Major Healthcare Legislation: Effects and Reactions by Large U.S. Pharmaceutical Manufacturers, 2001-2018

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Abstract

This study follows four large U.S. pharmaceutical manufacturers through periods prior, during, and post major U.S. healthcare legislation. The focus of the study is to understand how top management’s attention is affected by industry legislation. Using 18 years of letters to shareholders from four U.S. pharmaceutical companies from 2001 to 2018, I analyzed the textual data three ways using Provalis Research’s Wordstat software. First, I created word frequency clouds to identify key words overall and for each period of time before and after legislation. Second, using the “extraction” function in Wordstat, I used topic modeling to identify which groups of words (or topics) emerged from the application of a standard topic modeling algorithm. Finally, I applied pre-developed dictionaries of organizational constructs to the textual documents to compare frequencies among these time periods. From these analyses, I identify precautions and tactics used by executives of pharmaceutical manufacturers during periods of healthcare reform.

Keywords: Pharmaceutical manufacturers, pharma, topic modeling, healthcare reform, healthcare legislation, run-time, Affordable Care Act (ACA), Medicare Modernization Act (MMA), Pfizer, Amgen, Johnson & Johnson, Bristol-Myer Squibb
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Major Healthcare Legislation: Effects and Reactions by Large U.S. Pharmaceutical Manufacturers, 2001-2018

The United States operates a complex, multifaceted healthcare system, with players both public and private, ultimately providing healthcare to the largest economy in the world. Currently, the healthcare sector has come under great scrutiny based on affordability, level of care, and coverage. Pharmaceutical manufacturers, specifically, play a large role surrounding the current political affordability discourse as drug prices in the U.S. continue to rise. Although pharmaceutical manufacturers are not the sole entity to blame for drug prices at the pharmacy counter, they are the first in the pharmaceutical supply chain and set the beginning price of a drug before markups by various other sub-industries.

As well, the U.S. has a large number of “middleman” entities in its system and inefficient insurance companies. Having worked for a year trading and analyzing healthcare securities for various healthcare sub-industries, I was able to identify a few “middleman” entities responsible for high prices in the U.S. healthcare system.

Imagine if textbooks and school supplies went through “middlemen” before being purchased by schools. Say a textbook company invests money and years of time creating a textbook, but instead of being able to sell it directly to schools, they must sell indirectly to a complex network of interconnected companies. For the example’s purpose, let’s imagine there are textbook distributors, textbook stores, and textbook price insurance companies. Here, roughly, is how all the companies would interact. Basically, textbook price insurance companies would decide what books the schools could buy based on negotiated final textbook prices with partner textbook distribution companies. In the meantime, textbook distribution companies negotiate higher, marked-up prices to distribute textbooks to textbook stores based on the
maximum price insurance companies said they would cover/pay. Simultaneously, the textbook distributor is negotiating lower textbook prices with textbook manufacturers and searching for cheaper, generic textbooks from different manufacturers. Finally, the textbook management companies supply the textbooks stores with textbooks it knows insurance companies will cover at approximately the price it knows the insurance company is willing to pay.

So, what is the point of this complex analogy? By the time a school goes to the textbook store to buy the books its insurance company covers, the textbook has already been through two middlemen who both marked up the price to the amount the insurance company is willing to pay. The result, extremely high prices for textbooks based on negotiations between distributors, sellers, and insurance companies. As time goes on, the insurance companies will have to continually raise their premiums as the distributors and stores craftily estimate the insurance coverage and compute a “sellable price.”

Surprisingly, this process is how drugs get to pharmacy counters. Instead of textbook distribution companies and textbook sales companies, the entities are pharmacies and pharmacy benefits managers who liaison between pharmaceutical manufacturers, pharmacies, hospitals, and insurance companies to ultimately determine the final drug cost based on current legislation and insurance coverage. Consequently, healthcare reform and legislation change these interactions and influence manufacturers and the final drug price. Therefore, understanding the interactions between manufacturers and healthcare legislation becomes imperative when interpreting the pharmaceutical supply chain.

Without having complete power over the final drug price, pharmaceutical manufacturers must tread carefully when navigating these complex negotiations. These manufacturers must ensure the prices charged for the drugs, which they spend millions or billions on developing, are
appealing to private insurance companies and Medicare/Medicaid. Note the pluralization of the word prices above, pharmaceutical companies and their partner pharmacy benefits managers often negotiate different prices for different insurance companies and Medicare/Medicaid.

Adding to pharmaceutical manufacturers’ stress, once a drug hits the market its patent only lasts for a finite number of years before large generic manufacturers can launch an identical drug at a fraction of the cost without having to incur massive research and development investments. Additionally, not all developed drugs, which still cost millions to billions to develop, gain FDA approval or are successful, so the costs of these failed drugs must be covered by the profits of successful drugs, further inflating the price. When one considers all the factors pharmaceutical manufacturers must take into consideration – what drugs to develop, the budget for developing drugs, getting FDA approval, how much to sell drugs for, how much failed drug investment needs to be recovered by the successful drugs, how long can they be sold, will anyone buy or cover the drugs, and will legislation change effect any of the prior factors – the strategy and process for manufacturing drugs becomes overwhelmingly complex.

Specifically, research and development costs are a differentiating factor between the overall healthcare sector and pharmaceutical manufacturers. Compared to the rest of the sector, the U.S. pharmaceutical industry spends nearly 15% more on research and development annually, as shown on the next page by the “other” category in figure 1. The high proportion of R&D costs reflects the highly competitive and complicated nature of the pharmaceutical market and is evidence of manufacturers’ need to continually create new drugs.
Figure 1: Despite seemingly harsh industry conditions, the pharmaceutical manufacturing industry in the U.S. out-performs other areas of the healthcare sector. From: www.ibisworld.com

Ever since I began trading, studying, and analyzing the healthcare industry and healthcare securities for the University of Tennessee, I became fascinated by how pharmaceutical manufacturers survive. I have been especially intrigued by certain large manufacturers’ ability to adapt to major healthcare reform. The focus of this research is to address this question: What are those reactions – actions, attention and considerations – made by these companies across legislative changes?

