.04	.09	.03	.09	.08

See Tables 6.6 to 6.17 for variable descriptions; note: PO=PTO, AU=AUTO, EM=EMRG, BG=BIG, ER=EAR, MK=MKLD, CS=CUS

Table 6.20: Pairwise pearson correlations (continued)

	AU	TU	EM	BG	ER	MK	CS
AU	1						
TU	-.03	1					
EM	.03	.06	1				
BG	.05	-.08	-.13	1			
ER	-.02	.15	-.02	.05	1		
MK	-.06	-.02	-.04	.19	-.04	1	
CS	-.08	.04	.01	-.10	.08	-.06	1

See Tables 6.6 to 6.17 for variable descriptions; note: PO=PTO, AU=AUTO, EM=EMRG, BG=BIG, ER=EAR, MK=MKLD, CS=CUS

6.2.3 Common Methods Bias Tests

Harman's Single-Factor Test Harman's single-factor test involves performing an exploratory factor analysis with the indicators, and ensuring that they do not all load on a single factor. We found that 8 factors were maintained (eigenvalues greater than 1), and that the largest factor explained 19% of the variance. Examining the factors, it is clear that the propensity to outsource dependent variable loads onto its own factor, and does not appear to be correlated to the independent variables due to common method bias. Since a single factor does not explain the majority of the variance, this provides evidence that common method bias is not a major problem. Podsakoff et al. (2003), however, note that this test is insensitive.

Method Factor Now, we use a second approach, discussed in Podsakoff et al. (2003). In this approach, we introduce a method factor. This is a single factor that loads onto all items. Given the size of our model, we again needed to do this with just our multi-item scales. Here, we check to see if the correlations between the constructs are significantly lowered by the introduction of the method factor. Importantly, we find no significant difference in the correlations between the two models between any of the independent variables and the dependent variable. Within the capabilities and priorities, we do find significant reductions in correlations between quality capability and priority and cost capability and priority. This would indicate that common method variance may be a factor among the capabilities and priorities, but not between the capabilities and priorities and the dependent variable. There are also may be theoretical reasons (combinative capabilities, competitive progression

theory) why these capabilities and priorities may load onto one factor.

6.2.4 Discriminant Validity

The following table gives the chi-square difference between a constrained model where the correlation between constructs is forced to unity and a model where the correlation is allowed to be free. We tested all multi-item constructs with the dependent construct first, then tested among capabilities and priorities. A χ^2 difference of 3.84 between the constrained and unconstrained models indicates a significant difference between the models, thus providing evidence of discriminant validity.

Table 6.21: Discriminant validity tests

Description	$\chi^2(\text{constrained})^*$	$\chi^2(\text{unconstrained})^*$	Difference
CC-PTO	70.5(14)	15.2(13)	55.3
CP-PTO	106.0(14)	3.78(13)	81.5
QC-PTO	565.1(35)	54.9(34)	510.2
QP-PTO	266.0(35)	43.2(34)	222.8
CC-QC	251.4(14)	29.7(13)	221.7
CP-QP	132.2(14)	34.2(13)	98.0

*-degrees of freedom in parantheses

6.3 Essay 3 Appendices

6.3.1 Essay 3: Expert Panelists

Panelist 1 (P1) P1 is the author of the book on foreign material prevention in foods and president of an independent consulting firm offering expertise in assisting organizations to deliver sustainable improvements in product safety, quality, and ancillary business processes. P1's previous work experience includes roles in both quality assurance and manufacturing operations with major food and consumer products. During his tenure at a large FDA-regulated company, P1 oversaw several key areas of their business. As their Senior Quality Assurance Manager he was responsible for the oversight of the quality systems and personnel within their North American manufacturing facilities. P1 transitioned to the role of Business Unit Manager later in his career, and assumed operational responsibility for another unit. During this time P1 was intimately involved in the commercialization of new products and the development of the process improvement organization within their largest facility. P1 is now a highly sought after speaker/panelist for food industry events. P1 is a Senior Member of ASQ and holds current certifications as a Six Sigma Black Belt (SSBB) and a Hazard Analysis and Critical Control (HACCP) Auditor.

