The Evolution of Work and the Growing Contingency of Labor Practices in the Massachusetts Life Sciences Industry

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ABSTRACT

Contingent work has been used to describe a wide range of non-standard, short-term employment arrangements to include self-employment, home-based work, on-call work, temporary work, contracting, and other alternative employment arrangements. In 2005, the Bureau of Labor Statistics estimated that about four percent of total employment in the U.S. was comprised of contingent workers. Just five years later this figure nearly doubled to 7.9 percent according to a report by the U.S. Government Accountability Office, though more liberal measurements record this number to be closer to 40 percent (2015). Another five years later in a report published by Katz and Krueger, the estimate doubled once again to 15.8 percent (2016). It is clear that the use of contingent labor to complete work tasks is increasingly an essential element utilized by businesses as they shed non-essential functions in order to focus on their core competencies. This reflects a belief that a lean operating model will optimize companies' cost structures and provide flexibility to react efficiently during down and upturns in the economy.

The use of contingent labor modifies the conventional relationship between capital and labor in the formation of skill. Previously, skill was described as encompassing general and specific skills. General skills represent the skills and experiences workers bring to the job from formal training and tacit knowledge gained in previous work contexts. Specific skills represent skill augmentation that derives directly from the work experience gained by working with a unique employer. The labor contract typically includes the combination of both skill enhancing experiences. Rents are collected by both parties up to the value of each party's marginal product and hence contribution to labor productivity. Today's utilization of contingent labor ignores the significant costs associated with recruiting and training new hires as well as the indeterminable loss in value from utilizing a workforce that is less incented to see their companies succeed. The lack of specific skills of contingent workers diminishes productivity and causes the firm to incur training costs, which may not be recovered due to the shorter job tenure.

This thesis investigates the use of contingent work in the Massachusetts life science industry. The demands of capital markets are fiercely pressuring companies to grow and generate large returns for its investors. However, this places an uneven amount of focus on the commercialization of its products causing the industry to hone in on its core competencies and shed non-essential functions, thereby expanding the use of contingent labor.

This thesis is framed by the discussion of a looming imperative amidst industry constraints and the subsequent effects created by the dichotomy. The first part of this thesis describes the evolution of work

and the emergence of financial pressures compelling the life science industry to utilize contingent labor in several of its key R&D and manufacturing functions despite the obvious benefits associated with career jobs to both the employer and employee. The demands of capital markets continue to drive specific actions of the life science industry (imperative), however the industry is characterized by high cost, long production cycles, tremendous volatility, and a critical reliance on capital flows (industry constraints). Chapter five presents the findings, which examines the net results from the interplay between the imperative and constraints. What effects is this imperative having on life science companies facing these constraints and how are they reacting (subsequent effects)? Many are beginning to behave irrationally and at odds with its long-term goals diminishing the innovative potential of the industry as a whole and adversely impacting the workforce powering the entire mechanism. This thesis attempts to coalesce these broad themes to tell the story of what is happening to work in the Massachusetts life science industry.

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1.1 Evolution of Work in America

The nature of work and the social contract between employer and employee has undergone tremendous change since the post-World War II era. Everything from wages and benefits, to management and culture, to learning and development has shifted and been restructured to redefine the modern workplace. Sanford Jacoby calls this the extinction of career jobs (1999) where the archetype of lifetime employment by a single employer with comfortable compensation and benefits is replaced by a new standard with fragmented employer-employee relationships, depressed wages, minimal benefits, and precarious job tenure. Career jobs once afforded companies with loyalty and commitment from their employees not to mention significant cost savings on recruitment and job specific training. In return companies showed the same loyalty and provided stability to their employees by rewarding seniority. Now, as companies shed non-essential functions to drill down on their core competencies employees have become commoditized and packaged as an expense. In order to save on this expense, the employee commodity (objectified as 'human capital') has been outsourced to third parties thereby causing the terms of employment to be governed by multiple organizations. At the helm of this transformation are the demands of capital markets facilitated by leaps and bounds in technological advances, which apply immense pressures on companies to behave in ways that further investor interests while jeopardizing the companies' future well-being. The growing contingency of labor is proving to be a global phenomenon across all industries.

The telecommunications industry is an example of how companies are shedding jobs in favor of a lean operating model. In 2016, thousands of telecommunications workers went on strike in protest of Verizon's decision to transfer and outsource their jobs. In one of the largest labor action protests in years, nearly 40,000 of Verizon's employees participated in the strike after a 10-month negotiation with management failed to achieve a compromise. Verizon's goal was to shed employment by increasing the number of call center jobs to Mexico and the Philippines while hiring more non-union contractors to install and repair their wired telephone lines and fiber optic internet cables. Jobs like these that are absolutely essential to the operation of the business are increasingly outsourced as companies focus on their core competencies.

The hotel industry is another example where the traditional employment model has been transformed. InterContinental Hotels Group (IHG) owns only 16 of its 5,221 hotels and uses a franchise model to sustain its growing global footprint (IHG, 2017). In this business model, an individual or investment fund takes out a franchise on the brand while the parent company dictates terms and standards, effectively shedding the management function and transferring it to someone else. Although IHG does not own the actual brick-and-mortar of its hotels, it is able to prescribe everything from design layout to the color of the carpet since it owns the brand. The hotel owner, then, outsources many of the hotel's functions such as housekeeping, landscaping, and laundering services. Even the restaurants within the hotel are in many cases outsourced to external catering companies. This further separates the workers from the lead companies, which shifts the responsibilities and liabilities associated with managing those workers externally.

A focus on core competencies allows companies to react effectively during variations in the economy by providing flexibility while minimizing the initial capital investment required in the start of a new venture. Additionally, it shields companies by passing off much of the risks associated with doing business. The degree of separation created by the franchise between the parent company and the owner acts as a buffer to soften the blows from underperformance. To illustrate, consider the previous example of a hotel chain that operates a franchise model. The industry benchmark for measuring performance is the revenue per available room or *revpar*, and if *revpar* falls 1 percent at a hotel the owner suffers on average a 5 percent decline in profits; management fees, which are tied to a mix of the hotel's revenues and profits, fall by 3 percent; but, franchise fees, which are the fixed fees due to the parent company or franchisor, are tied only to revenues and therefore, fall by just 1 percent (The Economist, 2009). As

companies downsize and outsource many of their operations, they shift the risks of doing business out to smaller businesses and to its workers effectively safeguarding the company.

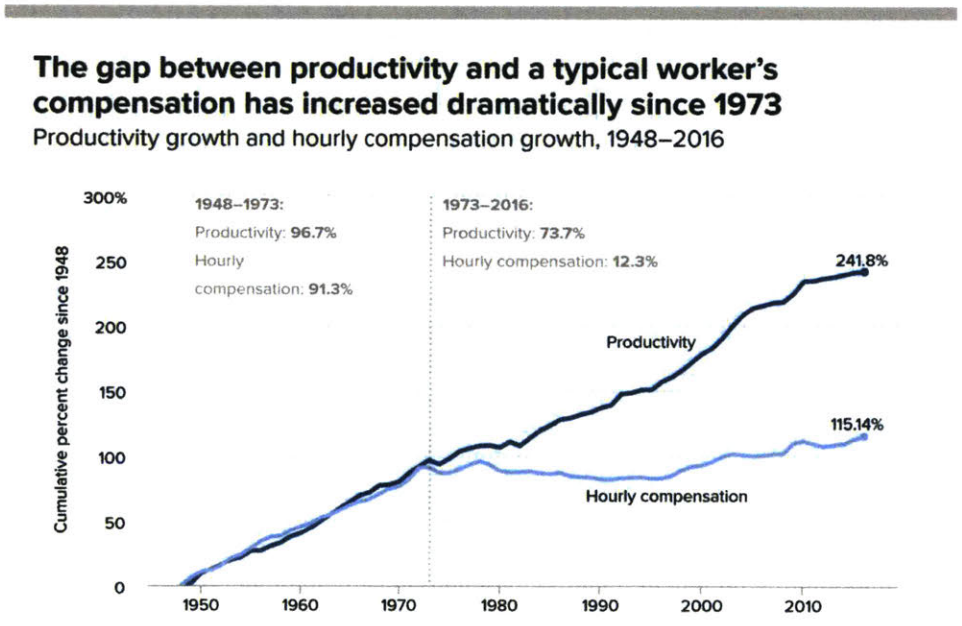
The externalization of work centered around a focus on core competencies is called by many names: outsourcing, just-in-time production, flexible specialization, virtual model, franchise model, services contracting, lean manufacturing, and others. Each slightly varies in its design, but the goal of each is to increase flexibility and reduce risks and costs via a modus operandi that externalizes non-essential processes. The new organizational structure negatively alters the behaviors of both employers and employees by dissolving attitudes such as loyalty, morale, and motivation. Employees are taking on more of the risks despite the decline in wages and job security, and through it all they are being told to take charge of their own careers being assured that their varied experiences will lead them to bigger and better opportunities elsewhere.

Background

Unnerved by the economic shocks of the 1970s and 80s, companies quickly adopted the concept of core competencies into their business models and by the early 90s the concept had fully taken root. Since then, employment has undergone dramatic changes. In 2005, the Bureau of Labor Statistics estimated that about four percent of total employment in the U.S. was comprised of contingent workers. Just five years later this figure nearly doubled to 7.9 percent according to a report by the U.S. Government Accountability Office (though more liberal measurements record this number to be closer to 40 percent depending on how contingent labor is defined) (2015). Another five years later in a report published by Katz and Krueger, the estimate doubled once again to 15.8 percent (2016). What is even more surprising is that Katz and Krueger concluded that "all of the net employment growth in the U.S. economy from 2005 to 2015 appears to have occurred in alternative work arrangements," which according to their analysis was a total of 9.1 million jobs between February 2005 and November 2015.

All this has produced some distressing trends in the American economy. Since the early 1970s, the hourly inflation-adjusted wages received by the typical worker have grown by only 0.2 percent per year (Shambaugh, Nunn, 2017). Meanwhile, net productivity rose 73.7 percent between 1973 and 2016 (see Figure 1), which means workers are not receiving wages commensurate with their productivity (EPI, 2017).

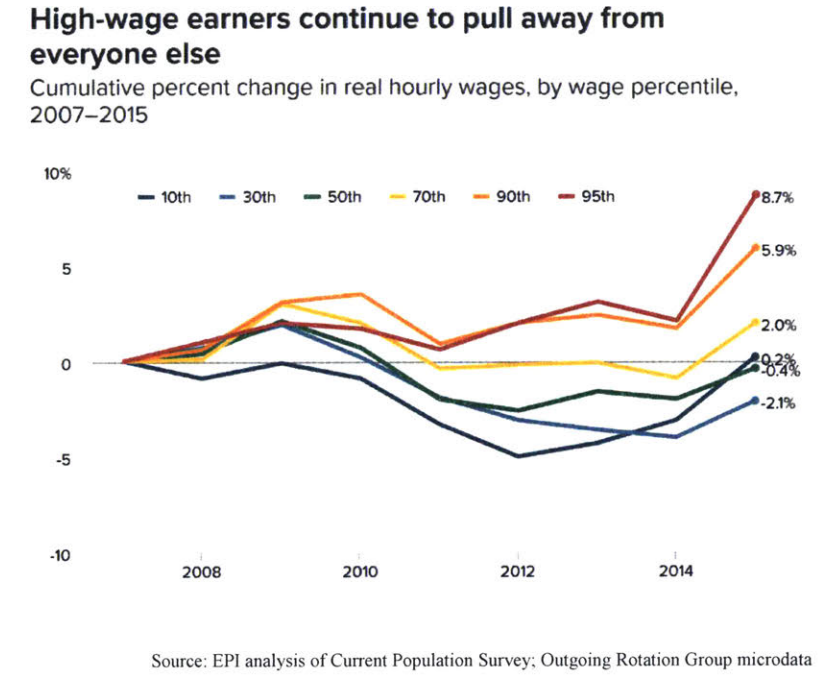
Figure 1.



Source: EPI analysis of Bureau of Labor Statistics and Bureau of Economic Analysis data

Instead, wages have disproportionately gone to the top establishing a wage inequality that has widened for 38 consecutive years. Had all workers' wages risen commensurate with the growth in productivity since 1980, an American earning $50,000 today would instead be making $75,000 (Gould, 2016). An outrageously disproportionate share of revenue is going to corporate profits and to the wealthiest 1 percent. Much of the growth experienced in real hourly wages for the typical worker has been largely due to dips in inflation while the top earners continued to realize wage growth. However, the gap between the middle and bottom earners has remained stable since 2000. This is illustrated in Figure 2, which shows the trends in wages between 2007 and 2015 in select deciles. The ratio of the 95th percentile earners over the 10th percentile earners was 5.9 in 2007, which grew to 6.3 in 2015. Similar trends are shown in the wage ratio for 95th percentile earners over the 50th percentile earners (Gould, 2016).

Figure 2.



Source: EPI analysis of Current Population Survey; Outgoing Rotation Group microdata

Perceptions of fairness have always influenced wage determination to some degree since these perceptions influence morale, which in turn affect performance and productivity. Therefore, companies paid special attention to not only ensuring a fair wage distribution based on their market position (the fair share of the pie) but also to the wages paid to employees in relation to one another, what Weil calls "enlightened self-interest" (2014). However, with the advent of new technologies that provide increased transparency of the global labor market, wages are driven less by endogenous factors – the internal labor market – but rather exogenous ones – the competitive forces of the external labor market. This has led to a new understanding of fairness.

The new organizational structure brings the combined pressures of both the product market and labor market to bear on the employee (Capelli et al., 1997). Whereas the traditional organizational structure buffered employees from market forces the new organizational structure is mediated by them.

The overwhelming amount of data aggregated in websites like Glassdoor and LinkedIn enables employers to set and justify wages by pegging them to the broader labor market allowing companies to adopt a more variable wage structure and eliminate their obligation of providing employees with a fair share of the pie. Further, technological advances have created new methods of measuring individual performance. Formal sit-downs with the boss for annual performance evaluations are slowly fading and being replaced with online peer feedback mechanisms. Patagonia is an example of a company that has adopted such software using crowdsourced feedback to measure employee performance to affect upward mobility (Burjek et al., 2017). Together with new forms of wage determination and new processes to affect promotions, traditional perceptions of fairness are being tossed to the wayside to make way for the contemporary belief that people should be paid what they are worth.

New technologies are revolutionizing work and employment on multiple levels. Data can instantly be transmitted, shared, and analyzed through cloud technologies, which is essentially dissolving traditional workplace arrangements. Companies can more easily outsource activities and conference virtually eliminating former challenges associated with communication and collaboration. And 3D printing technologies will soon close any remaining gaps associated even with the manufacture of products while automation diminishes the need for labor in systematized processes. In terms of human resource management, technology is creating platforms for online labor management, which will further expand the scope of the labor market. A suite of contingent workforce management tools such as Vendor Management System (VMS), Managed Service Provider (MSP), and Recruitment Process Outsourcing (RPO) provides employers with a contemporary option to quickly and seamlessly create a requisition for immediate labor needs, offboard workers, and manage contingent workers with just with a couple clicks of the mouse. This will further drive the use of contingent work as companies strive towards a comprehensive virtual model.

All this change has been and continues to be propelled by the financialization of the global economy. As the New Deal regulations that established constraints and safeguards on the finance industry unraveled the industry's growth accelerated. The financial services sector, as measured by share of GDP in the U.S., grew from 2.8 percent in 1950 to 4.9 percent in 1980 and 8.3 percent in 2006 (Greenwood and Scharfstein, 2013). As financialization emerged the American economy shifted its focus from manufacturing to capital investments that sought short term financial gains over long term goals such as in new technologies, which also diverted income from labor to capital (Collins, 2015). This shift in focus placed an uneven emphasis on the commercialization of products rather than the manufacturing of quality products. Consequently, through the 1980s and beyond, industries began to focus on their core competencies to maximize profits and minimize costs.

Contingent labor provides companies with flexibility enabling them to react quickly and efficiently during up and downturns in the business cycle. Especially with advances in modern technology, companies can quickly recruit workers when they experience sudden increases in demand and offboard workers as needed. Contingent labor also allows employers to shift the costs of employment over to third parties. This includes replacement costs, termination costs, mandatory social payments, and overhead costs associated with bringing on permanent staff. Further, by using contingent labor employers can effectively shift liability over to the third parties making them responsible for things like workplace injuries and adherence to labor laws. But all these benefits are not void of consequences, at least not for the contingent workforce.

Consequences

As companies shed employment workers are unfairly burdened with the risks and costs while receiving highly depressed wages. When companies shed non-essential functions (at times entire departments or branches of their business) a gap is formed where once those functions operated. The demand for those services drives the development of new markets creating a complex network of smaller businesses (hereafter referred to as subsidiary businesses). However, with new markets come new competitive pressures that depress wages – pressures that did not exist when the functions were housed

internally (Weil, 2014). Moreover, many subsidiary businesses also opt to contract out their labor needs through the use of employment agencies further depressing wages and fragmenting the employment structure. This fragmentation also leads to increasing instances of wage theft. One report found that workers in contracted jobs experienced routine incidences of wage theft with 25 percent of workers reporting minimum wage violations, and 70 percent of workers not paid overtime (Bernhardt et al., 2009). As more companies shed their non-essential functions, subsidiary businesses operate in an increasingly competitive environment subject to the strict rules determined by lead companies, which means they get to reap the benefits of utilizing cheap labor and dictate work standards while shifting management responsibilities and liability over to external organizations. This creates ripples that reverberate beyond just the direct participants and into the wider economy because when paychecks shrink taxpayers end up subsidizing low income benefits.

