Personalized Medicine
and
The Future of the Pharmaceutical Industry

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I. Introduction

The purpose of this paper is to provide an analysis of the future of the pharmaceutical industry in the context of the potential technology disruption brought by personalized medicine. The first section provides an overview of the current structure of the pharmaceutical industry, including a detailed analysis of the capabilities drug companies have developed to capture value and build barriers to entry. The second section looks at the limits and challenges the industry is currently facing, arguing that this industry is mature and ripe for a disruption. The third section introduces pharmacogenomics and the concept of personalized medicine, elaborating on the impact this technology disruption may have on the entire industry. Finally, the last section introduces a framework based on a scenario analysis, which provides a map to pharmaceutical firms to assess their business strategies going forward. Recommendations to one of the leading pharmaceutical firms are also included as an illustration.

II. Structure of the Pharmaceutical Industry

In order to understand the magnitude of the disruption personalized medicine may potentially inflict to the pharmaceutical industry, it is important to develop a good understanding of the current structure of this industry. In this section, we outline the set of mechanisms by which drug manufacturers capture value. In the first sub-section, we describe how uniqueness and complementary assets are used in tandem to maximize value capture. In the second sub-section, we outline the set of reinforcing loops that act as powerful barriers to entry protecting and accelerating the profitability of those firms. Finally, in the third sub-section, we show how the drug companies have gained control of the entire value chain, only disintegrating some of the activities in a very limited basis.

Uniqueness and Complementary Assets

Prior to the 70s, value capture in the pharmaceutical industry was mainly achieved through uniqueness. Uniqueness came mainly in the form of patent protection which provides a legal exclusivity to commercialize a drug compound for a period of 20 years. During the 80s and 90s, drug companies started to develop a fairly sophisticated web of complementary assets in order to sustain their profits, or, as some would argue, increase them. The need for complementary assets was exacerbated by the fact that competing drug makers were increasingly able to more easily design new products around existing patents. “Me-too drugs”, which were based on slightly different chemical compounds but with similar therapeutic effects, were specifically designed by competitors to offer an alternative to first-in class drugs. Practically, they significantly eroded the value capture ability of uniqueness from the patenting of a drug. While patent protection remains
today one of the pillars of value capture in this industry, the set of **complementary assets** the pharmaceutical firms have come to develop include:

- **Sales & Marketing:** Drug companies have developed first class global sales & distribution capabilities which allow them to effectively promote new drugs by directly contacting doctors and offering them drug samples. More recently, drug companies have experienced great success with Direct-To-Consumer advertising, especially with lifestyle drugs. As a result, brand recognition is created on both sides of the transaction.

- **Clinical Development:** Drug development requires an enormous amount of resources such as highly-skilled labor and high-speed computers and robotics to screen new drug compounds. Developing a new drug takes also a long time: 10 years on average. Consequently, the financial resources required by a new entrant to sustain such costly endeavor are very difficult to match, especially for small firms.

- **Portfolio Management:** A drug company’s portfolio is its greatest asset. As a patent for one drug nears expiration, newer drugs will offset the loss of an older drug’s revenue to generic entrants. This creates, for its product pipeline, a staggering effect that consistently produces revenue.

- **FDA process:** The drug approval process is comprised of three rigorous phases. Roughly one out of twenty compounds completes the entire process successfully, and yet, the approval could still be withdrawn due to insufficient data. Expertise and experience working with the FDA is therefore crucial, as the criteria for obtaining approval are extremely stringent since the safety of the public is at stake.

- **Financial Resources:** A pharmaceutical with enormous wealth can afford to absorb the risk of drug creation. For approximately 5000 new compounds discovered, only one becomes a commercial drug – odds that are not favorable to small or less-endowed pharmaceuticals. As an indication, the dollar amount of R&D spending reached $28 billion in 2003 from $7 billion in 1990 (CAGR: 11.25%).