Panelist 2 (P2) has held executive positions and extensive experience in Six Sigma, quality improvement, customer loyalty, cost reduction, and revenue growth. P2 has served several Fortune 500 companies as the senior corporate officer in charge of strategy, purchasing, quality, training and asset management. He has used his

ability to integrate systems and develop new paradigms to achieve world-class performance. P2's experience in Six Sigma and major change management are derived from both line and staff perspectives in diverse Union and Industry environments including merger facilitation. P2 has extensive global cross-cultural experience and is an expert at accelerating sustainable financial performance improvement. He has had the direct corporate responsibility for improvement efforts that have been publicly credited with over two billion dollars in benefits to the shareholders. P2 also served four years as a judge for the prestigious Malcolm Baldrige National Quality Award. In addition, he led a large utility company's quality effort. This was the first non-Japanese company to win the Deming Award. P2 has the distinction of being presented with awards for Outstanding Service to the Nation by two Secretaries of Commerce: William Verity and Robert Mosbacher. P2 is the founder and current CEO of a global provider of consulting and training in: corporate performance, quality improvement, Six Sigma, Lean, and Strategic Planning. His consultants have worked with Motorola, Allied Signal, ABB, York International, General Electric, ASQ, ING, the Singapore Government, and PwC. His areas of expertise includes Manufacturing, Service, Healthcare, Financial Services, and Government institutions.

Panelist 3 (P3) P3 is Manager, Quality Assurance at a technology center of a large medical device manufacturer where she has managed a number of quality disciplines, including validation, supplier quality, internal and supplier audit, inspection and test, calibration/metrology, quality engineering, and document control. P3 has

a B.S. in Mathematics/Economics and her M.S. in Industrial Administration. P3 is currently active in many facets of the American Society for Quality. She is currently the program chair for the Customer-Supplier Division, the education chair for Orange Empire Section, and is active with the Biomedical Division's Southern California Discussion Group. P3 presently teaches the section refresher courses for the Black Belt, Certified Quality Engineer, and Certified Biomedical Auditor Certification Exams.

Panelist 4 (P4) P4 is currently both a senior consultant with a regulatory consulting group and a faculty advisor to the School of Pharmacy at a major university on FDA matters. Prior to these roles, P4 served with Food and Drug Administration for over 30 years. During P4's last 17 years with the agency, P4 was a District Director where he was responsible for managing that field office and carrying out FDA programs with specific emphasis toward the pharmaceutical industry. P4's responsibilities in this role included overseeing and providing executive leadership and management direction for the agency's programs and enforcement activities. P4 also directed and managed the implementation of the Pre-Approval Compliance Program. During the last several years in this position P4 also served as chair of the Office of Regulatory Affairs (ORA) field drug committee where P4 interfaced on a regular basis with Center for Drug Evaluation and Research (CDER)'s management and program specialists. P4 also helped develop the Mutual Recognition Agreement (MRA) between the European Union and United States for pharmaceutical products. For P4's dedicated professionalism, leadership, and achievements

with the FDA, he was granted the Distinguished Career Service Award.

6.3.2 Delphi Documents

6.3.2.1 Letter to Solicit Expert Panelists

To: Quality expert in FDA-regulated industries

Buyer Beware? Quality Risk in Outsourcing

Invitation to serve on a panel of experts

This project is being conducted by researchers from the University of North Carolina-Chapel Hill and from Arizona State University. This work is partially funded and supported by the Juran Center for Leadership in Quality at the University of Minnesota.

We are studying conformance quality risks in outsourcing. We believe that outsourcing poses a risk to conformance quality. This risk is a result of the supremacy of costs in outsourcing decisions, misaligned incentives with regard to investments in robust quality improvements, and difficulty in observing the implementation of robust quality practices.

As a proxy for conformance quality capability, we are using data from Food and Drug Administration (FDA) audits. These audits are generally thorough, multi-day audits. Plants are required by law to provide any relevant information requested by the FDA. As such, we believe they provide the best available assessment of the robustness of a firm's quality systems at the establishment level.

We have obtained a database of all domestic audits performed by the FDA (in the drug, cosmetic, and medical device industries) since 1994 through the Freedom of Information Act. We are awaiting similar databases for the food industry and for all foreign audits. The database contains the name and location of each facility, the date(s) of the audit(s) at each facility, and the audit results. Audit results are given in two parts. First, a “Y” is given if a Form 483 was issued during the audit by the auditor. Second, the District Decision is given in the database, with one of four possible decisions listed on the following table:

See Table 4.2

We are looking to utilize this data to ascertain an establishment-level measure of conformance quality capability. We would like to believe we have enough information to create a valid and reliable measure from the database.

Requirements of a panel member

We expect the panel to consist of several people; at least one with auditing experience with the FDA. We anticipate that each panelist will have 2-3 individual conversations (less than 1 hour) with John Gray between March and June of 2006. We would then attempt to have a concluding conference call/meeting with the whole group.

Benefits to the panel member

The panel member will help answer the question of whether or not there is a quality risk in outsourcing, help create a measure of “quality capability” at the establishment

level based on publicly available data that could be used for future research. The panel member will also gain easy, legal access to quality data on all firms audited by FDA, and a small network of academics and practitioners interested in quality performance. Finally, the panel member will receive a copy of the study when complete; and input into future research projects.

