# Forefront

**ISSUE 2** | 2018

## Inside:



O'Keefe

Clarity. Results. Together.

# Forefront

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This quarter's Forefront focuses on intellectual property and specifically the generic drug market. We are currently working with a bio med company in the early stages of drug development in the diabetes area. The patent litigation costs, first to protect what has been filed, then to defend against expiring patents is substantial. Eventually as patents expire, the generics take over and quickly become 90% of the market. The ability for a drug maker to delay the inevitable has value in the short run. We are currently exploring the size of the advantage of being the first generic in. Studies have been done to show, not unlike other industries (casinos come to mind), that there is a first lure advantage. Under the premise that once doctors and pharmacists start recommending generics, how many do you need to have, the first entry has value. We are starting to study in what areas of medicine (diabetes, blood pressure, cholesterol, etc.) is this advantage distinct. The analysis we hope will assist drug makers in perhaps partnering with generics to grab a portion of the advantage of first lure. The value if quantified, may allow both parties (drug maker and generic) to partner in a financially economic way. We are assessing whether there is a quantifiable economic advantage. At the end of the day, if you are going to have a meaningful negotiation, knowledge is power.

# PROSPERING
## IN AN UNCERTAIN MIDDLE MARKET

**ON APRIL 10, O'KEEFE HELD ITS 6TH ANNUAL MIDDLE MARKET FORUM IN CONJUNCTION WITH NORTHWOOD UNIVERSITY. WE PRESENTED THE RESULTS OF OUR MIDDLE MARKET ECONOMIC SURVEY SENT OUT TO 3,000 BANKERS, PRIVATE EQUITY INVESTORS, SERVICE PROFESSIONALS AND MIDDLE MARKET BUSINESS LEADERS.**

**By Mike Deighan**

The general consensus was that the Middle Market economy is still moving along at an excellent pace in spite of spiking oil prices, a roller coaster stock market, and a rising fed rate.

Respondents remain bullish on the success of the Middle Market and are seeing same customer sales gains for the 3rd year. Merger and acquisition activity remains very strong and is seen as a strong revenue enhancement strategy. Over 80% believe that profits will increase in 2018 in the Middle Market.

For the fourth year in a row, healthcare costs remain the number one negative factor on profitability. The domestic economy was the most positive factor on profitability with 97% of respondents saying it will have a positive impact or no issue on their business. This is up almost 30% since our 2015 survey.

However, the global economy, trade wars and regulatory requirements continue to dog the Middle Market's profitability.

In a recurrent theme for the past 5 years, over 60% of respondents will be increasing headcounts.

When asked to determine the strength or weakness of 12 middle market economic segments, only the retail/dealer segment bled into the negative at 53%. Construction, Hospitality, Business Services and Technology, and Commercial Real Estate were all above 90% neutral to strong in the strength ranking.

With the ink barely dry on the new tax legislation and the regulations still to be completely promulgated by the IRS, 78% of our respondents feel that the new changes will help Middle Market company growth.

To see the full results of the O'Keefe Middle Market Economic Survey please go to our website and click on the Middle Market Forum box.

***Mike Deighan***
*JD, Managing Director, specializes in advising stakeholders on restructurings, bankruptcies, dispositions and acquisitions with an expertise as a real estate strategist. He has worked as a court-appointed receiver in a number of operating and real estate cases.*

# RECYCLING FOR PATENTS

[THE PHARMACEUTICAL COMPANIES HAVE BEEN RECYCLING AND REPURPOSING DRUGS RATHER THAN CREATING NEW MEDICINES.]

**By Susan Koss**

***Susan Koss***
*CPA/ABV/CFF, CVA, Partner and Managing Director, leads the firm's Litigation Support Practice Group. She specializes in litigation support, business valuation, quality of earnings and forensic accounting.*