To address this research question and analyze manufacturers’ resiliency to legislative change, I studied the reactions and behaviors of large pharmaceutical manufacturers during the running time after a bill’s proposal/announcement and when the change has been enacted. To gleam the best indication of a pharmaceutical manufacturing firm’s reaction and preparation for legislative change, I will track what strategies the CEOs were pursuing or no longer pursuing
during a bill’s runtime and post enactment phases. I will use three textual analysis approaches to compare the focus of executive attention across three time periods. First, I will create word frequency clouds to identify key words overall and for each period of time before and after legislation. Second, I will use topic modeling to identify which groups of words (or topics) emerged from the application of a standard topic modeling algorithm. Finally, I will apply pre-developed dictionaries of organizational constructs to the textual documents to compare frequencies among these time periods. From these analyses, I identify precautions and tactics used by executives of pharmaceutical manufacturers during periods of healthcare reform.

The Medicare Modernization Act (MMA) and the Affordable Care Act (ACA) constitute the two largest and most recent legislative changes impacting the U.S. pharmaceutical manufacturing industry. Therefore, my study is divided into three distinct phases: pre-MMA, post-MMA/pre-ACA, and post ACA. These periods allow for analysis of executive attention during the runtime and post legislative periods.

Author Background

My experience comes from years of undergraduate study surrounding the healthcare sector. Early on, I served as a fund manager specializing in healthcare securities for the Haslam College of Business where I researched, pitched, and traded pharmaceutical manufacturing companies, insurance companies, and medical device firms. My most memorable experience from my time on the fund was acquiring a newly vertically integrated firm in the pharmaceutical supply chain world which had just completed a merger. The firm’s future looked bright, but I miss predicted the effects of upcoming healthcare legislation, and, at the same time, the Affordable Care Act was placed under question nationally by a Texas judge. The legislation and the uncertainty surrounding the Affordable Care Act sent the sector through the floor, and my
chosen firm’s bright future was flipped on its head. In short, the dramatic change fascinated me and caused a newfound curiosity within myself towards these seemingly impossibly complicated manufacturing firms.

In addition to my time as a fund manager, I took technical writing/editing for publication classes where I frequently choose to study healthcare in my research. So, as my undergraduate time is ending, I wanted to produce one final study on a largely misunderstood and confusing sector to determine what really goes on within large pharmaceutical manufacturers.

**Industry Background**

Worldwide, healthcare varies drastically, but our own, in my opinion, holds first place regarding complexity, number of players, and coverage issues. We are the largest economy in the world and providing coverage on such a large scale undoubtably brings challenges and complexity. However, many of these issues have become more prevalent as U.S. citizens struggle to pay for their prescriptions, both with insurance and without.

This study will focus on the brand name pharmaceutical manufacturing industry in relation to legislation change. Currently, brand name pharmaceutical manufacturing is a $188.4 billion industry 3,248 businesses strong. Exporting $44.2 billion worth of drugs in 2019 and generating $35 billion in profits, the industry plays a large role in the overall healthcare sector (Spitzer, 2019). According to the 2019 IBIS World Report, a few primary drivers for the brand name pharmaceutical manufacturing industry are: federal funding to Medicare and Medicaid, the median age of the U.S. population, the number of privately insured, and, of course, regulation (Spitzer, 2019).
Major U.S. Healthcare Legislation 101

To best understand U.S. pharmaceutical manufacturers’ ability to adapt to healthcare change, one will benefit from knowledge of U.S. Healthcare history. Most know U.S. Healthcare is a privatized system with public elements (Medicare and Medicaid), but how long has the private/public approach really been around? According to Manchikanti, Helm, Benyamin, and Hirsch (2017), the history of public United States Healthcare legislation began in 1965 when President Lyndon B. Johnson passed Medicare and Medicaid into law. At last, President Johnson’s historic act provided government coverage for the poor, needy, and elderly. Now, pharmaceutical manufacturers had a new, very large client – the U.S. government.

Continuing through history, many revisions, additions, and subtractions were passed modifying Medicare and Medicaid, and new government programs were added to supplement the existing legislative structure. Now, pharmaceutical manufacturers, in conjunction with insurance companies and pharmacy benefits managers, were battling to gain the business of both the government and American citizens on private insurance. The next notable legislation change comes in the 1990s with the Clinton administration. President Bill Clinton, with the help of first lady Hillary, enacted the Health Security Act. The act created two new government organizations: HIPPA – Health Insurance Portability and Accountability Act – and SCHIP – State Children’s Health Insurance Program (Manchikanti et al. 2017). These programs protected personal healthcare information and children’s healthcare rights. However, the two largest sweeping overhauls to U.S. healthcare have come within the past 20 years.

Sweeping Change 1: Medicare Modernization Act, 2004-2006

The next legislative break came in the early 2000s. After the Clinton administration and the democrats placed their stamp on healthcare in the 90s, the election of President George W.
Bush gave Republicans an opportunity to shape healthcare reform. At the end of 2003, President George W. Bush passed the Medicare Modernization Act (MMA). The act redefined and modified existing parts of Medicare and Medicaid but, also, added new ones such as Medicare Part D which governs drugs under the Medicare and Medicaid programs. To be clear, Medicare and Medicaid only apply to those in the programs. Americans on private insurance are not directly affected by Medicare and Medicaid.