Outcomes

The outcome of the work of this panel will be either a specific formula that transforms the audit frequency and results (483 and district decision) into an index of conformance quality capability at the establishment level, or a realization that this is not possible, and a more detailed approach utilizing complete audit reports documented.

If interested, please contact me using one of the methods above,

John V. Gray

6.3.3 Round 1 Delphi Questionnaire

Thank you for taking the time to talk to me. My purpose in talking to you is two-fold: My primary (and only required) objective is to utilize experts like you to help me create a valid and reliable measure of conformance quality capability from publicly available FDA data. A secondary objective is to get suggestions from practitioners like you as to interesting research studies that could be performed utilizing this data.

I plan to record this call to prevent me from needing to write everything you say. Are you okay with that?

First, let me tell you a little bit about the data I have collected. Through the Freedom of Information Act, I have been able to obtain Excel spreadsheets containing information about all audits performed by the FDA in the drug industry from 1994-2005. These spreadsheets contain the name and address of the firm, the date of the audit, and two measures of the audit outcome: a “Yes/No” indicating whether a Form 483 was issued, and an indication of the district decision (No Action, Voluntary Action, Official Action, Referred to State, pending). Official Action should be accompanied by a warning letter, which is generally available. We can also get recall data, for any relevant firms that have had recalls. I hope to use this data for several research projects; I hope to use experts in industry (like you) to determine how to best use this data.

I first wish to get a handle on your background and experience with manufacturing in general:

(1) Please briefly describe your experience in manufacturing in industries or processes NOT regulated by the by FDA.

(2) Please briefly describe your experience with manufacturing in FDA-regulated industries. Include experience in staff roles, with suppliers, etc.

Next, I’d like to get a handle on your experience with the FDA auditing process.

(3) Please briefly describe your experience with FDA audits. Include direct partici-

pation, training on audits, “mock” audits, audits of your operation, etc.

(4) Please describe your familiarity with the FDA’s Form 483.

(6) Please describe your familiarity with the process an audit report takes after the site visit (district decision, etc.).

Finally, I’d like to get to the main purpose of this process-to get a Panel of Experts to come to a consensus on the appropriate way to use the data I have obtained from the FDA.

First, let me assess your comfort with the term “conformance quality capability.”

(7) I define “Conformance Quality Capability” as the ability to consistently ship product that is free of defects (either specified or not). Do you understand this definition?

Note: here I discuss how this is normally measured in academic research-perceptual surveys comparing one plant’s/MBU’s capability to others and/or (less commonly) measuring actual internal or external defect rates by some method

(8) Do you feel FDA audits provide a reasonably accurate assessment of conformance quality capability? Explain

Ultimately, I’d like to get to a mathematical transformation of the readily available data to a valid and reliable measure of conformance quality capability. The goal should be that we have some confidence that the “score” that results from this transformation has two properties: (i) it is monotonic in what we are trying to measure (i.e., a higher

score indicates a higher conformance quality capability), (ii) a specific difference between two scores across the scale corresponds to the same specific difference in conformance quality capability. Do you understand what I am trying to do?

I will use this variable to do studies where “conformance quality capability” is the dependent variable or the independent variable.

(9) We have information on whether a Form 483 was issued and the district decision for each audit, as well as the frequency and recency of audits. We also can obtain actual warning letters and recalls when they exist (i.e., when “official action is indicated”). Let’s talk through how these data may be used to obtain information about a firm’s conformance quality capability to achieve the objective discussed above.

(10) We also know whether a firm is ISO 9000 certified or not. Does that provide any additional information of its conformance quality capability, in your opinion?

(11) How would you recommend using these pieces of data (and only these pieces of data) to measure conformance quality capability?

6.3.4 Round 1 Delphi Summary to Experts

Summary of Round 1: All experts selected and spoken to are highly qualified to help with this research. After the first round, all are willing to continue.

The panelists helped clarify the process an inspection report takes: (1) inspector

comes (for cause or not for cause), (2) inspector issues 483s (if any) with EIR (Establishment Inspection Report), (3) inspector gives firm the opportunity to discuss every item on 483; firm sends response, (4) EIR goes to district; decision by district is based on report from investigation branch (EIR) and other data (recalls, consumer complaints, violative samples, etc.) to make a decision, (5) “Referred to State” cannot necessarily be classified as more or less severe than “VAI” or “OAI.” States are contracted for specific things and may get reports of varying severity. (6) Net, we have one two-level variable (Form 483 Yes or No), and one three level variable (NAI, VAI, OAI) which may be supplemented with the contents of a warning letter or recall.

Importantly, ALL panelists feel that FDA audits provide a reasonably accurate assessment of “conformance quality capability,” as I defined it in round 1 (“the ability to consistently ship product that is free of defects (either specified or not)”)

However, no panelists were completely comfortable with the definition of “conformance quality capability” above. REVISED CONSTRUCT: “Quality Risk” is the propensity for a product produced by a given facility to fail to perform as intended, due to manufacturing-related issues. (*note: the above definition slightly revised from the definition used in the Delphi process (“propensity” above replaced “likelihood.” Delphi participants contacted and concurred with the change.)