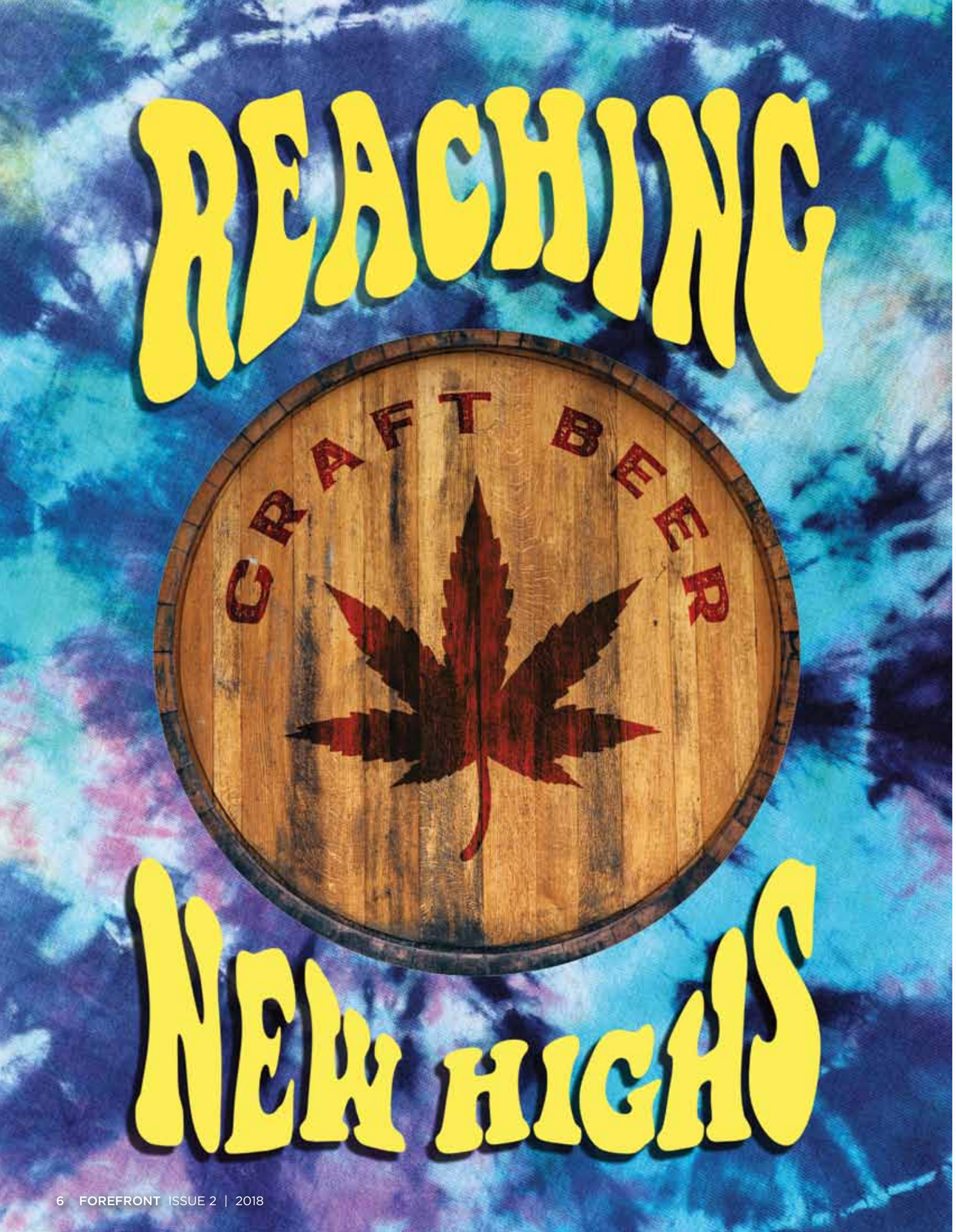
There has been a tremendous amount of media coverage surrounding the opioid crisis in America. Last November, the White House Council of Economic Advisers announced that the ongoing opioid crisis cost the country $504 billion in 2015 (2.8% of GDP), attributing the high dollar amount to health care, criminal justice spending and lost worker productivity. According to the National Institute on Drug Abuse, of the 8.8 million people that abused a prescription medication, nearly 60% abused painkillers. Further, the Centers for Disease Control and Prevention reports that 25% of patients who received prescriptions to pain-related drugs currently struggle with an opioid addiction.

Prescriptions for pain medications account for approximately 10.3% of the brand name prescriptions dispensed in the U.S. ($18.2 billion in revenue in 2017) according to IBISWorld. For generic prescriptions, pain product prescriptions account for approximately 6.4% of total dispensed generic prescriptions ($4.32 billion in revenue in 2017). The brand name pharmaceutical manufacturing industry has grown annually over the last five years by 4.4%. The growth in manufacturing of pain medications has partly been attributable to the ability of pharmaceutical companies to extend their patents over the last decade.