A growing contingent work structure also increases uncertainty in regards to job tenure. The share of employees who said that they were concerned about being laid off in 1981 was 12 percent. In 1999, that statistic jumped to 37 percent (Jacoby, 1999). In a report conducted by the Pew Research Center in 2016, the number of Americans that said that they have less job security now than they did 20 to 30 years ago was a staggering 63 percent while only 16 percent stated that their job security had increased (Brown, 2016). The construction industry is an example with notoriously low job security and a high degree of fragmentation. With razor-thin margins and a high degree of volatility and risk of failure, the construction industry can be among the first to feel the effects of economic downturns. For this reason, many contractors have resorted to using contingent labor to safeguard against such volatility. However, the contingent employment structure doesn't eliminate risk, rather, it simply passes it from employer to employee. By February of 2010, the unemployment rate for construction workers hit a peak of 22 percent (BLS JOLTS). Also, worth noting are the indirect effects of the contingent employment structure on workers' health which includes a series of adverse mental and physical health effects linked to the stresses of unemployment as evidenced by the increased number of appointments with physicians, increased consumption of medications, and more days spent sick in bed compared to their employed counterparts (Linn et al., 1985).

In many cases, contingent workers do not receive the same benefits package that permanent employees receive. As a matter of fact, many contingent workers do not receive any of the major fringe benefits to include health and dental insurance, retirement plans, vacation and sick days, tuition assistance, or long-term disability insurance. And what benefits they do receive are increasingly in decline. In 2005, the BLS determined that 18 percent of contingent workers were covered by employer-provided health insurance compared to 52 percent of permanently employed workers (2005). Defined-benefits plans in particular were hit hard as the number of working participants that were accruing benefits under defined-benefits plans declined from 80 percent to 40 percent between 1975 to 2011 (Wiatrowski, 2014). As career jobs become less and less likely employers are increasingly offering more easily transferrable retirement options such as 401(k)s. Unlike pension plans that were managed by the employer and guaranteed a steady payout over the course of retirement, 401(k)s are managed by the employee and are diversified over a spread of mutual funds and provide no such guarantee. This adds to the increasing labor market risk born by the employee.

According to a 2016 report by EY (f.k.a. Ernst & Young), half of all organizations in the U.S. have seen an increase in their use of contingent workers between 2010 to 2015 with 40 percent of those organizations expecting to increase their use of contingent workers in the coming five years. In the same report, the survey showed that 63 percent of contingent workers worry about a lack of paid vacation or sick leave, 48 percent have job insecurity, 40 percent lack health care benefits, and 20 percent lack retirement benefits. Furthermore, when companies were asked about the management of their contingent workforce, 37 percent admitted to having a fragmented governance model. Despite these statistics the use of contingent labor continues to rise rapidly.

1.2 Research Question and Methodology

This thesis investigates the use of contingent work in the Massachusetts life science industry. The demands of capital markets are fiercely pressuring companies to grow, innovate, and most importantly, generate large returns for its investors. However, investor pressure is also detracting attention away from research and development and placing an uneven amount of focus on the commercialization of its products causing the industry to hone in on a new set of core competencies.

This thesis is framed by the discussion of a looming imperative amidst industry constraints and the subsequent effects created by the dichotomy. Chapters 3 describes the evolution of work and the emergence of financial pressures compelling the life science industry to utilize contingent labor in several of its key R&D and manufacturing functions despite the obvious benefits associated with career jobs to both the employer and employee. The demands of capital markets continue to drive specific actions of the life science industry (imperative), however the industry is characterized by high cost, long production cycles, tremendous volatility, and a critical reliance on capital flows (industry constraints). Chapter 5 examines the net results from the interplay between the imperative and constraints. What effects is this imperative having on life science companies facing these constraints and how are they reacting (subsequent effects)? Many are beginning to behave irrationally and at odds with its long-term goals, which is unsustainable for the industry as a whole and detrimental to the contingent workforce powering the entire mechanism. This thesis attempts to coalesce these broad themes to tell the story of what is happening to work in the Massachusetts life science industry.

This thesis aims to answer the question: *why do life science companies hire contingent workers rather than hire permanent employees?* Three sub-questions directed the research. The first major effort identifies the impetus behind the use of contingent labor by examining the motivations of life science companies in driving major operational decisions by asking the question: *what are the critical success factors for companies in the life science industry?* Then this thesis attempts to uncover trends in companies' behaviors by asking the second question: *what are the strategic actions that companies undertake and prioritize in order to achieve those critical success factors?* Finally, this thesis identifies the net result of companies' actions and strategic decisions as it pertains to their use of contingent labor as well as the industry as a whole by asking the third and final question: *what are the wider impacts resulting from companies' strategic actions?*

This study draws from the extensive literature discussing the theories and historical origins of labor markets as well as the literature identifying major trends in the life science industry. In addition, several interviews were conducted with individuals in employment agencies, life science companies that sponsor new drug products (hereafter called sponsor companies), contract research organizations (CRO), contract manufacturing organizations (CMO), stakeholders, and independent consultants in the life science industry.

Before discussing some trends in the Massachusetts life science industry, a quick word on the definition of contingent labor. The literature surrounding contingent labor describes it in many different ways. The broadest definition includes independent contractors, individuals employed through employment agencies, day laborers, on call laborers, workers whose services are supplied by contract firms, freelancers, and just about anyone participating in the "gig economy." Therefore, the statistics used to measure the contingent workforce and identify trends in its use in the economy is highly varied and not very well aligned. For the purpose of this thesis contingent labor will be defined as those workers, who unlike many of the participants in the "gig economy," do not have much control over their fate and fortune – those workers who work from project to project, have high insecurity regarding their job tenure, have minimal to no fringe benefits, and lack an overall sense of permanence and stability in their employment and wage structure. Therefore, it excludes independent contractors and consultants who have a fairly strong presence in the Massachusetts life science industry. As soon to be discussed, contingent workers range in educational attainment and wages with some experiencing more precarious job security than others depending primarily on the demands of the industry.

Chapter 2 – Life Science Industry

This thesis is organized into six chapters. This chapter provides an overview of the life science industry. Chapter 3 goes on to provide a review of the literature describing the forces that shape the employment structure in the U.S. since the first industrial revolution. Chapter 4 discusses the drug development process and the inherent challenges and constraints of the life science industry. It also discusses the major challenges associated with bringing an approved, viable drug to market. In Chapter 5 the thesis attempts to draw conclusions based on the interplay between the forces described in Chapter 3 and the industry challenges and constraints described in Chapter 4 and identifies trends for the future of work in the Massachusetts life science industry. Finally, in Chapter 6, a way ahead is discussed with policy recommendations to conclude the thesis.

2.1 U.S. Life Science Industry

The life science industry as defined here is comprised of the traditional pharmaceutical industry and the biotechnology industry. Biopharmaceuticals require live organisms to extract and rearrange large molecules to develop biologics, the basis for biologically based drugs. This is distinct from pharmaceuticals, which are chemically synthesized with a defined chemical structure. Although each process is very different, currently there is innovative research being conducted attempting to synthesize the two processes to target a single disease. This thesis defines the life science industry to be comprised of 4 groups and 12 distinct industries within the North American Industry Classification System (NAICS):

32541 Pharmaceutical and Medicine Manufacturing:

- 325411 Medicinal and Botanical Manufacturing
- 325412 Pharmaceutical Preparation Manufacturing
- 325413 In-Vitro Diagnostic Substance Manufacturing
- 325414 Biological Product (except Diagnostic) Manufacturing

54171 Research and Development in the Physical, Engineering, and Life Sciences:

- 541714 Research and Development in Biotechnology
- 541712 Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)

33451 Electromedical and Electrotherapeutic Apparatus Manufacturing:

- 334510 Electromedical and Electrotherapeutic Apparatus Manufacturing
- 334516 Analytical Laboratory Instrument Manufacturing
- 334517 Irradiation Apparatus Manufacturing

33911 Medical Equipment and Supplies Manufacturing:

- 339112 Surgical and Medical Instrument Manufacturing
- 339113 Surgical Appliance and Supplies Manufacturing
- 339114 Dental Equipment and Supplies Manufacturing

The discovery of the DNA molecule and the characterization of its double-helical structure by Watson and Crick propelled the drug industry to new heights. Boosted by the focus on social welfare policies in the post-World War II era, specifically in health care, and coupled with government support to strengthen and cultivate the U.S. economy, the life science industry thrived. The next major discovery to launch the life science industry occurred in the 1970s when two scientists in California discovered recombinant DNA technology, which paved the way for the emergence of a new discipline known as biotechnology. Since then, there has been a major spike in drug development via genetic engineering of

biologics, which has augmented the traditional pharmaceutical approach of utilizing chemical synthesis. Advances in biotechnology has enabled much broader applications thus expanding the industry's market potential.

The U.S. leads the industry capturing 32.6 percent of total global revenue and has 11 out of the top 25 pharmaceutical companies headquartered within its borders (Kennedy, 2018). Its biggest competitors are the European and Asian markets, which together constitute between 60 and 65 percent of global revenue from exports (Ibisworld, 2018). In 2017, the U.S. exported nearly $90 billion worth of products, which is a 191 percent increase in pharmaceutical exports over the past 15 years (Kennedy 2018). This increase in exports is supported by a consistently high level of product development. Between 1999 and 2013, the U.S. accounted for between 40 to 45 percent of all patents filed within the U.S., Europe, and Japan combined, which is drawing significant investment activity – 74 percent of global venture capital (VC) investments in the industry (Kennedy, 2018).

2.2 Massachusetts Life Science Industry

It's not exactly clear when Massachusetts first emerged as a global innovation hub for the life sciences. According to a Boston Globe article, some point to the year 2002 when Swiss pharmaceutical giant, Novartis, established its global research headquarters in Cambridge while others are convinced it was in 2011 when the French pharmaceutical leader Sanofi also came to Cambridge to establish its biotech firm, Genzyme (Weisman, 2015). Regardless, Massachusetts is the undisputed leader in the life science industry with over 700 companies residing within its borders, roughly 70,000 employees receiving over $9.2 billion in total payroll, over 28 million square feet of commercial lab space, and the highest VC funding by state (MassBio, 2017).

Through a targeted effort by the state legislature and industry leaders to make Massachusetts a global innovation hub for the life sciences, the state established a 10-year, $1 billion investment in the industry in 2008. The perfect blend of advanced academic institutions, supportive policies, abundant research facilities, and attractive lifestyle amenities provided by a thriving urban environment set the conditions for Massachusetts to become the highest ranked U.S. life science cluster as ranked by JLL (2017). This is evidenced by the vast amount of public and private equity capital that flows into the state. The state receives 9 percent of total NIH funding, which is second only to California, but first when measured on a per capita basis (MassBio, 2017). Massachusetts also receives 30 percent of all VC funding to the industry totaling $2.9 billion, which provided 71 percent of Series A funding and 68 percent of Series B funding in 2016 (MassBio, 2017). Recently, the Boston Business Journal analyzed Massachusetts companies' SEC filings between 2014 and 2016 to determine the fastest growing companies. The results were not surprising with 24 out of the top 50 companies being in the life science industry and 9 of those companies within the top 10 fastest growing companies (BBJ, 2017). This shows that the life science industry in Massachusetts is a critical pillar that is driving the state's economy.

2.3 Employment and Wages in the Massachusetts Life Science Industry

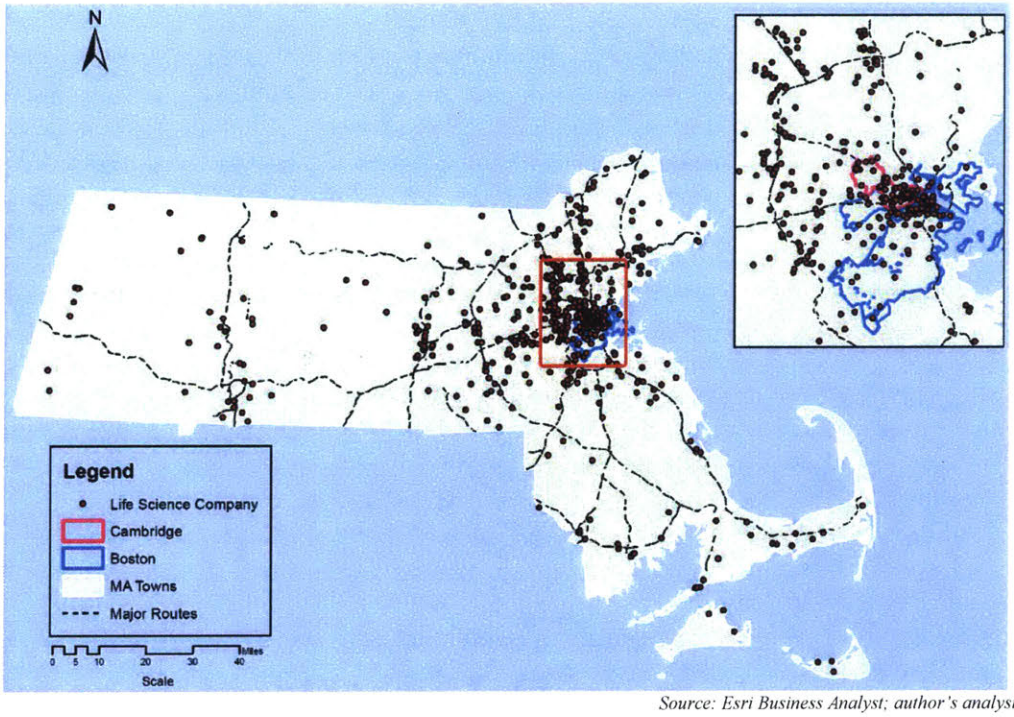
Across the U.S. the life science industry employs 1.66 million people with 4.2 percent of those employees residing and working in Massachusetts (BLS, 2017). And these Massachusetts employees account for 4.5 percent of the Boston region's total employment making it one of the highest proportions among the life science clusters in the country (JLL, 2017). Life science jobs within the state grew by 28 percent between 2006 and 2016 and by 4.8 percent since 2016 (MassBio, 2017).

The life science industry is comprised of a highly skilled and highly educated workforce earning an average annual wage of $138,768 in 2016 (MassBio, 2017). In the same year, the median personal income in the U.S. was only $31,100 and the average annual wage for all industries was $53,500 (TEConomy Partners, LLC, 2017). One study showed that average employee wages in the life science industry was 50 percent or greater than average private wages in 43 states and 75 percent or greater in 24 states (ibid). However, the income stated here is not representative of the income received by all life science industry workers. The Research and Development in Biotechnology subsector receives

significantly more than any other subsector and according to *The Scientist*'s 2015 Salary Survey, the lowest earning workers in the industry reported salaries between $22,000 and $35,000 (2015).

The location quotient (LQ, the relative measure of industry activity compared to the rest of country) for life scientists in Massachusetts is 4.32 (BLS), however in Cambridge the LQ skyrockets to 18.1. The below map shows the spatial concentration of the 731 Massachusetts life science companies in and around the Boston/Cambridge region as reported by Esri.

Figure 3. **Massachusetts Life Science Companies**



Source: Esri Business Analyst; author's analysis

2.4 Contingent Labor in the Massachusetts Life Science Industry

Despite its enormous growth and profitability, the life science industry continues to expand its use of contingent labor causing increased fracturing of the employment structure. Anecdotal evidence from key informants suggest that approximately 30 percent of the Massachusetts life science workforce is contingent with the majority (around 60 percent) comprised of workers with a bachelor's degree or lower. Further estimates show that about 25 percent of the contingent workforce within the industry holds a master's degree and approximately 15 percent have a Ph.D.

The life science industry is a highly competitive one and so companies are extremely selective in who they bring on to their team. And, contrary to popular belief, a high level of education does not guarantee job placement. Education level is the primary discriminating factor in sorting through viable candidates, however it only serves as an initial screener to get one's foot in the door. From there the two most important factors that companies look for in selecting new hires and determining wages are work experience and skill type. Therefore, it is possible for a person with lower education but several years of experience within a highly niche skillset to not only be selected over and above his highly educated counterparts but also receive higher wages. For this reason, recent graduates with little to no work experience have an extremely difficult time finding permanent work and must find employment through

temporary employment agencies, hence the high contingency of workers within the bachelor's degree and lower category. For this reason, many recent graduates approach employment agencies stating that they do not care as much about the starting wages as they do about the job title and description so that they can begin building their resume. Surprisingly, PhDs have a particularly difficult time finding even temporary work going, at times, three to four months without work because many do not have any real work experience outside of academia. Additionally, a common perception amongst employers is that they are overly qualified for most positions and even if hired would be quick to leave their employer in the lurch as soon as they secure a better position. Thus, boutique employment agencies that specialize in providing only highly educated and highly skilled candidates have emerged, however, as will be discussed in Chapter 5, the emergence of boutique employment agencies are also in response to increased demand from employers seeking to de-specialize work in favor of a leaner model.

Once a contingent worker arrives at a company, however, employers assess their contingent staff by a totally different criteria. Many contingent workers are hired on a full-time, permanent basis while many are released to their employment agency once the project or negotiated timeline is complete. These temp-to-hire positions are widely available, but difficult to secure because once the contingent workers enter the walls of a company employers expand their assessment criteria and begin to evaluate soft skills such as leadership traits, social skills, and negotiation skills to measure their value add to the company as well as their "fit". But frankly put, these soft skills are not a point of emphasis in most STEM training programs. Temp-to-hire positions provide the employer with a probationary or trial period to measure a worker's various skills prior to committing them as part of the permanent staff.