I gave examples of how conformance quality has been measured in previous academic research. None of the panelists liked the idea of surveying managers to assess themselves relative to competitors for quality capability, as is often done. All were satisfied

with checking actual conformance (percent defects in plant, warranty, etc.), but understood that would limit the study to very similar manufacturing processes and products. One suggested surveying customers to get their “independent measure of the quality of products.”

There were varying levels of comfort with my overall idea of using FDA inspection data as a proxy for quality risk/conformance quality capability.

We made little progress (as expected) on actually transforming the data. Importantly, all panelists understand what I want to do. Most felt the Form 483 was a lower bar than an Official Action Indicated/Warning Letter.

One stated that a “483 indicates the firm didn’t do a good job on some system, a warning letter is so serious it indicates the company did not even pay attention to a major quality system.”

One panelist was deeply concerned that two firms that received OAI or a 483 could be vastly different (similarly, two 483s) in terms of the severity of quality risk; i.e., this panelist was concerned about using only the spreadsheet as opposed to complete reports. This panelist gave an example of how restaurant scores “A” or “B” give only a little information; big difference between A=90 and A=100.

Another panelist thought it would be important to know the number of items in a 483 and the reason for the audit. I have called the FDA and neither of these are readily available. We will need to proceed without this knowledge.

One panelist gave an example that judged quality risk based on how easily a problem can be fixed. I hope not to focus on what happens after the audit; I want us to focus on the audit as an assessment of current quality.

Focus of Round 2

Review new definition of what we are trying to measure: “Quality Risk” is: The propensity for a product produced by a given facility to fail to perform as intended, due to manufacturing-related issues.

Reaffirm comfort with FDA inspections’ assessment of the above construct., and discuss my assumption that FDA audits assess behavior with regard to quality risk, and agree to ignore/declare negligible any effect past FDA audits have on future behavior.

Reevaluate the use of just the spreadsheet data as a proxy for “Quality Risk.”

Attempt to create a “first-cut” mathematical transformation of data available (think of weights of each variable and the effect of time/frequency).

6.3.5 Round 2 Delphi Interview

Thank you for your insights last time we spoke, and thank you for scheduling time to speak with me again. I am enjoying the process of working with you. On this interview, we will begin by discussing what I learned from all of you on the first round, and then we will quickly get into how we are going to utilize this data.

Before we begin, I'd like to schedule another time to speak.

First, we learned that all of you have a significant amount of knowledge with regard to the FDA auditing process, and quality practices. Also, you all bring diverse perspectives. Your varied perspectives are helpful for this kind of work. They will increase the likelihood that any consensus reached is valid.

(1) Did you have a chance to read the Summary document I sent out on Wednesday, April 5th?

If no, and they have it front of them, ask them to look it over.

If no, and not in front of them, review some of the key points on the document.

(2) Do you have any questions/comments/concerns about the document?

Okay, now I'd like to progress forward. We have a few key things to review before getting to the mathematical transformation of the data.

First, I have changed my construct name and definition to better define what I am trying to measure. The new construct name and definition is/are:

QUALITY RISK: The propensity for a product produced by a given facility to fail to perform as intended, due to manufacturing-related issues.

(3) Do you think FDA inspections provide a reasonable/good assessment of the above construct?

More than one panelist spoke, directly or indirectly, about how inspection results can drive future behavior. This came out at different points of discussion. The two examples were: a discussion about how firms that have received multiple 483s are a greater risk than those who have received a warning letter because a warning letter will drive real action, whereas 483s will make the firm feel as if they have slipped by; and a discussion about examples of possible outages where the panelist was judging severity based on how easily the problem can be addressed, not how likely there was a quality risk based on the problem that was identified.

I believe it confounds our discussion if we include the endogenous effect of the audits on future behavior. My preference is to focus our discussion on how well FDA audits assess quality risk, and neglect the possible effect that these have on future behavior.

(4) Are you comfortable doing this?

The final “sticky issue” before we get to transformation of the data is whether we can utilize only the spreadsheet data as opposed to having actual inspection reports. I understand that more data would be better, but make the following case for using only the spreadsheet data:: “coding” of audits would be quite subjective. It may be clear that a given warning letter is more severe than another warning letter (.e.g. intentionally and consistently releasing bad product vs. temporary error in one subsystem). However, it will rarely be so clear cut. While there will be some benefit, it will be less significant than one first might think; attaining inspection reports will take at least a year, even for a small subset of the database, and would be practically impossible for the complete

database. Coding them would take months. Thus, the cost will likely be greater than first thought; all of you agreed that a firm that has received a Form 483 likely poses a greater quality risk than one that does not. Thus, a simple solution to this problem would be to measure quality risk very coarsely, with a “1” for those firms that received a 483 in their last inspection, and a “0” for firms that did not. But, this seems to be wasting some available data that we have (multiple audits, district decisions, warning letters/recalls); finally, recall that other methods used for large-scale studies (e.g., surveys) are also quite limited. If we come up with something better than the standard, we are doing well.