Theoretically, a pharmaceutical company's monopoly on a drug disappears after its patent expires and its generic equivalent floods the market. However, the pharmaceutical companies have been recycling and repurposing drugs rather than creating new medicines. The patent system doesn't require a drug to be better, just different. For example, a company can file a new patent if it makes a version of a drug with a slightly different dosage or time release. Prescription opioid OxyContin, manufactured by Purdue Pharma, is a good example of this.

The patent for OxyContin was originally supposed to expire in 2013; however, Purdue Pharma made minor tweaks to the drug's chemical structure to create a slow-release pill. Consequently, the patent has been extended multiple times since 2013. As a result, Purdue Pharma has been able to aggressively market these highly profitable drugs to doctors which has translated into billions of dollars of revenue.

Recently, the pharmaceutical industry has come under fire by the U.S. Senate Homeland Security & Governmental Affairs Committee for financial ties between opioid manufacturers and patient advocacy and medical groups. As a result, Purdue Pharma announced in February that it would stop marketing opioid drugs to doctors and laid off 50% of its sales force. It remains to be seen whether other opioid manufacturers will follow suit and whether any new governmental regulations will impact the growing market of pain medications, such as limiting the extent to which patents can be extended.






**AS CRAFT BREWERIES STRIVE TO CREATE NOVEL BEERS IN ORDER TO CAPTURE EXTRA ATTENTION IN THIS OTHERWISE ULTRA-COMPETITIVE INDUSTRY, CERTAIN BEER COMPANIES, SUCH AS DESCHUTES, ARE FINDING WAYS TO TAKE THEIR BREWERIES TO NEW "HIGHS." BY NEW HIGHS, OF COURSE, WE ARE TALKING ABOUT MARIJUANA-INFUSED BEERS.**

**By Matthew Rizzo & Anson Smuts**

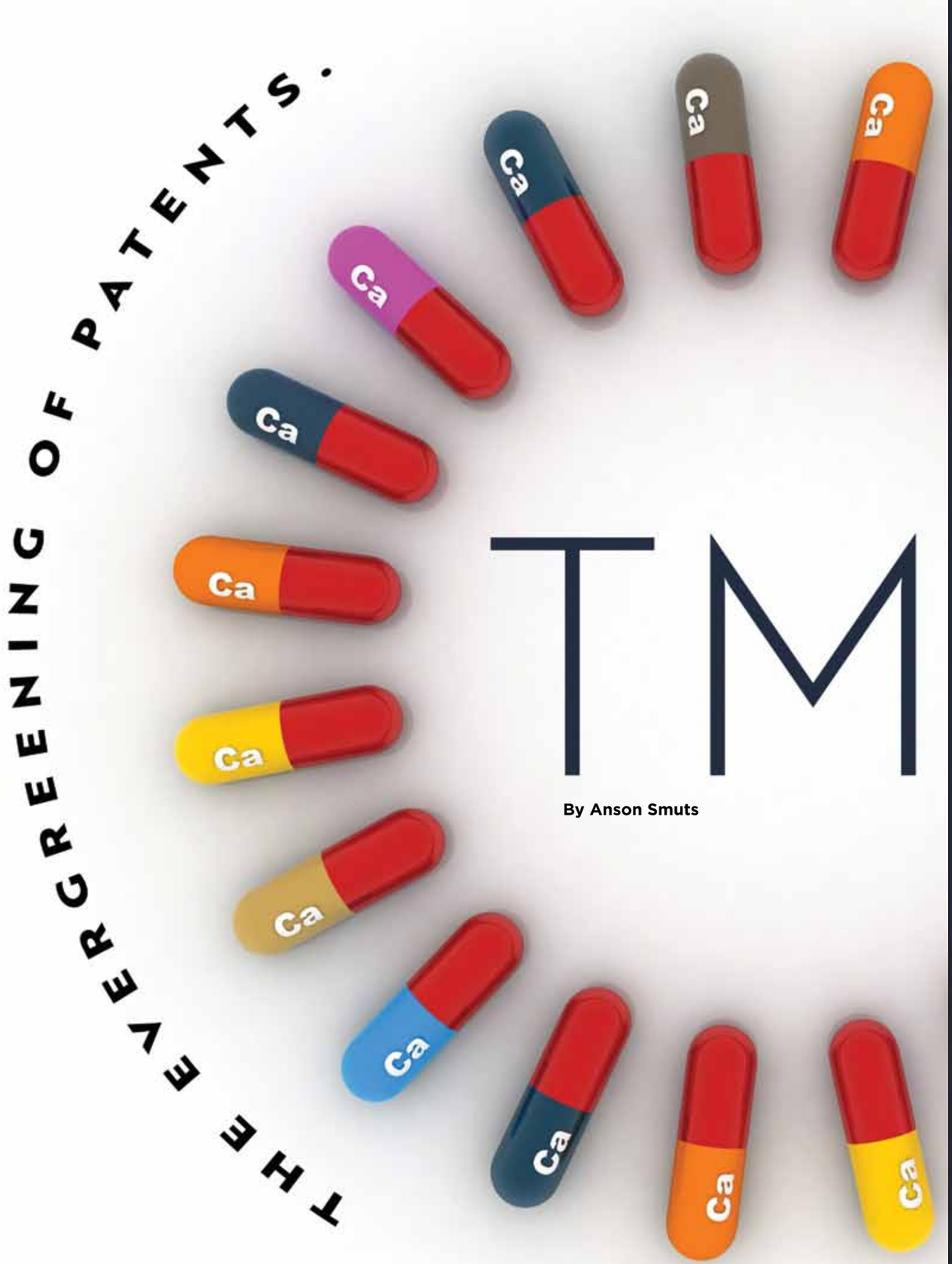
A big reason for this is the beer industry has seen a 13.8% drop in monthly beer sales in all U.S. counties that legalized recreational marijuana use according to a multi-university study in collaboration with the University of Chicago Booth School of Business. The same issue with monthly wine sales seeing as much as a 16.2% drop in the same counties. While there were efforts in the study to account for other potential variables impacting the decrease in monthly alcohol sales other than marijuana, all of those variables, such as unemployment and population, were not fully represented as their impacts were not fully provable. However, the contrast between the decreases in alcohol consumption in counties that have legalized marijuana versus the counties that have not makes for some compelling thoughts on the potential effects in regards to the alcohol industry.