As mentioned, wages are determined heavily by work experience and skill type, however on average entry level workers with a bachelor's degree and lower will receive between $17-30 per hour while those with a master's degree and PhD will receive on average $30-40 per hour and $40-70 per hour, respectively. Generally speaking, contingent workers with an associate's degree or lower work as technicians or equipment operators and are in positions that usually have well-defined standard operating procedures such as in the product manufacturing space. Interestingly, this group of contingent workers are hired primarily by academic institutions to include academic hospitals such as Massachusetts General Hospital, Partners Healthcare System, Inc., Brigham and Women's Hospital, and Beth Israel Deaconess Medical Center, Inc. The top universities hiring this group are Harvard University, University of Massachusetts Boston, Boston University, and Tufts University. Those with a bachelor's degree operate less as technicians and more as engineers, although the job title with the highest employment in this group is "Biological Technician." Other examples of workers with bachelor's degrees include accountants, sales representatives, IT staff, compliance officers, and quality control officers. This group of workers are hired primarily by the major staffing agencies such as Kelly Services and Randstad, CROs, and academic institutions. Contingent workers with a master's level education do more calculation and analysis-based work with the majority working as statisticians, computer and information research scientists, clinical research associates, economists, and epidemiologists. Interviews also point to a growing number of graduates with a master's degree – namely from Northeastern University – that are filling positions in regulatory affairs and pharmacovigilance, which may be telling of the industry's growing focus in this area. This group of workers are hired primarily by the major sponsor companies. Finally, PhDs work as the researchers with the majority of them working as biochemists, biophysicists, and medical scientists, and they are hired primarily by sponsor companies.

2.5 The Anomaly

Currently, sponsor companies hire the majority of contingent labor, however this balance may shift in coming years as more companies are increasingly outsourcing R&D and manufacturing functions to CROs and CMOs. This is surprising because the main justification for the continued use of contingent labor is centered around cost savings – a careful scrutiny of the company's bottom line. Life science companies are highly circumspect in making decisions that affect costs since even stagnant profits can decrease market value, which would result in loss of investors and in turn, diminished market

capitalization. Contingent labor presumably provides cost savings as discussed earlier, however discussions with employment agencies show that this is, in fact, not the case.

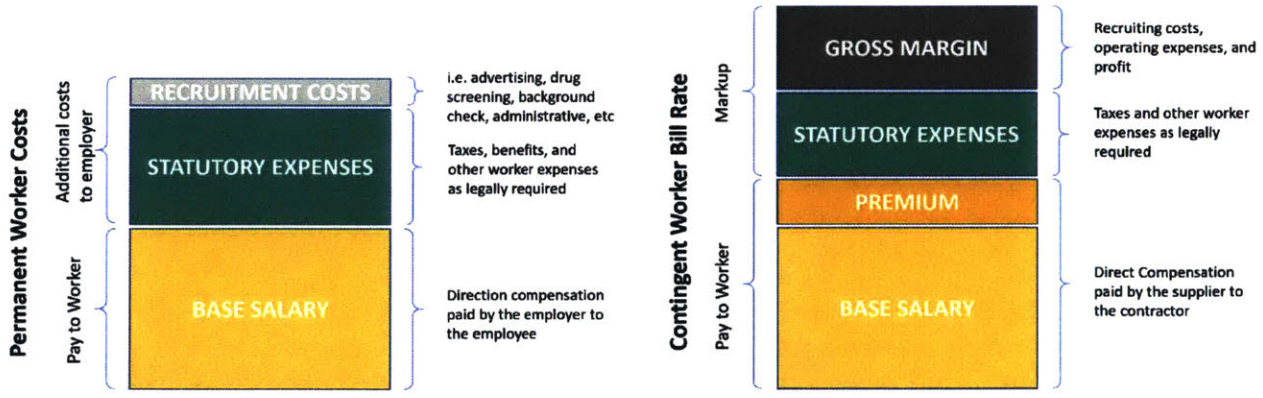
Conservatively, the costs associated with hiring a permanent employee includes recruitment costs, base salary, and statutory expenses, which includes employment taxes and benefits. Employment taxes include Social Security (currently 6.2% on the first $90,000 of salary), unemployment (FUTA, 6.2% on $7,000 of salary), and Medicare (1.45% with no salary cap) (SSA.gov). In most cases, benefits are also a mandatory social payment that conservatively includes health insurance ($2,000-3,000 for single; $6,000-7,200 for family), a dental plan ($240-650), and a 401(k) (varying employer contribution) (Hadzima, 2005). Considering a typical $50,000 salaried employee, the additional costs to the employer are between 25 to 40 percent of the base salary, or a total of $62,500 to $70,000 per permanent employee (Hadzima, 2005).

The discussions with employment agencies revealed that the costs associated with hiring a contingent worker include a massive markup (see Figure 4). This markup includes not only the statutory expenses (minus benefits) but the gross margin that the employment agency receives for their services. In addition, if a company employs a worker on a temp-to-hire basis the employment agency receives a "finder's fee," which could be either a flat rate or the remaining balance of the contract. The pay rate usually includes a premium over the base salary paid to permanent workers in lieu of benefits that range between 20 to 35 percent. The markup varies depending on a number of factors that includes, but not limited to, education level, experience, skill type, and length of contract, and can be anywhere between 25 to 45 percent. This is in line with a recent study that developed a theoretical framework to measure the costs and value of utilizing contingent labor (Fisher and Connelly, 2017). This means that a contingent worker receiving $50,000 could cost the employer an additional 45 to 80 percent of the permanent employee's base salary, or $72,500 to $90,000.

The theoretical framework developed by Fisher and Connelly also showed that contingent workers can have a detrimental effect on organizations by creating negative value. The study showed that contingent workers performed less effectively than permanent workers and had less skills, motivation, and experience resulting in overall less value to the company. Why then do companies in the life science industry continue to utilize contingent labor? This is a basic question that this thesis aims to answer.

Figure 4.

Comparison of Costs to Employer



This chapter provided an overview of the U.S. and Massachusetts life science industries. Despite being the largest and most profitable life science hub in the U.S., the Massachusetts life science industry continues to expand it use of contingent labor. Those with bachelor's degrees and lower makeup the

majority of the contingent workforce at an estimated 60 percent and are hired primarily by staffing agencies, CROs, teaching hospitals, and academic institutions. The remainder of the contingent workforce is comprised of workers with master's degrees and PhDs and are hired primarily by CROs and sponsor companies. These hiring patterns are in keeping with the general findings of this thesis. As companies move towards a core competency model, jobs at the bottom of the employment ladder are shed first and outsourced to CROs and partner institutions. More experienced and highly trained workers are retained, but even these positions are shrinking in availability. The following chapter describes the evolution of work, the arrival of investor capitalism, and how investors are influencing sponsor companies to pursue a core competency model.

Chapter 3 – Literature Review

3.1 The Theory of the Firm

Much of the twentieth century is characterized by an employment system where large organizations developed the critical skills of their employees within the organization. A steep job ladder existed where employees worked their way up from the bottom through an on-the-job learning process (Cappelli et al., 1997). Employees were promoted through an iterative process of skilling and evaluation, thus providing even the greenest high school graduate with the opportunity to one day become a supervisor or even part of the managerial staff. Now, the internal system is falling apart making the training and development of skilled workers nearly impossible. The new organizational structure essentially eliminates entry level positions leaving unskilled school leavers without opportunities to develop their trade. Consequently, unskilled workers are left incapacitated with fewer opportunities to develop their skills and secure higher paying jobs.

In order to understand why the firm is breaking apart it is essential to understand the forces that caused the firm to organize in the first place. Why was the management of employment brought inside the firm just to have it pushed back out? This points to a much broader question of why anything is brought inside the firm when it can be purchased on the open market.

Ronald Coase was the first to provide an answer to this question. He argued that firms exist because they provide an efficient solution to dealing with high transaction costs that would otherwise be incurred if purchased on the open market (1937). By organizing a firm market transactions are eliminated and replaced with an internal system coordinated by the entrepreneur. Therefore, Coase stated that companies will vertically integrate outside functions that have transactions costs that are higher than the costs associated with managing the functions internally.

Later, Oliver Williamson expanded on the Coasian framework to characterize transactions according to critical dimensions: uncertainty, frequency of recurrence, and the degree to which durable transaction-specific investments are incurred (1979). He then identified the most economical "governance structures" according to the varying transaction types. While competitive forces determine whether functions are structured internally or externally, critical dimensions of transactions determine the type of governance structure such as strategic partnerships or franchise agreements. Williamson also described these competitive forces in detail to include the concept of "hold-up," which describes a situation where parties make an investment, but because they do not extract all the surplus created by the investment the transaction becomes costly thereby disincentivizing the parties to transact. Therefore, competitive forces further encourage the integration of functions within the firm.

In the 1980s contract theorists or property rights theorists focused on contracts as a tool to efficiently manage market transactions by writing efficient contracts that outlined specific rights and obligations in order to capture the costs and benefits for the parties involved (Weil, 2014). However, this required comprehensive contracts that captured all the possible outcomes associated with doing business and outlined specific courses of action for every possible outcome, which obviously was not feasible. Further, having contracts as the main tool for governing transactions meant having to draw up a new comprehensive contract for each and every transaction, which was in and of itself a costly proposition. A single, long-term contract could replace the multiple, shorter contracts, but the uncertainty associated with longer periods made them risky and thus too expensive (Coase, 1937). This again encouraged firms to bring certain functions within their boundaries.

3.2 Managerial Capitalism

The period beginning in the late nineteenth century represented the initial boom of capitalism sparked by technologic innovations from the Second Industrial Revolution and the commodification of resources. The advent of the railroad, refrigerated car, telegraph networks, steamship, and cable decimated existing conceptions of time and space as commodities were able to be traded in new markets nationally and globally and without concerns of spoilage. Manufactured goods could be transported in

large masses opening up the flow of capital from the east, particularly in New York, and unlocking the potential for growth towards the west. This expansion of businesses into new markets incented manufacturers to scale up their operations.

Prior to the Second Industrial Revolution businesses increased output by adding more workers and machines – a "labor-intensive" approach to growth. However, with the introduction of specific technologies businesses expanded by rearranging inputs, replacing machinery with more advanced models, reorienting the production process, utilizing new sources and applications of energy, and consolidating intermediate processes within the production stream – a "capital-intensive" approach to growth (Chandler, 1984). As production was scaled up the "capital-intensive" approach reduced the cost per unit of output by much more than the "labor-intensive" approach. Therefore, companies quickly replaced their existing business models with "capital-intensive" strategies and ravenously searched out new ways to achieve greater economies of scale.

The falling costs of production realized from greater scale economies coupled with the explosive growth of markets continued to stimulate demand for technologic innovations. The Second Industrial Revolution pushed industrial operations to new heights with advancements in electricity, fossil fuels, and steel contributing to huge investments in new equipment and processes. Henry Ford's assembly line and interchangeable parts reduced the time to manufacture a Model T from 12.5 hours to just 1 hour and 33 minutes (Weil, 2014) and the Bessemer process introduced a new method for removing impurities in molten pig iron to provide an inexpensive industrial process for steel production. This allowed Andrew Carnegie to drastically reduce costs in the production of rails from $100 per ton to $12 per ton within a 20-year period (ibid.).

However, increased output alone could not effectively exploit the expansion of markets, therefore organizations had to devise new organizational structures, one that integrated mass production and mass distribution within a single enterprise. In the early twentieth century managerial hierarchies began to form in the U.S. in order to support the increased investments in marketing and distribution facilities (i.e. forward integration) (Chandler, 1984). Among the first were the managerial hierarchies established to coordinate the new railroad and telegraph networks (ibid). Then they rapidly spread to other industries allowing retail stores like Sears, Roebuck in Chicago to fill 100,000 mail orders in a single day (ibid). Whereas the former organizational structure consisted of a single owner/manager and authority was devolved to the foreman (who had complete authority to hire, fire, and pay employees), the modern management structure was characterized by a team of salaried managers centralized at the top to guide the complex manufacturing and distribution process (Cappelli et al., 1997).

Managerial hierarchies evolved in response to a growing need for an organizational system that could support increasingly complex operations. As "capital-intensive" industries grew so did the complexities associated with coordinating the production of multiple products and their marketing and distribution to multiple locations. Coordination of the exact "throughput" needed to maintain the minimum efficient scale (scale of operation that minimized unit costs) became a sophisticated balancing act between the flows of input from suppliers, the timing and efficient operation of the production process, and the delivery and sales of output to retailers and consumers (Chandler, 1984). Thus, modern management represents the increased specialization of the management function in response to the growing complexities associated with coordinating several products over several locations with respect to both production and distribution. Thus, managerial hierarchies represented the initial application of the rationalization of management as a science.

The organizations that were successful followed a hard and fast growth formula: 1) investing in equipment and facilities to capture economies of scale and scope, 2) investing in national and international marketing and distribution networks, and 3) investing in managerial hierarchies to coordinate production and distribution (to include vertical integration when necessary) (ibid). In his treatise concerning he rise of managerial capitalism, Alfred Chandler added a fourth element to the rule which was investment in research and development, although this was much less often seen (1984). In this way, organizations systematically transformed themselves into a multifunctional organization and

eventually into a multidivisional one expanding into international markets and diversifying their product offerings to capitalize on economies of scope (ibid).

Through the expansion of managerial hierarchies and mergers and acquisitions large manufacturing companies increased their size and international footprint on an unparalleled scale. At the turn of the century the United States already had the highest per capita income in the world and experienced global monopolies in some industries, especially in mass produced light machinery (Chandler, 1984). However, this immense growth experienced by the modern enterprise could no longer be sustained by a single source of capital (i.e. individual, family, or small number of partners). This led to the development of new financial markets that provided a huge influx of previously inaccessible capital in the form of equity and bond markets. And innovations within the financial markets provided new mechanisms and instruments to both raise capital and move money between sectors more efficiently (Weil, 2014).

These developments provided access to a large number of investors that provided the capital for increased market capitalization, however they also marked the separation of management and ownership. Whereas in the past an individual, a single family, or a set of partners owned and managed a business, the new capital structure piecemealed ownership over to many shareholders while the complex task of overseeing operations was left to managers. As organizations diversified their product lines and increased in size owners took a remote stance and observed from afar, rarely participating in managerial decisions and meeting with managers only around four times a year (Chandler, 1984). Without the necessary information and operational experience owners were not in a position to argue for alternative courses of action. In this way managers became key players in the capital accumulation process and by World War II managerial capitalism was a pervasive force in the American economy.

3.3 Internal Labor Markets

As organizations expanded in the early twentieth century managers had to deal with the major task of recruiting, hiring, training, compensating, and evaluating their workers to support their growing operations. Traditional labor management was more decentralized where decision making authority was devolved to the foremen in matters of hiring, firing, and compensating employees (Cappelli et al., 1997). Interestingly, employment practices took on unique and varied characteristics according to how each foreman ran the job site; work rules, norms regarding effort, and even the work culture were very much dependent on the foreman's personality (ibid). Therefore, traditional employment practices were also characterized by a high degree of variability even within the same organization. However, by the 1920s the increasing size and scale of industrial operations called for more formal and standardized employment practices that increased predictability and control. This restructuring towards more formal employment practices led to the development of what Peter Doeringer and Michael Piore termed internal labor markets (1971).

Characteristics of the Internal Labor Market

The internal labor market can be illustrated by an employment ladder (accessible only by its members) that workers climbed through promotions while vacant positions were backfilled internally based on seniority, skill, and competency. Governing this system were administrative rules and procedures set by managers as well as local and industry-wide customs, therefore decisions on wage setting, allocation, training, and tenure were unique to each organization and widely varied across different industries. Conversely, the external labor market was controlled by economic variables according to conventional economic theory (i.e. economic principles of supply and demand) (Doeringer and Piore, 1971).

Members of the internal system enjoyed exclusive rights that those in the external system were not privy to. The internal system, for example, was shielded from the competition faced in the open market, which allowed its members to have exclusive access to vacant positions. However, internal labor markets were not closed systems; ports of entry and exit located at entry level positions provided access

to and from internal labor markets. And despite the distinction between the two systems, they were interconnected and exhibited a continuous exchange. For this reason, internal labor markets were sensitive to external market conditions such as variations in unemployment, wage rates, and available supply of labor.

The degree to which the internal labor market retained its distinct characteristics apart from the external labor market was based not on the existence of administrative rules but rather on the rigidity of those rules (ibid). It was the rigidity of the administrative rules that defined the boundaries of internal labor markets and the extent to which external economic influences affected wage setting and allocation of labor resources within an organization. Therefore, the exclusivity of rights enjoyed within internal labor markets was dependent on this rigidity.

The internal labor market was structured by function with a standard management hierarchy (i.e. production, finance, accounting, human resources, etc.) overseeing each function. This organizational structure clearly delineated management from labor, and ports of entry and exit exited within each echelon. Typically, unskilled and inexperienced personnel backfilled entry level labor positions while college graduates backfilled entry level management positions. Training for entry level labor positions were primarily conducted through informal on-the-job training or apprenticeship programs while training for entry level management positions involved more formal programs that required classroom instruction. Both labor and management positions exhibited high specialization of skills, which created a variety of distinct job titles (Cappelli et al., 1997). For example, assembly operation in the production of a specific product might be differentiated into 100 distinct job titles. This meant each position was responsible for a very specific task with little to no overlap with other forms of work. For example, an accountant would never stray into marketing territory to conduct market research or work on advertising campaigns.

Promotions within internal labor markets worked very differently between labor and management employees. For labor employees, promotions were based primarily on seniority with open positions backfilled by the next senior-most employee until eventually an entry level position became available for a worker from the external labor market to fill. For management employees, however, promotions were based primarily on merit, but this is not to say that seniority was not at all a factor. Management employees that had been in a single position for a long period were given preferential consideration much like a system based on seniority (ibid). The greatest distinction between labor and management employees came with considerations in job security. While management employees were for all practical purposes awarded with a guarantee of lifetime employment, this was not the case for labor employees who frequently experienced layoffs according to variations in the economic cycle. Like promotions, layoffs were dependent on seniority with the most junior employees laid off first. However, during upturns in company performance the same workers were in many cases hired back and would often leave their current jobs to return to their former place of employment having invested something resembling property rights in the company (ibid).