(5) Given my above arguments, what is your assessment about the possibility of coming up with a valid measure of quality risk using only the data available on the spreadsheet?

(Assuming I can get past this point.)

Now we need to get serious about transforming the spreadsheet data. We have the following information: date of audits and the district decision and Form 483 Y/N for each audit.

We don’t immediately know when the plant was started up or if it still exists; let’s ignore that complexity for the moment.

As a way to tease out how you might come up with a score, I’m going to ask you some general questions:

Fill in the blank in the following statement: “For a given audit, I would consider

that a firm which receives an injunction, seizure, or recall as a result of an audit was x times more likely than one that just received a warning letter to have posed a quality risk prior to the audit.” Fill in the blank in the following statement: ”For a given audit, I would consider that a firm which receives a warning letter was x times more likely than one that just received a 483 to have posed a quality risk prior to the audit.” Fill in the blank in the following statement: “For a given audit, I would consider a that firm which receives a Form 483 was x times more likely than one that did not receive any action to have posed a quality risk prior to the audit.”

Given what you have said, let’s fill in the following table, for a single audit:

(Similar to Table 4.3)

How do you think I should handle multiple audits?

6.3.6 Round 2 Delphi Summary to Experts

All calls went well. More than one panelist had interesting research suggestions and other comments which are not directly related to creating a valid and reliable measure of quality risk at the establishment level; I do not record these on this writeup (but I have recorded them elsewhere).

We have settled on a definition of the construct we are measuring, at least for drugs (pharmaceuticals and OTC medicines):

QUALITY RISK: The propensity for a product produced by a given facility to fail to perform as intended, due to manufacturing-related issues.

One panelist felt that for medical devices, there may be some very important parts of the device that could “fail to perform as intended” that the FDA does not check in an inspection. This panelist was comfortable with this definition for drugs.

All panelists feel that FDA inspections provide a reasonable assessment of quality risk.

All panelists are comfortable with using only the spreadsheet data, for the following reasons: (1) cost of doing more is high (time, resources, money), (2) benefit of doing more may be low (subjective coding), (3) all panelists agree that establishments that get a 483 pose, on average, a higher quality risk than those that do not; we are doing more than this, (4) what we are doing is better than has done

The following points were made by one or more panelists regarding the use of spreadsheet data: (1) It is not perfect, especially given the fact that we don’t have the number of observations per 483. But, it seems better than other measures available (surveys, measures of conformance in tight industries), and therefore is useful. (2) Any research using this data should use a large enough sample that no individual plant scores are revealed. This is because there is enough noise in this quality risk score that we should not use this score for consulting/advice on the risk of specific plants. If actual Establishment Inspection Reports (EIRs), 483s, and Warning Letters were studied, this concern may be alleviated. (3) Inspections are a “coarse filter” of assessing quality risk; i.e., a clean

inspection does not mean there is not a quality risk; an inspection with observations implies a quality risk.

All panelists believe that the stream is important; that is, we should treat differently an inspection history that shows improvement (e.g., warning letter, only 483, clean) as opposed to one that shows no improvement.

One panelist believes that we should use only plants that have multiple inspections. This would cost us 1776 of our 4171 establishments in the drug database. I'd like to discuss this with all panelists in round 3; my preference is to keep these establishments.

Here are the scores assigned by each panelist in round 3, assuming no injunction or seizure (all panelists stated that an injunction or seizure led to a quality risk roughly 3 times that of their highest score).

Table 6.22: Single audit “quality risk” score based on audit outcome

483/District Dec	District Decision	P1	P2	P3	P4
No	N-No Action	1	0	0	0
No	E-Voluntary Action	2	0	0	1
No	A-Official Action	3	3	3	3
Yes	N-No Action	1.5	1	1	1.5
Yes	E-Voluntary Action	3	1	1	2
Yes	A-Official Action	4.5	3	3.5	3

Note: Panelist #'s do not match their descriptions in Appendix 6.3.1

I was amazed at the striking similarity between the panelists (particularly 2 and 3). Panelists 2 and 3 essentially gave no weight to a VAI from the district, which I found interesting; they also gave a lot of weight to a warning letter.

Given the similarity, I propose the following single audit score:

See Table 4.3

Multiple inspections were also discussed. All panelists agreed that the stream of inspections should be considered, and improvement should be rewarded. Details were not discussed in any of the calls.