To provide some scale, the MMA’s Part D policy was the most expensive addition to Medicare in history at the time of its passage, and the legislation had a two-part goal: increase senior citizen access to drugs and control escalating prescription drug prices. Medicare Part D alone was estimated to cost between $450 to $750 billion during its first ten years (Balotsky, 2009). Before launching the industry into the new policy, an integration time was implemented (or, as I will refer in this study, run/running time) during 2004 and 2005. The run time measures came in the form of drug coupons for senior citizens to provide companies an easy transition before the law came into full effect in 2006 (Balotsky, 2009). So, what exactly did pharmaceutical manufacturers have to prepare and adapt for to take advantage of the new plan? According to Megellas (2006), here are a few major MMA Part D parameters:

- The Center for Medicaid Services set a tentative monthly premium of $37 ($448 per year).
- Participants have a $250 annual deductible.
- “For drug costs between $251 and $2250, Medicare and the plan will share 75% of the cost and the beneficiary will pay for the remaining 25%.”
- “For drug costs between $2251 and $5100, the beneficiary is responsible for 100% of the cost; this is referred to as the gap or doughnut hole.”
• “For drug costs exceeding $5100, Medicare will pay 80%, the plan will pay 15%, and the beneficiary will pay 5%.”

Now consider yourself a CEO of a large Fortune 500 pharmaceutical manufacturer like Amgen. Which price range would you target your drugs to fall under? Well, I suppose the better question would be which price range would you not want your drugs to fall under? Obviously, the doughnut hole range. While some believed the Medicare Modernization Act was a step in the right direction, it does not take an expert to note it caused an ethical dilemma within the pharmaceutical supply chain while firms navigated the new legislation.

However, while Part D was the major new supplement the MMA added, changes to other parts of the bill dramatically affected firms in the pharmaceutical supply chain as well. For example, Medicare Part B changes altered the way drugs were sold and acquired via a change in government drug reimbursements (Megellas. 2006). The overall answer to the legislation seemed instead to target the elderly and take advantage of the new pricing legislation.

The American Association of Retired Persons (AARP) monitored drug prices following the implementation of the legislation and found the industry may be raising prices of prescription drugs. Specifically, drugs used and needed by the elderly. During the first quarter of 2006, AARP found 193 prescription drugs commonly used by Americans over 50 years old saw a price increase of around 6.2% relative to their prices 12 months prior from pharmaceutical manufacturers (Manchikanti et al. 2017). However, manufacturer prices for generic drugs saw little price change. Additionally, the participating Part D insurance companies’ policies were insufficiently negotiating against climbing prices. For example, the median price increase during the same 12-month period for the twenty most popular senior citizen drugs was 3.7% (Manchikanti et al. 2017). The Medicare Modernization Act (MMA) had substantial effects on
the pharmaceutical supply chain, especially insurance companies and pharmaceutical manufacturers, but the actual price containment left much to be desired.

So, what was the final result of the change on pharmaceutical manufacturers? By 2007, one year after full enactment, manufacturers now had a 39 million strong Medicare Part D market to sell drugs to (“Medicare Drug Plans Strong and Growing”). With Medicare Part D, the government had inserted itself as a large client into the complex negotiations of the pharmaceutical supply chain and caught the eye of many manufacturers hoping to sell new drugs.

**Sweeping Change 2: The Affordable Care Act, 2010**

After a change in political parties occupying the White House, the 2008 presidential election put democrats back in charge. Like today, voters a decade ago were concerned with the U.S. Healthcare system, and the elected administration was ready to restart and refresh government-based healthcare through the Affordable Care Act (ACA). Once implemented into law, the ACA was regarded as the largest change to U.S. Medicare ever. According to Manchikanti et al (2017), the Affordable Care act had three primary goals:

1. Increase the number of the insured.
2. Improve the quality of care.
3. Reduce the costs of healthcare.

The first and third being the most applicable to the U.S. pharmaceutical supply chain, especially U.S. pharmaceutical manufacturers. The first increased the size of the government ran healthcare market. The total increase to those insured under Medicare and Medicaid came primarily through Medicaid expansion (Manchikanti et al. 2017). Medicaid enrollment increased by approximately 13 million and Medicare increased by around 7 million, but, according to a
2015 RAND Corporation study, nearly 6 million lost their coverage (Manchikanti et al. 2017). No legislation is perfect and the ACA “widened the gap between providing patients the mechanism of paying for healthcare and actually receiving it (Manchikanti et al. 2017).” More specifically, the Affordable Act works well for certain protected classes but falls short for working- and middle-class citizens as the level of aid from Medicaid is determined based on one’s income level’s proximity to the federal poverty line (Manchikanti et al. 2017). Basically, like the MMA’s doughnut hole for drug coverage, the ACA’s doughnut hole is the middle- and working-class giving pharmaceutical manufacturers and other healthcare businesses a target market and price range for certain classes of the insured.

Former President Bill Clinton summarizes the ACA: “so you have got this crazy system where all of a sudden, 25 million more people have healthcare and then the people who are out there busting it, sometimes 60 hours a week, wind up with their premiums doubled and their coverage cut in half. It is the craziest thing in the world (Manchikanti).” Despite the confusion, the ACA offers beneficiaries “10 – essential benefits” according to Manchikanti et al.’s (2017) study:

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance abuse disorder services, including behavioral health treatment
6. Prescription drugs
7. Rehabilitative and habilitative services and devices
8. Laboratory services
9. Preventive and wellness services and chronic disease management
10. Pediatric services, including oral and vision care

Importantly, the ACA covered prescription drugs, and, unlike the MMA, most of the ACA’s reach applied to Medicaid, not Medicare, meaning the age demographic under government ran healthcare shifted down as Medicaid covers all ages and Medicare being reserved for the elderly. So, from a pharmaceutical manufacturer’s perspective, they know the government market now has twenty million more insured consumers that are younger and many with prescription drug coverage. Surprising to some, expected to others, the ACA did not prevent the rise of drug prices; in fact, the ACA escalated the increase in prescription drug pricing (Manchikanti et al. 2017). So, what are pharmaceutical manufacturers doing during these periods of change other than hiking prices? Is there a method to the madness? What strategies were employed to keep pharmaceutical firms successful amidst strong competition and with high risk businesses?