A final point in considering the major characteristics of internal labor markets is in regards to wages. For labor employees, wages were based solely on the number of hours worked with the only variation in pay coming from overtime work. Management employees, on the other hand, had bonus plans built into their salary based on overall corporate performance (ibid). Compensation for labor employees had essentially no association with company performance and was based solely on job title and seniority (ibid).

The Theory of Internal Labor Markets

The formation of internal labor markets is driven by a combination of two broad forces, each of which can be broken down into a series of three critical factors. First, internal labor markets are generated by an organizational force abstracted from theories on organizational behavior, economic sociology, and actual historical evidence. Therein lie the three factors critical to the development of internal labor markets: 1) skill specificity, 2) on-the-job training, and 3) customary law (Doeringer and Piore, 1971). Secondly, internal labor markets are dependent on a set of factors rooted in conventional

economic theory: 1) the value of internal labor markets to the labor force, 2) the cost of labor turnover to the employer and the role of such markets in the reduction of turnover, and 3) the technical efficiencies of an internal labor market in the recruitment, screening, and training of labor (Doeringer and Piore, 1971). Together, organizational and economic forces work to form internal labor markets.

- *Skill Specificity*

Workforce training can be defined as either general or specific training. General training is acquired externally and refers to a standard set of knowledge and skills that is required by every job across all industries. Put differently, general training increases the marginal productivity of a worker by the same amount in one enterprise as in another. On the other hand, specific training is acquired within an organization and refers to the knowledge and skills unique to a single enterprise within a single industry. From a management perspective this is important for two reasons. First, specific training raises the costs sustained by the employer as opposed to the worker and second, it increases the absolute costs associated with this kind of training (ibid). As the skills required within an organization become more specific, the more difficult it becomes for the worker to utilize the specific skills elsewhere. Therefore, the worker is less incented to invest in such training, which consequently increases the cost of training to the employer. Absolute costs also go up with increasing specificity because the highly niche skillset makes it more difficult for the worker to find institutions that provide such training, which decreases the economies of scale of training. Similarly, as skill specificity increases the costs of recruiting and screening for positions also goes up since economies of scale of advertising and standardized testing cannot be realized. This also adds to raising absolute costs. Despite these high costs, however, employers are forced to provide the specific training due to the lack of availability of the specific training elsewhere. Both of these reasons act to encourage the employer to reduce labor turnover (ibid).

- *On-the-Job Training*

The second critical factor in the formation of internal labor markets is the importance of on-the-job training. On-the-job training is less important for white-collar jobs where formal education is far and away the greater source of skill development, but even for professional and managerial jobs formal education serves more as a screening device in selecting new hires (ibid). On-the-job training is still highly pertinent because it acts as a prerequisite for successful utilization of the formal training (ibid). On the other hand, for many blue-collar workers on-the-job training provides the greater proportion of skills utilized in the job. On-the-job training is nearly essential for this group since in many cases there is no replacement for training on the job and the required skillset for the succeeding position builds on training received on the job below it. For these reasons, from a manager's perspective on-the-job training is a critical factor for creating an internal system. Furthermore, on-the-job training provides a costless training process that can, in fact, add value to the organization through the output produced by the trainee, which is otherwise missed when training is conducted externally. However, on-the-job training is not always a costless process since frequently materials are wasted, equipment is damaged, quality is diminished, and productivity of nearby workers is reduced (especially of supervisors who must tend to the trainee) (ibid).

- *Customary Law*

Whereas the first two factors can be categorized as organizational forces that provide an understanding of internal labor markets irrespective of past precedents, customary law is drawn from a historical analysis of organizational behavior including group and individual psychology as well as learning theory. Custom in the workplace refers to a set of rules that govern employment practices including wages and discipline and it determines the stability of an organization. This stability within an organization adds value through the efficient operation of an organization. Stability also causes workers to come in routine contact with one another, which results in the formation of social groups and communities (ibid). These workplace communities inevitably form rules governing the actions of its members and through a coordinated effort, community members are able to apply pressures on its members or even management if they act at variance with their rules. These rules or customs are of particular importance to internal labor markets because the rules governing important employment

practices like wages, allocation of labor, and disciplinary action are highly dependent on these customs. Historical analysis is important when considering customary law because customs are based on past practice. This means that any procedure if practiced repeatedly becomes customary and is validated or endorsed into "law" by outside social groups that support and eventually adopt them.

A key question that Doeringer and Piore ask in their treatise on internal labor markets is also one that is central to this thesis: "how can customary laws at the workplace continue to command allegiance in a context where institutional survival is dependent on economic success?" (ibid). Doeringer and Piore explain that although the ultimate sanctions on customs are in fact economic, the internal labor force is also able to wield economic pressures on management if their customs are threatened in the form of strike or sabotage (ibid). Further, a disgruntled internal labor force whose customs have been sanctioned or even dismantled can indirectly and inadvertently apply economic pressures on management through such actions like reduced work pace, "misplaced" tools and materials, increase in defective outputs, and the like (ibid). This is a major fear of managers and thus a major reason for the preservation of workplace customary laws. As customs become endorsed, adopted, preserved, and even constrained by management they become hardened against economic pressures explaining the rigidity of administrative rules that internal labor markets depend on (ibid).

- *Value to the Labor Force*

Through a series of interviews with management and union officials, Doeringer and Piore found that members of the labor force place a positive value on internal labor markets (ibid). Their study found that the labor force perceives internal labor markets to provide greater job security and higher chances of upward mobility. Another reason for the positive value placed on internal labor markets is due to the perception that internal labor markets are associated with higher standards of equity and due process (ibid). Opportunities in internal labor markets such as "open-door" policies with management and established administrative procedures for filing grievances provide worker protections that the external labor market does not. For these reasons, in order to secure a position in internal labor markets workers should be willing to forego a portion of their earnings equal to the perceived value of the benefits described. The cost savings that managers realize in reduced wages should incentivize managers to create an internal labor market.

- *Turnover Costs and Turnover Reduction*

The two costs associated with turnover are *replacement costs* and *termination costs* (ibid). With replacement costs there are three major elements: 1) recruiting, 2) screening, and 3) training. As discussed earlier, replacement costs are connected with skill specificity in that they increase as skill specificity increases thereby raising absolute costs. Termination costs can fall on both workers and employers and come in the form of severance payouts, unemployment insurance, or losses in time and manpower as both are spent in litigation and administrative hurdles battling formal grievance procedures or union restrictions. Since the labor force places positive value on internal labor markets turnover is reduced in such markets and the costs associated with turnover are reduced. Additionally, turnover is reduced when seniority is made a primary factor for advancement as it is in many internal labor markets. This incentivizes workers to stay within an organization in order to build seniority. This also reduces turnover costs because management can position its most senior workers in jobs where turnover costs are highest.

- *Technical Efficiencies in Recruitment, Screening, and Training*

Internal labor markets provide a level of efficiency that can further generate cost savings associated with turnover, specifically with respect to replacement. This is because internal labor markets are able to provide management with historical data on candidates compiled throughout their tenure within the organization. Information such as attendance, skill level, behavioral traits, and work ethic is readily available to managers through discussions with immediate supervisors or more formal documentation and performance review processes. A thorough screening process could provide a comparable level of information on external candidates but at a prohibitively high cost. Furthermore, candidates drawn from the internal system have acquired knowledge over time of the organization's

systems, design, operation, key personnel, and nuances that candidates from the external labor market would otherwise have to learn from scratch. These effects related to the recruiting, screening, and training of new workers further work to reduce transaction costs and develop internal labor markets. These advantages are outweighed by hiring externally if the external candidate brings with him or her knowledge or skills whose value add to the organization provides a marginal benefit that is greater than that of hiring internally.

The Rise of Internal Labor Markets

The most significant pressure in shaping internal labor markets came from trade unions whose goal was to limit competition based on labor costs by imposing standardized employment practices and wages on employers. But unions were met with fierce resistance by management. Coalitions like the Special Conference Committee and the American Management Association brought together executives from major companies in order to coordinate their efforts in fighting off unions. The most well-known union avoidance program was called "the American Plan," which was a coalition of anti-union employers that deemed unions to be un-American, adversarial, and inefficient (Wakstein, 1964). It even went as far as to imply that unions had some connection with Communism playing on the fears during the Red Scare.

Gradually employment practices started to become standardized and codified in the form of a series of government policies aimed at boosting efficiency and overall productivity. This rationalization of employment practices mirrored the military model of screening, selecting, and placing workers according to internal manpower planning systems (Cappelli et al., 1997). One of the first such policies was the "Washington Agreement," which imposed a series of regulations specifically aimed at the railroad industry in order to standardize employment practices related to safety and wages. Later, in the 1930s, important employment legislation further standardized employment practices across all industries in order to shield workers from the externalities of industrialization. Among the most significant employment legislations included the Fair Labor Standards Act (FLSA) and the National Labor Relations Act (NLRA), which offered protections from management abuses and gave significant power to employees by protecting their right to form unions and take collective action. These and other labor policies and agencies created during the first half of the twentieth century represented a methodological and scientific conception of employment issues. This rationalization of employment practices represented the first steps in delineating the boundaries of internal labor markets.

A watershed in the history of workers' rights came in the 1930s with the passage of the "Second New Deal" legislations which included the NLRA. The NLRA compelled employers to bargain with unions providing unions with the necessary support to grow. During the period between 1935 and 1954 the percentage of total employment that had union membership grew from 7 percent to 35 percent (Weil, 2014). As unions grew in influence different industries adopted the union model and through comparison and implicit competition the model permeated throughout the economy (Cappelli et al., 1997). However, the enacted legislation, despite being a major win for workers' rights, did not completely kill off union avoidance campaigns; employers simply adopted a more nuanced strategy. Union avoidance was still a major objective for most employers, therefore beginning in the 1920s they slowly implemented employee welfare programs to build employee loyalty and keep out worker-controlled unions (Cappelli, 1999). Consequently, employee welfare came to be managed through company-level social policies that included employee representation, vacation, stock ownership, health insurance, retirement plans, and other fringe benefits. But by doing so these employers were essentially building their own "company unions" by distributing these employee welfare benefits through an internalized system thereby building the foundations for welfare capitalism. True to form with the Coasian framework, the increased costs of labor associated with the rise of the welfare state in the 1930s helped shape internal labor markets.

During World War II, President Franklin D. Roosevelt signed an executive order that froze prices on just about anything that had to do with cost of living in an effort to control wartime inflation that the global crisis would have inevitably created. The executive order also prohibited wage increases along with any changes in employment. Such action led to the increased interest in benefits packages and the

expansion of welfare capitalism. It also paved the way for new mechanisms to enhance employee benefits such as multiemployer pension plans, which were created under the Labor Management Relations Act of 1947.

The Post-World War II era is seen as the golden age of employee protections characterized by deeply established internal labor markets with both unionized and non-unionized sectors. Welfare capitalism was also well-rooted in internal labor markets as companies competed for talent by offering greater incentives. As internal labor markets expanded along with the growing scope of welfare benefits and new workplace laws, the administrative rules required to govern the system became increasingly complex. This created a need for new departments to manage the internal labor system. In 1955, less than 30 percent of companies had human resource management departments, but by 1965 this figure grew to 35 percent (Weil, 2014). With the addition of several new workplace laws dealing with discrimination, occupational health and safety, and affirmative action the proportion of companies with human resource management departments grew to 50 percent in 1975 and 70 percent in 1985 (ibid).

However, by the 1970s, companies were realizing that the costs associated with internal labor markets were becoming too high. Employers tried to adapt to the internal system by reducing wages to compensate for the growing demand for benefits, but this only made the system of benefits more precarious as employers increasingly moved away from traditional pension plans towards a guarantee-free defined contribution plan such as the 401(k). In 1951, wages represented 83 percent of total compensation, but by 1961 it dropped to 78 percent, by 1971 to 74 percent, and by 1979 to only 70 percent (Weil, 2014). The period between post-World War II through the 1981 recession represents the golden age of employee protections, but the years following illustrate a serious degradation in the structural integrity of internal labor markets and the administrative rules governing their employment practices.

The Decline of Internal Labor Markets

As briefly discussed earlier, the integrity and resilience of internal labor markets are not dependent on administrative rules but on the rigidity of those administrative rules. These rules are derived from customs in wage setting, promotions, layoffs, and other employment practices that through repetition and industry sanctions have become law. And the rigidity of these rules is derived from the collective strength of workers and their ability to apply pressures on management when it attempts to test, dismantle, or attenuate those rules. By the 1970s, on account of increased global competition and a series of macroeconomic shocks, sophisticated union avoidance campaigns were established to break down internal labor markets in an effort to control costs and increase revenues. Eventually, institutional changes in capital markets provided the impetus to concentrate mainly on short term returns while technological advances provided the tools to redraw boundaries of internal labor markets.

Ironically, the very labor policies implemented during the 1930s designed to protect workers may have facilitated in the degradation of internal labor markets (Cappelli et al., 1997). Two of the most important labor laws passed during the height of the labor movement included the Fair Labor Standards Act (FLSA) of 1938 and the National Labor Relations Act (NLRA) of 1935. The FLSA was created in order to protect employees from management abuses such as excessive hours and was significant because it formally segregated management from employees through the introduction of such language as "exempt" and "non-exempt" employees. The government saw management employees as "exempt" from the protective measures of the regulation because they did not need such protections from the employer, however "non-exempt" employees were guaranteed protective measures such as national minimum wage and a 50 percent premium in overtime wages. Likewise, the language in the NLRA also made the distinction between laborers and managers. Both of these key labor laws imposed significant administrative costs to the employer, but they also provided employers with a way to avoid them. Employers could change the non-exempt status of its employees to exempt by either changing the hourly wages of its employees to a monthly salary or by shifting to a contingent payment system. By utilizing contingent workers leased through employment agencies employers could effectively avoid many of the

burdensome requirements mandated by the labor laws, thus eliminating the cost and administrative burdens associated with compliance. Additionally, employers could further reduce costs through the use of contingent labor by eliminating turnover costs as well as the costs of providing employee benefits. This provided huge incentives in the form of cost savings for employers. In this way, the very laws designed to provide worker protections encouraged employers to dismantle internal labor markets.

The most significant factor causing employers to change the employment relationship came from increased competitive pressures both within the U.S. and internationally. Within the U.S., competitive pressures significantly rose with the deregulation of airlines in 1978 and trucking and railroads in 1980 as well as the gradual easing of regulations in financial services and telecommunications (Cappelli et al., 1997). In industries that have always experienced high competition such as with meatpacking and tire production, competitive pressures increased through lower-wages and non-union operations (ibid). From the global economy, international competitors were able to gain market share primarily through their labor cost advantages. Competitive pressures from all angles forced U.S. companies to consider new ways to remain competitive aside from just cutting costs and prices. One strategy was to track changes in consumer demand more closely and align the production system with the changes in demand so that output could be quickly scaled up or down. This focus on flexibility became a major factor in the restructuring of employment because it encouraged employers to increasingly adopt a more variable cost structure. Japanese competitors like Toyota were among the first to display the efficiency and success of this flexible model, and almost immediately the rest of the world followed suit by adopting similar business models like just-in-time production and flexible specialization. The implication for internal labor markets was that this represented the beginning of the end. The long-term commitment required to hire and train unskilled workers represented a significant fixed cost for employers, which meant that a broad and indiscriminate move towards a more contingent work structure was well on its way.

3.4 Investor Capitalism

During the 1960s and 1970s, U.S. companies became obsessed with growth operating under the assumption that bigger was better. They believed that synergies could be created and economies of scale could be achieved by bringing together unrelated businesses under one roof, a corporate practice which was later aptly dubbed the "firm-as-portfolio" model. By 1980 these conglomerates dominated the global economic scene with fewer than 25 percent of the Fortune 500 companies making all their sales within a single industry (2-digit SIC) (Davis et al., 1994). But after the 1981 recession sentiments changed and new trends emerged driven by the notion that unbundling conglomerates and focusing on core competencies was more profitable. The restructuring of organizations was made possible by innovations in debt financing, specifically with the development of "junk bonds," which allowed for the raising of large amounts of capital to purchase public companies and take them private through leveraged buyouts. In a sense, the unbundling of conglomerates represented the initial dismantling of the managerial power structure.

Managerial capitalism was waning through the 1970s, but the 1981 recession marked the critical shift in power from managers to shareholders. Although this power shift had its roots in economic and political factors there was a significant philosophical basis for the change. Together, the perception that management had become complacent and resistant to change despite transformations in the competitive landscape along with the the notion that management operated the companies with more complicated goals than simply maximizing profits, made shareholders impatient and demanding (Useem, 1996). From this came the philosophy that if shareholder demands were prioritized capitalism would function better, therefore shareholders should be elevated in power and influence and managers placed beneath them in order to execute their demands (Fox and Lorsch, 2012). From this new mentality investor capitalism was born.

But in executing their newfound philosophy shareholders had to overcome a fundamental obstacle. With ownership so widely dispersed amongst the countless shareholders, how could they keep managers in check? The obvious answer was by selling shares, which disciplines managers by driving

down stock prices, however it would be nearly impossible for a single shareholder to make any discernible impact. And at the time no forums or communication channels existed to coordinate the buying and selling actions of all shareholders. That only left one other option, which was to cast votes, but that carried its own problems. The most significant was that many shareholders simply sold their shares when performance suffered, and since short-term investors aren't as good as long-termers in disciplining managers, casting votes was a weak solution. The tables soon turned in favor of shareholders following the regulatory easing of financial markets in the 70s and 80s and with advances in technology.