Some consumers may switch over to marijuana when it is legalized recreationally which may cause them to drink less, says Michael LaLonde, CEO of Deschutes Brewery. Mr. LaLonde also suggests that "It's so potent today. Someone might go and have a beer and do some edibles, and the combination of those two things means they don't consume as much alcohol." For those of you who do not know what "edibles" are, they are marijuana-infused foods, most popular in the form of baked goods and candies. The potency effect on people is not well understood for smoking marijuana let alone for marijuana oil, which is used for edibles. This creates a bit of a quandary when it comes to marijuana-infused beer as there is currently no strong regulations in place for the measurement of marijuana related chemicals unlike alcohol which is measured by volume or "ABV."

The fact remains that state and federal law are at odds with each other on marijuana legalization, but one thing is clear, federal agents are able to shut down marijuana related operations when they see fit. Brewers are going to have to tread carefully when testing this new idea or they could face federal consequences even when following the popular Cole Memorandum.

***Matthew Rizzo***
*CPA, CVA, Director, specializes in turnaround and restructuring, litigation support, and business valuation expertise in various types of transactions including, but not limited to mergers and acquisitions, shareholder disputes and gift tax valuations.*

***Anson Smuts***
*CMA, CFE, CVA, Senior Associate, utilizes his accounting and finance expertise in mergers and acquisitions, business valuation, intellectual property, and data analysis to identify strategies for business growth and development.*




# TM

**By Anson Smuts**

The idealized lifecycle of a pharmaceutical patent goes something like this: a pharmaceutical company engages in lengthy and costly R&D to develop a new drug and have it approved, the drug is patented to protect the investment of the company and reward them for their innovation, the patent eventually ends after a legally specified amount of time, generic companies ("generics") step in to seize upon a share of the market and thereby drive prices down.

## Research and repeat...

This cycle is inherently founded upon certain core principles, specifically that 1) pharmaceutical companies ("pharmas") are rewarded for their innovations, 2) patent protections end, and 3) it is economically viable for the generics to enter the market for the drug. Economics, however, are putting these principles to the test.

For large pharmas, the returns on newer drugs are not what they used to be and are no longer up to the standards that investors expect. A 2017 Deloitte Study of large-cap pharmas found that R&D returns have been steadily declining from 10.1% in 2010 to 3.2% in 2017. This is partially explained by the ever-higher costs to launch a drug in the marketplace. In addition, many large pharmas are over reliant upon their blockbuster drugs and have struggled to reinvent their business models.