Methods

To study pharmaceutical companies and their focus during times of legislative change, I chose to analyze four large U.S. pharmaceutical manufacturers by running advanced topic modeling software over 18 years of letters to shareholders from each firm from 2001 to 2018. I elected to analyze letters to shareholders because I wanted to see where CEO’s were shifting their focus during periods prior, during (run time), and after large legislative change.

Content Analysis and Attention-Based View

Documented in Sonpar and Golden-Biddle’s 2007 academic paper, content analysis is useful to identify how executive attention changes over time, according to an ABV or Attention-
Based View of the firm. Generally, ABV’s goal is to provide information regarding how a firm behaves and is based on the premise that an organization or firm’s behavior results from where it places its focus or attention (Sonpar & Golden-Biddle, 2007). The flow works like so: a firm’s top management’s attention to an issue trickles down influencing the organization’s attention to the issue and ultimately results in the firm taking action towards the issue.

Content analysis and the ABV model were used in a 2006 study of Regional Health Authorities (RHA) in the Canadian province of Alberta (Sonpar & Golden-Biddle, 2007). As with my own study, many precautions were taken to ensure the accuracy and reliability of the content analysis. The study archived all relevant published documents from the RHAs and the government. Once archived, the documents were loaded into advanced software and special topical dictionaries were compared to each document to identify a larger concept or topic. For example, words like promotion, healthy, living, and protection were loaded into a dictionary called wellness, so, when the software would see a high level of those words in a document, it would mark the document as containing the topic of wellness indicating management’s attention to wellness (Sonpar & Golden-Biddle, 2007). Thus, the content analysis using an ABV framework establishes causal relationships between certain programmed dictionary words to topics.

Distinct from the RHA study, I located business-specific dictionaries tailored for my content analysis software instead of crafting my own (See Appendix 1). To ensure accurate information, I edited and created an extensive exclusion dictionary, which kept the software from returning topics like the word “the” (See Appendix 3).
Brand Name Pharmaceutical Manufacturers Studied

For my analysis, I chose four of the largest brand name pharmaceutical manufacturers based in the U.S: Pfizer, Amgen, Bristol-Myers Squibb, and Johnson & Johnson. To ensure accurate results, I gathered annual reports from 2001 to 2018 capturing periods prior, during runtime, and after both the Medicare Modernization Act and the Affordable Care Act.

Pfizer Inc.

According to the IBIS Industry report for brand name pharmaceutical manufacturers (Figure 1), research-based Pfizer Inc. is the world’s largest pharmaceutical company and conducts most of its business in the U.S. capturing 11.8% of the total U.S. pharmaceutical industry’s market (Figure 2). Headquartered in New York with a global research facility network, the pharmaceutical giant serves two distinct business segments: innovative health and essential health (Spitzer, 2019). Lipitor, Norvasc, and Zoloft are a few recognizable drugs Pfizer currently sells. However, Pfizer’s full portfolio of drugs includes vaccines, small molecule medicines, and biologics (Spitzer, 2019). Overall, Pfizer has stood the test of time in the U.S. pharmaceutical industry since its inception in 1849.

Amgen Inc.

The youngest brand name pharmaceutical business in this study, Amgen Inc. specializes in developing biopharmaceutical products for human therapeutics (Spitzer, 2019). The 2019 IBIS Industry report indicates an industry market share of 9.7% for Amgen. With a human
therapeutics focus, Amgen focuses on therapies for oncology/hematology, cardiovascular disease, bone health, inflammation, nephrology, and neuroscience (Spitzer, 2019). A few recognizable drugs from Amgen include Neulasta, Enbrel, and Prolia. While Amgen sells products worldwide, it relies heavily on pharmaceutical distributors for sales within the U.S. accounting for 96% domestic sales in 2017 (Spitzer, 2019). Resultingly, Amgen, like the rest of the studied firms, has a large exposure to U.S. healthcare legislation.

**Bristol-Myers Squibb**

Another manufacturer who has stood the test of time, Bristol-Myers Squibb is an important U.S. name brand pharmaceutical manufacturer. However, unlike the Pfizer and Amgen, Bristol-Myers Squibb’s once great market share – the second largest pharmaceutical company in the world in 1989 – has since dwindled. Now, the firm only controls 6.9% of the U.S. name brand pharmaceutical industry (Spitzer, 2019). Operating solely in biopharmaceuticals, the firm’s focus is on cancer treatments. Like Pfizer, Bristol-Myers Squibb is headquartered in New York and conducts the majority (56%) of its business domestically. A few recognizable drugs from Bristol-Myers Squibb are Eliquis and Opdivo (Spitzer, 2019). While Bristol-Myers Squibb may not be leading the industry, it still remains a key player in the U.S. today.

**Johnson & Johnson**

Likely the most recognizable brand of the studied firms, Johnson & Johnson currently holds the second largest market share of the U.S. pharmaceutical market. Slightly different from the rest, Johnson & Johnson is a holding company with over 260 companies under its name. However, the entire Johnson & Johnson enterprise can be broken down to three lines of business: pharmaceutical, consumer products, and medical devices (Spitzer, 2019). Dissecting its
pharmaceutical arm, the firm currently serves six therapeutic areas: immunology, vaccines, nervous system disorders, oncology, metabolism and pulmonary hypertension, and cardiovascular. A few recognizable drugs from the firm are Remicade, Topamax, and Procrit (Spitzer, 2019). Johnson & Johnson, then, is the most diversified company included in the study, and its pharmaceutical branch has managed to edge out dedicated pharmaceutical manufacturers.