Some differences in the complementary assets exist across the players in this industry. For example, Pfizer is recognized for having one of the best sales and distribution capabilities in the industry, while Eli Lilly is often mentioned as having the best in-licensing capability. However, those differences are mainly limited to the
breath and depth of the complementary assets each firm has developed and not in the mix of complementary assets those firms have built.

Reinforcing Loops

At a high level, the current structure of the pharmaceutical industry rests on three key reinforcing loops, shown in Figure 1 (See APPENDIX).

- **“R&D investment – Patent Protection – High Willingness to Pay”** (loop C): R&D investments are the primary source of intellectual property and patents. Patents, in turn, provide a legal barrier to entry to competition, which allows the firm to fully extract the high consumer surplus created by the high willingness to pay. Given that the direct cost of producing drugs is relatively low, record profits are generating, allowing, in turn, to massively investing in R&D.

- **“Marketing Spending – Increased Market Size and Share – Increased Profit”** (loop B): High marketing spending increases doctors and consumers’ awareness of drugs. The associated increase in market share leads to further adoption of the drugs as both doctors and consumers interpret the market share increase as a validation of the drug’s safety and efficacy superiority (network externality around adoption and prescription). This phenomenon leads to the “first-in-class” release of a product (for example: Lipitor in the cholesterol lowering drug market commands both extremely high revenues and profits that can be used to further boost marketing). Also, because of the time pressure imposed by patent expiry, firms have particularly strong incentives to achieve rapid adoption through marketing efforts.

- **“Complementary Assets – Economies of Scale and Scope – Broader Product Offering”** (partially reflected in loop A): The development of strong complementary assets, such as a global sale & distribution network, a massive clinical development capability, or branding provide an avenue for economies of scale and scope in the development and commercialization of new drugs. This allows large firms to perform those tasks at a lower cost than what biotechnology start-ups could achieve, providing large firms with a strong value proposition to start-ups for commercializing their discoveries. Through this process, large firms add new products to the portfolio, which in turn, provide an opportunity to further strengthen the complementary assets mentioned.

Figure 1 shows the interconnectedness of these loops: Loops B and C demonstrate how investment in R&D and marketing initiates positive reinforcing loops that ultimately lead to greater profits which can in turn be reinvested. Loop A illustrates how economies of scope and scale resulting from B and C affect the
firms’ strategic choices. Marketing capabilities developed within a firm, as a consequence of loop B, become tightly held complementary assets that can be deployed across product classes (economies of scope) and with reduced average unit cost as more units are sold (economies of scale). Likewise, loop C builds internal capabilities and knowledge that lower unit costs as sales increase in volume and scope. Because of those effects, firms tend to seek drug targets that can address the needs of a very large patient population. The result is an emphasis on so-called “blockbuster” drugs that can achieve billions of dollars in sales before patents expire (loop A).

**Value Chain**

*Figure 2* provides a schematic representation of the value chain of the pharmaceutical industry. The first stage, research and discovery cover the activities associated with the identification of New Molecule Entities (NME), which are chemical compound candidates for becoming new drugs. The second stage of the value chain, clinical development, is perhaps the most time consuming and expensive. This stage involves testing the drug’s efficacy and side effects, if any, among patients. Clinical trials occur in three phases and are generally conducted through hospitals and academic research institutions. The last phase of the clinical development stage is to obtain regulatory approval from the Food and Drug Administration (FDA), a thorough and extensive review process of the efficacy and safety records of the drugs collected during the trials. Once a compound is approved, drug companies develop a manufacturing process that is economically viable to keep costs low for mass production. The various steps of manufacturing, including milling, mixing and micronizing of chemicals, are now highly automated. Lastly, the sales and marketing phase has become arguably the most crucial piece to capturing the drug’s value for firms today. As mentioned earlier, using their strong sales forces, drug companies interface and build relationships with doctors to push their drugs onto the patients. In addition, direct-to-consumer advertisements have lately been used to increased awareness and adoption of new products.