The end result being that these companies are highly resistant to relinquishing the profits related to these drugs. While pharmas have an array of options to offset impending losses once patents expire, such as launching their own generics or engaging in price cuts, the ideal scenario is to maintain existing cash flows by prolonging their exclusive rights to their blockbuster drugs.

The 2016 Study by Son and Han, titled Patent Cliff and Strategic Switch, explains how the "prevention strategy" involves extending the exclusive rights of the pharmaceutical through various legal actions, including the creation of secondary patents focused upon features other than the main ingredient of the drug. This practice of continuously extending the exclusivity of a drug, sometimes referred to as "evergreening," creates massive hurdles for generic-producing companies, which are not only seeking to avoid infringing on any patents but also the most cost-effective path to recreating a popular drug.

One of the most well-known drugs to be "evergreened" is Humira (manufactured by AbbVie), which recorded $18.4 billion in sales in 2017 and comprised approximately 65% of AbbVie's global sales. Humira has over 75 patents related to the manufacturing, formulation and dosage of the drug to secure the associated revenues for as long as possible. Despite that Humira's primary patent expired in 2017, the web of secondary patents has so far held off generics and biosimilars (drugs that have similar, if not identical, properties of another FDA-approved drug) from entering the U.S. market. In 2018, AbbVie reached two settlements to keep Humira biosimilars out of the U.S. until 2023, at which time royalties from the biosimilars will be paid to AbbVie. This arrangement provides validity to the secondary patents, some of which expire as late as 2034.

A win for AbbVie is a loss for generics, who lose out on a slice of Humira's profits. Generally, competition among generics is at an all-time high as a result of low-cost manufacturers from abroad and drug approvals from the FDA at all-time highs. This competition drives the need among generics for more established drugs to come off patent in order to maintain sales and profitability.

Generics face an uphill battle. Large pharmas are increasingly relying upon evergreening to secure profits. A 2017 Study out of University of California Hastings, titled "May Your Drug Price Be Ever Green," found that between 2005 and 2015 "78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs." The study finds this has increased over time, and one of the results has been higher drug prices.

The ability of large pharmas to prolong the exclusive rights to their blockbuster drugs is sure to meet increased challenges in the future. In addition to competition from generics and biosimilars, continued political pressure to decrease the cost of drugs may bring greater scrutiny to the manner in which "evergreening" occurs.

# NEW DRUGS TO MARKET

**By Andrew Malec, Ph.D.**

Counter-intuitive to how most business executives think of federal agencies, Scott Gottlieb, head of the Food and Drug Administration ("FDA"), has spent his first year at the agency focusing on getting more drugs to market, as opposed to increased regulation. In fact, the FDA has approved a record number of generic drugs in the past year and is looking for ways to address the burden of introducing new pharmaceutical drugs to the marketplace.

Pharmaceutical manufacturers are well aware that developing and launching a prescription drug is a costly endeavor. According to the Office of Health Economics, the typical cost of launching a drug in the marketplace has increased to $1.9 billion, compared to $199 million in the 1970s. The Pharmaceutical Research and Manufacturers of America have stated that it can take 10 to 15 years and about $1.5 billion to develop a new product, and only two out of 10 products ever recover their associated research and development ("R&D") costs. This has caused some pharmaceutical manufacturers to cut funding for certain treatments. Since R&D expenditures are correlated with the number of new drugs being released in the market, this may hamper the number of new drugs being introduced to the market. In fact, the number of in-house development products fell more than R&D expenditures, resulting in higher overall industry per-drug development costs.

Pharmaceutical companies must make a profit to fund past and present R&D efforts. As a result, prescription drugs are priced to reflect the costs of production and the significant R&D costs incurred in developing the drug. Even though discovering and developing new drugs is a time consuming, risky and costly endeavor, companies that are successful in doing so can earn sizable profit until generic versions of the drugs enter the market.

In an effort to lower the price of prescription drugs and increase competition in the marketplace, Mr. Gottlieb wants the agency to rethink how much information the FDA demands at an early stage. Lowering upfront costs should encourage investment, especially by smaller biotech firms with good ideas but fewer resources. This should also enable startups to raise capital easier, and lower development costs should mean higher returns for pharmaceutical manufacturers. The FDA is looking for ways to accelerate clinical trials and lower the standard of efficacy without compromising safety. For example, a pharmaceutical manufacturer may only need to show an improvement in a biological proxy, as opposed to having to demonstrate improvements in long-term outcomes. This approach is already in place for cancer drugs. Of course, lowering efficacy standards introduces the risk that new drugs will be approved that may not be effective.