**Data Analysis**

For my research, I focused on 71 letters to shareholders spanning from 2001 to 2018 from four major U.S. pharmaceutical manufacturers (18 letters from each, with the exception of 17 letters from Bristol-Myers Squibb) to capture where top management’s attention was during a given period as outlined in the ABV approach. I utilized my university’s extensive resources to find content analysis software (Provalis Research’s QDA Miner and Word Stat programs). I undertook three text analysis approaches: word frequencies, topic modeling, and dictionary application.

After all the letters to shareholders and dictionaries were loaded into the program, I chose to conduct a few different types of content analyses. For my first analysis, I divided the letters into three periods and identified word frequencies for each time period. The word frequencies are represented by word clouds from each period; these word clouds represent the most important keywords from a given period ranked by frequency per 10,000 words. Second, I used the topic modeling algorithm in Wordstat to identify the groups of words or topics for each period group. Finally, I overlaid dictionaries previously created in management research (Appendix 1) onto the letters from each period as another method to understand and statistically compare the attention of top management over these legislative periods.

The breakdown of the periods studied is shown below:

2. Post-Medicare Modernization Act/Pre-Affordable Care Act (2004 – 2009)
   a. First MMA legislative changes went into effect in 2004 and were finalized in 2006


Findings & Discussion

What are the reactions – actions, attention and considerations – made by these companies across legislative changes? The areas of focus across the studied periods did change; however, the resulting changes from top management were more often alike to shifts in focus rather than prominently introducing new focuses or dismissing old ones period to period. For example, major words in the word frequency clouds (Figures 3, 4, 5, and 6 on the following pages) show words from period to period gradually coming in and going out of focus, but few prominent words in one section disappear all altogether or appear only once. These shifts in focus, then, represent attention trade-offs from top management across legislative changes instead of entirely new strategic focuses tailored to each change. So, what are these focus-shifts before, during, and after legislative change, and what do they tell us about how these companies prepare and adapt to changes?
Analysis of the Entire Study Period, 2001-2018

The word frequency analysis in Figure 3 yielded findings for the overall period. Depicted above, the overall word frequency cloud shows words which the four firms’ top management wrote the most over the date range (2001 – 2018). Note, the larger, more centralized the word the more frequent the word arose in the CEOs’ letters to shareholders. Health, care, products, medicines, world, and people have been primary focuses of CEOs for the past twenty years, which, in turn, tells us the primary focuses of the firms over the time period. Surprisingly, strategy and the consumer gleamed relatively little focus from the firms over the period, but the larger emphasis on people over consumers implies large pharmaceutical manufacturers see their clients as people instead of consumers.

The topic model produced from the entire data range yielded interesting, surprising results. The topics, ranked from greatest attention by management to lowest attention by management follow as such (See Appendix 2 for full topic model results):

1. HIV/AIDS
2. Clinical Trials Lung Cancer

3. Medical Devices

4. Ownership Culture

5. Therapeutic Areas: Discovery and Development

The topic model informs us that during the entire date range brand name pharmaceutical manufacturers focused on producing new therapies/products. During the past twenty years, the top two areas of pharmaceutical manufacturer focus were AIDS and lung cancer. These make sense as areas of focus for manufacturers as they were, and still are, large areas of need within the pharmaceutical community. However, they are not the focus of firms today; the model overall shows the scale of the focus for AIDS and lung cancer as they held the most attention from large pharmaceutical companies. Additionally, we see the other remedy for preparing for legislative change during runtimes from the ownership culture topic. By focusing internally, the firms strengthen themselves to be best prepared for an uncertain future.

Period 1: Pre-Medicare Modernization Act, 2001-2003

Figure 4: Depicts word frequency over years 2001-2003 from letters to shareholders.
Period 1 or the Pre-Medicare Modernization Act time period provides a glimpse into what the firms were doing before any major healthcare reform was enacted, only the run time preparations for the upcoming Medicare Modernization Act are reflected above. Unlike the word cloud for the entire period 2001-2018, the attention of CEOs during this period was more business centered and internally focused. The words year, company, business, and products occurred the most during the period; therefore, in anticipation of legislation, the firms seem to prepare themselves by growing their product line and in turn strengthening business. Recall, the Medicare Part D provision first rolled out with the Medicare Modernization Act, so the internal focus makes sense as the firms all wanted to be prepared to take on the new, vast government-backed Part D plan.

The topic model falls somewhat in line with the word frequency cloud for this period. The topics produced by the content analysis from period one are as follows (See Appendix 2 for full topic model results):

1. Worldwide Sales Operational Growth
2. Research and Development
3. Pharmaceutical Company and People
4. Healthcare
5. Key Leadership
6. Food and Drug Administration Patents
7. Financial Performance/Corporate Governance

The topics for the first period carry some of the same themes as the word frequency cloud but show more specific areas of focus. For example, instead of year and company as the top two focuses, the topic model went into more detail informing us the primary focus of management
was worldwide sales operational growth. This shows us that the companies were attempting to take out an insurance policy, so to speak, during the run time for the Medicare Modernization Act by way of strengthening foreign drug sales unaffected by the legislation. Additionally, the topics of corporate governance and key leadership strongly indicate a push for internal stability before the legislative landscape for drugs changed.

The topics research and development and Food and Drug Administration patents show a second avenue of precaution taken during the time period. Pharmaceutical manufacturers are always focused on their drug pipeline and ensuring they have enough upcoming products to take place of older ones, but the topics were more defined during this period than the overall analysis. Therefore, I am inferring that the companies were ramping up their product lines to ensure sales stability/growth during the changing period and to prepare products for the upcoming Medicare Part D.