Focus of Round 3

Review proposed quality scoring system for single inspections (as described above).

Discuss how to handle multiple inspections.

A more complex solution is necessary to reward improvement.

Discuss how to handle firms with only one inspection.

Attached are inspection histories for a few establishments for which I have complete inspection reports (I decided to use these because then I can assess, by looking at the reports, the validity of our score). Use our system to come up with scores for these establishments and assess our comfort level with how our scoring system is working (Note: we looked at scores in round 3 that included both the trend and multiple audit adjustment; I have not included those scores here for brevity).

6.3.7 Round 3 Delphi Interview

First, thanks again for continuing with this process. I hope you are finding it interesting.

I have truly enjoyed it.

(1) Did you have the opportunity to read the summary I sent?

(2) Do you have any questions or comments?

Key points: we are measuring quality risk, we agree that FDA inspections provide an assessment of quality risk, we are okay with using only the spreadsheet data.

Now, how to score:

(3) Here are my proposed consensus scores; do you feel these are okay?

See Table 4.3

(4) Are you okay with scoring any inspection-related injunction or seizure at a 10?

We now have a score for a single inspection. No one was comfortable simply averaging those scores for an establishment's quality risk score.

(5) Should we raise quality risk due to frequent inspections (not knowing the cause)?

(6) Should we reward improvement/punish declines in inspection scores?

(7) Do you think we can include establishments with only one inspection?

(8) Let's look at some of the plants I sent out and try to score them, using our agreed to scoring system. (Note: we checked these with both the final scoring system after Round 3; panelists felt they were reasonable assessments given the audit patterns. The inspection histories checked are attached after the Round 3 summary)

6.3.8 Round 3 Delphi Summary to Experts

All calls went well. All panelists agreed on the following consensus score for a single audit. This score was not much different than any of the individual panelist's suggestions:

See Table 4.3

All panelists agreed that an inspection-related seizure or injunction should result in a score of 10 on this scale.

Because of some concern about the coarseness of this measure, I discussed with some of the panelists the possibility of actually reading the warning letters (since they do not require FOIs to obtain) and thus adding some information to the cases where warning letters were issued (most OAI's have warning letters). This would be a subjective interpretation, but could lead to increased validity and more granularity in our assessment of quality risk. We would use a scale from, say, 2.5 to 10 and grade the warning letters subjectively. One panelist agreed to help with this (if any others are willing to help, let me know). Another had concerns about the subjectivity of coding warning letters. For the first study using this data, a coding scheme for warning letters may be attempted

with at least one panelist.

One panelist expressed concern (which has been expressed before by others) that the reason for the inspection may affect the likelihood of a 483 being issued. This panelist felt that the above scoring system would be most valid if we considered only “routine” (district office work plan) inspections. I am still working with the FDA to try to get classifications, but cannot guarantee that I can get them. If I cannot, audit type will be additional “noise.” If I can, it would be possible to determine how much “reason” independently affects outcome, and/or perform the study with just the routine inspections to eliminate one source of “noise.”

Panelists had varying levels of concern about the validity of using a plant with a single audit. Comments ranged from (each panelist should see one bullet below reflecting their opinion): -It’s not a concern at all -It’s only a concern if the audit is old -It may be a concern because anything can happen on an audit, but the data loss might be too severe to eliminate all single-audit plants. -It is a concern; to check how big a concern it is studies should be done with and without single audit plants. I plan, if possible, to do a study with and without the single audit plants to see if it has an impact.

We then discussed how the quality risk score should be changed for multiple audits. There are two factors we considered:

(1) Is the fact that an inspection occurred a proxy for risk? That is, do we believe that if one plant has one audit with a 483/VAI and another has six audits with a 483/VAI, does the one that has had six audits carry a higher risk just because the FDA chose

to go there? 3 of 4 panelists thought so after the call (although one of those three was concerned that this was confounding product risk-i.e., public health impact of failure-with our definition of quality risk), and we had tentatively agreed on the following way to use this (n=# of audits, QR=quality risk score for a given audit, t=# years plant existed 1994-2005):

$$\frac{\sum_{i=1}^n QR_i}{n} \left(1 + \frac{n-1}{t}\right)$$

But, the 4th panelist interviewed noted that: “Work plan” (i.e., routine) audits are generally performed randomly; PreApproval audits are performed because of a new drug, and have no relation to the FDA’s assessment of quality risk at the plant; The above two types of inspections are the majority of inspections; the inspections that are “for cause” will often be the result of a bad previous inspection, which would already be incorporated in the quality risk average score. Thus, this panelist felt (and convinced me) that we should not increase a plant’s quality risk score due to frequent audits. Thus, before incorporating trend, the quality risk score would simply be the average. I will check back with the other panelists to see if they agree.