Historically, pharmaceutical firms emerged from within the manufacturing stage of the value chain. Most of today’s pharmaceutical giants can trace their origins in the chemical industry where the manufacturing of drugs for human consumption was performed by the same companies that manufacture a wide range of chemicals. Progressively, pharmaceutical firms have integrated the four stages of the chain, realizing the strategic importance of controlling all the activities from discovery to marketing in order to capture all the value created. This led to the emergence of FIPCOs (Fully Integrated Pharmaceutical Companies), which is how we know drug companies today. It is interesting to note that, recently, pharmaceutical companies have disintegrated some activities of the value chain, mainly for cost reduction purposes. One example is the outsourcing of some clinical development activities to CROs (Contract
Research Organization). However, this disintegration is very localized and limited, and it is clear that drug companies are using their muscle to still collect most of the value created in the chain².

III. An industry ripe for disruption?

**S-curve(s) of the pharmaceutical Industry**

Over its long history, the pharmaceutical industry has experienced several technology phases and disruptions (Figure 3). Initially, scientists looked at the biochemistry of tissues and at that of the cell. Medicinal synthetic organic chemistry and pharmacology were the primary drivers of pharmaceutical innovation. The conventional approach of treating acute disease was by providing symptomatic relief. Then, in the eighties, the drug discovery approach shifted from controlling symptoms to curing disease. Molecular biology became the main driver of innovation. Many new drugs were discovered thanks to numerous incremental improvements, from rational drug design to more recent high-throughput screening techniques, with an ever more sophisticated biological foundation.

Today, this approach is reaching its limits as illustrated by a decreasing total number of new drugs approved each year since 1996 while the amount of R&D spending has skyrocketed (Figure 4a). The productivity of drug discovery has again reached another plateau as indicated by our plot of the cumulative amount of annual R&D spend (a proxy for the effort) versus the cumulative number of New Molecule Entities approved by the FDA each year (a proxy for productivity). As Figure 4b clearly illustrates, we are currently in the top flat part of the industry’s S-curve.

**Limits of the current model**

Despite the increasing amount of money spent on research & development, discovering new drugs seems to be increasingly difficult. Some of the reasons that may explain this decrease in productivity include:

- **Difficulty of modeling drug behavior.** Unfortunately, despite breakthroughs in our understanding of molecular biology and human biochemical pathways, drug behavior in humans is still quite difficult to model in a test tube. Developments in biology have led to dramatically improved screening methods but even after a target passes through 6 years of pre-clinical screens into the first phase of clinical trials, it must go through a costly, ~8 year approval process to demonstrate safety and efficacy in humans, with only a 20% chance of

² For more details, please refer to “Contract Research Organizations and the Pharmaceutical Industry”, by Wayne Chang, Elizabeth Hawkins, and Frederic Zussa, Technology Strategy Assignment #4, May 10, 2005
ultimate FDA approval. The difficulty of replicating human biochemistry in a laboratory is a fundamental technological limitation in the industry’s current trajectory.

- **Low-hanging fruit has been picked.** Some suggest that the pharmaceutical productivity has declined because the “easy” drugs have already been developed. According to this theory, the limit is not a technological one per se, but an exhaustible supply of undiscovered drugs.

- **Business model and regulatory limitations.** Business and regulatory limitations have also contributed to the productivity plateau. Although there is vast unmet medical need, many therapeutic categories for possible drug development affect small populations. Unfortunately, the economics of pharmaceutical development provide incentives to focus on potential “blockbuster” drugs for large markets. Rather than allocating resources to smaller niches of disease where technological progress might be more dramatic, firms invest their research dollars developing competing drugs in crowded therapeutic areas (with very large markets). A final limitation stems from a changing regulatory environment. While in the past, clinical trials needed merely show efficacy relative to a placebo, the FDA now requires candidate drugs to show improvement over the best existing therapy. The industry is being held to a higher bar of performance and in some sense, is paying the price for its own success. Growing public demand for more scrutiny during the drug approval process following the Vioxx debacle might lead to heightened development costs, and thus, reduce profits.