Overall, the brand name pharmaceutical manufacturers appeared to be cautiously optimistic during the run time before the Medicare Modernization Act. First, they focused on growing the areas of the business largely unaffected by the change – overseas sales. However, their next priorities were to internally strengthen their leadership structure and grow their pipeline, areas of focus which help the firms take advantage of both global and domestic sales. It seems clear then, that the manufacturers were mitigating future risks during the run time before legislation took effect. The manufacturers placed bets on their international abilities and strengthening their own leadership and products to fully take advantage of the new legislative change.
Period 2: Post-Medicare Modernization Act/Pre-Affordable Care Act, 2004-2009

The second period’s word frequency cloud shows subtle changes from the prior period indicating some post-Medicare Modernization Act changes and evidence of preparations in anticipation of the upcoming Affordable Care Act. Words like year, products, and business shrank relative to the period one cloud, and words like growth, care, and health grew. The largest difference is the change from an overall internal focus to a new overall external growth focus.

The topic model produced from the letters in period two reflects the main focus of the word cloud: growth. Below are the topics, again ranked by most attention from management (See Appendix 2 for full topic model results):

1. Stage Pipeline
2. Sales Growth
3. Unmet Medical Disease Areas
4. Medical Devices
5. Patients
6. Research and Development
7. Company Performance
Undoubtedly, the manufacturers focused on rapid growth after the enactment of the Medicare Modernization Act. The growth focus in the period following the Medicare Modernization Act indicates the firms successfully weathered the legislative change and nuances, and they now were in full expansion and growth mode. Looking at the topics in context with the rest from the period, there is no topic which is not centered around growth and external focuses. Overall, it appears after the passage of the Medicare Modernization Act firms expanded as rapidly as possible during the brief period of semi-legislative stability.

More interesting than the growth focus, the lack of strong internally focused themes and attention areas from management is contradictory to the manufacturer’s actions in anticipation of the Medicare Modernization Act in the first period. The difference represents a break in procedure from the first sweeping legislative change to the second. I hypothesize the firms now had recent experience with dealing with large change, and the internal strengthening measures taken in preparation for the Medicare Modernization Act were deemed good enough by top management to not call for more in anticipation for the Affordable Care Act. Interestingly, the firms did not focus abroad in anticipation of the Affordable Care Act like they had done for the Medicare Modernization Act.

Further, the Affordable Care Act, while it was a large change, did not introduce an entirely new government drug coverage plan like the Medicare Modernization Act from a pharmaceutical manufacturing perspective. Rather, it altered Part D and changed the way businesses farther up the supply chain interacted with Part B. Importantly, the focus of the Affordable Care Act was to give all Americans access to health insurance. For pharmaceutical manufacturers, the change meant more Americans would have health insurance, so it was more likely than not that more Americans would buy prescription drugs. With the potential for the
Affordable Care Act to grow the number of covered Americans, the focus on growth makes sense as it prepares the firms to keep up with the potentially larger market.

Overall, the run-time preparations of growth and expansion for the Affordable Care Act are largely like the post-Medicare Modernization Act adaptations. However, the difference between run time preparations for the two bills indicates a lack of faith by the pharmaceutical manufacturers for the first sweeping change, but, for the second, the manufacturers had already learned to deal with new government drug programs and were more confident in their abilities to sell and manufacture drugs.

**Period 3: Post Affordable Care Act, 2010-2018**

*Figure 6: Depicts word frequency over years 2010-2018 from letters to shareholders.*

The post-Affordable Care Act period’s word frequency cloud yielded a new focus. With the firms having prepared and adapted for the Medicare Modernization Act and focused on growth in anticipation from the Affordable Care Act, the name brand pharmaceutical manufacturers found themselves in a stable legislative environment with no new major changes on the horizon. So, what did they do? From the word cloud, it appears top management directed
the firm’s attention to a customer focus. However, the apparent new patient focus may not be the result of a new adaptation or change in response to the Affordable Care Act; rather, the word patients has appeared in every word cloud and has grown with each one. The slowness of the patient focus transition, taken into context with the other periods, seems the result of the distraction of top management by the legislative pieces created to protect Americans. A frustrating phenomenon arises. When the government passes legislature to help patients gain access to drugs, the brand name pharmaceutical manufacturers take their focus off the patients. Albeit the manufacturers’ shift in focus is only temporary, so, once the runtime period for legislation ends, the patient becomes the center of attention for both the legislation and the manufacturers.

The topic model for the final period reveals topics mostly in line with the main words in the cloud. Although, a few new topics were introduced revealing new traits of brand name pharmaceutical manufacturers. Below are topics produced by the modeling software from the final period (See Appendix 2 for full topic model results):

1. Metastatic Melanoma (lung cancer)
2. Unmet Medical
3. Emerging Markets/Consumer Healthcare
4. Respect from Society/Trust
5. United States
6. Biopharma Company Long-term Success

For the first time, brand name pharmaceutical manufacturers display a sense of self awareness and a more pronounced focus on long-term success. The new topic of respect and trust from society indicates top management focused attention towards external appearances and
perception for the first time. I hypothesize the shift is a result of both the Affordable Care Act and the Medicare Modernization Act failing to lower drug prices as expected and the following negative perception of the pharmaceutical industry by the public. A testament to the complex pharmaceutical supply chain’s ability to adapt to legislative change, the pharmaceutical manufacturers, as with legislation, quickly shifted attention and adapted to attempt to regain the public’s faith.

The United States, unmet medical areas, and emerging consumer markets topics represent attention shifts taken by top management to restore public relations. By showing an attention shift and experimenting in new ways to expand customer markets and focus on the U.S.’s unmet needs, the manufacturers are now making tangible changes in line with management’s focus on growth via avenues that also appease the public. Playing into the dialogue of societally respectful growth, the topic of long-term success also shows the manufacturers now can more effectively strategically plan their business models without the burden of upcoming legislative change. Ultimately, without the presence of legislative change, top management focuses attention on appealing to the consumer and healthy, long-term growth instead of adapting to survive in new legislative landscapes.