(2) Should we adjust quality risk scores for a trend? All panelists thought we should, and all agreed with the following as a first cut adjustment, simply added to the average quality risk score. It is up to me to ensure that this adjustment does not cause negative scores, or overly award improvement:

$$\frac{\sum_{i=1}^{n-1} QR_{i+1} - QR_i}{n}$$

Given the above the above discussion, the quality risk score will be either:

$$\frac{\sum_{i=1}^n QR_i}{n} \left(1 + \frac{n-1}{t}\right) + \frac{\sum_{i=1}^{n-1} QR_{i+1} - QR_i}{n+1}$$

Or

$$\frac{\sum_{i=1}^n QR_i}{n} + \frac{\sum_{i=1}^{n-1} QR_{i+1} - QR_i}{n+1}$$

depending on whether we adjust for the number of audits.

My current proposal is to use (ii) above, as the fourth panelist convinced me that adjusting for the number of audits would be less valid than not adjusting. Other panelists, please let me know if you agree with using (ii), given the arguments presented above.

The main upcoming work is: (1) “cleaning” the data set so that I can get a distribution of our chosen quality risk score, (2) looking into adding some granularity to the quality risk score classified contract manufacturers and internal plants, based on reading the warning letters (with one or more panelists).

Next Steps for Panel

(1) Give your input on eliminating the multiple audit adjustment, given the arguments above. (note: panel agreed to not adjust for multiple audits) (2) Help code warning letters (currently one panelist agreed to do this, others?)

(3) Later, I will organize a call with the entire panel to discuss the process and research that can be done using this data set. That call will occur in mid-May.

6.3.8.1 Sample Audit Histories and Resulting Quality Risk Scores

In Table 6.23, we show the audit histories shared with the panel.

Each audit is represented by two letters. The first letter represents whether a Form 483 was issued (Y/N). The second letter indicates the district decision (N/E/A).

Table 6.23: Audit histories shared with panel for validity check

Audits (483,District Decision)	QR Score
NN, NN, NN	0
YE, NN	.25
NE	.5
YE, YE, NN	.63
YE, NE	.67
NN, NN, NN, YE	.68
YE,NN,YE,NN,YE,NN,YE	.86
YA,NN,YE	1.17
YN,YA,YA,YA,YN,NN,NN	1.66
NN,YE,NE,NE,YA,YA	2.17
NE,YA,YA,YE,YA*,NN,NN,NN,YA,YE,YA	2.81
YA,YA,YA*,NE,NN	2.92
YA	3.50

Note: Audit histories are in chronological order; *=recall

6.3.9 Delphi Wrap-Up Conference Call

Hi, everyone. Thank you for calling in. Did any of you get my e-mail from yesterday?

Do you have it in front of you?

First, although I know all of you fairly well, none of you know each other. So, let's begin with introductions.

(1) Introductions (all)

We'll go through the panel alphabetically. Please give some detail about your experience and what you currently do.

Ok, thanks. I hope you can all see that everyone on this panel has both experience in the topic we are working with and energy to help us figure out how best to use it.

Next, let me review the process we followed. We used the "Delphi" process, which has the purpose of "obtaining the most reliable consensus of opinion of a group of experts by a series of intensive questionnaires interspersed with controlled opinion feedback."

The Delphi process was first used by the RAND Corporation in the 1950s to determine the optimal US targets for the Soviets, and the number of A-Bombs required to reduce the munitions output by a required amount.

This method was appropriate in our case because our situation had the following characteristics: a clear problem/objective (how can we best use this data?), complex subject matter, multiple iterations appropriate, diverse experts with no history of com-

munication, helpful to preserve heterogeneity of experts; helpful to understand "why" experts believe what they do; dislocated/busy experts.

For problems with the above characteristics, it makes sense to utilize the Delphi method.

Next, let me review the highlights of the process and our main results (deleted for parsimony):

Okay, so that's a brief summary of 10 hours of phone conversations with you over the course of a month. Now that we're all together, I'd like to give each of you an opportunity to express two things: your comfort-level with the outcome and your assessment of the process.

Thanks for all of that. Next, I'd like to talk about our future work (some new future work may have just been created).

One of you agreed to review warning letters of the companies included in the study, so that we can possibly use the additional information readily available to us to better measure the quality risk of plants with warning letters (which often, but not always, accompany an official action).

Finally, I'd like to ask the panelists if they have any suggestions for future research utilizing our measure. Thanks again for your time. I will send you any papers that come from this research and will likely be in touch again.

6.4 Description of Process to Classify and Retain Companies for the Study

The initial round of classifications selected companies based on their websites, SEC filings, news reports, etc. There were eight possible classifications (contract manufacturer, internal plant, upstream(for a chemical plant), pharmacy, medical gas, generic, mixed(produced both internal brands and on contract, for example), and “unable to classify.” Only plants classified “contract manufacturer” or “internal plant” were considered for further analysis.