On May 1, 1975 the U.S. Securities and Exchange Commission (SEC) mandated the deregulation of the brokerage industry, which abolished high fixed rates for trading stocks and allowed market competition to dictate commissions. This significantly decreased market transaction costs allowing investors to trade high volumes with high frequency. And with advances in technology came developments in financial engineering and computing hardware and software providing much greater sophistication to the market and thus, greater capacity to capture value. With these advances came new mechanisms for trading, price decimalization, an automated trading system, financial derivatives, and even new markets. Together, lower costs and computerized systems allowed for huge volumes to be traded at lightning speeds, but these factors also acted to decrease holding periods. Whereas in the 1950s the average holding period for common stocks traded on the New York Stock Exchange was around seven years, now it is closer to six months, and some high frequency traders could even make trades whose holding periods were measured in milliseconds (Fox and Lorsch, 2012). There is no doubt that these two developments catapulted financial markets to new levels of efficiency, but they also added a significant degree of volatility and complexity that the average household could not easily follow. As a result, household investors that once dominated the stock market had to make way for professionals and institutional investors.

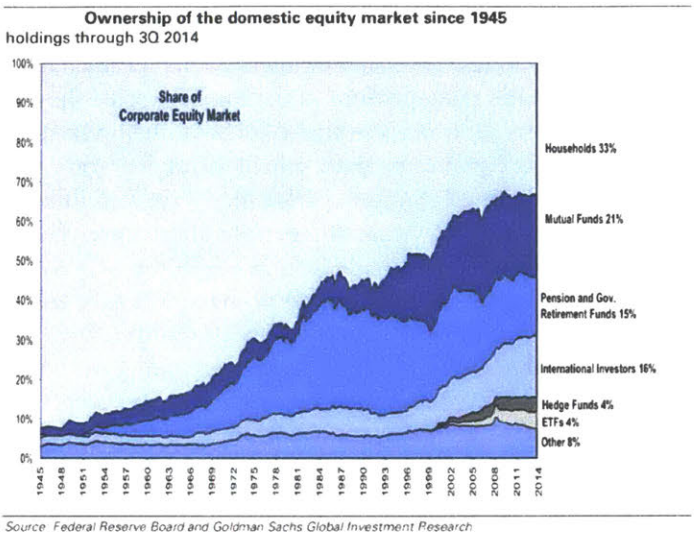
Institutional Investors

A major impetus in the rise of investor capitalism came from a growing base of institutional investors compared to individual or household investors. In 1950, households owned more than 90 percent of outstanding shares of U.S. companies, but by 2012, institutions owned between 65 and 70 percent of outstanding shares (see Figure 5) (Fox and Lorsch, 2012). This trend of institutional ownership really began to take shape sometime in the 1980s through changes in employee retirement plans. In 1980, approximately 58 percent of the workforce had defined benefit plans (pensions) with only 10 percent of the workforce holding defined contribution plans (i.e. 401(k)s and IRAs). However, by 2011 these figures were reversed with 10 percent of the workforce holding defined benefit plans and 60 percent of the workforce with defined contribution plans (Weil, 2014). This is significant for the discussion of the rise of institutional investors because a hefty portion of defined contribution plans are managed through mutual funds resulting in a steep climb in the value of household assets held by major investment companies. In 1980, only 3 percent of household financial assets in the U.S. were held in investment companies, but by 2011 that proportion grew to 23 percent (Weil, 2014).

By 2011, mutual funds held nearly a quarter of all U.S. issued stocks (Weil, 2014). Moreover, the trillions of dollars of private assets held by mutual funds became concentrated in just a handful of companies. In 2011, the top five mutual funds managed 40 percent of total net assets, the top 10 managed 53 percent, and the top twenty-five managed 73 percent (ibid). Compounding these concerns related to the growth of institutional ownership is the evolution of investment strategy. Around the 1990s the largest institutions adopted the practice of passive investing or index investing. This is a long-term investment strategy aimed at maximizing returns by allocating investments over a preset market index in order to keep the buying and selling of shares to a minimum. In 1996, nearly 16 percent of all institutional stock holdings were indexed (Useem, 1996). Looking forward, a report published by Moody's Investors Service Inc. stated that index funds will hold over 50 percent of investment-management business by 2024 (2017). This is significant because index investing forces institutional investors to play the long game rather than dumping shares at the first sign of declining performance,

which causes them to be a lot more invested in matters of corporate governance. Even actively managed investments suffering from poor performance cannot be easily disposed of since this requires finding buyers that are willing to purchase the shares, which can run in the millions.

Figure 5.



Source: Federal Reserve Board and Goldman Sachs Global Investment Research

By placing household wealth in the hands of a relatively few number of institutions, investors across the country unwittingly unleashed the forces of investor capitalism. As a result, pensions funds, hedge funds, bank trusts, insurance companies and a whole slew of different money managers began pressing companies, especially distressed ones, to become more productive, more competitive, more profitable. In the 1980s, institutional investors demanded shareholder proxy resolutions, which gave them access to the executive board room and even a seat at the table. Soon after, institutions were able to influence governance by rescinding poison pill provisions from the company bylaws, introducing confidential voting, and establishing shareholder advisory committees (Useem, 1996). Furthermore, through the extension of corporate governance to institutional investors, executives were voted out and replaced, bust-ups were authorized, takeovers were encouraged, and mergers and acquisitions were given the green light. Ownership began to convey the right to do whatever was necessary to turn a profit (Weil, 2014).

Private equity in the form of hedge funds deserve special mention because they represent a particularly aggressive and risky form of investment. Hedge funds are unique in that the fund managers are given curiously wide latitude in their investment strategies in order to make money on its portfolio positions. As a matter of fact, hedge funds are only limited by their mandate and can basically invest in anything anywhere in the world and utilize a variety of investment tools such as derivatives to "hedge" their investments. Therefore, hedge funds are indifferent to the market direction of their proposed investments. Another key characteristic of hedge funds is that they typically employ leveraged capital to amplify returns. Since this leveraged capital (short-term and very high-interest) constitutes the lion's share of the total invested capital, hedge funds are under extreme pressure to realize high returns. For this reason, institutional pressures applied specifically by hedge funds tend to be aggressive and very much hands-on. Interestingly, it is precisely from this pressure that hedge funds derive their profits since the radical restructuring caused by the pressure produces results. In fact, studies have shown that hedge funds generate on average 5 percent returns just from the announcement of their involvement with a target company (Schor & Greenwood, 2007). Thus, institutional pressures specifically from hedge funds have warranted its own distinct appellation, "hedge fund activism."

Many hedge funds focused on takeovers like to target companies that are considered distressed and undervalued. Through its private equity and leveraged capital hedge funds often bid for majority ownership of the targeted company in both hostile and non-hostile takeovers. But in situations where the hedge funds decide not to pursue a takeover they still utilize their new ownership position to apply immense pressure on management to radically restructure the organization. Hedge fund activism can include changing the board of directors, appointing new management, or pushing for the sale of the company. Between 1994 and 2006, the number of hedge funds increased by a factor of ten (Schor & Greenwood, 2007). From the perspective of the shareholders of the targeted companies, takeover bids are almost welcomed because this pressures management to get the best price they can for shareholders. And if they don't, shareholders are quick to remind them that they have the opportunity to sell themselves.

Even executive compensation came to be determined through a vote. This fostered the development of a performance-based compensation system for CEOs and other senior executives, which could be seen in some lights as a means of buying managerial compliance. Between 1930 and 1970, executive compensation for CEOs of the fifty largest companies in the U.S. stayed relatively constant at the $1 million mark (in 2000 dollars), however beginning in the 1970s compensation for top executives spiked hitting $1.2 million, then in the 1980s it was around $1.8 million, $4.1 million in the 1990s, and $9.2 million in the first half of the 2000s (Weil, 2014). Also, beginning in the 1960s salary and bonuses began to represent a decreasing share of total compensation for top executives. As company ownership became increasingly valuable, executive compensation started to be replaced with stocks and options. In the 2000s, only 40 percent of total compensation came from salary and bonuses (ibid). Consequently, top executives became increasingly invested in their companies' stock performance. The performance-based compensation system added to the increasing income disparity between the top and middle-income earners. In 1979 the ratio of an average CEO compensation package to that of an average production worker was 37.2 to 1; in 2007 this ratio was 277 to 1 (ibid).

Core Competency and the Pressures to Restructure Employment

The 1981 recession marked a shift in power from managers to investors, which heralded a change in the way businesses were to be conducted. As investors took hold of the reigns a new trend emerged across the business landscape – a move towards core competency and the shedding of non-essential functions. The idea was simple: discover exactly what your company was best at and drop everything else. At the core of this concept was the intent to minimize operating costs and maximize profits. The way companies did this was by pursuing greater efficiency and increasing quality in order to boost sales. Therefore, in the 1980s and 1990s, companies started to clean house by selling, outsourcing, and downsizing.

The core competency model was justified by the fact that expelling non-essential functions decreased transaction costs. Ironically, the same justification that allowed for the development of internal labor markets was now the impetus for its deconstruction. Janitorial and maintenance functions were among the first to be pushed out as the focus on core competency grew (Weil, 2014). As more and more companies eliminated these functions from within their walls, new competitive markets developed to fill the demand for these services. And as the market for these services grew competitive pressures lowered prices to the point where the transaction costs of outsourcing these services became lower than bringing them internally.

In the 1960s, 22 percent of Fortune 500 companies were acquired in mergers, but through the 1980s and 1990s outsourcing became a central part of companies' strategies. Apple is a key example of how the world's most valuable company used the core competency model and outsourcing to grow. By 2012, the company had an estimated 750,000 people working on its products worldwide, but the company directly employed only 63,000 employees to support its core functions in design, engineering, and sales (Weil, 2014). Other broad functions that companies retained as part of their core competency strategy included accounting, finance, marketing and more recently, IT. Interestingly, as is the case with the life sciences, companies are beginning to outsource even functions that are deemed part of their core

competency suggesting that the former focus on developing companies' distinctive niche or competency has further devolved to just those functions necessary to market and sell their respective goods or services.

As discussed by Coase and Williamson, transaction costs were the reason for the development of the firm, but it was Doeringer and Piore that theorized the major factors for the development of the internal labor market. Central to Doeringer and Piore's argument was the concept of *rigidity* applied to administrative rules. It was this inelastic quality that supported and gave strength to the walls of internal labor markets, however with the advent of new technologies and the breakdown of customary laws in the workplace rigidity gave way and soon succumbed to the pressures of management. During the same time, managerial capitalism was coming to its end as institutional investors came to the fore. The rise of institutional ownership and the decline of household investors signaled the beginnings of investor capitalism characterized by a shift in decision-making power from managers to investors. All this was spurred by a growth chasing model and the reckless pursuit after profits. Now, the breakdown of internal labor markets and the rise in investor capitalism has led to the current focus on core competencies, which has led to widespread downsizing and outsourcing of work functions.

Chapter 4 discusses the challenges and constraints facing the life science industry. These challenges and constraints put immense pressures on companies' ability to control costs as well as revenues. Coupled with investors' ravenous pursuit after profits, the life science industry is facing significant restructuring and potentially dangerous consequences. This is the topic of Chapter 5.

Chapter 4 – Challenges and Constraints

Year after year the life science industry is plagued by the same challenges and constraints, but instead of mitigating their effects or better yet, overcoming and eliminating them altogether, the industry continues to see those same challenges and constraints intensify and gradually diminish its competitive advantage. The challenges stem from the inherent complexity of bringing a successful drug to market, and that complexity has been increasing each year with advances in science. With each new discovery and advancement in technology new skills are required, which in turn calls more talent with greater specialized skill sets, more lab space and equipment, more time for R&D to sort and validate the volume of data, and more investments to sustain the whole process. Moreover, the industry is increasingly constrained by a series of factors making it increasingly difficult to realize profits. This chapter discusses the major challenges and constraints faced by the life science industry.

4.1 Challenges

The life science industry is highly research intensive and one of the most technically complex industries in the world. It is characterized by a very long R&D pipeline taking on average 14 years from initial discovery to the marketplace with clinical trials alone taking on average six to seven years (Paul et al., 2010; PhRMA, 2015). The length of the R&D timeline represents a major concern for biopharmaceutical companies not only due to the accruing costs but also because a long timeline could affect their product's market potential. As several companies simultaneously pursue a marketable product targeting the same disease, companies engage in an all-out race to be first to market with their product. A loss in that race could have devastating consequences affecting market performance. Also, any unforeseen extensions in the R&D timeline is equally worrisome as this could eat into the drug's commercially usable patent term further reducing the ROI (Schuhmacher et al., 2016).

In order to support this long process significant manpower and capital are required, which is why 22 percent of U.S. life science employees work specifically in the R&D pipeline and costs an estimated $2.6 billion to research and develop a drug (Kennedy, 2018; PhRMA, 2015). However, a more comprehensive accounting of all expenditures directly and indirectly associated with drug R&D produces a figure between $3-12 billion (Schumacher et al., 2016). These costs have significantly increased over time. One study calculated that the annual inflation-adjusted increase of R&D costs was 8.6 percent from 1950 to 2009 (Munos, 2009). Whereas in the 1990s the average cost per new molecular entity (NME) was $250 million, by the 2000s this figure jumped to $403 million and $873 million by 2010 (Schuhmacher et al., 2016). If calculated by phase, drug discovery and preclinical development consume 33 percent of the total cost per NME, clinical trials represent 63 percent, and the costs accumulated during submission to FDA and marketing represent 5 percent of total costs (Paul et al., 2010).

This high cost of developing a new drug can be attributed to two major factors: 1) the long development timeline and 2) the low success rate of bringing a drug to market. First, the long drug development timeline affects total costs because the capital used to support R&D is partially leveraged, which means those funds are continuously capitalized until returns are realized. This represents a significant increase in the overall R&D costs. Secondly, according to the Center for Medicine Research International (CMR) the average success rate from first toxicity dose to FDA approval is 4.9 percent (CMR, 2014). This low success rate consequently affects the growth rate of new NMEs, which is a mere 2.1 percent per year (Scherer, 2011), however the inflation-adjusted R&D expenditures are rising at about 8.6 percent per year, which means the low success rate and the respective investments lost in failed projects is causing R&D growth to outpace NME growth. In addition, the infrastructure and personnel requirements stemming from advances in technology and drug development processes such as target-based drug discovery, combinatorial chemistry, DNA sequencing, high-throughput screening (HTS), and virtual drug design are further increasing the R&D timeline and costs (Paul et al., 2010).

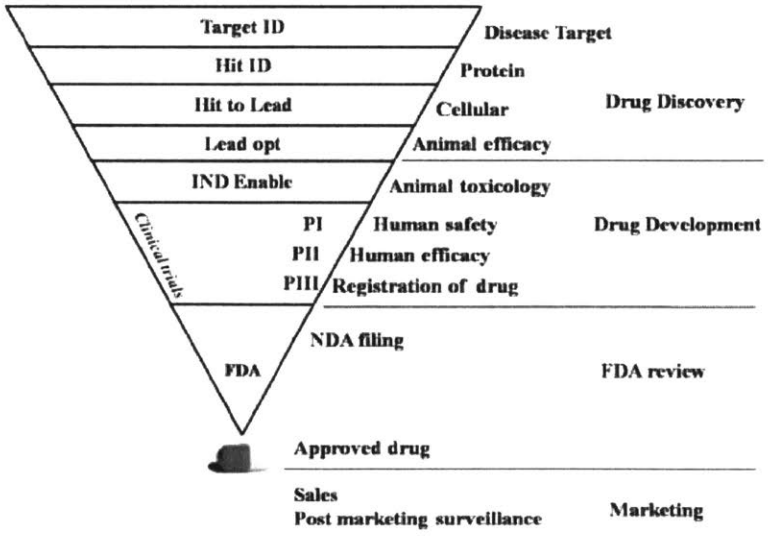
The literature discussing the success rate of NME development points to a variety of reasons for the low probability of technical and regulatory success. Schuhmacher et al., conducted a review of this literature and created the following list of attributing factors (2016):

- lack of reliability of published data
- suboptimal pharmacokinetics (PK) results
- poorly predictive preclinical models in discovery research and preclinical testing including animal trials
- the complexity and uncertainty of target-based drug discovery with the related advanced complexity of target selection, a competition for proprietary targets, and the complex process of target validation
- complexity of clinical trials
- increasing demands from regulatory authorities and payers
- the lack of know-how of smaller organizations resulting in a lower probability of success than large organizations

The drug development model still operating today has remained essentially unchanged for more than 50 years. It is a sequential process with mainly four phases: A) drug discovery, B) drug development, C) FDA review, and D) manufacturing and marketing (see Figure 6). This process begins with the identification of a target that causes or contributes to a disease. The target can be either a protein, DNA, or RNA, which once identified must be validated by demonstrating that the modulation of the target had a therapeutic effect. If a therapeutic effect is observed assays are developed in order to screen compounds for interaction and/or modification of the target, and from a pool of select compounds a "lead" is generated. This process of progressing to a lead compound is an extremely complex process which can involve cellular assays, toxicological surrogate assays, biopharmacological surrogates, and surrogates for absorption, distribution, metabolism, and excretion (Institute of Medicine, 2014).

Figure 6.

The Drug Development Process



Source: Raghavendra et al., 2012

Despite the complexity involved in the drug discovery phase it has a relatively high success rate of 51 percent (Paul et al., 2010). On the other hand, the drug development phase, which includes clinical trials, has a success rate of only 12.8 percent, which is commonly attributed to a lack of efficacy (ibid). Not only do clinical trials represent the longest stage in the overall timeline (6 to 7 years) it also represents the most expensive (63 percent of total R&D costs). Therefore, clinical trials alone are considered a major challenge, in which life science companies invest significant resources in order to overcome. In 2016, Eli Lilly's widely anticipated Alzheimer drug, solanezumab, failed clinical trials due to a lack of efficacy. The drug did not show a statistically significant slowing in cognitive decline when compared to a control group given a placebo. This acted as an indicator to other companies pursuing similar drugs.