**Comparison Across the Three Periods Using Dictionaries**

While the topic models and word frequency clouds gave good qualitative insights to the adaptations and strategies employed by pharmaceutical manufacturers, specialty business dictionaries for content analysis provide another way to identify broad changes undertaken by management across the three time periods. The dictionary analysis provides a word list for particular constructs. These word lists are then overlaid on the textual materials to provide frequency counts of words which can be used to statistically compare word frequencies across
the three time periods. Instead of the computer program creating its own topics based on an
algorithm of words in the letters, using dictionaries can show how topics changed from period to
period and were statistically significant. The dictionary analysis is provided below in Figure 7.

<table>
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<tr>
<th>Dictionaries</th>
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<th>2 Frequency/Word Count</th>
<th>3 Frequency/Word Count</th>
<th>Chi2</th>
<th>P (2-tails)</th>
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</thead>
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<td>455 0.561%</td>
<td>25.735</td>
<td>0.000</td>
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<td>PROACTIVE</td>
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<td>159 0.263%</td>
<td>205 0.253%</td>
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<td>RISKTAKEING</td>
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<td>89 0.110%</td>
<td>13.082</td>
<td>0.001</td>
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<td>340 0.419%</td>
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<td>0.054</td>
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<td>ORIENTATION CUSTOMER</td>
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<td>166 0.274%</td>
<td>188 0.232%</td>
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<td>0.067</td>
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<td>ORIENTATION INTERFIRM</td>
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<td>211 0.348%</td>
<td>412 0.508%</td>
<td>19.061</td>
<td>0.000</td>
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<td>ORIENTATION LONG TERM FOCUS</td>
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<td>0.003</td>
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<tr>
<td>ORIENTATION PROFITS</td>
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<td>0.056</td>
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<tr>
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<td>0.714</td>
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<tr>
<td>VIRTUE INTEGRITY</td>
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<td>42 0.069%</td>
<td>54 0.067%</td>
<td>0.073</td>
<td>0.964</td>
</tr>
</tbody>
</table>

*Figure 7: Dictionary frequency counts divided by total word count per page and resulting statistics
noting statistical change over periods.*

The dictionary context analysis yielded interesting results both confirming and
questioning some of the results from the topic models. Some of the dictionaries found no
statistically significant change period to period, such as the organizational constructs of
proactiveness, conscientiousness, and integrity, while others displayed significant change. The
dictionary results mostly confirm the results of the topic models and word frequency clouds, and
this is explained below.

Innovativeness showed the most significant change over the periods and reflects earlier
hypothesizes about the firms transitioning to new healthy ways of growth instead of rapid growth
to meet demands of new government programs. It also confirms the topics introduced in period
three which focus on emerging markets and new ways to regain trust. Note the slow transition
from period one to period three. The transition represents the tradeoff between government
legislation change and the pharmaceutical manufacturers’ focus on innovation as the periods
where change was introduced saw lower levels of innovation.
Next, the interfirm statistic is another major confirmation of results from the topic models and frequency clouds. The interfirm dictionary returned a higher level of interfirm focus during the runtime for the Medicare Modernization Act followed by a drop after the legislation’s enactment and during the run time for the Affordable Care Act. The period one to two change represents the firms’ changing strategies for adapting to the Affordable Care Act and taking advantage of the Medicare Modernization Act. Lastly, the return of the interfirm focus in the third period likely represents the firms’ focus on regaining trust and establishing respect from society.

Long-term focus and risk taking both saw statistically significant change over the periods, each with an increased focus every period. The dictionaries’ findings surrounding the two areas of focus agree largely with the discussion based off the topic models and frequency clouds. Risk taking changed period over period in line with the initially conservative approach to the Medicare Modernization Act, the rapid growth after, and the focus on emerging markets and unmet medical needs. The long-term focus, like in the topic models, appears to be most apparent in the latter periods.

Lastly, the customer focus dictionary, while just missing statistical significance, does reflect a change over the periods. Conversely, the dictionary analysis seems to disagree with the last period having the strongest focus on the customer, favoring period two. However, I take the dictionary results hesitantly because the CEOs of major healthcare firms often do not use the word “customer” and instead use “patient” or “people.” Unfortunately, the words patient and people are not included in this dictionary. As a result, the unique vocabulary used by the brand name pharmaceutical manufacturers when referring to customers likely skewed the dictionary results, so the customer dictionary will be ignored for purposes of this study.
### Summary Table of the Three Analyses’ Findings:

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<th></th>
<th></th>
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<tbody>
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<td><strong>Word Frequency Cloud (Top 6 Words):</strong></td>
<td>Health, Care, Medicines, Products, People, and World</td>
<td>Year, Company, Business, Products, World, and Sales</td>
<td>Growth, Care, Health, Company, Medicines, and Products</td>
<td>Patients, Year, Company, Health, Growth, and Medicines</td>
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<td>2. Research and Development</td>
<td>2. Sales Growth</td>
<td>2. Unmet Medical</td>
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<td></td>
<td>5. Key Leadership</td>
<td>5. Patients</td>
<td>5. United States</td>
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<td><strong>Dictionary:</strong></td>
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<td>Innovativeness: 0.428%</td>
<td>Innovativeness: 0.561%</td>
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<td>Risk taking: 0.110%</td>
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<td></td>
<td></td>
<td>Long Term Focus: 0.694%</td>
<td>Long Term Focus: 0.826%</td>
<td>Long Term Focus: 0.929%</td>
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<tr>
<td><strong>Overall Takeaways:</strong></td>
<td>Firm’s focused primarily internally and on sales outside U.S.</td>
<td>Firm’s focused primarily on rapid growth and new markets.</td>
<td>Firm’s focused primarily on patients and long-term success.</td>
<td></td>
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</table>
Conclusion

U.S. pharmaceutical manufacturers operate in one of the most complex and ever-changing industries in the world. With a lengthy supply chain passing through multiple “middlemen” parties, large brand name pharmaceutical companies have managed to survive, even prosper, during periods where their rules of operation change, and new legislation creates different markets. These firms’ ability to adapt to legislative changes in stride is remarkable, and they take great risks in doing so.