**What’s next?**

The pharmaceutical industry has not experienced a major disruption in a number of years. Given the shift into maturity and plateauing productivity, the industry appears to be ripe for disruption. Potential disruptive technological innovations that could emerge include: the convergence between pharma and biotechnology; personalized medicine; genomics, informatics or even nanotechnology. In the next sections, we will analyze the potential disruption personalized medicine may cause to the pharmaceutical industry as well as the strategic questions it raises to drug companies’ CEOs.

**IV. A Look at Personalized Medicine**

**Introduction**

Pharmacogenomics is the study of the underlying causes of disease based on a person’s DNA structure. In other words, ‘markers’ within one’s DNA will allow scientists to determine why he or she is predisposed to a particular disease. An outgrowth of pharmacogenomics is personalized medicine, where an optimal
treatment is created for a patient based on his or her genetic structure. Through pharmacogenomics, doctors will be able to anticipate what drug is most effective and least likely to have side effects based on the patient’s genetic profile, creating a more personalized and targeted approach to drug prescription.

**Potential Benefits**

Some of the potential benefits of pharmacogenomics and personalized medicine often cited include:

- **More powerful, safer drugs and vaccines.** Through genomics, doctors can determine the effectiveness of a drug for a DNA type and prescribe the compound best fit for the patient. No longer will compounds that do not satisfy a large population be discarded or ‘shelved’. Instead, they can be marketed to patients who may not exhibit side effects but still react positively to the compounds. Additionally, advanced drug screening methods will allow doctors to determine appropriate drug dosages.

- **Improvement of drug discovery and approval.** As the knowledge base of a disease and its drug effectiveness for a certain DNA type increases, pharmaceutical firms can further produce better treatments from this gained knowledge, increasing the number of marketable compounds. The approval process may change due to the fact that the one-size-fits-all approach is no longer the only approach. A targeted approach to drug treatment will result in drug trials conducted with pre-selected focus groups rather than a random sampling of a larger population. By understanding who the target patients are based on their genetic data, pharmaceutical firms can anticipate who their ideal subjects for the new compound are. This could reduce the substantial development time of clinical trials.

- **Decrease in Overall Health Care Cost.** Related to the previous point, the approval process may take less time for personalized medicine and result in lower development costs. As it stands, pharmaceuticals face ~10 years in development time before the drug reaches the market. Any reduction in development time could result in higher profit margins.

**Technology Drivers**

Some of the technology drivers behind pharmacogenomics and personalized medicine include:

- **Lower Costs in Bioinformatics & Gene Sequencing.** Bioinformatics is the gathering and managing of not only a patient’s DNA information but his or her markers for disease and the
possible drug effects for that individual. Meeting Human Genome Project sequencing goals by 2003 has required continual improvements in sequencing speed, reliability, and costs\(^3\).

- **Increased Capacity to Test More Genes:** Newer platforms for gene mapping have increased productivity dramatically. Total sequencing output in the community was about 200 Mb for 1998 but by January 2003, the DOE Joint Genome Institute alone sequenced 1.5 billion bases for the month\(^4\).

**Impact on Value Capture**

We anticipate that the nature of value capture will not fundamentally change. Patent protection and the ultimate promise of value capture that it brings will still be at the root of the economic incentive that underlies investments in the industry. On the other side, the complementary assets required to achieve marketplace success are more likely to change. For example, managing the relationship directly with the consumer and providing the personalized care that pharmacogenetics enables might become a far more strategic complementary asset while the global capability to visit doctors to hand out drug samples might lose of its predominance. Looking at each of the complementary assets we have identified in a bit more depth, we predict the following:

- **Sales & Marketing:** Strong sales and marketing capabilities will still be essential for success but the shape of these competencies will change. Scale will still yield benefits as widespread access to doctors and hospitals will remain a source of competitive advantage. However, the ideal personalized medicine sales force will need to be both more focused around specific therapeutic areas and more knowledgeable about the underlying mechanism of disease and treatment. Consequently, we believe the drug industry will evolve into more of a **niche market** with greater numbers and variety of organizations playing a part.