The pharmaceutical industry is an industry that faces significant competition in getting new drugs to the marketplace, which itself is a very costly endeavor. As companies contend with patent expirations on brand name pharmaceuticals and price competition from generic pharmaceutical manufacturers, it appears that the FDA is on a course to find a path to lower the cost of getting a drug to market. From an economics perspective, lowering the cost of pharmaceutical drugs would lower the price of prescription drugs and allow for more drugs to successfully reach the market; hence, benefitting the patient. Time will tell if this will be the case.

***Andrew Malec, Ph.D.***
*Partner and Managing Director, is the head of the firm's Intellectual Property ("IP") Practice Group. He is a recognized expert in providing economic advisory services, litigation support, and valuation opinions.*



# Inflation

## A Business Owner's Plan to Prepare

**By Bill Fetterman**

Inflationary pressures can be relentless on businesses and make owners feel powerless. Preparation for inflationary periods can be akin to preparing for any kind of volatility. To weather an inflationary storm, owners should commit to a business strategy that includes operational excellence as a competitive advantage - including three important pillars: flexibility, scalability, and reliability.

**Flexibility:** In this context, means the capability to adjust to changes in product mix with almost no change to the cost structure, and with minimal extra costs of changeover. Many businesses are excellent at execution once the production mix is established, but changing the mix late in the game is often catastrophic to the variable cost structure and subsequently to margins.

Flexibility can be established as a competitive advantage by focusing on the design of the production processes and asking key questions during the design phase. In equipment-intensive environments, ensuring that the equipment performance and changeover practices are benchmarked against industry leaders can help toward these goals. Maximizing inventory turns contributes toward the ability to pivot production when necessary. If processes are more labor-intensive, many options are available for process design that minimize costs and maximize flexibility – generally involving cross-trained teams that can perform functions based on demand.

**Scalability:** This means the capability to adjust to changes in volume with minimal change to cost structure. This sounds simple, but adding more volume usually exacerbates existing flow and process defect issues and will almost always cause other unexpected costs, from additional steps for quality assurance to buffer stocks to added labor necessary to move more product.

Production process design with a goal of scalability is key to achieving this goal, whether for existing production processes or for new processes. There are many options available to address these goals, such as modular cellular layouts that are easily replicated, cross-training of personnel to enable coverage across processes, and evolution toward smaller batches to minimize material risks.

**Reliability:** In a business operation, reliability means freedom from error whereby quality does not rely on detecting but rather preventing problems through process design. It stems from the philosophy of systems thinking and systems design, with an emphasis on designing production systems with error-prevention as a goal. There have been remarkable advances in this sub-science. Generally, the idea is that simple is better and defect and waste prevention is a primary system design objective.

**Capital Expenditures and Uncovering Hidden Capacity:** Expenditure decisions can impact cost structures and also impose constraints that work against the three goals of flexibility, scalability, and reliability. When facing decisions about adding additional capacity the primary objective is to uncover hidden capacity in current systems first. Most production systems have significant amounts of hidden capacity (capacity that can be had by executing differently, using different production flow practices, or scheduling). Typically this hidden capacity is free – and our experience demonstrates it's often 20% or more of current capacity.

Business Owners Win Either Way. These operating strategies are powerful ways to prepare your company for volatility, including inflationary cycles. Whether inflation materializes in the future or not, owners and their businesses win. These strategies are great for building sustainability through any period of volatility and adopting operational excellence as an organizational goal.

***Bill Fetterman***
*CPIM, CQE, CMA, Founder and Managing Partner of Advanced Manufacturing Group, LLC ("AMG"). AMG's operational, engineering, logistics and cost accounting specialists work with under-performing companies and also healthy companies seeking operational excellence as a competitive advantage. AMG is a strategic partner for O'Keefe.*

# RECEIVERSHIP LAW CHANGE IN MICHIGAN

## we're no longer the WILD WEST

By Stephen Weber

**As defined by Michigan law, a receivership is an equitable remedy allowing the court to oversee the orderly management and disposition of property subject to a lawsuit. A receiver is the court's representative and owes a duty to both debtors and creditors of a property in receivership.**

In the dark days of the Great Recession, many commercial real estate properties were placed into receiverships under Michigan law. The use of receiverships shortened the process of dealing with underwater properties in a more cost- and time-effective manner than traditional bankruptcy. Receiverships were one of the first choices for banks when dealing with properties that were potentially environmentally impacted. Receiverships also allowed a measure of control when owner/debtors were unwilling to cooperate.