Probably the most important for the purpose of this discussion on the growing contingency of labor in the life science industry is the challenge of reconciling the immense overhead costs associated with hiring personnel and acquiring lab space and equipment with the value added from the investments. The reason this is such a significant challenge is because the R&D process requires an immense scope of specialized skills, but the volume of work required by each function is not large enough to justify the huge investment in personnel and infrastructure. Considering just the scientific research functions involved in R&D and excluding any of the support functions that sustain the drug development and marketing process, a life science company requires a wide array of personnel specializing in fields such as medicine and disease coding, quality and metric reporting, biologic assay development, pharmacokinetic studies, drug targeting, therapeutics, and several other functions. However, even this list is too broad – these examples only list general processes required by all life science companies conducting validation and trial testing. Within the field of biotechnology there are several sub-fields that focus on gene therapy, viral vectors, bioinformatics, bioprocessing, cellular fusion, tissue engineering, and so on. Furthermore, depending on the targeted disease additional specializations are required (i.e. oncology, central nervous system, infectious disease, metabolic disorders, and cardiovascular disease). And, if all the support functions are included such as project management, IT support, marketing and sales, clinical trial data management, validation programming, safety and efficacy summaries, pharmacovigilance studies, and so on, the various functions needed to produce a drug would be impossible to house within a single company. All this is to show that internalizing all these functions is prohibitively expensive because the personnel and infrastructure required to support many of these specializations do not generate scale economies to justify the immense overhead costs. This is a major contributing factor for the use of contingent labor and CROs. For this reason, a vast market for CROs has emerged to provide the necessary functions in the drug development process while taking advantage of scale economies by providing just a few specialized services to the many life science companies.

This addresses the anomaly described in chapter 2. By utilizing contingent labor, employers indeed pay over and above the wage rate provided to permanent employees, however as research progresses through the R&D pipeline into new stages requiring different specializations, employers can easily offload their former contingent workers for new ones with different skill sets, thereby saving on wages that would have otherwise been paid out to a stagnant workforce. Likewise, CROs also provide sponsor companies with the flexibility to conduct research on a contract basis. This allows sponsor companies to save on costs from maintaining permanent employees and building out infrastructure. Essentially, contingent labor and CROs allow life science companies to keep a variable cost structure.

However, the emergence of CROs brings with it a new set of challenges. By externalizing critical functions that should remain at the core of life science companies there is a loss of control in the R&D process, which affects quality and efficiency. Also, the increased specialization of the industry may even affect opportunities for innovation or eureka moments that arise from the close interaction between different functions. By isolating specific R&D functions within CROs, synergies are lost, which reduce potential innovation and economic opportunities. Lastly, the use of CROs and reduce the workforce's loyalty, pride, and ownership in a product, which further diminishes R&D quality and efficiency.

4.2 Institutional Infrastructure Requirements & Critical Success Factors

Institutional Infrastructure Requirements

The above section described the major challenges for life science companies as they strive to bring a successful drug to market. Presented next are the institutional infrastructure requirements and critical success factors that life science companies depend on in order to succeed. Without any one of these elements, the life science industry would destabilize and experience a loss of market share. It is in this context that the constraints are introduced in the final section to illustrate the industry's limitations.

Listed below are the general and industry specific institutional infrastructure requirements of the life science industry (Kennedy, 2018).

General Infrastructure
- Effective corporate tax system
- Robust incentives for research and development
- A strong patent system
- Effective rule of law

Industry Specific Infrastructure
- High talent pool - trained life science workers
- Access to research labs
- Experienced investment community
- Effective regulatory approval system
- Fair device and drug payment system
- Generous government funding for research

Based on this list of infrastructure requirements Massachusetts exhibits the qualities of a very robust and healthy life science industry. It boasts having the largest life science cluster as measured by lab space as well as the highest concentration of life science employees anywhere. Further, a report by JLL ranked the greater Boston area's cluster first in the nation according to a series of factors including employment concentration, funding availability, and total lab space (2017). It is a mecca for workers in the industry attracting not only scientists directly linked to drug R&D but also professionals that support the institutional infrastructure listed above. And to top it off, the Massachusetts life science industry is supported by generous government funding and strong private equity flows.

However, as will be discussed in the following chapter, the life science industry as a whole is experiencing a weakening of incentives for research and development, one of the key general institutional infrastructure requirements listed above. In short, the major challenges described here associated with R&D is fueling investor pressure to minimize R&D, which is stifling the innovation potential of the industry. This has significant consequences for employment, which is experiencing significant layoffs, outsourcing, and a general move away from internal labor markets.

Critical Success Factors

A report published last year by TEConomy Partners LLC submitted five critical success factors for the life science industry (Schuhmacher et al., 2016). These critical success factors are distinct from the general and industry specific institutional infrastructure requirements because without any one of these five factors the life science industry would not be able to exist. If any of these five pillars were significantly weakened the industry's survival would be threatened.

The first critical success factor for the life science industry is a close interface between the support infrastructure, clinical care, academic R&D, patient advocates, health insurance, and public health officials. This interface between scientific research, clinical care, and product development facilitates a steady procedural flow moving from discovery to applied research to testing and regulatory approval.

Additionally, there are important synergies that are created by the establishment of close ties between industry, academia, and healthcare. A study by the Tufts Center for the Study of Drug Development found that nearly 80 percent of the most transformative drugs in the past 25 years originated from collaborative research conducted between the life science industry and academia (TEConomy Partners LLC, 2017).

Second, the life science industry is dependent on a group of highly skilled and highly trained workers including scientists, technicians, and engineers with expertise in both research and manufacturing, therefore access to professionals with the right set of experiences and know-how is critical. Increasingly, the required skill sets are expanding from advanced molecular biology and research techniques during clinical trials to big data, IT, remote monitoring, and diagnostics.

Third, the success of the life science industry requires very large investments in the physical infrastructure for R&D. Sophisticated lab spaces with the right capabilities are critical in sustaining R&D, the life blood of the industry. This is particularly challenging for small startup companies that require the necessary infrastructure to carry out their discovery and clinical trial research. Therefore, small startups require easy access to and an abundance of a very specific type of capital.

This leads us to the fourth critical success factor, which is the need for innovation capital or investors that are willing to invest in early stage research. Innovation capital is critical for new startups because it provides the seed money that is necessary to build out the required R&D infrastructure. The availability of innovation capital fuels the entrepreneurial ecosystem and the generation of innovation.

Lastly, the industry needs capital that is conducive to long development times and high volatility due to scientific and regulatory uncertainty. This calls for patient investors who understand the long game strategy of the industry as well as the risks associated with it rather than investors seeking short-term gains and utilizing frequent trading techniques.

4.3 Constraints

Competitive Constraint

One of the major constraints affecting the industry is the shortage of skilled labor. One report showed that from a survey of life science executives 59 percent of participants stated that finding and retaining the best talent was very difficult and remained a priority over any other competitive factor (PwC, 2013). Since the life science industry is one of the most research intensive and technically complex industries in the world, it requires numerous talented personnel that have the requisite knowledge and experience at each stage of the R&D process. This is true in terms of both the quantity and quality of talent. Quantity is important because in order to develop a healthy life science ecosystem, there needs to exist a concentration of skilled workers where positive externalities arise from clustering. On the other hand, differences in the quality of talent is the main reason for one company's competitive advantage over another. The creation of such a talent pool is driven heavily by academia and the interface between industry, academia, and healthcare. For this reason, the life science industry is clustered in areas where this trifecta exists.

Although finding that perfect ecosystem is a critical factor for life science clusters, increasingly proximity to amenities is becoming a major factor in deciding where to locate. This is telling of how important it is to life science companies to have access to the best talent. Despite the high rents and R&D costs top companies are choosing to remain in major urban areas as millennials become the prime target for talent recruitment. And even with the very high rents nine out of the top 10 life science clusters have single-digit vacancy rates for class A lab space (JLL, 2017). Life science companies are also boosting salaries particularly in the R&D space as demand for talent increases. Between 2012 and 2017 average salaries increased by 19.2 percent, but the total number of life science employees only grew by 4.2 percent (JLL, 2017). This competitive constraint is increasing overall costs for the industry.

Cost Constraint

Rising costs are a major challenge for larger, established life science firms, but are proving to be a significant constraint for smaller, startup companies. This is because smaller companies do not have the working capital to invest in overhead costs to build out the necessary infrastructure to create an internal R&D pipeline. For this reason, smaller companies are unable to acquire lab space and trained personnel and therefore, must utilize contingent labor and CROs. This perpetuates the breakdown of internal labor markets as new startups are forced to adopt outsourcing strategies from the start.

Capital Constraint

The availability of capital is a major constraint for the industry, particularly for startups, as investors are increasingly putting their money in companies that have already passed the discovery phase and have moved onto clinical trials in order to minimize risk. The increasing shortage of innovation capital creates a wasteland of research opportunities with huge innovative and economic potential, what the TEConomy report calls the "valley of death" separating biopharmaceutical discovery from capital investments (2017). As the availability of capital dwindles startups are looking to other options to sustain their businesses such as mergers and acquisitions.

Market Constraint

Many important decisions depend greatly on the accuracy of forecasts of biopharmaceutical revenues, however it is commonly known that forecasts are often wrong and off by a significant measure. These forecasts inform decisions on properly designing a clinical program, deploying a proportional sales force, and geographic resource allocation. Drug revenue forecasts are also probably the most important factor in investors' decisions to buy or sell shares. However, one study concluded that more than 60 percent of the consensus forecasts were either over or under by more than 40 percent (Cha et al., 2013). Although this is not surprising news to anyone the sheer magnitude of the error suggests that there is ongoing misallocation of resources as well as destruction of value in the industry, which contributes to the high cost of R&D (ibid).

Regulatory Constraint

The U.S. Food and Drug Administration (FDA), the European Medicine Agency (EMA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) are the three major regulatory bodies for the global life science industry. These three regulatory bodies are also located in the three largest global life science regions, which together represent over 90 percent of the world's biopharmaceutical exports. Individual country legislation and market regulations are inhibiting operational and product strategy at the global level. Although these agencies conduct the very important work of overseeing standards and regulations of the global life science industry, growing regulatory hurdles are constraining the life science industry's ability to produce a marketable product within shorter timelines, which affects total R&D costs and ultimately the costs to the end user. One report showed that FDA regulations have been growing at a rate of approximately 12,000 words per year (Fagnan, 2015). In addition, the NIH budget has declined over the past decade, hitting an all-time low in 2013. And to boot, the life science industry is experiencing significant backlash from government and public spheres in regards to biopharmaceutical pricing. President Trump has made promises to lower drug prices, which is causing growing apprehension about the introduction of price controls. Together, growing regulatory hurdles, decreasing federal funding, and the threat of price controls are weakening the competitive advantage of the U.S. life science industry.

Patent cliffs are probably the biggest concern for the life science industry and the most important factor affecting R&D productivity. The industry's profitability and prospects for growth are already under immense pressure as R&D timelines increase and healthcare budgets are strained, but patent cliffs are exacerbating the situation as branded drugs lose 80-90 percent of their market share essentially overnight. The life of a patent is 20 years during which new products are protected from copycat

versions, but upon expiry of the patent generic drugs priced at a fraction of the branded drugs are introduced to market. These generics make up approximately 70 percent of all prescriptions written in the U.S. and are estimated to have put at risk more than $209 billion in annual drug sales between 2010 and 2014 (Paul et al., 2010). Therefore, looming patent cliffs pressures the industry to maximize profits during their patent life.

Together, the challenges and constraints in the life science industry are negatively impacting companies' top and bottom lines. To combat their effects, the industry requires patient investors, activism to change regulations, and large investments in building out its critical success factors. However, investors' ravenous pursuit after profits is causing them to behave myopically, which is negatively impacting the industry's ability to innovate. The next chapter discusses the results of the interplay between the challenges and constraints and actions of investors aimed at short-term payoffs.

Chapter 5 – Findings and Discussion

This thesis set out to answer the question: *why do life science companies hire contingent workers rather than hire permanent employees?* The findings show that the primary reason contingent labor practices persist in the life science industry is because there has been a critical breakdown in the organizational and economic forces supporting the internal labor market. Earlier in Chapter 3 these two forces were discussed in detail. To recapitulate, Doeringer and Piore theorized that two broad forces were responsible for the development and preservation of the internal labor market: the organizational force and economic force. And within each force were three critical factors that contributed to the formation and sustainment of the internal labor market. Presented next is an explanation of how each of these factors have changed and how they are now allowing the industry to push its workforce to the external labor market.

Section 5.1 discusses the breakdown of internal labor markets and Section 5.2 talks about what is causing the breakdown and why this is happening. Investors are realizing decreasing returns on their investments in R&D, which is the driving factor leading them to restructure the way they do business. This restructuring is the topic of Section 5.3, which discusses *how* the industry is changing. The industry is downsizing, outsourcing, and moving towards a core competency model. Through current examples this section talks about the changing landscape of the life science industry. Section 5.4 discusses the effect this restructuring is having on the industry and how it is affecting its competitive advantage. Finally, in Section 5.5 the chapter concludes with a discussion on how the effect from restructuring is perpetuating the loss of innovation experienced by the industry.

5.1 Breakdown of Internal Labor Markets

Skill Specificity

The life science industry requires a high degree of skill specificity. Although the federal regulations guiding the R&D process provides a common playing field for all life science companies the idiosyncratic rules, tactics, techniques, and procedures vary greatly by company. The life science industry also requires a large scope of different skills each of which requires its own specific training. This raises the costs sustained by the employer as opposed to the worker since a high degree of specific training means that the employer must invest a great deal of training resources into its new hires to get them work ready. And since employee wages make up a significant share of life science companies' total costs, it would make sense for these companies to want to minimize this expense in any way possible.

Aside from adopting an outsourcing strategy and utilizing contingent labor, one way the industry is addressing the issue of high skill specificity is by hiring highly educated personnel with PhDs and master's degrees and giving them a greater range of responsibilities. By hiring workers with a broader range of skills who have the knowledge and lab experience to handle the job of a researcher as well as an equipment technician, employers are able to save on training costs and also decrease the scope of required workers.

Additionally, part of the reason for the recent push for IT technology within the life science industry is to address the rising costs associated with specificity. The R&D process is in many cases disparate, inconsistent, and siloed across phases and even departments within the same organization. Therefore, the industry is pushing for digitization of business processes through the use of new information technologies such as blockchain in hopes that standardization will resolve the internal dysfunction and ultimately decrease costs associated with skill specificity.

On-the-Job Training

On-the-job training is the second critical factor within the organizational force contributing to the formation of internal labor markets. In the life science industry this factor is less significant because formal education plays a greater role in skill development than on-the-job training. Nonetheless, on-the-

job training is still very important. This is supported by discussions with key informants who state that life science companies prefer candidates with prior work experience over candidates with only formal education but no work experience. However, the industry has essentially eliminated entry-level positions in major sponsor companies and forced these positions onto CROs and other institutions. The need for on-the-job training and the entry-level positions that provide this training should continue to work towards the formation of internal labor markets, but this factor is outweighed by the remaining factors that encourages the dissolution of internal labor markets.

Customary Law

Probably the most influential factor in the formation of internal labor markets is custom in the workplace. This refers to the informal rules that govern employment practices and are tacitly agreed upon between employer and employee. However, custom is greatly dependent on a sizeable community and its ability to coordinate efforts since there is power in numbers. It is also dependent on past practice because over time repetition leads to endorsement, which ultimately leads to a practice becoming customary. Unions were the vessel by which customs were created and enforced, but throughout the twentieth century unions were suppressed until they were castrated and weeded out.

Now, with the introduction of the internet and new technologies work customs have changed. For example, it has become customary to set wages not internally, but rather externally based on median data that is publicly available on the internet. Since wages and promotions are based on externally collected data rather than on some form of internal system based on seniority and skill, internal labor markets have lesser value to the labor force. And as the practice of outsourcing and the use of contingent labor has grown over the years the workforce has grown accustomed to this new form of procurement and allocation of labor bringing in a new tide of customary laws.

Value to the Labor Force

Less time was invested into researching the value of internal labor markets to the labor force, however discussions with key informants suggested that a sizeable proportion of contingent workers preferred the independent nature of the new work structure over the traditional system that confined workers to a single organization. However, this sentiment is unlikely to be shared by the group of contingent workers who are negatively impacted by the unstable work structure and are constantly worried about their next source of employment. Nevertheless, it does appear that the value of internal labor markets to the labor force is diminishing especially as society in general places increasingly greater value on the diversity of skillsets and experiences. Surprisingly, an overwhelming majority of key informants stated that work experience was a critical factor in hiring decisions and that a diversity of experiences in different positions and organizations was also important. This encourages workers to jump from company to company in order to experience as many different positions and organizational settings as possible. If this is in fact the case, internal labor markets would be less valued to the labor force.

Turnover Costs and Turnover Reduction

As the labor force places lesser value on internal labor markets, turnover is increased, which raises both replacement costs and termination costs. The increased turnover costs should incentivize management to hire permanent employees, however they continue to use contingent labor particularly through employment agencies because these agencies have consolidated replacement costs into a single flat fee. Employment agencies take on the task of recruiting and screening viable candidates for life science companies and charge a flat fee for their services in some cases even providing some initial job-related training prior to sending them off to work at a company. This means that replacement costs are totally accounted for in the fixed fee. Furthermore, the fixed fee charged by employment agencies is still likely to be less than if a company recruited, screened, and trained candidates independently because the economies of scale realized from recruiting hundreds and thousands of workers allow them to charge a lower fee while still making out with a hefty profit. The termination costs which are also a part of

turnover costs are essentially eliminated because the contractual relationships between the company and employment agency as well as between the employment agency and the worker shields the company from having to pay out for things like severance, unemployment insurance, and legal redress. This and any statutory fees are all packaged into the single fixed fee charged by the employment agency.