- **Clinical Development:** Resources to support efficiently and carefully executed clinical trials will still be an essential determinant of value capture in a pharmaceutical industry built around personalized medicine. However, many features of the clinical development process will change. **Recruitment** becomes targeted toward patients with a specific gene pattern. Developing trials for pharmacogenetic-based treatments will be accompanied by a new **learning curve.** **Feedback into discovery process** and **diagnostic tools** development will be essential.

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\(^3\) Human Genome Project; See Website: http://genome.gsc.riken.go.jp

\(^4\) Human Genome Project; See Website http://genome.gsc.riken.go.jp/hgmis/faq/seqfacts.html
- **Portfolio Management**: Portfolio management will still be critical in a personalized medicine world. The smaller markets of personalized medicine-based drugs give pharma firms very high incentives to innovate and continually introduce new products into their portfolio. In addition, with new drug risks and new relationships between products (e.g., two drugs that treat patient segments with different genetic markers), careful portfolio management to mitigate risk can be a source of competitive advantage over the long term. Firms can leverage their portfolio management expertise to select exploratory projects that have high risks but high potential payoffs in the form of entry into a new personalized medicine niche. Finally, the same rationale for portfolio management in pharma today will hold, as patent expiry will still be a reality. (On the other hand, with fewer blockbuster drugs, pharmaceutical firms’ revenues will be less dependent on any one drug.)

- **FDA process**: Skillful navigation through a changing FDA approval process will be essential. A shift to pharmacogenetic-based treatment implies a new risk paradigm for drug safety. Under the old model, drugs must pass requirements set by the FDA, though even when drugs are approved, pharmaceutical firms bear significant downside in the event of safety failures/extreme side effects. With personalized medicine, treatments that work effectively on one patient may harm another. In theory, the treatment should never be administered to the latter party; but such an outcome could result from an inaccurate diagnostic result or poor judgment on the part of the prescribing physician. The new regulatory model is uncertain, but value capture will rely on skillfully maneuvering through it.

- **Financial Resources**: Big pharma firms’ financial resources will subsidize their forays into pharmacogenetics-based projects. Assuming that realignment around a new business model would create a “worse-before-better” scenario, financial resources may enable them to survive the transition.

**Impact on Reinforcing Loops**

Having laid out the fundamental reinforcing loops driving the pharmaceutical industry today and introduced key shifts that accompany a personalized medicine business model, one can next examine how the old loops might change. **Figure 5** captures our hypothesized changes to the old loops that previously drove the industry:

While loop C (R&D-patents-profits) will continue to exist, the strength of loop B (marketing spend, market share, profits) will be diminished: Because of the heterogeneity of demand for pharmacogenetics-
based treatments, marketing competencies cannot be deployed across product lines to the same extent. As described in the previous section, marketing and sales efforts are much more targeted and accordingly, resources are less scalable. Marketing will also become very reliant on the role of diagnostic tools, in that availability and reliability of these tools (which screen for particular genetic sequences) are necessary for driving demand for personalized therapies. Knowledge of genetics and disease mechanisms become skills required by the sales and marketing teams, making the function more specialized.

Furthermore, because of the focus on smaller market segments that necessarily accompanies a personalized medicine focus, the blockbuster model shown in loop A will likely break down. While there are still economies of scale and economies of scope inherent in the R&D and to some extent marketing, these economies cannot be exploited as effectively in a personalized medicine world.