There were downsides to receiverships as well. Michigan law only permitted a receivership to be put in place in connection with another legal action, such as a foreclosure. However, Michigan law was vague and caused issues for judges, plaintiffs, defendants, and other creditors who were unfamiliar with the process. This caused some unfortunate outcomes when unqualified receivers were put in place and their permitted actions were not well-documented in a detailed receivership order.

On May 7, 2018, Public Act 16-2018 became effective in Michigan. The new law is titled as the "Uniform Commercial Real Estate Receivership Act." This new law will remove many of the uncertainties that previously existed. The new law is a blending of certain powers and actions from federal bankruptcy law to provide clarity and certainty. The new law will:

- Provide for various duties and powers of the receiver over the property including:
  - Collect, control, manage, conserve, and protect the receivership property.
  - Operate a business constituting the receivership property.
  - Incur debt and pay expenses incidental to the receiver's duties.
  - Assert a right, claim, or cause of action, or defense that relates to the receivership property.
- Require notice and provide for a distribution of the proceeds from the receivership property to the creditors following the priority of the creditor's claim against the estate.
- Provide that a receivership order will operate as a stay against action against the receivership property.
- Court may order the petitioning party and/or a person whose conduct justified the appointment of a receiver to pay fees and expenses of receivership.
- Allow for the appointment of a receiver before the initiation of another action (such as non-payment of a mortgage if provided for in the documents).
- Require the receiver to prepare and retain business records, account for receivership property, and file with the appropriate recording office a copy of the receivership order.
- Require the property owner to assist the receiver in its duties or face civil contempt.
- Permit the sale of the receivership property, with court approval, free and clear of liens (which transfer to the sale proceeds).
- Permit, with court approval, the acceptance or rejection of executory contracts relating to the receivership property.

Public Act 16-2018 will enable creditors and debtors alike to understand the actions of a receivership which are well defined. It will allow for the orderly management and potential liquidation of troubled real estate assets in a uniform and court-monitored method. This will provide clarity to all parties, including the receiver, of their roles and responsibilities. It will no longer be the "Wild West."

***Stephen Weber***

*CPA/CFF, CTA, Director, works with many different types of clients in the fields of turnaround management and business refinancing, litigation support, forensic accounting and fraud investigation, as well as performance improvement plans.*

O'Keefe
2 Lone Pine Road
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# Did you know:

**O'Keefe provides strategic planning which is imperative to lead organizational growth.**
Due to resource constraints it's often overlooked in many middle market companies. O'Keefe provides the additional resources needed to bridge the gap. We have the experience and business acumen to establish initiatives and design tactics that align client resources and ensure a strategic plan's success. We provide clarity and direction to achieve a more sustainable and profitable organization.

Beginning with an understanding of our client's future vision, goals and core competencies, we proceed with a collaborative evaluation and analysis including:

- Relative markets
- Relative positioning
- Industry trends
- Technological changes
- Regulatory environments
- Financial performance trends

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**O'Keefe is proud to announce that Susan J. Koss** is a recipient of Crain's Detroit Business' Notable Women in Finance Award. Ms. Koss is being recognized for her contribution to the Finance industry. Ms. Koss' diverse expertise reveals her ability to prepare complex financial analyses used in business valuations, turnarounds, bank-workout assignments, and in litigation. Being lead of O'Keefe's Litigation Support Group, Ms. Koss was integral to the company winning the Best Litigation Consulting Services from Michigan Lawyers Weekly in 2017. She has served as a financial expert witness regarding shareholder disputes, breach of contract, lost profits, economic damages, and fraudulent conveyance.

**Pat O'Keefe** will be speaking on a panel at the 30th Annual Bankruptcy Section Seminar hosted by the Federal Bar Association Western District of Michigan, titled, "Shadow Banking, Fulcrum Security, Claims Trading and the End Game." The workshop is July 26-28, 2018, at Park Place Hotel in Traverse City.

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