Technical Efficiencies in Recruitment, Screening, and Training

It is true that there are technical efficiencies in recruitment, screening, and training associated with internal labor markets which translate into cost savings, however those efficiencies are now replicated within employment agencies. Recruitment, screening, and even sometimes training is conducted within employment agencies for a fixed fee and so life science companies save on manpower, time, and other resources involved with workforce replacement. Additionally, data on workers' histories, skill level, behavioral traits, and work ethic can now be pulled from labor management databases such as VMS, MSP, and RPO. The most significant loss in terms of efficiencies from the breakdown of internal labor markets is the transferrable specific training held by candidates if selected from the internal system. Candidates drawn from the internal labor market know the organization's operating procedures, chain of command, and other idiosyncrasies that contribute to skill specificity, however, as discussed, the industry is making great strides towards standardizing processes especially with information technologies in order to decrease the specificity experienced across departments and enterprises. This move to generalize processes is also acting to eliminate internal labor markets.

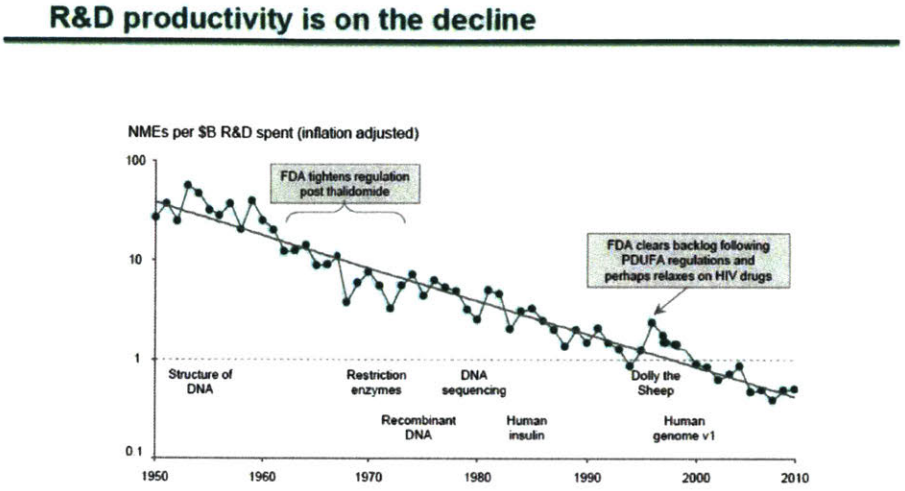
5.2 What is Causing the Breakdown of Internal Labor Markets?

The pressures exerted on the industry by investors is the driving force causing the breakdown of internal labor markets, but what is causing them to behave this way? The root cause is the decline in R&D productivity, which is now generating negative returns. For over 60 years the industry has seen a general decline in productivity, however within the past two decades returns have been below the cost of capital, which means globally the industry has been experiencing negative returns on an annual basis. This would not be as detrimental of an issue if companies maintained exclusive manufacturing and selling rights indefinitely, but patent cliffs limit the marketable life of a product providing a relatively short window to collect revenues, repay debts, and realize earnings for their investors.

Declining R&D Productivity

Just like in any business life science companies need to constantly monitor their costs as well as their revenues, and success is assessed through these two indicators in the form of a measurement called the return on investment (ROI). The challenge is to produce an ROI greater than the cost of capital, however over the past several years the global life science industry has failed to achieve this. Good returns on investment in a healthy company is in the double digits or a minimum of 10 percent, but a report by Deloitte showed that in 2016 the returns on investment on R&D for the top 12 companies had fallen to 3.7 percent per year while the cost of capital hovered around 6 percent. In terms of NMEs, the industry as a whole did not produce the required 2-3 NMEs per year per company necessary to meet growth objectives (Schuhmacher et al., 2016). As a matter of fact, the number of NMEs per billion dollars spent on R&D has been declining since the 1950s at a rate of around 50 percent every 9 years (see Figure 7) (Fagnan, 2015). This means that as a whole the life science industry is bringing in negative returns on investment, which is driving the restructuring of the industry.

Figure 7.



Source: The Boston Consulting Group

There are several reasons that can explain the loss in productivity. Listed below are a few explanations as gathered from discussions with key informants in the industry:

- Life science companies are too big: it has long been known that the quality and efficiency of R&D in large companies is a lot worse than in small cap companies. The reasons for this is twofold. First, large companies lose a lot of nimbleness due to the internal bureaucracies, increased paperwork, and greater number of rules that govern the R&D process. These seemingly insignificant hindrances when taken collectively act as a series of traffic lights that greatly frustrate the innovative process. Second, smaller companies have a lot more skin in the game and therefore, have a lot more to lose. For smaller companies, their entire financial future is based on one or two drugs. If those drugs fail, then their financial futures are over, which means there is much greater risk for smaller companies. On the other hand, larger companies often have several drugs in the works and therefore, if one of their drugs fail there is not as much at risk, relatively speaking. This means that larger companies are much less incented to a particular project because it has several other potential drugs to fall back on. For this reason, there is much better alignment of employees with their work in small companies.
- Excess competition: market competition is not unhealthy for innovation, however excess competition generated by non-market forces can be detrimental. Nowadays it seems that every city and every state want to attract a life science cluster to their region and oftentimes governments will intervene through financial bailouts or the enactment of policies favoring weaker firms in order to artificially foster a life science ecosystem. These actions can adversely affect the life science industry in existing clusters by allowing weaker firms to detract sales from stronger firms which would otherwise be reinvested into R&D.
- Diminishing target pool: a drug target is a specific molecule in the human body in the form of a protein, DNA, or RNA which causes or contributes to a disease. Out of all the possible molecules in the human body only a small handful have a known link with a disease, which means viable targets are an exhaustive resource. And increasingly less targets are available to exploit. Despite this well-known fact, life science companies continue to use the traditional drug development model, which has not fundamentally changed in more than 50 years, and they continue to focus on finding targets for major diseases because they have the highest payoff. Little exploratory research has been done at the cellular and molecular level to expand the knowledge of disease

causes, which could lead to discoveries and ultimately innovative techniques and processes for drug development. Since identifying new causes and targets is time-consuming and expensive many "me-too" drugs have hit the scene using the same therapeutic target.

The literature also points to an overall shift in the industry towards riskier projects, which may be contributing to decreasing R&D productivity in recent years. Over the past decade, new breakthroughs in human genome mapping and gene sequencing have created a new wave of ventures pursuing a new frontier in drug development. However, a lack of understanding of these targets means it is more difficult to create a product. The literature also points to the higher burden for approval due to increased FDA regulations for drug development as discussed in the section discussing industry constraints.

Patent Cliffs

Most of the proposed factors explaining the decline in R&D productivity point to an increase in R&D costs to be the primary cause. However, it is not cost related factors that most greatly impact R&D productivity but rather a single factor that constrains revenue – patent cliffs. Large sponsor companies usually dedicate around 15 percent of their revenues to R&D. This means that they are pegged effectively to their top line. However, if a product goes off patent and the company has promised to its shareholders to spend roughly 15 percent on R&D, that company is going to release thousands of workers. Discussions with key informants show that patent cliffs are in fact the main driver affecting almost all decisions throughout the drug development pipeline and beyond and therefore, act as the single greatest factor in how a company operates.

A company's product can lose up to 80-90 percent of their value essentially overnight as the product goes off patent. By the end of 2011, one of the most successfully branded prescription drugs of all time went off patent – Pfizer's blockbuster drug, Lipitor. It was the last branded drug in a list of the top 15 best-selling drugs to go off patent. Lipitor was bringing in nearly $5 billion per year, but generic drug manufacturers had huge batch plants prepared and ready to be fired up the day Lipitor's patent went offline. If sponsor companies do not have a suitable replacement drug available this could lead to huge layoffs.

All sponsor companies continue to produce their branded drug past the patent expiration because there will always be a market for the branded option, but production capacity is significantly diminished to around ten percent of peak production. This means that around 90 percent of the business moves to the generic product. Sponsor companies could drop the prices of the branded drug to compete with generics causing a price war, but on the cost side of things it is still significantly more expensive to manufacture the branded drug. This makes it so that margins are much less and usually not sustainable. Therefore, if a sponsor company fails to realize profits during their patent window chances are slim that they ever will.

Earnings Per Share – The Measure of Success

For investors, the benchmark for measuring the worth of a company is not the ROI, but the earnings per share (EPS). This is the magic number that investors judge the value of companies on and what they care about the most. This number is calculated by subtracting dividends from net income and dividing the result by the number of outstanding shares. Once a year, or in some cases once a quarter, a company will come out and publicly announce their expected EPS in what is called a future earnings estimate, which analysts derive using complex forecasting models. These estimates are then used by prospective investors to value a firm and inform their decisions on whether or not to invest. However, by giving guidance on a future earnings estimate the company has announced to the world that they will earn a certain amount of money in that time period (i.e. $6 per share in 2019).

Now, in a company's financial statements R&D is not capitalized, but rather it is expensed as it is incurred. This means that unlike tangible assets like property and equipment, which are capitalized under the *assets* heading in the balance sheet, R&D is expensed in the income statement and decreases the bottom line, or the net income. Therefore, R&D expenditures instantly drag down the EPS. If a company

has communicated to the world a certain EPS figure and it is trying to hit that figure, the company is highly disincentivized to spend money on research because the research is directly going to eat into the EPS. Therefore, these companies, or more specifically the companies' shareholders, are happier if the research does not happen in their own income statement; they would prefer it happen in some other company. Once that 'other company' has been de-risked or has created an investigational new drug (IND) that has cleared the majority of the drug development phase (which also happens to be the riskiest phase), a larger company will come around and buy the company. However, the purchase does not include a marketable product since it has yet to receive FDA approval. In fact, as is the case with most mergers and acquisitions (M&A), larger companies will purchase small startups midway during their R&D pipeline. Interestingly, one would guess that this purchase would seriously diminish the EPS since R&D is expensed as incurred, but R&D costs as acquired via M&As are capitalized as an intangible asset in the balance sheet under the heading *In-process R&D* (IPR&D). Instead of dragging down the EPS, the M&A greatly increases the value of the company and in turn, its share prices as well. Future costs to develop these assets are recorded as regular R&D expenses in the income statement, but nonetheless, M&As significantly decrease R&D expenses for new drugs and boost ROI. Therefore, investors are pressuring life science companies to conduct less R&D and more M&As. As a result, research-based companies are dwindling and thereby jeopardizing the industry's innovative capacity and long-term survival.

5.3 Restructuring the Massachusetts Life Science Industry

The industry's growing challenges and constraints are increasing costs and constraining the industry's ability to collect revenues. These challenges and constraints are reducing R&D productivity, which negatively impacts companies' share prices as reflected in the earnings per share. Consequently, investors are responding by pressuring companies to restructure their operations towards a leaner model favoring the core competency approach. This section discusses the two major restructuring trends that are driving layoffs and the use of contingent labor practices in the life science industry.

Mergers and Acquisitions

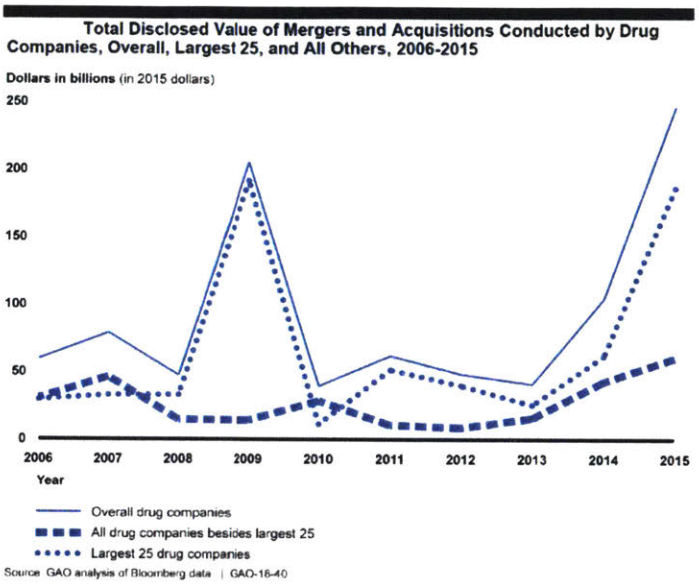
Mergers and Acquisitions are definitely not a new development in the life science industry as they have been in the news for the past twenty years, but recently there has been a huge upsurge in the number of M&As in the industry. M&As typically took a back seat as a secondary option in most companies' business strategies. During the Great Recession the value of M&As spiked, but companies quickly returned to a focus on R&D to seek new products (see Figure 8). However, as global revenue in the life science industry slumped between 2011 and 2013 (see Figure 9), the industry re-shifted its focus back on M&As and formally adopted it as a primary strategic element in capturing new products.

This is because M&As provide a favorable solution to both large and small companies that are experiencing financial difficulties amidst an increasingly austere business climate. The challenges and constraints of the industry affect both large and small companies alike. Patent cliffs affect larger companies by limiting their ability to collect revenues while the shortage of innovation capital and huge overhead costs from equipment and lab space disable smaller companies' ability to operate. Therefore, M&As may seem like a panacea that remedies the financial ailments of both sides, but is this really the case?

Discussions with key informants suggest that M&As provide positive short-term results but fail to produce the intended advantages in the long run. One reason why M&As fail in the long run is because the entrepreneurial spirit and culture that fuels the innovative potential in smaller startups disappears once a larger company consumes them. As discussed earlier, smaller companies are better at R&D because of the greater nimbleness and better alignment of employees with their work due to the greater financial leverage. However, after consolidating the smaller company is completely restructured and layoffs numbering in the hundreds and thousands are commonplace. Consequently, the entrepreneurial spirit,

nimbleness, and alignment of employees with their work disappears. This often leads to projects seeing their demise, which could further lead to greater decrease in productivity.

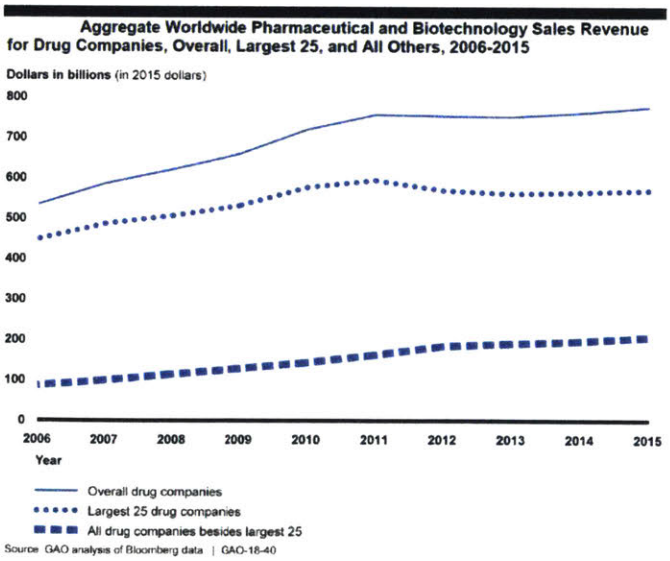
Figure 8.



Notes: Totals do not include transactions with undisclosed values. Data are adjusted to 2015 U.S. dollars using the gross domestic product price index.

Merger and acquisition transactions were attributed to the largest 25 if the company Bloomberg designated as the "acquirer" in the transaction was one of the largest 25 drug companies by 2015 pharmaceutical and biotechnology sales revenue. Transactions attributed to all other companies included those for which Bloomberg designated a company other than one of the largest 25 as the "acquirer."

Figure 9.



Note: The largest 25 drug companies consist of those with the highest pharmaceutical and biotechnology sales revenue in 2015. Data are adjusted to 2015 U.S. dollars using the gross domestic product price index.

Another reason why M&As may not be a good long-term strategy is because of the sudden and artificial nature of the companies' growth. Good research is to some degree based on a steady and natural progression of knowledge, procedures, techniques, and even professional relationships. Innovation is cultivated organically through years of incremental growth in knowledge and from researchers working closely with one another day in and day out, but M&As try to foster this essentially overnight by putting strangers together and telling them to piecemeal two separate research streams to create a blockbuster product. The intended synergies are rarely realized in this way.

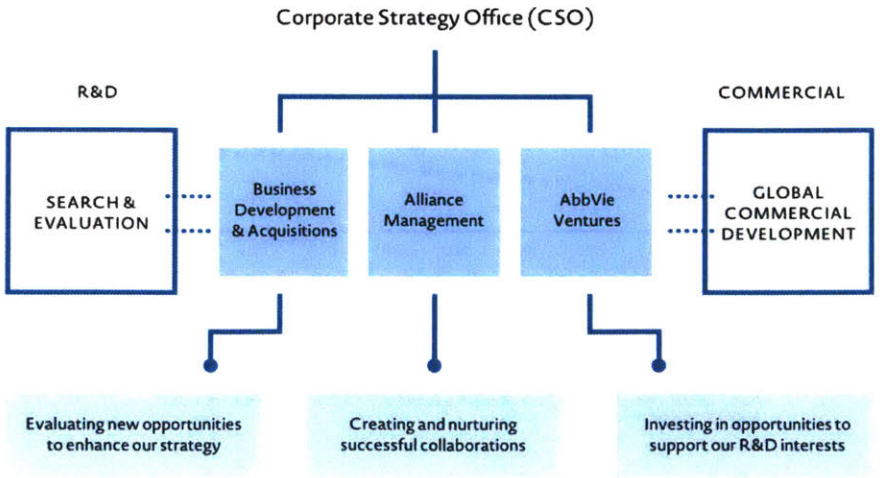
Strategic Partnerships and Research Collaborations

Strategic partnerships and research collaborations are also an old concept that has recently gained traction as more and more companies mine for innovation in new ways. Companies like GlaxoSmithKline (GSK), Pfizer, and Merck and Co. have longstanding relationships with academic institutions and other organizations in Massachusetts in order to boost their innovation potential. GSK, for example, spends approximately one-half of its R&D budget on research collaborations with academia and other industry partners, and Pfizer, in 2014, opened a collaborative research facility in Cambridge bringing together 1000 of its own employees to work together with academic institutions like MIT and Harvard as well as more than 150 life science companies (Schuhmacher et al., 2016).