In addition to the changes to existing loops, we anticipate a new loop to emerge (Figure 6). We expect this loop to play a significant role in reshaping the industry. As new personalized medicine treatments are developed, tested and distributed, new data will be generated regarding the link between a drug’s mechanism of action and a patient’s genetic make-up. This data will then inform both the development of better diagnostic tools and improve the discovery process for new personalized medicine treatments. This loop essentially captures the industry learning curve. Spillovers will be low. Therefore, firms who can capitalize on these reinforcing loops early will have an advantage in the marketplace. This particular loop has several implications for the pharmaceutical value chain as outlined below.

**Impact on the Value Chain**

As a consequence of the loop in Figure 6, new players, namely diagnostics and bioinformatics, will enter the pharmaceutical value chain, changing the dynamics of value capture, while increasing the overall PIE. Diagnostics, on one hand, will provide the tools and processes for understanding a potential patient’s genetic make-up, a critical step in personalized medicine-based therapies. Bioinformatics, on the other hand, will allow collecting, analyzing and visualizing the massive amounts of data that match genetic information to particular disease pathways and treatment outcomes, which will become a critical input to the improvement of existing products and discovery of new treatments.

As for integration across the value chain, we envision that over the long term, personalized medicine drug development firms will gain competitive advantage by integrating into these activity areas, primarily due to the loop shown in Figure 6. The combination of low spillover and synergies that exist between treatment delivery, diagnostic development, clinical data gathering and bioinformatics suggests that the benefits offered
by these reinforcing loops will make it attractive to vertically integrate. We anticipate a reversal of the trend toward CRO outsourcing for this reason.

On the other hand, as we have touched on, the diminished importance of economies of scale and scope – particularly as they relate to marketing competency – means that pharmaceutical firms will no longer realize the same benefits of offering such broad categories of therapeutics. Fragmentation and specialization around specific disease classes may prove to be a better organizational industry structure in the age of personalized medicine.

**Takeaways**

To conclude, it appears that personalized medicine offers a number of benefits to both customers and pharmaceutical firms as described above. This technology could lead to new types of treatments with potentially significant and positive impacts on clinical development efficiency. However, adoption of personalized medicine requires a significant shift in pharmaceutical firms’ business strategies, as pharmacogenomics-based products cannot be mass-marketed; personalized medicine outdates the one-drug-fits-all solution approach. The variation in customers’ genetic make-up creates heterogeneity of demand, resulting in more targeted products with smaller markets. Given that economies of scale and scope are at the heart of the pharmaceutical business, the rise of personalized medicine undermines pharmaceutical firms’ existing strategies. Complicating this scenario further, we predict that adoption of personalized medicine would be accompanied by significant changes to the regulatory environment and legal accountability for drug safety. The future of the personalized medicine business is uncertain; to help navigate this uncertainty, we’ve applied the frameworks used in our preceding analysis to speculate on the changes that may come.

**V. Scenario Analysis and Recommendations**

As outlined in the previous sections, the emergence of personalized medicine will likely change the structure of the pharmaceutical industry. When transitioning to this new area, today’s business models -- which have made the fortune of the large pharmaceutical firms -- could become tomorrow’s liabilities, hampering the on-going performance of the currently established global firms.

With this in mind, this section provides a scenario analysis of the future of the pharmaceutical industry by assessing the potential disruption personalized medicine could engender. We will use this analysis to put in perspective the strategic repositioning some of the leading pharmaceutical firms have begun to implement. Finally, we will build upon our framework to provide a set of recommendations to Pfizer, one of the leading
pharmaceutical firm and arguably, one of the firms that has most wholeheartedly embraced the blockbuster model.

**Scenario Analysis**

When considering the impact of personalized medicine on today’s prevailing blockbuster business model, two uncertainties are important to consider:

- **Uncertainty # 1:** Will personalize medicine materialize and fully deliver on its promise? Or is it just a passing fad similar to other hypes such as high-throughput screening or combinatorial chemistry?