The two largest pieces of healthcare legislation in U.S. history happened over the last two decades. The Medicare Modernization Act completely restructured public healthcare’s pharmaceutical drug policies and represented a large potential client for many pharmaceutical companies. Then, just six years later, the entire U.S. healthcare system was overhauled by the Affordable Care Act. So how do the pharmaceutical manufacturers stay ahead?

In periods after a piece of legislation is announced and before enactment, large name brand pharmaceutical manufacturers quickly adapt. My study found few similarities between the run time before the Medicare Modernization Act and the Affordable Care Act, indicating manufacturers tailor adaptations specifically to each piece of legislation. For the Medicare Modernization Act, pharmaceutical manufacturers contracted by focusing internally on leadership and corporate governance. To ensure stability, they also focused on sales channels outside the U.S. For the Affordable Care Act, they focused more externally with top management’s attention set on rapid growth and expansion via expanding product lines and exploring unmet needs.

Once the legislation changes ceased, the pharmaceutical manufacturers shifted to a more stable, healthy growth focus. The firms began to focus more on long-term success and rebuilding
their societal reputation. Resultantly, they focused on the U.S. market and continued to explore areas of unmet need. Overall, the manufacturers’ attention centered around their patients during times without legislative change and towards themselves during times of change.
References


Spitzer, D. (n.d.). On the Mend: Raising prices on widely used specialty drugs will boost industry revenue (pp. 1–48). IBIS World.

Appendix 1 – Source of Organizational Dictionaries

- **EO – Innovativeness, Risk-taking, and Proactive Dictionaries**

- **Market Orientation – Orientation Interfirm, Long Term Focus, Competitor, Profits, Customer**

- **Organization Virtue Orientation – Conscientiousness, Integrity**
## Appendix 2 – Topic Model Results

### From Entire Period Studied (2001-2018):

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<thead>
<tr>
<th>NO</th>
<th>TOPICS - Entire Study Period</th>
<th>KEYWORDS</th>
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<th>CASES</th>
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<td>21</td>
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<td>7</td>
<td>PATIENTS</td>
<td>MILLIONS OF PEOPLE; CLINICAL TRIALS; PEOPLE AROUND THE WORLD; CLINICAL DATA; CLINICAL TRIAL; MANUFACTURING; PRODUCTIVITY; GLOBAL; RESEARCH; COST; RESOURCES; DEVELOPMENT; LARGE; MARKETS;</td>
<td>0.405</td>
<td>478</td>
<td>24</td>
<td>100.00%</td>
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<td>2</td>
<td>RESEARCH AND</td>
<td>RESEARCH AND DEVELOPMENT; EMERGING MARKETS; GLOBAL; RESEARCH; COST; RESOURCES; DEVELOPMENT; LARGE; MARKETS;</td>
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<td>MANUFACTURING</td>
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<td>1</td>
<td>COMPANY PERFORMANCE</td>
<td>COMPANY; PERFORMANCE; MISSION; COMMITMENT; FUTURE; LONG; CUSTOMERS; PAST; MAKE; HEALTH; CHANGE; FINANCIAL;</td>
<td>0.360</td>
<td>397</td>
<td>24</td>
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From Period 3 (2010-2018):

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<th>NO</th>
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<th>KEYWORDS</th>
<th>COHERENCE</th>
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<td>PERCENT INCREASE</td>
<td>PERCENT; BILLION; ADJUSTED; DIVIDEND; SALES; INCREASE; TOTAL; CASH; RETURN; GREW; APPROXIMATELY; SHARE; INCREASED; OPERATIONAL; YEAR; SHAREHOLDER RETURN; PERCENT INCREASE; BILLION IN SALES; CASH FLOW; PERCENT OPERATIONALLY; TOTAL SHAREHOLDER RETURN; DIGIT GROWTH; ADJUSTED DILUTED EARNINGS PER SHARE; ADJUSTED EARNINGS PER SHARE; CONSEQUENTIAL YEAR; SHARE REPURCHASES; SALES GREW; ADJUSTED COST OF SALES; ADJUSTED INCOME; BILLION TO SHAREHOLDERS; INCREASED OUR DIVIDEND; INFORMATIONAL AND ADMINISTRATIVE EXPENSES; PREVIOUS YEAR; METASTATIC MELANOMA; CLINICAL; LINE; DATA; STUDIES; LUNG; PHASE; IMMUNE; COMBINATION; ONCOLOGY; TREATMENT; CANCER; POSITIVE; THERAPY;</td>
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<td>LUNG CANCER; METASTATIC MELANOMA; CANCER PATIENTS; TUMOR TYPES; CLINICAL DATA; CLINICAL TRIAL; CLINICAL TRIALS; IMMUNE SYSTEM; CLINICAL STUDIES; ONCOLOGY PORTFOLIO; UNMET; MOLECULES; MEDICAL; PIPELINE; DISEASE; STAGE; AREAS; EARLY; THERAPEUTIC; ADVANCING; POTENTIAL; CARDIOVASCULAR; PHASE; DEVELOPMENT; RESEARCH;</td>
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<td>UNMET MEDICAL; STAGE PIPELINE; THERAPEUTIC AREAS; RESEARCH AND DEVELOPMENT; CARDIOVASCULAR DISEASE; SIGNIFICANT UNMET; AREAS OF HIGH UNMET MEDICAL; SIGNIFICANT UNMET MEDICAL; MARKETS; EMERGING; CONSUMER; PHARMACEUTICALS; BUSINESSES; PRODUCTS; BRANDS; GROWTH; KEY; BUSINESS; OPERATIONAL;</td>
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