Separately, lists of contract manufacturers were found from trade publications and websites. Also, lists of drug brand names and manufacturers were found and searched as possible candidates for internal plants. And, we created a list from local store shelves for possible manufacturing plants.

From these two sources, plants that we thought might be contract manufacturers or internal plants were further studied. We generated a data sheet on each company. This data sheet contained our coding of whether a company was producing “only regulated” product or not; we coded companies that appeared to primarily producing regulated products as “only regulated.” We also discovered, through the standard search process, that three small internal plants actively disagreed with the FDA’s right to regulate them; we have discarded those three facilities as the drivers of their quality risk are different than those hypothesized here. Virtually all contract manufacturers’ plants were from

small companies.

The data sheet included the variables obtained from Harris and ReferenceUSA. Some plants for which we were otherwise confident did not appear in either database, and so were discarded. In just a few cases, a plant for which we had a high confidence was not listed in Harris but was listed in Reference USA. In these cases, we used the ReferenceUSA data to input plant size, age, and company size. We decided that ReferenceUSA's estimates would be superior to imputation.

Importantly, in this second round, "confidence of classification" scores were added. Plants with a score of 5 were so classified for one of two reasons. First, there may have been some slight contrary evidence, but the balance of evidence still favored the classification. Or, there may have just been extremely little evidence available. Plants with a score of 6 were those for which detailed specific information about the plant operation could not be found, but there was no opposing evidence. We scored plants with a confidence of seven when we had some supporting evidence (such as a news report on the plant; or a very informative website) that nearly positively identified the plant's classification.

In the end, we had 258 observations, 154 of which were classified with a confidence score of 7. We examined a subsample of the data, and observed the plants classified 5, 6, and 7 differed in the variables of interest in the study. After this examination, we decided to keep only those plants for which we had the most confidence, as inclusion of the other plants could add significant noise to the analysis.

6.5 Description of Data Sources Used for Control Variables

The control variables of age, size, and financial health are obtained from existing databases. Private company data is notoriously difficult to obtain (Ojala, 2005)Refworks:1259. Also, plant-level information on any company can be a challenge. As noted by Ojala (2004), “Frequently the best bets for private company information are the company’s own website, assuming it has one, and news sources.” (p.46) Where possible and necessary, we also used web sites and news sources to confirm and find information. Below is a description of the two databases used. Harris was used in most cases; ReferenceUSA was used for the few plants that were not listed in Harris. While we cannot absolutely guarantee the validity of the data, we believe that these databases provide reasonably accurate assessments of the control variables, as described below.

Harris’ Company Reach

This database is available by subscription. Harris focuses on manufacturing, as outlined in their website (<http://www.harrisinfo.com/harrisinfo/products/data/index.aspx>)

Harris’ special commitment to premium manufacturing data is supported by relationships with numerous state and regional chambers of commerce and business associations. Our database is the only one published in cooperation with the National Association of Manufacturers.

The sources utilized are numerous. The following information is taken from the company website (<http://www.harrisinfo.com/harrisinfo/products/data/dunsright.aspx>)

Dun and Bradstreet's extensive business information database covers over 82,000,000 companies worldwide. Information is collected from a wide variety of sources, including: direct investigations and interviews with the company principals; payment and banking data from company suppliers, which provides over 650,000,000 payment experiences annually; suits, liens, judgments, UCCs, business registrations, corporate details and bankruptcy filings from state and county courthouses, resulting in over 130,000,000 records on file; corporate financial reports and filings within 48-72 hours of filing; contracts, grants, loans and debarments from the federal government; web source and mining of over 27,000,000 domains; news and media sources; phone books and print directories.

Harris, which is a subsidiary of Dun and Bradstreet, compiles and maintains the databases. The DUNSRight process is utilized to make the database as accurate as possible. This includes 2000 automated checks as well as manual checks to drive accuracy. We checked the data against several plants where we had inside information and it was reasonably accurate.

ReferenceUSA

This database is maintained by InfoUSA, Inc. An independent assessment in *Library Journal* recommended ReferenceUSA over other databases due to "the producer's commitment to accuracy and quality control." Thousands of telephone books, annual reports, 10-K reports and other SEC documents, and trade journals are used to collect this data.

Thousands of telephone calls are made to verify the facts. This fastidiousness shows in the final product, where this reviewer came across just one typo. (e.g., Tallent, 2002).

In spite of the recommendation, we found deviations between ReferenceUSA and reality in plant size for plants for one plant for which we had firsthand data, and did not find the same problems with the Harris database. Thus, we chose to use the Harris database as the primary source of data for our control variables.

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