- **Uncertainty #2:** Will new blockbuster drugs still be discovered? Or will the pipeline of such compounds irreversibly dry?

First of all, it is important to keep in mind that all the combinations of outcomes are possible. Personalized medicine is often presented as a replacement of the blockbuster model. But there is no evidence, at least today, suggesting that this will be the case. On the contrary, an historic outlook at the health care industry reveals that a world with more treatment options is often favored to a world with less.

Secondly, it is also important to recognize that the pharmaceutical industry faces other significant challenges in addition to the two considered here. The worsening of regulatory environment due to the fiasco caused by the Cox-II inhibitors (Vioxx, and Bextra) and an increase in pricing pressure are probably two of the most salient threats. However, since the focus of this paper is on the potential technology disruption caused by pharmacogenomics, we will keep other issues aside for our analysis.

**Figure 7** illustrates the four possible scenarios the pharmaceutical industry may face depending on the potential outcomes of the two uncertainties mentioned earlier:

- **The “Official Future” scenario:** This scenario represents the continuation of the environment the way it has been for the past 15 to 20 years. It assumes that blockbuster drugs are still discovered in abundance while pharmacogenomics fails to deliver on its promise to bring personalized medicine to society and to revolutionize drug discovery.

- **The “Revenge of the Generics” scenario:** In this doomsday scenario, both the blockbuster model and personalized medicine fail to deliver the breakthrough cures of tomorrow. As a consequence, the premium currently charged to patients for patent-protected drugs might
become harder and harder to sustain. This is a world in which the incentives to develop new drug may significantly diminish and in which generics manufacturers may strive.

- **The “Niche Play” scenario:** In this scenario, only the firms that have invested in pharmacogenomics and personalized medicine will survive. Custom-design treatments will be offered to patients by matching their genetic profile to large knowledge-bases. Diagnostic tools will be used to follow the evolution of the disease at each of its stages. New players will be able to enter the market by offering innovative and breakthrough solutions in niche markets. The pharmaceutical market will move from a mass market to a market of many specialized products.

- **The “Coexistence” scenario:** This is the scenario where both the blockbuster medicine and personalize medicine prevail. Arguably, the market and heterogeneity of demand is sufficiently large to accommodate the coexistence of those two approaches. For pharmaceutical firms, it will mean leveraging the pharmacogenomics technology to improve trials’ design in order to reduce cost and duration. Pharmaceutical firms will also have to develop a more patient-centric approach of delivering drugs as patients may start to demand the same kind of attention that they are getting from personalized medicine.

With this framework in mind, it is interesting to go over the current pharmaceutical industry landscape to put in context some of the strategic moves some players have recently made. A perfect example of a pharmaceutical firm that has been created on the premise that personalized medicine will prevail while the blockbuster model will disappear is Millennium Pharmaceutical⁵. On the other side, when looking Novartis’ acquisition earlier this year of Sandoz, a large generic manufacturer, it seems that Daniel Vasella, Novartis’ CEO, is at least hedging in anticipation of a “Revenge of the Generics” future. Finally, it seems that a third group of pharmaceutical firms, including Johnson & Johnson⁶ and Roche⁷, are progressively putting together a portfolio of medical devices and diagnostic equipment that go hand-in-hand with some of the drugs they sell.

**Recommendations**

Pfizer⁸ is one of the many pharmaceutical firms who have not yet unveiled its strategic positioning in response to the potential end of the blockbuster model and possible emergence of personalized medicine. Recent public statements form Hank McKinnell, Pfizer’s CEO, such as “People who advocate [the end of the

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⁵ See Millennium Pharmaceutical’s web site: [http://www.mlnm.com/about/index.asp](http://www.mlnm.com/about/index.asp)


⁷ Corporate website: [http://www.roche.com](http://www.roche.com)

blockbuster model] don’t understand our business"", clearly suggest that, at least publicly, Pfizer is camping in the “Official Future”.