Strategic partnerships and research collaborations expand the field and scope of skilled professionals contributing to the development of innovative products, however what used to be an ancillary effort to support a company's product is now central to its business model. Increasingly, businesses are moving towards a core competency model that abandons the notion of research taking place within their own walls in exchange for an outsourcing strategy. This, too, like M&As, is a move to restructure the R&D ecosystem due to low R&D productivity. While the larger, more established companies like Novartis, Amgen, AstraZeneca, and Sanofi are slowly evolving their operations towards a core competency model by gradually increasing the allocation of their R&D budgets dedicated to more traditional collaborative efforts as just described, newer companies like AbbVie have committed to this strategy wholesale and operate a business model purely based on partnerships and collaborations – they call this 'alliance management' (see Figure 10).

Figure 10.

Core Competency in the Massachusetts Life Science Industry



Source: www.abbvie.com partnerships our-approach

As shown by their organization chart, AbbVie outsources the entire R&D pipeline to include the manufacturing of their product. In this way, AbbVie can cut ties with any of their so-called "partners" if an IND fails to pass validation or testing at any point in the R&D process, which allows AbbVie to remain flexible and highly profitable. And still, AbbVie boasts having one of the most successful drugs of all time, Humira, bringing in a whopping $18.4 billion in sales just in 2017.

This model has huge implications for workers in the life science industry. As the industry moves towards a core competency model, workers are finding themselves further removed from sponsor companies and only finding work within CROs on a contract basis. This model is inevitably increasing layoffs as sponsor companies cut ties with their "partners" when INDs fail clinical trials or when products reach the end of their patent lives or when any number of issues arise during the highly volatile drug development process.

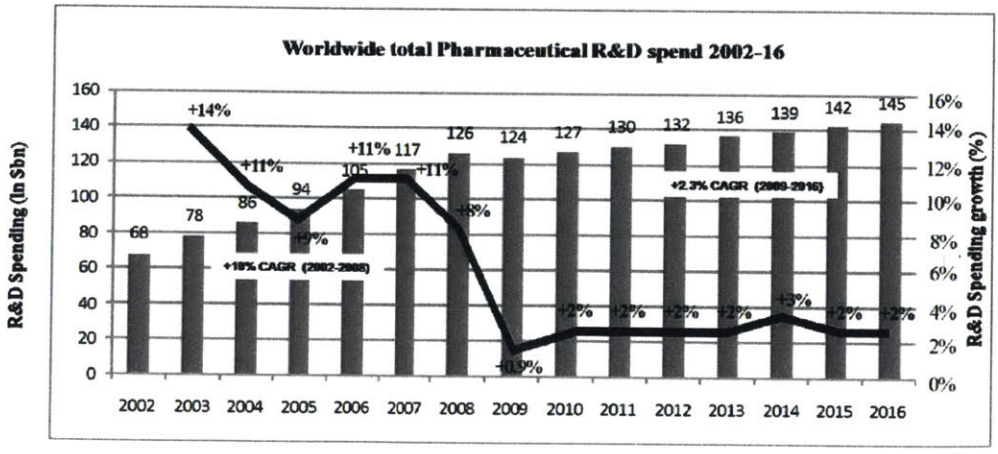
5.4 The Font of Innovation Cut Off

Both M&As and the use of research collaborations through licensing agreements piggy-back off of existing research conducted by smaller enterprises and CROs. These strategies are an effective means of mitigating the risks and costs of R&D. Therefore, these actions appease investors who perceive their investments to be growing the company and generating positive returns. And as anyone who has experience with financial markets understands, it is investor sentiment that determines asset valuation. This myopic behavior is causing the industry to chase after short-term gains and ignore long-term growth, thus sealing its own fate. The example of Pfizer and Merck and Co. illustrates this point perfectly.

In 2011, two newly appointed chief executives from two of the largest drug companies each publicly announced their strategies for their respective companies. CEO Ken Frazier of Merck and Co. stated that he would not be making any cuts to meet the year's earnings target, but instead would be investing more heavily in R&D to drive growth (WSJ, 2011). On the other hand, Pfizer's CEO Ian Read promised to cut R&D expenditures by a third and spend $5 billion to buy back its stock (ibid). The result: investors punished Merck with a 2.7 percent drop in share prices while Pfizer's stock shot up by 5.2 percent, all in the same week the announcements were made (ibid).

At the heart of this divergence is the issue of patent cliffs, which threatens the loss of tens of billions of dollars in revenue. Investors and managers alike are not ignorant to the fact that R&D is the lifeblood of the industry, but they continue to struggle to reconcile low returns with high investments in R&D. As M&As and the move towards core competency wins out, investments in R&D are declining causing the font of innovation to be slowly cut off. Since the Great Recession global R&D investments have plummeted averaging 2.3% CAGR growth between 2009 and 2016 (see Figure 11) (Raghavendra et al., 2012). When adjusted for inflation the R&D spending growth is practically nil.

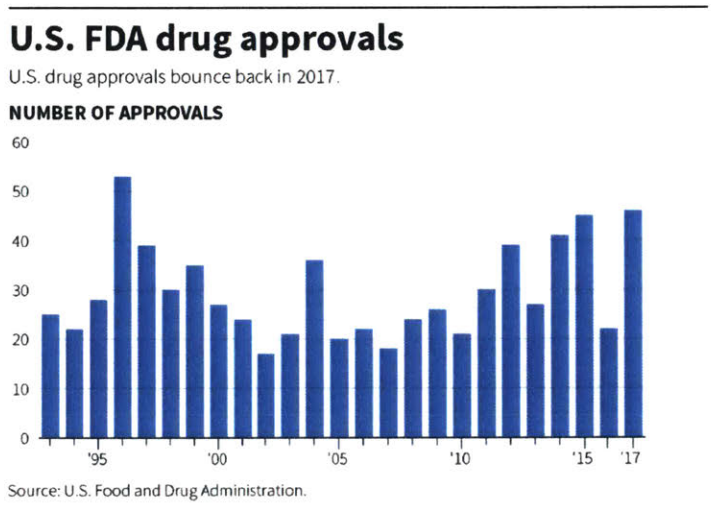
Figure 11.



Source: Raghavendra et al., (2012)

Despite the low growth in R&D spending since 2008, the number of FDA drug approvals since that time has generally increased (see Figure 12). This could lead some to believe that innovation is not tied to R&D expenditures, but a significant portion of the approved drugs are "me-too" drugs otherwise known as "follow-on" drugs, which are drugs that have a similar mechanism of action to pre-existing drugs (first-in-class drug) and do not create a significant therapeutic benefit over and above the first-in-class drug. Since a clear definition for "me-too" drugs does not exist there is not an accurate statistic on the total number, but if measured by therapeutic benefit, around 67% of FDA approved drugs were thought unlikely by the FDA to confer a significant benefit (Hollis, 2004). "Me-too" drugs utilize the same target as the first-in-class drug and therefore, "me-too" drugs save on R&D costs by shaving off years in the discovery phase. This trend has picked up pace in recent years, which would support the argument that innovation is declining.

Figure 12.



5.5 Perpetuating the Problem

During the early years of biotechnology when the science was coming to the fore, fundamental research that aimed to uncover the root causes of diseases was central to the work done by scientists. However, much has changed since the 1980s as much of the research has become industrialized and moved away from its exploratory focus. The life science industry now places an unrestrained level of attention on finding ways to commercialize the fundamental discoveries of the past and not enough attention on fundamental research at the cellular and molecular level. This focus on application over exploration is driven by a pursuit of profits, and is resulting in short-term payoffs with limited long-term growth.

This pursuit has also caused the industry to search out new ways to become more efficient – by downsizing, outsourcing, merging, and collaborating. In terms of the R&D process, the life science industry now follows a prescribed formula, which the industry is constantly trying to shorten and speed up in an effort to reduce costs. This is constraining the R&D process further reducing the potential for innovation.

Decline in Blockbuster Drugs

While the number of approved drugs has remained fairly consistent over the years, blockbuster drugs are rapidly on the decline. Blockbuster drugs, defined as drugs with forecasted sales of greater than $1 billion per year, was at 21 in 2016 compared to 55 in 2010, and 2018 is expected to be even lower

(Deloitte, 2016). This is due to the lack of investments in resources, time, and commitment in R&D. As more is taken away from the R&D process in order to save on costs, the less potential there is for innovative discoveries. And as innovative discoveries dwindle, blockbuster drugs decline, which affects long-term shareholder value. Thus, the restructuring of the life science industry that started with investor pressures to manage the declining returns on investment is now perpetuating the fall of the industry itself.

Orphan Drugs

The reduced R&D productivity and the decline of the blockbuster drug business model has caused many players in the industry to shift their focus to orphan drugs or drugs that target a niche market comprised of those suffering from rare medical conditions, the conditions themselves referred to as orphan diseases. This shift is also related to R&D productivity in that life science companies are seeing greater returns from orphan drugs than pursuing blockbuster drugs. Therefore, the orphan drug market is expected to nearly double in the next five years reaching $209 billion (Deloitte, 2018). The FDA reported 75 approved orphan drugs in 2017 while only 27 were approved in 2016 (ibid).

The greater returns from orphan drugs are attributed to the shockingly high costs to the patient compared to non-orphan drugs. In 2016, the average cost per patient per year for an orphan drug was $140,443 compared to $27,756 for a non-orphan drug (ibid). As the industry shifts its focus to developing orphan drugs the industry may see better returns, but the costs to the patient and payers increase. This adds fuel to the public outcry, especially from the government and payers who already feel that drug costs have gotten out of control, thus further constraining the industry through regulations such as pricing controls.

Chapter 6 – Recommendations and Conclusion

This chapter submits four major policy recommendations for the life science industry. Each recommendation targets a different element influencing the overall drug development process: 1) the managers and their decision to outsource, 2) the investors and their influence on managerial decisions, 3) clinical trials and the associated cost and risk, and 4) patent cliffs and the constraints they impose on revenues. Through these recommendations the life science industry may regain the balance between employee welfare, shareholder value, innovative potential, and company profits.

6.1 Recommendations

Managers and Outsourcing

As the life science industry adopts a core competency strategy, companies are increasingly downsizing and outsourcing R&D functions to CROs and other institutions. Much of the impetus driving this decision has to do with the risks and associated costs of carrying permanent employees. But by extending the liability for those workers all the way up to the sponsor companies, it may prevent outsourcing companies from demanding the lowest possible prices. Furthermore, by holding sponsor companies' feet to the fire, it may encourage them to be more selective with their contracted partners ensuring that they meet basic labor laws. This should be implemented at the state and local levels by their respective labor departments and the established regulation should extend the liability of the contracted workers to any enterprise involved in the supply chain.

State and local governments should also institute policies that incentivize sponsor companies to hire permanent workers rather than contract contingent labor. These incentives can come in the form of tax credits that are directed specifically at qualifying companies that meet stringent criteria for employing permanent employees with full benefits.

Investors as Activist

Life science companies are inherently slow-growth companies characterized by long production cycles that require huge amounts of capital for investment in R&D, which is why patient investors are needed. But a company owned primarily by buy-and-hold investors would be unhealthy for a company because it would not be able to achieve adequate levels of liquidity. On the other hand, short-term investors add volatility to the market. Volatility to some degree is good because it provides liquidity, but beyond a certain point volatility kills liquidity. Therefore, it is important to have a healthy balance of short-term and long-term investors, but when it comes to shareholder activism, generally speaking, a company is better off if its long-term investors are given more clout. This is because short-term investors are interested in one thing only – immediate profits – while long-term investors' interests are generally more aligned with a company's fundamental values. The search for immediate profits drives the decisions of short-term investors as well as their trading practices. This explains why high-frequency traders have holding periods that can at times be measured in milliseconds.

Financial markets should adopt policies that provide voting power commensurate with seniority or length of ownership. By adopting such a policy, short-termers would have less clout in company decisions, which would presumably moderate investor myopia while giving more say to those who may genuinely have the best interest of the company at heart.

High Cost of Clinical Trials

Clinical trials are not only expensive to conduct but also very time consuming, which also adds to the total cost of conducting clinical trials. Included in these costs are patient recruitment costs, patient retention costs, and all the ancillary costs associated with conducting clinical trials such as maintaining an administrative staff, executing clinical procedures, and data management. Recruiting patients can be a long and painful process because patients need to match the very specific parameters for the trials. This

means that trials need to be advertised in many different ways and in many different locations to achieve the required sample size. Additionally, most drugs require multiple trials beginning with a dosing trial, then a safety and efficacy trial, and the long-term use trial. Once the drug is marketed, the FDA requires post-marketing trials as well.

If clinical trials make up 63 percent of the total cost of developing a new drug, efforts should be made to find new ways to mitigate the time and costs involved. One way to do this is to allow companies to recruit patients from other countries to include developing countries. Kennedy found that by broadening the pool of potential patients, companies could potentially reduce their costs per patient by 40 to 60 percent and speed up recruitment by 20 to 30 percent (2018).

Problem with Patent Cliffs

Patent cliffs are effective for 20 years from the date the patent is filed, however this does not necessarily mean that sponsor companies can market a product and collect revenues for 20 straight years. Patent information is due at the time the new drug application (NDA) is submitted to the FDA, but the FDA approval process could take several years barring any issues that may arise. More importantly, however, is the issue with a little known FDA statutory provision called market exclusivity. Patents and market exclusivity work essentially in the same way by bestowing certain rights and protections to the filing party, however they are very different in that they are granted independent of one another. While patents are granted by the patent and trademark office, exclusivity is a right granted by the FDA given FDA approval. Also, exclusivity is much shorter than the life of patents: orphan drugs get seven years of exclusivity and other drugs get five. Patents and exclusivity may run concurrently or not and exclusivity cannot be tacked onto the end of a patent life. One example of them not running concurrently is with AstraZeneca's diabetes drug, Bydureon. AstraZeneca has 18 patents in total covering Bydureon and two of them don't expire until 2026. However, its market exclusivity expires in September of this year. This means that barring any patent infringement issues, generics could submit NDAs for diabetes drugs of their own.

One way to mitigate the pressures from patent cliffs is to provide all new drugs with 15 years of market exclusivity upon approval of the drug. This gives sponsor companies more than enough time to recoup costs and collect profits to reinvest into R&D. By softening the blows experienced by patent cliffs companies are less likely to make decisions based on the challenges and constraints in the industry and more likely to behave according to its fundamental values and long-term goals.

6.2 Conclusion

Over the past seventy years institutional investors have gained a vast majority presence in capital markets compared to individual or household investors. This has translated into the capital markets being dominated by short-term investors executing high-frequency trades and private equity investors dictating company decisions favoring short-term payoffs over long-term growth. Years of such myopic behavior is jeopardizing the future of the Massachusetts life science industry, and its workers are forced to deal with the backlash.

As investors gained significant power and control over management in the 1980s companies shifted to a focus on core competency. In the life science industry this move towards core competency was fueled by the growing challenges and constraints confronting the industry. Today, those challenges and constraints continue to increase the cost of R&D while constraining the industry's ability to generate revenues and thus, its ability to recoup costs and reinvest into future R&D. Most significant among the challenges and constraints are patent cliffs and market exclusivity that limit the marketable window of a drug. The result is decreased R&D productivity, which has been dwindling since the 1950s. Now, globally, returns on investments are unable to cover the cost of capital, which means businesses are desperately searching out new ways to reduce costs and maximize revenues during the viable patent term. This is driving life sciences companies to outsource and downsize its operations and even shed critical elements of R&D, all of which is affecting its innovative potential.

The costs of carrying permanent employees are adding to the already burdensome challenges faced by the industry and so companies are downsizing, which deteriorates its internal labor markets and pushes its workforce to external markets. In order to meet and fill the demand for the services these workers provided a large and extensive market for temporary workers has emerged. The competitive pressures created by this market have caused the combined costs of specific skill training costs, on-the-job training costs, and turnover costs minus the cost savings realized from technical efficiencies in recruiting, screening, and training to be cheaper in external markets than in internal ones. Now, the landscape of the Massachusetts life science industry is littered with contract research organizations, temporary staffing agencies, and thousands of workers in between jobs.

Moving even beyond outsourcing and downsizing, some Massachusetts life science companies have undergone a wholesale transformation of its organizational structure by retaining just its essential managerial functions and contracting out the entirety of its R&D and manufacturing processes. Through research collaborations and other strategic partnerships kept at an arms-length distance, these companies have created a complex work stream comprised of numerous contracts with external suppliers. Only those functions that are considered central to its operating strategy remain organic to the sponsor companies – 'business development and acquisitions,' 'alliance management,' and 'ventures.' Gone are the days of research-based drug companies. This is drastically reducing the synergies realized through proximity; the exchange of ideas that took place when the research pipeline was housed under one roof.

Now, the Massachusetts life science industry is in danger of losing its innovative edge and the competitive advantage it holds from research. The pursuit after short-term returns is restructuring the life science industry by looking to mergers and acquisitions and research collaborations to boost R&D productivity. Consequently, this is causing companies to decrease their investments in R&D, the life blood sustaining the life science industry . Over the past several years this trend has caused the decline in blockbuster drugs and a shift towards a focus on orphan drugs due to the higher returns. But these returns are only possible due to the enormous costs charged to the patient and payers compared to non-orphan drugs. Thus, the industry's myopic behavior is causing it to seal its own fate.

But all hope is not lost. By mitigating the effects of certain challenges and constraints that are placing downward pressure on R&D productivity, namely the high costs and risks of clinical trials and looming patent cliffs, investors may be incentivized to increase investment in R&D. However, this is not enough. Controls must be placed on both investors and managers to limit their myopic behavior and unrestrained outsourcing practices. An innovation industry, as described by Ezell et al., creates value through new technologies, new business models, new products and services, or new forms of social entrepreneurship and drives long-term economic growth as well as improvements in quality of life (2016). As such, the life science industry plays a valuable role in advancing the global economy, society, and health, which is why it is so important to foster innovation in the industry.

INTERVIEWS

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