However, it is also clear that, like many other large pharmaceutical companies, the productivity of Pfizer’s R&D has steadily been declining. The company could therefore find itself at a strategic disadvantage if pharmacogenomics materializes and if the company lags behind competition in leveraging personalized medicine as a mechanism to lower clinical trials costs, for example. On the other side, Pfizer is in a unique position to capitalize on the emergence of lifestyle drugs, a recently developed, growing, and very lucrative market in which the blockbuster model would most likely remain relevant.

For those reasons respectively, we recommend that Pfizer hedge its exposure to personalized medicine and develop a strategy that assumes the “Coexistence” scenario. More specifically we recommend that Pfizer:

○ **On the R&D front:**
  - Opportunistically leverage pharmacogenomics to better design drug trials, eventually making strategic investments in start-ups that develop promising solutions to this problem.
  - Increase linkage between the research and clinical areas of the drug discovery and development units, fostering a translational approach to medicine. This would include working in an interrelated fashion with the CROs (Contract Research Organizations).

○ **On the Sales & Marketing front:**
  - Organize their sales force around disease areas to develop greater knowledge of patient conditions and efficacy of drug regimens. Feed information back to R&D to incorporate in the drug discovery or enhancement process.
  - Build a patient-centric approach to medicine by working closely on patient treatments with hospitals, laboratories, doctors and healthcare organizations.

○ **On the Alliance Management front:**
  - Develop strategic partnerships with diagnostic platform makers to manufacture and sell the diagnostic devices that complement the drug. Potentially develop private, open standard as a

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9 Source: “Pfizer’s funk”, Business Week Magazine, Cover Story, February 28, 2005 issue: [http://www.businessweek.com/magazine/content/05_09/b39222001_mz001.htm](http://www.businessweek.com/magazine/content/05_09/b39222001_mz001.htm)
mechanism to lower the cost of the diagnostic device, whose cost could be subsidized to boost adoption of a specific drug by the market.

We believe that, by implementing those recommendations, Pfizer will be in a position to progressively integrate the benefits of pharmacogenomics without completely betting the company on it.

VI. Conclusion

After many years of restless new product introductions, outstanding financial performance, and double-digits growth, the pharmaceutical industry is reaching the limits of its current business model. From a drought in product innovation, to increasing pricing pressure and a worsening regulatory environment, it seems that large pharmaceutical firms will have increasing difficulty in staying on the same path. A technology disruption such as pharmacogenomics and personalized medicine could very well become the driver of widespread industry transformation. Naysayers would argue that some predicted technology disruptions, such as high-throughput screening and combinatorial chemistry, were supposed to transform the industry but instead turned out to be fads with at best an incremental effect. Whether personalized medicine will be the catalyst of change can be argued, but suffice it to say, the industry is clearly ripe for disruption. It is just a matter of time before it will happen, and picking the right strategy will set apart the winners from the losers.
APPENDIX

Figure 1 – Reinforcing Loops of the Pharmaceutical Industry

Figure 2 – Value Chain of the Pharmaceutical Industry

Figure 3 – Chronology of Drug Innovation
Source: The annual R&D spending data was collected from various reports published by PhRMA, the Pharmaceutical Research and Manufacturers of America association. The annual number of New Molecule Entities (NMEs) was collected from the FDA’s website. See http://www.fda.gov/cder/rdmt/pstable.htm
Figure 5 – Potential Changes to Loops Assuming Personalized Medicine-Based Model

Figure 6 – New Loop, Specific to Personalized Medicine
Figure 7 - Scenario Analysis on the impact of Personalized Medicine on the Pharmaceutical Industry

- More blockbusters are discovered
- Official future
- Revenge of the Generics
- Niche Players Dominate
- Personalized Med materializes
- Blockbuster model dies
- Personalized Med is a fad

Coexistence